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Post Hearing Information Pack of



Clover Biopharmaceuticals, Ltd.

三葉草生物製藥有限公司

(Incorporated in the Cayman Islands with limited liability)

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Clover Biopharmaceuticals, Ltd.

三葉草生物製藥有限公司

(Incorporated in the Cayman Islands with limited liability)

[REDACTED]

Number of [REDACTED] under the : [REDACTED] Shares (subject to the
[REDACTED] [REDACTED])
Number of Hong Kong [REDACTED] : [REDACTED] (subject to adjustment)
Number of [REDACTED] : [REDACTED] (subject to adjustment
and the [REDACTED])
Maximum [REDACTED] : HK\$[REDACTED] per Share, plus
brokerage of 1.0%, SFC transaction
levy of 0.0027% and Stock Exchange
trading fee of 0.005% (payable in full
on application in Hong Kong Dollars
and subject to refund)
Nominal Value : US\$[REDACTED] per Share
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EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

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SUMMARY

This summary aims to give you an overview of the information contained in this document. As this is a summary, it does not contain all the information that may be important to you. Moreover, there are risks associated with any [REDACTED]. Some of the particular risks in [REDACTED] in the [REDACTED] are set out in the section headed “Risk Factors”. In particular, we are a biotechnology company seeking to [REDACTED] under Chapter 18A of the Listing Rules on the basis that we are unable to meet the requirements under Rule 8.05(1), (2) or (3) of the Listing Rules. In particular, our Core Products, SCB-2019 (CpG 1018/Alum) and SCB-808, may not be successfully developed or marketed. You should read the entire document carefully before you decide to [REDACTED] in the [REDACTED].

OVERVIEW

Founded in 2007, we are a global clinical-stage biotechnology company committed to developing novel vaccines and biologic therapeutic candidates for infectious diseases as well as cancer and autoimmune diseases. The indications for our lead product in each therapeutic area are COVID-19, malignant ascites and ankylosing spondylitis, respectively. From GenHunter, we in-licensed the Trimer-Tag™ technology platform, a product development platform for the creation of novel vaccines and biologic therapies. We have leveraged the Trimer-Tag™ technology platform to become a COVID-19 vaccine developer and created SCB-2019 (CpG 1018/Alum), one of our Core Products, to address the COVID-19 pandemic caused by SARS-CoV-2. Leveraging our expertise in protein bioengineering, manufacturing capabilities, and in-house manufacturing facility, we developed another Core Product, SCB-808, for the treatment of rheumatic diseases. Our pipeline also consists of nine additional product candidates in development as of the Latest Practicable Date.

We may not be able to successfully develop or market our Core Products, namely our SCB-2019 (CpG 1018/Alum) and SCB-808.

We expect to address the significant global need for COVID-19 vaccines with our near-commercial protein-based COVID-19 vaccine candidate SCB-2019 (CpG 1018/Alum) since there is only one fully approved COVID-19 vaccine on the market globally. In September 2021, SCB-2019 (CpG 1018/Alum) achieved the primary efficacy endpoint and secondary efficacy endpoints in SPECTRA (Study Evaluating Protective-Efficacy and Safety of Clover’s Trimeric Recombinant Protein-based and Adjuvanted COVID-19 Vaccine), our global pivotal Phase 2/3 clinical trial. Based on the SPECTRA results, SCB-2019 (CpG 1018/Alum) demonstrated 100% efficacy against severe COVID-19, 100% efficacy against hospitalizations due to COVID-19, and 84% efficacy against moderate-to-severe COVID-19 caused by any strain of SARS-CoV-2 in SPECTRA. Against the globally dominant Delta variant, SCB-2019 (CpG 1018/Alum) demonstrated 79% efficacy against COVID-19 of any severity in SPECTRA. SCB-2019 (CpG 1018/Alum) also had a favorable safety profile in SPECTRA. We will potentially become one of the first companies to commercialize a protein-based COVID-19 vaccine globally through the COVAX Facility. Compared to other non-protein-based COVID-19 vaccine candidates, protein-based COVID-19 candidates are highly stable and well-suited for global storage and distribution, can be rapidly scaled-up to large quantities using well-characterized manufacturing processes and are compatible with a diverse range of adjuvants which can potentially strengthen the immunogenicity of the vaccine.

SUMMARY

We have built our product pipeline by employing the Trimer-Tag™ technology platform and leveraging our in-house biologics manufacturing infrastructure and capabilities. As of the Latest Practicable Date, our product pipeline consisted of (i) six Trimer-Tag™ subunit vaccine candidates, including SCB-2019 (CpG 1018/Alum), for which we obtained SPECTRA results in September 2021, (ii) two Trimer-Tag™ oncology product candidates, including SCB-313 for which we are conducting five Phase 1 clinical trials in China and Australia, and (iii) three Fc-fusion product candidates, including SCB-808, for which we are conducting a pivotal Phase 3 clinical trial in China. To date, all of our product candidates were developed in-house. The chart below summarizes the development status of our product candidates as of the Latest Practicable Date.

SUMMARY

Assets	Product Candidate	Target	Indication(s)	Discovery	Preclinical	IND	Phase I	Phase II	Phase III	Future Milestone
Trimer-Tag™ Subunit Vaccines	SCB-2019 (CpG 1018/Alum) ⁽¹⁾	SARS-CoV-2 S-Trimer™ (Original Strain)	COVID-19							Expect to obtain conditional approvals between Q4-2021 and mid-2022
	SCB-2020S ⁽²⁾	SARS-CoV-2 S-Trimer™ (B.1.351 variant)	COVID-19							-
	Rabies Vaccine ⁽³⁾	RABV G-Trimer	Rabies							-
	RSV Vaccine ⁽⁴⁾	RSV F-Trimer	RSV							-
	Influenza Vaccine ⁽⁵⁾	HA-Trimers	Quadrivalent Seasonal Flu Pandemic Flu							-
	HIV/AIDS Vaccine ⁽⁶⁾	gp120-Trimers	HIV/AIDS							-
Trimer-Tag™ Oncology	SCB-313 ⁽⁶⁾	TRAIL-Trimer	Malignant Ascites							Expect to initiate a Phase 2 clinical trial in 1H2022
			Malignant Pleural Effusions							-
			Peritoneal Carcinomatosis							-
	Undisectol ⁽⁶⁾	4-1BB Agonist	Immuno-Oncology							Expect to enter IND-enabling studies in 2H2021
Fc-Fusion	SCB-808 (Etemerept Prefilled Syringe) ⁽⁷⁾	TNFR1-Fc	Ankylosing Spondylitis (AS)							Expect Phase 3 trial to complete in 2H 2023
	SCB-420 (Aflibercept) ⁽⁷⁾	VEGFR1/2-Fc	Wet Age-related Macular Degeneration (wAMD)							Expect to initiate a Phase 1 clinical trial in 4Q 2021
	SCB-219 (Novol) ⁽⁷⁾	TPO Mimetic-Fc Bispecific	Chemotherapy-Induced Thrombocytopenia (CIT)							Expected to initiate a Phase 1 clinical trial in 2Q 2022
			Idiopathic Thrombocytopenic Purpura (ITP)							

* Core Products

Notes:

- (1) Our Core Product and our COVID-19 vaccine candidate, We announced SPECTRA met the primary and secondary efficacy endpoints in September 2021. We expect to obtain conditional approvals between the fourth quarter of 2021 and the middle of 2022. Post conditional approval, we expect to commence product launch which may occur as early as year end 2021.
- (2) Our pre-clinical stage second-generation COVID-19 vaccine candidate designed with the NTD based on the original strain and RBD based on the Beta variant. This construct could potentially induce neutralization against multiple SARS-CoV-2 variants by including (a) anti-RBD antibodies targeting E484K and K417N mutations that can neutralize the Beta Variant and Gamma Variant and (b) anti-NTD antibodies that can neutralize the original strains.
- (3) Our vaccine candidates are in early stage development.
- (4) Our oncology product candidate for the treatment of malignant ascites (MA), malignant pleural effusions (MPE), and peritoneal carcinomatosis (PC) to address global unmet medical need of intracavitary malignancies. We are conducting five Phase 1 clinical trials for SCB-313 in China and Australia for the treatment of intracavitary malignancies. We expect to advance the development of SCB-313 for the treatment of MA to a Phase 2 clinical trial in the first half of 2022. We plan to initiate additional Phase 1 clinical trials for SCB-313 to explore new indications, such as bladder cancer, and combination approaches in 2022.
- (5) Our oncology product candidate is in early stage development and we are assessing the target indication(s) for this product.
- (6) Our Core Product and Fc-Fusion product candidate as a biosimilar to Enbrel. In China, Enbrel was approved by the NMPA in February 2010 to treat RA and AS. We received the IND approval from NMPA in November 2017 and completed a Phase 1 clinical trial in January 2019. We are conducting a Phase 3 clinical trial, which is expected to complete in the second half of 2023. To date, the NMPA did not raise any objections or material concerns with respect to the development of SCB-808.
- (7) Our Fc-Fusion product candidates are in early stage development.

SUMMARY

We have an in-house, commercial-ready biologics manufacturing facility in Changxing, Zhejiang province, China. This facility is prepared for the rapid scale-up and commercial production of SCB-2019. Our Changxing facility was designed to adhere to the cGMP standards in accordance with the U.S., EU, and Chinese regulatory authorities. The Changxing facility has received certification by a Qualified Person (QP), a requirement to achieve EU cGMP standards. We expect the NMPA, the EMA and the WHO to conduct GMP inspections on our Changxing facility in the second half of 2021 in connection with their regulatory review process for conditional approval.

We have assembled a seasoned, global management team with deep and complementary experience and capabilities in drug discovery, clinical operations, biomanufacturing, drug commercialization, and capital markets.

OUR BUSINESS MODEL

We are a global clinical-stage biotechnology company that is focused on the research, development, and if approved, commercialization of novel vaccines and biologic therapeutic candidates. We operate a business model focused on in-house research and development of novel vaccines and biologic therapeutic products. We have in-licensed the Trimer-Tag™ technology platform and developed a pipeline of innovative vaccine and oncology candidates including our most advanced asset, our COVID-19 vaccine candidate, SCB-2019 (CpG 1018/Alum). We also expect to continue to advance our remaining pipeline of clinical-stage and pre-clinical stage assets and discover new compounds over time.

OUR PRODUCT PORTFOLIO

As of the Latest Practicable Date, our product pipeline consisted of six Trimer-Tag™ subunit vaccine candidates, two Trimer-Tag™ oncology product candidates and three Fc-fusion product candidates covering 13 indications. In addition, we had initiated ten clinical trials as of the same date. As of the Latest Practicable Date, we had three clinical-stage assets, namely SCB-2019 (CpG 1018/Alum), SCB-808 and SCB 313. SCB-2019 (CpG 1018/Alum) and SCB-808 are our Core Products.

Our Core Products

SCB-2019 (CpG 1018/Alum) – Our COVID-19 Vaccine Candidate

SCB-2019 (CpG 1018/Alum), our COVID-19 vaccine candidate, is anticipated to potentially be one of the first protein-based COVID-19 vaccines commercialized globally through the COVAX Facility. It consists of two key components, an antigen and an adjuvant. Employing the Trimer-Tag™ technology platform, we developed a SCB-2019 antigen, a stabilized trimeric form of the S-protein (referred to as S-Trimer™) based on the original strain of the SARS-CoV-2 virus. We created our COVID-19 vaccine candidate by combining SCB-2019 with Dynavax’s CpG 1018 advanced adjuvant and aluminum hydroxide (alum). Numerous adjuvanted protein-based vaccines have been approved and commercialized prior to the COVID-19 pandemic.

SUMMARY

In September 2021, we announced SPECTRA, our global pivotal Phase 2/3 clinical trial for SCB-2019 (CpG 1018/Alum), met the primary and secondary efficacy endpoints. Based on the SPECTRA results, SCB-2019 (CpG 1018/Alum) demonstrated 100% efficacy against severe COVID-19, 100% efficacy against hospitalizations due to COVID-19, and 84% efficacy against moderate-to-severe COVID-19 caused by any strain of SARS-CoV-2 in SPECTRA. Against the globally dominant Delta variant, SCB-2019 (CpG 1018/Alum) demonstrated 79% efficacy against COVID-19 of any severity in SPECTRA. SCB-2019 (CpG 1018/Alum) also had a favorable safety profile in SPECTRA. We plan to submit conditional regulatory approval applications to the EMA, the NMPA and the WHO in the fourth quarter of 2021. We expect to obtain conditional approvals between the fourth quarter of 2021 and the middle of 2022. Post conditional approval, we expect to commence product launch which may occur as early as year end 2021. We expect to commercialize SCB-2019 (CpG 1018/Alum) globally to address the global shortage of COVID-19 vaccines and capture a significant market share of the approximately 15 billion COVID-19 vaccine doses required through 2026. In addition, periodic booster shots or re-vaccination may be needed especially as new variants emerge, resulting in a significant global need for COVID-19 vaccines for years to come. Clover and investigators also plan to conduct multiple clinical trials exploring SCB-2019 (CpG 1018/Alum) as a heterologous booster, which is the administration of a different vector or delivery system expressing the same or overlapping antigenic inserts from the primary vaccination, and as a homologous booster for SCB-2019 (CpG 1018/Alum).

The market for COVID-19 healthcare products can be generally categorized into preventative care, diagnostics and treatment. Preventative care primarily consists of prophylactic vaccines like our SCB-2019 (CpG 1018/Alum), other potential prophylactic therapeutics are still being evaluated in preclinical studies and clinical trials. Diagnostics refers to diagnostic testing kits to test for parts of the SARS-CoV-2 virus to diagnose a current infection of SARS-CoV-2 and confirm COVID-19. Treatment primarily refers to anti-viral treatments and cell therapy. Vaccines are widely considered to be the most effective solution to control the pandemic and reduce disease burden. As of the Latest Practicable Date, one vaccine, Pfizer-BioNTech’s COVID-19 vaccine, was fully approved by the U.S. FDA. As of the same date, three vaccines have been authorized for emergency use by the FDA and four vaccines have been conditionally approved by the EMA. There has also been one protein subunit COVID-19 vaccine approved in China, one in Russian Federation, one in China (Taiwan), and one in Cuba, as well as 14 phase 2/3 or later stage protein subunit COVID-19 candidates globally as of the Latest Practicable Date. There are also a number of vaccine candidates in clinical development. For details, see “Industry Overview – COVID-19 Vaccine Market Globally.”

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET SCB-2019 (CPG 1018/ALUM) SUCCESSFULLY.

SUMMARY

Agreements for SCB-2019 (CpG 1018/Alum)

Funding Agreements with CEPI

We and CEPI entered into two outbreak response funding agreements, including a step 1 agreement and a step 2 agreement (collectively, the “CEPI Funding Agreement”), pursuant to which CEPI agreed to provide funding for our development of adjuvanted SCB-2019. The step 1 agreement of the CEPI Funding Agreement was entered into in April 2020, which covers funding for our development activities up to the first subject enrolled in the Phase 1 clinical trial. We and CEPI entered into the step 2 agreement of the CEPI Funding Agreement in May 2020, which replaced the step 1 agreement. The step 2 agreement covers funding for the entire development process through global licensure of SCB-2019 (CpG 1018/Alum).

Pursuant to the CEPI Funding Agreement and mutually agreed request, CEPI agreed to provide up to US\$360.5 million in funding in total for the development of adjuvanted SCB-2019, which shall be paid according to the payment schedule associated with the completion of various development milestones. In addition, CEPI agreed to forego any share of potential commercial benefits that may arise from the commercial exploitation of the results of our COVID-19 vaccine development project. We and CEPI agreed that the pricing of SCB-2019 (CpG 1018/Alum) shall be of a reasonable nature to ensure equitable access for populations in need as well as an appropriate return on investment for us that makes on-going supply sustainable. We agreed to supply SCB-2019 (CpG 1018/Alum) to the global allocation mechanism, which was later identified by the parties to be the COVAX Facility during the pandemic period (as defined by WHO). As of December 31, 2019 and 2020 and April 30, 2021, we recorded nil, RMB931.1 million and RMB1,183.8 million in deferred revenue, respectively. Our deferred revenue represented the amount of funding received from CEPI and it will be recognized as revenue upon our fulfilment of future performance obligation, which is long-term in nature.

For more details on the funding agreement with CEPI, see “Business – Licensing and Collaboration Arrangements – Agreements for SCB-2019 (CpG 1018/Alum)” and “Risk Factors – Risks Relating to Our Financial Position And Need For Additional Capital – We may not be able to fulfil our obligation in respect of deferred revenue, which may have impact on our liquidity position.”

Adjuvant Collaboration and Supply Arrangements with Dynavax

We created our COVID-19 vaccine candidate by combining SCB-2019 with Dynavax’s CpG 1018 advanced adjuvant and aluminum hydroxide (alum). The CpG 1018 adjuvant is a well-developed technology, has been used in a FDA- and EMA-approved and commercialized vaccine, produced at scale, and has a significant safety database in clinical and post-marketing studies. Utilizing Dynavax’s CpG 1018 adjuvant, we have achieved positive Phase 1 clinical data in December 2020 and positive Phase 2/3 clinical data in September 2021 for SCB-2019 (CpG 1018/Alum). We plan to submit conditional regulatory approval applications for our SCB-2019 (CpG 1018/Alum) that uses Dynavax’s CpG 1018. To ensure the continued supply of CpG 1018, we entered into several collaboration and supply agreements with Dynavax in relation to the supply of its CpG 1018 adjuvant. We are still determining if the CpG 1018 adjuvant will be used for our second generation COVID-19 vaccine candidate to date.

SUMMARY

We and Dynavax entered into a collaboration agreement and a clinical collaboration and supply agreement in March 2020 and May 2020, respectively, pursuant to which Dynavax agreed to supply its CpG 1018 adjuvant to us for our pre-clinical studies and Phase 1 clinical trial for the development of SCB-2019. Under the clinical collaboration and supply agreement, Dynavax agreed to supply its CpG 1018 adjuvant to us for our SCB-2019 (CpG 1018/Alum) Phase 1 clinical trial and a safety follow-up study to the Phase 1 clinical trial. Moreover, we entered into several amendments to the clinical collaboration and supply agreement with Dynavax in February and March 2021, pursuant to which Dynavax agreed to supply its CpG 1018 adjuvant to us for our Phase 2/3 clinical trial and other development activities including formulation and stability for the development of SCB-2019 (CpG 1018/Alum).

In June 2021, we entered into a supply agreement with Dynavax for the commercial supply of CpG 1018 adjuvants for our SCB-2019 (CpG 1018/Alum). The supply agreement will be effective until the end of 2022 with renewal rights subject to mutual written agreements. Pursuant to the supply agreement, we have committed to purchase, and Dynavax has agreed to manufacture and supply specified quantities of its CpG 1018 adjuvant for use in our commercialization of SCB-2019 (CpG 1018/Alum) with delivery dates in 2021 and 2022. However, the specified quantities and timing of CpG 1018 adjuvant for delivery in 2021 are subject to modification by CEPI at its sole discretion. In the event of a significant adjuvant supply shortage from Dynavax, we are entitled to a manufacturing technology transfer to enable us to make or have the CpG 1018 adjuvant made by a designated contract manufacturer for SCB-2019 (CpG 1018/Alum). We and Dynavax will endeavor to amend our existing supply agreement or enter into further supply agreements to ensure the sustained supply of CpG 1018 after 2022 if we still need CpG 1018 adjuvant from Dynavax that time. If we are unable to obtain sufficient supply of CpG 1018 from Dynavax or pursuant to the manufacturing technology transfer, we may seek to purchase CpG 1018 biosimilars on the market. As of the Latest Practicable Date, Medigen’s COVID-19 vaccine has been authorized by China (Taiwan) under emergency use and is the only commercial-stage COVID-19 vaccine that uses Dynavax’s CpG 1018 adjuvant. There are no approved COVID-19 vaccines that use CpG 1018 biosimilars on the market. However, according to Frost & Sullivan, CpG 2006, which is part of the same CpG-ODN family as CpG 1018, is currently used in clinical trials for influenza, and share a similar manufacturing pathway as CpG 1018. We believe several manufacturers have the potential ability to supply GMP-grade CpG 1018 biosimilar adjuvants. For details, see “Risk Factors – Risks Relating to Manufacturing and Commercialization of Our Product Candidates – Reductions in available raw materials or product components or increases in costs of our raw materials or product components, could have a negative impact on our business, financial condition and operations outcome.” We will be required to undertake additional clinical studies if we use a CpG 1018 biosimilar or an alternative adjuvant in combination with SCB-2019.

For more details on the adjuvant collaboration and supply arrangement with Dynavax, see “Business – Licensing and Collaboration Arrangements – Adjuvant Collaboration and Supply Arrangements with Dynavax”.

SUMMARY

Advance Purchase Agreement with GAVI

We and GAVI entered into an advance purchase agreement in June 2021, pursuant to which we and GAVI shall collaborate to ensure fair allocation and distribution of our COVID-19 vaccine candidates around the world.

Under the advance purchase agreement, we shall manufacture and clinically evaluate our COVID-19 vaccine candidates and GAVI shall provide certainty to ensure the demand for COVID-19 vaccine candidates. GAVI shall procure the purchase of (i) 64.0 million doses of our SCB-2019 (CpG 1018/Alum), and (ii) up to 350.0 million doses of our SCB-2019 (CpG 1018/Alum) pursuant to the options stated therein. GAVI may allocate SCB-2019 (CpG 1018/Alum) doses to any COVAX participant or any organization or person that procure vaccine doses on behalf of refugees, asylum seekers or other vulnerable populations or missed communities, or other populations eligible to receive humanitarian buffer doses under the terms and conditions of the COVAX Facility. We shall take all reasonable steps to seek to ensure that SCB-2019 (CpG 1018/Alum) shall receive initial approval, i.e. the approval for use during a public health emergency by a competent authority and the WHO by no later than December 31, 2021 and regulatory approval, i.e. the marketing authorization from a competent authority or WHO prequalification, by no later than October 31, 2022. For more details on the key terms of the advance purchase agreement, see “Business – Licensing and Collaboration Arrangements – Advance Purchase Agreement with GAVI.”

SCB-808 – Our Fc-fusion Product Candidate

We are developing SCB-808, a Core Product, as a biosimilar to Enbrel (etanercept). Enbrel is a blockbuster TNF- α inhibitor marketed by Amgen, Pfizer, and Takeda Pharmaceuticals with global sales of US\$6.3 billion in 2020. Since the initial FDA approval in November 1998, Enbrel has been approved for various indications worldwide, including rheumatoid arthritis (RA), ankylosing spondylitis (AS), juvenile idiopathic arthritis, psoriatic arthritis, and psoriasis. In China, Enbrel was approved by the NMPA in February 2010 for the indications of RA and AS. According to Frost & Sullivan, the total prevalence of RA and AS reached 9.9 million individuals in 2020 in China and is expected to reach 10.5 million by 2030. SCB-808 is expected to primarily compete with the reference drug Enbrel and other etanercept biosimilars that have been launched or currently under development in China. As of the Latest Practicable Date, there were five marketed etanercept products in China, including Enbrel and four biosimilars. As of the same date, there were three candidates in BLA stage, our SCB-808 in phase 3 clinical trial stage and another candidate in phase 1 clinical trial stage. See “Industry Overview – Market for Rheumatoid Arthritis and Ankylosing Spondylitis in China.” We expect to price SCB-808 competitively to other etanercept biosimilars. Based on the Phase 1 clinical trial results, we believe SCB-808 is the potential first-to-market ready-for-injection prefilled syringe formulation of Etanercept biosimilar in China. We initiated a Phase 3 clinical trial in December 2019 to evaluate SCB-808’s efficacy, safety, and pharmacokinetics for the treatment of AS as compared with Enbrel which is expected to be completed in the second half of 2023.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET SCB-808 SUCCESSFULLY.

SUMMARY

Other Product Candidates

SCB-313 – Our Clinical-stage Oncology Product Candidate

With the Trimer-Tag™ technology platform, we have successfully designed and developed SCB-313 as a covalently-linked, native-like trimeric fusion protein which is structurally and functionally differentiated from the dimeric antibody-based structures and other native ligand-based candidates targeting this pathway. We are developing SCB-313 for the treatment of malignant ascites (MA), malignant pleural effusions (MPE), and peritoneal carcinomatosis (PC) to address the global unmet medical need of intracavitary malignancies. Currently, the standard of care involves therapies directed against the primary tumor and/or drainage to manage MA symptoms and there is no therapeutic option available for the treatment of MPE or PC. The indications that we are targeting for SCB-313 are diseases commonly observed in late-stage cancer patients. According to Frost & Sullivan, the global intracavitary malignancies incidence reached 2.5 million in 2019 and is expected to grow to 2.8 million and 3.0 million by 2024 and 2030, respectively. Despite the high incidence, the current standard of care fails to provide meaningful clinical benefit for most patients.

There are very few drug candidates for intracavitary malignancies in clinical development. SCB-313 is the only drug candidate being evaluated clinically for the treatment of MA, MPE and PC. For details, see “Industry Overview – Market for Intracavitary Malignancies Globally and in China.” Based on the pre-clinical data for SCB-313, we believe our therapeutic candidate has the potential to be both highly bioactive and have a favorable safety profile. We are conducting five Phase 1 clinical trials for SCB-313 in China and Australia for the treatment of intracavitary malignancies. We expect to advance the development of SCB-313 for the treatment of MA to a Phase 2 clinical trial in the first half of 2022. In addition, we plan to initiate additional Phase 1 clinical trials for SCB-313 to explore new indications, such as bladder cancer, and combination approaches in 2022.

Selected Pre-clinical and Discovery Stage Product Candidates

- *Second generation COVID-19 vaccine candidates.* We are actively advancing our research and development of our second-generation COVID-19 vaccine candidates. In early 2021, we initiated the production of vaccine antigens against three variants of concern. We are conducting pre-clinical studies for our second-generation COVID-19 vaccine candidates and have received informative preliminary results. Our pre-clinical immunogenicity study in mice indicated that a modified Beta Variant (B.1.351) protein-based COVID-19 vaccine candidate could potentially be protective against the original SARS-CoV-2 strain and certain variants of concern.

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- *Rabies vaccine candidate.* Our rabies vaccine candidate (RABV G-Trimer) is currently in early-stage development. Currently approved rabies vaccines have limitations in their production capacities, required administration schedules, storage requirements, and cost. There continues to be a need for better rabies vaccines in certain countries, such as China, where animal immunization programs have been unsuccessful.
- *RSV vaccine candidate.* Our RSV vaccine candidate (Fusion F Antigen-Trimer) is currently in early-stage development. Our RSV vaccine candidate induced a strong neutralizing antibody response in a rat immunization model and demonstrated high binding affinity (sub-picomolar) to palivizumab.
- *Influenza vaccine candidate.* Our influenza vaccine candidate (Hemagglutinin (HA)-Trimer) is currently in early-stage development. Our influenza vaccine candidate demonstrated proof-of concept immunogenicity and viral-challenge results *in vivo* in mice (pandemic and seasonal).
- *HIV/AIDS vaccine candidate.* Our HIV/AIDS vaccine candidate (gp120-Trimer) is currently in early-stage development. The preliminary data demonstrated positive results, showing that our HIV/AIDS vaccine candidate, if successfully developed and commercialized, could potentially be an effective prophylactic vaccine for HIV/AIDS.
- *4-1BB agonist candidate.* We are conducting discovery programs evaluating trimeric fusion protein candidates targeting the 4-1BB pathway. Activation of the 4-1BB receptor is an attractive candidate for applications in cancer immunotherapy and demonstrated potent cytotoxic immune cell activation and antitumor responses in multiple pre-clinical studies. We expect to make a candidate selection and enter IND-enabling studies in the second half of 2021.
- *SCB-420.* SCB-420 is an aflibercept biosimilar currently in pre-clinical development for ophthalmologic diseases such as wAMD. Clinical trials are expected to initiate in the fourth quarter of 2021.
- *SCB-219.* SCB-219 is a novel TPOR agonist currently in pre-clinical development for the treatment of CIT and ITP. Clinical trials are expected to initiate in the second quarter of 2022.

SUMMARY

LICENSING AGREEMENT

License Agreement with GenHunter

GenHunter is a biotechnology company headquartered in the United States and was founded in 1992 by our Chairman and Chief Scientific Officer, Dr. Peng Liang. After its establishment, GenHunter was owned by Dr. Liang and a minority shareholder. Dr. Liang became the sole shareholder upon the decease of the minority shareholder. GenHunter was primarily engaged in research and development of innovative technologies in the field of biomedical and life sciences.

In October 2019, we and GenHunter entered into a license agreement (the “GenHunter License Agreement”), which replaced the previous license agreement entered into between us and GenHunter in October 2013. Pursuant to the GenHunter License Agreement, GenHunter granted us an exclusive worldwide license under relevant patents and patent applications, trademarks, and copyrights related to Trimer-Tag™ technology platform to develop, manufacture, and commercialize drug products, or the licensed products. We also have the right to grant sublicenses to third-parties subject to GenHunter’s approval, which shall not be unreasonably withheld. The Trimer-Tag™ technology platform has never been sub-licensed or utilized for any other uses as of the Latest Practicable Date. Under the GenHunter License Agreement, we shall pay GenHunter a low-single-digit royalty based on the net sales of the products engineered using the Trimer-Tag™ technology platform on a country-by-country and product-by-product basis. Other than the royalty payment, we do not have monetary obligations to GenHunter.

We entered into a license arrangement instead of an ownership transfer for the Trimer-Tag™ technology platform considering the continuous financial returns to the previous GenHunter minority shareholder and employees of GenHunter who have contributed to the development of Trimer-Tag™ technology platform. In addition, Sichuan Clover had limited funding as a start-up company in 2013 when the license agreement with GenHunter was signed to acquire the Trimer-Tag™ technology platform. Since then, we have advanced the drug development projects utilizing the Trimer-Tag™ technology platform and attract a few rounds of investments. We continue to maintain the licensing arrangement with GenHunter, and our Directors are of the view that the license arrangement is ideal and serves the best interests of both parties because: (i) there are very low intellectual property risks since GenHunter and the Company are both founded and guided by Dr. Liang; (ii) we are focused on investing the proceeds from previous rounds of financing on developing our product candidates instead of acquiring the Trimer-Tag™ technology platform; and (iii) we have sufficient wholly owned patent protection as we have filed our own patent applications for patent compositions, methods and uses related to the Trimer-Tag™ technology platform in vaccine and cancer, in particularly for SCB-2019 (CpG 1018/Alum) and SCB-313.

For more details on the license agreement with GenHunter, see “Business – Licensing and Collaboration Arrangements – License Agreement with GenHunter” and “Risk Factors – Risks Relating to Our Intellectual Property Rights – Our rights to develop and commercialize our Trimer-Tag™ pipeline products are subject, in part, to the terms and conditions of licenses granted to us by our licensor GenHunter.”

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RESEARCH AND DEVELOPMENT

We believe research and development is critical to our future growth and our ability to remain competitive in the global biopharmaceutical market. We are dedicated to building an innovative product pipeline with a focus on vaccines, oncology, and autoimmune disorders by leveraging our in-house research and development capabilities, which span internal discovery, CMC, pre-clinical, and clinical development.

We have built our product pipeline by employing the Trimer-Tag™ technology platform. The Trimer-Tag™ technology platform can trimerize* any protein of interest and target a broad spectrum of naturally trimerization-dependent disease and biologic targets. These include dozens of enveloped RNA viruses (e.g. coronaviruses, rabies, respiratory syncytial virus (RSV), influenza, human immunodeficiency virus (HIV), and Ebola) and the tumor necrosis factor (TNF) superfamily (TNFSF), which have diverse biological functions and are linked to serious diseases, such as certain cancers and autoimmune disorders. Globally, Trimer-Tag™ is the only trimerization technology platform for designing and producing recombinant, covalently-linked, trimeric fusion proteins (trimer-tagged proteins) exploiting a human-derived trimerization tag, according to Frost & Sullivan. The trimer-tagged proteins produced by the Trimer-Tag™ technology platform have high potency against trimerization-dependent disease targets and favorable safety profiles. As such, the employment of Trimer-Tag™ technology platform accelerated the research and development of novel vaccines and biologic therapies.

In addition, we conduct our research and development activities through an in-house research and development team, and we have established a full range of in-house product discovery capabilities. We established a COVID-19 Scientific Advisory Board (COVID-19 SAB) comprised of esteemed key opinion leaders (KOLs), who provide valuable insights and guidance regarding our global COVID-19 vaccine development strategy. We perform core functions such as designing clinical development strategy and protocol in-house, and exercising control and oversight over key functions of clinical trial management, including data source validation. We use CROs and consultants to manage, conduct, and support our clinical trials and pre-clinical studies in Asia, Latin America, EU, and Australia. See “Business – Research and Development” for details.

* A “trimer” refers to a molecule or an anion formed by combination or association of three molecules or ions of the same substance. Trimerization is a chemical reaction that uses three identical molecules to produce a single trimer. Proteins that are created through the joining of two or more genes that originally coded for separate proteins and consist of three identical simpler parts are referred to as “trimeric fusion proteins.” Trimerization tag refers to a protein tag from the C-propeptide domain of procollagen (Trimer-Tag™), which is capable of self-assembly into a disulfide bond-linked trimer.

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MANUFACTURING

We have an in-house, commercial-ready biologics manufacturing facility in Changxing, Zhejiang province, China which occupies approximately 50,000 sq.m. of land with a total gross building floor area of approximately 32,000 sq.m. Our Changxing manufacturing facility was designed to adhere to the cGMP standards of the U.S., EU, and China. Our Changxing facility will potentially be able to produce more than one billion doses of antigen for SCB-2019 annually at peak capacity. We can also produce supply of our other pipeline products, such as SCB-808, at commercial scale. We expanded our fill and finish area in 2020 by adding two vial filling lines for our future demands, and the lines have been qualified under cGMP standards and are operational as of the third quarter of 2021. We expect the NMPA, the EMA and the WHO to conduct GMP inspections on our Changxing facility in the second half of 2021 in connection with their regulatory review process for conditional approval. In addition to our internal manufacturing capabilities, we have engaged multiple CMOs, including Wuxi Vaccines, to potentially produce hundreds of millions of additional doses of SCB-2019 (CpG 1018/Alum) starting in 2022. As of the Latest Practicable Date, technology transfer activities from Clover to WuXi Vaccines for the manufacturing of SCB-2019 (CpG 1018/Alum) have begun. In addition, we have an R&D and pilot manufacturing facility located in Chengdu, Sichuan province, China to supply materials for our pre-clinical, IND, and early-stage clinical trials. See “Business – Manufacturing” for details.

COMMERCIALIZATION

During the Track Record Period and as of the Latest Practicable Date, we did not have a commercialization team. We are in the process of executing our launch readiness plan and formulating our sales and marketing plans in anticipation of multiple potential product launches within the next few years. In particular, we may consider commercializing SCB-2019 (CpG 1018/Alum) post conditional approval via the COVAX Facility and potentially evaluate bilateral negotiations and supply arrangements with global governments. We intend to build our commercialization capabilities through a combination of efficient and specialized internal sales and marketing teams and external marketing and distribution partnerships, with the goal of achieving broad product access across the globe. See “Business – Commercialization” for details.

INTELLECTUAL PROPERTY

We have an extensive global portfolio of patents to protect our product candidates and technologies. As of the Latest Practicable Date, our patent portfolio consists of one issued U.S. patent, and 24 patent applications, including 20 PCT patent applications in seven families, three U.S. patent applications and one China patent application. Our patents and patent applications primarily include compositions, methods and uses related to TNFSF and certain vaccines against enveloped RNA viruses, including SCB-2019 (CpG 1018/Alum), and the manufacturing methods for SCB-808. As of the Latest Practicable Date, we in-licensed the exclusive worldwide rights for the Trimer-Tag™ technology platform including twelve issued patents, comprising of three issued U.S. patents and nine issued patents in other jurisdictions,

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namely PRC, Japan and certain European countries. While there are different methods for trimerization on the market, Trimer-Tag™ is the only trimerization technology platform that produce recombinant, covalently-linked, trimeric fusion proteins (trimer-tagged proteins) exploiting a human-derived trimerization tag which is not substitutable. For details, see “Risk Factors – Risks Relating to Our Intellectual Property Rights – Our rights to develop and commercialize our Trimer-Tag™ pipeline products are subject, in part, to the terms and conditions of licenses granted to us by our licensor GenHunter.” Our in-licensed patents and patent applications primarily relate to methods and compositions for producing secreted trimeric fusion proteins employing the Trimer-Tag™ technology. See “Business – Intellectual Property” for details.

OUR CUSTOMERS AND SUPPLIERS

During the Track Record Period and up to the Latest Practicable Date, we had no commercialized products and therefore had no customers. During the Track Record Period, our suppliers primarily consisted of suppliers of raw materials and consumables, equipment and devices and CROs. We have established stable relationships with qualified suppliers. For the years ended December 31, 2019 and 2020 and the four months ended April 30, 2021, our purchases from our five largest suppliers in aggregate accounted for 46.3%, 50.8% and 71.2% of our total purchases, respectively, and purchases from our largest supplier alone accounted for 14.0%, 22.3% and 40.1% of our total purchases, respectively. None of our Directors, their associates or any Shareholders who, to the knowledge of our Directors, owned more than 5% of our issued share capital as of the Latest Practicable Date, held any interest in any of our five largest suppliers during the Track Record Period.

OUR STRENGTHS

We believe the following strengths have contributed to our success and differentiated us from our competitors: (i) Trimer-Tag™ technology platform accelerating the development of novel vaccines and biologic therapies, (ii) our protein-based COVID-19 vaccine candidate SCB-2019 (CpG 1018/Alum) potentially launching by the end of 2021, (iii) novel oncology TRAIL-Trimer fusion protein to address the unmet global need for the treatment of intracavitary malignancies, (iv) robust pipeline with novel vaccines and biologic therapeutic candidates against infectious diseases as well as cancer and autoimmune diseases, (v) established in-house cGMP biologics manufacturing infrastructure and capabilities, ready for commercial launch, (vi) seasoned management team with decades of industry and scientific expertise, supported by our COVID-19 Scientific Advisory Board and global healthcare investors.

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OUR STRATEGIES

Leveraging our strengths, we plan to implement the following strategies: (i) accelerate the development and commercialize SCB-2019 (CpG 1018/Alum), (ii) develop our second-generation COVID-19 vaccines, (iii) advance the development and commercialize SCB-313 and SCB-808, (iv) expand and advance our product pipeline in vaccines and immuno-oncology, (v) further enhance our research and development, manufacturing, and commercialization capabilities to build an integrated biotechnology company, (vi) explore synergistic and collaborative opportunities to enhance our growth and increase our value as a global biotechnology company.

COMPETITION

We face competition in several different forms. Product candidates engineered using the Trimer-Tag™ technology platform face actual or potential competition from various companies. The Trimer-Tag™ technology platform also faces actual or potential competition from other technology platforms.

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, competition, and a strong emphasis on proprietary products. We believe the Trimer-Tag™ technology platform, our well-established management team, and our robust pipeline of clinical and pre-clinical stage product candidates will provide us with competitive advantages. We face actual or potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical, biotechnology companies, academic institutions, and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing products and new products that may become available in the future.

We operate in the segments of the pharmaceutical, biotechnology, and other related markets that develop vaccines, oncology, or autoimmune disorders. There are other companies working to develop similar vaccines or therapies in these fields. We face competition from companies developing or testing product candidates for the same or similar targets we are pursuing with our own pipeline. As of Latest Practicable Date, there are currently 21 COVID-19 vaccines on the market and 30 candidates in phase 2/3 or later stage globally. In particular, there has been one protein subunit COVID-19 vaccine approved in China, one in Russian Federation, one in China (Taiwan), and one in Cuba, as well as 14 phase 2/3 or later stage protein subunit COVID-19 vaccine candidates globally as of the same date. We believe our SCB-2019 (CpG 1018/Alum) has the potential to help address the global shortage of COVID-19 vaccines and capture a significant market share of the approximately 15 billion COVID-19 vaccine doses required through 2026. In addition, periodic booster shots or re-vaccination may be needed especially as new variants emerge, resulting in a significant global need for COVID-19 vaccines for years to come. There are currently three etanercept biosimilars marketed in China, three under BLA review and two undergoing evaluation in clinical trials. Please refer to “Business – Our Product Candidates” and “Industry Overview” for further details of our major competitors. In addition, there may be additional competitors working on the targets of our critical programs of whom we are currently unaware.

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Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more potent and effective, are safer and have fewer side effects, are more convenient, or are less expensive than any drugs that we may develop. Our competitors also may obtain the relevant regulatory approvals for their drugs or vaccines earlier than we obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of our product candidates, if approved, are likely to be their efficacy, safety, convenience and price, the effectiveness of companion diagnostics in guiding the use of related therapeutics, the level of generic competition, and the availability of reimbursement from government and other third-party payers.

SUMMARY OF KEY FINANCIAL INFORMATION

This summary of the key financial information set forth below have been derived from and should be read in conjunction with our consolidated audited financial statements, including the accompanying notes, set forth in the Accountants’ Report in Appendix I to this document, as well as the information set forth in the section headed “Financial Information.”

Summary of Consolidated Statements of Profit or Loss

We currently have no products approved for commercial sale and have not generated any revenue from product sales. For the years ended December 31, 2019 and 2020 and the four months ended April 30, 2021, we had a total loss for an amount of RMB48.6 million, RMB912.9 million and RMB909.2 million, respectively. Our total loss for the year mainly resulted from research and development expenses and administrative expenses, as well as fair value changes on convertible redeemable preferred shares.

The following table sets forth the summary of our consolidated statements of profit or loss for the periods indicated:

	Year Ended December 31,		Four Months Ended April 30,	
	2019	2020	2020	2021
	<i>(RMB in thousands)</i>			
	<i>(Unaudited)</i>			
Other income and gains	16,908	24,341	13,152	5,491
Administrative expenses	(17,035)	(76,429)	(11,983)	(78,989)
Research and development expenses	(45,799)	(228,219)	(28,857)	(370,815)
Fair value changes of convertible redeemable preferred shares	9,245	(597,659)	(119,870)	(454,770)
Other expenses	(1,570)	(31,959)	(13)	(3,660)
Finance costs	(10,332)	(2,973)	(585)	(6,444)
Loss before tax	(48,583)	(912,898)	(148,156)	(909,187)
Income tax expense	—	—	—	—
Loss for the year/period	(48,583)	(912,898)	(148,156)	(909,187)

SUMMARY

Summary of Consolidated Statements of Financial Position

The following table sets forth a summary of our consolidated statements of financial position as of the dates indicated:

	As of December 31,		As of
	2019	2020	April 30, 2021
	<i>(RMB in thousands)</i>		
Total non-current assets	21,870	139,103	175,329
Total current assets	164,346	1,048,425	2,394,780
Total current liabilities	27,487	66,734	158,045
Net current assets	136,859	981,691	2,236,735
Total assets less current liabilities	158,729	1,120,794	2,412,064
Total non-current liabilities	226,551	2,103,535	4,295,560
Net liabilities	(67,822)	(982,741)	(1,883,496)

We recorded net liabilities of RMB67.8 million, RMB982.7 million and RMB1,883.5 million as of December 31, 2019 and 2020 and April 30, 2021, respectively, mainly attributable to our convertible redeemable preferred shares of RMB198.7 million, RMB1,127.3 million and RMB3,063.3 million as of December 31, 2019 and 2020 and April 30, 2021, respectively. The increase in our net liabilities as of April 30, 2021 was primarily attributable to the convertible redeemable preferred shares we issued in previous rounds of financing. Our redeemable preferred shares will be re-designated from financial liabilities to equity as a result of the automatic conversion into ordinary shares upon our [REDACTED], which would ameliorate our net liabilities position. Prior to the conversion into ordinary shares, fair value changes of the redeemable preferred shares will continue to affect our financial performance in 2021. Moreover, the increase in our net liabilities as of April 30, 2021 was also attributable to the increase of our deferred income due to the deferred revenue we received from CEPI for the continuous research and development of our SCB-2019 (CpG 1018/Alum). We only recognized such deferred income as revenue upon fulfillment of future performance obligations which is long-term in nature. For details, see “Risk Factors – Risks Relating to Our Financial Position And Need For Additional Capital – We may not be able to fulfil our obligation in respect of deferred revenue, which may have impact on our liquidity position” and “Financial Information – Description of Certain Consolidated Statements of Financial Position Items – Deferred Income.”

We recorded net current assets of RMB136.9 million, RMB981.7 million and RMB2,236.7 million as of December 31, 2019 and 2020 and April 30, 2021, respectively, mainly attributable to our cash and cash equivalents of RMB148.7 million, RMB516.2 million and RMB1,828.8 million as of the same dates, respectively. The increase in our net current assets as of April 30, 2021 was primarily due to the proceeds we received from our Series C financing and the funding we received from CEPI for the development of SCB-2019 (CpG 1018/Alum) in early 2021.

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Summary of Consolidated Statements of Cash Flow

The following table sets forth the components of our consolidated statement of cash flows for the periods indicated:

	Year Ended December 31,		Four Months Ended April 30,	
	2019	2020	2020	2021
	<i>(RMB in thousands)</i>			
	<i>(Unaudited)</i>			
Cash flows from operating activities				
before movement in working capital	(45,966)	(277,988)	(27,565)	(439,155)
Changes in working capital	19,349	754,915	11,300	249,613
Net cash flows (used in)/from operating activities	(26,617)	476,927	(16,265)	(189,542)
Net cash flows (used in)/from investing activities	(2,598)	(394,120)	(63,987)	28,779
Net cash flows from financing activities	142,050	316,847	47,873	1,474,261
Net increase in cash and cash equivalents	112,835	399,654	(32,379)	1,313,498
Cash and cash equivalents at beginning of year/period	35,744	148,694	148,694	516,184
Effects of foreign exchange rate changes, net	115	(32,164)	(137)	(902)
Cash and cash equivalents at end of year/period	148,694	516,184	116,178	1,828,780

We incurred net cash flows used in operating activities for certain periods during the Track Record Period, primarily due to our significant R&D efforts to advance our pipeline. Since inception, we mainly relied on capital contributions by our shareholders, our partnership with CEPI, and equity financing as the major sources of liquidity. Our management monitors and maintains a level of cash and bank balances deemed adequate to finance our operations and mitigate the effects of fluctuations in cash flows. In addition, we plan to reduce our costs through (i) continuing to reduce reliance on third-party consultants as we continue to grow our internal headcount and expertise; (ii) benefiting from economies of scale upon the commercialization of our drug candidates; (iii) continuing to revise and improve our business policies and processes across different legal entities; and (iv) continuing to consolidate our vendors to increase our bargaining power. As our business develops and expands, we expect to generate more net cash from our operating activities, through increasing sales revenue by launching new biological products. We are on track to submit conditional regulatory approval applications for SCB-2019 (CpG 1018/Alum) in the fourth quarter of 2021 and if approved, we believe we will be able to significantly improve our net operating cash flow position considering the high demand for COVID-19 vaccines worldwide.

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The Directors are of the opinion that, taking into account (i) the financial resources available to our Group, including cash and cash equivalents of RMB1,828.8 million as of April 30, 2021, cash flows from operating activities, and available financing facilities and the estimated [REDACTED] based on the [REDACTED] of the [REDACTED] from the [REDACTED], and (ii) our cash burn rate, which is our cash and cash equivalents balance divided by average monthly net cash used in operating activities plus payments for property, plant and equipment, we have sufficient working capital to cover at least 125% of our costs, including research and development expenses, general and administrative expenses, finance costs and other expenses for at least the next 12 months from the date of this document. Without taking into account the estimated [REDACTED] from the [REDACTED], our Directors believe that we have sufficient working capital for at least 12 months from the date of this document.

Cash Operating Costs

The following table provides information regarding our cash operating costs for the periods indicated:

	As of December 31,		As of
	2019	2020	April 30, 2021
	<i>(RMB in thousands)</i>		
<i>Research and Development costs for</i>			
<i>Core Products (SCB-2019</i>			
<i>(CpG 1018/Alum) and SCB-808)⁽¹⁾</i>			
Clinical trial expenses	5	44,375	207,129
Raw material costs	42	104,824	26,290
Testing expenses	4	6,685	3,910
Salaries and benefits	2,916	55,642	43,039
Others ⁽²⁾	1,132	19,849	8,492
	4,099	231,375	288,860
<i>Subtotal</i>			
<i>Research and development costs for</i>			
<i>other product candidates⁽³⁾</i>			
Clinical trial expenses	8,448	13,769	75,411
Raw material costs	8,418	7,524	2,370
Testing expenses	162	10,529	593
Salaries and benefits	8,731	4,223	18,847
Others ⁽²⁾	3,115	1,506	85
	28,874	37,551	97,307
<i>Subtotal</i>			
Workforce employment	14,992	16,055	29,585
Non-income taxes, royalties and other government charges	86	105	–
Prepaid item ⁽⁴⁾	–	167,390	684
Other	11,315	48,161	2,396

SUMMARY

Notes:

- (1) We recorded an amount of RMB4.1 million and RMB231.4 million, RMB288.9 million of research and development costs of our Core Products for the years ended December 31, 2019 and 2020 and the four months ended April 30, 2021, respectively. The research and development costs we allocated to our Core Products in 2019 were related to SCB-808, and the amounts recorded in 2020 and 2021 were primarily related to SCB-2019 (CpG 1018/Alum) because we initiated the research and development activities of our SCB-2019 (CpG 1018/Alum) in 2020.
- (2) Others mainly consisted of professional fees, office and travel expenses.
- (3) Research and developments costs for other product candidates, primarily including clinical expenses and raw material costs incurred in relation to the development of SCB-313.
- (4) Prepaid item primarily represents our advance payment to CROs in relation to the development of SCB-2019 (CpG 1018/Alum).

KEY FINANCIAL RATIO

Current ratio increased from 6.0 as of December 31, 2019 to 15.7 as of December 31, 2020 due to an increase in current assets in relation to our cash and cash equivalents and time deposits and restricted cash. We recorded a relatively stable current ratio of 15.2 as of April 30, 2021.

SUMMARY OF MATERIAL RISK FACTORS

Our business faces risks including those set out in the section headed “Risk Factors.” As different investors may have different interpretations and criteria when determining the significance of a risk, you should read the “Risk Factors” section in its entirety before you decide to [REDACTED] in our Company. Some of the major risks that we face include: (i) we have incurred net losses and net operating cash outflows since our inception, and we may continue to incur net losses and net operating cash outflows. Investors are at risk of losing substantially all of their investments in our Shares, (ii) our financial prospects depend on the successful development, approval, and commercialization of our clinical-stage and pre-clinical stage pipeline, (iii) we may not be able to successfully use and expand the Trimer-Tag™ technology platform to build a pipeline of product candidates, (iv) our rights to develop and commercialize our Trimer-Tag™ pipeline products are subject, in part, to the terms and conditions of licenses granted to us by our licensor GenHunter, and any disagreement with GenHunter may render us under unfavorable conditions, (v) reductions in available raw materials or product components, or increases in costs of our raw materials or product components, could have a negative impact on our business, financial condition and operations outcome, (vi) clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results, (vii) all material aspects of the research, development, manufacturing and commercialization of pharmaceutical products are heavily regulated, (viii) any failure to comply with existing regulations and industry standards or any adverse actions by the drug-approval authorities against us could negatively impact our reputation and our business, financial condition, results of operations and prospects, (ix) we may rely on third parties to manufacture a portion of our clinical and, if approved, commercial product supplies, and (x) our business could be harmed if those third parties fail to provide us with sufficient quantity of products or fail to do so at acceptable quality levels or prices.

SUMMARY

SUBSTANTIAL SHAREHOLDERS

So far as our Directors are aware, immediately following completion of the [REDACTED] and the [REDACTED] and assuming that the [REDACTED] and the share options granted under the Pre-[REDACTED] Share Option Plan are not exercised, (i) Dr. Liang and Mr. Joshua Liang will be entitled to exercise the voting rights attaching to approximately [REDACTED]% of the total issued share capital of our Company, and (ii) Hillhouse will be interested in [REDACTED]% of the total issued share capital of our Company. Therefore, Dr. Liang and Mr. Joshua Liang, as a group, and Hillhouse will be regarded as our Substantial Shareholders. For further details, please refer to the section headed “Substantial Shareholders.”

PRE-[REDACTED] INVESTORS

We received five series of Pre-[REDACTED] Investments since our establishment. Our Pre-[REDACTED] Investors include global and Chinese institutional investors and dedicated healthcare and biotech funds. For details, please see “History, Reorganization and Corporate Structure – Pre-[REDACTED] Investments.”

SHARE INCENTIVE SCHEMES

In order to reward or incentivize our Directors, employees and consultants for their contribution or potential contribution, we adopted the Pre-[REDACTED] Share Option Plan and the RSU Scheme on April 15, 2021, as amended from time to time, and conditionally adopted the Post-[REDACTED] Share Option Plan with effect from the [REDACTED]. For details, please see “Statutory and General Information – D. Share Incentive Plans” in Appendix IV to this document.

DIVIDEND POLICY

We did not declare or pay dividends on our Shares during the Track Record Period. We currently expect to retain all future earnings for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. The declaration and payment of any dividends in the future will be determined by our Board of Directors, in its discretion, and will depend on a number of factors, including our earnings, capital requirements, overall financial condition and contractual restrictions. In addition, our Shareholders may by ordinary resolution declare a dividend, but no dividend may exceed the amount recommended by our Board of Directors. If we pay dividends in the future, in order for us to distribute dividends to our Shareholders, we will rely to some extent on any dividends distributed by our PRC subsidiaries. Any dividend distributions from our PRC subsidiaries to us will be subject to PRC withholding tax. In addition, regulations in the PRC currently permit payment of dividends of a PRC company only out of accumulated distributable after-tax profits as determined in accordance with its articles of association and the accounting standards and regulations in China. See “Risk Factors – Risks Relating to Doing Business in China.” In the future, we may rely to some extent on dividends and other distributions on equity from our principal operating subsidiaries to fund offshore cash and financing requirements.

SUMMARY

As advised by our Cayman Islands counsel, under the Companies Act a Cayman Islands company may pay a dividend out of either profits or share premium account, provided that in no circumstances may a dividend be paid if this would result in the company being unable to pay its debts as they fall due in the ordinary course of business. In light of our accumulated losses as disclosed in this document, it is unlikely that we will be eligible to pay a dividend out of our profits in the foreseeable future. We may, however, pay a dividend out of our share premium account unless the payment of such a dividend would result in our Company being unable to pay our debts as they fall due in the ordinary course of business. There is no assurance that dividends of any amount will be declared to be distributed in any year.

[REDACTED] STATISTICS⁽¹⁾

	Based on an [REDACTED] of HK\$[REDACTED]	Based on an [REDACTED] of HK\$[REDACTED]
Market capitalization of our Shares ⁽²⁾	HK\$[REDACTED]	HK\$[REDACTED]
Unaudited pro forma adjusted consolidated net tangible assets of the Group attributable to owners of the Company per Share ⁽³⁾	HK\$[REDACTED]	HK\$[REDACTED]

Notes:

- (1) All statistics in this table are on the assumption that the [REDACTED] are not exercised.
- (2) The calculation of market capitalization is based on [REDACTED] Shares expected to be in issue immediately after completion of the [REDACTED].
- (3) The pro forma adjusted consolidated net tangible assets of our Group attributable to owners of our Company per Share is calculated after making the adjustments referred to in “Financial Information – Unaudited Pro Forma Adjusted Consolidated Net Tangible Assets.”

USE OF [REDACTED]

We estimate that we will receive [REDACTED] from the [REDACTED] of approximately HK\$[REDACTED], after deducting [REDACTED] commissions, fees and estimated expenses payable by us in connection with the [REDACTED], and assuming an [REDACTED] of HK\$[REDACTED] per Share, being the [REDACTED] of the [REDACTED] stated in this Document. We currently intend to apply these [REDACTED] for the following purposes: (i) approximately [REDACTED]%, or HK\$[REDACTED], will be used for the research and development, manufacturing and commercialization of our Core Products and related products, including (a) approximately [REDACTED]%, or HK\$[REDACTED], to be used for regulatory submission, commercial preparation and launch, and post-marketing studies of SCB-2019 (CpG 1018/Alum), (b) approximately [REDACTED]%, or HK\$[REDACTED], will be used for research and development and regulatory submission for second generation COVID-19 vaccine candidates, and (c) approximately [REDACTED]%, or HK\$[REDACTED], will be used for the research and development and commercial preparation and launch of SCB-808, (ii) approximately [REDACTED]%, or HK\$[REDACTED] for the research and development, manufacturing and commercialization of other products, SCB-313, SCB-420 as well as other potential product candidates, and (iii) approximately [REDACTED]%, or HK\$[REDACTED], will be used for working capital and other general corporate purposes.

SUMMARY

[REDACTED] EXPENSES

[REDACTED] expenses to be borne by us are estimated to be approximately HK\$[REDACTED] (including [REDACTED] commission, assuming an [REDACTED] of HK\$[REDACTED] per Share, being the [REDACTED] of the [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per Share), representing approximately [REDACTED]% of the estimate [REDACTED] and [REDACTED]% of the estimated gross [REDACTED] from the [REDACTED] assuming no Shares are issued pursuant to the [REDACTED]. [REDACTED] expenses to be borne by us include (i) [REDACTED] expenses of HK\$[REDACTED]; (ii) fees and expenses of legal advisors and Reporting Accountants of HK\$[REDACTED]; and (iii) other fees and expenses of HK\$[REDACTED]. No such expenses were incurred in 2019. In 2020, the [REDACTED] expenses charged to profit or loss were RMB[REDACTED] (approximately HK\$[REDACTED]) and the issue costs capitalized to deferred issue costs were RMB[REDACTED] (approximately HK\$[REDACTED]). After December 31, 2020, approximately HK\$[REDACTED] is expected to be charged to our consolidated statements of profit or loss, and approximately HK\$[REDACTED] is expected to be accounted for as a deduction from equity upon the [REDACTED]. The [REDACTED] expenses above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

RECENT DEVELOPMENTS

In June 2021, we entered into an advance purchase agreement with GAVI, pursuant to which we committed up to 414 million doses of our COVID-19 vaccine candidates to the COVAX Facility. For more details on the key terms of the advance purchase agreement, see “Business – Licensing and Collaboration Arrangements – Advance Purchase Agreement with GAVI.”

In June 2021, we entered into a supply agreement with Dynavax (the “Supply Agreement”) for the commercial supply of CpG 1018 adjuvants for the use with our SCB-2019 (CpG 1018/Alum). For details on the terms of the supply agreement, see “Business – Licensing and Collaboration Arrangements – Adjuvant Collaboration and Supply Arrangements with Dynavax.”

In September 2021, we entered into a letter of intent (the “Proposed Lease”) with Shanghai Pinjiasheng Enterprise Management Co., Ltd. (上海品佳生企業管理有限公司) (“Shanghai Pinjiasheng”), pursuant to which Shanghai Pinjiasheng agreed to lease an aggregate gross floor area of 25,989.39 square meters to our Company for office use and research and development laboratory. The Proposed Lease has a term of eight years. Under the Proposed Lease, we are obliged to pay period-based fixed monthly rent and relevant property management fees as defined therein. Moreover, Shanghai Pinjiasheng needs to return all the lease deposits already paid by our Company within specified period if the lease cannot be performed. We need to inform Shanghai Pinjiasheng in advance and pay liquidated damages to them if we cancel the lease within the lease term. The Proposed Lease does not constitute a lease contract and any amendments shall be made in a supplementary agreement signed by the parties. As of the Latest Practicable Date, we have paid an amount of RMB4.7 million to Shanghai Pinjiasheng as intention deposit. We expect to execute a formal lease contract in November 2021.

SUMMARY

Since late 2019 and early 2020, COVID-19 has quickly spread around the world. The WHO declared the COVID-19 outbreak as a global pandemic on March 11, 2020. Significant numbers of COVID-19 cases have been reported since then, causing governments around the world to implement unprecedented measures such as city lockdowns, travel restrictions, quarantines and business shutdowns. We have employed various measures to mitigate any impact the COVID-19 outbreak may have on our operations or the development of our products, including offering personal protection equipment such as masks to our employees, regularly checking the body temperature of our employees and closely monitoring their health conditions. We have not experienced any material disruption since the outbreak of the COVID-19 pandemic. Although the COVID-19 outbreak has caused some delays in the enrollment of patients in our SCB-313 and SCB-808 clinical trials primarily in the first half of 2020, enrollment of patients in China substantially recovered by the second half of 2020. The COVID-19 outbreak caused around six months delay for SCB-313 and one month to three months delay for SCB-808. Our financial performance was not materially and adversely affected by the delays in patient enrollment. Although our Phase 2/3 clinical study for SCB-2019 (CpG 1018/Alum) was conducted in countries where the COVID-19 outbreak may be ongoing, we did not experience any delay in participant enrollment and clinical operations given the high motivation of subjects to participate in COVID-19 vaccine clinical trials, and the fact that various measures have been implemented at clinical trial centers to protect study staff and participants.

The Delta Variant was identified as early as October 2020 and has since spread to over 185 countries around the world including certain cities in China, including Guangzhou and Shenzhen. According to Frost & Sullivan, there were approximately 0.1 million confirmed COVID-19 cases in China and approximately 236.1 million confirmed cases globally as of October 2021. Generally, the COVID-19 pandemic in 2021 did not have a material adverse impact on our clinical trial progress for SCB-2019 (CpG 1018/Alum), clinical plan for our second-generation COVID-19 vaccine candidates or business strategies regarding the utilization of our SCB-2019 (CpG 1018/Alum) as a booster shot, as the continuation of the COVID-19 pandemic solidified the need for more COVID-19 vaccines, especially those that are effective against the emerging variants. In fact, SPECTRA participant enrollment remained strong as we were able to enroll over 30,000 adult and elderly participants in approximately 3 months. Having obtained data from SPECTRA in September 2021, we are on track to submit conditional regulatory approval applications to the EMA, the NMPA, and the WHO in the fourth quarter of 2021. We expect to obtain conditional approvals between the fourth quarter of 2021 and the middle of 2022. Post conditional approval, we expect to commence product launch which may occur as early as year end 2021.

On August 23, 2021, the U.S. FDA granted full approval of Pfizer-BioNTech's COVID-19 vaccine for individuals 16 years of age and older. Other than this vaccine, all other COVID-19 vaccines authorized by the FDA are for emergency use. Given the current unmet need for COVID-19 vaccines around the world, we believe there is no near-term material impact on our development and commercialization of SCB-2019 (CpG 1018/Alum). For details, please see "Industry Overview – COVID-19 Vaccine Competitive Landscape Globally."

SUMMARY

During the Track Record Period and as of the Latest Practicable Date, our financial performance and business operation were not materially and adversely affected by the outbreak of COVID-19 pandemic. Our Directors believe that, based on information available as of the Latest Practicable Date, the outbreak of COVID-19 would not result in a material disruption to our business operations or have any material impact on our clinical trial progress, because (i) none of our offices are located in regions under lockdown; (ii) our operations have not experienced any material disruption since the outbreak of the COVID-19 pandemic; and (iii) most of our employees do not reside in regions under lockdown. We cannot guarantee that the outbreak of COVID-19 will not further escalate or have a material adverse effect on our business operations. Please refer to the paragraphs headed “Risk Factors – Risks Relating to Our Operations – We face risks related to natural disasters, health epidemics, civil and social disruption and other outbreaks, which could significantly disrupt our operations. In particular, the COVID-19 outbreak in China and worldwide has adversely affected, and may continue to adversely affect, our business, results of operations and financial condition” for more information of the relevant risks.

NO MATERIAL ADVERSE CHANGE

Since the end of the Track Record Period, we have continuously developed our business and continued to advance our product development programs. We may continue to incur significant net losses for the foreseeable future as we continuously advance research, conduct pre-clinical studies, conduct clinical trials, and seek regulatory approvals of our product candidates, maintain and expand our manufacturing facilities, and add additional infrastructures. Compared with the corresponding period in 2020, our staff and research and development expenses in the four months ended April 30, 2021 increased significantly due to launch of SPECTRA, a global pivotal Phase 2/3 clinical trial for SCB-2019 (CpG 1018/Alum), and an increase in CMC and R&D headcount.

Our forecasted net loss will increase significantly for the year ending December 31, 2021 mainly due to the increase of our research and development expenses as we further advance the development of certain product candidates, as well as the changes in fair value of convertible redeemable preferred shares. These shares will be converted into ordinary shares upon [REDACTED], and would no longer affect our results of operations going forward. Our Directors confirm that, save as disclosed in this section, there has been no material adverse change in our financial, operational or trading positions or prospects since April 30, 2021, being the date of our consolidated statements as set out in “Appendix I – Accountants’ Report” to this document, and up to the date of this document.

DEFINITIONS

In this document, unless the context otherwise requires, the following terms shall have the meanings set out below. Certain other terms are explained in the section headed “Glossary of Technical Terms” in this document.

“ACT-Accelerator”	access to COVID-19 Tools-Accelerator, a global collaboration to accelerate the development, production, and equitable access to COVID-19 tests, treatments, and vaccines
“Acting-in-concert Deed”	the acting-in-concert deed entered into by Dr. Liang and Mr. Joshua Liang on March 16, 2021, details of which are described in the section headed “History, Reorganization and Corporate Structure – Acting-in-concert Deed and Voting Proxy Agreements”
“Amgen”	Amgen Inc., an American pharmaceutical company
“AnGes”	AnGes MG, Inc., a Japanese pharmaceutical company
“Anhui Zhifei Longcom Biopharmaceutical”	Anhui Zhifei Longcom Biopharmaceutical Co., Ltd., a Chinese pharmaceutical company
“Aratinga.Bio, Inc.”	a preclinical-stage immunotherapy biotechnology company founded in March 2017 developing novel immunotherapies to treat cancer
“Articles of Association”	the articles of association of the Company adopted on September 26, 2021, which will become effective on the [REDACTED], as amended from time to time, a summary of which is set out in Appendix III to this document
“associate(s)”	has the meaning ascribed to it under the Listing Rules
“AstraZeneca”	AstraZeneca plc, a British-Swedish pharmaceutical company
“Audit Committee”	the audit committee of the Board
“Australia Clover”	CLOVER BIOPHARMACEUTICALS AUS PTY LTD, a proprietary company limited by shares registered in Australia on June 6, 2017, and a subsidiary of our Company

DEFINITIONS

“Beijing Clover”	Clover Biopharmaceutical (Beijing) Co., Ltd. (克洛菲生物製藥(北京)有限公司), a limited liability company established in the PRC on September 1, 2020, and a wholly-owned subsidiary of our Company
“Beijing Institute of Biological Products”	a subsidiary of Sinopharm in Beijing
“Beijing Institute of Biotechnology”	a national leading co-educational public university, located in Beijing, China
“Betta Capital”	Hangzhou Betta Capital Investment Fund
“Bharat Biotech International Limited”	an Indian pharmaceutical company
“Bill & Melinda Gates Foundation”	an American private foundation founded by Bill and Melinda Gates
“BioNTech”	BioNTech SE, a German pharmaceutical company
“Board” or “Board of Directors”	the board of Directors of our Company
“Business Day”	a day banks in Hong Kong are generally open for normal banking business to the public and is not a Saturday, Sunday or public holiday in Hong Kong
“BVI”	the British Virgin Islands
“CanSino”	CanSino Biologics Inc., a Chinese pharmaceutical company

[REDACTED]

DEFINITIONS

[REDACTED]

“CEPI”	Coalition for Epidemic Preparedness Innovations, a foundation that takes donations from public, private, philanthropic, and civil society organisations, to finance independent research projects to develop vaccines against emerging infectious diseases
“Chengdu Fuya”	Chengdu Fuya Enterprise Management Co., Ltd. (成都福雅企業管理有限公司), a limited liability company established in the PRC on October 30, 2020, and a wholly-owned subsidiary of our Company
“China” or the “PRC”	the People’s Republic of China, but for the purpose of this document and for geographical reference only and except where the context requires, references in this document to “China” and the “PRC” do not include Hong Kong, the Macau Special Administrative Region of the PRC and Taiwan
“Chinese Academy of Medical Sciences”	an academic center for medical sciences in China and multidiscipline medical research institution
“close associate(s)”	has the meaning ascribed thereto under the Listing Rules
“CMA”	Conditional Marketing Authorization, an approval of a medicine that addresses unmet medical needs of patients on the basis of less comprehensive data than normally required
“Companies Act” or “Cayman Companies Act”	the Companies Act, Cap. 22 (Law 3 of 1961, as consolidated and revised) of the Cayman Islands, as amended, supplemented or otherwise modified from time to time

DEFINITIONS

“Companies Ordinance”	the Companies Ordinance (Chapter 622 of the laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
“Companies (Winding Up and Miscellaneous Provisions) Ordinance”	the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Chapter 32 of the Laws of Hong Kong) as amended, supplemented or otherwise modified from time to time
“Company” or “Clover”	Clover Biopharmaceuticals, Ltd., an exempted company incorporated in the Cayman Islands on October 31, 2018
“connected person”	has the meaning ascribed thereto under the Listing Rules
“connected transaction”	has the meaning ascribed thereto under the Listing Rules
“core connected person”	has the meaning ascribed thereto under the Listing Rules
“Core Product”	has the meaning ascribed to it in Chapter 18A of the Listing Rules; for purpose of this document, our Core Products refers to SCB-2019 (CpG 1018/Alum) and SCB-808
“COVAXX”	C19 Corp., a subsidiary of Vaxxinity
“CureVac AG”	CureVac N.V., a German pharmaceutical company
“Delos Capital”	Delos Capital Fund II, LP, a life sciences venture capital firm
“Director(s)” or “our Directors”	director(s) of our Company
“Drug Price Competition and Patent Term Restoration Act of 1984”	informally known as the Hatch-Waxman Act, is a 1984 United States federal law that encourages the manufacture of generic drugs by the pharmaceutical industry and established the modern system of government generic drug regulation in the United States
“Dr. Liang”	Dr. Peng Liang, the founder, an executive Director and the chairman of the Board of our Company
“Dynavax”	Dynavax Technologies Corporation, a fully-integrated pharmaceutical company develops, and commercializes novel vaccines

DEFINITIONS

“EIT Law”	the PRC Enterprise Income Tax Law (中華人民共和國企業所得稅法), as enacted by the NPC on March 16, 2007 and effective on January 1, 2008, as amended, supplemented or otherwise modified from time to time
“EMA”	European Medicines Agency
“Extreme Conditions”	extreme condition(s) including but not limited to serious disruption of public transport services, extensive flooding, major landslides and large-scale power outage caused by a super typhoon according to the revised “Code of Practice in Times of Typhoons and Rainstorms” issued by the Labour Department of the government of Hong Kong in June 2019, as announced by the government of Hong Kong
“European Commission (EC)”	the executive branch of the European Union
“FAMHP”	Federal Agency for Medicines and Health Products of Belgium
“FBRI”	a biological research center in Koltsovo, Novosibirsk Oblast, Russia
“FDA”	Food and Drug Administration, a United States federal agency of the Department of Health and Human Services
“Finlay Vaccine Institute”	a Cuban scientific organization dedicated to the development of vaccines
“Fosun Pharma”	Shanghai Fosun Pharmaceutical Co., Ltd., a Chinese pharmaceutical company
“Frost & Sullivan”	Frost & Sullivan (Beijing) Inc., Shanghai Branch Co., a global market research and consulting company, which is an Independent Third Party
“Frost & Sullivan Report”	an independent market research report commissioned by us and prepared by Frost & Sullivan for the purpose of this document
“Gamaleya”	the Gamaleya Research Institute of Epidemiology and Microbiology, a Russian medical-research institute headquartered in Moscow

DEFINITIONS

“GAVI”	the Vaccine Alliance, a public–private global health partnership with the goal of increasing access to immunisation in poor countries
“Genentech, Inc.”	an American biotechnology corporation which is a subsidiary of Roche
“GenHunter”	GenHunter Corporation, a biotechnology company headquartered in the U.S.
“GHIT”	Global Health Innovative Technology Fund, headquartered in Japan, an international public-private partnership between the Government of Japan, 16 pharmaceutical and diagnostics companies, the Bill & Melinda Gates Foundation, the Wellcome Trust and United Nations Development Programme
	[REDACTED]
“Greater China”	PRC, Hong Kong, Macau and Taiwan
	[REDACTED]
“Group”	our Company and all of its subsidiaries
“GSK”	GlaxoSmithKline plc, a British multinational pharmaceutical company
“HK Clover”	Clover Biopharmaceuticals (Hong Kong) Co., Limited, a limited company incorporated in Hong Kong on November 30, 2018, and a subsidiary of our Company
“HK\$” or “Hong Kong Dollars”	Hong Kong dollars, the lawful currency of Hong Kong

[REDACTED]

DEFINITIONS

“Hong Kong” the Hong Kong Special Administrative Region of the PRC

[REDACTED]

“Hong Kong Stock Exchange” or “Stock Exchange” The Stock Exchange of Hong Kong Limited, a wholly owned subsidiary of Hong Kong Exchange and Clearing Limited

“Hong Kong Takeovers Code” or “Takeover Code” the Codes on Takeovers and Mergers and Share Buy-backs issued by the SFC, as amended, supplemented or otherwise modified from time to time

[REDACTED]

“Independent Third Party(ies)” party or parties that, to the best of our Directors’ knowledge, information and believe, having made all reasonable enquiries, is or are not a connected person or connected persons of the Company within the meaning of the Listing Rules

“Institute of Microbiology, Chinese Academy of Sciences” the largest microbiological research institution in China

DEFINITIONS

[REDACTED]

“International Vaccine Institute”	an independent, nonprofit, international organization that was founded working to improve the health of children in developing countries by the use of new and improved vaccines
“Janssen Pharmaceuticals”	a pharmaceutical company headquartered in Belgium, and owned by Johnson & Johnson
“Johnson & Johnson”	an American multinational corporation founded in 1886 that develops medical devices, pharmaceuticals, and consumer packaged goods

[REDACTED]

DEFINITIONS

[REDACTED]

“Joint Sponsors” the joint sponsors of the [REDACTED] of the Shares on the Main Board of the Stock Exchange as named in “Directors and Parties Involved in the [REDACTED]”

“Latest Practicable Date” October 3, 2021, being the latest practicable date for the purpose of ascertaining certain information in this document prior to its publication

“Leukocare” Leukocare AG, a pharmaceutical company operates in Germany

[REDACTED]

“Listing Committee” the listing committee of the Hong Kong Stock Exchange

[REDACTED]

“Listing Rules” the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended or supplemented from time to time

“Macau” the Macau Special Administration Region of the PRC

“Main Board” the stock exchange (excluding the option market) operated by the Stock Exchange which is independent from and operated in parallel with the Growth Enterprise Market of the Stock Exchange. For the avoidance of doubt, the Main Board excludes the Growth Enterprise Market of the Stock Exchange

“Memorandum of Association” or “Memorandum” the memorandum of association of our Company adopted on [REDACTED] with effect from the [REDACTED], a summary of which is set out in “Appendix III – Summary of the Constitution of Our Company and Cayman Islands Company Law” to this document

“Medicago” Medicago Inc., a Canadian biotechnology company

“Medigen” Medigen Vaccine Biologics Corporation, a Taiwan-based biotechnology company

DEFINITIONS

“Moderna”	Moderna, Inc., a commercial stage biotechnology company
“MOFCOM” or “Ministry of Commerce”	the Ministry of Commerce of the PRC (中華人民共和國商務部)
“ <i>Nature</i> ”	a British weekly scientific journal founded and based in London, England, which is a multidisciplinary publication and features peer-reviewed research from a variety of academic disciplines, mainly in science and technology
“NCI”	National Cancer Institute, part of the U.S. Department of Health and Human Services
“NDRC”	the National Development and Reform Commission of the PRC (中華人民共和國國家發展和改革委員會)
“NHC”	the National Health Commission of the PRC (中華人民共和國國家衛生健康委員會), or its predecessors
“NIAID”	National Institute of Allergy and Infectious Diseases, part of the United States Department of Health and Human Services
“NIBSC”	National Institute for Biological Standards and Control, a government agency that works in the field of biological standardisation and is part of the United Kingdom’s Medicines and Healthcare products Regulatory Agency
“NMPA”	the National Medical Products Administration (國家藥品監督管理局), the Chinese agency for regulating drugs and medical devices, or its predecessors
“Non-PRC Resident Enterprise”	as defined under the EIT Law, means companies established pursuant to a non-PRC law with their de facto management conducted outside the PRC, but which have established organizations or premises in the PRC, or which have generated income within the PRC without having established organizations or premises in the PRC
“Novartis”	Novartis International AG, a Swiss pharmaceutical company based in Switzerland

DEFINITIONS

“Novavax” Novavax, Inc., an American vaccine development company

“NPC” the National People’s Congress of the PRC (中華人民共和國全國人民代表大會)

[REDACTED]

“Osaka University” a public research university located in Osaka Prefecture, Japan

“PAHO” Pan American Health Organization, an international public health agency working to improve health and living standards of the people of the Americas

“PCT” Patent Cooperation Treaty, which provides a unified procedure for filing patent applications to protect inventions in each of its contracting states

DEFINITIONS

“Pfizer”	Pfizer Inc., an American multinational pharmaceutical corporation
“Portola Pharmaceuticals”	an American pharmaceutical company acquired by Alexion
“Post-[REDACTED] Share Option Plan”	the post-[REDACTED] share option scheme adopted by our Company on September 26, 2021, effective from the [REDACTED], as amended from time to time, the principal terms of which are set out in “Appendix IV – Statutory and General Information – D. Share Incentive Plans – 3. Post-[REDACTED] Share Option Plan” to this document
“PRC Company Law”	the Company Law of the PRC (中華人民共和國公司法), promulgated by the Standing Committee of the NPC on December 29, 1993 and came into effect on July 1, 1994, as amended, supplemented or otherwise modified from time to time
“PRC Legal Adviser”	Tian Yuan Law Firm, our legal adviser as to PRC laws
“Pre-[REDACTED] Investments”	certain rounds of financing carried out by the Group before the [REDACTED], details of which are set out in the section headed “History, Reorganization and Corporate Structure – Pre-[REDACTED] Investments” in this document
“Pre-[REDACTED] Investors”	the investors of the Pre-[REDACTED] Investments
“Pre-[REDACTED] Share Option Plan”	the pre-[REDACTED] share option plan adopted by our Company on April 15, 2021, the principal terms of which are set out in “Appendix IV – Statutory and General Information – D. Share Incentive Plans – 1. Pre-[REDACTED] Share Option Plan” to this document
“Preferred Shares”	the Series A Preferred Shares, the Series B Preferred Shares, the Series B-2 Preferred Shares and the Series C Preferred Shares

[REDACTED]

DEFINITIONS

[REDACTED]

“QIB”	qualified institutional buyer within the meaning of Rule 144A
“Regulation S”	Regulation S under the U.S. Securities Act
“ReiThera”	ReiThera Srl, an Italian biotechnology company
“Remuneration Committee”	the remuneration committee of the Board
“Reorganization”	the reorganization conducted by our Group in preparation for the [REDACTED] as described in the section headed “History, Reorganization and Corporate Structure – Reorganization”
“Research Institute for Biological Safety Problems, Rep of Kazakhstan”	a Kazakhstani scientific research organization
“RMB” or “Renminbi”	Renminbi, the lawful currency of the PRC
“Roche”	Roche Holding AG, a multinational pharmaceutical company headquartered in Switzerland
“RSU Scheme”	the restricted share units scheme adopted by our Company on April 15, 2021, as amended from time to time, principal terms of which are set out in “Appendix IV – Statutory and General Information – D. Share Incentive Plans – 2. RSU Scheme” to this document
“Rule 144A”	Rule 144A under the U.S. Securities Act
“SAFE”	the State Administration of Foreign Exchange of the PRC (中華人民共和國國家外匯管理局)

DEFINITIONS

“SAMR”	the State Administration for Market Regulation of the PRC (中華人民共和國國家市場監督管理總局)
“Sanofi-Aventis”	Sanofi S.A., a French pharmaceutical company
“SAT”	the State Taxation Administration of the PRC (中華人民共和國國家稅務總局)
“ <i>Scientific Reports</i> ”	an online peer-reviewed open access scientific mega journal published by Nature Research, covering all areas of the natural sciences
“Securities and Futures Ordinance” or “SFO”	the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
“Series A Investors”	holder(s) of the Series A Preferred Shares
“Series A Preferred Shares”	the series A preferred shares held by the Series A Investors in the authorized share capital of the Company following the Reorganization, details of which are described in the section headed “History, Reorganization and Corporate Structure”
“Series B Investors”	holder(s) of the Series B Preferred Shares
“Series B Preferred Shares”	the series B preferred shares held by the Series B Investors in the authorized share capital of the Company following the Reorganization, details of which are described in the section headed “History, Reorganization and Corporate Structure”
“Series B-2 Investor”	holder of the Series B-2 Preferred Shares
“Series B-2 Preferred Shares”	the series B-2 preferred shares held by the Series B-2 Investor in the authorized share capital of the Company following the Reorganization, details of which are described in the section headed “History, Reorganization and Corporate Structure”
“Series C Investors”	holder(s) of the Series C Preferred Shares

DEFINITIONS

“Series C Preferred Shares”	the convertible series C preferred shares with a par value of US\$0.0001 per share in the authorized share capital of the Company allotted and issued to the Series C Investors during the Pre-[REDACTED] Investments
“Serum Institute of India”	Serum Institute of India Pvt. Ltd., an Indian pharmaceuticals company
“SFC”	The Securities and Futures Commission of Hong Kong
“Shanghai Clover”	Clover Biopharmaceuticals (Shanghai) Co., Ltd. (愷洛菲生物製藥(上海)有限公司), a limited liability company established in the PRC on February 9, 2021, and a wholly-owned subsidiary of our Company
“Share(s)”	shares in the share capital of our Company, with a nominal value of US\$0.0001 each
“Shareholder(s)”	holder(s) of our Share(s)
“Sichuan Clover”	Sichuan Clover Biopharmaceuticals, Inc. (四川三葉草生物製藥有限公司), a limited liability company established in the PRC on June 4, 2007, a wholly-owned subsidiary of our Company
“Sinopharm”	Sinopharm Group Co., Ltd., a Chinese pharmaceutical company
“Sinovac”	Sinovac Biotech Ltd, a Chinese pharmaceutical company
“Sophisticated Investor(s)”	has the meaning ascribed to it under Guidance Letter HKEX-GL92-18 issued by the Stock Exchange and for the purpose of this document refers to Hillhouse Capital Management, Ltd., Delos Capital, Beijing Lapam Healthcare Investment Center (Limited Partnership) (北京龍磐健康醫療投資中心(有限合夥)) and Hangzhou Yuhang Lapam Healthcare Equity Investment Fund Partnership Enterprise (Limited Partnership) (杭州余杭龍磐健康醫療股權投資基金合夥企業(有限合夥)), all of which have made meaningful investment in our Company at least six months before the [REDACTED]

DEFINITIONS

[REDACTED]

“State Council” the State Council of the PRC (中華人民共和國國務院)

[REDACTED]

“Stock Exchange” the Stock Exchange of Hong Kong Limited

“subsidiary(ies)” has the meaning ascribed to it in section 15 of the Companies Ordinance

“Substantial Shareholder(s)” has the meaning ascribed to it under the Listing Rules and for the purpose of this document refers to Dr. Liang and Mr. Joshua Liang as a group and Hillhouse

“Super Novel” SUPER NOVEL INTERNATIONAL LIMITED, a BVI company which holds the Shares underlying the awards under the RSU Scheme

“Takara Bio” Takara Bio Inc., a Japanese biotechnology company headquartered in Shiga, Japan founded in 2002

“Takeda” The Takeda Pharmaceutical Company Limited, a Japanese multinational pharmaceutical company

“Takeovers Code” the Codes on Takeovers and Mergers and Share Buy-backs issued by the SFC, as amended, supplemented or otherwise modified from time to time

“The Global Fund” an international financing and partnership organization that aims to “attract, leverage and invest additional resources to end the epidemics of HIV/AIDS, tuberculosis and malaria to support attainment of the Sustainable Development Goals established by the United Nations”

“*The Lancet*” a weekly peer-reviewed general medical journal, which is among the world’s oldest and best-known general medical journals

“the World Bank” an international financial institution that provides loans and grants to the governments of low- and middle-income countries for the purpose of pursuing capital projects

DEFINITIONS

“Track Record Period” the two years ended December 31, 2019 and 2020 and the four months ended April 30, 2021

[REDACTED]

“UNICEF” United Nations International Children’s Emergency Fund, a United Nations agency responsible for providing humanitarian and developmental aid to children worldwide

“Unitaid” a global health initiative that works with partners to bring about innovations to prevent, diagnose and treat major diseases in low- and middle-income countries, with an emphasis on tuberculosis, malaria, and HIV/AIDS and its deadly co-infections

“United Biomedical” United Biomedical, Inc., a pharmaceutical company founded in 1983

“United Nations Development Programme” a global development network of the United Nations, which promotes technical and investment cooperation among nations and advocates for change and connects countries to knowledge, experience and resources to help people build a better life for themselves

“Univercells” Univercells SA, a global provider of innovative biomanufacturing technologies headquartered in Brussels, Belgium

“University of Oxford” a collegiate research university in Oxford, Oxfordshire, England

“U.S.” or “United States” the United States of America, its territories, its possessions and all areas subject to its jurisdiction

“U.S. Clover” Clover Biopharmaceuticals USA, Inc., a stock corporation incorporated in the State of Delaware, U.S. on March 30, 2020, and a wholly-owned subsidiary of our Company

DEFINITIONS

“U.S. dollars” or “US\$”	United States dollars, the lawful currency of the United States
“U.S. persons”	U.S. persons as defined in Regulation S
“USPTO”	United States Patent and Trademark Office
“U.S. Securities Act”	United States Securities Act of 1933, as amended, supplemented or otherwise modified from time to time
“Vanderbilt University”	a private research university in Nashville, Tennessee, founded in 1873
“VAT”	value-added tax; all amounts are exclusive of VAT in this document except where indicated otherwise
“Vaxxinity”	a U.S.-based pharmaceutical company pioneering a new class of medicines to democratize health
“we”, “us” or “our”	the Company or the Group, as the context requires
“Wellcome Trust”	charitable foundation focused on health research based in the United Kingdom

[REDACTED]

“WHO”	World Health Organization, a specialized agency of the United Nations responsible for international public health
“Wuhan Institute of Biological Products”	Wuhan Institute of Biological Products Co., Ltd., a subsidiary of Sinopharm in Wuhan
“Wyeth”	Wyeth, LLC, an American pharmaceutical company

DEFINITIONS

“Zhejiang Clover”	Zhejiang Clover Biopharmaceutical, Inc. (浙江三葉草生物製藥有限公司), a limited liability company established in the PRC on August 23, 2016, and a wholly-owned subsidiary of our Company
“Zydus Cadila”	Cadila Healthcare Limited, an Indian pharmaceutical company.

Certain amounts and percentage figures included in this document have been subject to rounding adjustments. Accordingly, figures shown as totals in certain tables may not be an arithmetic aggregation of the figures preceding them.

The English translation and/or transliteration of the names of PRC nationals, entities, enterprises, government authorities, departments, facilities, certificates, titles, laws and regulations included in this document is provided for identification purposes only. In the event of any inconsistency between the English translation and/or transliteration and the Chinese versions, the Chinese versions shall prevail.

GLOSSARY

“3 LNP-mRNAs”	Messenger ribonucleic acid, mRNA sequence is encapsulated within a lipid nano-particle (LNP) to enable drug delivery. The LNP enables delivery of the mRNA. Once inside the cell the information encoded in the mRNA sequence provides the template to produce viral antigen proteins which generate an immune response
“4-1BB”	also known as CD137, a member of the tumor necrosis factor (TNF) receptor family
“4-1BB agonist”	a substance which initiates a physiological response when combined with a 4-1BB receptor
“accelerated titration dosing (ATD)”	the principle that allows inpatient dose-escalation for a patient who remains on study and has no evidence of toxicity at the current dose. Specifically, the dose for the next course is escalated if less than moderate toxicity was observed for the patient during the current course
“ACE2”	angiotensin-converting enzyme 2, an enzyme attached to the cell membranes of cells located in the lungs, arteries, heart, kidney, and intestines
“Ad26.COV2.S”	a COVID-19 vaccine candidate developed by Janssen Vaccines in Leiden, Netherlands, and its Belgian parent company Janssen Pharmaceuticals, subsidiary of American company Johnson & Johnson by eroding a full-length and stabilized SARS-CoV-2 S protein with a recombinant, replication-incompetent adenovirus serotype 26 (Ad26) vector
“Adeno-based (rAd26-S+rAd5-S)”	a COVID-19 vaccine candidate developed by the Gamaleya National Research Centre for Epidemiology and Microbiology comprising two vector components, recombinant adenovirus type 26 (rAd26) and recombinant adenovirus type 5 (rAd5), both of which carry the gene for SARS-CoV-2 full-length glycoprotein S
“adenovirus”	a DNA virus originally identified in human adenoid tissue, causing infections of the respiratory system, conjunctiva, and gastrointestinal tract, and including some capable of inducing malignant tumors in experimental animals

GLOSSARY

“Adenovirus Type 5 Vector”	a COVID-19 vaccine candidate developed by Cansino based on Type 5 adenovirus, a species C adenoviruses which can rapidly infect mitotic and non-mitotic cells
“adenovirus-based viral vectors”	tools commonly used by molecular biologists to deliver genetic material into cells using adenovirus. This process can be performed inside a living organism (in vivo) or in cell culture (in vitro)
“adjuvant”	a drug or other substance, or a combination of substances, that is used to increase the efficacy or potency of certain drugs
“affinity capture”	a technique in molecular biology used to isolate desired compounds based on their chemical properties and a solid substrate
“aflibercept”	a medication used to treat wet age-related macular degeneration and metastatic colorectal cancer
“AG0301-COVID19”	a COVID-19 vaccine candidate developed by AnGes Inc. and Osaka University. a plasmid DNA vaccine candidate that disables the connection between the coronavirus’ protein spikes and human cells’ receptors
“agonist monoclonal antibodies (mAbs)”	a monoclonal antibody, a type of protein made in the laboratory that can bind to substances in the body, that aims to boost the human immune system either to fight infection or cancer
“AIDS”	Acquired Immunodeficiency Syndrome (AIDS), a disease in which there is a severe loss of the body’s cellular immunity, greatly lowering the resistance to infection and malignancy
“Alpha Variant”	Variant of lineage B.1.1.7 of SARS-CoV-2, the virus that causes COVID-19
“amino acid sequence”	the arrangement of amino acids in a protein. Proteins can be made from 20 different kinds of amino acids, and the structure and function of each protein is determined by the kinds of amino acids used to make it and how they are arranged
“ankylosing spondylitis (AS)”	a rare type of arthritis that causes pain and stiffness in spine

GLOSSARY

“anorexia”	an eating disorder characterized by an abnormally low body weight, an intense fear of gaining weight and a distorted perception of weight
“anti-tumor efficacy”	the ability to inhibit the growth of a tumor or tumors
“antibodies”	an immunoglobulin protein produced in response to and counteracting a specific antigen. Antibodies bind to substances which the body recognizes as alien, such as bacteria, viruses, and foreign substances in the blood
“antigen”	a molecule or molecular structure, which may be present at the outside of a pathogen or cancer cell surface, that can be bound to by an antigen-specific antibody or B cell antigen receptor
“antigenic epitopes”	the part of an antigen that is recognized by the immune system, specifically by antibodies, B cells, or T cells
“apoptosis”	the death of cells that occurs as a normal and controlled part of an organism’s growth or development
“apoptotic signaling pathway”	two major pathways of apoptotic cell death induction: extrinsic signaling through death receptors that leads to the formation of the death-inducing signaling complex (DISC), and intrinsic signaling mainly through mitochondria which leads to the formation of the apoptosome
“AUC _{0-∞} ”	area under the concentration-time curve from the first time point measured (0) extrapolated to infinity (∞)
“AUC _{0-t} ”	area under the concentration-time curve from the first time point measured (0) to the last time point measured (t)
“autoimmune diseases”	diseases which arise from an abnormal immune response, where the immune system mistakenly attacks healthy body cells
“baculovirus”	a family of insect viruses that have a large double-stranded DNA (dsDNA) genome that can accommodate multiple additional foreign genes to produce recombinant proteins

GLOSSARY

“Beta Variant”	Variant of lineage B.1.351 of SARS-CoV-2, the virus that causes COVID-19
“biological effective dose (BED)”	the amount of an absorbed compound that reaches targets or sites of action within the body to cause a biologic effect
“Biologics License Application (BLA)”	a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce
“biomarker”	a measurable indicator of the severity or presence of some disease state. More generally a biomarker is anything that can be used as an indicator of a particular disease state or some other physiological state of an organism
“bioreactors”	any manufactured device or system that supports a biologically active environment
“biosimilar”	a biologic medical product (also known as biologic) highly similar to another already approved biological medicine (the ‘reference medicine’)
“bivalent vaccine”	a vaccine that works by stimulating an immune response against two different antigens, such as two different viruses or other microorganisms
“booster vaccine”	a booster dose is an extra administration of a vaccine after an earlier (primer) dose. After initial immunization, a booster injection or booster dose is a re-exposure to the immunizing antigen. It is intended to increase immunity against that antigen back to protective levels, after memory against that antigen has declined through time
“broadly-neutralizing antibodies (bNAbs)”	neutralizing antibodies defend a cell from an infectious pathogen
“C-terminal domain”	the end of an amino acid chain (protein or polypeptide), terminated by a free carboxyl group (-COOH)
“C-terminal domain of Type I procollagen”	the end of an amino acid chain of type I collagen, a protein that in humans is encoded by the COL1A1 gene

GLOSSARY

“cancer metastasis”	the spread of cancer cells from the original tumor to another part of the body. In metastasis, cancer cells break away from the original (primary) tumor, travel through the blood or lymph system, and form a new tumor in other organs or tissues of the body
“carcinoma”	a type of cancer that starts in cells that make up the skin or the tissue lining organs, such as the liver or kidneys
“carcinomatosis”	a condition in which multiple carcinomas develop simultaneously, usually after dissemination from a primary source
“caspases”	a family of protease enzymes playing essential roles in programmed cell death. Caspase 3 is a caspase protein that interacts with caspase-8 and caspase-9. Caspase 6 is an enzyme in humans that plays a role in the early immune response via de-repression. Caspase 7 is a human protein that plays a central role in the execution-phase of cell apoptosis. Caspase 8 is a caspase protein that participates in the activation cascade responsible for death receptor-induced cell death and nonapoptotic processes
“catheter blockage”	the blockage of catheter, a soft hollow tube, which is passed into the bladder to drain urine
“CD4+ T-cell”	a type of T cell that plays an important role in the immune system, particularly in the adaptive immune system. They “help” the activity of other immune cells by releasing cytokines, small protein mediators that alter the behavior of target cells that express receptors for those cytokines
“cell membrane”	a biological membrane that separates the interior of all cells from the outside environment (the extracellular space) which protects the cell from its environment
“cGMP”	current Good Manufacturing Practices, the regulations that guide the design, monitoring, and maintenance of manufacturing facilities
“ChAdOx1-S”	a COVID-19 vaccine candidate developed by AstraZeneca based on a chimpanzee adenovirus modified to avoid replication

GLOSSARY

“chemical pleurodesis”	a therapeutic procedure applied to create the symphysis between the parietal and visceral pleura by intrapleural administration of various chemical agents
“chemotherapy-induced thrombocytopenia (CIT)”	a platelet count less than $100 \times 10^9/L$ with or without bleeding in cancer patients receiving chemotherapy
“CHO-cell”	Chinese hamster ovary cells, an epithelial cell line derived from the ovary of the Chinese hamster, often used in biological and medical research and commercially in the production of recombinant therapeutic proteins
“ C_{max} ”/“ C_{min} ”	“ C_{max} ” is the maximum observed plasma and/or serum drug concentration. “ C_{min} ” is the minimum or “trough” concentration of a drug in plasma and/or serum observed after its administration and just prior to the administration of a subsequent dose
“CMC”	chemistry, manufacturing, and controls processes in the development, licensure, manufacturing, and ongoing marketing of pharmaceutical products
“CMO(s)”	contract manufacturing organization(s), a company that serves other companies in the pharmaceutical industry on a contract basis to provide comprehensive services from drug development through drug manufacturing
“conditional approval”	the regulatory authority determines the benefit of the immediate availability of the medicine outweighs the risk and allows the drug company to legally sell the drug before proving it meets the “substantial evidence” standard of effectiveness for full approval
“collagen”	the most abundant protein in the human body, found in the bones, muscles, skin, and tendons. It is the substance that holds the body together. Collagen forms a scaffold to provide strength and structure
“COLO205”	a human colon cancer cell line derived from a patient with adenocarcinoma of the colon (Dukes Classification type D)

GLOSSARY

“colorectal cancer”	also known as bowel cancer, colon cancer, or rectal cancer, is a type of cancer that begins in the colon or rectum (parts of the large intestine)
“convalescent sera”	serum that is obtained from an individual who has recovered from an infectious disease and contains antibodies against the infectious agent
“Coronavirus-Like Particle COVID-19 (CoVLP)”	a COVID-19 vaccine candidate developed by Medicigo and GlaxoSmithKline (GSK)
“coronaviruses”	a group of related RNA viruses that cause diseases in mammals and birds. In humans and birds, they cause respiratory tract infections that can range from mild to lethal
“covalent bond-linkage”	linkage via chemical bonds that involves the sharing of electron pairs between atoms
“covalently-trimerized structures”	a chemical structure that has three identical molecules connected by covalent bonds
“COVAX Facility”	COVID-19 Vaccines Global Access, a global initiative aimed at equitable access to COVID-19 vaccines led by UNICEF, GAVI, the Vaccine Alliance, the World Health Organization, the Coalition for Epidemic Preparedness Innovations, and others
“COVID-19”	a viral respiratory disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
“Covishield”	the Oxford-AstraZeneca COVID-19 vaccine, codenamed AZD1222, and sold under the brand name Covishield
“CpG”	Cytosine phosphoguanine (CpG), a synthetic form of DNA that mimics bacterial and viral genetic material
“CpG-ODN adjuvant”	CpG oligodeoxynucleotides, interact with TLR9 to stimulate maturation and proliferation of multiple cell types of the immune system and provide strong vaccine adjuvant effects

GLOSSARY

“CRO(s)”	contract research organization(s), a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis
“cytokines”	a large group of proteins, peptides or glycoproteins that are secreted by specific cells of immune system. Cytokines are a category of signaling molecules that mediate and regulate immunity, inflammation and hematopoiesis
“cytoplasmic domains”	the part of a transmembrane protein which projects into the cytoplasm
“cytoreductive surgery (CRS)”	the removal of all sites of cancer within the abdominal cavity
“cytotoxicity”	the quality of being toxic to cells
“data readout”	the results of a clinical trial are made public
“death receptor 4 (DR4)”	also known as TRAIL receptor 1 (TRAILR1) and tumor necrosis factor receptor superfamily member 10A (TNFRSF10A), a cell surface receptor of the TNF-receptor superfamily that binds TRAIL and mediates apoptosis
“death receptor 5 (DR5)”	also known as TRAIL receptor 2 (TRAILR2) and tumor necrosis factor receptor superfamily member 10B (TNFRSF10B), a cell surface receptor of the TNF-receptor superfamily that binds TRAIL and mediates apoptosis
“debilitating diseases”	diseases causing serious impairment of strength or ability to function
“decortication”	type of surgical procedure performed to remove a fibrous tissue that has abnormally formed on the surface of the lung, chest wall or diaphragm
“Delta Variant”	variant of lineage B.1.617.2 of SARS-CoV-2, the virus that causes COVID-19

GLOSSARY

“disease-modifying antirheumatic drugs (DMARDs)”	a category of otherwise unrelated drugs defined by their use in rheumatoid arthritis to slow down disease progression
“diuretic therapy”	a treatment that promotes diuresis, the increased production of urine
“DNA”	deoxyribonucleic acid, a self-replicating material which is present in nearly all living organisms as the main constituent of chromosomes and is the carrier of genetic information
“DNA vaccines”	a type of vaccine that transfects a specific antigen-coding DNA sequence onto the cells of an immunized species
“dose limiting toxicity (DLT)”	the level of toxicity that is serious enough to prevent an increase in dose or level of that treatment
“dose-escalation phase”	a phase in a clinic trial in where different doses of an agent (e.g. a drug) are tested against each other to establish which dose works best and/or is least harmful
“drug metabolism and pharmacokinetics (“DMPK”)	a core discipline in drug development that considers the biotransformation of a drug compound and other pharmacokinetic properties to assess drug safety
“dyspnoea” or “dyspnea”	difficult or labored breathing
“Ebola”	a viral hemorrhagic fever of humans and other primates caused by ebolaviruses. Signs and symptoms typically start between two days and three weeks after contracting the virus with a fever, sore throat, muscular pain, and headaches
“effector”	an organ or cell that acts in response to a stimulus
“electrolyte abnormalities”	an abnormality in the concentration of electrolytes, a substance that produces an electrically conducting solution when dissolved in a polar solvent, such as water in the body
“ELISA”	enzyme-linked immunoassay, a commonly used laboratory test to detect antibodies in the blood

GLOSSARY

“ELISpot”	a type of assay that focuses on quantitatively measuring the frequency of cytokine secretion for a single cell
“Enbrel (etanercept)”	a biopharmaceutical that treats autoimmune diseases by interfering with tumor necrosis factor (TNF), a soluble inflammatory cytokine that acts as a TNF inhibitor, sold under the brand name Enbrel among others
“endogenous cytokine”	cytokines that originate from within a system such as an organism, tissue, or cell
“EpiVacCorona”	a COVID-19 vaccine developed by the Vector Institute, it contains fragments extracted from the virus synthetic peptide antigens
“equimolar”	of or relating to an equal number of moles an equimolar mixture
“extrinsic apoptosis pathway”	one way that initiates apoptosis, a form of programmed cell death, triggered by a death ligand binding to a death receptor, such as TNF- α to TNFR1
“exudate”	a mass of cells and fluid that has seeped out of blood vessels or an organ, especially in inflammation
“Fas-associated death domain”	an adaptor protein that is recruited to the death-inducing signaling complex (DISC) during signaling via death receptors
“Fc segment”	Fragment crystallizable (Fc) region, and is composed of two heavy chains that contribute two or three constant domains depending on the class of the antibody
“Fc-fusion”	homodimers in which an Fc domain of an antibody is covalently linked to another protein
“Fc-fusion protein”	bioengineered polypeptides that joins the crystallizable fragment (Fc) domain of an antibody with another biologically active protein domain or peptide to generate a molecule with unique structure–function properties and significant therapeutic potential

GLOSSARY

“FDA”	The U.S. food and drug administration is responsible for protecting public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices
“fill-finish lines”	lines for the process of filling vials with vaccine and finishing the process of packaging the medicine for distribution
“FINLAY-FR2 anti-SARS-CoV-2 Vaccine”	a COVID-19 vaccine candidate developed by Finlay Vaccine Institute
“fistula”	an abnormal connection between two body parts, such as an organ or blood vessel and another structure
“formaldehyde”	a colorless, strong-smelling gas with the formula CH ₂ O
“freeze-dried (lyophilized) powder formulation”	a powder formula made through freeze-drying process
“Fusion F Antigen-Trimer”	a RSV vaccine candidate developed by Clover Biopharmaceuticals
“fusion protein”	a protein consisting of at least two domains that are encoded by separate genes that have been joined so that they are transcribed and translated as a single unit, producing a single polypeptide
“Gamma Variant”	Variant of lineage P.1 of SARS-CoV-2, the virus that causes COVID-19
“gastrointestinal cancer”	a cancer that develops from the lining of the stomach
“gastrointestinal malignancies”	malignant conditions of the gastrointestinal tract (GI tract) and accessory organs of digestion, including the esophagus, stomach, biliary system, pancreas, small intestine, large intestine, rectum and anus
“geometric mean titers (GMTs)”	geometric mean titer, the average antibody titer for a group of subjects calculated by multiplying all values and taking the nth root of this number, where n is the number of subjects with available data

GLOSSARY

“Good Clinical Practice (GCP)”	good clinical practice, an international ethical and scientific quality standard for the performance of a clinical trial on medicinal products involving humans
“Good Manufacturing Practices (GMP)”	good manufacturing practices, the aspect of quality assurance that ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification
“GRAd-COV2 (Replication defective Simian Adenovirus (GRAd) encoding S)”	a COVID-19 vaccine candidate developed by ReiThera based on a novel replication-incompetent simian adenovirus strain, encoding the full-length Spike (S) protein of SARS-CoV-2
“hACE2”	human angiotensin-converting enzyme 2 (hACE2) is an enzyme attached to the membrane of cells located in the intestines, kidney, testis, gallbladder, and heart. ACE2 lowers blood pressure by catalyzing the hydrolysis of angiotensin II (a vasoconstrictor peptide) into angiotensin (1-7) (a vasodilator). ACE2 also serves as the entry point into cells for some coronaviruses, including SARS-CoV and SARS-CoV-2. The SARS-CoV-2 spike protein itself is known to damage the epithelium via downregulation of ACE2. The human version of the enzyme can be referred to as hACE2
“half-life”	the time required for a quantity to reduce to half of its initial value
“hepatic arterial injection”	a medical procedure that delivers chemotherapy directly to the liver
“hepatitis-B”	an infectious disease caused by the hepatitis B virus (HBV) that affects the liver; it is a type of viral hepatitis
“hepatocyte toxicity”	toxicity toward hepatocyte, a cell of the main parenchymal tissue of the liver
“heterologous prime-boost”	administration of two different vectors or delivery systems expressing the same or overlapping antigenic inserts

GLOSSARY

“HIV”	human immunodeficiency virus, a virus that attacks the body’s immune system
“homotrimer”	a protein which is composed of three identical units of polypeptide
“host cells”	living cells invaded by or capable of being invaded by an infectious agent (such as a bacterium or a virus)
“humoral immunity”	the aspect of immunity that is mediated by macromolecules found in extracellular fluids such as secreted antibodies, complement proteins, and certain antimicrobial peptides
“hyperthermic intraperitoneal chemotherapy”	a cancer treatment that involves filling the abdominal cavity with chemotherapy drugs that have been heated
“IgG antibodies”	Immunoglobulin G, the most common type of antibody found in blood and other body fluids, and protects against bacterial and viral infections. IgG molecules are created and released by plasma B cells and each IgG has two antigen binding sites
“IL-17”	Interleukin 17 family (IL17 family), a family of pro-inflammatory cystine knot cytokines
“IL-24”	a protein in the interleukin family, a type of cytokine signaling molecule in the immune system. In humans, this protein is encoded by the IL24 gene
“IL-4”	a cytokine that induces differentiation of naive helper T cells (Th0 cells) to Th2 cells
“IL-5”	an interleukin produced by type-2 T helper cells and mast cells
“immune co-stimulation”	a secondary signal which immune cells rely on to activate an immune response in the presence of an antigen-presenting cell
“immune responses”	a reaction which occurs within an organism for the purpose of defending against foreign invaders

GLOSSARY

“immune thrombocytopenic purpura (ITP)”	also known as idiopathic thrombocytopenic purpura or immune thrombocytopenia, is a type of thrombocytopenic purpura defined as an isolated low platelet count with a normal bone marrow in the absence of other causes of low platelets
“immuno-oncology”	the study and development of treatments that take advantage of the body’s immune system to fight cancer
“immunocompromised patients”	patients with a reduced ability to fight infections and other diseases
“immunogenicity”	the ability of a particular substance, such as an antigen, to provoke an immune response in the body of a human or other animal
“immunology”	a branch of biology that covers the study of immune systems in all organisms
“ <i>in vivo</i> ”	a medical test, experiment or procedure that is done on (or in) a living organism, such as a laboratory animal
“inactivated COVID-19 vaccine”	COVID-19 vaccine made by taking the disease-carrying virus or bacterium, or one very similar to it, and inactivating or killing it using chemicals, heat or radiation
“incidence”	the number of new cases that develop in a given period of time
“IND”	investigational new drug or investigational new drug application, also known as clinical trial application in China
“IND-enabling studies”	studies conducted to evaluate potential toxicity risks prior to human studies and to estimate starting doses for clinical trials. Key IND-enabling studies include pharmacology, pharmacokinetics, and toxicology assessments
“indwelling pleural catheter”	a specially designed small tube used to drain pleural fluid from around lungs easily and painlessly, whenever needed

GLOSSARY

“influenza”	commonly called “the flu”, is an infectious disease caused by influenza viruses
“initial antigen expression”	the initial expression of antigen molecules on the surface of a macrophage or other antigen-presenting cell
“initiator procaspases 10”	an initiator caspase recruited to death receptors, it is activated through two cleavage events that proceed in a defined order to generate the large and small subunits of the mature protease
“initiator procaspases 8”	an initiator caspase recruited to death receptors, it is activated through two cleavage events that proceed in a defined order to generate the large and small subunits of the mature protease
“INO-4800+electroporation”	a DNA vaccine candidate developed by Inovio Pharmaceuticals matched to the novel coronavirus SARS-CoV-2, which causes the COVID-19 disease in humans
“inter-molecular disulfide bonds”	the covalent bond between sulfur atoms that binds two peptide chains or different parts of one peptide chain
“intracavitary malignancies”	a malignant tumor situated or occurring within a body cavity
“intraperitoneal hyperthermic chemotherapy (HIPEC)”	a high-concentration treatment directed at treating certain types of cancer in which drug delivery and susceptibility of cancer cells is enhanced. It is a process during which heated chemotherapy is applied directly into the abdomen after cytoreductive surgery while the patient is still under anesthesia
“intraperitoneal injection (IP)”	the injection of a substance into the peritoneum (body cavity)
“intrapleural chemotherapy”	treatment in which anticancer drugs are put directly into the abdominal cavity through a thin tube
“intrapleural injection”	injection through the chest wall into the pleural space or instilled through a chest tube placed intrapleurally for drainage

GLOSSARY

“intratumor injection”	direct injection of agents into the tumor itself
“intravenous (IV)”	existing or taking place within, or administered into, a vein or veins
“intravenous bolus”	a relatively large volume of fluid or dose of a drug or test substance given intravenously and rapidly to hasten or magnify a response
“intravenous infusion”	the direct injection of medication into a vein through an intravenous line, needle, or catheter
“juvenile idiopathic arthritis”	a group of conditions involving joint inflammation (arthritis) that first appears before the age of 16. This condition is an autoimmune disorder, which means that the immune system malfunctions and attacks the body’s organs and tissues, in this case the joints
“kDa”	kilodalton (1,000 dalton). One molecular hydrogen molecular atom has molecular mass of 1 Da, so 1 Da = 1 g/mol. Proteins and other molecular macromolecule molecular weights are usually measured in molecular kDa or kD (kilodaltons) – 1000 Da
“kinetics”	the mechanism by which a physical or chemical change is effected
“ligand”	a substance that forms a complex with a biomolecule to serve a biological purpose
“loculations”	the localized failure of a region to drain fluids, resulting in an enlarged mass
“lymphatic fluids (chylous ascites)”	a rare form of ascites that results from the leakage of lipid-rich lymph into the peritoneal cavity. This usually occurs due to trauma and rupture of the lymphatics or increased peritoneal lymphatic pressure secondary to obstruction
“lymphoma”	a usually malignant tumor of lymphoid tissue
“lyophilizer”	a device used to carry out the process of freeze-drying

GLOSSARY

“malignant neoplasm”	a cancerous tumor, an abnormal growth that can grow uncontrolled and spread to other parts of the body
“malignant ascites (MA)”	abnormal accumulation of fluid within the peritoneal cavity caused by the intraperitoneal spread of the original cancer
“malignant pleural effusions (MPE)”	a condition in which cancer causes an abnormal amount of fluid to collect between the thin layers of tissue (pleura) lining the outside of the lung and the wall of the chest cavity. Lung cancer, breast cancer, lymphoma, and leukemia cause most malignant pleural effusions
“maximum tolerated dose (MTD)”	maximum tolerated dose, which is the highest dose of a drug or treatment that does not cause unacceptable side effects. The MTD is determined in clinical trials by testing increasing doses on different groups of people until the highest dose with acceptable side effects is found
“MERS-CoV”	the virus that causes Middle East respiratory syndrome (MERS)
“metastasis”	the development of secondary malignant growths at a distance from a primary site of cancer
“monovalent vaccine”	a monovalent vaccine contains a single strain of a single antigen
“mRNA”	messenger ribonucleic acid (mRNA) is a single-stranded molecule of RNA that contains the genetic sequence for synthesizing a protein
“mRNA-1273”	a COVID-19 vaccine candidate developed by Moderna/NIAID based on mRNA encapsulated with lipid nanoparticles (LNPs)
“mRNA-based vaccines”	a type of vaccine that uses a copy of synthetic messenger RNA to create an immune response and protect against a pathogen
“multiple ascending dose (MAD)”	studies that investigate the pharmacokinetics and pharmacodynamics (PK and PD) of multiple doses of a drug, looking at safety and tolerability

GLOSSARY

“mouse model”	the use of special strains of mice to study a human disease or condition, and how to prevent and treat it
“Mu Variant”	Variant of lineage B.1.621 of SARS-CoV-2, the virus that causes COVID-19
“myalgia”	muscle aches and pain which can involve ligaments, tendons and fascia, the soft tissues that connect muscles, bones and organs. Injuries, trauma, overuse, tension, certain drugs and illnesses can all bring about myalgia
“nCoV Vaccine”	a DNA plasmid based COVID-19 vaccine candidate developed by Zydus Cadila
“NDA”	new drug application
“neutralizing antibodies”	an antibody that defends a cell from a pathogen or infectious particle by neutralizing any effect it has biologically
“neutralizing antibody titers”	a laboratory test that measures the presence and amount of neutralizing antibodies in blood
“Non-steroidal anti-inflammatory drugs (NSAID)”	members of a drug class that reduces pain, decreases fever, prevents blood clots, and in higher doses, decreases inflammation
“NTD”	N-terminal domain, a region of the protein’s polypeptide chain located at the start of the protein that is selfstabilizing and that folds independently from the rest
“ophthalmology”	the branch of medicine concerned with the study and treatment of disorders and diseases of the eye
“ovarian cancer”	a type of cancer that begins in the ovaries
“palivizumab”	a monoclonal antibody produced by recombinant DNA technology used to prevent severe disease caused by respiratory syncytial virus (RSV) infections sold under the brand name Synagis
“palliative care”	care for the terminally ill and their families, especially that provided by an organized health service

GLOSSARY

“pancreatic cancer”	a type of cancer that begins in the pancreas, an organ of the digestive system and endocrine system of vertebrates
“paracentesis”	a procedure in which a thin needle or tube is put into the abdomen to remove fluid from the peritoneal cavity
“pathway”	a sequence of chemical reactions undergone by a compound or class of compounds in a living organism
“pediatric population”	a number of subpopulations. The Food and Drug Administration (FDA) Guidance (1998) breaks down this population into the following groups: neonates (birth to 1 month), infants (1 month to 2 years), developing children (2–12 years), and adolescents (12–16 years)
“peritoneal carcinomatosis (PC)”	intraperitoneal dissemination (carcinosis) of any form of cancer that does not originate from the peritoneum itself
“peritoneal catheter drainage”	a treatment using a peritoneal catheter, a small plastic tube implanted under the skin, to provide a painless way of withdrawing excess fluid from or delivering anti-cancer drugs into the abdominal or peritoneal cavity over a period of weeks, months or even years
“peritoneal mesothelioma”	a type of cancer that develops in the thin layer of tissue lining the abdomen (the peritoneum)
“peritoneovenous shunting”	a shunt which drains peritoneal fluid from the peritoneum into veins, usually the internal jugular vein or the superior vena cava. It is sometimes used in patients with refractory ascites
“pharmacodynamics (PD)”	the study of the biochemical and physiologic effects of drugs (especially pharmaceutical drugs). The effects can include those manifested within animals (including humans), microorganisms, or combinations of organisms (for example, infection)
“pharmacokinetics (PK)”	a branch of pharmacology dedicated to determine the fate of substances administered to a living organism

GLOSSARY

“Phase 1 clinical trial”	clinical trials that provide initial safety data to (i) find a safe dose; (ii) decide how the new treatment should be given (by mouth, in a vein, etc.); and (iii) see how the new treatment affects the human body and fights the disease
“Phase 2 clinical trial”	clinical trials that seek further safety data and preliminary evidence in support of biological effect to (i) determine if the new treatment has an effect on a certain disease (such as cancer); and (ii) see how the new treatment affects the body and fights the disease
“Phase 3 clinical trial”	clinical trials of which the main focus are large confirmatory studies meant to establish an acceptable benefit/safety profile in order to gain regulatory approval for a precisely defined indication (“registrational clinical trials”), including by comparing the new treatment (or new use of a treatment) with the current standard treatment Phase 3 trials are well-controlled trials that provide scientifically credible and statistically strong evidence about the treatment indication hypothesized at the end of Phase 2 investigation
“phosphate-buffered saline (PBS)”	a buffer solution commonly used in biological research. It is a water-based salt solution containing disodium hydrogen phosphate, sodium chloride and, in some formulations, potassium chloride and potassium dihydrogen phosphate. The buffer helps to maintain a constant pH. The osmolarity and ion concentrations of the solutions match those of the human body (isotonic)
“pivotal trial”	typically a Phase 3 clinical trial in the multi-year process of clinical research intended to demonstrate and confirm the safety and efficacy of a treatment – such as a drug candidate, medical device or clinical diagnostic procedure – and to estimate the incidence of common adverse effects
“pleural space”	the potential space between the pleurae of the pleural sac that surrounds each lung
“pleurectomy”	surgery to remove part of the pleura (a thin layer of tissue that covers the interior wall of the chest cavity)

GLOSSARY

“pleuroperitoneal shunts”	surgically implanted catheters for transport of fluid from a pleural space into the peritoneal cavity, where it is absorbed; used mainly for treatment of malignant pleural effusions
“pneumothorax”	an abnormal collection of air in the pleural space between the lung and the chest wall
“portal hypertension”	an increase in the pressure within the portal vein, which carries blood from the digestive organs to the liver
“pre-clinical study”	studies testing a drug on non-human subjects, to gather efficacy, toxicity, pharmacokinetic and safety information and to decide whether the drug is ready for clinical trials
“prefilled syringe formulation”	the formulation of a single-dose packet of vaccine to which a needle has been fixed by the manufacturer
“preservatives”	a substance or a chemical that is added to products such as food products, beverages, pharmaceutical drugs, paints, biological samples, cosmetics, wood, and many other products to prevent decomposition by microbial growth or by undesirable chemical changes
“prevalence”	the number of cases of a disease that are present in a particular population at a given time
“pro-inflammatory cytokine”	a type of signaling molecule (a cytokine) that is secreted from immune cells like helper T cells (Th) and macrophages, and certain other cell types that promote inflammation
“prophylactic vaccine”	vaccine administered to individuals as a precautionary measure to prevent or ameliorate the effects of a future infection by a natural pathogen
“protein-based subunit vaccines”	a vaccine that presents an antigen to the immune system without viral particles, using a specific, isolated protein of the pathogen
“proteolytic cleavage”	the process of breaking the peptide bonds between amino acids in proteins

GLOSSARY

“pseudomyxoma peritonei”	a rare disease characterized by the presence of mucin in the abdominal (peritoneal) cavity
“pseudovirus”	a virus artificially created by pseudotyping to contain envelope proteins from a different virus
“psoriasis”	a chronic skin disease characterized by circumscribed red patches covered with white scales
“psoriatic arthritis”	a form of arthritis that affects some people who have psoriasis – a condition that features red patches of skin topped with silvery scales
“Qualified Person (QP)”	technical term used in European Union pharmaceutical regulation (Directive 2001/83/EC for Medicinal products for human use) and typically refers to a licensed pharmacist, biologist or chemist (or a person with another permitted academic qualification) who is authorized to certify and release drug product batches in EU countries
“rabies”	an acute virus disease of the nervous system of mammals that is caused by a rhabdovirus (species Rabies virus of the genus Lyssavirus) usually transmitted through the bite of a rabid animal and that is characterized typically by increased salivation, abnormal behavior, and eventual paralysis and death when untreated
“radiographic axial spondyloarthritis (r-axSpA)”	a chronic, autoinflammatory disease predominantly affecting the axial skeleton (sacroiliac joints and spine)
“RBD”	receptor binding domain, a key part of a virus located on its “spike” protein that allows it to dock to body receptors to gain entry into cells and lead to infection
“RBD-Dimer”	ZF2001, trade-named RBD-Dimer, is an adjuvanted protein subunit COVID-19 vaccine developed by Anhui Zhifei Longcom in collaboration with the Institute of Microbiology at the Chinese Academy of Sciences
“reactogenicity”	a subset of reactions that occur soon after vaccination, and are a physical manifestation of the inflammatory response to vaccination

GLOSSARY

“receptor”	a structure in the cell membrane or within a cell that combines with a drug, hormone, chemical mediator to alter an aspect of the functioning of the cell
“receptor binding domain (RBD)”	a short immunogenic fragment from a virus that binds to a specific endogenous receptor sequence to gain entry into host cells
“recombinant”	the formation by the processes of crossing-over and independent assortment of new combinations of genes in progeny that did not occur in the parents
“recombinant subunit-Trimer vaccines”	vaccines containing trimeric protein subunits formed by recombination
“RP2D”	Recommended Phase II Dose, usually the highest dose with acceptable toxicity, usually defined as the dose level producing around 20% of dose-limiting toxicity
“renal dysfunction”	poor function of the kidneys that may be due to a reduction in blood-flow to the kidneys caused by renal artery disease
“renal filtration”	the process that kidneys use to filter excess fluid and waste products out of the blood into the urine collecting tubules of the kidney, so they may be eliminated from the body
“rheumatic diseases”	autoimmune and inflammatory diseases that cause the immune system to attack joints, muscles, bones and organs
“rheumatoid arthritis (RA)”	an autoimmune disorder that occurs when the body’s immune system mistakenly attacks its healthy tissues, affect the joints and, in some cases, damage a wide range of human body systems, including the skin, eyes, lungs, heart and blood vessels
“RNA viruses”	a virus that has RNA (ribonucleic acid) as its genetic material

GLOSSARY

“rolling submission”	a drug company can submit completed sections of its NDA for review, rather than waiting until every section of the application is completed before the entire application can be reviewed
“RSV”	respiratory syncytial virus, also called human respiratory syncytial virus and human orthopneumovirus, is a very common, contagious virus that causes infections of the respiratory tract
“S protein”	spike protein, a highly glycosylated and large type I transmembrane fusion protein that is made up of amino acids
“Spike-Dimer”	a dimeric form of the spike protein
“S-Trimer TM /Spike-Trimer”	a stabilized trimeric form of the spike protein
“SARS-CoV-2 virus”	severe acute respiratory syndrome coronavirus 2, is the virus that causes coronavirus disease 2019 (COVID-19), the respiratory illness responsible for the COVID-19 pandemic
“SCB-2019 (CpG 1018/Alum)”	a COVID-19 vaccine candidate developed by our Company
“secondary peritoneal surface malignancies”	tumors that begin in other abdominal organs, and spread (metastasize) to the peritoneum
“seroconversion”	the development of detectable antibodies in the blood that are directed against an infectious agent
“sereopositive”	the presence of detectable levels of a specific marker within the serum
“seronegative”	the absence of detectable levels of a specific marker within the serum
“shingles”	an acute viral inflammation of the sensory ganglia of spinal and cranial nerves that is associated with a vesicular eruption and neuralgic pain and is caused by reactivation of the herpesvirus causing chicken pox

GLOSSARY

“single ascending dose (SAD)”	in single ascending dose studies, small groups of subjects are given a single dose of the drug while they are observed and tested for a period of time to confirm safety. If they do not exhibit any adverse side effects, and the pharmacokinetic data are roughly in line with predicted safe values, the dose is escalated, and a new group of subjects is then given a higher dose
“spike protein (S protein)”	a glycoprotein that protrudes from the envelope of some viruses (such as a coronavirus) and facilitates entry of the virion into a host cell by binding to a receptor on the surface of a host cell followed by fusion of the viral and host cell membranes
“sub-picomolar”	having a concentration of less than one picomole per litre
“systemic antitumor therapy”	a collective term to describe the growing number of differing therapies used in malignancy to achieve palliation. Improving symptoms, quality of life (QOL) and where possible quantity of life are the goals of these treatments
“systemic chemotherapy”	treatment with anticancer drugs that travel through the blood to cells all over the body
“T cells”	cells that originate in the thymus, mature in the periphery, become activated in the spleen/nodes if their T-cell receptors bind to an antigen presented by an MHC molecule and they receive additional co-stimulatory signals driving them to acquire killing (mainly CD8+ T cells) or supporting (mainly CD4+ T cells) functions
“Th1 cytokines”	the cytokines that stimulate macrophages, lymphocytes, and PMNs in the destruction of bacterial pathogens
“Th1-biased cell-mediated immune response”	the immune response in which Th1 cells stimulate cellular immune response, participate in the inhibition of macrophage activation and stimulate B cells to produce IgM, IgG1
“Th17 cell-mediated immune response”	the immune response in which Th17 cell play a critical role in the activation of other immune cells such as B cells and cytotoxic T cells, as well as in the regulation of immune responses

GLOSSARY

“Th17 cells”	a subset of pro-inflammatory T helper cells defined by their production of interleukin 17 (IL-17)
“Th2-biased cell-mediated immune response”	the immune response in which Th2 stimulates humoral immune response, promotes B cell proliferation and induces antibody production (IL-4)
“therapeutic paracentesis”	removal of fluid from a body cavity via a needle, a trocar, a cannula, or another hollow instrument, as part of the plan of treatment
“therapeutic thoracentesis”	removal of fluid from the space between the lungs and the chest wall (the pleural cavity) for therapeutic purposes using a needle inserted between the ribs
“thoracentesis”	an invasive medical procedure to remove fluid or air from the pleural space for diagnostic or therapeutic purposes
“titers”	a laboratory test that measures the presence and amount of antibodies in blood
“TM”	a symbol to indicate that the preceding mark that has not been registered at the U.S. Patent and Trademark Office
“TNF- α ”	tumor necrosis factor alpha, a protein that stimulates the inflammatory response in the body
“TNF- α inhibitor”	a pharmaceutical drug that suppresses the physiologic response to tumor necrosis factor (TNF), which is part of the inflammatory response
“toxicology”	a scientific discipline, overlapping with biology, chemistry, pharmacology, and medicine, that involves the study of the adverse effects of chemical substances on living organisms and the practice of diagnosing and treating exposures to toxins and toxicant
“TPO-mimetic”	Thrombopoietin-mimetic, that considerably increases platelet production by stimulating the receptor for the hormone thrombopoietin
“TPOR agonist”	thrombopoietin receptor agonist, a chemical that binds to a thrombopoietin receptor and activates the receptor to produce a biological response

GLOSSARY

“TRAIL”	TNF-related apoptosis-inducing ligand, a protein functioning as a ligand that induces the process of cell death called apoptosis
“TRAIL-DR4/DR5 pathway”	a pathway that facilitates the selective elimination of malignant cells through the induction of apoptosis with TRAIL (TNF-related apoptosis-inducing ligand) death receptors DR4 and DR5
“TRAIL-Fc”	TNF-related apoptosis-inducing ligand with a fragment crystallizable region
“trimer”	a molecule or an anion formed by combination or association of three molecules or ions of the same substance
“trimeric fusion proteins (trimer-tagged proteins)”	proteins created through the joining of two or more genes that originally coded for separate proteins and consist of three identical simpler parts
“trimerization”	a chemical reaction that uses three identical molecules to produce a single trimer product
“trimerization tag”	a protein tag from the C-propeptide domain of procollagen (Trimer-Tag™), which is capable of self-assembly into a disulfide bond-linked trimer
“tumor”	an abnormal mass of tissue that forms when cells grow and divide more than they should or do not die when they should. Tumors may be benign (not cancer) or malignant (cancer)
“tumor necrosis factor (TNF) superfamily (TNFSF)”	a protein superfamily of type II transmembrane proteins containing TNF homology domain and forming trimers
“type I immunoglobulin IgG1”	Immunoglobulin G (IgG) is a type of antibody. Representing approximately 75% of serum antibodies in humans, IgG is the most common type of antibody found in blood circulation

GLOSSARY

“Type I procollagen”	the most abundant collagen of the human body. It forms large, eosinophilic fibers known as collagen fibers. It is present in scar tissue, and is the end product when tissue heals by repair, as well as tendons, ligaments, the endomysium of myofibrils, the organic part of bone, the dermis, the dentin, and organ capsules
“UB-612”	a COVID-19 S-protein based vaccine candidate developed by COVAXX
“vaccine”	a vaccine is a biological preparation that provides active acquired immunity to a particular disease
“vaccine associated enhanced respiratory disease (“VAERD”)	an adverse event where an exacerbated course of respiratory disease occurs with higher incidence in the vaccinated population in comparison with the control group
“vaccine-related adverse events”	any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine
“vascular permeability”	characterizes the capacity of a blood vessel wall to allow for the flow of small molecules (drugs, nutrients, water, ions) or even whole cells (lymphocytes on their way to the site of inflammation) in and out of the vessel
“virion”	the complete, infective form of a virus outside a host cell, with a core of RNA and a capsid
“virus-specific T-cell”	T cells that specifically target one or more species of virus
“VSV (Ervebo)”	known as Ebola Zaire vaccine live and sold under the brand name Ervebo, a vaccine for adults that prevents Ebola caused by the Zaire ebolavirus
“wet age-related macular degeneration (wAMD)”	a chronic eye disorder that causes blurred vision or a blind spot in the visual field
“yeast expression”	A yeast expression platform is a strain of yeast used to produce large amounts of proteins, sugars or other compounds for research or industrial uses

FORWARD-LOOKING STATEMENTS

We have included in this document forward-looking statements. Statements that are not historical facts, including statements about our intentions, beliefs, expectations or predictions for the future, are forward-looking statements.

This document contains certain forward-looking statements and information relating to us and our subsidiaries that are based on the beliefs of our management as well as assumptions made by and information currently available to our management. When used in this document, the words “aim,” “anticipate,” “believe,” “could,” “estimate,” “expect,” “going forward,” “intend,” “may,” “might,” “ought to,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “will,” “would” and the negative of these words and other similar expressions, as they relate to us or our management, are intended to identify forward-looking statements. Examples of forward-looking statements include, but are not limited to, statements we make regarding our projections, business strategy and development activities as well as other capital spending, financing sources, the effects of regulation, expectations concerning future operations, margins, profitability and competition. The foregoing is not an exclusive list of all forward-looking statements we make.

Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. We give no assurance that these expectations and assumptions will prove to have been correct. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. Our results may differ materially from those contemplated by the forward-looking statements. They are neither statements of historical fact nor guarantees or assurances of future performance. We caution you therefore against placing undue reliance on any of these forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward-looking statements include regional, national or global political economic, business, competitive, market and regulatory conditions and the following:

- the timing of initiation and completion, and the progress of our pre-clinical studies and clinical trials;
- the timing and likelihood of regulatory filings and approvals, such as IND, NDA and BLA;
- our ability to advance our product candidates into products, and the successfully completion of clinical trials;
- the receipt and timing of any payments in relation to the CEPI Funding Agreement or GAVI Advance Purchase Agreement;
- the commercialization strategies and pricing policy of our product candidates;
- the market opportunities of our product candidates;

FORWARD-LOOKING STATEMENTS

- estimates of our costs, expenses, future revenues, capital expenditures and our needs for additional financing;
- our ability to attract and retain senior management and key employees;
- our operations and business prospects;
- future developments, trends, conditions and competitive landscape in the industry and markets in which we operate;
- our strategies, plans, objectives and goals and our ability to successfully implement these strategies, plans, objectives and goals;
- our ability to compete in the markets in which we operate;
- our ability to identify and integrate suitable acquisition targets;
- changes to regulatory and operating conditions in the industry and markets in which we operate;
- the amount and nature of, and potential for, future development of our business; and
- certain statement in the sections headed “Risk Factors,” “Industry Overview,” “Regulation Overview,” “Business,” “Financial Information” and “Future Plans and Use of [REDACTED]” with respect to trends in interest rates, foreign exchange rates, prices, operations, margins, risk management and overall market trends.

Any forward-looking statement made by us in this document speaks only as of the date on which it is made. Statements of or references to our intentions or those of the Directors are made as of the date of this document unless specified otherwise. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. Subject to the requirements of applicable laws, rules and regulations, we undertake no obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise. All forward-looking statements contained in this document are qualified by reference to this cautionary statement.

RISK FACTORS

You should carefully consider all of the information in this document, including the risks and uncertainties described below, before making an investment in our Shares. Our business, financial condition and results of operations could be materially and adversely affected by any of these risks and uncertainties. The [REDACTED] of our Shares could decline due to any of these risks, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us, or not expressed or implied below, or that we deem immaterial, could also harm our business, financial condition and results of operations.

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We have incurred net losses and net operating cash outflows since our inception, and we may continue to incur net losses and net operating cash outflows. Investors are at risk of losing substantially all of their investments in our Shares.

Investment in pharmaceutical product development is highly speculative. It entails substantial upfront capital expenditures and significant risks; a product might fail to demonstrate sufficient efficacy or safety to gain regulatory approval or become commercially viable. Our ongoing operations bring significant expenses. As a result, we have incurred losses in each period since our inception. For the years ended 2019 and 2020 and the four months ended April 30, 2021, we experienced a loss of RMB48.6 million, RMB912.9 million and RMB909.2 million, respectively. As of December 31, 2019 and 2020 and April 30, 2021, we had an accumulated deficit attributable to owners of RMB120.6 million, RMB1,033.5 million and RMB1,942.7 million, respectively. We also had net cash used in operating activities of RMB26.6 million and RMB189.5 million for the year ended December 31, 2019 and the four months ended April 30, 2021, respectively. Substantially all of our operating losses and net operating cash outflows resulted from costs incurred in connection with our research and development programs, administrative expenses and fair value changes of convertible redeemable preferred shares.

We may continue to incur net losses for the foreseeable future, and that these losses may increase as we continuously expand our development, including:

- conducting clinical trials and advancing pre-clinical studies of our current product candidates;
- maintaining and expanding our own manufacturing facilities;
- seeking regulatory approvals for our product candidates that successfully complete clinical trials;
- commercializing our product candidates for which we have obtained marketing approval;

RISK FACTORS

- building up our commercialization, distribution, and sales workforce in anticipation of the future roll-out of our product candidates;
- initiating pre-clinical studies, clinical trials or other research and development activities for new product candidates;
- maintaining, protecting and expanding our intellectual property portfolio; and
- creating additional infrastructures to support our operations as a public company, our product development, and planned future commercialization efforts.

Developing biopharmaceutical products, including conducting pre-clinical studies and clinical trials, is a very time consuming, expensive and uncertain process that takes years to complete. During the process, we may encounter unforeseeable expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. The size of our future net losses will depend partially on the number and scope of our drug or vaccine development programs and the associated costs, the rate of the future growth of our expenses and the commercialization costs of any approved products. If any of our product candidates fails during clinical trials or does not gain regulatory approval, or, even if approved, fails to achieve market acceptance, our business may not become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods thereafter. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our working capital and Shareholders' equity. A decline in our value may also bring negative impact on substantially all or part of your investment.

In addition, while we believe we have sufficient working capital to fund our current operations, we expect that we may continue to experience net cash outflows from our operating activities for the foreseeable future. We believe that we will continuously need substantial capital support, particularly as we advance the clinical development of our clinical-stage product candidates, continue the research and development activities of our pre-clinical stage product candidates, initiate additional clinical trials of, and seek regulatory approval for, these and other future product candidates.

If we obtain regulatory approvals for any of our product candidates, we expect to incur significant commercialization expenses relating to product manufacturing, marketing, sales and distribution and post-approval commitments to continue monitoring the efficacy and safety data of our future products on the market. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations through public or private equity offerings, debt financing, collaborations or licensing arrangements or other sources.

Our future capital funding requirements will depend on many factors, including:

- the progress, timing, scope, and costs of our clinical trials, including our ability to timely enroll patients or participants in our planned and potential future clinical trials;

RISK FACTORS

- the outcome, timing and costs of regulatory approvals of our product candidates;
- the costs and timing of future commercialization activities for our products, if any of our product candidates are approved for marketing, including product manufacturing, marketing, sales and distribution costs;
- the number and characteristics of product candidates that we may develop;
- the timing, receipt, and amount of sales of, or upfront, royalties or milestone payments on, our future products, if any;
- the costs involved in filing, prosecuting, defending, and enforcing any patent claims or other intellectual property rights, including litigation costs and the outcome of such litigation;
- the terms and timing of any potential future collaborations, licensing or other arrangements that we may establish;
- cash requirements of any future development of other pipeline product candidates; and
- our headcount growth and associated costs.

We plan to primarily use the [REDACTED] from the [REDACTED] and cash and cash equivalents on hand to fund our future operations. However, if the commercialization of our product candidates, including SCB-2019 (CpG 1018/Alum), is delayed or terminated, or if expenses increase, we may need to obtain additional financing to fund our operations. Additional funds may not be readily available when we need them, on terms that are acceptable to us, or at all. Our ability to raise funds will depend on the worldwide financial, economic and market conditions and other factors, many of which are beyond our control. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate pre-clinical studies, clinical trials or other research and development activities or commercialization for one or more of our product candidates, and in turn will adversely affect our business prospects.

It may be difficult to evaluate our current business and predict our future performance.

Our operations to date have primarily focused on drug and vaccine discovery, as well as pre-clinical studies and clinical trials of our product candidates. We obtained data from SPECTRA, a global pivotal phase 2/3 clinical trial for SCB-2019 (CpG 1018/Alum) in September 2021. In addition, we have two clinical-stage product candidates and several pre-clinical product candidates. As of the Latest Practicable Date, we had not yet successfully advanced any of our product candidates towards commercial sale, nor generate any revenue from product sales. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history.

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We primarily focused on the discovery and development of innovative vaccines and drugs. Particularly in light of the rapidly evolving drug research and development industry in which we operate and the changing regulatory and market environments we encounter, it may be difficult to evaluate our prospects for future performance. As a result, any assessment of our future performance or viability is subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by biopharmaceutical and biotechnology companies in rapidly evolving fields as we seek to transition to a company capable of supporting commercial activities. If we do not address these risks and difficulties successfully, our business will suffer.

Our financial prospects depend on the successful development, approval, and commercialization of our clinical-stage and pre-clinical stage pipeline. We may not be able to successfully use and expand the Trimer-TagTM technology platform to build a pipeline of product candidates.

Our ability to generate revenue and become profitable in the future depends upon our ability to successfully complete the development of, obtain the necessary regulatory approvals for, and the commercialization of our product candidates. Specifically, the future financial prospects also depend upon our continuous usage and expansion of the Trimer-TagTM technology platform to build a pipeline of product candidates and the progress of these product candidates through clinical trial development, regulatory approval, and commercialization for the treatment of various diseases.

We have three product candidates in clinical trial stage. We also have several pre-clinical product candidates. We have invested a significant portion of our efforts and financial resources in the utilization of the Trimer-TagTM technology platform and the development of our existing product candidates. Although our research and development efforts to date have resulted in our clinical development of our core products and a few other product candidates under pre-clinical and clinical development, these clinical stage product candidates may not be safe or effective as a treatment. None of our product candidates have been approved for marketing in China or any other jurisdictions and may never receive such approval.

Even if we succeed in commercializing one or more of our product candidates, we expect to continue to incur substantial and increasing expenditures. Our ability to achieve revenue and profitability is dependent on our ability to complete the development, obtain necessary regulatory approvals, and manufacture and successfully market our product candidates.

The success of these product candidates will depend on several factors, including:

- completion of pre-clinical studies and successful enrollment in, and completion of, clinical trials;
- receipt of regulatory conditional and formal approvals from the NMPA, the EMA, and the WHO and other regulatory authorities for our COVID-19 vaccine candidates;

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- receipt of regulatory approval from the EMA and the NMPA for our other product candidates;
- relying on third parties to conduct our clinical trials safely and efficiently;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity;
- protecting our rights in our intellectual property;
- ensuring we do not infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property rights of third parties;
- obtaining and maintaining sufficient degree of market acceptance following the regulatory approvals;
- competition with other product candidates and vaccines; and
- continued acceptable safety profile for our product candidates following regulatory approval, if and when received.

Moreover, because we have limited financial and managerial resources, we focus our product pipeline on research and development programs and vaccine candidates that we identify for specific indications. As a result, we may forego or delay the pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial vaccines or other profitable market opportunities. Our spending on current and future research and development programs of our product candidates for specific indications may not yield any commercially viable products.

We incurred net liabilities during the Track Record Period, and may continue to have net liabilities going forward, which can expose us to liquidity risk.

We incurred net liabilities of RMB67.8 million as of December 31, 2019, primarily due to the convertible redeemable preferred shares and deferred income. As of December 31, 2020, we incurred net liabilities of RMB982.7 million as of December 31, 2020, the increase of net liabilities was primarily attributable to the increase of convertible redeemable preferred shares and deferred income. We recorded net liabilities of RMB1,883.5 million as of April 30, 2021, primarily attributable to the increase of convertible redeemable preferred shares and the deferred income.

A net liabilities position can expose us to liquidity risks because it would require us to seek adequate financing via external sources, which would normally not be immediately available on terms favorable or commercially reasonable to us, or at all. Any difficulty or failure in meeting our liquidity needs as and when needed could bring us material adverse impact.

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A large balance of indebtedness, whether from banks or related parties, would require that we devote our financial resources to service such debt, as opposed to funding our operating activities and investments in research and development. Such a focus would restrain our capital flexibility, and in turn adversely affect the anticipated timeline of our drug or vaccine development. It may also be challenging for us to service our interest and principal repayments in a timely manner, or at all, with risks of potentially triggering cross-defaults with other debt, and limiting our ability to obtain further debt financing options. Given our historical reliance on external financing sources, such development could have a material adverse effect on our business, financial condition and results of operations.

Our results of operations, financial condition and prospects may be adversely affected by fair value changes in our convertible redeemable preferred shares.

During the Track Record Period, we issued convertible redeemable preferred shares which are designated as financial liabilities at fair value through profit or loss. For the years ended December 31, 2019 and 2020 and the four months ended April 30, 2021, we recorded fair value changes of convertible redeemable preferred shares of RMB9.2 million, RMB(597.7) million, RMB(119.9) million and RMB(454.8) million, respectively, which contributed to our net losses. Fair value changes of the convertible redeemable preferred shares may continue to affect our financial performance until the [REDACTED]. The automatic conversion of the convertible redeemable preferred shares into ordinary shares upon the [REDACTED] is expected to ameliorate our net liabilities position. Moreover, we do not expect to recognize any further loss or gain on fair value changes from the convertible redeemable preferred shares in the future. If we continue to incur such fair value losses, our results of operations, financial condition and prospects may be adversely affected.

The preferred shares we issued are redeemable preferred shares designated as financial liabilities at FVTPL. As of December 31, 2019 and 2020 and April 30, 2021, we had RMB198.7 million, RMB1,127.3 million and RMB3,063.3 million level 3 financial liabilities, respectively. For level 3 financial liabilities, we adopted the back-solve method option-pricing method to determine the fair value of the redeemable preferred shares. For details, please see Note 2.4 to the Accountants’ Report in Appendix I to this document. The fair value measurement of our preferred shares involves estimates and assumptions that are subject to significant uncertainties and risks. Valuation techniques are certified by an independent qualified professional valuer before being implemented for valuation and are calibrated to ensure that outputs reflect market conditions. Valuation models established by the valuer make the maximum use of market inputs and rely as little as possible on our specific data. However, some significant unobservable inputs, such as fair value of our ordinary shares, possibilities under different scenarios such as [REDACTED], liquidation and redemption, and discount for lack of marketability, require management estimates. Management estimates and assumptions are reviewed periodically and are adjusted when necessary. Should any of the estimates and assumptions change, it may lead to changes in the fair value of financial liabilities at FVTPL. In addition, the valuation methodologies may involve a significant degree of management judgment and are inherently uncertain, which may result in material adjustment to the carrying amounts of certain liabilities and in turn may materially and adversely affect our results of operations.

RISK FACTORS

We are subject to valuation uncertainty and our results of operations, financial conditions, and prospects may be adversely affected by our financial instruments at fair value through profit or loss (FVTPL).

During the Track Record Period, we had certain financial assets at fair value through profit or loss, primarily consisting of financial assets included in prepayments, other receivables and other assets, time deposits and restricted cash, as well as cash and cash equivalents. All such assets were issued and managed by banks, and substantially all of them were principal protected. As a result, we are exposed to credit risk in relation to the financial assets, which may adversely affect our net changes in their fair value. The financial assets at fair value through profit or loss are stated at fair value, and net changes in the fair value are recorded as other gains or losses, thus directly impacting our results of operations. We cannot assure you that market conditions and regulatory environment will create fair value gains and we will not incur any fair value losses on our financial assets at fair value through profit or loss in the future.

We had foreign currency forward contracts, which are financial instruments at fair value through profit or loss. Our foreign currency forward contracts are classified as level 2 financial assets at FVTPL. As of December 31, 2019 and 2020 and April 30, 2021, we had nil, nil and RMB167,000 level 2 financial assets, respectively. Level 2 financial assets are not quoted in an active market, and we use valuation techniques to estimate the fair value of these assets. For details, please see Note 2.4 to the Accountants’ Report in Appendix I to this document. When estimating fair value using these valuation techniques, we consider observable inputs and market data, such as foreign exchange rates. Changes in these factors will affect the estimated fair value of our level 2 financial assets and therefore these assets will face uncertainty in accounting estimation.

We cannot assure that we will continue to receive government grants.

We have historically received various government grants mainly for compensation for the capital expenditure and recurring costs and expenses incurred in research activities of certain projects. We recognized government grants as other income and gains of RMB15.9 million and RMB20.4 million, RMB11.1 million and RMB3.2 million for the years ended December 31, 2019 and 2020 and the four months ended April 30, 2020 and 2021, respectively, which are of a non-recurring nature. There is no assurance that we could maintain or continue to receive the government grants described above at the historical levels, or at all. Any change, suspension withdrawal or termination of these government grants to us may have an effect on our business, financial condition and results of operations.

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We may not be able to fulfil our obligation in respect of deferred revenue, which may have impact on our liquidity position.

Funding received from CEPI to support the research and development of our SCB-2019 (CpG 1018/Alum) and is generally collected in advance and is initially recorded as deferred revenue. As of December 31, 2019 and 2020 and April 30, 2021, we recorded nil, RMB931.1 million and RMB1,183.8 million in deferred revenue, respectively. Our deferred revenue will be recognized as revenue, subject to our fulfilment of future performance obligations, such as the fulfilment of supply of SCB-2019 (CpG 1018/Alum) to certain countries. Our deferred revenue is recognizable upon fulfillment of future obligations, which is long-term in nature. Due to potential future changes in the progress of the research and development of our SCB-2019 (CpG 1018/Alum) and the variants for COVID-19, deferred revenue at any particular date may not be representative of actual revenue for any current or future period. Any failure to fulfil the obligations in respect of deferred revenue may have an adverse impact on our results of operations and liquidity.

Raising additional capital may cause dilution to our Shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We may seek additional funding through a combination of equity offerings, debt financings, collaborations, and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interests will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our Shares. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our Shares to decline.

In the event that we enter into collaborations or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms.

We may not be able to effectively manage our inventory levels.

Our inventories primarily consisted of raw materials for our research and development activities. We manage our inventory levels based on our forecasts of the demand for our ongoing research and development for the existing product candidates and potential new projects. The demand for raw materials for our research and development activities can be affected by numerous uncertainties, including in relation to the progress of preclinical studies, pending regulatory approvals, timing and success of clinical trials and other factors beyond our control. Our inventories amounted to RMB0.4 million, RMB50.9 million and RMB146.7 million as of December 31, 2019 and 2020 and April 30, 2021, respectively.

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If we fail to manage our inventory levels effectively, we may be subject to a heightened risk of inventory obsolescence, a decline in the value of inventories, and potential inventory write-downs or write-offs. Procuring additional inventories may also require us to commit substantial working capital, preventing us from using such capital for other purposes. Any of the foregoing may materially and adversely affect our results of operations and financial condition.

RISKS RELATING TO OUR BUSINESS AND INDUSTRY

Risks Relating to Pre-clinical and Clinical Development of Our Product Candidates

We depend substantially on the success of our product candidates, all of which are in discovery stage, pre-clinical or clinical development. If we are unable to successfully complete clinical development, obtain regulatory approval and commercialize our product candidates, or experience significant delays in doing so, our business will be significantly harmed.

Our business will depend on the successful development, regulatory approval and commercialization of our product candidates, all of which are still in discovery stage, pre-clinical or clinical development, and other new product candidates that we may identify and develop. As of the Latest Practicable Date, we had initiated ten clinical trials. However, we cannot guarantee that we are able to obtain regulatory approvals for any of our existing product candidates in a timely manner, or at all. In addition, none of our product candidates has been approved for marketing in China or any other jurisdictions yet. Each of our product candidates will require additional pre-clinical and/or clinical development, regulatory approvals in multiple jurisdictions. Substantial investments are required before we generate any revenue from product sales.

The success of our product candidates will depend on several factors, including the successful completion of pre-clinical studies and/or clinical trials, receipt of regulatory approvals from applicable regulatory authorities for planned clinical trials, future clinical trials or product registrations, future manufacturing, commercialization of our existing product candidates, hiring sufficient technical experts to oversee all development and regulatory activities and meeting of the prerequisite safety requirements.

If we do not achieve one or more of these in a timely manner or at all, we could experience significant delays in our ability to obtain approval for our product candidates, which would materially harm our business. As a result, we may not be able to generate sufficient revenue or cash flow to continue our operations, and our financial condition, results of operations and prospects will be materially and adversely harmed.

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To accelerate the development of the COVID-19 vaccines, regulatory authorities, such the EMA and the NMPA, conditionally approve certain COVID-19 vaccines. For example, as of the Latest Practicable Date, the EMA conditionally approved two mRNA-based vaccines and two adenovirus-based viral vector vaccines. Please refer to “Industry Overview – COVID-19 Vaccine Market Globally” for details. We will experience a delay in obtaining the EUL from the WHO for our SCB-2019 (CpG 1018/Alum), if we do not obtain a conditional approval from the NMPA or EMA as planned. If we fail to timely obtain conditional approval for SCB-2019 (CpG 1018/Alum) from relevant regulatory authorities, we may take longer time to commercialize SCB-2019 (CpG 1018/Alum) and consequently fall behind our competitors in the global COVID-19 vaccine market.

If we encounter difficulties enrolling patients or participants in our clinical trials, our clinical development activities could be delayed and result in increased costs and longer development periods or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients or participants who remain in the trial until its conclusion. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients or participants to participate in these trials, or if there are delays in the enrollment of eligible patients or participants as a result of the competitive clinical enrollment environment.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including:

- the obstacles in meeting size and nature of the patient population;
- severity of the disease under investigation;
- design and eligibility criteria for the clinical trial in question;
- perceived risks and benefits of the product candidate under study;
- our resources to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- availability of competing therapies also undergoing clinical trials;
- our investigators’ or clinical trial sites’ efforts to screen and recruit eligible patients or participants; and
- proximity and availability of clinical trial sites for prospective patients or participants.

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In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients or participants who would otherwise be eligible for our clinical trials may instead enroll in the clinical trials of our competitors' product candidates, which may further delay our clinical trial enrollments.

Even if we are able to enroll a sufficient number of patients or participants in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

We may rely on third parties to monitor, support and/or conduct clinical trials of our product candidates.

We may rely on third-party organizations, CROs, hospitals and clinics, who are beyond our control to monitor, support, conduct pre-clinical studies and/or clinical trials of our product candidates. We also rely on third parties to perform clinical trials on our product candidates when they reach that stage. As a result, we have less control over the quality, timing and cost of these studies and the ability to recruit trial subjects than if we conducted these trials wholly by ourselves. If we are unable to maintain or enter into agreements with these third parties on acceptable terms, or if any such engagement is terminated, we may be unable to enroll subjects on a timely basis or otherwise conduct our trials in the manner we anticipate.

In addition, there is no guarantee that these third parties will devote adequate time and resources to our studies or perform as required by a contract or in accordance with regulatory requirements, including maintenance of clinical trial information regarding our future product candidates. If these third parties fail to meet expected deadlines, fail to timely transfer to us any regulatory information, fail to adhere to protocols or fail to act in accordance with regulatory requirements or our agreements with them, or if they otherwise perform in a substandard manner or in a way that compromises the quality and/or accuracy of their activities and/or the data they obtain, then clinical trials of our future product candidates may be extended, delayed or terminated, or our data may be rejected by the EMA, the NMPA and the WHO or other regulatory agencies.

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Interim and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or top-line data from our pre-clinical studies and clinical trials, which is based on a preliminary analysis of then-available data, whose results, related findings and conclusions are subject to changes following a more comprehensive review of such data. We also make assumptions, estimations, calculations and conclusions as part of our analyses progress, for which we may not necessarily receive or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results reported by us may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our pre-clinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risks that one or more of the clinical outcomes may materially change along with patient enrollment where more patient or participant data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or our competitors could result in volatile prices of our Shares after this [REDACTED].

Moreover, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses, or may interpret or weigh the importance of data differently, which could impact the value of our particular program, the approvability or commercialization of our particular product candidate or product and us in general.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining regulatory approval for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates on humans. We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including: regulators, institutional review boards (IRBs), or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; our inability to reach agreements on acceptable terms with prospective CROs and trial sites, the term of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; manufacturing issues relating to our third-party CMOs or in the future after we establish our

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own facilities, including problems with manufacturing, supply quality, compliance with current good manufacturing practice (cGMP), or obtaining from third parties sufficient quantities of a product candidate for use in a clinical trial; clinical trials of our product candidates may produce negative or inconclusive results, and additional clinical trials or abandoning product development programs may be required; the number of patients or participants required for clinical trials of our product candidates may be larger than we anticipated, enrollment may be insufficient or slower than we anticipated, or patients or participants may drop out at a higher rate than we anticipated; our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; we might have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding of a lack of clinical response or other unexpected characteristics or a finding that participants are being exposed to unacceptable health risks; the cost of clinical trials of our product candidates may be greater than we anticipate; and the supply or quality of our product candidates, companion diagnostics or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, or if the results of these trials or tests are not positive or are only modestly positive or if they raise safety concerns, we may (i) be delayed in obtaining regulatory approval for our product candidates; (ii) not obtain regulatory approval at all; (iii) obtain approval for indications that are not as broad as intended; (iv) have the product removed from the market after obtaining regulatory approval; (v) be subject to additional post-marketing testing requirements; (vi) be subject to restrictions on how the product is distributed or used; or (vii) be unable to obtain reimbursement for the use of the product.

Our product candidates may cause undesirable adverse events or have other properties that could delay or prevent their regulatory approval, limit their commercial profile or result in significant negative post-approval consequences.

Undesirable adverse events caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval. Results of our trials could reveal a high and unacceptable level of severity or prevalence of adverse events. In such event, our trials could be suspended or terminated and the regulatory authority may order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. For example, undesirable adverse events could be caused by SCB-2019 (CpG 1018/Alum). For details of the adverse events and side effects of our product pipeline as observed during clinical trials, please see "Business – Our Product Candidates – Trimer-Tag™ Subunit Vaccine Candidates – SCB-2019 (CpG 1018/Alum)." Adverse reactions could affect patient recruitment or the ability of enrolled subjects to complete the trial, and could result in potential product liability claims. Any of these occurrences may harm our reputation, operations, financial condition and prospects significantly.

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Additionally, if one or more of our product candidates receive regulatory approval, and we or others later identify undesirable adverse events caused by such products, a number of potentially significant negative consequences could result, including the following:

- we may suspend the marketing of the product;
- regulatory authorities may withdraw approvals or revoke licenses of the product;
- regulatory authorities may require additional warnings on the label;
- we may be required to develop risk evaluation and mitigation measures for the product or, if risk evaluation and mitigation measures are already in place, to incorporate additional requirements under the risk evaluation and mitigation measures;
- we may be required to conduct post-market studies;
- we could be sued and held liable for harm caused to subjects, patients or participants; and
- our reputation may suffer.

Any of these occurrences may prevent us from achieving or maintaining market acceptance of our particular product candidate, and significantly harm our business, results of operations and prospects.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing is expensive and can take many years to complete, while its outcomes are inherently uncertain. We exclusively focus on developing product candidates with potential to become transformative biologic therapies and vaccines, but we cannot guarantee that we are able to achieve this for any of our product candidates. Failure can occur at any time during the clinical development process. The results of pre-clinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials, and initial or interim results of a trial may not be predictive of the final results. Product candidates during later stages of clinical trials may fail to show the desired outcomes in safety and efficacy despite of having progressed through early stage clinical trials, and of the level of scientific rigor in the study, design and adequacy of execution. In some instances, there can be significant variability in safety and/or efficacy results among different trials of the same product candidates due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, this include genetic differences, patient adherence to the dosing regimen and other trial protocol elements and the rate of dropout among clinical trial participants.

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In any trials we conduct, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries and languages involved in such trials. We cannot assure you that non-head-to-head analyses (e.g., comparisons with competing drugs based on their publicly available study and trial data) will be predictive of future clinical results. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to a lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. We cannot guarantee that our future clinical trial results will be favorable based on the current available clinical and pre-clinical data.

We may not be able to identify and discover novel and suitable product candidates.

We may fail to identify and discover novel and suitable product candidates for a number of reasons. For example, with respect to identifying and discovering new product candidates for in-house development, our research methodology may not be successful in identifying potential product candidates; or those we identify may be shown to have harmful side effects or other characteristics that make them unmarketable or unlikely to receive regulatory approval. Research programs to pursue the development of our product candidates for additional indications and to identify new product candidates and disease targets require substantial technical, financial and human resources regardless if we are ultimately successful. Our research and development efforts may initially show promise in identifying potential indications and/or product candidates, yet fail to yield results for clinical development for a number of reasons, including: (i) potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective products; or (ii) it may take greater human and financial resources to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs than we will possess, thereby limiting our ability to diversify and expand our product portfolio.

Accordingly, we cannot assure you that we will ever be able to identify additional therapeutic opportunities for our product candidates or develop suitable potential product candidates through internal research programs, any of which could materially and adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

The data and information that we gather in our research and development process could be inaccurate or incomplete, which could harm our business, reputation, financial condition and results of operations.

We collect, aggregate, process, and analyze data and information from our pre-clinical studies and clinical trials. We also engage in substantial information gathering following the identification of a promising product candidate. Because data in the healthcare industry are fragmented in origin, inconsistent in format, and often incomplete, the overall quality of data collected or accessed in the healthcare industry is often subject to challenge, the degree or amount of data which is knowingly or unknowingly absent or omitted can be material, and we

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often discover data issues and errors when monitoring and auditing the quality of our data. If we make mistakes in the capture, input or analysis of these data, our ability to advance the development of our product candidates may be materially harmed and our business, prospects and reputation may suffer.

We also engage in the procurement of regulatory approvals necessary for the development and commercialization of our products under development, for which we manage and submit data to governmental entities. These processes and submissions are governed by complex data processing and validation policies and regulations. Notwithstanding such policies and regulations, interim, top-line or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data, in which case we may be exposed to liability to a customer, court or government agency that concludes that our storage, handling, submission, delivery, or display of health information or other data was wrongful or erroneous. Although we maintain insurance coverage for clinical trials, this coverage may prove to be inadequate or could cease to be available to us on acceptable terms, if at all. Even unsuccessful claims could result in substantial costs and diversion of management time, attention, and resources. A claim brought against us that is uninsured or under-insured could harm our business, financial condition and results of operations.

In addition, we rely on CROs and other third parties to monitor and manage data for some of our ongoing pre-clinical and clinical programs and control only certain aspects of their activities. If any of our CROs, our partners or other third parties do not perform to our standards in terms of data accuracy or completeness, data from those pre-clinical and clinical trials may be compromised as a result, and our reliance on these parties does not relieve us of our regulatory responsibilities. For a detailed discussion, see “– Risks Relating to Our Reliance on Collaborators and Other Third Parties – We engage CROs to conduct certain of our pre-clinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.”

We may experience significant volatility in the market price of our Shares following announcements and data releases regarding our ongoing development of SCB-2019 (CpG 1018/Alum).

Pharmaceutical companies that are developing potential therapeutics and vaccines to combat COVID-19 pandemic, including us, have experienced significant volatility in the price of the securities upon publication of pre-clinical and clinical data as well as news about the development programs. Given the attention surrounding the COVID-19 pandemic and the public scrutiny of COVID-19 development announcement and data releases to date, we expect that the public announcements intend to make in the coming months regarding our ongoing development of SCB-2019 (CpG 1018/Alum) will attract significant attention and scrutiny and that, as a result, the price of our Shares may be particularly volatile during this time.

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Risks Relating to Obtaining Regulatory Approval for Our Product Candidates

The regulatory pathway for COVID-19 vaccines is highly dynamic and continues to evolve and may result in unexpected or unforeseen challenges.

The speed at which all parties are acting to develop and test many vaccines against the SARS-CoV-2 virus is unusual, and evolving or changing plans or priorities within the EMA, the NMPA, the WHO and other regulatory authorities, including changes based on new knowledge of COVID-19 and how the disease affects the human body, may significantly affect the regulatory timeline for SCB-2019 (CpG 1018/Alum).

Results from clinical testing may also raise new questions and require us to redesign proposed clinical trials, including revising proposed endpoints or adding new clinical trial sites or cohorts of subjects. For example, the EMA mandates any company developing a COVID-19 vaccine to submit application material containing data from various studies, including pharmaceutical quality studies, non-clinical studies and clinical studies. On each sub-category of those studies, the EMA imposes stringent yet detailed requirements on COVID-19 vaccine developers. Similarly, the NMPA and the WHO also prioritize the regulatory administration on COVID-19 vaccines, while emphasizing on various regulatory requirements on pre-clinical studies and clinical trials. Although we intend to design any future clinical trials for SCB-2019 (CpG 1018/Alum) in accordance with this guidance, we cannot be certain that, as the regulatory pathway continues to evolve, we will be able to complete a clinical trial in accordance with the applicable guidance and regulations then in effect.

A failure to complete a clinical trial in accordance with guidance and regulations then in effect could impair our ability to obtain approval for SCB-2019 (CpG 1018/Alum), which may adversely affect our operating results, reputation and ability to raise capital and enter into or maintain collaborations to advance our other product candidates.

Even if conditional or formal regulatory approval is received for our SCB-2019 (CpG 1018/Alum), the later discovery of previously unknown problems associated with SCB-2019 (CpG 1018/Alum) may result in restrictions or prohibitions, including withdrawal of the product from the market, and lead to significant liabilities and reputational damage.

Because the path to marketing approval of any vaccine against the SARS-CoV-2 virus is unclear, we may have a widely used vaccine in circulation in the EU, China or another country based on conditional approval and prior to our receipt of formal marketing approval. Unexpected safety issues, including any that we have not yet observed in our clinical trials for SCB-2019 (CpG 1018/Alum), could lead to significant reputational damage for us going forward, as well as other issues, including delays in our other programs, the need for re-design of our clinical trials and the need for significant additional financial resources.

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We may also be restricted or prohibited from the marketing and/or manufacturing of our SCB-2019 (CpG 1018/Alum), even after obtaining condition or formal product approval, if previously unknown problems with the product or its manufacturing are subsequently discovered. We cannot assure you that newly discovered or developed safety issues will not arise following regulatory approval. With the use of any vaccine by a wide patient population, serious adverse events or adverse events may occur from time to time that did not arise in the clinical trials of the vaccine or that initially appeared to be unrelated to the vaccine itself and only with the collection of subsequent information were found to be causally related to the product. Any such safety issues could cause us to suspend or cease marketing of our approved products, possibly subject us to substantial liabilities, and adversely affect our ability to generate revenue and our financial condition.

The regulatory approval processes of the EMA, the NMPA, and WHO and other comparable regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

Our business is substantially dependent on our ability to complete development, obtain regulatory approval, and successfully commercialize our product candidates in a timely manner. We cannot commercialize our product candidates without obtaining regulatory approval to market each product from the EMA, the NMPA, the WHO and other regulatory agencies. The time required to obtain approval from these regulatory agencies is unpredictable but typically takes years following the commencement of pre-clinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. Moreover, changes in regulatory requirements and guidance during our clinical trials may occur, which may result in necessary changes to clinical trial protocols, which could increase our costs, delay the timeline for or reduce the likelihood of regulatory approval for our product candidates. It is possible that none of our existing product candidates or any product candidates we may discover, in-license or acquire and seek to develop in the future will ever obtain regulatory approval, and any such failure could adversely affect our business, financial condition, results of operations and prospects.

In particular, our product candidates could fail to receive regulatory approval for many reasons, including:

- failure to begin or complete clinical trials due to disagreements with regulatory authorities;
- failure to demonstrate that a product candidate is safe and effective or, if it is a biologic, that it is safe, pure and potent for its proposed indication;
- failure of clinical trial results to meet the level of statistical significance required for approval;

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- data integrity issues related to our clinical trials;
- our CROs may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- disagreement with our interpretation of data from pre-clinical studies or clinical trials;
- our failure to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols;
- clinical sites, investigators or other participants in our clinical trials deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

The EMA, the NMPA and the WHO or a comparable regulatory authority may require more information, including additional pre-clinical or clinical data, to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program.

Changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Resubmission may increase our costs, be time consuming or even prevent us from initiating or completing the clinical trial. In addition, changes in government regulations or in practices relating to the pharmaceutical industry, such as heightened standards imposed due to regulatory requirements, may increase the difficulty for us to reach such standards, and have a material adverse impact on our business, financial condition, results of operations, and prospects.

If we experience delays in the completion of, or the termination of, a clinical trial of any of our product candidates, the commercial prospects of that product candidate will be harmed, and our ability to generate product sales revenue from any of those product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate related revenue for that candidate. Any of such occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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We are at risk of governmental actions that are detrimental to our business, such as product seizure, resumed price controls and additional regulations imposed on our SCB-2019 (CpG 1018/Alum).

During the pandemic period (as declared by the WHO), SCB-2019 (CpG 1018/Alum) will be purchased by and allocated through the COVAX Facility pursuant to the orders to be placed by GAVI, UNICEF, PAHO, or other potential parties. We may also consider commercializing SCB-2019 (CpG 1018/Alum) post conditional approval via bilateral supply agreements. During the post-pandemic period (as declared by the WHO), we may sell up to 50% of our production capacity for our COVID-19 vaccine candidate to the COVAX Facility if required, and we intend to sell the remaining amount through bilateral negotiations and supply arrangements with global governments. During both the pandemic period and post-pandemic period, there is a heightened risk that our SCB-2019 (CpG 1018/Alum) may be subject to adverse governmental actions in certain countries, including product seizures, intellectual property expropriation, compulsory licenses or other actions. We are likely to face challenges related to the allocation of supply of SCB-2019 (CpG 1018/Alum), particularly with respect to geographic distribution. Thus, even if SCB-2019 (CpG 1018/Alum) is conditionally or formally approved, such governmental actions may limit our ability to recoup our current and future expenses.

Furthermore, public sentiment regarding commercialization of a COVID-19 vaccine may limit or negate our ability to generate revenue from sales of SCB-2019 (CpG 1018/Alum), particularly during the post-pandemic period when we intent to sell certain amount of SCB-2019 (CpG 1018/Alum) through bilateral negotiations and supply arrangements with global governments. We are likely to face significant public attention and scrutiny over any future business models and pricing decisions with respect to SCB-2019 (CpG 1018/Alum). If we are unable to successfully manage these risks, we could face significant reputational harm, which could negatively affect the price of our ordinary shares.

All material aspects of the research, development, manufacturing and commercialization of pharmaceutical products are heavily regulated. Any failure to comply with existing regulations and industry standards or any adverse actions by the drug-approval authorities against us could negatively impact our reputation and our business, financial condition, results of operations and prospects.

All jurisdictions in which we intend to conduct our pharmaceutical-industry activities regulate these activities in great depth and detail. We intend to focus our manufacturing and earlier-stage development activities in China while pursuing global late-stage and commercial opportunities, including but not limited to the EU and other jurisdictions. These geopolitical areas all strictly regulate the pharmaceutical industry, and in doing so they employ broadly similar regulatory strategies, including regulation of product development and approval, manufacturing, and marketing, sales and distribution of products. However, there are differences in the regulatory regimes—some minor, some significant—that make for a more complex and costly regulatory compliance burden for a company like ours that plans to operate in each of these regions.

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The process of obtaining regulatory approvals and compliance with appropriate laws and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development process, approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the regulator's approval, refusal or withdrawal, license revocation, or total or partial suspension of production or distribution. Failure to comply with these regulations could have a material adverse effect on our business. Such suspension can negatively affect our commercial prospects and financial position.

In many countries or regions where a drug is intended to be ultimately sold, such as China, the U.S. and Europe, the relevant government agencies and industry regulatory bodies impose high standards on the efficacy of such drug, as well as strict rules, regulations and industry standards on how we develop such drug. These regulatory authorities may conduct scheduled or unscheduled periodic inspections of our facilities to monitor our regulatory compliance. Although we passed all the inspections and obtained clearance in relation to discovery and development, if applicable, from the regulatory authorities in all material respects during the Track Record Period; we cannot assure you that we will be able to do so going forward. Any failure to comply with existing regulations and industry standards could result in fines or other punitive actions against us, and the disqualification of data for submission to regulatory authorities, each of which could have a material adverse impact on our reputation, business, financial condition, results of operations and prospects. In addition, any action against us for violation of the relevant regulations or industry standards, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business, and adversely affect our reputation and financial results.

Even if we obtain marketing approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our products, and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.

Any of our future approved product candidates will be subject to ongoing or additional regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including requirements of regulatory authorities in China and other countries.

As a general rule, manufacturers and manufacturers' facilities are required to comply with extensive rules promulgated by NMPA in China and comparable regulatory authority requirements in other relevant jurisdictions ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any New Drug Application (NDA), other marketing application, and previous responses to any inspection observations if we were to build manufacturing facilities in the future. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

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Any approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, which could adversely affect the product’s commercial potential or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the product candidate. The EMA, the NMPA, the WHO or a comparable regulatory authority may also require a risk evaluation mitigation strategy program as a condition of approval of our product candidates or following approval. In addition, if the EMA, the NMPA, the WHO or a comparable regulatory authority approves our product candidates, we will have to comply with requirements, including, for example, submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and good clinical practice (GCP), for any clinical trials that we conduct post-approval. The EMA, the NMPA, the WHO and other regulatory authorities strictly regulate the marketing, labeling, advertising and promotion of products that are placed on the market.

Given the stringent regulatory requirements and active enforcement imposed by the EMA, the NMPA, the WHO and other regulatory authorities, our abilities on how we manufacture and market our products may remain limited, as compliance with such requirements likely involves our substantial resources, which could materially impair our ability to generate revenue.

Approval pathway for biosimilars in China remains fluid, which may adversely affect the regulatory approval of our biosimilar product candidates.

The Guidelines for the R&D and Evaluation of Biosimilar Drugs (for Trial Implementation) (《生物類似藥研發與評價技術指導原則(試行)》) and Technical Guidelines for Similarity Evaluation and Indication Extrapolation of Biosimilars (《生物類似藥相似性評價和適應症外推技術指導原則》) (collectively, the Biosimilar Guidelines), which are the prevailing PRC regulation on biosimilar evaluation and marketing approval, outline the regulatory framework for biosimilars, aiming to move toward a clear industry structure for the development of biosimilars. The Biosimilar Guidelines do not offer an alternative pathway for launching biosimilar products in China; rather, under Biosimilar Guidelines, biosimilars are essentially subject to the same approval pathway as novel biologics, only with a different set of data requirements. Applicants must mark in their IND applications and NDAs that submissions are intended to be reviewed as biosimilars. In addition, various uncertainties surrounding the application and interpretation of the Biosimilars Guidelines could adversely affect the regulatory approval of our existing biosimilar product candidates, including SCB-808, as well as other biosimilars we may develop in the future. Uncertainties surrounding the approval pathway for biosimilars in China include:

- the Biosimilar Guidelines serve as a technical guidance only and cannot address several fundamental issues for the administration of biosimilars in the absence of a clear legislative authorization, such as interchangeability with reference products, naming rules and labelling requirements for biosimilars;

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- although the Biosimilar Guidelines adopt a stepwise comparability approach, they do not contain sufficient details to be regarded as overarching guidelines and it is also not clear whether the NMPA will take further steps to develop product-specific guidelines on our biosimilars candidates and guidelines addressing issues such as immunogenicity assessment;
- while under the Biosimilar Guidelines, biosimilars are subject to the same approval pathway as innovative biologics with a different set of technical review criteria, it remains unclear if the time to market for biosimilars will be reduced compared with the lengthy review process for innovative biologics; and
- since changes in regulatory requirements and guidance may occur, it is unpredictable whether the NMPA and other regulatory authorities will issue updated policies or guidelines on biosimilars to replace or supplement the Biosimilar Guidelines, or whether such updated policies or guidelines will bring additional compliance costs or substantial impediments for our biosimilar candidates to obtain regulatory approvals.

As such, we cannot assure you that our biosimilar candidates will be approved under the Biosimilar Guidelines or any further updated policies or guidelines in the future, in a timely manner or at all, and we may not ultimately be able to develop and market any or all of them successfully.

Risks Relating to Manufacturing and Commercialization of Our Product Candidates

Reductions in available raw materials or product components or increases in costs of our raw materials or product components, could have a negative impact on our business, financial condition and operations outcome.

Certain raw materials and product components necessary for the development and formulation of our product candidates are provided by single-source, unaffiliated third-party suppliers, some of which are the proprietary products of these unaffiliated third-party suppliers, including the CpG 1018 adjuvant provided by Dynavax. If those third-party suppliers were to cease or interrupt production or otherwise fail to adequately supply the materials or products to us for any reason, including regulatory requirements or actions, adverse financial developments of the suppliers, limitation on production capacity, unexpected demand, and/or labor shortages or disputes, we may not be able to immediately find a replacement. We may not be able to identify suitable replacement for these materials and devices in a reasonable time or on reasonable terms or at all if such accessible supply was subsequently found to not be in compliance with our quality standards or resulted in quality failures or product contamination and/or recall when used to manufacture, formulate, fill or finish our products. While we believe it is unlikely that we will experience any shortage in adjuvant supply from Dynavax given the related contractual obligations in place, we cannot guarantee that Dynavax will fulfill its contractual obligations to us under the agreement or that we will be able to obtain sufficient supply of CpG 1018. Under the supply agreement, in the event of a significant adjuvant supply shortage from Dynavax, we are entitled to a manufacturing technology transfer to make or have the CpG 1018 adjuvant made by a designated contract manufacturer for SCB-2019 (CpG

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1018/Alum). However, we cannot guarantee that we will be able to obtain sufficient supply of CpG 1018, or any supply at all, even with such a technology transfer, for reasons beyond our control, such as certain issues with CpG 1018 itself. In such event, we may need to seek CpG 1018, biosimilars or other adjuvants entirely. Even if we are able to identify replacements, we may be required to arrange further consultations with regulators on its approval pathway and perform additional studies with such adjuvants. This may increase our costs and delay our development and commercialization progress. Such events could adversely affect our ability to satisfy demand for our products, which could materially and adversely affect our product sales and operating results. In particular, if Dynavax terminates its agreement with us due to reasons beyond our control, we may not be able to identify suitable replacements for vaccine adjuvants with the same safety data and may incur additional development time and expenses to conduct clinical trials with an alternative source of adjuvants.

To avoid overreliance on any particular supplier of raw materials or devices, we typically maintain supply arrangements with a number of suppliers for the principal raw materials. However, given the potentially lengthy procedures to replace or engage a new supplier and other factors such as shortfall of market supply, in the event that any of such supply arrangements is terminated or the ability of our suppliers to perform their underlying obligations is materially and adversely affected, we cannot assure you that we would be able to obtain sufficient raw materials or at a commercially reasonable price or quality or at all, without any interruption or undue burden. If any interruption of raw material supply occurs, our production volume, product quality and profit margins might be adversely affected.

In addition, raw materials used in our production may be subject to price volatility caused by external conditions, such as market supply and demand, fluctuations in transportation costs, changes in governmental policies, and natural disasters. We cannot assure you that our raw material cost will not increase significantly in the future, or that we could pass any increased raw material costs around to our customers. As a result, any significant price increase or reductions in the availability of our raw materials may have an adverse effect on our profitability and results of operations.

Our rights to develop and commercialize our Trimer-TagTM pipeline products are subject, in part, to the terms and conditions of licenses granted to us by our licensor GenHunter.

We rely on the global exclusive in-licensing of certain patent rights and other intellectual property from GenHunter, which are important or necessary for the development, manufacture or commercialization of our Trimer-TagTM pipeline products. For details of arrangements with GenHunter, please refer to "Business – Licensing and Collaboration Arrangements – License Agreement with GenHunter." We may not have the right to control the preparation, filing, prosecution, maintenance, enforcement or defense of patents and patent applications covering the Trimer-TagTM platform. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our licensor GenHunter fails to prosecute, maintain, enforce or defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our Trimer-TagTM products that are subject to such licensed rights could be adversely affected.

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In the event of controversy or claim arising out of or relating to any provision of the license agreements, if both parties are unable to resolve or settle promptly, GenHunter and us shall be settled through arbitration conducted in accordance with the rules of American Arbitration Association and such arbitration shall be final and binding. The arbitration may be expensive and time-consuming, and may not result in a ruling in our favor. If GenHunter goes bankrupt, some or all of our exclusive rights under the License Agreement may be rejected during the bankruptcy proceeding. As such, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We do not have experience in launching and marketing product candidates. If we are unable to maintain sufficient distribution, marketing, and sales capabilities, we may not be able to generate product sales revenues.

We have yet to demonstrate our capabilities in launching and commercializing any of our product candidates. In a short term, during the pandemic period (as declared by the WHO), our COVID-19 vaccine candidate will be purchased by and allocated through the COVAX Facility pursuant to the orders placed by GAVI, UNICEF, PAHO, or other potential parties. In the long term, if we intend to distribute our products worldwide after the COVID-19 pandemic, we would need to develop and expand our in-house marketing organization and sales force, which will require significant expenditures, management resources and time. We potentially would then have to compete with other biopharmaceutical companies to recruit, hire, train and retain marketing and sales personnel. As a result, our ability to successfully commercialize our product candidates may involve more inherent risk, additional commercialization efforts, and cost more than it would if we were a company with experience launching and marketing product candidates.

If we are unable or decide not to establish internal sales, marketing and commercial distribution capabilities for any or all of the products we develop, we will likely pursue collaborative arrangements regarding the sales and marketing of our products. However, we cannot assure you that we will be able to establish or maintain such collaborative arrangements, or, if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend on the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We will also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates. In addition, we cannot assure you that we will be able to maintain marketing and sales capabilities sufficient to support our future approved products. As a result, we may not be able to generate product sales revenue.

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We may be unable to produce a successful COVID-19 vaccine and generate demand for our vaccine or before the COVID-19 outbreak is effectively contained or the risk of coronavirus infection is significantly diminished. Even if we are successful in producing a vaccine against COVID-19, we may need to devote significant resources to its scale-up and development.

Concurrently, a large number of vaccine manufacturers, academic institutions and other organizations are in the process of developing COVID-19 vaccine candidates. Our competitors pursuing vaccine candidates may have greater financial, development, manufacturing and marketing resources than we do. Larger pharmaceutical and biotechnology companies have extensive experience in clinical testing and obtaining regulatory approval for their products, and may have the resources to heavily invest to accelerate discovery and development of their vaccine candidates.

Our efforts to develop SCB-2019 (CpG 1018/Alum) for regulatory approval and commercialization or generate demand may fail if competitors develop and commercialize one or more COVID-19 vaccines before we are able to do so, or if they develop and commercialize one or more COVID-19 vaccines that are safer, more effective, produce longer immunity against COVID-19, require fewer administrations, have fewer or less severe side effects, have broader market acceptance, and are more convenient or are less expensive than any vaccine candidate that we may develop. Since late 2020, multiple SARS-CoV-2 variants including variants of concern have emerged. For details of the latest development of COVID-19, please see “Summary – Recent Development.” As such, since the COVID-19 pandemic continues to evolve in China and globally, the long-term effectiveness and protection of any marketed or development-stage COVID-19 vaccines against various SARS-CoV-2 strains continues to be evaluated in longitudinal studies.

While we believe that our research, development and collaboration could result in an effective COVID-19 vaccine, clinical trials involve a lengthy and expensive process with an uncertain outcome. Given the severity and urgency of the COVID-19 pandemic, we have committed significant capital and resources to fund and supply the development of SCB-2019 (CpG 1018/Alum) and second generation COVID-19 vaccine candidates. However, the development of SCB-2019 (CpG 1018/Alum) will require us to expend financial and other resources and may cause delays in or otherwise negatively impact our other development programs, despite uncertainties surrounding the longevity and extent of COVID-19 as a global health concern. Furthermore, our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could rapidly dissipate or against which our vaccine, if developed, may not be partially or fully effective.

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If any clinical trials for our SCB-2019 (CpG 1018/Alum) are perceived to be successful, we may need to work toward the large-scale development and manufacturing scale-up of this vaccine candidate. We may also need to utilize our in-house facilities to rapidly manufacture SCB-2019 (CpG 1018/Alum) in the volumes necessary to support large-scale clinical trials or commercial sales. If we are unable to produce SCB-2019 (CpG 1018/Alum) in large quantities or if our vaccine requires more doses to achieve sufficient efficacy than we expect, we may not complete our product development or commercialization efforts in a timely manner. In addition, during a global health crisis, such as the COVID-19 pandemic, where the spread of a disease needs to be controlled, closed or heavily regulated national borders will create challenges and potential delays in our development and production activities and may necessitate that we pursue strategies to develop and produce our vaccine candidates at potentially much greater expense and with longer timeframes for public distribution.

The clinical development and regulatory pathway for COVID-19 vaccines is highly dynamic and continues to evolve and may result in unexpected or unforeseen delays or challenges.

We obtained data from SPECTRA, a global pivotal phase 2/3 clinical trial for SCB-2019 (CpG 1018/Alum) in September 2021. We subsequently plan to submit conditional regulatory approval applications to the EMA, the NMPA, and the WHO in the fourth quarter of 2021. We expect to obtain conditional approvals between the fourth quarter of 2021 and the middle of 2022. Post conditional approval, we expect to commence product launch which may occur as early as year end 2021.

The speed at which all parties are acting to create and test vaccines for COVID-19 is unusual. While we obtained data from SPECTRA in September 2021, the submission of our conditional regulatory approval applications and subsequent review can depend on factors out of our control and may take longer than we expect. Evolving or changing plans or priorities within the NMPA, EMA and WHO, including changes based on new knowledge of COVID-19 and how the disease affects the human body, may significantly affect the regulatory timeline for SCB-2019 (CpG 1018/Alum). Results from clinical testing may raise new questions and require us to redesign proposed or conduct new clinical trials, including revising proposed endpoints or adding new clinical trial sites or cohorts of subjects. As such, there might be a delay in generating sufficient clinical data for conditional regulatory approval applications for SCB-2019 (CpG 1018/Alum).

To date, the NMPA and EMA has enabled COVID-19 vaccine companies to utilize rolling submission process to facilitate the review for conditional approval. Additionally, the FDA has the authority to grant an Emergency Use Authorization to allow unapproved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives.

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Although we intend to design our clinical trials and preclinical studies and submit for conditional regulatory approval for SCB-2019 (CpG 1018/Alum) in accordance with the current guidance, we cannot be certain that, as the regulatory pathway continues to evolve, we will be able to generate sufficient preclinical, clinical or supporting data for approval or launch our SCB-2019 (CpG 1018/Alum). Any delays in sufficient data readout could impair our ability to obtain approval for SCB-2019 (CpG 1018/Alum), which may adversely affect our operating results, reputation and ability to raise capital and enter into or maintain collaborations to advance our other product candidates.

The manufacture of biologics is a complex process which requires significant expertise and capital investment, and if we encounter problems in manufacturing our future products, our business could suffer.

We have limited experience in managing the manufacturing process of biologics. The manufacturing of biologics is a complex process, in part due to strict regulatory requirements.

As of the Latest Practicable Date, we have an in-house commercialization-ready biologics manufacturing plant in Changxing, Zhejiang province, China (the “Changxing facility”) which was designed to adhere to the cGMP standards of the U.S., EU, and China. While our facilities have went through and passed the EU QP inspection by the qualified auditor, future problems may arise for a variety of reasons, including equipment malfunction, failure to follow the EU, China or the U.S. protocols and procedures, problems with raw materials, delays related to the reconfiguration and/or expansion of the Changxing facility, including changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements, physical limitations that could inhibit continuous supply, human-made or natural disaster, and environment factors.

If any problems arise during our production of a certain batch of product, that batch of product may have to be discarded, for which we may experience product shortage or incur increased expenses. Such incident could, among other things, lead to increase of our costs, decline in revenue, damage to customer relations, increase of time and expenses spent on investigating the causes, and dependent on the causes, similar losses associate with other batches or products. If any of those problems was not discovered prior to the product’s release to the market, we might also incur costs related to product recall or product liability disputes and our business prospects may be seriously harmed.

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Our future approved product candidates may fail to achieve the degree of market acceptance by global health organizations, governments, physicians, patients, third-party payers and others in the medical community necessary for commercial success.

Even if one of our product candidates receive approvals from the EMA, the NMPA, the WHO or other regulatory agencies, the commercial success of any of our current or future product candidates might be lower than expected and will depend significantly on the broad procurement, adoption and use of the resulting product by global health organizations, governments, physicians and patients for approved indications. For a variety of reasons, including among other things, competitive factors, pricing or physician preference, reimbursement by insurers, the degree and rate of physician and patient adoption of our current or future product candidates, if approved, will depend on a number of factors, including:

- the clinical indications for which the product is approved and patient demand for approved products that treat those indications;
- the safety and efficacy of our product as compared to other available therapies;
- the time required for manufacture and the timing of market introduction of our product candidate as well as competitive products;
- the availability of coverage and adequate reimbursement from managed care plans, private insurers, government payors and other third-party payors for any of our product candidates that may be approved;
- acceptance by physicians, operators of hospitals and clinics and patients of the product as a safe and effective treatment;
- physician and patient willingness to adopt a new therapy over other available therapies for a particular indication;
- proper training and administration of our product candidates by physicians and medical staff;
- patient satisfaction with the results and administration of our product candidates and overall treatment experience, including, for example, the convenience of any dosing regimen;
- the cost of treatment with our product candidates in relation to alternative treatments and reimbursement levels, if any, and willingness to pay for the product, if approved, on the part of insurance companies and other third-party payers, physicians and patients;
- the prevalence and severity of side effects;

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- limitations or warnings contained in the approved labeling for our products;
- the willingness of physicians, operators of hospitals and clinics and patients to utilize or adopt our products as a solution;
- the effectiveness of our sales, marketing and distribution efforts;
- adverse publicity about our products or favorable publicity about competitive products; and
- potential product liability claims.

We cannot assure you that our current or future product candidates, if approved, will achieve broad market acceptance among physicians and patients. Any failure by our product candidates that obtain regulatory approval to achieve market acceptance or commercial success would adversely affect our results of operations.

Even if we are able to commercialize any approved product candidates, the products may become subject to national or other third-party reimbursement practices or unfavorable pricing regulations, which could harm our business.

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or licensing approval is granted. In some non-U.S. markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval. For example, according to a statement, Opinions of the State Council on Reforming the Review and Approval System for Pharmaceutical Products and Medical Devices (《國務院關於改革藥品醫療器械審評審批制度的意見》), issued by the PRC State Council in August 2015, the enterprises applying for new drug approval will be required to undertake that the selling price of a new drug in the PRC market shall not be higher than the comparable market prices of the product in its country of origin or PRC’s neighboring markets, as applicable.

Our ability to commercialize any products successfully also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the global healthcare industry is cost containment. Government authorities and these third-party payors have attempted to control costs by

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limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product for which we obtain regulatory approval. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with products administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

There may be significant delays in obtaining reimbursement for approved product candidates, and coverage may be more limited than the purposes for which the product candidates are approved by the EMA, the NMPA, the WHO or other comparable regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future weakening of laws that presently restrict imports of products from countries where they may be sold at lower prices compared to the others. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any future approved product candidates and any new products that we develop could have a material adverse effect on our business, our operating results, and our overall financial condition.

Our products, like any other biologic product, may involve risks of contamination.

Production of biologics usually requires cultivation steps, including growth of the appropriate organism and the use of substances of animal origin, which makes it easy to be exposed to a contaminant and thus amplifying the impact of contamination caused. In addition, manufacturing operations based on the sharing of equipment and facilities is common, other activities such as diagnosis and research frequently linked to which may increase chances of cross-contamination.

Contamination of our future biologic products could cause customers or other third parties with whom we conduct business to lose confidence in the reliability of our manufacturing procedures, which could in turn adversely affect our sales and profits. In addition, contaminated products that are unknowingly distributed could result in harm on vaccinators, threaten the reputation of our products and expose us to product liability claims, criminal charges and administrative sanctions.

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Undetected errors or defects in our production could harm our reputation or expose us to product liability claims.

We face an inherent risk of product liability caused by undetected errors or defects of our products after their approvals for marketing. Any such product liability claims may include allegations of defects in manufacturing, defects in design, improper, insufficient or improper labelling of products, insufficient or misleading disclosures of side effects or dangers inherent in the product, negligence, strict liability and a breach of warranties. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. There is also risk that third parties we have agreed to indemnify could incur liability. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates or any resulting products;
- damage to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial subjects;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize our product candidates; and
- a decline in our Share price.

If we are unable to defend ourselves against such claims in the PRC or other jurisdictions which we operate in, among other things, we may be subject to civil liability for adverse events or other losses caused by our products and to criminal liability and the revocation of our business licenses if our products are found to be defective. In addition, we may be required to recall the relevant products, suspend sales or cease sales. Even if we are able to successfully defend ourselves against any such product liability claims, doing so may require significant financial resources and the time and attention of our management.

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Existing PRC laws and administrative regulations require us to maintain liability insurance to cover product liability claims on clinical trials. Any product liability insurance for clinical trials, when obtained, may be prohibitively expensive, or may not fully cover our potential liabilities. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of product candidates we develop. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Guidelines, recommendations and studies published by various organizations could disfavor our product candidates.

Government agencies, professional societies, practice management groups, private health and science foundations and organizations focused on various diseases may publish guidelines, recommendations or studies that affect our or our competitors’ product candidates. Any such guidelines, recommendations or studies that reflect negatively on our product candidates, either directly or relative to our competitive product candidates, could result in current or potential decreased use, sales of, and revenues from one or more of our product candidates. Furthermore, our success depends in part on our and our partners’ ability to educate healthcare providers and patients about our product candidates, and these education efforts could be rendered ineffective by, among other things, third-parties’ guidelines, recommendations or studies.

Risks Relating to Our Intellectual Property Rights

If we are unable to obtain and maintain patent protection for our product candidates or the Trimer-TagTM technology platform, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and our ability to successfully commercialize any product or technology may be adversely affected.

Our success depends in large part on our ability to protect the Trimer-TagTM technology platform, and product candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights, including patent rights. As of the Latest Practicable Date, our patent portfolio consists of one issued U.S. patent, and 24 patent applications, including 20 PCT patent applications in seven patent families, three U.S. patent applications, and one China patent application. For further information on our patent portfolio, see “Business – Intellectual Property.”

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We seek to protect the product candidates and technology that we consider commercially important by filing patent applications in China, the U.S. and other countries, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. If we are unable to obtain or maintain patent protection with respect to our product candidates and technologies, our business, financial condition, results of operations and prospects could be materially harmed.

The scope of patent protection in various jurisdictions is also uncertain. Changes in either the patent laws or their interpretation in China, the U.S. or other countries may diminish our ability to protect our inventions, obtain, maintain, defend, and enforce our intellectual property rights, and, more generally, could affect the value of our intellectual property or narrow the scope of our patent rights. We cannot predict whether the patent applications we are currently pursuing and may pursue in the future will issue as patents in any particular jurisdiction or whether the claims of any future issued patents will provide sufficient protection from competitors.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner in all desirable territories. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in all such fields and territories. Patents may be invalidated and patent applications may not be granted for a number of reasons, including known or unknown prior art, deficiencies in the patent application, or the lack of novelty of the underlying invention or technology.

It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to obtain patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Furthermore, China and, recently, the U.S. have adopted the “first-to-file” system under which whoever first files a patent application will be awarded the patent if all other patentability requirements are met and no objection are raised by other parties. Under the first-to-file system, third parties may be granted a patent relating to a technology which we invented.

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In addition, under the PRC patent law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to report to the China National Intellectual Property Administration, or CNIPA, for confidentiality examination. Otherwise, if an application is later filed in China, the patent right will not be granted.

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we hold may be challenged, narrowed, circumvented, or invalidated by third parties. In addition, the patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patent rights may be challenged in the courts or patent offices in China, the U.S. and other countries. We may be subject to a third-party pre-issuance submission of prior art to the patent office in a jurisdiction, or become involved in opposition, derivation, revocation, re-examination, post-grant review, *inter partes* review, or interference proceedings or similar proceedings in foreign jurisdictions challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates, and compete directly with us without payment to us, or result in our inability to manufacture or commercialize product candidates without infringing, misappropriating or otherwise violating third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the patent office of a jurisdiction to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge the priority of our invention or other features of patentability of our patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial costs and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Consequently, we do not know whether any of our technology or product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

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Furthermore, although various extensions may be available, the life of a patent and the protection it affords is limited. Even if we successfully obtain patent protection for an approved product candidate, it may face competition from generic or biosimilar medications once the patent has expired. Manufacturers of generic or biosimilar drugs may challenge the scope, validity or enforceability of our patents in court or before a patent office, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. Our issued patents for our product candidates are expected to expire on various dates as described in “Business – Intellectual Property” of this document. Upon the expiration of these patents, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such candidates are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours, which could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects. Additionally, patent rights we own currently or in the future or may license in the future may be subject to a reservation of rights by one or more third parties.

If we are sued for infringing, misappropriating or otherwise violating intellectual property rights of third parties or engaging in unfair competition, such litigation could be costly and time-consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends in part on our and our collaborators’ avoiding infringement, misappropriation and other violations of the patents and other intellectual property rights of third parties. We are aware of numerous issued patents and pending patent applications belonging to third parties that exist in fields in which we are developing our product candidates. There may also be third-party patents or patent applications of which we are currently unaware, and given the dynamic area in which we operate, additional patents are likely to issue that relate to aspects of our business. There is a substantial amount of litigation and other claims and proceedings involving patent and other intellectual property rights in the pharmaceutical and vaccine industries generally. As the pharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

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Third parties may assert that we are using technology in violation of their patent or other intellectual and proprietary rights. We may also be subject to allegations by third parties of unfair competition, defamation or violation of their other rights. Defense of these claims, regardless of their merit, could involve substantial litigation expense and divert our technical personnel, management personnel or both from their normal responsibilities. Even in the absence of litigation, we may seek to obtain licenses from third parties to avoid the risks of litigation, and if a license is available, it could impose costly royalty and other fees and expenses on us.

Even if we believe third-party intellectual property claims are without merit, we cannot assure you that a court would find in our favor on questions of infringement, validity, enforceability or priority, and it could materially and adversely affect our ability to develop and commercialize any of our product candidates and any other product candidates covered by the asserted third-party patents. The burden of successfully challenging a third-party claim may be high and require us to present clear and convincing evidence as to the invalidity of any such claim, there is no assurance that a court of competent jurisdiction would invalidate any such third-party claim.

If third parties bring successful claims against us for infringement, misappropriation or other violations of their intellectual property rights, we may be subject to injunctive or other equitable relief, which could prevent us from developing and commercializing one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense, and would be a substantial diversion of employee resources from our business. In the event of a successful claim against us of infringement, misappropriation or other violation of intellectual property, or a settlement by us of any such claims, we may have to pay substantial damages, which we may not be able to be indemnified against by our licensing partners. In the event of an adverse result in any such litigation, or even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. Any such license might not be available on reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. In the event that we are unable to obtain such a license, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We may also elect to enter into license agreements in order to settle patent and other intellectual property infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could significantly harm our business.

Even if litigation or other proceedings are resolved in our favor, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our shares. Such litigations or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

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Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications are due to be paid to the China National Intellectual Property Administration, or CNIPA, United States Patent and Trademark Office, or USPTO and other patent agencies in several stages over the lifetime of a patent. The CNIPA, USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Intellectual property litigation may lead to unfavorable publicity which may harm our reputation and result in additional expense and distraction of our personnel. This may further cause the market price of our Shares to decline.

During the course of any intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our product candidates, future drugs and vaccines, programs or intellectual property could be diminished. Accordingly, the market price of our Shares may decline. Such announcements could also harm our reputation or the market for our product candidates, which could have a material adverse effect on our business.

In addition, any future intellectual property litigation, interference or other administrative proceedings will result in additional expense and distraction of our personnel. An adverse outcome in such litigation or proceedings may expose us or any future strategic partners to loss of our proprietary position, expose us to significant liabilities, or require us to seek licenses that may not be available on commercially acceptable terms, if at all, each of which could have a material adverse effect on our business.

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Changes in patent laws could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

Newly enacted patent laws can change the procedures through which patents may be obtained and by which the validity of patents may be challenged. These changes may impact the value of our patent rights or our other intellectual property rights. In China, intellectual property laws are constantly evolving, with efforts being made to improve intellectual property protection in China. For example, the PRC Patent Law (《中華人民共和國專利法》) was revised and released on October 17, 2020 and came into effective from June 1, 2021, or the 2021 Patent Law, has introduced patent extensions to eligible innovative drug patents. The 2021 Patent Law may enable the patent owner to submit applications for a patent term extension. The length of any such extension is uncertain while such extension shall not exceed five years, and the total validity period of patent rights shall not exceed 14 years after the drug obtained market license. If we are required to delay commercialization for an extended period of time, technological advances may develop and new products may be launched, which may in turn render our products non-competitive. We cannot guarantee that any other changes to PRC intellectual property laws would not have a negative impact on our intellectual property protection.

The absence of patent linkage, patent term extensions and data and market exclusivity for pharmaceutical products could increase the risk of early generic competition.

In the U.S., the Federal Food, Drug and Cosmetic Act, the FDCA, as amended by the law generally referred to as “Hatch-Waxman,” provides the opportunity for patent term restoration that provides a patent term extension of up to five years to reflect patent time period lost during certain portions of product development and the FDA regulatory review process. Hatch-Waxman also has a process for patent linkage, pursuant to which the FDA will stay approval of certain follow-on applications for a period of up to 30 months if, within 45 days of receiving notice of a follow-on application, we file a patent infringement suit against such applicant. Finally, Hatch-Waxman provides for statutory exclusivities that can prevent submission or approval of certain follow-on marketing applications. For example, federal law provides a five-year period of exclusivity within the U.S. to the first applicant to obtain approval of a new chemical entity (as defined by the FDCA) and three years of exclusivity protecting certain innovations to previously approved active ingredients where the applicant was required to conduct new clinical investigations to obtain approval for the modification. Similarly, the United States Orphan Drug Act provides seven years of market exclusivity for certain drugs to treat rare diseases, where the FDA designates the product candidate as an orphan drug and the drug is approved for the designated orphan indication. These provisions, designed to promote innovation, can prevent competing products from entering the market for a certain period of time after the FDA grants marketing approval for the innovative product.

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Dependent upon the timing, duration and specifics of any FDA marketing approval process for any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under Hatch-Waxman. Hatch-Waxman permits a patent extension term of up to five years as compensation for patent time period lost during clinical trials and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval; only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. According to the PRC Patent Law effective from June 1, 2021, patentees of inventions on new drugs could enjoy an extended patent term capped at 5 years after request, and the resulting total effective patent term shall not exceed 14 years from the approval for marketing of the new drug.

However, there were few precedents for patent term extension in the PRC, and we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner than we expect. Also, the scope of our exclusive right during any patent term extension period may be limited or may not cover a competitor’s product or product use.

If we are unable to obtain patent term extension, or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

Our intellectual property may be subject to further priority disputes or to ownership disputes and similar proceedings. Should we be unsuccessful in any of these proceedings, we might be required to obtain licenses from third parties, in terms not necessarily commercially reasonable to us, or to cease the development, manufacturing and commercialization of one or more of our product candidates, which could have a material adverse impact on our business.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents or other intellectual property as an inventor or co-inventor. If we or our licensors are unsuccessful in any interference proceedings or other priority or validity disputes (including any patent oppositions) to which we or they are subject, we may lose valuable intellectual property rights through the loss of one or more patents owned or licensed or our owned or licensed patent

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claims may be narrowed, invalidated, or held unenforceable. In addition, if we or our licensors are unsuccessful in any inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights, such as exclusive ownership of, or the exclusive right to use, our owned or in-licensed patents. If we or our licensors are unsuccessful in any interference proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to modify or cease the development, manufacture and commercialization of one or more of our product candidates. The loss of exclusivity or the narrowing of our owned and licensed patent claims could limit our ability to stop others from using or commercializing similar or identical drug products.

Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations, or prospects. Even if we are successful in an interference proceeding or other similar priority or inventorship disputes, it could result in substantial costs and be a distraction to our management and other employees.

Issued patents covering one or more of our product candidates could be found invalid or unenforceable if challenged in court.

Despite measures we take to obtain and maintain patent and other intellectual property rights with respect to our product candidates, our intellectual property rights could be challenged or invalidated. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, the CNIPA of China, or the applicable foreign counterpart, or made a misleading statement, during prosecution.

Although we believe that we have conducted our patent prosecution in accordance with a duty of candor and in good faith, the outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on a product candidate. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may not be an adequate remedy. In addition, if the breadth or strength of protection provided by our patents is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize our current or future product candidates. Any loss of patent protection could have a material adverse impact on one or more of our product candidates and our business.

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Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend and could require us to pay substantial damages, cease the sale of certain drugs or enter into a license agreement and pay royalties (which may not be possible on commercially reasonable terms or at all).

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. We may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their former employers or claims asserting ownership of what we regard as our own intellectual property.

In addition to our patents, we rely on trade secrets and confidential information, including unpatented know-how, technology and other proprietary information to maintain our competitive position and to protect our product candidates. We seek to protect this trade secret and confidential information, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to them, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

Furthermore, many of our employees, consultants and advisors, including our senior management, were previously employed at other pharmaceutical or biotechnology companies, including our competitors or potential competitors. Some of these employees, consultants and advisors, including each member of our senior management, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management or general management, but there is no assurance that we will not be subject to such claims or involved in litigations to defend against such claims in the future. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management.

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In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Further, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, each of which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel and could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may not be successful in obtaining or maintaining necessary rights for our development pipeline through acquisitions and in-licenses.

Our programs involve additional product candidates that require the use of proprietary rights held by third parties, and we have obtained and may need to further acquire and maintain licenses or other rights to use these proprietary rights. However, we may be unable to acquire or in-license any compositions, methods of use or other intellectual property rights from third parties that we identify.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights, we may have to abandon development of the relevant program or product candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects for growth.

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Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to any product candidates we may develop or utilize similar technology that are not covered by the claims of the patents that we own or license now or in the future;
- we or any future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or may license in the future;
- we or any future collaborators might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- patents that may be issued from our pending patent applications may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Any of the aforementioned events could have a material adverse effect on our business, financial condition, results of operations and prospects.

RISK FACTORS

Risks Relating to Our Reliance on Collaborators and Other Third Parties

We engage CROs to conduct certain elements of our pre-clinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We engage CROs, hospitals and clinics to monitor, support, conduct pre-clinical studies and/or clinical trials of our product candidates. Our arrangements with collaborators, including CROs, plays an important role to successfully bringing products to market and commercializing them. We rely on collaborators in various respects, including to undertake research and development programs and conduct clinical trials, manage or assist with the regulatory filings and approval process and to assist with our commercialization efforts.

Because we do not control these third-party collaborators, we have limited influence over the quality, timing and cost of those studies and may not be able to sufficiently recruit trial subjects. If any of our relationships with our third-party CROs is terminated, we may not be able to (i) enter into arrangements with alternative CROs or do so on commercially reasonable terms or (ii) enroll subjects on a timely basis or otherwise conduct our trials in the manner we anticipate. In addition, there is a natural transition period when a new CRO commences work, and the new CRO may not provide the same type or level of services as the original provider and data from our clinical trials may be compromised as a result. There is also a need for relevant technology to be transferred to the new CRO, which may take time and further delay our development timelines. In addition, these third parties are not our employees and, except for requirements imposed by our contracts with such third parties and the remedies available to us thereto, we have limited ability to control the amount or timing of resources that they devote to our programs, including the maintenance of clinical trial information regarding our product candidates in the future. Although we rely on such third parties to conduct the clinical studies, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on such third parties do not entirely relieve us of our regulatory responsibilities.

Because we rely on third parties, our internal capacity to perform these functions is limited. Outsourcing these functions involves certain risks that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. If these third parties fail to meet our expected deadlines, transfer to us any regulatory information in a timely manner, adhere to protocols or act in accordance with regulatory requirements or our agreements with them, or otherwise perform in a substandard manner or in a way that compromises the quality and/or accuracy of their activities and/or the data they obtain, the clinical trials of our future product candidates may be extended, delayed or terminated, or our data may be rejected by the NMPA or regulatory agencies. Further, switching or adding CROs involves additional cost and delays, which can materially influence our ability to meet our desired clinical development timelines. In addition, the use of third-party service providers requires us to disclose our proprietary information to these third parties, which could increase

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the risk that such information will be misappropriated. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

The success of our business may in part depend on collaboration and other strategic arrangements with third parties. We have been seeking for cooperation with leading academic institutions to enhance our research capabilities. These scientific experts are not, however, our employees and may have other commitments that limit their availability to collaborate with us. If a conflict of interest arises between their work for us and for other entities, we may lose the collaboration with these scientists and institutions. Any cessation or suspension of our collaborations with academic institutions or other research partners may increase our research and development costs, lengthen our vaccine development process and materially deteriorate our capability in developing new vaccine products.

We may rely on third parties to manufacture a portion of our clinical and, if approved, commercial product supplies. Our business could be harmed if those third parties fail to provide us with sufficient quantity of products or fail to do so at acceptable quality levels or prices.

Certain third parties provide components needed to manufacture the clinical supply of our product candidates, some of which are among our five largest suppliers during the Track Record Period. In particular, we rely on Dynavax to supply its CpG 1018 adjuvant for SCB-2019 (CpG 1018/Alum) currently for our clinical trials and, if approved, commercial supply. In the event that the agreements entered into between Dynavax and us are breached or are terminated, and if we fail to renew and/or extend such agreements on terms favorable to us, or at all, we will need to find alternative sources of adjuvants and conduct additional clinical trials with different adjuvants, which may delay or prevent the development progress and launch of our SCB-2019 (CpG 1018/Alum).

Reliance on third-party suppliers would expose us to the following risks:

- we may be unable to identify suppliers on acceptable terms or at all because the number of potential manufacturers is limited and the EMA, the NMPA, the WHO or other comparable regulatory authorities must evaluate and/or approve any manufacturers as part of their regulatory oversight of our product candidates. This evaluation would require new testing and cGMP-compliance inspections by the EMA, the NMPA, the WHO or other comparable regulatory authorities;
- our third-party suppliers might be unable to produce the quantity and quality in a timely manner required to meet our clinical and commercial needs;

RISK FACTORS

- suppliers are subject to ongoing periodic unannounced inspection by the regulatory authorities to ensure strict compliance with cGMP and other government regulations. We do not have control over third-party suppliers' compliance with these regulations and requirements;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party suppliers in the development stage and manufacturing process for our product candidates;
- suppliers may not properly obtain, protect, maintain, defend or enforce our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- suppliers may infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property rights of third parties;
- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects; and
- our suppliers may be subject to inclement weather, as well as natural or human-made disasters.

Each of the abovementioned risks could delay or prevent the completion of our clinical trials or the approval of any of our product candidates, result in higher costs, or adversely impact commercialization of our future approved product candidates.

Suppliers of drug products and vaccines may encounter difficulties in production, particularly in scaling up or out and assuring high reliability of the manufacturing process (including the absence of contamination). These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, product testing, operator error, availability of qualified personnel, as well as compliance with strictly enforced regulations. We cannot assure you that any stability failures or other issues relating to the manufacture of our product candidates will not occur in the future, such as issues relating to our third-party suppliers. Additionally, our suppliers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide any future approved product candidates for commercial sale and our product candidates to patients in clinical trials would be jeopardized. Any delay or interruption in the provision of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs, and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

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We have entered into collaborations and may form or seek collaborations or strategic alliances or enter into licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We have entered into strategic collaboration agreements in the past, including our strategic collaborations with Dynavax, CEPI and GAVI. We may form or seek strategic alliances, create joint ventures or collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing Shareholders, or disrupt our management and business.

We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at a premature stage of development for collaborative effort, and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability. If and when we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. For any product candidates that we may seek to in-license from third parties, we may face significant competition from other pharmaceutical companies with greater resources or capabilities than us, and any agreement that we do enter into may not result in the anticipated benefits.

There are other risks associated with strategic collaboration with third party partners. Disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources. Our collaborations may be terminated and, if terminated, may have adverse effect on the development or commercialization of our product candidates.

As a result, we may not be able to realize the benefit of current or future collaborations, strategic partnerships or potential license of products if we are unable to successfully integrate such products with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. If we are unable to reach agreements with suitable collaborators on a timely basis or acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization, or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional

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expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, there may be material adverse impact on our business prospects, financial condition and results of operations.

RISKS RELATING TO OUR OPERATIONS

We face competition from entities that have developed or may develop technology platforms for the disease or vaccine pathways that we may target. If these entities develop technology platforms more rapidly than we do, or if their technology platforms are more effective, our ability to develop and successfully commercialize our technology platforms may be adversely affected.

There is intense and rapidly evolving competition in the biotechnology, pharmaceutical, disease prevention and vaccine fields. We compete with a variety of large pharmaceutical companies, multinational biopharmaceutical companies, developed vaccine companies and specialized biotechnology companies, as well as technology being developed at universities and other research institutions. Many of our competitors have significantly greater financial, development, manufacturing, marketing, sales and supply resources or experience than we do. We believe that the Trimer-Tag™ technology platform, the associated intellectual property, the characteristics of our existing product candidates and potential future product candidates, and our scientific and technical know-how together give us a competitive advantage in this space, however competition from many sources remains. Our commercial opportunity and success will be reduced or eliminated, if any competing technology platforms become available that are more effective or less expensive than the therapeutic candidates we develop with Trimer-Tag™ technology platform.

Our reputation is key to our business success. Negative publicity with respect to us, our management, employees, business partners, affiliates, or our industry, may materially and adversely affect our reputation, business, results of operations growth and prospects.

We believe that market awareness and recognition of our brand image have contributed significantly to the success of our business. We also believe that maintaining and enhancing our brand image is crucial to retain our competitive advantage. While we will continue to promote our brands to remain competitive, we may not be successful in doing so. In addition, we may expand our network of third-party promoters to increase our marketing efforts. It may be difficult to effectively manage our brand reputation as we have relatively limited control over these third-party promoters. Any negative publicity, including disputes regarding our intellectual property rights, concerning us or our affiliates, even if untrue, could adversely affect our reputation and business prospects.

RISK FACTORS

Our reputation is vulnerable to many threats that can be difficult or impossible to control, and costly or impossible to remediate. Negative publicity about us, such as alleged misconduct or improper activities, or negative rumors relating to us, our management, employees, business partners or affiliates, can harm our business and results of operations, even if they are unsubstantiated or are satisfactorily addressed. Any regulatory inquiries or investigations or other actions against our management, any perceived unethical, fraudulent, or inappropriate business conduct by us or perceived wrong doing by any key member of our management team or other employees, our business partners or our affiliates, could harm our reputation and materially adversely affect our business. Regardless of the merits or final outcome of any such regulatory inquiries or investigations or other actions, our reputation may be substantially damaged, which may impede our ability to attract and retain talent pool and business partners and grow our business.

Moreover, any negative media publicity about the pharmaceutical industry in general or product or service quality problems of other companies in the industry, including our peers, may also negatively impact our reputation. If we are unable to maintain a good reputation, our ability to attract and retain key employees and business partners could be harmed which, in turn, may materially and adversely affect our business, results of operations and prospects. For example, in 2016, a scandal of vaccine mis-selling were uncovered in Shandong province regarding failure to comply with cold chain regulations and distribution policies. Although this scandal was a mere result of improper distributions and indicated no quality issues from the vaccine makers’ end, it adversely impacted public confidence in the safety of immunizations and the safety of vaccines in general, which in turn slowed down the market growth rate that year. Shortly thereafter, the scandal also resulted in more stringent regulations, as the State Council immediately amended the Regulation on the Administration of Circulation and Vaccination of Vaccines (《疫苗流通和預防接種管理條例》), requiring direct sales of vaccines by vaccine makers to county-level CDCs through provincial public resource trading platform and tightening the requirements and standards of vaccine transportation and storage.

Further, in the event that any negative publicity occurred with respect to our own products and business, the adverse impact on our financial condition or results of operations might be more significant. Any such negative publicity may adversely impact the public confidence in our reputation, brand image, business prospects, or impair the development of our existing vaccine products, commercialized of any approved vaccine products or demand for any product that we have developed or may develop, which may in turn adversely affect our business operations and financial performance. Investigations and increasingly stringent regulations due to such negative publicity, if any, may draw time and attention from our management team, which would have otherwise been devoted into our business operations, or may incur additional compliance expenses. However, we cannot assure you that there will be no future negative publicity in the PRC drug and vaccine industry related to drug safety and efficacy, which may potentially have a material adverse impact on our business and financial condition.

RISK FACTORS

Our future success depends on our ability to retain key executives and to attract, train, retain and motivate qualified and highly skilled personnel. If we lose any of them and are unable to find proper replacements in a timely fashion, our business prospects could be adversely affected.

Our future success depends heavily upon our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. In particular, the industry experience, management expertise, professional knowledge and contributions of our key members of our senior management and general management are crucial to our success. We are highly dependent on Dr. Peng Liang, our founder, Chairman and Chief Scientific Officer and Mr. Joshua Liang, our Chief Executive Officer and executive Director as well as other principal members of our management and scientific teams. Although we have formal employment agreements with each of our executive officers, these agreements do not prevent our executives from terminating their employment with us at any time. We do not maintain key-person insurance for members of our management team. If we lose the services of any of these individuals or one or more of our other members of senior management, we may not be able to locate suitable or qualified replacements, and may incur additional expenses to recruit and train new personnel, which could severely disrupt our business and prospects. We also rely on other key personnel for, among other things, research and development, production, and sales and marketing, to develop new products, technologies and applications, enhance our existing products, ensure quality and safety control in production and enhance sales of our products both at home and abroad.

To incentivize valuable employees to remain at our Company, in addition to salary and cash incentives, we have provided share incentives that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in the market price of our Shares that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery, clinical development and commercialization strategy. The loss of the services of our executive officers or other key employees and consultants could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

Furthermore, replacing executive officers, key employees or consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products like those we develop. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel or consultants on acceptable terms given the competition among numerous pharmaceutical companies for similar personnel. Although we have not historically experienced undue difficulties attracting and retaining qualified employees, we could encounter such problems in the future for various reasons. We may not be able to retain the services of our senior management or key scientific personnel, or offer competitive packages to attract or retain experienced senior management or key personnel, which could have a material adverse impact on our business and prospects. In addition, with our expansion of commercialization and manufacturing capability in the future, we will need to hire additional employees and may not be able to attract and retain qualified employees on acceptable terms.

RISK FACTORS

If we fail to effectively manage our anticipated growth or execute on our growth strategies, our business, financial condition, results of operations and prospects could suffer.

Our growth strategies aim to discover, develop and deliver innovative and next-generation biologic therapeutics and vaccines globally. For more information, see “Business – Our Strategies.” Pursuing our growth strategies has resulted in, and will continue to result in, substantial demands on capital and other resources. In addition, managing our growth and executing on our growth strategies will require, among other things, our ability to continue to innovate and develop advanced technology in the highly competitive global and Chinese pharmaceutical market, effective coordination and integration of our facilities and teams across different sites, successful hiring and training of personnel, effective cost control, sufficient liquidity, effective and efficient financial and management control, effective quality control, and management of our suppliers to leverage our purchasing power. Any failure to execute on our growth strategies or realize our anticipated growth could adversely affect our business, financial condition, results of operations and prospects.

We will need to increase the size and capabilities of our organization, and we may experience difficulties in managing our growth.

We had 716 employees as of the Latest Practicable Date. We expect to experience significant growth in the number of our employees and consultants and the scope of our operations. As our development and commercialization plans and strategies evolve, we must add a significant number of additional managerial, operational, development, regulatory, manufacturing, sales, marketing, financial and other personnel. Our recent growth and any future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and regulatory authority review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems, and procedures.

Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage our recent growth and any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

RISK FACTORS

Due to our limited financial resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. If we are not able to effectively manage our growth and further expand our organization by hiring new employees and expanding our groups of consultants and contractors as needed, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals. Any inability to manage growth could delay the execution of our business plans or disrupt our operations, and have a material adverse effect on our business.

If our commercial manufacturing facilities are damaged or destroyed or production at such facilities is otherwise interrupted, our business and prospects would be negatively affected.

Our commercial manufacturing site is located in Changxing, Zhejiang province, China. We rely on the facilities located at this site for potentially manufacture of commercial supply of our products.

Natural disasters or other unanticipated catastrophic events, including power outage, water shortage, storms, fire, earthquakes, terrorist attacks and wars, as well as changes in governmental planning for the land underlying our facilities, could significantly impair our ability to develop and manufacture products and disrupt our business operations. Although we maintain property insurance for our production facilities and equipment and maintain business interruption insurance, the amount of our insurance coverage may not be sufficient to cover our losses in the event of a significant disruption to any of our production facilities or our business operations. If our relevant facilities were damaged or destroyed, or otherwise subject to disruption, it would require substantial lead-time for use to search for alternative measures to continue our business and operations. In such event, we would be forced to identify alternative premises for relocation. We may incur substantial expenses as a result of such events, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Not only might these facilities and equipment be difficult to be replaced on a timely basis, but catastrophic events might destroy inventories stored in those facilities. The occurrence of any such an event could significantly disrupt our business and materially reduce our revenue and profitability.

Any disruption or delays at these facilities or their failure to meet regulatory compliance would impair our ability to develop and commercialize our product candidates or meet market demand for our products, which would adversely affect our business and results of operations.

RISK FACTORS

We may be subject to liability lawsuits arising from our clinical trials.

We currently carry liability insurances covering our clinical trials. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or which is in excess of the limits of our insurance coverage. Our insurance policies also contain various exclusions and we may be subject to particular liability claims for which we have no coverage. We will have to pay any amount awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. In addition, if we cannot successfully defend ourselves against such claims, we may incur substantial liabilities and be required to suspend or delay our ongoing clinical trials. Even a successful defense would require significant financial and management resources.

Regardless of the merits or eventual outcome, liability claims may result in significant negative consequences to our business and prospects, including:

- decreased demand for our product candidates or any resulting products;
- damage to our reputation;
- withdrawal of other clinical trial participants;
- costs to defend the related litigation;
- a diversion of our management's time and resources;
- substantial monetary awards to trial participants or patients;
- inability to commercialize our product candidates; and
- a decline in the market price of our Shares.

We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.

We maintain insurance policies that are required under PRC laws and regulations as well as insurance based on our assessment of our operational needs and industry practice. We also maintain liability insurance covering our clinical trials. In line with industry practice in the PRC, we have elected not to maintain certain types of insurances, such as business interruption insurance. Our insurance coverage may be insufficient to cover any claim for product liability, damage to our fixed assets or employee injuries. Any liability or damage to, or caused by, our facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.

RISK FACTORS

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of fraud, misconduct or other illegal activities by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to:

- comply with the laws of the NMPA, the EMA, the WHO and other comparable regulatory authorities;
- provide true, complete and accurate information to the NMPA, the EMA, the WHO and other comparable regulatory authorities;
- comply with manufacturing standards we may establish;
- comply with healthcare fraud and abuse laws in the PRC, the United States, the EU, and similar fraudulent misconduct laws in other applicable jurisdictions; or
- report financial information or data accurately or disclose unauthorized activities to us.

If we obtain approval of any of our product candidates and begin commercializing those products in the PRC, the United States or other applicable jurisdictions, our potential exposure under the laws of such jurisdictions will increase significantly and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation.

The existence of legal, regulatory and administrative proceedings against any of our employees, independent contractors, consultants, commercial partners and vendors, even if they do not involve our company, may harm our reputation, and adversely affect our business and operations. In addition, it is not always possible to identify and deter misconduct by employees and other parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

RISK FACTORS

If we engage in acquisitions or strategic partnerships, this may increase our capital requirements, dilute our Shareholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may form or seek strategic alliances, create joint ventures or collaborations, or enter into acquisitions or additional licensing arrangements with third parties that we believe will complement or expand our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third party for the development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party.

Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management’s attention from our existing product programs and initiatives in pursuing such a strategic partnership or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the assimilation of operations, corporate culture and personnel of the acquired business;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and its existing products or product candidates and regulatory approvals;
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs; and
- changes in accounting principles relating to recognition and measurement of our investments that may have a significant impact on our financial results.

RISK FACTORS

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

As a result, if we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. However, if we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market and generate product sales revenue, which would harm our business, financial condition, results of operations and prospects.

Our and/or others’ failure to obtain or renew certain approvals, licenses, permits, registrations, and certificates required for our business may materially and adversely affect our business, financial condition and results of operations.

Pursuant to the relevant laws, regulations and regulatory practices by enforcement agencies, parties related to our operations, such as landlords or managers of premises on or local science parks in which we operate, are required to obtain and maintain various approvals, licenses, permits, registrations, and certificates (e.g. drainage permits) from the relevant authorities to operate our business. Some of these approvals, permits, licenses, registrations, and certificates are subject to periodic renewal and/or reassessment by the relevant authorities, whose standards remain changed from time to time.

Any failure to obtain or renew any approvals, licenses, permits, registrations, and certificates necessary for our operations may result in enforcement actions thereunder, including orders issued by the relevant regulatory authorities ceasing our operations, and corrective measures requiring capital expenditure or remedial actions, which could materially and adversely affect our business, financial condition and results of operations. We cannot assure you that the relevant authorities would not take any enforcement actions against us. In the event where such enforcement action was taken, our business operations could be materially and adversely disrupted.

Further, if any interpretation or implementation of currently existing laws and regulations changes in the near future, or new regulations come into effect which require us to obtain any additional approvals, permits, licenses, registrations, or certificates previously not so required, we cannot assure you that we and parties related to our operation will be able to successfully obtain such approvals, permits, licenses, registrations, or certificates. The failure of these parties or us to obtain the yet necessary approvals, permits, licenses, registrations, or certificates may restrict the conduct of our business, decrease our revenue and increase our costs, which could materially reduce our profitability and prospects.

RISK FACTORS

Any of our future approved product candidates will be subject to ongoing or additional regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

If the EMA, the NMPA, the WHO or a comparable regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements on pharmacovigilance. These requirements include submissions of safety and other post-marketing information and reports, registration, random quality control testing, adherence to any chemistry, manufacturing, and controls (CMC), variations, continued compliance with cGMPs, and GCPs and potential post-approval studies for the purposes of license renewal.

Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing studies, including Phase 4 studies for the surveillance and monitoring of the safety and efficacy of the drug.

In addition, once a drug is approved by the EMA, the NMPA, the WHO or a comparable regulatory authority for marketing, it is possible that there could be a subsequent discovery of previously unknown problems with the drug, including problems with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements. If any of the foregoing occurs with respect to our products, it may result in:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on our clinical trials;
- refusal by the EMA, the NMPA, the WHO or comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- refusal by the EMA, the NMPA, the WHO or comparable regulatory authorities to accept any of our other IND approvals, NDAs or BLAs;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil, administrative or criminal penalties.

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Any government investigation of alleged violations of law could require us to spend significant time and resources which could also generate negative publicity. Moreover, regulatory policies may change or additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are not able to maintain regulatory compliance, we may lose the regulatory approvals that we have already obtained and may not achieve or sustain profitability, which in turn could significantly harm our business, financial condition and prospects.

We face risks related to natural disasters, health epidemics, civil and social disruption and other outbreaks, which could significantly disrupt our operations. In particular, the COVID-19 outbreak in China and worldwide has adversely affected, and may continue to adversely affect, our business, results of operations and financial condition.

Natural disasters, acts of war or terrorism, health epidemics, or other factors beyond our control may adversely affect the economy, infrastructure and livelihood of the people in the regions where we conduct our business. Our operations may be under the threat of floods, earthquakes, sandstorms, snowstorms, fire or drought, power, water or fuel shortages, failures, malfunction and breakdown of information management systems, unexpected maintenance or technical problems, or may be susceptible to potential wars or terrorist attacks. Serious natural disasters may result in loss of lives, injury, destruction of assets and disruption of our business and operations. Acts of war or terrorism may also injure our employees, cause loss of lives, disrupt our business network and destroy our markets. Any of these factors and other factors beyond our control could have an adverse effect on the overall business sentiment and environment, cause uncertainties in the regions where we conduct business, cause our business to suffer in ways that we cannot predict and materially and adversely impact our business, financial conditions and results of operations. Our business could be adversely affected by the effects of epidemics, including COVID-19, avian influenza, severe acute respiratory syndrome (SARS), influenza A (H1N1), Ebola or another epidemic. Any such occurrences could cause severe disruption to our daily operations and may even require a temporary closure of our offices and laboratories. The global outbreak of COVID-19, the disease caused by a novel strain of coronavirus, has created significant business disruption which could materially and adversely affect our business and operations. Since late 2020, multiple SARS-CoV-2 variants including variants of concern have emerged. For details of the latest development of COVID-19, please see “Summary – Recent Development.” The outbreak has resulted in governments implementing numerous measures to contain COVID-19, such as travel bans and restrictions, quarantines, shelter-in-place, temporary shutdown of factories, business limitations, or total lock-down orders. These containment measures are subject to change and may be further tightened. Although this outbreak has led to some level of impact to our operation for the first quarter of 2020, such as cancellation of physical participation in meetings, restrictions on employee travels, and lots of our employees temporarily working from home, the work efficiency and productivity, and the continuity of our business operations and certain clinical trials are ongoing as normal.

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The outbreak of COVID-19 and the resulting government measures may materially and adversely impact our planned and ongoing clinical trials and development. Clinical site initiation, including recruiting clinical site investigators and clinical site staff, and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. The diversion of healthcare resources away from the conduct of clinical trials to focus on pandemic concerns, including the attention of physicians serving as our clinical trial investigators and hospitals serving as our clinical trial sites, or other staff supporting the conduct of our clinical trials may significantly disrupt our research activities. Hospitals have also had reduced patient flow in general during the outbreak period. As a result, the expected timeline for data readouts of our clinical trials and potential submission and filings will likely be negatively impacted, which would adversely affect and delay our ability to obtain certain regulatory approvals, increase our operating expenses and have a material adverse effect on our financial condition. In the first half of 2020, the clinical trials for SCB-313 experienced delay in patient enrollment primarily due to the lockdown of clinical sites. We resumed patient enrollment in the first quarter in 2021 as clinical sites reopened.

Furthermore, we could face the interruption of key clinical activities such as trial site data monitoring, which may impact the integrity of clinical data. Similarly, our ability to recruit and retain patients or participants and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may be impeded, which would also materially and adversely impact our clinical trial operations. As a result of disruptions caused by the COVID-19 pandemic, we may require additional capital to continue our research activities, which we may be unable to secure on favorable terms, if at all. In addition, we believe that our business partners, such as our licensing partners, CROs or suppliers, have also experienced and may continue to experience similar or more severe disruptions to their business operations. Any disruption to the business operations of us and our business partners could materially and adversely affect the development of our product candidates, our business, financial condition and results of operations.

We are subject to the risks of doing business globally. Disruptions in the financial markets and economic conditions could affect our ability to raise capital.

Because we operate in China and other countries, our business is subject to risks associated with doing business globally. Global economies could suffer dramatic downturns as the result of a deterioration in the credit markets and related financial crisis as well as a variety of other factors, including extreme volatility in security prices, severely diminished liquidity and credit availability, ratings downgrades of certain investments and declining valuations of others. In the past, governments have taken unprecedented actions in an attempt to address and rectify these extreme market and economic conditions by providing liquidity and stability to the financial markets. If these actions are not successful, the return of adverse economic conditions may cause a significant impact on our ability to raise capital, if needed, on a timely basis and on acceptable terms or at all.

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COVID-19 had a severe and negative impact on the global economy in the entire year of 2020. Whether this will lead to a prolonged slowdown in the economy is still unknown. Even before the outbreak of COVID-19, the global macroeconomic environment was facing numerous challenges. The growth rate of the Chinese economy had already been slowing since 2010. There is considerable uncertainty over the long-term effects of the expansionary monetary and fiscal policies adopted by the central banks and financial authorities of some of the world’s leading economies, including the United States and China, even before 2020. Unrest, terrorist threats and the potential for war in the Middle East and elsewhere may increase market volatility across the globe. There have also been concerns about the relationship between China and other countries, including the surrounding Asian countries, which may potentially have economic effects. In particular, there is significant uncertainty about the future relationship between the United States and China with respect to trade policies, treaties, government regulations and tariffs. Economic conditions in China are sensitive to global economic conditions, as well as changes in domestic economic and political policies and the expected or perceived overall economic growth rate in China. In addition, the U.K. held a referendum on 23 June 2016 on its membership in the European Union, in which a majority of voters in the U.K. voted to exit the European Union (commonly referred to as “Brexit”). On January 31, 2020, the U.K. withdrew from the European Union and entered into a transition period to, among other things, negotiate an agreement with the European Union governing the future relationship between the European Union and the U.K. The referendum and subsequent withdrawal of the U.K. from the European Union has created significant uncertainty about the future relationship between the U.K. and the European Union. Brexit could adversely affect European and worldwide economic and market conditions and could contribute to instability in global financial and foreign exchange markets. It is unclear whether these challenges and uncertainties will be contained or resolved, and what effects they may have on the global political and economic conditions in the long term. Any severe or prolonged slowdown in the global or Chinese economy may result in disruptions in the financial markets, which may materially and adversely affect our ability to raise capital.

We may be restricted from transferring our scientific data abroad.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》), or the Scientific Data Measures, which provide a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal.

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If and to the extent our research and development of product candidates will be subject to the Scientific Data Measures and any relevant laws as required by the relevant government authorities, we cannot assure you that we can always obtain relevant approvals for sending scientific data (such as the results of our pre-clinical studies or clinical trials conducted within China) abroad. If we are unable to obtain necessary approvals in a timely manner, or at all, our research and development of product candidates may be hindered, which may materially and adversely affect our business, results of operations, financial conditions and prospects. If the relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to fines and other administrative penalties imposed by those government authorities.

If we face allegations of non-compliance with laws and encounter sanctions, our reputation, revenues and liquidity may suffer, and our product candidates and future products could be subject to restrictions or withdrawal from the market.

Our business is subject to extensive laws, governmental regulations and policies. We must comply with various requirements mandated by laws and regulations in the jurisdictions we operate. Such laws and regulations affect various aspects of our business operation, including, but limited to, our research and development activities, manufacturing and distribution of products, taxation and employee benefits. We may incur costs to ensure compliance with such laws and regulations. Any government investigation of alleged violations of laws could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenues from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected. Additionally, if we are unable to generate revenues from our product sales, our potential for achieving profitability will be diminished and the capital necessary to fund our operations will be increased.

If we fail to comply with applicable anti-bribery laws, our reputation may be harmed and we could be subject to penalties and significant expenses that have a material adverse effect on our business, financial condition and results of operations.

We are subject to anti-bribery laws in China that generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing any other improper advantages. In addition, although currently our primary operating business is in China, we are subject to the FCPA. The FCPA generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Although we have policies and procedures designed to ensure that we, our employees and our agents comply with anti-bribery laws, there is no assurance that such policies or procedures will prevent our agents, employees and intermediaries from engaging in bribery activities. Failure to comply with anti-bribery laws could disrupt our business and lead to severe criminal and civil penalties, including imprisonment, criminal and civil fines, loss of our export licenses, suspension of our ability to do business with the government, denial of government reimbursement for our products and/or exclusion from participation in government

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healthcare programs. Other remedial measures could include further changes or enhancements to our procedures, policies, and controls and potential personnel changes and/or disciplinary actions, any of which could have a material adverse effect on our business, financial condition, results of operations and liquidity. We could also be adversely affected by any allegation that we violated such laws.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may produce hazardous waste products. We may contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

We maintain work-related injury insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of or exposure to hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We also maintain certain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of biological materials.

In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our internal computer systems, or those used by our partners or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our partners, contractors and consultants are vulnerable to damages from computer viruses and unauthorized access. Although to our knowledge we have not experienced any material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations.

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In the ordinary course of our business, we collect and store sensitive data, including, among other things, personally identifiable information about our employees, intellectual property and proprietary business information. We manage and maintain our applications and data utilizing on-site systems and outsourced vendors. These applications and data encompass a wide variety of business-critical information including research and development information, commercial information, and business and financial information. Because information systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions at our sites or our vendors that provide information systems, networks or other services to us pose increased risks. Such disruptions may be caused by events such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial-of-service attacks, and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. Such events could have an adverse impact on us and our business, including loss of data and damage to equipment and data. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. Significant events could result in a disruption of our operations, damage to our reputation or a loss of revenues. In addition, we may not have adequate insurance coverage to compensate for any losses associated with such events.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification, or intentional or accidental release or loss of information maintained in the information systems and networks of us and our vendors, including personal information of our employees and patients or participants, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. Like other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems, including malicious codes and viruses, phishing, and other cyberattacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes are costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payers and patients, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems.

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To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

In conducting drug discovery and development, we face potential liabilities, in particular, product liability claims or lawsuits that could cause us to incur substantial liabilities.

We face an inherent risk of product liability as a result of the clinical testing and any future commercialization of our product candidates inside and outside China. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the drug, negligence, strict liability or a breach of warranties. Claims could also be asserted under applicable consumer protection laws. If we cannot successfully defend ourselves against or obtain indemnification from our collaborators for product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: decreased demand for our product candidates; damage to our reputation; withdrawal of clinical trial participants and inability to continue clinical trials; initiation of investigations by regulators; costs to defend the related litigation; a diversion of management’s time and our resources; substantial monetary awards to trial participants or patients; product recalls, withdrawals, or labeling, marketing or promotional restrictions; loss of revenue; exhaustion of any available insurance and our capital resources; the inability to commercialize any approved product candidate; and a decline in the market price of our Shares.

To cover such liability claims arising from clinical studies, we have purchased clinical trial insurance in the conduct of our clinical trials. However, it is possible that our liabilities could exceed our insurance coverage or that our insurance will not cover all situations in which a claim against us could be made. We may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired. Should any of these events occur, it could have a material adverse effect on our business, financial condition and results of operations.

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Any future litigation, legal disputes, claims or administrative proceedings against us could be costly and time-consuming to defend.

We may become subject to, from time to time, legal proceedings and claims that arise in the ordinary course of business or pursuant to governmental or regulatory enforcement activity. While we do not believe that the resolution of any lawsuits against us will, individually or in the aggregate, have a material adverse effect on our business, financial condition and results of operations, litigation to which we subsequently become a party might result in substantial costs and divert management’s attention and resources. Furthermore, any litigations, legal disputes, claims or administrative proceedings which are initially not of material importance may escalate and become important to us due to a variety of factors, such as the facts and circumstances of the cases, the likelihood of loss, the monetary amount at stake, and the parties involved.

Our insurance might not cover claims brought against us, might not provide sufficient payments to cover all of the costs to resolve one or more such claims, and might not continue to be available on terms acceptable to us. In particular, any claim could result in unanticipated liability to us if the claim is outside the scope of the indemnification arrangement we have with our collaborators, our collaborators do not abide by the indemnification arrangement as required, or the liability exceeds the amount of any applicable indemnification limits or available insurance coverage. A claim brought against us that is uninsured or underinsured could result in unanticipated costs and could have a material adverse effect on our financial condition, results of operations or reputation.

RISKS RELATING TO DOING BUSINESS IN CHINA

The pharmaceutical industry in China is highly regulated and such regulations are subject to change which may affect approval and commercialization of our product candidates.

We conduct a substantial portion of our operations in China, which we believe confers development and manufacturing advantages. The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new products. See “Regulation Overview” for a discussion of the regulatory requirements that are applicable to our current and planned business activities in China. In recent years, the regulatory framework in China regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development or commercialization of our product candidates in China and reduce the benefits we believe are available to us from developing and manufacturing products in China. PRC authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in China. We believe our strategy and approach are aligned with the PRC government’s regulatory policies, but we cannot ensure that our strategy and approach will continue to be aligned.

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Changes in the political and economic policies of the PRC government may materially and adversely affect our business, financial condition and results of operations and may result in our inability to sustain our growth and business development strategies.

Due to our extensive operations in China, our business, results of operations, financial condition and prospects are affected to a significant extent by economic, political, legal and social developments in China. China’s economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources.

While the PRC economy has experienced significant growth over the past 30 years, growth has been uneven across different regions and among various economic sectors of China. The PRC government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall PRC economy, but may have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are currently applicable to us. In addition, the PRC government had, in the past, implemented certain measures, including interest rate increases, to control the pace of economic growth. These measures may cause decreased economic activity in China, which may adversely affect our business and results of operation. More generally, if the business environment in China deteriorates from the perspective of domestic or international investment, our business in China may also be adversely affected.

Government control of currency conversion may limit our ability to use capital effectively and could negatively affect our financial condition, operations, and our ability to pay dividends, increase competition from foreign competitors, and affect the value of our net assets, earnings, and dividends in foreign currency terms.

The PRC government imposes controls on the convertibility of foreign currencies into Renminbi. Under China’s existing foreign-exchange regulations, foreign-exchange transactions under capital accounts continue to be subject to significant foreign-exchange controls and require the registration with, and approval of, PRC governmental authorities. In particular, if one subsidiary receives foreign-currency loans from us or other foreign lenders, these loans must be registered with State Administration of Foreign Exchange, or SAFE, or its local counterparts. If we finance such subsidiary by means of additional capital contributions, these capital contributions must be reported to, filed with or approved by certain government authorities, including the Ministry of Commerce of the People’s Republic of China, or MOFCOM, or its local counterparts.

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In August 2008, SAFE promulgated the Circular on the Relevant Operating Issues Concerning the Improvement of the Administration of the Payment and Settlement of Foreign Currency Capital of Foreign Invested Enterprises (《關於完善外商投資企業外匯資金支付結匯管理有關業務操作問題的通知》), or SAFE Circular 142, providing that the Renminbi capital converted from foreign-currency-registered capital of a foreign-invested enterprise may only be used for purposes within the business scope approved by the applicable government authority and may not be used for equity investments within the PRC.

On March 30, 2015, SAFE released the Notice of the State Administration of Foreign Exchange on Reforming the Management Mode of Foreign Exchange Capital Settlement of Foreign Investment Enterprises (《國家外匯管理局關於改革外商投資企業外匯資金結匯管理方式的通知》), or SAFE Circular 19, which came into force and superseded SAFE Circular 142 from June 1, 2015. On June 9, 2016, SAFE further promulgated the Circular on the Reform and Standardization of the Management Policy of the Settlement of Capital Projects (《關於改革和規範資本項目結匯管理政策的通知》), or SAFE Circular 16. SAFE Circular 19 has made certain adjustments to some regulatory requirements on the settlement of foreign exchange capital of foreign-invested enterprises, and some foreign exchange restrictions under SAFE Circular 142 are expected to be lifted. Under SAFE Circular 19 and SAFE Circular 16, the settlement of foreign exchange by foreign invested enterprises shall be governed by the policy of foreign exchange settlement on a discretionary basis. However, SAFE Circular 19 also reiterates that the settlement of foreign exchange shall only be used for its own operation purposes within the business scope of the foreign invested enterprises and following the principles of authenticity. Considering that SAFE Circular 19 and SAFE Circular 16 are still new, it is unclear how they will be implemented, and there exist high uncertainties with respect to its interpretation and implementation by authorities. For example, under SAFE Circular 19 and SAFE Circular 16, we may still not be allowed to convert foreign-currency-registered capital of our PRC subsidiaries which are foreign-invested enterprises into RMB capital for securities investments or other finance and investment except for principal-guaranteed bank products. Further, SAFE Circular 19 and SAFE Circular 16 restrict a foreign-invested enterprise from using Renminbi converted from its registered capital to provide loans to a its non-affiliated company.

Violations of SAFE Circular 19 and SAFE Circular 16 could result in severe monetary or other penalties. We cannot assure you that we will be able to complete the necessary government registrations or obtain the necessary government approvals on a timely basis, if at all, with respect to future loans or capital contributions by us to our PRC subsidiaries, and conversion of such loans or capital contributions into Renminbi. If we fail to complete such registrations or obtain such approvals, our ability to capitalize or otherwise fund our PRC operations may be negatively affected, which could adversely affect our ability to fund and expand our business.

RISK FACTORS

Fluctuations in exchange rates of the Renminbi could result in foreign currency exchange losses and could materially reduce the value of your investment.

We are exposed to exchange rate risks related to other currency that can affect our revenue, costs, margins and profits. We recorded foreign exchange loss of RMB31.9 million and RMB3.6 million in 2020 and the four months ended April 30, 2021, respectively. An increase in the value of the US dollar against the Renminbi may have a material adverse effect on our profitability. When managing our exposure to currency risk, we may continue to use foreign currency forward contracts and other strategies to mitigate currency risk and there can be no assurances that these strategies will be successful.

Nonetheless, very limited hedging options are available in China to reduce our exposure to exchange rate fluctuations. Although we have entered into select hedging transactions in an effort to reduce our exposure to foreign currency exchange risk, the availability and effectiveness of these hedges may be limited and we may not be able to adequately hedge our exposure or at all. In addition, our currency exchange losses may be magnified by PRC exchange control regulations that restrict our ability to convert Renminbi into foreign currency. As a result, fluctuations in exchange rates may have a material adverse effect on your Shares.

Restrictions on currency exchange may limit our ability to utilize our revenue effectively in the future.

The PRC government imposes controls on the convertibility of RMB into foreign currencies and, in certain cases, the remittance of currency out of China. Shortages in availability of foreign currency may then restrict the ability of our PRC subsidiaries to remit sufficient foreign currency to our offshore entities for our offshore entities to pay dividends or make other payments or otherwise to satisfy our foreign-currency-denominated obligations. The RMB is currently convertible under the “current account,” which includes dividends, trade and service-related foreign exchange transactions, but not under the “capital account,” which includes foreign direct investment and foreign currency debt, including loans we may secure for our onshore subsidiaries. Currently, our PRC subsidiaries may purchase foreign currency for settlement of “current account transactions,” including payment of dividends to us, without the approval of SAFE by complying with certain procedural requirements. However, the relevant PRC governmental authorities may limit or eliminate our ability to purchase foreign currencies in the future for current account transactions. Foreign exchange transactions under the capital account remain subject to limitations and require approvals from, or registration with, SAFE and other relevant PRC governmental authorities. This could affect our ability to obtain foreign currency through debt or equity financing for our subsidiaries.

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Uncertainties with respect to the PRC legal system may affect the legal protection afforded to our business and our investors.

Our primary business is governed by PRC laws and regulations. Our primary business operation is supervised by relevant regulatory authorities in China. The PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions may be cited for reference but have limited precedential value. Additionally, written statutes in the PRC are often principle-oriented and require detailed interpretations by the enforcement bodies to further apply and enforce such laws.

Since 1979, the PRC government has developed a comprehensive system of laws, rules and regulations in relation to economic matters, such as foreign investment, corporate organization and governance, commerce, taxation and trade. The overall effect of legislation over the past four decades has significantly enhanced the protections afforded to various forms of foreign investment in China. However, the interpretation and enforcement of these laws, rules and regulations involve uncertainties and may not be as consistent or predictable as in other more developed jurisdictions. As these laws and regulations are continually evolving in response to changing economic and other conditions, and because of the limited volume of published cases and their non-binding nature, any particular interpretation of PRC laws and regulations may not be definitive. Moreover, we cannot predict the effect of future developments in the PRC legal system and regulatory structure. Such unpredictability towards our contractual, property and procedural rights as well as our rights licensed, approved or granted by the competent regulatory authority could adversely affect our business and impede our ability to continue our operations.

In addition, the PRC legal system is based in part on government policies and internal rules, some of which are not published on a timely basis, if at all, and which may have a retroactive effect. Hence, we may not be aware of violation of these policies and rules until after such violation has occurred. For example, PRC laws and regulations afford significant protection to state-owned assets. Transactions which may lead to losses of state-owned assets are subject to heightened scrutiny by the competent authorities, and the competent authorities have significant discretion in interpreting and implementing the relevant laws and regulations. In the event we or our affiliates are involved in transactions with state-owned enterprises or their affiliates, there might be risks that we might be found to have caused losses of state-owned assets, which may subject us to liabilities and could materially and adversely affect our business, financial condition and results of operation. Further, the legal protections available to us and our investors under these laws, rules and regulations may be limited. For us specifically, the NMPA’s recent reform of the drug-approval system may face implementation challenges. The timing and full impact of such reforms is uncertain and could prevent us from commercializing our product candidates in a timely manner.

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In addition, any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention. Since PRC administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy than we would in more developed legal systems. These uncertainties may impede our ability to enforce the contracts we have entered into and could materially and adversely affect our business, financial condition and results of operations.

You may experience difficulties in effecting service of legal process or enforcing foreign judgments against us and our management.

Most of our major operating subsidiaries are incorporated in China. All of our senior management reside in China from time to time. In addition to sizable cash and equivalent in Cayman and Australia, most of our assets and some of the assets of our management are located in China. As a result, it may not be possible for investors to effect service of process upon us or our management inside China. China has not entered into treaties or arrangements providing for the reciprocal enforcement of civil judgments of courts with the United States, the United Kingdom, Japan or many other countries. In addition, Hong Kong has no arrangement for the reciprocal enforcement of judgments with the United States. As a result, recognition and enforcement in the PRC or Hong Kong of judgments of a court obtained in the United States and any of the other jurisdictions mentioned above may be difficult or impossible.

On July 14, 2006, the Supreme People’s Court of the PRC and the government of the Hong Kong Special Administrative Region entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and the Hong Kong Special Administration Region Pursuant to Choice of Court Agreements between Parties Concerned (《關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》) (the “2006 Arrangement”). Under the 2006 Arrangement, a party with a final court judgment rendered by a Hong Kong court requiring payment of money in a civil and commercial case according to a choice of court agreement in writing may apply for recognition and enforcement of the judgment in China. Similarly, a party with a final judgment rendered by a Chinese court requiring payment of money in a civil and commercial case pursuant to a choice of court agreement in writing may apply for recognition and enforcement of such judgment in Hong Kong. A choice of court agreement in writing is defined as any agreement in writing entered into between parties after the effective date of the Arrangement in which a Hong Kong court or a Chinese court is expressly designated as the court having sole jurisdiction for the dispute. On January 18, 2019, the Supreme People’s Court of the PRC and the Hong Kong Special Administrative Region (Hong Kong SAR) signed the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》) (the “2019 Arrangement”), which seeks to establish a mechanism with greater clarity and certainty for recognition and enforcement of judgments in a wider range of civil and commercial matters between Hong Kong SAR and the Mainland. The New Arrangement

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discontinued the requirement for a choice of court agreement for bilateral recognition and enforcement. The New Arrangement will only take effect after the promulgation of a judicial interpretation by the Supreme People’s Court and the completion of the relevant legislative procedures in the Hong Kong SAR. The New Arrangement will, upon its effectiveness, supersede the 2006 Arrangement. Therefore, before the New Arrangement becomes effective it may be difficult or impossible to enforce a judgment rendered by a Hong Kong court in China if the parties in the dispute do not agree to enter into a choice of court agreement in writing.

Failure to pay the social insurance and housing provident funds for any on behalf of our employees in accordance with the Labor Contract Law or comply with other PRC regulations may have an adverse impact on our financial conditions and results of operation.

PRC companies are required to pay for their employees’ social insurance (in most cases including pension insurance, unemployment insurance, medical insurance, work-related injury insurance and maternity insurance) and housing provident funds in amounts equal to certain percentage of salaries, including bonuses and allowances, of their employees up to a maximum amount specified by the local government from time to time at locations where they operate their business.

According the applicable PRC laws and regulations, an employer shall open social insurance registration account and housing provident funds account and pay social insurance and housing provident funds for its employees. During the Track Record Period, some of our PRC subsidiaries engaged a third-party human resources agency primarily for the purpose of keeping the salary of our employees confidential. For convenience of our employees, the human resources agency also paid social insurance and housing provident funds for certain of our employees during the Track Record Period. The human resources agency has confirmed in writing that during the Track Record Period, it has fully paid insurance premium and housing provident funds according to the relevant agreements between us, and none of these subsidiaries had received any administrative penalty or labor arbitration application from employees for its agency arrangement with the third-party human resources agency. We may be subject to penalties imposed by the local social insurance authorities and the local housing provident fund management centers if the human resources agency fails to pay the social insurance premium or housing provident funds for our employees as required by our agreements and applicable PRC laws and regulations, while the human resources agency also confirmed that during the Track Record Period, if we failed to to pay the insurance premium and housing provident funds due to its fault, or we are subject to any penalty due to any non-payment arising from its default, the human resources agency would pay such fees for us. We believe that paying social insurance and housing provident funds through third-party human resources agencies would not have a material adverse effect on our business or results of operations, considering that: (i) as of the Latest Practicable Date, we had not received any administrative penalty or labor arbitration application from employees for our agency arrangement with third-party human resources agencies, (ii) our PRC Legal Adviser interviewed the competent authorities to Sichuan Clover, the Social Security Department of the Administrative Service Center of Chengdu Hi-Tech Industrial Development Zone (成都高新區政務服務中心社會保障部門) and Chengdu Housing Provident Fund Management Center (成都

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住房公積金管理中心), who confirmed that paying employees' social insurance and housing provident funds through third-party human resources agencies does not constitute a material violation of applicable laws and regulations, (iii) based on such confirmation, our PRC Legal Adviser was of the view that the likelihood that we would be subject to administrative penalties due to paying social insurance fund through third-party human resources agencies is low if we timely rectify such non-compliance within the period stipulated by relevant authorities. As of the Latest Practicable Date, we have been paying social insurance and housing provident funds for China employees by ourselves, unless our employees choose to participate in local pension schemes offered in their place of residency other than the cities where we are located. For ex-China employees who are located in countries where Clover does not have a legal entity, their social benefit or welfare are paid through third-party human resource agency.

Also, as the interpretation and implementation of labor laws and regulations are still evolving, we cannot assure you that our employment practice policy would at all times be deemed as in full compliance with labor-related laws and regulations in the PRC, which might subject us to labor disputes or governmental investigations, which might adversely affect our financial condition and operation.

We may be subject to penalties, including restrictions on our ability to inject capital into our PRC subsidiaries and on our PRC subsidiaries' ability to distribute profits to us, if our PRC resident Shareholders or beneficial owners fail to comply with relevant PRC foreign exchange regulations.

SAFE promulgated the Circular on Relevant Issues concerning Foreign Exchange Administration of Overseas Investment and Financing and Round-tripping Investments Conducted by Domestic Residents through Overseas Special Purpose Vehicles (《國家外匯管理局關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》), or the SAFE Circular 37 on July 4, 2014, which, requires PRC residents to register with local branches of SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with the PRC residents' legally owned assets or equity interests in domestic enterprises or offshore assets or interests, referred to in SAFE Circular 37 as a "special purpose vehicle." SAFE further promulgated the Notice on Further Simplifying and Improving the Foreign Exchange Management Policies for Direct Investment (《國家外匯管理局關於進一步簡化和改進直接投資外匯管理政策的通知》) in 2015, according to which the above mentioned registration will be handled directly by appropriate bank and SAFE and its local branches shall perform indirect supervision over the direct investment related foreign exchange registration via banks.

We have notified substantial beneficial owners of Shares who we know are PRC residents of their filing obligation, and pursuant to SAFE Circular 37, our PRC resident shareholders have filed the above-mentioned foreign exchange registration. However, we may not be aware of the identities of all of our beneficial owners who are PRC residents. We do not have control over our beneficial owners, and there can be no assurance that all of our PRC-resident beneficial owners will comply with SAFE Circular 37 and subsequent implementation rules. The failure of our beneficial owners who are PRC residents to register or amend their SAFE

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registrations in a timely manner pursuant to SAFE Circular 37 and subsequent implementation rules, or the failure of future beneficial owners of our Company who are PRC residents to comply with the registration procedures set forth in SAFE Circular 37 and subsequent implementation rules, may subject the beneficial owners or our PRC subsidiaries to fines and legal sanctions.

Furthermore, since it is unclear how those SAFE regulations, and any future regulation concerning offshore or cross-border transactions, will be further interpreted, amended and implemented by the relevant PRC government authorities, we cannot predict how these regulations will affect our business operations or future strategy. Failure to register or comply with relevant requirements may also limit our ability to contribute additional capital to our PRC subsidiaries and limit our PRC subsidiaries’ ability to distribute dividends to our Company. These risks may have a material adverse effect on our business, financial condition and results of operations.

We may be deemed to be a PRC tax resident enterprise under the EIT Law and be subject to PRC taxation on our worldwide income.

Under China’s Enterprise Income Tax Law, or the EIT Law, an enterprise established outside of China with “de facto management bodies” within China is considered a “resident enterprise,” meaning that it can be treated in a manner similar to a Chinese enterprise for PRC enterprise income tax purposes. A tax circular issued by the PRC State Taxation Administration (SAT) on April 22, 2009, or Circular 82, regarding the standards used to classify resident enterprises clarified that dividends and other distributions paid by such resident enterprises which are considered to be PRC source income will be subject to PRC withholding tax, currently at a rate of 10%, when received or recognized by non-PRC resident enterprise shareholders. This circular also subjects such resident enterprises to various reporting requirements with the PRC tax authorities. The implementing rules of the EIT Law define “de facto management bodies” as “management bodies that exercise substantial and overall management and control over the production and operations, personnel, accounting and properties” of the enterprise. In addition, Circular 82 specifies that certain China-invested enterprises controlled by Chinese enterprises or Chinese group enterprises will be classified as resident enterprises if the following are located or resident in China: (i) senior management personnel and departments that are responsible for daily production, operation and management; (ii) financial and personnel decision-making bodies; (iii) key properties, accounting books, company seal and minutes of board meetings and shareholders’ meetings; and (iv) half or more of senior management or directors having voting rights. On July 27, 2011, the PRC State Administration of Taxation issued Administrative Measures of Enterprise Income Tax of Chinese-Controlled Offshore Incorporated Resident Enterprises (Trial), or Bulletin 45, which became effective on September 1, 2011, to provide further guidance on the implementation of Circular 82. Bulletin 45 clarifies certain issues related to determining PRC resident enterprise status, including which competent tax authorities are responsible for determining offshore incorporated PRC resident enterprise status, as well as post-determination administration.

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Currently, senior management of our Company is located in China. However, Circular 82 and Bulletin 45 only apply to offshore enterprises controlled by PRC enterprises or PRC enterprise groups, not those controlled by foreign individuals like us. In the absence of detailed implementing regulations or other guidance determining that offshore companies controlled by foreign individuals like us are PRC resident enterprises, we do not currently consider our Company or any of our overseas subsidiaries to be a PRC resident enterprise.

Despite the foregoing, the SAT may take the view that the determining criteria set forth in Circular 82 and Bulletin 45 reflect the general position on how the “de facto management body” test should be applied in determining the tax resident status of all offshore enterprises. Additional implementing regulations or guidance may be issued determining that our Cayman Islands holding company is a “resident enterprise” for PRC enterprise income tax purposes. If the PRC tax authorities determine that our Cayman Islands holding company or any of our non-PRC subsidiaries is a resident enterprise for PRC enterprise income tax purposes, a number of unfavorable PRC tax consequences could follow. First, we and our non-PRC subsidiaries may be subject to enterprise income tax at a rate of 25% on our worldwide taxable income, as well as to PRC enterprise income tax reporting obligations. Second, although under the EIT Law and its implementing rules, dividends paid by a PRC tax resident enterprise to an offshore incorporated PRC tax resident enterprise controlled by a PRC enterprise or enterprise group might qualify as tax-exempted income, we cannot assure that dividends paid by our PRC subsidiaries to us will not be subject to a 10% withholding tax, as the PRC foreign-exchange control authorities and tax authorities have not yet issued guidance with respect to the processing of outbound remittances to entities that are treated as resident enterprises for PRC enterprise income tax purposes but not controlled by a PRC enterprise or enterprise group like us. Finally, under the EIT Law and its implementing rules issued by PRC tax authorities dividends paid by us to our non-PRC shareholders may be subject to a withholding tax of 10% for non-PRC enterprise shareholders and 20% for non-PRC individual shareholders, and gains recognized by our non-PRC shareholders may be subject to PRC tax of 10% for non-PRC enterprise shareholders and 20% for non-PRC individual shareholders. Any PRC tax liability on dividends or gain described above may be reduced under applicable tax treaties. However, it is unclear whether, if our Cayman Islands holding company is considered a PRC resident enterprise, non-PRC shareholders might be able to claim the benefit of income tax treaties entered into between PRC and their countries. Similarly, these unfavorable consequences could apply to our other offshore companies if they are classified as a PRC resident enterprise.

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Dividends payable by us to our foreign investors and gains on the sale of our Shares may become subject to withholding taxes under the PRC tax laws.

Under the applicable PRC tax laws, both the dividends we pay to non-PRC resident individual holders (“non-resident individual holders”), and gains realized through the sale or transfer by other means of our shares by such shareholders, are subject to PRC individual income tax at a rate of 20%, unless reduced by the applicable tax treaties or arrangements.

Under applicable PRC tax laws, the dividends we pay to, and gains realized through the sale or transfer by other means of our shares by, non-PRC resident enterprise holders of our shares (“non-resident enterprise holders”) are both subject to PRC enterprise income tax at a rate of 10%, unless reduced by applicable tax treaties or arrangements. Pursuant to the Arrangements between the Mainland China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Tax Evasion on Incomes (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》) dated August 21, 2006, any non-resident enterprise registered in Hong Kong that holds directly at least 25% of the shares of our PRC subsidiaries shall pay Enterprise Income Tax for the dividends declared and paid by our PRC subsidiaries at a tax rate of 5% when satisfying certain conditions.

Non-resident holders of our Shares should be aware that they may be obligated to pay PRC income tax on the dividends and gains realized through sales or transfers of our Shares.

The Chinese tax authorities have strengthened their scrutiny over transfers of equity interests in a PRC resident enterprise by a non-resident enterprise, which may negatively affect our business and our ability to conduct mergers, acquisitions or other investments.

On February 3, 2015, the PRC State Administration of Taxation issued the Public Announcement on Several Issues Concerning Enterprise Income Tax for Indirect Transfer of Assets by Non-Resident Enterprises (《關於非居民企業間接轉讓財產企業所得稅若干問題的公告》), or Circular 7, which supersedes certain provisions in the Notice on Strengthening the Administration of Enterprise Income Tax on non-Resident Enterprises (《關於加強非居民企業股權轉讓企業所得稅管理的通知》), or Circular 698, which was previously issued by the State Taxation Administration on December 10, 2009, as well as certain other rules providing clarification on Circular 698. Circular 7 provides comprehensive guidelines relating to, and heightened the PRC tax authorities’ scrutiny over, indirect transfers by a non-resident enterprise of assets (including equity interests) of a PRC resident enterprise, or PRC Taxable Assets.

For example, Circular 7 specifies that when a non-resident enterprise transfers PRC Taxable Assets indirectly by disposing of equity interests in an overseas holding company which directly or indirectly holds such PRC Taxable Assets, the PRC tax authorities are entitled to reclassify the nature of an indirect transfer of PRC Taxable Assets by disregarding the existence of such overseas holding company and considering the transaction to be a direct transfer of PRC Taxable Assets, if such transfer is deemed to have been conducted for the purposes of avoiding PRC enterprise income taxes and without any other reasonable commercial purposes.

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Except as provided in Circular 7, transfers of PRC Taxable Assets satisfying all of the following circumstances shall be automatically deemed as having no reasonable commercial purpose, and are subject to PRC enterprise income tax: (i) more than 75% of the value of the equity interest of the overseas enterprise is directly or indirectly attributable to the PRC Taxable Assets; (ii) more than 90% of the total assets (cash excluded) of the overseas enterprise are directly or indirectly composed of investment in China at any time during the year prior to the indirect transfer of PRC Taxable Assets, or more than 90% of the income of the overseas enterprise is directly or indirectly from China during the year prior to the indirect transfer of PRC Taxable Assets; (iii) the overseas enterprise and its subsidiaries directly or indirectly hold PRC Taxable Assets and have registered with the relevant authorities in the host countries (regions) in order to meet the local legal requirements in relation to organization forms, yet prove to be inadequate in their ability to perform their intended functions and withstand risks as their alleged organization forms suggest; or (iv) the income tax from the indirect transfer of PRC Taxable Assets payable abroad is lower than the income tax in China that may be imposed on the direct transfer of such PRC Taxable Assets.

Circular 7 contains certain exemptions, including (i) the Public Market Safe Harbor described below; and (ii) where there is an indirect transfer of PRC Taxable Assets, but if the non-resident enterprise had directly held and disposed of such PRC Taxable Assets, the income from the transfer would have been exempted from enterprise income tax in the PRC under an applicable tax treaty or arrangement. However, it remains unclear whether any exemptions under Circular 7 will be applicable to the transfer of our Shares that do not qualify for the Public Market Safe Harbor or to any future acquisition by us outside of the PRC involving PRC Taxable Assets, or whether the PRC tax authorities will reclassify such transactions by applying Circular 7. Therefore, the PRC tax authorities may deem any transfer of our Shares that do not qualify for the Public Market Safe Harbor by our Shareholders that are non-resident enterprises, or any future acquisition by us outside of the PRC involving PRC Taxable Assets, to be subject to the foregoing regulations, which may subject our Shareholders or us to additional PRC tax reporting obligations or tax liabilities. Provisions of Circular 7, which impose PRC tax liabilities and reporting obligations, do not apply to “non-resident enterprise acquiring and disposing of the equity interests of the same offshore listed company in a public market,” or the Public Market Safe Harbor, which is determined by whether the parties, number and price of the shares acquired and disposed are not previously agreed upon, but determined in accordance with general trading rules in the public securities markets, according to one implementing rule for Circular 698. In general, transfers of the Shares by Shareholders on the Stock Exchange or other public market would not be subject to the PRC tax liabilities and reporting obligations imposed under the Circular 7 if the transfers fall under the Public Market Safe Harbor. As stated in “Information about This Document and the [REDACTED]” in this document, potential investors should consult their professional advisors if they are in any doubt as to the tax implications of [REDACTED], purchasing, holding, disposing of and dealing in the Shares.

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Our business benefits from certain financial incentives and discretionary policies granted by local governments.

In the past, local governments in China granted certain financial incentives from time to time to us as part of their efforts to encourage the development of local businesses. The timing, amount and criteria of government financial incentives are determined within the sole discretion of the local government authorities and cannot be predicted with certainty before we actually receive any financial incentive. We generally do not have the ability to influence local governments in making these decisions. Governments authorities may decide to reduce or eliminate incentives or may amend or terminate the relevant financial incentive policies at any time. In addition, some of the government financial incentives are granted on a project basis and subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements and completion of the specific projects therein. We cannot guarantee that we will satisfy all relevant conditions, and if we fail to satisfy any such conditions, we may be deprived of the relevant incentives. We cannot assure you of the continued availability of the government incentives currently enjoyed by us. Any reduction or elimination of incentives would have an adverse effect on our results of operations.

The political relations between China and other countries or regions may affect our business operation.

The U.S. government has recently made statements and taken certain actions that may lead to potential changes to U.S. and international policies with regard to China. It is unknown whether and to what extent other new laws or regulations will be adopted, or the effect that any such actions would have on us or our industry. While we have not started commercialization of product candidates, any unfavorable international government policies, such as capital controls or tariffs, may affect the demand for our products, the competitive position of our products, the hiring of scientists and other research and development personnel, and import or export of raw materials in relation to product development, or prevent us from selling our products in certain countries. If any new legislation and/or regulations are implemented, or in particular, if the U.S. government takes retaliatory actions due to the recent U.S.-China tension, such changes could have an adverse effect on our business, financial condition and results of operations.

Our leasehold interests in leased properties might not be protected by relevant PRC laws. The failure to register leasehold interests may expose us to potential fines.

During the Track Record Period, we leased a number of properties in Chengdu, Beijing, Shanghai and Boston for various functions. We have not registered our lease agreements with the relevant government authorities. Under the relevant PRC laws and regulations, we may be required to register and file with the relevant government authority executed leases. The failure to register the lease agreements for our leased properties will not affect the validity of these lease agreements, but the competent housing authorities may order us to register the lease agreements in a prescribed period of time and impose a fine ranging from RMB1,000 to RMB10,000 for each non-registered lease if we fail to complete the registration within the prescribed time frame. The maximum penalty that we may be liable in relation to the failure of registering lease agreements during the Track Record Period was approximately RMB270 thousand. See “Business – Land and Properties.”

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A lessor who leased us a property with gross floor area of around 120 square meters, has not provided us with its property ownership certificate, of which the application is in process, or any other documentation proving its right to own or lease the property. If such lessor is not entitled to lease the relevant property to us, such lease might be invalidated. We may have to renegotiate with new lessors and the terms of the new leases may be less favorable to us.

RISKS RELATING TO THE [REDACTED]

No public market currently exists for our Shares; an active trading market for our Shares may not develop and the market price for our Shares may decline or become volatile.

No public market currently exists for our Shares. The initial [REDACTED] for our Shares to the public will be the result of negotiations between our Company and the [REDACTED] (on behalf of the [REDACTED]), and the [REDACTED] may differ significantly from the market price of the Shares following the [REDACTED]. We have applied to the Stock Exchange for the [REDACTED] of, and permission to [REDACTED], the Shares. A [REDACTED] on the Stock Exchange, however, does not guarantee that an active and liquid trading market for our Shares will develop, or if it does develop, that it will be sustained following the [REDACTED], or that the market price of the Shares will not decline following the [REDACTED].

The price and trading volume of our Shares may be volatile, which could lead to substantial losses to investors.

The price and trading volume of our Shares may be subject to significant volatility in response to various factors beyond our control, including the general market conditions of the securities in Hong Kong and elsewhere in the world. In particular, the business and performance and the market price of the shares of other companies engaging in similar business may affect the price and trading volume of our Shares. In addition to market and industry factors, the price and trading volume of our Shares may be highly volatile for specific business reasons, such as the results of clinical trials of our product candidates, the results of our applications for approval of our product candidates, regulatory developments affecting the pharmaceutical industry, healthcare, health insurance and other related matters, fluctuations in our revenue, earnings, cash flows, investments and expenditures, relationships with our suppliers, movements or activities of key personnel, or actions taken by competitors. Moreover, shares of other companies listed on the Stock Exchange with significant operations and assets in China have experienced price volatility in the past, and it is possible that our Shares may be subject to changes in price not directly related to our performance.

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There will be a gap of several days between [REDACTED] and [REDACTED] of our Shares, holders of our Shares are subject to the risk that the price of our Shares when [REDACTED] begins could be lower than the [REDACTED].

The [REDACTED] of our Shares sold in the [REDACTED] is expected to be determined on the [REDACTED]. However, the Shares will not commence [REDACTED] on the Stock Exchange until they are delivered, which is expected to be five Business Days after the [REDACTED]. As a result, investors may not be able to sell or otherwise deal in the Shares during that period. Accordingly, holders of our Shares are subject to the risk that the price of the Shares when [REDACTED] begins could be lower than the [REDACTED] as a result of adverse market conditions or other adverse developments that may occur between the time of sale and the time [REDACTED] begins.

Future sales or perceived sales of our Shares in the public market by major Shareholders following the [REDACTED] could materially and adversely affect the price of our Shares.

Prior to the [REDACTED], there has not been a public market for our Shares. Future sales or perceived sales by our existing Shareholders of our Shares after the [REDACTED] could result in a significant decrease in the prevailing market price of our Shares. Only a limited number of the Shares currently outstanding will be available for sale or issuance immediately after the [REDACTED] due to contractual and regulatory restrictions on disposal and new issuance. Nevertheless, after these restrictions lapse or if they are waived, future sales of significant amounts of our Shares in the public market or the perception that these sales may occur could significantly decrease the prevailing market price of our Shares and our ability to raise equity capital in the future.

You will incur immediate and significant dilution and may experience further dilution if we issue additional Shares or other equity securities in the future, including pursuant to the share incentive schemes.

The [REDACTED] of the [REDACTED] is higher than the net tangible asset value per Share immediately prior to the [REDACTED]. Therefore, purchasers of the [REDACTED] in the [REDACTED] will experience an immediate dilution in pro forma net tangible asset value. In order to expand our business, we may consider offering and issuing additional Shares in the future. Purchasers of the [REDACTED] may experience dilution in the net tangible asset value per share of their Shares if we issue additional Shares in the future at a price which is lower than the net tangible asset value per Share at that time. Furthermore, we may issue Shares pursuant to the share incentive schemes, which would further dilute Shareholders' interests in our Company.

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Because we do not expect to pay dividends in the foreseeable future after the [REDACTED], you must rely on price appreciation of our Shares for a return on your investment.

We currently intend to retain most, if not all, of our available funds and any future earnings after the [REDACTED] to fund the development and commercialization of our pipeline product candidates. As a result, we do not expect to pay any cash dividends in the foreseeable future. Therefore, you should not rely on an investment in our Shares as a source for any future dividend income.

Our Board has complete discretion as to whether to distribute dividends. Even if our Board decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions (if any) received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our Board. Accordingly, the return on your investment in our Shares will likely depend entirely upon any future price appreciation of our Shares. There is no guarantee that our Shares will appreciate in value after the [REDACTED] or even maintain the price at which you purchased the Shares. You may not realize a return on your investment in our Shares and you may even lose your entire investment in our Shares.

We have significant discretion as to how we will use the net [REDACTED] of the [REDACTED], and you may not necessarily agree with how we use them.

Our management may spend the net [REDACTED] from the [REDACTED] in ways you may not agree with or that do not yield a favorable return to our Shareholders. We plan to use the net [REDACTED] from the [REDACTED] to conduct clinical trials in China and the U.S. on our most promising product candidates and to expand our sales and marketing staff in preparation for the approval and commercialization of those product candidates. For details, see “Future Plans and Use of [REDACTED] – Use of [REDACTED].” However, our management will have discretion as to the actual application of our net [REDACTED]. You are entrusting your funds to our management, whose judgment you must depend on, for the specific uses we will make of the net [REDACTED] from this [REDACTED].

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We are a Cayman Islands company and, because judicial precedent regarding the rights of shareholders is comparatively more limited under the laws of the Cayman Islands than other jurisdictions, you may have difficulties in protecting your rights.

Our corporate affairs are governed by our Memorandum and Articles, together with the Cayman Companies Act and common law of the Cayman Islands. The rights of Shareholders to take legal action against our Directors and us, actions by minority Shareholders and the fiduciary responsibilities of our Directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from English common law, which has persuasive, but not binding, authority on a court in the Cayman Islands. The laws of the Cayman Islands relating to the protection of the interests of minority shareholders differ in some respects from those established under statutes and judicial precedent in existence in the jurisdictions where minority Shareholders may be located. See “Appendix III – Summary of the Constitution of Our Company and Cayman Islands Company Law” in this document.

As a result of all of the above, minority Shareholders may have difficulties in protecting their interests under the laws of the Cayman Islands through actions against our management or Directors, which may provide different remedies to minority Shareholders when compared to the laws of the jurisdiction in which such Shareholders are located.

Facts, forecasts and statistics in this document relating to the pharmaceutical industry may not be fully reliable.

Facts, forecasts and statistics in this document relating to the pharmaceutical industry in and outside China are obtained from various sources that we believe are reliable, including official government publications as well as a report prepared by Frost & Sullivan that we commissioned. However, we cannot guarantee the quality or reliability of these sources. Neither we, the [REDACTED], the Joint Sponsors, the [REDACTED] nor our or their respective affiliates or advisers have verified the facts, forecasts and statistics nor ascertained the underlying economic assumptions relied upon in those facts, forecasts and statistics obtained from these sources. Due to possibly flawed or ineffective collection methods or discrepancies between published information and factual information and other problems, the statistics in this document relating to the pharmaceutical industry in and outside China may be inaccurate and you should not place undue reliance on them. We make no representation as to the accuracy of such facts, forecasts and statistics obtained from various sources. Moreover, these facts, forecasts and statistics involve risk and uncertainties and are subject to change based on various factors and should not be unduly relied upon.

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You should read the entire document carefully, and we strongly caution you not to place any reliance on any information contained in press articles or other media regarding us or the [REDACTED].

Subsequent to the date of this document but prior to the completion of the [REDACTED], there may be press and media coverage regarding us and the [REDACTED], which may contain, among other things, certain financial information, projections, valuations and other forward-looking information about us and the [REDACTED]. We have not authorized the disclosure of any such information in the press or media and do not accept responsibility for the accuracy or completeness of such press articles or other media coverage. We make no representation as to the appropriateness, accuracy, completeness or reliability of any of the projections, valuations or other forward-looking information about us. To the extent such statements are inconsistent with, or conflict with, the information contained in this document, we disclaim responsibility for them. Accordingly, prospective investors are cautioned to make their investment decisions on the basis of the information contained in this document only and should not rely on any other information.

You should rely solely upon the information contained in this document, the [REDACTED] and any formal announcements made by us in Hong Kong when making your investment decision regarding our Shares. We do not accept any responsibility for the accuracy or completeness of any information reported by the press or other media, nor the fairness or appropriateness of any forecasts, views or opinions expressed by the press or other media regarding our Shares, the [REDACTED] or us. We make no representation as to the appropriateness, accuracy, completeness or reliability of any such data or publication. Accordingly, prospective investors should not rely on any such information, reports or publications in making their decisions as to whether to invest in our [REDACTED]. By applying to purchase our Shares in the [REDACTED], you will be deemed to have agreed that you will not rely on any information other than that contained in this document and the [REDACTED].

**WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES
AND EXEMPTION FROM STRICT COMPLIANCE WITH THE COMPANIES
(WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE**

In preparation for the [REDACTED], we have sought the following waivers from strict compliance with the relevant provisions of the Listing Rules and certificates of exemption from strict compliance with the relevant provisions of the Companies (Winding Up and Miscellaneous Provisions) Ordinance:

MANAGEMENT PRESENCE IN HONG KONG

According to Rule 8.12 of the Listing Rules, our Company must have sufficient management presence in Hong Kong. This normally means that at least two of our executive Directors must be ordinarily resident in Hong Kong.

Since all our business operations are not principally located, managed or conducted in Hong Kong, our Company does not, and, for the foreseeable future, will not, have two executive Directors who are ordinarily resident in Hong Kong for the purpose of satisfying the requirements under Rule 8.12 of the Listing Rules.

Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted], a waiver from strict compliance with the requirements under Rule 8.12 of the Listing Rules. We will ensure that there is a regular and effective communication between us and the Stock Exchange by way of the following arrangements:

- (a) both of our Company’s authorized representatives, Mr. Joshua Liang, an executive Director and our chief executive officer, and Ms. Po Ting Fung (馮寶婷) (“**Ms. Fung**”), our joint company secretary, will act as our Company’s principal channels of communication with the Stock Exchange. Accordingly, the authorized representatives of our Company will be able to meet with the relevant members of the Stock Exchange on reasonable notice and will be readily contactable by telephone, facsimile and email;
- (b) each of the authorized representatives of our Company has means of contacting all Directors (including our independent non-executive Directors) promptly at all times as and when the Stock Exchange proposes to contact a Director with respect to any matter;
- (c) each Director has provided his or her mobile phone number, office phone number, fax number and e-mail address to the authorized representatives of our Company and the Stock Exchange, and in the event that any Director expects to travel or otherwise be out of the office, he or she will provide the phone number of the place of his or her accommodation to the authorized representatives;
- (d) each of our Directors not ordinarily residing in Hong Kong possesses or can apply for valid travel documents to visit Hong Kong and will be able to meet with the relevant members of the Stock Exchange within a reasonable period of time;

**WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES
AND EXEMPTION FROM STRICT COMPLIANCE WITH THE COMPANIES
(WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE**

- (e) we have appointed Somerley Capital Limited as the compliance adviser of our Company (the “**Compliance Adviser**”), in compliance with Rule 3A.19 of the Listing Rules, who will also act as an additional channel of communication with the Stock Exchange from the [REDACTED] to the date when our Company complies with Rule 13.46 of the Listing Rules in respect of its financial results for the first full financial year immediately following the [REDACTED]. The Compliance Adviser will maintain constant contact with the authorized representatives, Directors and senior management of our Company through various means, including regular meetings and telephone discussions whenever necessary. Our authorized representatives, Directors and other officers of our Company will provide promptly such information and assistance as the Compliance Adviser may reasonably require in connection with the performance of the Compliance Adviser’s duties as set forth in Chapter 3A of the Listing Rules;
- (f) any meeting between the Stock Exchange and our Directors will be arranged through the authorized representatives or the Compliance Adviser or directly with our Directors within a reasonable time frame. We will inform the Stock Exchange promptly in respect of any changes in our authorized representatives and/or our Compliance Adviser; and
- (g) we will also retain legal advisers to advise on on-going compliance requirements as well as other issues arising under the Listing Rules and other applicable laws and regulations of Hong Kong after the [REDACTED].

JOINT COMPANY SECRETARIES

Pursuant to Rules 3.28 and 8.17 of the Listing Rules, the company secretary must be an individual who, by virtue of his or her academic or professional qualifications or relevant experience, is, in the opinion of the Stock Exchange, capable of discharging the functions of the company secretary. The Stock Exchange considers the following academic or professional qualifications to be acceptable: (i) a member of The Hong Kong Institute of Chartered Secretaries; (ii) a solicitor or barrister (as defined in the Legal Practitioners Ordinance); and (iii) a certified public accountant (as defined in the Professional Accountants Ordinance).

In assessing “relevant experience”, the Stock Exchange will consider the individual’s: (i) length of employment with the issuer and other listed companies and the roles he/she played, (ii) familiarity with the Listing Rules and other relevant law and regulations including the Securities and Futures Ordinance, Companies Ordinance, Companies (Winding Up and Miscellaneous Provisions) Ordinance and the Takeovers Code, (iii) relevant training taken and/or to be taken in addition to the minimum requirement of taking not less than fifteen hours of relevant professional training in each financial year under Rule 3.29 of the Listing Rules, and (iv) professional qualifications in other jurisdictions.

**WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES
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Our Company considers that while it is important for the company secretary to be familiar with the relevant securities regulation in Hong Kong, he/she also needs to have experience relevant to our Company’s operations, nexus to the Board and close working relationship with the management of our Company in order to perform the function of a company secretary and to take the necessary actions in the most effective and efficient manner. It is for the benefit of our Company to appoint a person who has been a member of the management for a period of time and is familiar with our Company’s business and affairs as company secretary.

We have appointed Mr. Brian Krex (“**Mr. Krex**”) as one of our joint company secretaries. Mr. Krex is our general counsel and his biographical information is set out in the section headed “Directors and Management” in the document. Since Mr. Krex does not possess a qualification stipulated in Rule 3.28 of the Listing Rules, he is not able to solely fulfill the requirements as a company secretary of a listed issuer stipulated under Rules 3.28 and 8.17 of the Listing Rules. Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted], a waiver from strict compliance with the requirements under Rules 3.28 and 8.17 of the Listing Rules in relation to the appointment of Mr. Krex as our joint company secretary. In order to provide support to Mr. Krex, we have appointed Ms. Fung, an associate member of The Hong Kong Institute of Chartered Secretaries and The Chartered Governance Institute in the United Kingdom, who meets the requirements under Rules 3.28 and 8.17, as a joint company secretary to provide assistance to Mr. Krex, for a three-year period from the [REDACTED] so as to enable him to acquire the relevant experience (as required under Rule 3.28(2) of the Listing Rules) to duly discharge his duties.

Such waiver has been granted on the conditions that: (i) Ms. Fung is appointed as a joint company secretary to assist Mr. Krex in discharging his functions as a company secretary and in gaining the relevant experience under Rule 3.28 of the Listing Rules and such waiver will be revoked immediately if and when Ms. Fung ceases to provide such assistance during the three-year period; and (ii) the waiver can be revoked if there are material breaches of the Listing Rules by our Company. We expect that Mr. Krex will acquire the qualifications or relevant experience required under Rule 3.28 of the Listing Rules prior to the end of the three-year period after the [REDACTED]. We will liaise with the Stock Exchange before the end of the three-year period to enable it to assess whether Mr. Krex, having had the benefit of Ms. Fung’s assistance for three years, will have acquired relevant experience within the meaning of Rule 3.28 of the Listing Rules so that a further waiver will not be necessary.

See the section headed “Directors and Management” in this document for further information regarding the experiences and qualifications of Mr. Krex and Ms. Fung.

**WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES
AND EXEMPTION FROM STRICT COMPLIANCE WITH THE COMPANIES
(WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE**

**EXEMPTION FROM STRICT COMPLIANCE WITH SECTION 342(1) OF THE
COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE
AND PARAGRAPH 27 OF PART I OF THE THIRD SCHEDULE TO THE COMPANIES
(WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE**

According to section 342(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance, this document shall include an accountants' report which contains the matters specified in the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

According to paragraph 27 of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, our Company is required to include in this document a statement as to the gross trading income or sales turnover (as the case may be) of our Company during each of the three financial years immediately preceding the issue of this document as well as an explanation of the method used for the computation of such income or turnover and a reasonable breakdown of the more important trading activities.

According to paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, our Company is required to include in this document a report prepared by our Company's auditor with respect to profits and losses of our Company in respect of each of the three financial years immediately preceding the issue of the document and the assets and liabilities of our Company at the last date to which the financial statements were prepared.

According to section 342A(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance, the SFC may issue, subject to such conditions (if any) as the SFC thinks fit, a certificate of exemption from strict compliance with the relevant requirements under the Companies (Winding Up and Miscellaneous Provisions) Ordinance if, having regard to the circumstances, the SFC considers that the exemption will not prejudice the interests of the investing public and compliance with any or all of such requirements would be irrelevant or unduly burdensome, or is otherwise unnecessary or inappropriate.

According to Rule 4.04(1) of the Listing Rules, the Accountants' Report contained in this document must include, inter alia, the results of our Company in respect of each of the three financial years immediately preceding the issue of this document or such shorter period as may be acceptable to the Stock Exchange.

According to Rule 18A.06 of the Listing Rules, an eligible biotech company shall comply with Rule 4.04 modified so that references to "three financial years" or "three years" in that rule shall instead reference to "two financial years" or "two years", as the case may be.

**WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES
AND EXEMPTION FROM STRICT COMPLIANCE WITH THE COMPANIES
(WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE**

Accordingly, we applied to the SFC for, and the SFC [has granted], a certificate of exemption from strict compliance with the requirements under section 342(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance and paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, on the conditions that the particulars of the exemption are set forth in this document, on the following grounds:

- (a) our Company is primarily engaged in research and development and commercialization of biotech products, and falls within the scope of biotech company as defined under Chapter 18A of the Listing Rules;
- (b) the Accountants' Report for each of the two financial years ended December 31, 2019 and 2020 and the four months ended April 30, 2021 has been prepared and is set out in Appendix I to this document in accordance with Rule 18A.06 of the Listing Rules;
- (c) notwithstanding that the financial results set out in this document are only for the two years ended December 31, 2019 and 2020 and the four months ended April 30, 2021 in accordance with Chapter 18A of the Listing Rules, other information required to be disclosed under the Listing Rules and requirements under the Companies (Winding up and Miscellaneous Provisions) Ordinance has been adequately disclosed in this document pursuant to the relevant requirements; and
- (d) furthermore, as Chapter 18A of the Listing Rules provides that track record period for biotech companies in terms of financial disclosure is two years, strict compliance with the requirements of section 342(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance and paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance would be unduly burdensome for our Company.

Our Company is of the view that the Accountants' Report covering the two years ended December 31, 2019 and 2020 and the four months ended April 30, 2021, together with other disclosure in this document, has already provided the potential investors with adequate and reasonably up-to-date information in the circumstances to form a view on the track record of our Company; and our Directors confirm that all information which is necessary for the investing public to make an informed assessment of the business, assets and liabilities, financial position, management and prospects has been included in this document. Therefore, the exemption would not prejudice the interests of the investing public.

**WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES
AND EXEMPTION FROM STRICT COMPLIANCE WITH THE COMPANIES
(WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE**

**WAIVER AND EXEMPTION IN RELATION TO THE PRE-[REDACTED] SHARE
OPTION PLAN**

Under Rule 17.02(1)(b) of, and paragraph 27 of the Part A of Appendix I to the Listing Rules, and paragraph 10(d) of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, this document is required to include, among other things, details of the number, description, and amount of any shares in or debentures of our Company which any person has, or is entitled to be given, an option to subscribe for, together with certain particulars of each option, namely the period during which it is exercisable, the price to be paid for shares or debentures subscribed for under it, the consideration (if any) given or to be given for it or for the right to it, the names and addresses of the persons to whom it was given, and their potential dilution effect on the shareholding upon [REDACTED] as well as the impact on the earnings per share arising from the exercise of such outstanding options (the “**Share Option Disclosure Requirements**”).

As of the date of this document, our Company has granted options under the Pre-[REDACTED] Share Option Plan to 141 grantees to subscribe for an aggregate of 2,820,698 Shares ([REDACTED] Shares as adjusted after the [REDACTED]), representing approximately [REDACTED] of the total issued share capital immediately after completion of the [REDACTED] and the [REDACTED] (assuming the [REDACTED] and the options under the Pre-[REDACTED] Share Option Plan are not exercised), on the terms set out in “Appendix IV – Statutory and General Information – D. Share Incentive Plans – 1. Pre-[REDACTED] Share Option Plan” to this document.

Our Company has applied to the Stock Exchange and the SFC for: (i) a waiver from strict compliance with the applicable Share Option Disclosure Requirements; and (ii) a certificate of exemption under section 342A of the Companies (Winding Up and Miscellaneous Provisions) Ordinance exempting our Company from strict compliance with paragraph 10(d) of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, respectively, on the ground that strict compliance with the above requirements would be unduly burdensome for our Company for the following reasons, and the exemption would not prejudice the interests of the investing public:

- (a) given that 141 grantees are involved, strict compliance with such disclosure requirements in setting out full details of all the grantees under the Pre-[REDACTED] Share Option Plan in this document would be costly and unduly burdensome for our Company in light of a significant increase in cost and time for information compilation, document preparation and printing;

**WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES
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- (b) as of the Latest Practicable Date, except for one grantee who was a connected person of our Company, none of the grantees under the Pre-[REDACTED] Share Option Plan was a Director, member of management or other connected persons of our Company. Strict compliance with the applicable Share Option Disclosure Requirements to disclose names, addresses, and entitlements on an individual basis in this document will require number of additional pages of disclosure that does not provide any material information to the investing public;
- (c) the grant and exercise in full of the options under the Pre-[REDACTED] Share Option Plan will not cause any material adverse impact in the financial position of our Company;
- (d) lack of full compliance with the above disclosure requirements would not prevent our Company from providing its potential investors with an informed assessment of the activities, assets, liabilities, financial position, management and prospects of our Company; and
- (e) material information relating to the options under the Pre-[REDACTED] Share Option Plan will be disclosed in this document, including the total number of Shares to be issued subject to the Pre-[REDACTED] Share Option Plan, the exercise price per Share, the potential dilution effect on shareholding. For the avoidance of doubt, the exercise of the options granted under the Pre-[REDACTED] Share Option Scheme will not result in any impact on the earnings per Share. Our Directors consider that the information that is reasonably necessary for the potential investors to make an informed assessment of our Company in their investment decision making process has been included in the document.

The Stock Exchange [has granted] to us a waiver under the Listing Rules on the conditions that:

- (a) full details of the share options granted under the Pre-[REDACTED] Share Options Plan to the connected person of our Company will be disclosed in "Appendix IV – Statutory and General Information – D. Share Incentive Schemes – 1. Pre-[REDACTED] Share Option Plan" to this document, as required under the applicable Share Option Disclosure Requirements;
- (b) for the remaining grantees, disclosure will be made for, on an aggregate basis, of (1) the aggregate number of grantees and the number of Shares underlying the options granted to all the grantees under the Pre-[REDACTED] Share Option Plan, (2) the consideration (if any) paid for the grant of the options under the Pre-[REDACTED] Share Option Plan, and (3) the exercise period and (4) the exercise price for the options granted under the Pre-[REDACTED] Share Option Plan;

**WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES
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- (c) there will be disclosure in this document for the aggregate number of Shares underlying the options under the Pre-[REDACTED] Share Option Plan and the percentage of our Company's total issued share capital represented by such number of Shares as of the Latest Practicable Date;
- (d) the dilutive effect upon full exercise of the options under the Pre-[REDACTED] Share Option Plan will be disclosed in "Appendix IV – Statutory and General Information – D. Share Incentive Schemes – 1. Pre-[REDACTED] Share Option Plan" to this document;
- (e) a summary of the major terms of the Pre-[REDACTED] Share Option Plan will be disclosed in "Appendix IV – Statutory and General Information – D. Share Incentive Plans – 1. Pre-[REDACTED] Share Option Plan" to this document;
- (f) the particulars of the waiver and the exemption will be disclosed in the document;
- (g) a full list of all the grantees under the Pre-[REDACTED] Share Option Plan, containing all the particulars as required under the applicable Share Option Disclosure Requirements be made available for public inspection in accordance with the section headed "Appendix V – Documents Delivered to the Registrar of Companies and on Display" to this document;
- (h) further information relating to the grantees who have been granted options is provided to the Stock Exchange; and
- (i) the grant of a certificate of exemption under the Companies (Winding Up and Miscellaneous Provisions) Ordinance from the SFC exempting our Company from the disclosure requirements provided in paragraph 10(d) of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

The SFC has agreed to grant to our Company the certificate of exemption under section 342A of the Companies (Winding Up and Miscellaneous Provisions) Ordinance from strict compliance with paragraph 10(d) of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance on the conditions that:

- (a) full details of the share options granted under the Pre-[REDACTED] Share Options Plan to the connected person of our Company will be disclosed in "Appendix IV – Statutory and General Information – D. Share Incentive Schemes – 1. Pre-[REDACTED] Share Option Plan" to this document, as required under paragraph 10 of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance;

**WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES
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- (b) for the remaining grantees, disclosure will be made of, on an aggregate basis, (1) the aggregate number of grantees and the number of Shares underlying the options granted to them under the Pre-[REDACTED] Share Option Plan, (2) the consideration (if any) paid for the grant of the options under the Pre-[REDACTED] Share Option Plan, (3) the exercise period and (4) the exercise price for the options granted under the Pre-[REDACTED] Share Option Plan;
- (c) a full list of all the grantees under the Pre-[REDACTED] Share Option Plan, containing all the particulars as required under paragraph 10 of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, will be made available for public inspection in accordance with the section headed “Appendix V – Documents Delivered to the Registrar of Companies and on Display” to this document; and
- (d) the particulars of the exemption will be disclosed in this document and this document will be issued on or before [REDACTED].

CONTINUING CONNECTED TRANSACTIONS

We have entered into, and are expected to continue to engage in certain transaction which will constitute a non-exempt continuing connected transaction of our Company under the Listing Rules upon the [REDACTED]. Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted], a waiver in relation to such continuing connected transaction between us and certain connected persons under Chapter 14A of the Listing Rules.

Please see “Connected Transactions” of this document for further details.

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]

DIRECTORS

Name	Address	Nationality
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Executive Directors

Dr. Peng LIANG	Unit 3, Building 17 No. 1, Zhonghai Chengnan Chengdu PRC	American
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Mr. Joshua LIANG	Yintai Center, Huayueju No. 1199, North Section of Tianfu Avenue High-tech Zone, Chengdu Sichuan PRC	American
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Non-executive Directors

Dr. Xiaodong WANG	4416 95th Avenue NE Yarrow Point, WA 98004 U.S.	American
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Mr. Ting XIAO (肖汀)	Kam Ning Mansion 13-15 Bonham Road Hong Kong	Chinese
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Mr. Dong LYU (吕东)	Gate 201, Building 14, First District, Yutaoyuan Xicheng District Beijing PRC	Chinese
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Independent non-executive Directors

Dr. Xiaobin WU	No. 1248, District D Youshan Meidi, Shunyi District Beijing PRC	German
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Mr. Xiang LIAO	4593 Meadow Drive Nazareth, PA 18064 U.S.	American
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DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]

Name	Address	Nationality
Mr. Jeffrey FARROW	130 Randall Street San Francisco, CA 94131 U.S.	American
Mr. Thomas LEGGETT	84 North Street Newton Center MA 02459 U.S.	American

Please see the section headed "Directors and Management" in this document for further details of our Directors.

PARTIES INVOLVED IN THE [REDACTED]

Joint Sponsors

Goldman Sachs (Asia) L.L.C.

68/F, Cheung Kong Center
2 Queen's Road Central
Hong Kong

China International Capital Corporation

Hong Kong Securities Limited

29/F, One International Finance Centre
1 Harbour View Street
Central
Hong Kong

[REDACTED]

DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]

Legal Advisors to Our Company

As to Hong Kong and United States laws:

Kirkland & Ellis

26/F, Gloucester Tower
The Landmark
15 Queen's Road Central
Central
Hong Kong

As to PRC laws:

Tian Yuan Law Firm

10/F, Tower B
China Pacific Insurance Plaza
28 Fengsheng Hutong
Xicheng District
Beijing
PRC

As to Cayman Islands laws:

Maples and Calder (Hong Kong) LLP

26th Floor, Central Plaza
18 Harbour Road
Wanchai
Hong Kong

**Legal Advisors to the Joint Sponsors and
the [REDACTED]**

As to Hong Kong and United States laws:

**Skadden, Arps, Slate, Meagher &
Flom and affiliates**

42/F, Edinburgh Tower, The Landmark
15 Queen's Road Central
Central
Hong Kong

As to PRC laws:

Commerce & Finance Law Offices

12-14th Floor,
China World Office 2,
No.1 Jianguomenwai Avenue
Beijing
PRC

DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]

Auditor and Reporting Accountants

Ernst & Young
Certified Public Accountants
Registered Public Interest Entity Auditor
27/F, One Taikoo Place
979 King’s Road
Quarry Bay
Hong Kong

Industry Consultant

Frost & Sullivan (Beijing) Inc., Shanghai Branch Co.,
Room 1014-1018, Tower B, Green Center
500 Yunjing Road
Shanghai
PRC

Compliance Adviser

Somerley Capital Limited
20/F, China Building
29 Queen’s Road Central
Hong Kong

[REDACTED]

CORPORATE INFORMATION

Registered Office	PO Box 309, Uglan House Grand Cayman, KY1-1104 Cayman Islands
Head Office and Principal Place of Business in the PRC	B5-19, Building 1, High-tech Incubation Park No. 1480 North Section of Tianfu Avenue Chengdu High-tech Zone China (Sichuan) Pilot Free Trade Zone Chengdu, Sichuan Province PRC
Principal Place of Business in Hong Kong	Room 1901 19/F, Lee Garden One 33 Hysan Avenue Causeway Bay Hong Kong
Company's Website	www.cloverbiopharma.com <i>(information on this website does not form part of this prospectus)</i>
Joint Company Secretaries	Mr. Brian KREX 102 Prospect Street Providence Rhode Island USA Ms. Po Ting FUNG <i>(ACIS and ACS)</i> Room 1901 19/F, Lee Garden One 33 Hysan Avenue Causeway Bay Hong Kong

CORPORATE INFORMATION

Authorized Representatives

Mr. Joshua LIANG
Yintai Center
Huayueju No. 1199
North Section of Tianfu Avenue
High-tech Zone
Chengdu
Sichuan
PRC

Ms. Po Ting FUNG
(*ACIS and ACS*)
Room 1901
19/F, Lee Garden One
33 Hysan Avenue
Causeway Bay
Hong Kong

Audit Committee

Mr. Thomas LEGGETT (Chairman)
Mr. Jeffrey FARROW
Mr. Ting XIAO

Remuneration Committee

Dr. Xiaobin WU (Chairman)
Mr. Xiang LIAO
Dr. Xiaodong WANG

Nomination Committee

Dr. Peng LIANG (Chairman)
Mr. Thomas LEGGETT
Dr. Xiaobin WU

Compliance Adviser

Somerley Capital Limited
20/F, China Building
29 Queen's Road Central
Hong Kong

[REDACTED]

CORPORATE INFORMATION

[REDACTED]

Principal Banks

Bank of China Chengdu Tianfu Avenue Branch

1st Floor, Block E
High-tech International Plaza
No. 186 Tianyun Road, Tianfu Avenue
Chengdu High-tech Zone
Chengdu, Sichuan
PRC

The Hongkong and Shanghai Banking Corporation Limited

HSBC Main Building
1 Queen's Road Central
Hong Kong

INDUSTRY OVERVIEW

The information and statistics set out in this section and other sections of this document were extracted from different official government publications, available sources from public market research and other sources from independent suppliers. In addition, we engaged Frost & Sullivan for preparing the Frost & Sullivan Report, an independent industry report in respect of the [REDACTED]. We believe that the sources of the information in this section and other sections of this document are appropriate sources for such information, and we have taken reasonable care in extracting and reproducing such information. We have no reason to believe that such information is false or misleading or that any fact has been omitted that would render such information false or misleading. The information from official and non-official sources has not been independently verified by us, the [REDACTED], Joint Sponsors, [REDACTED], [REDACTED], any of the [REDACTED], any of their respective directors and advisers, or any other persons or parties involved in the [REDACTED], except Frost & Sullivan, and no representation is given as to its accuracy. Accordingly, the information from official and non-official sources contained herein may not be accurate and should not be unduly relied upon. Our Directors confirm that, after making reasonable enquiries, there is no adverse change in the market information since the date of the Frost & Sullivan Report that would qualify, contradict or have a material impact on the information in this Section.

COVID-19 VACCINE MARKET GLOBALLY

Overview of the COVID-19 Pandemic

COVID-19 is a global pandemic caused by infections due to the SARS-CoV-2 virus. The SARS-CoV-2 virus is easily spread from person to person through small droplets from the nose or mouth, which are expelled when an infected person coughs, sneezes, or speaks. Common symptoms at onset of illness include fever, dry cough, dyspnoea, fatigue, myalgia, and anorexia. The SARS-CoV-2 virus is highly transmissible with an incubation period of 4-12 days. Many patients display mild or no symptoms, leading to undetected transmission.

Due to its high transmissibility, according to Frost & Sullivan, the COVID-19 pandemic has resulted in approximately 0.1 million confirmed COVID-19 cases in China and approximately 236.1 million confirmed COVID-19 cases globally as of the Latest Practicable Date. According to Frost & Sullivan, there has been a steady increase in the cumulative cases of COVID-19 worldwide since March 2020, when WHO declared COVID-19 a pandemic.

The disease burden of the COVID-19 pandemic is significant. The global economy is expected to suffer between \$5.8 trillion and \$8.8 trillion in losses – equivalent to 6.4% to 9.7% of global gross domestic product (GDP) in 2020 – as a result of the COVID-19 pandemic, according to the Asian Development Bank and UNDP. Moreover, the COVID-19 pandemic has strained the public healthcare infrastructure.

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Sustained High Demand for COVID-19 Vaccines

Whilst cell therapy has been considered as a potential treatment method for the SARS-CoV-2 virus, there is no effective anti-viral treatment for the SARS-CoV-2 virus on the market currently. The research and development of cell therapy is normally longer than vaccine development. Vaccines have been widely considered by public health experts worldwide as the only effective solution to control the pandemic. As of the Latest Practicable Date, there are approximately six billion doses of COVID-19 vaccines have been administered, according to Frost & Sullivan. The global COVID-19 vaccine market accounted for US\$0.6 billion in terms of sales volume in 2020. As such, there is a significant demand and unmet need for effective and safe COVID-19 vaccines globally. According the Frost & Sullivan, approximately 15 billion COVID-19 vaccine doses will be required through 2026 worldwide, assuming a two-dose vaccine regimen and taking into consideration global government procurement and stockpiling. Moreover, periodic booster shots or re-vaccination may be needed especially if new variants emerge, resulting in a significant global need for COVID-19 vaccines for years to come.

Some nations, including France, Germany, Italy, Ireland, and Israel, have authorized booster shots for certain populations including the elderly or individuals at high risk. On October 3, 2021, Israel required receiving a booster shot as a requirement to considered fully vaccinated for individuals 12 years and older.

In the United States, federal officials authorized a third shot of the Pfizer and Moderna vaccines for people with compromised immune systems because of organ transplants, chemotherapy or other medical conditions. On September 22, 2021, U.S. FDA authorized the use of a booster shot of Pfizer's COVID-19 vaccine for individuals 65 years of age or older, 18 through 64 years of age at high risk of severe COVID-19, or 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19.

Comparison of COVID-19 Vaccine Development Platforms

A vaccine that could successfully control the COVID-19 pandemic must have four essential characteristics: safety, efficacy, scalability of manufacturing, and suitability of global distribution:

- *Safety.* COVID-19 vaccines are expected to be administered to the entire global population. Therefore, the safety of a COVID-19 vaccine is critical. Prior to the COVID-19 pandemic, no vaccines based on mRNA or DNA technologies have been approved for use in humans, therefore there is no long-term safety databases of such vaccines. The risk of vaccine-associated enhanced respiratory disease (VAERD) is also a key challenge for the development of COVID-19 vaccines, which has been observed in vaccine candidates tested in animal models and could lead to significantly enhanced hospitalization, severity, and mortality for those vaccinated.

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- *Efficacy.* Vaccines against COVID-19 that elicit protective immune responses are crucial to the prevention and mitigation of infection by the SARS-CoV-2 virus. Current understanding suggests that a balanced immune response of neutralizing antibody titers and Th1-biased cell-mediated immune response may be important for protection from COVID-19.
- *Scalability of manufacturing.* The ability to achieve rapid manufacturing scale up is critical for a COVID-19 vaccine to be widely available and capture a significant market share.
- *Suitability of global distribution.* The ability to store a COVID-19 vaccine in standard refrigeration or room temperatures makes it more suitable and cost-effective for global distribution, including to less developed regions, by leveraging existing and commonly available infrastructure.

With the support of global initiatives like GAVI, CEPI and the WHO as well as local governments around the world, COVID-19 vaccines have been and are in the process of being developed swiftly. Currently, five major vaccine development platforms are being used to develop COVID-19 vaccines globally, including the protein-based subunit, mRNA, inactivated virus, adenovirus-based viral vector, and DNA. Multiple vaccine candidates using these platforms have been approved and entered into clinical testing stage. The table below illustrates an overview of vaccine development platforms for COVID-19, according to Frost & Sullivan:

Platform	Development Target	Existing, Licensed Human Vaccines Using the Same Platform	Approved COVID-19 vaccine	For clinical development COVID-19 vaccine	Advantages	Disadvantages
Protein-based vaccines	S protein	Yes for baculovirus (influenza, HPV) and yeast expression (HBV, HPV)	Adjuvanted recombinant protein (RBD-Dimer); EpiVacCorona; CIGB-66; MVC-COV1901	Full Length Recombinant SARS CoV-2 glycoprotein Nanoparticle Vaccine Adjuvanted with Matrix M; FINLAY-FR2 anti-SARS-CoV-2 Vaccine; VAT00002; SCB-2019	No infectious virus needs to be handled; production can be rapidly scaled-up to large quantities using well-characterized manufacturing processes; adjuvants can be used to increase immunogenicity.	Global production capacity might be limited. Antigen and/or epitope integrity needs to be confirmed.
Inactivated vaccines	Whole virion	Yes	Whole-Virion Inactivated SARS-CoV-2 Vaccine; KoviVac; Qaz Vac	Inactivated SARS-CoV-2 Vaccine; ERUCOV-VAC;	Straightforward process used for several licensed human vaccines, existing infrastructure can be used, has been tested in humans for SARS-CoV-1, adjuvants can be used to increase immunogenicity.	Large amounts of the virus need to be handled (could be mitigated by using an attenuated seed virus). Antigen and/or epitope integrity needs to be confirmed.
Viral vector-based vaccines	S protein	Yes for VSV (Ervebo), but not for other viral vectored vaccines	Ad26.COV2.S; Sputnik V; Covishield	GRAd-COV2;	No infectious virus needs to be handled, strong preclinical and clinical data for many emerging viruses, including MERS-CoV.	Vector immunity might negatively affect vaccine effectiveness (depending on the vector chosen).
mRNA vaccines	S protein	Yes	LNP-encapsulated mRNA; 3 LNP-mRNAs;	INO-4800+E lectroporation;	No infectious virus needs to be handled, vaccines are typically immunogenic, rapid production possible.	Safety issues with reactogenicity have been reported.
DNA vaccines	S protein	No	ZyCoV-D;	AG0301-COVID19;	No infectious virus needs to be handled; easy scale up, low production costs; high heat stability; tested in humans for SARS-CoV-1 virus; rapid production possible.	Vaccine needs specific delivery devices to reach good immunogenicity; no approved vaccines for human use developed using this platform.

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Most protein-based vaccines require the assistance of adjuvants. The functions of adjuvants mainly include: (i) improving the immunogenicity of the vaccine; (ii) changing the nature of immune response; and (iii) reducing the amount of antigen and the required number of shots of immunization. CpG 1018 is classified as CpG-ODNs adjuvants. According to Frost & Sullivan, there are more than 20 vaccines currently under clinical development using CpG-ODNs adjuvants.

Protein-based vaccines have historically been tested, developed, and proven to be safe and effective for other infectious diseases, including influenza, shingles, and Hepatitis B. The production for protein-based vaccines can be rapidly scaled-up to large quantities using well-characterized manufacturing processes. Protein-based vaccines also have the benefit of being compatible with a diverse range of adjuvants which can potentially strengthen the protectiveness of vaccines. The protein-based vaccine formulation is generally stable for an extended period of time in standard refrigeration or room temperatures, making them suitable for global distribution.

COVID-19 Vaccine Competitive Landscape Globally

As of Latest Practicable Date, there are currently 21 COVID-19 vaccines on the market and 30 candidates in phase 2/3 or later stage globally. In particular, there has been one protein subunit COVID-19 vaccines approved in China, one in Russian Federation, one in China (Taiwan), and one in Cuba, as well as 14 phase 2/3 or later stage protein subunit candidates globally. On August 23, 2021, the U.S. FDA granted full approval of Pfizer-BioNTech’s COVID-19 vaccine for individuals aged 16 and over. Other than this vaccine, all other COVID-19 vaccines authorized by the FDA are for emergency use. Given the current unmet demand for COVID-19 vaccines, we believe there is no material impacts on our development and commercialization of SCB-2019 (CpG 1018/Alum).

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The charts below illustrate the COVID-19 vaccine competitive landscape as of the Latest Practicable Date globally.

COVID-19 Vaccine developer/manufacture	Vaccine platform	Type of candidate vaccine	Status/ Clinical Stage	Doses*	First Approval date	Marketed countries
Moderna/NIAID	RNA	LNP-encapsulated mRNA	FDA, EMA Conditionally Approved	2	2020/12/18	69 countries
BioNTech/Fosun Pharma/Pfizer	RNA	3 LNP-mRNAs	FDA approved, EMA Conditionally Approved	2	2020/12/11	98 countries
Beijing Institute of Biological Products / Sinopharm	Inactivated	Inactivated	NMPA Conditionally Approved	2	2020/12/30	60 countries
University of Oxford/AstraZeneca	Non-Replicating Viral Vector	ChAdOx1-S	EMA, MHRA (UK) Conditionally Approved	2	2020/12/30	121 countries
Sinovac	Inactivated	Inactivated	NMPA Conditionally Approved	2	2021/2/5	39 countries
Janssen Pharmaceutical	Non-Replicating Viral Vector	Ad26.COVS.2.S	FDA, EMA Conditionally Approved	1-2	2021/2/27	59 countries
CanSino/Beijing Institute of Biotechnology	Non-Replicating Viral Vector	Adenovirus Type 5 Vector	NMPA Conditionally Approved	1	2021/2/25	8 countries
FBRI	Protein Subunit	EpiVacCorona	Russia Conditionally Approved	2	2020/10/14	Russian Federation Turkmenistan
Serum Institute of India	Non-Replicating Viral Vector	Covishield	India Conditionally Approved	2	2021/1/1	45 countries
Gamaleya	Non-Replicating Viral Vector	Sputnik Light	Conditionally Approved	2	2021/6/5	13 countries
Gamaleya	Non-Replicating Viral Vector	Sputnik V	Conditionally Approved	2	2021/8/25	71 countries
Wuhan Institute of Biological Products/Sinopharm	Inactivated	Inactivated	NMPA Conditionally Approved	2	2021/2/25	China
Anhui Zhifei Longcom Biopharmaceutical/Institute of Microbiology, Chinese Academy of Sciences	Protein Subunit	Adjuvanted recombinant protein (RBD-Dimer)	NMPA Conditionally Approved	2-3	2021/3/17	Uzbekistan China
Bharat Biotech International Limited	Inactivated	Whole-Virion Inactivated SARS-CoV-2 Vaccine	India Conditionally Approved	2	2021/3/12	9 countries
Chumakov Center	Inactivated	KoviVac	Russia Conditionally Approved	2	2021/5	Russian Federation
Center for Genetic Engineering and Biotechnology (CIGB)	Protein Subunit	CIGB-66	Cuba Conditionally Approved	3	2021/7/9	Cuba
Kazakhstan RIBSP	Inactivated	Qaz Vac	Kazakhstan Conditionally Approved	2	2021/7/19	Kazakhstan
Medigen: MVC-COV1901	Protein Subunit	MVC-COV1901	China (Taiwan) Conditionally Approved	2	2021/7/19	China (Taiwan)
Minhai Biotechnology Co.	Inactivated	SARS-CoV-2 Vaccine (Vero Cells)	NMPA Conditionally Approved	2	2021/5/14	China
Shifa Pharmed Industrial Co	Inactivated	COVID-19 Inactivated Vaccine	Iran Conditionally Approved	2	2021/6/14	Iran
Zydus Cadila	DNA	ZyCoV-D	India Conditionally Approved	3	2021/7/1	India
Clover/Dynavax	Protein Subunit	SCB-2019(CpG 1018/Alum)	III	2	-	-
Research Institute for Biological Safety Problems, Rep of Kazakhstan	Inactivated	Inactivated	III	2	-	-
Institute of Medical Biology + Chinese Academy of Medical Sciences	Inactivated	Inactivated	III	2	-	-
Zydus Cadila	DNA Based Vaccine	nCoV Vaccine	III	2	-	-
Novavax	Protein Subunit	Full Length Recombinant SARS CoV-2 glycoprotein Nanoparticle Vaccine Adjuvanted with Matrix M	III	2	-	-
CureVac AG	RNA	mRNA	III	2	-	-
Instituto Finlay de Vacunas	Protein Subunit	FINLAY-FR2 anti-SARS-CoV-2 Vaccine	III	2	-	-
Sanofi Pasteur + GSK	Protein Subunit	VAT00002: SARS-CoV-2 S protein with adjuvant	III	2	-	-
Instituto Finlay de Vacunas	Protein Subunit	FINLAY-FR-2 anti-SARS-CoV-2 Vaccine	III	2	-	-
Center for Genetic Engineering and Biotechnology (CIGB)	Protein Subunit	CIGB-66 (RBD+Aluminium Hydroxide)	III	3	-	-
Vaxxinity	Protein Subunit	UB-612	II/III	2	-	-
Academy of Military Science (AMS), Walvax Biotechnology and Suzhou Abogen Biosciences	RNA Based Vaccine	INO-4800+E lectroporation	III	2	-	-

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COVID-19 Vaccine developer/manufacture	Vaccine platform	Type of candidate vaccine	Status/ Clinical Stage	Doses*	First Approval date	Marketed countries
AnGes + Takara Bio + Osaka University	DNA Based Vaccine	AG0301-COVID19	II/III	2	–	–
ReiThera + Leukocare + Univercells	Viral Vector (Non-replicating)	GRAd - COV2 (Replication Defective Simian Adenovirus (GRAd) Encoding S)	II/III	1	–	–
Medicago	Virus-like Particle	Coronavirus-Like Particle COVID-19 (CoVLP)	III	2	–	–
CSL Ltd. + Seqirus + University of Queensland	Protein Subunit	MF59 Adjuvanted SARS - CoV-2 Sclamp Vaccine	II/III	2	–	–
Shenzhen Kangtai Biological Products	Inactivated	Inactivated SARS-CoV-2 Vaccine	III	1, 2 or 3	–	–
West China Hospital/ Sichuan University	Protein Subunit	RBD (Baculovirus Production Expressed in SP Cells) Recombinant SARS-CoV-2 Vaccine	III	2	–	–
Erciyee University	Inactivated	ERUCOV-VAC, Inactivated Virus	III	2	–	–
Areturus Therapeutics	RNA	ARCT-154 mRNA Vaccine	II/III	2	–	–
Sinocelltech	Protein subunit	SCTV01C. A Bivalent Recombinant Trimeric S Protein vaccine against SARS-CoV 2 Variants	II/III	1	–	–

Government	Company	Order Size	Number of Doses	Date Announced
United States	AstraZeneca/Oxford	\$1.2 billion	300 million	May 21, 2020
	Novavax	\$1.6 billion (including support for clinical trials)	100 million	Jul 7, 2020
	BioNTech/Pfizer		100 million	Jul 22, 2020
	GSK/Sanof	\$2.1 billion	100 million	Jul 31, 2020
	JNJ	\$2 billion	200 million	Mar 10, 2021
	Moderna	\$1.5 billion	100 million	Aug 11, 2020
	BioNTech/Pfizer	Undisclosed	200 million	Nov 23, 2020
	Moderna	Undisclosed	100 million	Dec 12, 2020
United Kingdom	BioNTech/Pfizer	Undisclosed	100 million	Dec 23, 2020
	AstraZeneca/Oxford	undisclosed	100 million	May 10, 2020
	BioNTech/Pfizer	undisclosed	30 million	Jul 20, 2020
	GSK/Sanof	625 million	60 million	Jul 6, 2020
	JNJ	undisclosed	30 million	Aug 14, 2020
EU	Novavax	undisclosed	60 million	Aug 14, 2020
	Valneva	€470 million	60 million	Jul 20, 2020
	AstraZeneca/Oxford	\$843 million	300 million	Aug 14, 2020
	BioNTech/Pfizer	\$3.668 billion	200 million	Sep 9, 2020
	GSK/Sanof	undisclosed	300 million	Aug 14, 2020
	JNJ	undisclosed	200 million	Aug 13, 2020
CureVac	\$2.664 billion	225 million	Nov 19, 2020	
BioNTech/Pfizer	Undisclosed	300 million	Dec 29, 2020	

Note: Only vaccine candidates in phase 2/3 or later are listed.

* Data as of the Latest Practicable Date.

** Doses required for each product in clinical phase are based on the clinical information publicly available.

Source: F&S Report

INDUSTRY OVERVIEW

Our SCB-2019 is adjuvanted with Dynavax’s CpG 1018 and alum. There are three other COVID-19 vaccine candidates that use the same adjuvants as us. The following table sets forth details of these candidates:

Company	Country	Vaccine development		Product name	Doses	Dosing schedule	Route of administration	Phase	Description
		platform							
Clover	China	Protein subunit		SCB-2019 (CpG 1018/ Alum)	2	2 Day 0+ 21	Intramuscular injection	3	SCB-2019 antigen, a stabilized trimeric form of the S-protein (S-Trimer™) based on the original strain of the SARS-CoV-2 virus. Clover created its COVID-19 vaccine candidate by combining SCB-2019 with Dynavax’s CpG 1018 advanced adjuvant and aluminum hydroxide (alum).
Medigen Vaccine Biologics Corporation	China (Taiwan)	Protein subunit		MVC-COV1901	2	2 Day 0+ 28	Intramuscular injection	Conditionally Approved in China (Taiwan)	Stable prefusion SARS-CoV-2 spike (S-2P)-based vaccine adjuvanted with CpG 1018 from Dynavax. Modification of two prolines and inactivation of the furin site have been made to the S protein to lock in its prefusion form to enhance its stability and immunogenicity.
Valveva	France	Inactivated whole virus particles		VLA2001	2	2 Day 0+ 21	Intramuscular injection	3	Produced on Valveva’s Vero-cell platform, VLA2001 consists of inactivated whole virus particles of SARS-CoV-2 with high S-protein density, in combination with two adjuvants, alum and CpG 1018. The process includes inactivation with BPL (β-Propiolactone) to preserve the native structure of the S-protein.

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Company	Country	Vaccine development		Doses	Dosing schedule	Route of administration	Phase	Description
		platform	Product name					
Biological E	India	Protein subunit	Bio E COVID-19	2	2 Day 0+ 28	Intramuscular injection	3	Bio E’s SARS-CoV-2 Spike RBD COVID-19 vaccine, contains an antigen in-licensed from Baylor College, BCM Ventures, (RBD N1C1) absorbed to the adjuvant alhydrogel (alum) and an advanced adjuvant CpG 1018, which is supplied by Dynavax. The SARS-CoV-2 RBD protein, expressed at high levels in yeast (<i>Pichia pastoris</i>), has two modifications into the wild-type RBD gene, resulting in RBD219-N1C1.

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There are ten leading protein subunit vaccine candidates that use adjuvants currently in Phase 2/3 or later globally. The following table sets forth details of these candidates as of the Latest Practicable Date:

Vaccine platform description	Name of candidate vaccine	Type of protein	Adjuvant	Number of doses	Schedule	Route of administration	Developers	Phase	Locations	Estimated Enrollment
Protein subunit	SARS-CoV-2 rS/Matrix M1-Adjuvant	Full length recombinant SARS-CoV-2 glycoprotein nanoparticle vaccine	Matrix M	2	Day 0 + 21	IM	Novavax	Phase 3	US, Mexico, Puerto Rico US UK	33,000 2,650 15,000
Protein subunit	VAT00002	SARS-CoV-2 S protein	AS03	2	Day 0 + 21	IM	Sanofi Pasteur + GSK	Phase 3	US, Honduras, Panama	722
Protein subunit	COVAX-19® Recombinant spike protein + adjuvant	Recombinant spike protein	Advaq-SM	1	Day 0 + 21	IM	Vaccine Pty Ltd./CinnaGen Co.	Phase 3	Iran	16,876
Protein subunit	FINLAY-FR-2 anti-SARS-CoV-2 Vaccine	RBD	Tetanus toxoid plus adjuvant	2	Day 0 + 28	IM	Instituto Finlay de Vacunas	Phase 3	Cuba	44,010
Protein subunit	EpiVacCorona	Peptide antigens	/	2	Day 0 + 21	IM	Federal Budgetary Research Institution State Research Center of Virology and Biotechnology “Vector” West China Hospital + Sichuan University	Phase 3	Russia	3,000
Protein subunit	Recombinant SARS-CoV-2 vaccine	RBD	/	2	Day 0 + 28	IM	West China Hospital + Sichuan University	Phase 3	Indonesia, Kenya, Philippines	40,000
Protein subunit	SCB-2019 + CpG 1018 adjuvant	Trimeric subunit Spike Protein	CpG 1018	2	Day 0 + 21	IM	Clover Biopharmaceuticals Inc./Dynavax	Phase 3	South Africa, Ukraine	300
Protein subunit	Recombinant SARS-CoV-2 vaccine (CHO Cell)	RBD Dimer	Alum	2-3	Day 0 + 21	IM	Anhui Zhifei Longcom Biopharmaceutical	Conditionally Approved	China	29,000
Protein subunit	MVC-COV1901	S-protein	CpG 1018+Alum	2	Day 0 + 28	IM	Medigen Vaccine Biologics + Dynavax	Conditionally Approved	China (Taiwan)	3,700
Protein subunit	Coronavirus-Like Particle COVID-19 (CoVLP)	VLP	/	2	Day 0 + 28	IM	Medicago	Phase 3	Canada, Ontario	900

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Market Drivers

The primary market drivers for the COVID-19 vaccine market include:

- *Desire for protection against the SARS-CoV-2 virus and its variants.* Since December 2019, the outbreak of COVID-19 has spread around the world and affected millions of people. Governments in many countries have imposed a number of measures to curb the spread of COVID-19, including but not limited to, quarantines, travel restrictions, closing of schools and workplaces, as well as the complete or partial lockdowns in locations with multiple cases. As a result, the global economy was materially and adversely affected. Individuals, business entities and governments around the world desire a solution to return to normal social and economic activities with protection against the SARS-CoV-2 virus and its multiple variants. Vaccines provide an effective way to control the outbreak of COVID-19. As a result, safe and effective COVID-19 vaccines are in high demand.
- *Demand for expedited vaccine development.* The development of a safe and effective vaccine usually requires years of pre-clinical and clinical testing. The outbreak of COVID-19 and the emergence of new variants of the SARS-CoV-2 virus have brought unprecedented global challenges to public health and therefore demand an expedited approach to developing COVID-19 vaccines. In light of the global challenges, the governmental regulators of many countries have accelerated the vaccine review and approval process. In addition, the governmental entities and international institutions have provided vaccine companies with various financial and resource-based support. Expedited regulatory pathways and resources are enabling vaccine companies to rapidly develop and produce COVID-19 vaccines.
- *Strong government policy support.* Governments in many countries have adopted policies to increase vaccination rates. For example, many governments provide the vaccines free of charge to residents and actively conduct public awareness and education activities to promote vaccination. As of October 2021, more than six billion COVID-19 vaccine doses have been inoculated worldwide. The push for vaccination will likely continue until the population reaches herd immunity, and potentially after to prevent the pandemic from re-emerging.
- *Next generation COVID-19 vaccines.* Since its identification in late 2019, COVID-19 has spread rapidly around the world. In late 2020, variants emerged with health authorities characterizing the most concerning variants as Variants of Concern (VOC). The potential of VOCs to escape naturally induced and vaccine-induced immunity generates demand for the development of vaccines that elicit broadly neutralizing antibodies against current and potential future variants resulting in a potential increase in the market for COVID-19 vaccines.

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Key Entry Barriers

The following are major entry barriers in the COVID-19 vaccine market:

- *Platform to develop safe and effective vaccines.* Although there is a significant unmet need for COVID-19 vaccines, the safety and efficacy of COVID-19 vaccines remain a crucial concern when considering the expedited development process and projected global inoculation. Vaccine companies that have weak and unproven technology platforms or fail to demonstrate good safety and efficacy results will not be successful in the COVID-19 vaccine market.
- *Manufacturing capacity.* The ability to produce highly stable COVID-19 vaccines at a large scale is critical for a successful COVID-19 vaccine to capture market share. In order to ensure the stable supply of quality vaccines, vaccine companies need to have a mature commercial production process and a strict quality control system in line with major international standards. New entrants may lack the in-depth expertise and process know-how required for manufacturing vaccines, and may fail to establish a commercial mass production process with effective quality control in a timely manner.
- *Ability to complete clinical trials.* Completing a clinical trial in line with guidance depends on a multitude of factors. For example, a COVID-19 clinical trial requires that a vaccine company enroll a sufficient number of participants who remain in the trial until its conclusion. As the vaccination rates increase and as COVID-19 comes under control, some countries, including China, may not have a sufficient participants for clinical trials. In addition, clinical trials are exceptionally cost-intensive and a vaccine company needs substantial resources to screen, recruit and enroll eligible participants, regularly monitor and follow up with the participants, and collect, process and analyze data and information throughout the process. This is a financial undertaking many companies cannot afford on a global scale.
- *Intensive capital investment.* A large amount of investment is required for the launch of a new vaccine. Research and development of a clinical asset, the onboarding of internal medical experts and the conducting of clinical trials all necessitate significant financial investments. Once a therapeutic program progresses into late-stage clinical development, an even greater amount of capital is needed for the construction of manufacturing facilities and the preparation and execution of commercialization.

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OVERVIEW OF VACCINES

A vaccine is a biological preparation that provides active acquired immunity against a particular disease. A vaccine typically contains one or several antigens from, or similar to, a disease-causing microorganism and improves immunity to a particular disease upon administration by inducing specific immune responses. The science of vaccinology has rapidly developed with advances in immunology, microbiology and genomics, as well as adjuvants to boost the efficacy of vaccines. The market size of the global vaccine market grew from US\$27.6 billion in 2015 to US\$36.5 billion in 2020, representing a CAGR of 5.8%. The market size is expected to reach US\$126.8 billion in 2030 at a CAGR of 13.3% from 2020. China vaccine market has grown rapidly in recent years. The size of China vaccine market in terms of sales revenue grew from RMB29.3 billion in 2015 to RMB75.3 billion in 2020, representing a CAGR of 20.8%. The market size is expected to reach RMB333.3 billion in 2030 at a CAGR of 16.0% from 2020.

Rabies Vaccines

Rabies is a viral disease that causes inflammation of the brain in humans and other mammals. Currently approved rabies vaccines have limitations in their production capacities, required administration schedules, storage requirements, and cost. There continues to be a need for better rabies vaccines in certain countries, such as China, where animal immunization programs have been unsuccessful. As of the Latest Practicable Date, there were 14 rabies vaccines marketed in China. The market size of rabies vaccine in China amounted to RMB6.1 billion in 2020.

RSV Vaccine Candidates

RSV is an enveloped RNA virus that could cause acute respiratory tract illness, especially in vulnerable populations such as children, the elderly and the immunocompromised. To date, there are no approved treatments specifically targeting RSV. Despite the concerted efforts over the years, an effective vaccine against RSV has remained elusive. As of the Latest Practicable Date, there were only seven RSV vaccine candidates in phase II or later clinical trials globally.

Influenza Vaccines

Influenza is an infectious disease caused by different strains of the influenza viruses. The disease is common around the world, and appears as seasonal or pandemic outbreaks. As of the Latest Practicable Date, there were 19 influenza vaccines marketed in China. The market size of influenza vaccine in China amounted to RMB6.0 billion in China in 2020.

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HIV/AIDS Vaccine Candidates

HIV, or human immunodeficiency virus, is a virus that attacks the immune system in human body. AIDS, or acquired immune deficiency syndrome, occurs in the late stage of a HIV infection when the body’s immune system is severely damaged because of the HIV. To date, there is no approved effective vaccine against HIV. As of the Latest Practicable Date, there were only ten HIV vaccine candidates in phase II or later clinical trials globally.

MARKET FOR INTRACAVITARY MALIGNANCIES GLOBALLY AND IN CHINA

Overview

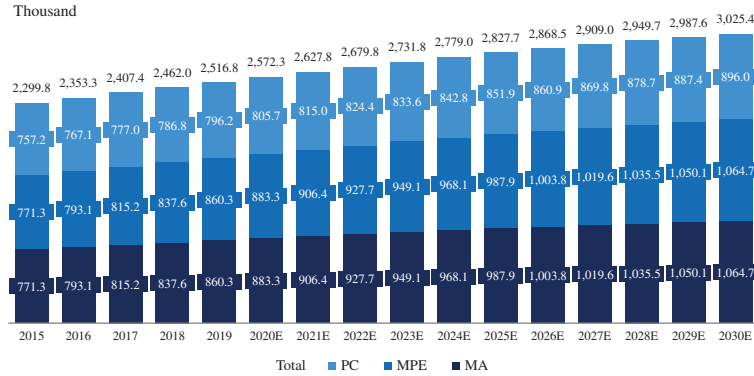
Intracavitary malignancies refers to malignant cancers found in body cavities, such as the chest, abdomen, or pelvis. Common tumors types that spread and/or cause complications within specific body cavities include lung cancer and mesothelioma (pleural cavity), gastrointestinal cancers and ovarian cancers, and bladder cancers. Treatment generally involves therapy directed against the associated malignant neoplasm. However, when the intracavitary malignancy is too advanced or becomes refractory to known anti-cancer therapies, treatments are often directed specifically toward the palliation of symptoms such as abdominal discomfort, pain, cough and shortness of breath. The global incidence of intracavitary malignancies reached 2.5 million in 2019 and is estimated to grow to 3.0 million in 2030. In China, the incidence of intracavitary malignancies reached 707.9 thousand in 2019 and is estimated to grow to 756.9 thousand in 2030.

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Intracavitary malignancies mainly includes malignant ascites (MA), malignant pleural effusions (MPE), and peritoneal carcinomatosis (PC). The following diagram illustrates the global incidence of intracavitary malignancies globally and in China for the period indicated.

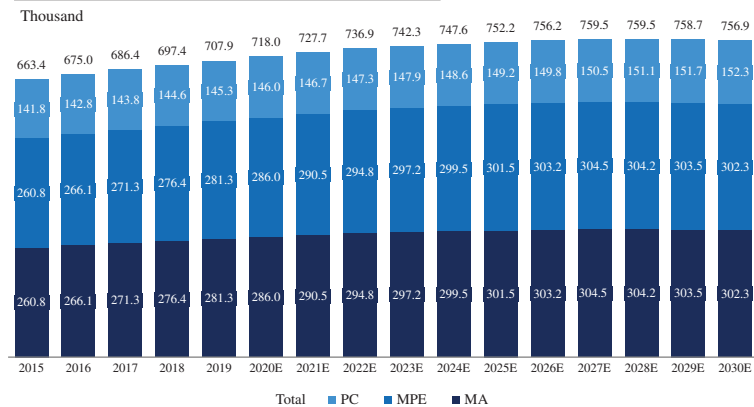
Global Incidence of Intracavitary Malignancies, 2015-2030E

Period	MA	MPE	PC	Total
2015-2019	2.8%	2.8%	1.3%	2.3%
2019-2024E	2.4%	2.4%	1.1%	2.0%
2024E-2030E	1.6%	1.6%	1.0%	1.4%



Incidence of Intracavitary Malignancies in China, 2015-2030E

Period	MA	MPE	PC	Total
2015-2019	1.9%	1.9%	0.6%	1.6%
2019-2024E	1.3%	1.3%	0.5%	1.1%
2024E-2030E	0.2%	0.2%	0.4%	0.2%



Source: F&S Report

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Malignant Ascites (MA)

MA is the accumulation of significant amounts of exudate or fluid in the abdominal/peritoneal cavity, accompanied by the presence of malignant cells or tumor tissue. MA accounts for 10% of all cases of ascites and occurs in association with a variety of cancers. The mechanisms by which fluid accumulates is multifactorial including changes in vascular permeability directly linked to carcinomatosis, massive liver metastases causing portal hypertension, cancer associated with liver cirrhosis, or the accumulation of lymphatic fluids (chylous ascites) usually associated with a lymphoma. Tumors causing carcinomatosis are commonly (a) secondary peritoneal surface malignancies, which include ovarian, colorectal, pancreatic and uterine tumors, (b) extra-abdominal tumors originating from lymphoma, lungs and breast, and (c) a small number of unknown primary tumors. According to Frost & Sullivan, global MA incidence reached 0.9 million in 2019 and is expected to grow to 1.1 million by 2030. The incidence of MA in China reached 281.3 thousand in 2019 and is expected to grow to 302.3 thousand by 2030.

Traditional ways to treat MA include sodium restricted diets, diuretic therapy, therapeutic paracentesis, peritoneal catheter drainage and peritoneovenous shunting. These methods are palliative and have limited efficacy, leading to high recurrence rates. For example, diuretics, which is a common method for alleviating symptoms associated with ascites, only appears to be successful in achieving symptomatic relief in 43%-44% cases with many patients quickly experiencing a recurrence of ascites. Some treatments also have serious adverse effects. For example, continuous large-volume paracentesis can lead to hypovolemia or kidney injury, and peritoneal catheter drainage can easily lead to infections. When used in high doses, diuretics may cause systemic blood volume depletion, electrolyte abnormalities and renal dysfunction.

Malignant Pleural Effusions (MPE)

MPE is the accumulation of significant amounts of exudate or fluid in the pleural space, accompanied by the presence of malignant cells or tumor tissue. MPE is an indication that a primary tumor has metastasized and affects approximately 15% of lymphoma, breast, lung, and ovary cancer patients globally. The most common symptom for patients with MPE is breathlessness. As MPE is associated with an average survival period of four to seven months, treatments aim to relieve dyspnea in a minimally invasive manner, and ideally minimize repeated procedures and interaction with the healthcare system.

There are no explicit MPE treatment guidelines aside from the palliative management of disease symptoms, such as drainage. The most commonly used treatments for MPE include treatment of the underlying malignancy with systemic antitumor therapy or radiation, intra-pleural chemotherapy, therapeutic thoracentesis, chemical pleurodesis, complete or partial pleurectomy with decortication, indwelling pleural catheter, and pleuroperitoneal shunts. However, these approaches have limitations such as metastasis, recurrence and complications (pneumothorax, bleeding, infections, pain, loculations, catheter blockage, among others) and their effectiveness in providing symptomatic palliative relief is often short-lived. Patients may also develop drug resistance to the drugs used in such treatments.

INDUSTRY OVERVIEW

Peritoneal Carcinomatosis (PC)

PC is the intraperitoneal dissemination of any form of cancer commonly seen as an advanced or late stage manifestation of malignancies. In PC tumors metastasize to and deposit on the peritoneal surface, thus it has historically been considered a terminal condition with a poor prognosis and median survival from five to twelve months, with proper palliative care. PC can be divided into 2 categories: primary PC and PC from cancer metastasis. Most of PC patients are from cancer metastasis such as appendix cancer, colon cancer, rectal cancer, pancreatic cancer, gastric cancer. Primary PC (PPC) only accounts for a small portion of total PC patients, where surgery remains critically important for both diagnosis and therapy of PPC.

Multimodal approaches combining aggressive cytoreductive surgery (CRS), intraperitoneal hyperthermic chemotherapy (HIPEC) and systemic chemotherapy have been considered as promising treatments for PC. However, these approaches have limitations such as the possibility of complications (such as, bleeding, infections, intestinal perforation, urinary disturbance, blood clots, fistula, death). Patients may also develop drug resistance to the drugs used in such treatments.

Competitive Landscape for Drug Treatment of Intracavitary Malignancies

There are currently no marketed drugs indicated for the treatment of intracavitary malignancies globally and in China. There are only a few drug candidates for intracavitary malignancies in clinical development. SCB-313 is the only drug candidate undergoing concurrent development for the treatment of MA, PC and MPE indications. The following chart sets forth the competitive landscape for intracavitary malignancies.

Competitive Landscape for Intracavitary Malignancies

Drug Code/ INN	Company	Indication	Status	Approval Date/ First Posted Date
BSG-001	BioSyngen Pte Ltd	Malignant Ascites; Malignant Pleural Effusion	Phase I/II in Australia (Not yet recruiting)	2018/11-08
SCB-313	Clover	Peritoneal Malignancies	Phase I in Australia	2018/02/23
		Peritoneal Carcinomatosis	Phase I in China	2019/08/09
		Malignant Ascites	Phase I in China	2019/07/24
		Malignant Pleural Effusion	Phase I in Australia	2019/03/11
			Phase I in China	2019/10/08
M701	Wuhan ZY Biopharma Co., Ltd.	Malignant Ascites	Phase I in China	2018/08/14

Source: F&S Report

INDUSTRY OVERVIEW

MARKET FOR RHEUMATOID ARTHRITIS AND ANKYLOSING SPONDYLITIS IN CHINA

Rheumatoid Arthritis (RA)

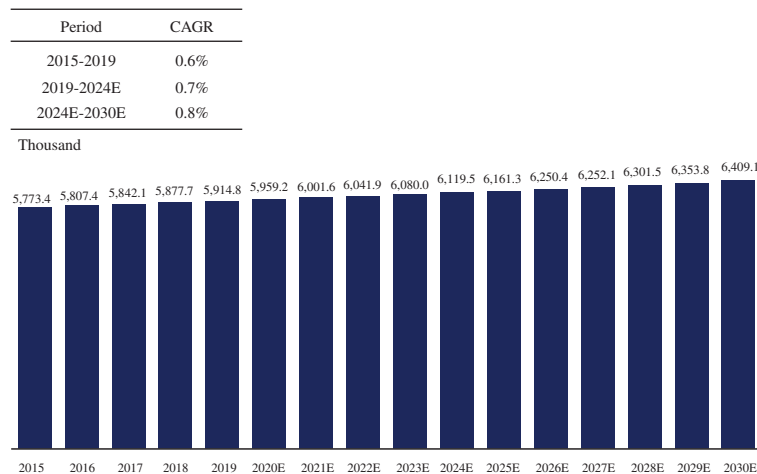
Overview

RA is an autoimmune disease that causes chronic inflammation of the joints and other areas of the body. This creates inflammation that causes the tissue that lines the inside of joints (the synovium) to thicken, resulting in swelling and pain in and around the joints. Currently, common treatments for RA involve a combination of patient education, rest and exercise, joint protection, medications, and occasionally surgery.

Prevalence of RA in China

Because of the aging population and detrimental lifestyle habits such as smoking, the prevalence of RA in China had reached 5,914.8 thousand in 2019, with a CAGR of 0.6% from 2015 to 2019. It is estimated to grow to 6,409.1 thousand in 2030 at a 0.7% CAGR. The following graph sets forth the prevalence of RA in China.

Prevalence of Rheumatoid Arthritis in China, 2015-2030E



Source: F&S Report

Current Treatment Paradigm in China

There are two main treatments for RA, the conventional synthetic disease-modifying antirheumatic drugs (DMARDs) and targeted drugs, such as TNF- α inhibitor mAbs and small-molecule drugs. According to Frost & Sullivan, while conventional synthetic DMARDs are universally acknowledged as the first-line therapy for RA, DMARDs are less effective compared to biologics such as TNF- α inhibitor mAbs in relieving symptoms and preventing joint damage in patients with moderate/severe disease. Currently, biologics that target molecules involved in the activation of the immune system are recommended only if two or three synthetic DMARDs do not work.

INDUSTRY OVERVIEW

Ankylosing Spondylitis (AS)

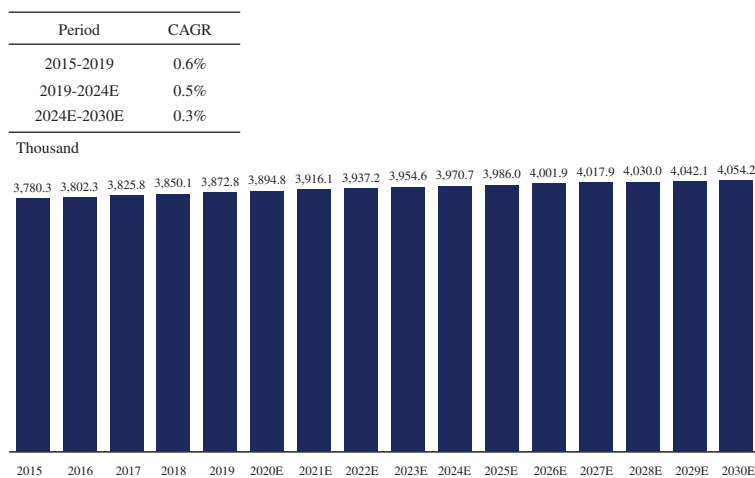
Overview

Ankylosing spondylitis is a type of arthritis that causes inflammation in certain parts of the spine. This inflammation in the joints and tissues of the spine can cause stiffness over time. Although the cause of ankylosing spondylitis is unclear, it is speculated to be a combination of genetic and environmental factors.

Prevalence of Ankylosing Spondylitis in China

According to epidemiology studies, the prevalence of ankylosing spondylitis in China reached 3,872.8 thousand in 2019, with a CAGR of 0.6% from 2015 to 2019. The number of patients is expected to reach 4,054.2 thousand in 2030 at a 0.4% CAGR.

Prevalence of Ankylosing Spondylitis in China, 2015-2030E



Source: F&S Report

Current Treatment Paradigm in China

There is no cure for ankylosing spondylitis, but there are available treatments to lessen symptoms and slow progression of the disease. The goal of treatment is to relieve pain and stiffness, control or reduce inflammation, prevent complications, prevent further joint damage, maintenance of function and improve the quality of life. Non-steroidal anti-inflammatory drugs (NSAID) are recommended as the first line treatment and TNF- α inhibitors are the second line treatment.

INDUSTRY OVERVIEW

NSAID therapy is able to quickly improve patients’ lower back pain and stiffness, as well as reduce joint swelling and pain. However, NSAID therapy may lead to side effects such as nausea, allergy and high blood pressure and may result in an inadequate therapeutic response. In such instance, TNF- α inhibitors are able to rapidly reduce disease activity and has demonstrated substantial disease improvement in randomized clinical trials. The long-term benefit of TNF- α inhibitor therapy appears to be durable.

Market for Enbrel and Etanercept Biosimilars in China

Overview

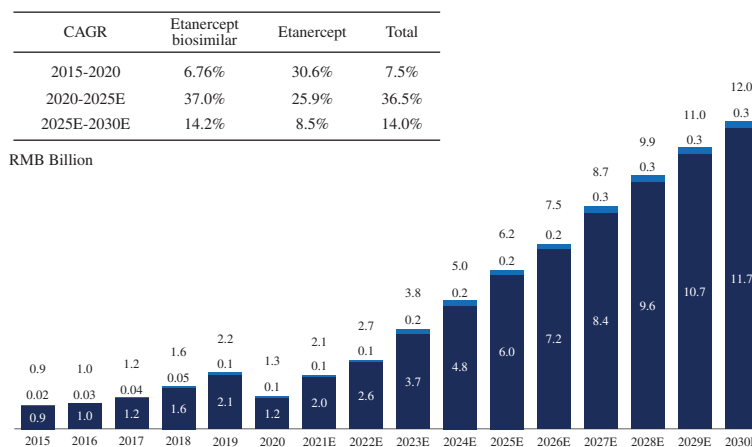
Etanercept is a TNF- α inhibitor, which is an artificially engineered dimeric fusion protein that specifically binds to TNF- α in the human body. TNF- α is involved in the normal inflammatory and immune responses of the body. By binding to TNF- α , etanercept blocks TNF- α ’s biological functions, thereby inhibiting the inflammatory process in the diseases mentioned above.

Enbrel (etanercept) is a blockbuster drug marketed by Amgen, Pfizer and Takeda Pharmaceuticals with global sales of US\$6.3 billion in 2020. Since the initial FDA approval in November 1998, Enbrel has been approved for various indications worldwide, including RA, AS, juvenile idiopathic arthritis, psoriatic arthritis and psoriasis. In China, Enbrel was approved by the NMPA in February 2010 for the indications of RA and AS. According to Frost & Sullivan, several etanercept biosimilars have been approved and marketed in China.

Market Size

The following diagram sets forth the historical and forecast market size of China’s etanercept and its biosimilar market from 2015 to 2030.

Breakdown of Etanercept and its Biosimilar Market in China, 2015-2030E



Source: Frost & Sullivan Analysis

INDUSTRY OVERVIEW

Competitive Landscape in China

There are currently three etanercept biosimilars marketed in China, three under BLA review and two undergoing evaluation in clinical trials. The following chart sets forth the competitive landscape for etanercept biosimilars in China.

Competitive Landscape for Etanercept Biosimilars in China

Brand Name/Drug Code	Company	Indication	Dosage form	Status	CDE Processing Date/ Approval Date/First Published Date	NRDL Inclusion
Yi Sai Pu	Shanghai Cp Guojian	RA, AS, PS	Powder	Marketed	2005	List B
			Injection	BLA	2019/08/06	
Enbrel	Pfizer	RA, AS	Powder	Marketed	2010/02/26	List B
			Injection	Marketed	2018/05/17	List B
Qiang Ke	Shanghai Celgen Bio-Pharmaceutica	AS	Powder	Marketed	2011	List B
An Bai Nuo	Hisun Biological	RA, AS, PS	Powder	Marketed	2015/04/09	List B
			Injection	BLA	2020/07/04	N/A
QL0902	Qilu	RA, AS	Powder	BLA	2020/07/23	N/A
BF02	Genemen Biotech	AS	Injection	Clinical Trial Phase 1	2016/04/27	N/A
SCB-808	Clover	RA, AS	Injection	Clinical Trial Phase 3	2018/07/24	N/A

Note: CDE Processing Date refers to the date when application is accepted.

All of the approved etanercept biosimilars are in freeze-dried powder formulation. Such drugs must be reconstituted by trained medical personnel before injection. In addition, as all currently marketed etanercept biosimilars in China were approved before the implementation of the The Guidelines for the R&D and Evaluation of Biosimilar Drugs (for Trial Implementation) promulgated by the NMPA in 2015, none of such etanercept biosimilars released clinical trial results demonstrating their bioequivalence to Enbrel. Clover Biopharmaceuticals’s SCB-808 is the only candidate conducting bioequivalence studies to Enbrel in China.

KEY DRIVERS FOR THE PHARMACEUTICAL MARKET IN CHINA

- Increasing Disposable Income.* The annual disposable income of Chinese residents has grown rapidly for the past few years. It was increased from RMB22.0 thousand in 2015 to RMB32.2 thousand in 2020 representing a CAGR of 7.9%. The growth of annual income per capita among the Chinese residents will result in a positive effect on the purchasing power and the level of health awareness, in turn drive the China’s pharmaceutical market to grow.

INDUSTRY OVERVIEW

- *Increasing Aging Population.* Elderly populations are more likely to suffer from chronic diseases as their overall metabolic and immune capacities gradually decline. It will result in high costs with long-term medication and disease management. Aging population has reached 185.4 million in 2020, accounting for 13.2% of the total population in China according to Frost & Sullivan. It is estimated the proportion of aging population will further increase to 16.9% in terms of total population in China in 2025, representing a population of 240.7 million. Given the large and increasing addressable populations, the pharmaceutical market in China will grow rapidly.
- *Favorable Government Policies.* The Chinese government promulgated a series of policies to encourage the research and development to strengthen the pharmaceutical market. For example, they have shortened the review and approval time for innovative drugs, which will accelerate the commercialization process for drugs with the potential to address the unmet clinical needs. Furthermore, the Chinese government has issued favorable policies in terms of tax reduction and R&D subsidies to support R&D activities of Chinese pharmaceutical company. Therefore, the favorable government policies will sustain the growth of the pharmaceutical industry in China.

SOURCE OF INFORMATION

In connection with the [REDACTED], we have commissioned Frost & Sullivan, an Independent Third Party, to conduct a detailed analysis and to prepare an industry report on the global and PRC vaccine markets. The F&S Report has been prepared by Frost & Sullivan independent from our influence. We have agreed to pay Frost & Sullivan a fee of RMB650,000 for the preparation of the F&S Report which we consider is in line with the market rates. Except as otherwise noted, all data and forecasts in this section are derived from the F&S Report. Frost & Sullivan prepared its report based on its in-house database, Independent Third Party reports and publicly available data from reputable industry organizations. To prepare the F&S Report, Frost & Sullivan also conducted analysis on projected figures based on historical data, macroeconomic data and specific industry related drivers, and reviewed annual reports of listed companies in the global and PRC vaccine markets. In compiling and preparing the F&S Report, Frost & Sullivan has adopted the following assumptions: (i) the social, economic and political environments of the PRC will remain stable during the forecast period, which will ensure a sustainable and steady development of the PRC healthcare industry; (ii) the PRC healthcare market will grow as expected due to rising healthcare demand and supply; and (iii) the PRC government will continue to support healthcare reform. Our Directors confirm that, after taking reasonable care, there is no adverse change in the market information since the date of the F&S Report which may qualify, contradict or have an impact on the information disclosed in this section.

REGULATION OVERVIEW

We are subject to a variety of PRC laws, rules and regulations affecting many aspects of our business. This section summarizes the principal PRC laws, rules and regulations that we believe are relevant to our business and operations.

REGULATORY AUTHORITIES

In the PRC, the National Medical Products Administration, or the NMPA, which was previously known as China Food and Drug Administration (together with the NMPA, hereinafter collectively referred to as the NMPA), is the primary regulatory agency for pharmaceutical products and businesses and regulates almost all of the key stages of the life-cycle of pharmaceutical products, including non-clinical studies, clinical trials, marketing approvals, manufacturing, advertising and promotion, distribution, and pharmacovigilance (i.e., post-marketing safety reporting obligations). The Center for Drug Evaluation, or the CDE, which is a subsidiary under the NMPA, conducts the technical evaluation on each drug and biologic application to assess the safety and efficacy of each candidate.

The National Health Commission, or the NHC (formerly known by names of the Ministry of Health and National Health and Family Planning Commission), is the primary healthcare regulatory agency in China. It is responsible for overseeing the operation of medical institutions, some of which also serve as clinical trial sites.

Also, the Ministry of Commerce, or the MOFCOM, and the State Administration for Market Regulation, or the SAMR, are the main regulatory authorities on our PRC subsidiaries with regard to the foreign investment activities and business supervision.

REGULATIONS RELATING TO DRUGS

Introduction

In 2017, the drug regulatory system entered a new and significant period of reform. In October 2017, the General Office of the State Council and the General Office of the Central Committee of the China Communist Party jointly issued the *Opinions on Deepening the Reform of the Evaluation and Approval System to Encourage Innovation in Drugs and Medical Devices* (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》), or the Innovation Opinion, to encourage, among others, the reform of clinical trial management and acceleration of the review and approval for drugs and medical devices marketing.

To implement the regulatory reform introduced by the Innovation Opinion, the National People’s Congress, or the NPC and the NMPA has been revising the fundamental laws, regulations and rules regulating pharmaceutical products and the industry, which include the framework law known as the *PRC Drug Administration Law* (《中華人民共和國藥品管理法》), or the Drug Administration Law. The Drug Administration Law was promulgated by the Standing Committee of the NPC, or the SCNPC, on September 20, 1984 and latest amended on August 26, 2019 and took effect as of December 1, 2019. The State Council issued the *Regulations for Implementation of the Drug Administration Law of the PRC* (《中華人民共和國藥品管理法實施條例》), which was promulgated on August 4, 2002 and latest amended on March 2, 2019, to further implement the Drug Administration Law. The NMPA also has its own set of regulations for the Drug Administration Law, and the primary one governing clinical trial applications, marketing approval, and post-approval amendment and renewal is known as the *Drug Registration Regulation* (《藥品註冊管理辦法》), or the Drug Registration Regulation, which was latest amended by the NMPA on January 22, 2020 and effective from July 1, 2020.

REGULATION OVERVIEW

Drug Research and Development

Non-Clinical Research

The NMPA requires preclinical data to support registration applications for imported and domestic drugs. According to the Drug Registration Regulation, non-clinical safety studies shall be carried out in an institution that has passed the certification of the Good Laboratories Practice of Non-clinical Laboratory and comply with the *Administrative Measures for Good Laboratories Practice of Non-clinical Laboratory* (《藥物非臨床研究質量管理規範》), or the GLP, which was issued by NMPA on August 6, 2003 and revised on July 27, 2017. The GLP has been promulgated to improve the quality of non-clinical research. Pursuant to the *Circular on Administrative Measures for Certification of Good Laboratory Practice for Non-clinical Laboratory* (《關於印發藥物非臨床研究質量管理規範認證管理辦法的通知》) issued by the NMPA on April 16, 2007, the NMPA is responsible for the certification of non-clinical safety evaluation and research institutions nationwide and local provincial drug administrative department is in charge of the daily supervision of non-clinical safety evaluation and research institution. The NMPA decides whether an institution is qualified for undertaking pharmaceutical non-clinical research by evaluating such institution’s organizational administration, its research personnel, its equipment and facilities, and its operation and management of non-clinical pharmaceutical projects.

Clinical Trials Approval

Before registering a new drug, a sponsor shall complete clinical trials according to the Drug Registration Regulation. To start the clinical trial, a sponsor needs to apply for clinical trial approval first, and the *Administrative Regulations of Quality of Drug Clinical Practice* (《藥物臨床試驗質量管理規範》), or the GCP, has been promulgated to further promote the research into good practice for clinical trials of drugs and enhance the quality thereof. The GCP was promulgated by NMPA on August 6, 2003 and latest amended by NMPA and NHC which came into effect on July 1, 2020. All clinical trials conducted in China for new drug registration purposes must be approved and conducted at pharmaceutical clinical trial institutions filed according to the *Regulations on the Administration of Drug Clinical Trial Institutions* (《藥物臨床試驗機構管理規定》) promulgated by NMPA and NHC on November 29, 2019.

According to the *Announcement of Several Policies on the Evaluation and Examination for Drug Registration* (《關於藥品註冊審評審批若干政策的公告》) promulgated by NMPA on November 11, 2015, an umbrella approval would be issued by NMPA for all phases (typically three) of a new drug clinical trial, instead of approvals phase by phase. Provided by the *Announcement of the Adjustment of Procedures of the Evaluation and Examination for Drug Clinical Trial* (《關於調整藥物臨床試驗審評審批程序的公告》) issued by NMPA on July 24, 2018, applicants could proceed with their clinical trials if they have not received any objection or query from the CDE within 60 business days after the application has been accepted and the relevant application fees have been paid. The newly revised Drug Administration Law further confirms that the drug administrative department under the State Council shall, within 60 working days from the date on which the application for a clinical trial is accepted, decide on whether to approve it and then notify the clinical trial applicant. In the case of failure to notify the applicant within the prescribed time limit, it shall be deemed as approved.

Overseas Clinical Trial

On January 30, 2015, the NMPA promulgated the *Guidelines for International Multi-Center Clinical Trials of Drugs (for Trial Implementation)* (《國際多中心藥物臨床試驗指南(試行)》) to guide the application, implementation and administration of international multi-center drug clinical trials in China. When the data of international multi-center drug clinical trials are used to support the drug registration applications in China, a further trend analysis concerning clinical trial data in China and Asia shall be conducted, during which the consistency of characteristics between subjects in the study and subjects in China shall be considered. The sample size of Chinese subjects shall be sufficient to evaluate and infer the safety and effectiveness and meet the requirements of statistics and relevant laws and regulations. Also, both domestic and overseas centers involved in the multi-center clinical trial are subject to on site inspection organized by PRC drug administrative departments.

REGULATION OVERVIEW

Pursuant to the Innovation Opinion, the clinical trial data obtained from overseas centers may be used to apply for drug registration in China if they meet the relevant requirements for the drug registration in China. If any application is filed to put a drug on the market in China for the first time, the applicant for registration shall provide the clinical trial data on racial difference, if any.

According to the *Announcement on Promulgation of the Guiding Technical Principles for the Acceptance of Overseas Clinical Trial Data of Drugs* (《關於發佈接受藥品境外臨床試驗數據的技術指導原則的通告》) issued by NMPA on July 6, 2018, if drug registration applicants use overseas clinical trials for drug registration applications in China, all overseas clinical trial data shall be provided, rather than selectively. If drug registration applicants plan to carry out follow-up clinical research and development following the early overseas clinical trials, they shall evaluate the early clinical trial data and only after having obtained complete clinical trial data and communicated with the CDE, these data could be used to support the follow-up clinical trials.

Drug Clinical Trial Registration

Pursuant to the Drug Registration Regulation, upon obtaining the clinical trial approval and before commencing a clinical trial, the sponsor shall register the scheme on the clinical trial and other information on the Drug Clinical Trial Registration and Information Platform for clinical trials of drugs. During the clinical trial of drugs, the sponsor shall update registration information continuously, and register information on the outcome of the clinical trial of drugs upon completion of the clinical trial of drugs. The registration information shall be published on the platform and the sponsor shall be responsible for the veracity of such information. More details are provided in the *Announcement on Drug Clinical Trial Information Platform* (《關於藥物臨床試驗信息平臺的公告》) released by the NMPA on September 6, 2013, providing that for all clinical trials approved by the NMPA and conducted in China shall be published through the Drug Clinical Trial Registration and Information Platform. The applicant shall complete trial pre-registration within one month after obtaining the clinical trial approval to obtain the trial’s unique registration number and shall complete certain follow-up information and first submission for publication before the first subject’s enrollment in the trial. If the foregoing first time of publication has not been submitted within one year after obtaining the clinical trial approval, the applicant shall submit an explanation, and if the procedure is not completed within three years, the clinical trial approval shall automatically be annulled.

Human Genetic Resources Approval and Registration

According to the *Interim Measures for the Administration of Human Genetic Resources* (《人類遺傳資源管理暫行辦法》), promulgated by the Ministry of Science and Technology and the Ministry of Health jointly on June 10, 1998, an approval is required for international collaborative project involving human genetic resources in PRC. The Chinese collaborating party shall be responsible for going through the due formalities of application for approval from the Human Genetic Resources Administration of China, or HGRAC, which is an agency under the Ministry of Science and Technology, to sample, collect, research, develop, trade or export any genetic materials which contain human genome, genes or gene products as well as the information relating to such genetic materials. Furthermore, one of the key concerns for the HGRAC review and approval process is the IP sharing arrangement between Chinese and foreign parties. The parties are required to share patent rights of inventions arising from the international collaborative project. Conducting clinical trials in China without obtaining the relevant HGRAC approval will subject the sponsor and trial site to administrative liability and even judiciary liability.

REGULATION OVERVIEW

The Ministry of Science and Technology promulgated the *Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading or Exporting Human Genetic Resources, or Taking Such Resources out of the PRC* (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》) in July 2015, according to which, if the sampling, collection or research activities of human genetic resources by a foreign-invested sponsor fall within the scope of international cooperation, and the cooperating organization of China shall apply for approval of the China Human Genetic Resources Management Office through the online system. On October 26, 2017, the Ministry of Science and Technology issued the *Announcement on Optimizing the Administrative Examination and Approval of Human Genetic Resources* (《關於優化人類遺傳資源行政審批流程的通知》), which simplified the approval for utilizing human genetic resources for the purpose of obtaining the marketing license of a drug in the PRC.

On May 28, 2019, the State Council of PRC issued the *Administrative Regulations on Human Genetic Resources* (《人類遺傳資源管理條例》), or the Human Genetic Resource Regulation, which became effective on July 1, 2019. According to the Human Genetic Resource Regulation, human genetic resource includes human genetic resource materials and information. Human genetic resource materials refer to organs, tissues, cells and other genetic materials containing human genome, genes and other genetic materials. Human genetic resource information refers to information, such as data, generated by human genetic resources materials. The Human Genetic Resource Regulation formalized the approval requirements pertinent to research collaborations between Chinese and foreign-owned entities, under which, a new filing system (as opposed to the advance approval approach originally in place) is put in place for clinical trials utilizing China’s human genetic resources in order to obtain market license at clinical institutions without involving the export of human genetic resources materials outside of China. Foreign organizations, individuals and institutions established or actually controlled by foreign organizations and individuals are not allowed to collect or preserve human genetic resources in China or provide human genetic resources abroad.

Clinical Trial Process and Good Clinical Practices

Typically, pursuant to the Drug Registration Regulation, drug clinical trials in China shall go through four phases. Based on the characteristics of drugs and research objective, the research contents shall include clinical pharmacology research, exploratory clinical trial, confirmatory clinical trial and post-marketing research clinical. The NMPA requires that the different phases of clinical trials in China shall receive ethics committee approval respectively and comply with the relevant requirements of quality management standards for clinical trial of drugs in PRC. The sponsor shall submit safety update reports on the CDE website regularly during the research and development period. The sponsor shall promptly report to the CDE regarding suspicious and unexpected serious adverse reaction and other potential serious safety risks arising in the course of the clinical trial. Based on the severity of the safety risks, the sponsor may be required to adopt measures to strengthen risk control, and may be required to suspend or terminate the clinical trial of drugs where necessary.

According to the GCP, the sponsor shall provide investigators and the clinical trial institution with legal and economic insurance or guarantee relating to the clinical trial, and ensure that such insurance or guarantee is appropriate to the nature and degree of risks of the clinical trial, excluding the damages caused by the negligence of investigators or the clinical trial institution. Pursuant to the Innovation Opinion, the accreditation of the institutions for drug clinical trials shall be subject to record-filing administration. The conduct of clinical trials must adhere to the PRC’s GCP, and the protocols must be approved by the ethics committees. Pursuant to the newly amended Drug Administration Law and the *Regulations on the Administration of Drug Clinical Trial Institution* (《藥物臨床試驗機構管理規定》) jointly promulgated by NMPA and NHC on November 29, 2019 and effective from December 1, 2019, drug clinical trial institutions shall be subject to filing administration. Entities that only conduct analysis of biological samples related to clinical trials of drugs are not required perform filing procedures.

REGULATION OVERVIEW

New Drug Application, Approval and Re-Registration

According to the Drug Registration Regulation, an applicant shall, upon completion of studies including pharmacy, pharmacology and toxicology and clinical trial of drugs which support the registration of drug marketing, determination of quality standards, verification of commercial scale manufacturing process, and preparation to undergo examination and inspection for drug registration, submit an application for drug marketing authorization, and submit the relevant research materials in accordance with the submission requirements. The CDE shall organize pharmacist, medical and other technical personnel to comprehensively review the application regarding the safety, effectiveness and quality control of the drug. Where the application is cleared by the comprehensive review, the drug shall be approved for marketing and a drug registration certificate shall be issued. Under the Drug Registration Regulation, drugs are classified into Chinese medicine, chemical medicine, biological products and others. Biological products are further divided in 3 categories in the Registration Classification and Application Documents Requirements of Biological Products (《生物製品註冊分類及申報資料要求》), or the Registration Category, which was promulgated by the NMPA on June 29, 2020 and replaced the previous version issued in 2007. Pursuant to the Registration Category, Category I therapeutic biological products or vaccines refer to those have not been marketed in the PRC or abroad. Category II therapeutic biological products or vaccines refer to improved ones which, compared with the existing products marked in the PRC or abroad, could improve the safety, effectiveness and quality controllability, and have obvious advantages. Category III therapeutic biological products or vaccines refer to those have been marketed in the PRC or abroad, including biosimilars.

Pursuant to the newly amended Drug Administration Law, an applicant who has obtained a drug registration certificate shall be recognized as a drug marketing authorization holder, responsible for non-clinical laboratory studies, clinical trials, production and distribution, post-market studies, and the monitoring, reporting, and handling of adverse reactions in connection with pharmaceuticals in accordance with the provisions of the Drug Administration Law. The drug marketing authorization holder may engage in manufacturing or distribution on their own or to entrust a licensed third party. At the time of application for drug marketing authorization, the applicant and the manufacturing enterprise shall have held the corresponding Pharmaceutical Manufacturing Permit.

Pursuant to the Drug Registration Regulation, the validity period of a drug registration certificate shall be five years. The drug marketing authorization holder of the drug registration certificate shall ensure the safety, effectiveness and quality control of the marketed drug at all times during the validity period of the certificate and apply for re-registration of the drug six months before the expiry of such validity period.

Drug Manufacturing

According to the Drug Administration Law and *Administrative Measures on Supervision of Pharmaceutical Manufacturing* (《藥品生產監督管理辦法》) which was promulgated by the NMPA on December 11, 2002 and last amended on January 22, 2020 and effective on July 1, 2020, all facilities that manufacture drugs in China must apply for a Pharmaceutical Manufacturing Permit which are issued by the drug supervision and administration department of the province, autonomous region or municipality directly under the central government where it is domiciled. The Pharmaceutical Manufacturing Permit is valid for five years and shall be renewed six months before the expiry date. The drug marketing authorization holder who entrusts another party to produce preparations shall meet the requirements as specified in *Administrative Measures on Supervision of Pharmaceutical Manufacturing*, sign an entrustment agreement and a quality agreement with a qualified drug producer, and submit the relevant agreements and the application materials of the actual production site to provincial drug administrative departments where the drug marketing authorization holder is located to apply for the drug production license. When an application for marketing authorization is submitted, the applicant and the manufacturer shall have obtained the corresponding Pharmaceutical Manufacturing Permit.

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These drug manufacturing facilities shall comply with drug manufacturing quality management norms, establish a sound drug manufacturing quality management system and ensure the whole drug manufacturing process continuously comply with statutory requirements. The drug marketing authorization holder shall establish a quality assurance system for pharmaceuticals, employ designated personnel to be independently in charge of quality control for pharmaceuticals.

Drug Operation

As required by Drug Administration Law and *Administrative Measures for Drug Business Permits* (《藥品經營許可證管理辦法》) which was promulgated by the NMPA on February 4, 2004 and amended on November 17, 2017, operation of drug business, including drug wholesale and drug retail, is prohibited without a Drug Business Permit. A Drug Business Permit shall state the validity period and the scope of business and be subject to review and reissuance upon expiry of the validity period.

Drug business operators shall comply with the drug operation quality management norms, establish and improve their business operation quality management system, and ensure that the whole drug business process continuously comply with statutory requirements.

In China, governmental pricing controls on drugs (other than narcotic and certain psychiatric drugs) have been lifted since May 2015 when the Opinions on Advancing Drug Price Reform (《推進藥品價格改革意見》) came into effect. Instead of direct governmental controls, the government exercises control over the drugs through establishing a centralized tender process or centralized procurement mechanism, revising the National Reimbursement Drug List or provincial medical insurance drug catalogues and strengthening regulation of medical and pricing practices. Also, according to the Opinions on the Reform of Review and Approval System for Drugs and Medical Devices (《關於改革藥品醫療器械審評審批制度的意見》) promulgated by the State Council in August 2015, enterprises which apply for the registration of new drugs should promise that the prices of their products on the PRC market should not be higher than the comparable market prices in original countries or the surrounding area of the PRC.

Regulations on Dual Invoicing System

According to the *Implementing Opinions on Promoting the “Dual Invoicing System” for Drug Procurement By Public Medical Institutions (For Trial Implementation)* (《關於在公立醫療機構藥品採購中推行“兩票制”的實施意見(試行)》) issued on December 26, 2016, or the Dual Invoicing System Notice, the dual invoicing system refers to a system that requires one invoice to be issued from pharmaceutical manufacturers to pharmaceutical distributors and the other invoice to be issued from pharmaceutical distributors to medical institutions. According to the Dual Invoicing System Notice and the *Several Opinions of the General Office of the State Council on Further Reform and Improvement in Policies of Drug Production, Circulation and Use* (《國務院辦公廳關於進一步改革完善藥品生產流通使用政策的若干意見》) issued on January 24, 2017, dual invoicing system would be promoted in pilot provinces (autonomous regions and municipalities directly under the Central Government) involved in the comprehensive medical reform program and pilot cities for public hospital reform on a priority basis, and encouraged to be fully implemented by 2018.

Regulations on Centralized Procurement

On January 17, 2009, the Ministry of Health, together with other 5 departments, issued *Opinions on Further Regulating Centralized Procurement of Medical Institutions* (《關於進一步規範醫療機構藥品集中採購工作的意見》), which promoted the comprehensive implementation of online drug procurement in a centralized manner that directed by government.

The State launched the trials for the centralized volume-based drug procurement in 11 cities in November 2018. On November 15, 2018, the Joint Procurement Office published the *Papers on Drug Centralized Procurement in “4+7 Cities”* (《4+7城市藥品集中採購文件》), which launched the national pilot scheme for centralized volume-based drug

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procurement in the public medical institutions. The pilot scheme will be carried out in 11 cities, including Beijing, Tianjin, Shanghai, Chongqing, Shenyang, Dalian, Xiamen, Guangzhou, Shenzhen, Chengdu and Xi'an, or collectively, the 4+7 Cities. On January 1, 2019, the General Office of the State Council also published the *Notice of the General Office of the State Council on the Promulgation of the Pilot Program for Centralized Drug Procurement and Use Organized by the State* (《國務院辦公廳關於印發〈國家組織藥品集中採購和使用試點方案〉的通知》), which provides detailed measures for the implementation of the national pilot scheme for centralized volume-based drug procurement in the 4+7 Cities.

On the basis of the centralized volume-based drug procurement implemented by 4+7 cities, the Joint Procurement Office issued *The Document for Centralized Drug Procurement in the Alliance area (GY-YD2019-1)* (《聯盟地區藥品集中採購文件(GY-YD2019-1)》) on September 1, 2019, according to which the alliance area includes the provinces and autonomous regions of Shanxi, Inner Mongolia, Liaoning, Jilin, Heilongjiang, Jiangsu, Zhejiang, Anhui, Jiangxi, Shandong, Henan, Hubei, Hunan, Guangdong, Guangxi, Hainan, Sichuan, Guizhou, Yunnan, Xizang, Shaanxi, Gansu, Qinghai, Ningxia and Xinjiang (including Xinjiang Production and Construction Army Unit) along with the 4+7 cities.

The State promoted the centralized volume-based drug procurement nationwide in December 2019. According to the *Implementing Opinions on Expanding the Pilot Program for Conducting Centralized Procurement and Use of Drugs by the State to Wider Areas* (《關於國家組織藥品集中採購和使用試點擴大區域範圍的實施意見》) promulgated and effective on September 25, 2019, together with the *Documents on National Centralized Drug Procurement (GY-YD2019-2)* (《全國藥品集中採購文件(GY-YD2019-2)》) issued by the Joint Procurement Office on December 29, 2019 to launch the second batch of state-organized centralized volume-based drug procurement. The model of centralized procurement in the pilot program would be promoted nationwide and all manufacturers (including drug marketing authorization holder) of drugs within the scope of centralized procurement marketed in China, with the approval of the medical products administration, may participate in the pilot program. The *Notice on the Commencement of the Second Batch of State Organized Centralized Drug Procurement and Use* (《關於開展第二批國家組織藥品集中採購和使用工作的通知》) was issued on January 13, 2020 and effective on the same date, according to which the second batch of national organization of centralized procurement and use of drugs will no longer be carried out in selected areas but nationwide with all public medical institutions and military medical institutions shall be involved, and social medical institutions and retail pharmacies designated by medical insurance can be involved voluntarily.

In order to comprehensively deepen the reform and establish a standardized and normalized mode of centralized volume-based drug procurement and use, the Joint Procurement Office issued the *Documents on National Centralized Drug Procurement (GY-YD2020-1)* (《全國藥品集中採購文件(GY-YD2020-1)》) on July 29, 2020 and launched the third batch of State organizations for the centralized volume-based drug procurement.

Drug Advertisements

The *PRC Advertising Law* (《中華人民共和國廣告法》), as recently amended and effective on April 29, 2021, outlines the regulatory framework for the advertising industry. Advertisers, advertising service providers and advertising publishers are required to ensure that the contents of the advertisements they prepare or distribute are true and in full compliance with applicable laws and regulations. For advertisement of drugs, the advertisement contents shall be examined by the relevant authorities prior to the publishing. Pursuant to the *Interim Administrative Measures for the Review of Advertisements for Drugs, Medical Devices, Health Food and Formula Food for Special Medical Purposes* (《藥品、醫療器械、保健食品、特殊醫學用途配方食品廣告審查管理暫行辦法》) promulgated by State Administration for Market Regulation on December 24, 2019 and effective from March 1, 2020, advertisements for drugs shall not contain any false or misleading contents. Advertisers shall be responsible for the veracity and legitimacy of the contents of advertisements for drugs, medical devices, health food and formula food for special medical purposes.

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Drug Recalls

According to the *Measures on Drug Recall* (《藥品召回管理辦法》) effective from December 10, 2007, a drug manufacturer should establish and improve its recall system by collecting relevant information about drug safety and conducting investigation and evaluation with respect to the drugs with potential safety hazards. If there are any potential safety hazards that endanger human health and life safety in respect of any drugs sold in PRC, such manufacturer must start the drug recall procedures. Where a drug is recalled, the drug operating and using institutions should assist such manufacturer to satisfy its recall obligations by communicating the drug recall information and any feedback, controlling and recovering such drugs according to the recall plan.

REGULATIONS RELATING TO VACCINES

Vaccine Policies

The *Laws on Prevention and Treatment of Infectious Diseases* (《中華人民共和國傳染病防治法》), issued in February 1989 and amended in August 2004 and June 2013, stipulates that a planned prophylactic vaccination system is performed in the PRC. The health administration department under the State Council and such departments under the people’s governments of provinces, autonomous regions, and municipalities directly under the central government shall, in accordance with the requirements of prevention and control of infectious diseases, draw up plans for prophylactic vaccination against infectious diseases and coordinate efforts for their implementation. Vaccines used for prophylactic vaccination shall conform to the quality standards of the PRC.

According to the *Vaccine Administration Law of the PRC* (《中華人民共和國疫苗管理法》), or the Vaccine Administration Law, which was promulgated by the SCNPC on June 29, 2019 and came into effect on December 1, 2019, the State applies the most stringent management system for vaccines, and adheres to the principles of safety first, risk management, whole-process control, scientific supervision and social co-governance. Also, a National immunization Program system is applied in the PRC, under which the government would provide vaccines under the immunization program to the residents free of charge.

Vaccine Administration

On January 15, 2017, the General Office of State Council issued *Opinions on Further Enhancing Administration of Circulation and Vaccination of Vaccines* (《關於進一步加強疫苗流通和預防接種管理工作的意見》), or the Vaccine Opinion, among others, to improve the work mechanism for the management of vaccines and promote the independent R&D and quality improvement of vaccines. On June 29, 2019, the SCNPC released the Vaccine Administration Law, which requires the most stringent management system for vaccines, and at the same time, supports the basic research and applied research on vaccines, promotes the development and innovation of vaccines, including the development, production and reserve of vaccines for the prevention and control of serious diseases in the national strategy. Entities and individuals engaged in vaccine development, production, circulation and vaccination shall abide by the laws, regulations, rules, standards and specifications, ensure that the information during the whole process is true, accurate, complete and traceable, assume responsibilities in accordance with the law and accept social supervision.

Vaccine marketing authorization holders shall establish an electronic vaccine traceability system, which is connected with the national electronic vaccine traceability collaboration platform to realize the traceability and verifiability of the smallest packaging units of vaccines in the whole process of production, circulation and vaccination. In addition, vaccine marketing authorization holders are required to purchase compulsory liability insurance for their vaccines in accordance with the Vaccine Administration Law. For details, please see “Business – Health, Safety And Environment – Governance of Environmental and Social Matters”. Where an inoculated person suffers any damage due to vaccine quality problems, the insurance company shall pay compensation within the limit of liability insured.

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Development and Registration of Vaccines

On October 14, 2005, the NMPA promulgated the *Notice on Issuing Six Technical Guidelines including the Technical Guidelines on Preclinical Study of Preventive Vaccines* (《關於印發<預防用疫苗臨床前研究技術指導原則>等6個技術指導原則的通知》), which specified the requirements on preclinical research, change of production process, quality control in clinical stages of vaccine to ensure its safety and efficacy.

According to the Vaccine Administration Law, clinical trials of vaccines shall not be conducted without obtaining the approval of the drug administrative department under the State Council. Clinical trials of vaccines shall be conducted or organized for implementation by Grade III medical institutions that meet the conditions prescribed by the drug administrative department under the State Council and the competent health department under the State Council, or by disease prevention and control institutions at or above the provincial level.

A vaccine to be marketed within the territory of China shall be approved by the drug administrative department under the State Council and obtain a drug registration certificate; when applying for registration of a vaccine, an applicant shall provide true, sufficient and reliable data, information and samples. With respect to the vaccines urgently needed for disease prevention and control as well as the innovative vaccines, the drug administrative department under the State Council shall prioritize their evaluation and approval.

According to the Vaccine Administration Law, for vaccines urgently needed for disease prevention and control as well as the innovative vaccines, the NMPA shall prioritize the evaluation and approval work. With respect to a vaccine urgently needed for responding to a major public health emergency or any other vaccines urgently needed as determined by the health department under the State Council, if the benefits outweigh the risks upon assessment, the drug administrative department under the State Council may conditionally approve the vaccine registration application.

According to the Drug Registration Regulation, before the applicant submits an application for drug marketing authorization, it shall communicate with the CDE and, upon communication and confirmation, submit the application for drug marketing authorization and simultaneously submit an application for prioritized review and approval. Upon included in the procedures for prioritized review and approval, the sponsors could enjoy, among others, a shortened review period for drug marketing authorization within 130 days.

Production and Batch Release of Vaccines

According to the Vaccine Administration Law, whoever engages in vaccine production activities shall, in addition to meeting the conditions for engaging in drug production activities as prescribed in the Drug Administration Law, also meet the following conditions: (1) Having moderate scale and sufficient capacity reserves; (2) Having systems, facilities and equipment for ensuring bio-safety; and (3) Meeting the needs of disease prevention and control. A vaccine marketing authorization holder shall have the capacity for production of vaccines. If it is really necessary to entrust the production of vaccines in excess of its capacity, the vaccine marketing authorization holder shall obtain the approval of the drug administrative department under the State Council. Where it accepts the entrustment to produce vaccines, it shall abide by the provisions of this Law and the relevant provisions of the State, so as to guarantee the quality of vaccines.

The State adopts a batch release system for vaccines. Each batch of vaccines shall, before being sold or imported, be examined and inspected according to the relevant technical requirements by the batch release institution designated by the drug administrative department under the State Council. If the requirements are met, a batch release certificate shall be issued; otherwise, a notice on rejecting batch release shall be issued. According to the *Measures for Administration of Batch Release of Biological Products* (《生物製品批簽發管理辦法》) issued on December 13, 2002 and latest amended on December 11, 2020 and effective on March 1, 2021, the vaccine products with marketing approval shall be subject to document review and sample inspection by the drug batch release institution designated by NMPA and pass the

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biological product batch release approval before the marketing and sales of each batch of products. Vaccines that are urgently needed for infectious disease prevention and control or for emergencies shall be exempted from the biological product batch release approval upon approval by the NMPA.

Circulation of Vaccines

According to the Vaccine Opinion issued by the General Office of State Council on January 15, 2017, vaccines should be procured online on the provincial public resource trading platform in accordance with the principles of transparency, competition, and fair trade.

According to the Vaccine Administration Law, the competent health department under the State Council shall, in concert with the finance department under the State Council and other departments, organize centralized bidding or unified negotiation to form and publish the bid-winning price or transaction price of vaccines under the National Immunization Programs, and all provinces, autonomous regions and municipalities directly under the central government shall implement centralized procurement for such vaccines. The procurement of vaccines under other immunization programs other than those under the National Immunization Program and vaccines not under any immunization program shall be organized by provinces, autonomous regions and municipalities directly under the central government through provincial public resources trading platforms.

According to the Vaccine Administration Law, the price of vaccines shall be set reasonably and independently by the vaccine marketing authorization holder according to law. The price level, price difference rate and profit rate of vaccines shall be kept within a reasonable range. A vaccine marketing authorization holder shall, as agreed upon in the procurement contract, supply vaccines to the disease prevention and control institution. A vaccine marketing authorization holder shall, as agreed upon in the procurement contract, deliver vaccines to the disease prevention and control institution or the inoculation entity designated thereby. The vaccine marketing authorization holder and disease prevention and control institution that distribute vaccines themselves shall have the conditions for cold chain storage and transport of vaccines or may entrust eligible vaccine distribution entities to distribute vaccines. A vaccine marketing authorization holder shall, in accordance with the provisions, set up true, accurate and complete sales records, and preserve them for inspection for at least five years after expiry of the validity of the vaccines.

With regard to storage and transportation of vaccines, the present *Notice for Distributing Regulations on Administration of Vaccine Storage and Transportation (2017 Edition)* (《疫苗儲存和運輸管理規範(2017年版)》), which promulgated by the NMPA and NHC on December 15, 2017 and effective on the same day, requires that, among others, vaccine production enterprises shall be equipped with full-time staff for vaccine management, establish a management system for vaccine storage and transport, maintain cold chain facilities and equipment for storage and transport of vaccines to ensure the quality of vaccines, and must store and transport vaccines in light of the instructions for use of vaccines, the vaccination work rules and other relevant requirements on temperature for storage and transport of vaccines.

REGULATIONS RELATING TO IMPORTATION AND EXPORTATION OF GOODS

According to the *Administrative Provisions on the Registration of Customs Declaration Entities of the PRC* (《中華人民共和國海關報關單位註冊登記管理規定》), promulgated by the General Administration of Customs of the PRC on March 13, 2014, latest amended and became effective on July 1, 2018, import and export of goods shall be declared by the consignor or consignee itself, or by a customs declaration enterprise entrusted by the consignor or consignee and duly registered with the customs authority. Consignors and consignees of imported and exported goods shall go through customs declaration entity registration formalities with the competent customs departments in accordance with the applicable provisions. After completing the registration formalities with the customs, consignors and consignees of the imported and exported goods may handle their own customs declarations at customs ports or localities where customs supervisory affairs are concentrated within the customs territory of the PRC.

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REGULATIONS RELATING TO NATIONAL MEDICAL INSURANCE PROGRAM

Pursuant to the *Notice of Opinion on the Diagnosis and Treatment Management, Scope and Payment Standards of Medical Service Facilities Covered by the National Urban Employees Basic Medical Insurance Scheme* (《關於印發<城鎮職工基本醫療保險診療項目管理、醫療服務設施範圍和支付標準意見>的通知》) promulgated on June 30, 1999, part of the fees of diagnostic and treatment devices and diagnostic tests would be paid through the basic medical insurance scheme. Detailed reimbursement coverage and rate are subject to provincial local policies. Pursuant to the *Decision on the Establishment of the Urban Employee Basic Medical Insurance Program* (《關於建立城鎮職工基本醫療保險制度的決定》) issued by the State Council on December 14, 1998, *Opinions on the Establishment of the New Rural Cooperative Medical System* (《關於建立新型農村合作醫療制度意見的通知》) issued by the General Office of the State Council on January 16, 2003, the *Guiding Opinions of the State Council about the Pilot Urban Resident Basic Medical Insurance* (《國務院關於開展城鎮居民基本醫療保險試點的指導意見》) issued by the State Council on July 10, 2007, and the *Opinions on Integrating the Basic Medical Insurance Systems for Urban and Rural Residents* (《國務院關於整合城鄉居民基本醫療保險制度的意見》) promulgated on January 3, 2016, all employees and residents in rural and urban areas would be involved in medical insurance program.

The General Office of the State Council further released the *Guidance On Further Deepening the Reform of the Payment Method of Basic Medical Insurance* (《關於進一步深化基本醫療保險支付方式改革的指導意見》) in June 2017. The main objectives are to implement a diversified reimbursement mechanism including diagnosis related groups, per-capita caps, and per-bed-day caps. These new reimbursement methods will be rolled out nationwide by 2020 to replace the current reimbursement method that is based on service category and product price. Local administration of healthcare security will introduce a total budget control for their jurisdictions and decide the amount of reimbursement to public hospitals based on hospitals' performance and the spending targets of individual basic medical insurance funds.

LAWS AND REGULATIONS RELATING TO PRODUCT LIABILITY

Pursuant to the *Product Quality Law* (《中華人民共和國產品質量法》) promulgated on February 22, 1993 and amended on July 8, 2000, August 27, 2009 and December 29, 2018 respectively by SCNPC, Seller shall be responsible for the repair, replacement or return of the product sold if (1) the product sold does not possess the properties for use that it should possess, and no prior and clear indication is given of such a situation; (2) the product sold does not conform to the applied product standard as carried on the product or its packaging; or (3) the product sold does not conform to the quality indicated by such means as a product description or physical sample. If a consumer incurs losses as a result of purchased product, the seller shall compensate for such losses.

Pursuant to the *PRC Civil Code* (《中華人民共和國民法典》) promulgated by the NPC on May 28, 2020 and coming into effect on January 1, 2021, where a patient suffers damage due to defects in drugs, he may seek compensation from the drug marketing authorization holder or also from the medical institution. Where the patient seeks compensation from the medical institution, the medical institution, after it has made the compensation, shall have the right to recover the compensation from the liable drug marketing authorization holder.

The *Law of the PRC on the Protection of the Rights and Interests of Consumers* (《中華人民共和國消費者權益保護法》) was promulgated on October 31, 1993 and was amended on August 27, 2009 and October 25, 2013 to protect consumers' rights when they purchase or use goods and accept services. All business operators must comply with this law when they manufacture or sell goods and/or provide services to customers. Under the amendments made on October 25, 2013, all business operators must pay high attention to protecting customers' privacy and must strictly keep confidential any consumer information they obtain during their business operations.

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LAWS AND REGULATIONS RELATING TO FOREIGN INVESTMENT

Foreign Investment

Investment activities in the PRC by foreign investors are principally governed by *The Special Administrative Measures (Negative List) for Access of Foreign Investment (2020 version)* (《外商投資准入特別管理措施(負面清單)(2020年版)》), or the Negative List, and *Catalogue of Industries for Encouraging Foreign Investment (2020 version)* (《鼓勵外商投資產業目錄(2020年版)》), or the Encouraging List. The Negative List, which came into effect on July 23, 2020, sets out special administrative measures in respect of the access of foreign investments in a centralized manner, and the Encouraging List which came into effect on January 27, 2021, sets out the encouraged industries for foreign investment.

Foreign-Invested Enterprises

On December 29, 1993, the SCNPC issued the *PRC Company Law* (《中華人民共和國公司法》), or the Company Law, which was latest amended on October 26, 2018. The Company Law regulates the establishment, operation and management of corporate entities in China and classifies companies into limited liability companies and limited companies by shares, including foreign invested companies.

According to the *Foreign Investment Law of the PRC* (《中華人民共和國外商投資法》), or the Foreign Investment Law, promulgated by the NPC on March 15, 2019 and came into effect as of January 1, 2020, the state shall implement the management systems of pre-establishment national treatment and negative list for foreign investment, and shall give national treatment to foreign investment beyond the negative list. Simultaneously, *Sino-foreign Equity Joint Ventures of the PRC* (《中華人民共和國中外合資經營企業法》), the *Wholly Foreign-owned Enterprises Law of the PRC* (《中華人民共和國外資企業法》) and *Sino-foreign Cooperative Joint Ventures of the PRC* (《中華人民共和國中外合作經營企業法》) have been repealed since January 1, 2020, and organization form and structure and operating of foreign invested companies are all subject to the Company Law.

In December 2019, the State Council promulgated the *Regulations on Implementing the Foreign Investment Law of the PRC* (《中華人民共和國外商投資法實施條例》), which came into effect in January 2020 and forms specific operable and detailed rules for the Foreign Investment Law. After the *Regulations on Implementing the Foreign Investment Law of the PRC* came into effect, the *Regulation on Implementing the Sino-Foreign Equity Joint Venture of the PRC* (《中華人民共和國中外合資經營企業法實施條例》), *Provisional Regulations on the Duration of Sino-Foreign Equity Joint Venture* (《中外合資經營企業合營期限暫行規定》), the *Regulations on Implementing the Wholly Foreign-owned Enterprise Law of the PRC* (《中華人民共和國外資企業法實施細則》) and the *Regulations on Implementing the Sino-foreign Cooperative Joint Venture of the PRC* (《中華人民共和國中外合作經營企業法實施細則》) have been repealed simultaneously.

According to the Foreign Investment Law, a foreign investment information report system is established in the PRC. On December 30, 2019, the MOFCOM and the SAMR issued the *Measures for the Reporting of Foreign Investment Information* (《外商投資信息報告辦法》), which came into effect on January 1, 2020 and replaced the *Interim Measures for the Recordation Administration of the Incorporation and Change of Foreign-Invested Enterprises* (《外商投資企業設立及變更備案管理暫行辦法》), for carrying out investment activities directly or indirectly in PRC, the foreign investors or foreign-invested enterprises shall submit investment information to the commerce authorities pursuant to these measures.

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LAWS AND REGULATIONS RELATING TO ENVIRONMENTAL PROTECTION AND FIRE PREVENTION

Environment Protection

The *Environmental Protection Law of the PRC* (《中華人民共和國環境保護法》), which was promulgated by the SCNPC on December 26, 1989, came into effect on the same day and last amended on April 24, 2014, outlines the authorities and duties of various environmental protection regulatory agencies. The Ministry of Environmental Protection is authorized to issue national standards for environmental quality and emissions, and to monitor the environmental protection scheme of the PRC. Meanwhile, local environment protection authorities may formulate local standards which are more rigorous than the national standards, in which case, the concerned enterprises must comply with both the national standards and the local standards.

Environmental Impact Appraisal

According to the *Administration Rules on Environmental Protection of Construction Projects* (《建設項目環境保護管理條例》), or the Construction Environmental Protection Rule, which was promulgated by the State Council on November 29, 1998, amended on July 16, 2017 and became effective on October 1, 2017, depending on the impact of the construction project on the environment, a construction employer shall submit an environmental impact report or an environmental impact statement, or file a registration form. As to a construction project, for which an environmental impact report or the environmental impact statement is required, the construction employer shall, before the commencement of construction, submit the environmental impact report or the environmental impact statement to the relevant authority at the environmental protection administrative department for approval. If the environmental impact assessment documents of the construction project have not been examined or approved upon examination by the approval authority in accordance with the law, the construction employer shall not commence the construction.

According to the *Environmental Impact Appraisal Law of PRC* (《中華人民共和國環境影響評價法》), which was promulgated by the SCNPC on October 28, 2002, amended on July 2, 2016 and December 29, 2018, for any construction projects that have an impact on the environment, an entity is required to produce either a report, or a statement, or a registration form of such environmental impacts depending on the seriousness of effect that may be exerted on the environment.

Pollutant Discharge Licensing

Pursuant to the *Administrative Measures for Pollutant Discharge Licensing (for Trial Implementation)* (《排污許可管理辦法(試行)》) promulgated on January 10, 2018 and partially revised on August 22, 2019 by the Ministry of Ecology and Environment, or the MEE, enterprises and public institutions as well as other producers and operators included in the Catalog of Classified Administration of Pollutant Discharge License for Stationary Pollution Sources shall apply for and obtain a pollutant discharge license within a prescribed time limit. Any enterprise that fails to obtain a pollutant discharge license as required shall not discharge pollutants.

According to the *Catalog of Classified Administration of Pollutant Discharge License for Stationary Pollution Sources (2019 Version)* (《固定污染源排污許可分類管理名錄(2019年版)》) issued by the MEE on December 20, 2019 and effective on the same day, key management, simplified management and registration management of pollutant discharge permits are implemented according to factors such as the amount of pollutants generated, the amount of emissions, the degree of impact on the environment, etc., and only pollutant discharge entities that implement registration management do not need to apply for a pollutant discharge permit.

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The State Council issued the *Regulation on Pollutant Discharge Permit Administration* (《排污許可管理條例》) on January 24, 2021 to further enhance the pollutant discharge administration. The administration on pollutant discharge units are divided into key management and simplified management pursuant to the amount of pollutant caused and discharged and the impact on the environment. The review, decision and information disclosure of pollutant discharge licenses shall be handled through the national pollutant discharge license management information platform. The pollutant discharge license is valid for 5 years and the discharging units should apply for renewal 60 days before the expiry for the continues pollutant discharge.

Acceptance Inspection on Environmental Protection Facilities

The Construction Environmental Protection Rule also requires that upon completion of construction for which an environment impact report or environment impact statement is formulated, the constructor shall conduct acceptance inspection of the environmental protection facilities pursuant to the standards and procedures stipulated by the environmental protection administrative authorities of the State Council, formulate the acceptance inspection report, and announce the acceptance inspection report pursuant to the law except for circumstances where there is a need to keep confidentiality pursuant to the provisions of the State. Where the environmental protection facilities have not undergone acceptance inspection or do not pass acceptance inspection, the construction project shall not be put into production or use.

Fire Prevention Design and Acceptance

The *Fire Prevention Law of the PRC* (《中華人民共和國消防法》), or the Fire Prevention Law, was adopted on April 29, 1998 and latest amended on April 29, 2021. According to the Fire Prevention Law, for special construction projects stipulated by the housing and urban-rural development authority of the State Council, the developer shall submit the fire safety design documents to the housing and urban-rural development authority for examination, while for construction projects other than those stipulated as special development projects, the developer shall, at the time of applying for the construction permit or approval for work commencement report, provide the fire safety design drawings and technical materials which satisfy the construction needs. According to *Interim Regulations on Administration of Examination and Acceptance of Fire Control Design of Construction Projects* (《建設工程消防設計審查驗收管理暫行規定》) issued by the Ministry of Housing and Urban-Rural Development of the PRC on April 1, 2020, an examination system for fire prevention design and acceptance only applies to special construction projects, and for other projects, a record-filing and spot check system would be applied.

LAWS AND REGULATIONS RELATING TO EMPLOYMENT AND SOCIAL SECURITIES

Employment

The major PRC laws and regulations that govern employment relationship are the *Labor Law of the PRC* (《中華人民共和國勞動法》), or the Labor Law, issued by the SCNPC on July 5, 1994, effective on January 1, 1995 and revised on August 27, 2009 and December 29, 2018, the *Labor Contract Law of the PRC* (《中華人民共和國勞動合同法》), or the Labor Contract Law, which was promulgated by the SCNPC on June 29, 2007 and became effective on January 1, 2008, and then amended on December 28, 2012, and the *Implementation Rules of the Labor Contract Law of the PRC* (《中華人民共和國勞動合同法實施條例》), which was issued by the State Council on September 18, 2008 and came into effect on the same day. According to the aforementioned laws and regulations, labor relationships between employers and employees must be executed in written form. The laws and regulations above impose stringent requirements on the employers in relation to entering into fixed-term employment contracts, hiring of temporary employees and dismissal of employees. As prescribed under the

REGULATION OVERVIEW

laws and regulations, employers shall ensure its employees have the right to rest and the right to receive wages no lower than the local minimum wages. Employers must establish a system for labor safety and sanitation that strictly abide by state standards and provide relevant education to its employees. Violations of the Labor Contract Law and the Labor Law may result in the imposition of fines and other administrative liabilities and/or incur criminal liabilities in the case of serious violations.

Social Securities

According to the *Social Insurance Law of PRC* (《中華人民共和國社會保險法》), which issued by the SCNPC on October 28, 2010 and came into effect on July 1, 2011 and was newly revised on December 29, 2018, enterprises and institutions in the PRC shall provide their employees with welfare schemes covering basic pension insurance, unemployment insurance, maternity insurance, work-related injury insurance and basic medical insurance. The employer shall apply to the local social insurance agency for social insurance registration within 30 days from the date of its formation. And it shall, within 30 days from the date of employment, apply to the social insurance agency for social insurance registration for the employee. Any employer who violates the regulations above shall be ordered to make correction within a prescribed time limit; if the employer fails to rectify within the time limit, the employer and its directly liable person will be fined. If the employer fails to pay social insurance contributions on time and in full, the social insurance agency shall place an order with the employer demanding full payment within a prescribed period, and an overdue payment fine at the rate of 0.5% shall be levied as of the date of indebtedness. When the payment is not made at the expiry of the prescribed period, a fine above the overdue amount but less than its triple shall be demanded by the authoritative administrative department. Meanwhile, the *Interim Regulation on the Collection and Payment of Social Insurance Premiums* (《社會保險費徵繳暫行條例》) (issued by the State Council on January 22, 1999 and came into effect on the same day and was recently revised on March 24, 2019) prescribes the details concerning the social securities.

Apart from the general provisions about social insurance, specific provisions on various types of insurance are set out in the *Regulation on Work-Related Injury Insurance* (《工傷保險條例》) (issued by the State Council on April 27, 2003, came into effect on January 1, 2004 and revised on December 20, 2010), the *Regulations on Unemployment Insurance* (《失業保險條例》) (issued by the State Council on January 22, 1999 and came into effect on the same day), the *Trial Measures on Employee Maternity Insurance of Enterprises* (《企業職工生育保險試行辦法》) (issued by the Ministry of Labor on December 14, 1994 and came into effect on January 1, 1995). Enterprises subject to these regulations shall provide their employees with the corresponding insurance.

Housing Provident Fund

According to the *Regulation Concerning the Administration of Housing Provident Fund* (《住房公積金管理條例》), implemented since April 3, 1999 and amended on March 24, 2002 and March 24, 2019, any newly established entity shall make deposit registration at the housing accumulation fund management center within 30 days as of its establishment. After that, the entity shall open a housing accumulation fund account for its employees in an entrusted bank. Within 30 days as of the date an employee is recruited, the entity shall make deposit registration at the housing accumulation fund management center and seal up the employee's housing accumulation fund account in the bank mentioned above within 30 days from termination of the employment relationship.

Any entity that fails to make deposit registration of the housing accumulation fund or fails to open a housing accumulation fund account for its employees shall be ordered to complete the relevant procedures within a prescribed time limit. Any entity failing to complete the relevant procedure within the time limit will be fined RMB10,000 to RMB50,000. Any entity fails to make payment of housing provident fund within the time limit or has shortfall in

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payment of housing provident fund will be ordered to make the payment or make up the shortfall within the prescribed time limit, otherwise, the housing provident management center is entitled to apply for compulsory enforcement with the People’s Court.

LAWS AND REGULATIONS RELATING TO INTELLECTUAL PROPERTIES

Patents

Pursuant to the *Patent Law of the PRC* (《中華人民共和國專利法》), or the Patent Law, which was issued by the SCNPC on March 12, 1984, and latest revised on October 17, 2020 and came into effect on June 1, 2021, any organization or individual proposing to implement the patent of others shall enter into a licensing contract with the patentee for implementation and pay royalties to the patentee. A licensee shall have no right to allow any other organization or individual that is not stipulated in the contract to implement such patent.

Trademarks

Pursuant to the *Trademark Law of the PRC* (《中華人民共和國商標法》) which was promulgated on August 23, 1982 and last amended on April 23, 2019 and came into effect on November 1, 2019, the *Implementation Regulations of the Trademark Law of PRC* (《中華人民共和國商標法實施條例》) which was issued on August 3, 2002 and amended on April 29, 2014, the Trademark Office under the State Administration for Industry and Commerce of the PRC, or the Trademark Office, shall handle trademark registrations and grant a term of ten years to registered trademarks, which may be renewed for additional ten year period upon request from the trademark owner. The Trademark Law of the PRC has adopted a “first-to-file” principle with respect to trademark registration. Where an application for trademark for which application for registration has been made is identical or similar to another trademark which has already been registered or is under preliminary examination and approval for use on the same kind of or similar commodities or services, the application for registration of such trademark may be rejected. Any person applying for the registration of a trademark may not prejudice the existing right of others, nor may any person register in advance a trademark that has already been used by another party and has already gained a “sufficient degree of reputation” through such party’s use. A trademark registrant may, by entering into a trademark licensing contract, license another party to use its registered trademark. Where another party is licensed to use a registered trademark, the licensor shall report the license to the Trademark Office for recordation, and the Trademark Office shall publish it. An unrecorded license may not be used as a defense against a third party in good faith.

Domain Names

In accordance with the *Measures for the Administration of Internet Domain Names* (《互聯網域名管理辦法》) which was issued by the Ministry of Information Industry on August 24, 2017 and came into effect on November 1, 2017, the Ministry of Information Industry is responsible for supervision and administration of domain name services in the PRC. Communication administrative bureaus at provincial levels shall conduct supervision and administration of the domain name services within their respective administrative jurisdictions. Domain name registration services shall, in principle, be subject to the principle of “first apply, first register”. A domain name registrar shall, in the process of providing domain name registration services, ask the applicant for which the registration is made to provide authentic, accurate and complete identity information on the holder of the domain name and other domain name registration related information.

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LAWS AND REGULATIONS RELATING TO FOREIGN EXCHANGE AND OVERSEAS INVESTMENT

On January 29, 1996, the State Council promulgated the *Administrative Regulations on Foreign Exchange of the PRC* (《中華人民共和國外匯管理條例》) which became effective on April 1, 1996 and was amended on January 14, 1997 and August 5, 2008. Foreign exchange payments under current account items shall, pursuant to the administrative provisions of the foreign exchange control department of the State Council on payments of foreign currencies and purchase of foreign currencies, be made using self-owned foreign currency or foreign currency purchased from financial institutions engaging in conversion and sale of foreign currencies by presenting the valid document. Domestic entities and domestic individuals making overseas direct investments or engaging in issuance and trading of overseas securities and derivatives shall process registration formalities pursuant to the provisions of the foreign exchange control department of the State Council.

On November 19, 2012, the State Administration of Foreign Exchange, or the SAFE, issued the *Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on Foreign Direct Investment* (《國家外匯管理局關於進一步改進和調整直接投資外匯管理政策的通知》), or the SAFE Circular 59, which came into effect on December 17, 2012 and was revised on May 4, 2015, October 10, 2018 and partially abolished on December 30, 2019. The SAFE Circular 59 aims to simplify the foreign exchange procedure and promote the facilitation of investment and trade. According to the SAFE Circular 59, the opening of various special purpose foreign exchange accounts, such as pre-establishment expenses accounts, foreign exchange capital accounts and guarantee accounts, the reinvestment of RMB proceeds derived by foreign investors in the PRC, and remittance of foreign exchange profits and dividends by a foreign-invested enterprise to its foreign shareholders no longer require the approval or verification of SAFE, as well multiple capital accounts for the same entity may be opened in different provinces. Later, the SAFE promulgated the *Circular on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of Direct Investment* (《關於進一步簡化和改進直接投資外匯管理政策的通知》) in February 2015, which was partially abolished in December 2019 and prescribed that the bank instead of SAFE can directly handle the foreign exchange registration and approval under foreign direct investment while SAFE and its branches indirectly supervise the foreign exchange registration and approval under foreign direct investment through the bank.

On May 10, 2013, the SAFE issued the *Administrative Provisions on Foreign Exchange in Domestic Direct Investment by Foreign Investors* (《外國投資者境內直接投資外匯管理規定》), or the SAFE Circular 21, which became effective on May 13, 2013, amended on October 10, 2018 and partially abolished on December 30, 2019. The SAFE Circular 21 specifies that the administration by SAFE or its local branches over direct investment by foreign investors in the PRC must be conducted by way of registration and banks must process foreign exchange business relating to the direct investment in the PRC based on the registration information provided by SAFE and its branches.

According to the *Notice of the State Administration of Foreign Exchange on Reforming the Management Mode of Foreign Exchange Capital Settlement of Foreign Investment Enterprises* (《國家外匯管理局關於改革外商投資企業外匯資本金結匯管理方式的通知》), or the SAFE Circular 19 promulgated on March 30, 2015, coming effective on June 1, 2015 and partially abolished on December 30, 2019, foreign-invested enterprises could settle their foreign exchange capital on a discretionary basis according to the actual needs of their business operations. Whilst, foreign-invested enterprises are prohibited to use the foreign exchange capital settled in RMB (a) for any expenditures beyond the business scope of the foreign-invested enterprises or forbidden by laws and regulations; (b) for direct or indirect securities investment; (c) to directly or indirectly provide entrusted loans (unless permitted in the

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business scope), repay loans between enterprises (including advances by third parties) or repay RMB bank loans that have been relented to a third party; and (d) to purchase real estates not for self-use purposes (save for real estate enterprises).

On June 9, 2016, SAFE issued the *Notice of the State Administration of Foreign Exchange on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account* (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》), or the SAFE Circular 16, which came into effect on the same day. The SAFE Circular 16 provides that discretionary foreign exchange settlement applies to foreign exchange capital, foreign debt offering proceeds and remitted foreign listing proceeds, and the corresponding RMB capital converted from foreign exchange may be used to extend loans to related parties or repay inter-company loans (including advances by third parties). However, there remain substantial uncertainties with respect to SAFE Circular 16's interpretation and implementation in practice.

On October 23, 2019, SAFE promulgated the *Notice on Further Facilitating Cross-Board Trade and Investment* (《國家外匯管理局關於進一步促進跨境貿易投資便利化的通知》), which became effective on the same date (except for Article 8.2, which became effective on January 1, 2020). The notice cancelled restrictions on domestic equity investments made with capital funds by non-investing foreign-funded enterprises. In addition, restrictions on the use of funds for foreign exchange settlement of domestic accounts for the realization of assets have been removed and restrictions on the use and foreign exchange settlement of foreign investors' security deposits have been relaxed. Eligible enterprises in the pilot area are also allowed to use revenues under capital accounts, such as capital funds, foreign debts and overseas listing revenues for domestic payments without providing materials to the bank in advance for authenticity verification on an item-by-item basis, while the use of funds should be true, in compliance with applicable rules and conforming to the current capital revenue management regulations.

Pursuant to the *Circular of the SAFE on Relevant Issues concerning Foreign Exchange Administration of Overseas Investment and Financing and Round-tripping Investments Conducted by Domestic Residents through Overseas Special Purpose Vehicles* (《國家外匯管理局關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》), or the Circular 37, which was promulgated by the SAFE and became effective on July 4, 2014, a PRC resident shall register with the local SAFE branch before he or she contributes assets or equity interests in an overseas special purpose vehicle, or the Overseas SPV, that is directly established or controlled by the PRC resident for the purpose of conducting investment or financing. Following the initial registration, if there is any change in the basic information of the Overseas SPV, such as the PRC resident individual shareholder, name, term of business, or a significant change such as increase or reduction of capital contribution, equity transfer or exchange by the PRC resident individual, merger or division, foreign exchange registration change formalities shall be promptly completed with the foreign exchange bureau. Pursuant to the *Circular of the SAFE on Further Simplifying and Improving the Direct Investment Related Foreign Exchange Administration Policies* (《國家外匯管理局關於進一步簡化和改進直接投資外匯管理政策的通知》), or the Circular 13, which was promulgated on February 13, 2015 and became effective on June 1, 2015, the above mentioned registration will be handled directly by the bank that has obtained the financial institution identification codes issued by the foreign exchange regulatory authorities and has opened the capital account information system at the foreign exchange regulatory authorities in the place where it is located and the foreign exchange regulatory authorities shall perform indirect regulation over the direct investment related foreign exchange registration via banks.

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LAWS AND REGULATIONS RELATING TO TAXATION

Enterprise Income Tax

The *Enterprise Income Tax Law of the PRC* (《中華人民共和國企業所得稅法》), or the EIT Law, promulgated by the NPC on March 16, 2007, came into effect on January 1, 2008 and amended on February 24, 2017 and December 29, 2018, as well as the *Implementation Rules of the EIT Law* (《中華人民共和國企業所得稅法實施條例》), or the EIT Implementation Rules, promulgated by the State Council on December 6, 2007, came into force on January 1, 2008 and amended on April 23, 2019, are the principal law and regulation governing enterprise income tax in the PRC. According to the EIT Law and the EIT Implementation Rules, enterprises are classified into resident enterprises and non-resident enterprises. Resident enterprises refer to enterprises that are legally established in the PRC, or are established under foreign laws but whose actual management bodies are located in the PRC. And non-resident enterprises refer to enterprises that are legally established under foreign laws and have set up institutions or sites in the PRC but with no actual management body in the PRC, or enterprises that have not set up institutions or sites in the PRC but have derived incomes from the PRC. A uniform income tax rate of 25% applies to all resident enterprises and non-resident enterprises that have set up institutions or sites in the PRC to the extent that such incomes are derived from their set-up institutions or sites in the PRC, or such income are obtained outside the PRC but have an actual connection with the set-up institutions or sites. And non-resident enterprises that have not set up institutions or sites in the PRC or have set up institutions or sites but the incomes obtained by the said enterprises have no actual connection with the set-up institutions or sites, shall pay enterprise income tax at the rate of 10% in relation to their income sources from the PRC.

Withholding Tax

Pursuant to the EIT Law and the EIT Implementing Rules, if a non-resident enterprise has not set up an organization or establishment in the PRC, or has set up an organization or establishment but the income derived has no actual connection with such organization or establishment, it will be subject to a withholding tax on its PRC-sourced income at a rate of 10%. According to the *Arrangement between Mainland China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Tax Evasion on Income* (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》) effective from August 21, 2006, dividends repatriated from a PRC entity to its Hong Kong shareholder owning more than 25% of the its capital would be entitled to a reduced withholding tax rate of 5% subject to certain conditions.

The State Taxation Administration, or the SAT, issued the *Administrative Measures on Entitlement of Non-residents to Treatment under Treaties* (《非居民納稅人享受協定待遇管理辦法》) on October 14, 2019 and effective on January 1, 2020, which applies to non-resident taxpayers who have tax liability in China and need to claim treaty benefits. Non-resident taxpayers enjoying its tax treaty benefits shall adopt the method of “self-assessment, claims by declaration and retention of the relevant materials for future inspection”. Non-resident taxpayers who make their own declaration shall make self-assessment regarding whether they are entitled to tax treaty benefits and submit the relevant reports, statements and materials as required, and simultaneously collect and retain the relevant materials for future inspection. Also, tax authorities at any level shall, through strengthening follow-up administration for non-resident taxpayers’ entitlement to tax treaty benefits, implement tax treaties accurately and prevent risks of indiscriminately application of tax treaties, tax evasion and tax avoidance.

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Value-Added Tax

The major PRC law and regulation governing value-added tax are the *Interim Regulations on Value-added Tax of the PRC* (《中華人民共和國增值稅暫行條例》) (issued on December 13, 1993 by the State Council, came into effect on January 1, 1994, and revised on November 10, 2008, February 6, 2016 and November 19, 2017), as well as the *Implementation Rules for the Interim Regulations on Value-Added Tax of the PRC* (《中華人民共和國增值稅暫行條例實施細則》) (issued on December 25, 1993 by the Ministry of Finance, or the MOF, came into effect on the same day and revised on December 15, 2008 and October 28, 2011), any entities and individuals engaged in the sale of goods, supply of processing, repair and replacement services, and import of goods within the territory of the PRC are taxpayers of VAT and shall pay the VAT in accordance with the law and regulation. Unless otherwise required, the rate of VAT shall be 17%.

On March 23, 2016, the MOF and the SAT issued the *Notice of the Ministry of Finance and the State Taxation Administration on Full Launch of the Pilot Scheme on Levying Value-added Tax in Place of Business Tax* (《財政部、國家稅務總局關於全面推開營業稅改徵增值稅試點的通知》), under which the rate of VAT shall be (1) 11% for providing transportation, postal, basic telecommunication, construction services, leasing of immovables, sale of immovables and transfer of land use right; (2) 17% for providing leasing services of tangible movables; (3) zero for cross-border taxable acts of entities or individuals in China, and the specific scope shall be separately stipulated by the MOF and the SAT; and (4) 6% for the other items stipulated in above items.

With the VAT reforms in the PRC, the rate of VAT has been changed several times. The MOF and the SAT issued the *Notice of on Adjusting VAT Rates* (《關於調整增值稅稅率的通知》) on April 4, 2018 to adjust the tax rates of 17% and 11% applicable to any taxpayer's VAT taxable sale or import of goods to 16% and 10%, respectively, this adjustment became effect on May 1, 2018. Subsequently, the MOF, the SAT and the General Administration of Customs jointly issued the *Announcement on Relevant Policies for Deepening the VAT Reform* (《關於深化增值稅改革有關政策的公告》) on March 20, 2019 to make a further adjustment that the tax rate of 16% applicable to the VAT taxable sale or import of goods shall be adjusted to 13%, and the tax rate of 10% applicable thereto shall be adjusted to 9%.

REGULATIONS FOR COVID-19 VACCINES

EMA Regulations

Vaccine development for COVID-19 vaccines is being fast-tracked globally. EMA offers informal consultation with its COVID-19 Task Force (ETF) and rapid scientific advice. COVID-19 vaccine developers can receive prompt guidance and direction on the best methods and study designs to generate robust data.

- Vaccine manufacturers and academics use established production systems already used for safe and effective vaccines. In addition, they continuously research novel approaches to producing and developing vaccines, and some of the advances made to date are also applied to developing vaccines for COVID-19.
- Some vaccines for COVID-19 are developed using novel methods intended to increase the volume and speed of production compared to other types of vaccines, enhance product stability and bring about strong immune responses.
- Other vaccines are developed using existing methods used for vaccines for other diseases, making it easier to use existing production facilities to produce COVID-19 vaccines at a large scale than for newer vaccine types.

REGULATION OVERVIEW

COVID-19 vaccines can only be approved and used if they comply with all the requirements of quality, safety and efficacy set out in the EU pharmaceutical legislation.

The EU’s pharmaceutical legislation ensures that vaccines are only approved after scientific evaluation has demonstrated that their overall benefits outweigh their risks. A vaccine’s benefits in protecting people against COVID-19 must be far greater than any side effect or potential risks.

To gain approval for a vaccine in the EU, the vaccine developer submits the results of all testing/investigations to the medicines regulatory authorities in Europe. This is part of a marketing authorisation application. EMA can also use its rolling review procedure for promising medicines for COVID-19. This allows EMA to begin assessing data as they become available during the development process, to expedite the subsequent formal marketing authorisation application assessment even further.

WHO Regulations

The WHO Emergency Use Listing (EUL) is a procedure for assessing unlicensed vaccines, therapeutics and in vitro diagnostics during public health emergencies with the ultimate goal of expediting the availability of these products to people who need them.

The EUL is used during public health emergencies, such as COVID-19 pandemic. When products are not licensed yet (still in development), WHO will assess the quality, safety and efficacy (or performance) data generated during development and conduct a risk-benefit assessment to decide if they can be used outside clinical trials.

WHO will assess the suitability of products from a global public health perspective and, on a case-by-case basis, may assess aspects of the quality, safety, efficacy and performance of the products. The EUL allows products in development (not licensed) to be assessed by WHO for listing. WHO review is expedited to ensure timely evaluation.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

OVERVIEW

We are a global clinical-stage biotechnology company committed to developing novel vaccines and biologic therapeutic candidates for infectious diseases as well as cancer and autoimmune diseases. The history of our Group can be traced back to June 2007, when Dr. Liang, our Chairman and Chief Scientific Officer, established Sichuan Clover to develop a new generation of biologics based on the Trimer-Tag™ technology platform he invented. For more information on the experiences and background of Dr. Liang, please refer to the section headed “Directors and Management.”

Our Company was incorporated in the Cayman Islands as an exempted company with limited liability on October 31, 2018 and has been an investment holding company since incorporation. As part of the Reorganization, our Company became the holding company and the [REDACTED] vehicle of our Group.

MILESTONES OF DEVELOPMENT

The following is a summary of our major business development milestones:

Year	Event
June 2007	Sichuan Clover was established as a research laboratory.
December 2011	We completed the Angel Round Investment (as defined below) and raised RMB10 million.
November 2015	Sichuan Clover completed IND filing for SCB-808.
December 2015	Sichuan Clover initiated GLP studies on SCB-313 at the National Shanghai Center for New Drug Safety Evaluation and Research.
January 2016	Sichuan Clover commenced research on HIV subunit vaccine.
July 2016	Sichuan Clover entered into an agreement to establish and build 32,000 sqm commercial-scale cGMP biomanufacturing facility in Changxing, Zhejiang Province, China.
December 2017	We completed the Series A Investment (as defined below) and raised approximately RMB62.8 million.
June 2018	Our first patient was dosed with SCB-313 for treatment of cancer patients with malignant ascites in Phase 1 clinical trial.
November 2019	We completed the Series B Investment (as defined below) and raised approximately RMB304.1 million.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Year	Event
January 2020	We initiated development of SCB-2019 (CpG 1018/Alum), our COVID-19 vaccine candidate.
April 2020	We obtained funding from and established collaboration with CEPI for SCB-2019 (CpG 1018/Alum).
May 2020	We completed the Series B-2 Investment (as defined below) and raised approximately RMB171.8 million.
June 2020	Our first participant was dosed with SCB-2019 (CpG 1018/Alum) in a Phase I clinical trial.
November 2020	CEPI extended partnership with us to fund up to US\$328 million for SCB-2019 (CpG 1018/Alum) through a global Phase 2 and Phase 3 clinical trial.
December 2020	We announced positive Phase 1 data for SCB-2019 (CpG 1018/Alum), our COVID-19 vaccine candidate.
February 2021	We completed the Series C Investment (as defined below) and raised approximately US\$230 million.
March 2021	We initiated the global Phase 2/3 clinical trial of SCB-2019 (CpG 1018/Alum) and dosed the first participant at a clinical trial site located in the Philippines.
June 2021	We completed an advanced purchase agreement with GAVI to supply up to 414 million doses of our COVID-19 vaccine candidate for procurement through the COVAX Facility.
June 2021	We completed a commercial supply agreement with Dynavax for their CpG 1018 adjuvant for use in SCB-2019 (CpG 1018/Alum).
July 2021	CEPI additionally endorsed US\$32.8 million to a total of up to US\$360.5 million for SCB-2019 (CpG 1018/Alum) CMC activities.
September 2021	We obtained and announced results from SPECTRA, our global pivotal Phase 2/3 clinical trial for SCB-2019 (CpG 1018/Alum).

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

OUR GROUP

Our Company

Our Company was incorporated as an exempted company with limited liability in the Cayman Islands on October 31, 2018 with an authorized share capital of US\$50,000 divided into 500,000,000 shares with par value of US\$0.0001 each. Immediately after its incorporation, one Share was issued and transferred to Dr. Liang.

Our Principal Operating Entities

As at the Latest Practicable Date, we had three principal operating entities, namely Sichuan Clover, Zhejiang Clover and Australia Clover, which made material contributions to our results of operation during the Track Record Period. The details of our principal operating entities are set forth below:

Name of Entity	Principal Business Activities	Date of Establishment/ Incorporation	Place of Establishment/ Incorporation
Sichuan Clover	research and development as well as manufacturing	June 4, 2007	the PRC
Zhejiang Clover	clinical and commercial manufacturing	August 23, 2016	the PRC
Australia Clover	research and development	June 6, 2017	Australia

Sichuan Clover

Establishment and Early Development

Sichuan Clover was established as a wholly foreign-owned company by Dr. Liang through GenHunter, a company controlled by Dr. Liang, in the PRC on June 4, 2007 with an initial registered capital of RMB50 million. At the time of its establishment, the registered capital of RMB50 million was not fully paid up. In May 2008, GenHunter transferred its 100% equity interest in Sichuan Clover to Dr. Liang at a nominal consideration.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Angel Round Investment

On December 1, 2011, Dr. Liang entered into an equity transfer agreement with Chengdu Tianhe Conventional Chinese and Medicine Technology Nurture Co., Ltd. (成都天河中西醫科技保育有限公司) (“**Chengdu Tianhe**”), pursuant to which Dr. Liang agreed to transfer 20% of the unpaid registered capital of Sichuan Clover, i.e. RMB10 million, to Chengdu Tianhe and Chengdu Tianhe agreed to pay up such registered capital accordingly (the “**Angel Round Investment**”). As at March 1, 2012, the registered capital of Sichuan Clover has been fully paid by Chengdu Tianhe paying RMB10 million in cash and Dr. Liang paying RMB40 million with a combination of cash and intangible assets.

The shareholding structure of Sichuan Clover following the completion of the Angel Round Investment was set forth below:

Name of Shareholder	Amount of registered capital (RMB)	Shareholding Percentage
Dr. Liang	40 million	80%
Chengdu Tianhe	10 million	20%
Total	50 million	100%

Transfer of Interest by Dr. Liang to Nominators

In March 2012, Dr. Liang agreed to transfer RMB4,000,000, RMB2,000,000, RMB1,200,000 and RMB800,000 of the registered capital, representing 8%, 4%, 2.4% and 1.6% of the total equity interest, of Sichuan Clover to Dr. Xiaodong Wang, Dr. Jianwei Zhu, Mr. Zheng Ping and Mr. Pu Jiang at the considerations of RMB40,000, RMB20,000, RMB12,000 and RMB8,000, respectively, to recognize their contribution in providing strategic advice and guidance on the research and development and management of Sichuan Clover since its establishment and incentivize them to continue making efforts to our long-term development. Further in January 2016, Dr. Liang agreed to transfer RMB2,500,000 of the registered capital, representing 5% of the total equity interest, of Sichuan Clover to his son Mr. Joshua Liang, an executive Director and the chief executive officer of our Company (together with Dr. Xiaodong Wang, Dr. Jianwei Zhu, Mr. Zheng Ping and Mr. Pu Jiang the “**Nominators**”) at nil consideration. Taking into account the administrative cost and burden that may be incurred with respect to such transfers, Dr. Liang had held such registered capital as nominee for the Nominators since the date of the respective equity transfer arrangements until September 2019, when he transferred all the registered capital he held on his own and on behalf of the Nominators to HK Clover, and since then HK Clover held the relevant registered capital as nominee for the Nominators (the “**Trust Arrangements**”). Such Trust Arrangements were terminated on March 16, 2021 when our Company allotted and issued a total of

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

10,500,000 Shares to the Nominators or their offshore holding companies on a pro-rata basis with reference to their beneficial interests in Sichuan Clover as part of the Reorganization. Please refer to the paragraph headed “– Reorganization – Step 2. Allotment and Issue of Shares to Our Individual Shareholders” for further details. As advised by our PRC Legal Adviser, the PRC laws and regulations do not prohibit trust arrangement.

Series A Investment

From August to December 2017, Sichuan Clover entered into several capital increase agreements with, among others, Sichuan Tianhe Biomedicine Venture Capital Fund Partnership Enterprise (Limited Partnership) (四川天河生物醫藥產業創業投資基金合夥企業(有限合夥)) (“**Sichuan Tianhe**”), Nanjing Songweijun Information Technology Co., Ltd. (南京崧維駿信息技術有限公司) (“**Nanjing Songweijun**”) and Zhejiang Changxing Jinkong Holdings Co., Ltd. (浙江長興金控控股股份有限公司) (“**Changxing Jinkong**”), pursuant to which Sichuan Tianhe, Nanjing Songweijun and Changxing Jinkong agreed to subscribe for RMB4.38 million, RMB1.51 million and RMB1,961,413 of the registered capital of Sichuan Clover at considerations of RMB35 million, RMB12.07 million and RMB15.69 million, respectively (the “**Series A Investment**”). The considerations were determined after arm’s length negotiation taking into consideration the research and development progress of the product candidates of our Group at that time, i.e. SCB-313 and SCB-808.

The shareholding structure of Sichuan Clover following the completion of the Round A Investment was set forth below:

Name of Shareholder	Amount of registered capital (RMB)	Shareholding Percentage
HK Clover ^(note)	40,000,000	69.14%
Chengdu Tianhe	10,000,000	17.29%
Sichuan Tianhe	4,380,000	7.57%
Nanjing Songweijun	1,510,000	2.61%
Changxing Jinkong	1,961,413	3.39%
Total	57,851,413	100%

Note: In September 2019, Dr. Liang transferred the entire equity interests he held in Sichuan Clover for himself and on behalf of the Nominators to HK Clover, an entity wholly owned by him at that time. As such, the registered capital held by HK Clover in Sichuan Clover after such transfer included an aggregate amount of RMB10,500,000 held as nominee for the Nominators pursuant to the Trust Arrangements.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Series B Investment

From September to November 2019, Sichuan Clover entered into several capital increase agreements with, among others, Elasa, Beijing Lapam Healthcare Investment Center (Limited Partnership) (北京龍磐健康醫療投資中心(有限合夥)) (“**Lapam Fund III**”), Hangzhou Yuhang Lapam Healthcare Equity Investment Fund Partnership Enterprise (Limited Partnership) (杭州余杭龍磐健康醫療股權投資基金合夥企業(有限合夥)) (“**Lapam Fund IV**”), Hangzhou Beixin Equity Investment Fund Partnership (Limited Partnership) (杭州貝欣股權投資基金合夥企業(有限合夥)) (“**Beixin Fund**”), Beijing Kaiyuan Hongdao Venture Capital Investment Center (北京開元弘道創業投資中心(有限合夥)) (“**Kaiyuan Hongdao**”), Sichuan Provincial Health Care Equity Investment Fund Partnership Enterprise (Limited Partnership) (四川省健康養老產業股權投資基金合夥企業(有限合夥)) (“**Sichuan Health Care**”) and Hangzhou Golden Dragon Group Corp., Ltd. (杭州金龍集團有限公司) (“**Hangzhou Golden Dragon**”) pursuant to which Elasa, Lapam Fund III, Lapam Fund IV, Beixin Fund, Kaiyuan Hongdao, Sichuan Healthcare and Hangzhou Golden Dragon agreed to subscribe for RMB8,951,401, RMB5,021,824, RMB7,030,554, RMB1,506,547, RMB2,008,730, RMB5,021,824 and RMB1,004,365 of the of the registered capital of Sichuan Clover at considerations of RMB89.125 million, RMB50 million, RMB70 million, RMB15 million, RMB20 million, RMB50 million and RMB10 million, respectively (the “**Series B Investment**”). The considerations were determined after arm’s length negotiation after taking into consideration the substantial research and clinical development of our pipeline products achieved in 2018 and 2019 and the progress of the construction of our manufacturing facility in Changxing, Zhejiang Province, China.

On December 31, 2019, Changxing Jinkong entered into an equity transfer agreement with Qianhai Funds of Funds (Limited Partnership) (前海股權投資基金(有限合夥)) (“**Qianhai FoF**”), pursuant to which Changxing Jinkong agreed to transfer the entire equity interests in Sichuan Clover it held to Qianhai FoF at a consideration of RMB19,528,890. The consideration was determined after arm’s length negotiation.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

The shareholding structure of Sichuan Clover following the completion of the Series B Investment and the above transfer was set forth below:

Name of Shareholder	Amount of registered capital (RMB)	Shareholding Percentage
HK Clover	40,000,000	45.26%
Chengdu Tianhe	10,000,000	11.31%
Sichuan Tianhe	4,380,000	4.95%
Nanjing Songweijun	1,510,000	1.71%
Qianhai FoF	1,961,413	2.22%
Elasa	8,951,401	10.13%
Lapam Fund III	5,021,824	5.68%
Lapam Fund IV	7,030,554	7.95%
Beixin Fund	1,506,547	1.70%
Kaiyuan Hongdao	2,008,730	2.27%
Sichuan Health Care	5,021,824	5.68%
Hangzhou Golden Dragon	1,004,365	1.14%
Total	88,396,658	100%

Series B-2 Investment

On May 29, 2020, Sichuan Clover, Dr. Liang, HK Clover and AUT-XXI HK Holdings Limited (“**AUT-XXI**”) entered into a capital increase agreement pursuant to which AUT-XXI agreed to subscribe for RMB10,399,596 of the registered capital of Sichuan Clover at a consideration of RMB171,786,000 (the “**Series B-2 Investment**”). The consideration was determined after arm’s length negotiation taking into consideration the technology and development of our COVID-19 vaccine candidate, SCB-2019 (CpG 1018/Alum) as a response to the COVID-19 pandemic.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

The shareholding structure of Sichuan Clover following the completion of the Series B-2 Investment was set forth below:

Name of Shareholder	Amount of registered capital (RMB)	Shareholding Percentage
HK Clover	40,000,000	40.49%
Chengdu Tianhe	10,000,000	10.12%
Sichuan Tianhe	4,380,000	4.43%
Nanjing Deauville ^(note)	1,510,000	1.53%
Qianhai FoF	1,961,413	1.99%
Elasa	8,951,401	9.06%
Lapam Fund III	5,021,824	5.08%
Lapam Fund IV	7,030,554	7.12%
Beixin Fund	1,506,547	1.52%
Kaiyuan Hongdao	2,008,730	2.03%
Sichuan Health Care	5,021,824	5.08%
Hangzhou Golden Dragon	1,004,365	1.02%
AUT-XXI	10,399,596	10.53%
Total	98,796,254	100%

Note: In September 2020, Nanjing Songweijun transferred the entire equity interests it held in Sichuan Clover to its affiliate, Nanjing Deauville Equity Investment Partnership (General Partnership) (南京德奧維爾股權投資管理合夥企業(普通合夥)) (“Nanjing Deauville”).

For information and further shareholding changes of Sichuan Clover during the Reorganization, please refer to the paragraph headed “– Reorganization”.

Zhejiang Clover

Zhejiang Clover was established by Sichuan Clover as a wholly foreign-owned company in the PRC on August 23, 2016. The initial registered capital of Zhejiang Clover was RMB50 million upon its establishment and was increased to RMB70 million in June 2020. Zhejiang Clover is principally engaged in clinical and commercial manufacturing.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Australia Clover

Australia Clover was incorporated as a proprietary company limited by shares in Australia on June 6, 2017. Sichuan Clover was the sole shareholder of Australia Clover upon its incorporation. On March 16, 2021, Sichuan Clover transferred the entire equity interest in Australia Clover to our Company. Australia Clover is principally engaged in research and development.

ISSUANCE AND CONVERSION OF CONVERTIBLE NOTES

On February 10, 2021, our Company entered into a note purchase agreement with, among others, the Series C Investors in relation to the issuance of certain convertible promissory notes (the “**Convertible Notes**”) in the aggregate principal amount of US\$230,000,013.37 (the “**Series C Investment**”). The consideration was determined after arm’s length negotiation taking into consideration our progress on developing the COVID-19 vaccine candidate, SCB-2019 (CpG 1018/Alum) and the expansion of our management team. The consideration was fully settled on February 16, 2021. The table below sets out the identity and investment amount of each Series C Investor. On March 16, 2021, the Convertible Notes were fully converted into Series C Preferred Shares. Please refer to the paragraph headed “– Reorganization – Step 4. Conversion of the Convertible Notes” for further details.

Name of Investors	Amount of Investment <i>(US\$)</i>
JNRY V Holdings Limited	95,000,002.74
Aranda Investments Pte. Ltd.	95,000,002.74
Oceanpine Investment Fund II LP	12,000,003.04
The Biotech Growth Trust PLC	6,999,996.16
OrbiMed New Horizons Master Fund, L.P.	2,000,002.75
OrbiMed Genesis Master Fund, L.P.	1,000,001.38
Elasa	10,000,000.29
C&D Emerging Industry International Investment Limited	5,000,000.14
Easter Lily Global Limited	1,000,001.38
Mindtouch High Technology Co., Limited	1,000,001.38
Score High Holdings Limited	1,000,001.38
Total	<u><u>230,000,013.37</u></u>

Issuance of Shares to Super Novel

On July 1, 2021 and October 8, 2021, we allotted and issued 7,250,000 and 3,800,000 ordinary Shares, respectively to Super Novel which holds the shares underlying the awards under the RSU Scheme.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

ACTING-IN-CONCERT DEED AND VOTING PROXY AGREEMENTS

Dr. Liang and Mr. Joshua Liang have entered into the Acting-in-concert Deed on March 16, 2021, pursuant to which Dr. Liang and Mr. Joshua Liang confirmed that, since January 2016 (i) they had acted and would continue to act in concert and collectively for all material management affairs and the arrival and/or execution of all commercial decisions, including but not limited to financial and operational matters, of our Group; (ii) they had given and would continue to give unanimous consent, approval or rejection on any other material issues and decisions in relation to the business of our Group; (iii) they had casted and would continue to cast unanimous vote collectively for or against all resolutions in all board and shareholders’ meetings and discussions of our Group; and (iv) they had cooperated and would continue to cooperate with each other to maintain and consolidate control and management of our Group. The Acting-in-concert Deed shall terminate once either Dr. Liang and Mr. Joshua Liang ceases to have any shareholding, direct or indirect, in our Group.

Pursuant to the voting proxy agreements (the “**Voting Proxy Agreements**”) entered into between Dr. Liang and each of Dr. Xiaodong Wang, Dr. Jianwei Zhu, Mr. Zheng Ping and Mr. Pu Jiang on March 16, 2021, Dr. Xiaodong Wang, Dr. Jianwei Zhu, Mr. Zheng Ping and Mr. Pu Jiang have granted the voting right of the Shares held by them to Dr. Liang. Dr. Liang shall have the right to exercise the voting right of the Shares held by them regarding all matters submitted to the general meetings of the Company requiring the voting of Shareholders, except matters in respect of which the Dr. Liang is required to abstain from voting according to relevant laws and regulations.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

PRE-[REDACTED] INVESTMENTS

We received five series of Pre-[REDACTED] Investments since our establishment. The following table sets forth a summary of the details of the Pre-[REDACTED] Investments. Please refer to the paragraphs headed “– Our Principal Operating Entities – Sichuan Clover” and “– Issuance and Conversion of Convertible Notes” for further details.

	Angel Round	Series A	Series B	Series B-2	Series C
Amount of registered capital of Sichuan Clover acquired before the Reorganization	RMB10 million	RMB7,851,413	RMB30,545,245	RMB10,399,596	N/A
Number of Shares subscribed	10,000,000 Shares	7,851,413 Series A Preferred Shares	30,545,245 Series B Preferred Shares	10,399,596 Series B-2 Preferred Shares	34,170,135 Series C Preferred Shares
Amount of consideration paid	RMB10,000,000	RMB62,760,000	RMB304,125,000	RMB171,786,000	US\$230,000,013.37
Date of investment agreement	December 1, 2011	August 25, November 26, and December 12, 2017	September 30 and November 27, 2019	May 29, 2020	February 10, 2021
Date of payment of full consideration	February 27, 2012	January 3, 2018	May 20, 2020	June 23, 2020	February 16, 2021
Post-money valuation ⁽¹⁾⁽²⁾	RMB50 million	RMB462.43 million	RMB880.12 million	RMB1.63 billion	US\$930 million/RMB6.07 billion ⁽⁴⁾⁽⁵⁾
Cost per Share ⁽²⁾	[RMB1]	[RMB7.99]	[RMB9.96]	[RMB16.52]	[US\$6.73/RMB52.27]
Discount to the middle point of the [REDACTED] range ⁽³⁾	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

	Angel Round	Series A	Series B	Series B-2	Series C
Use of proceeds and whether they have been fully utilized	We utilize the proceeds to finance our research and development activities and fund our daily operations. As of the Latest Practicable Date, 100% of the net proceeds from the Angel Round Investment, Series A Investment, Series B Investment and Series B-2 Investment had been utilized by our Group. We have used approximately 14.9% of the net proceeds from the Series C Investment as of the Latest Practicable Date.				
Lock-up period	The Shares held by the Pre-[REDACTED] Investors will be subject to lock-up for a period of six months commencing from the [REDACTED].				
Strategic benefits of the Pre-[REDACTED] Investment brought to our Group	Our Group would benefit from the additional capital injected by the Pre-[REDACTED] Investors in our Group, their business resources, knowledge and experience, potential business opportunities and benefits that may be provided by them, and their investments demonstrate their commitment and confidence in the business performance and operations, strengths and long-term prospects of our Group.				

Notes:

- (1) Equals the total consideration paid by each round of Pre-[REDACTED] Investors divided by the shareholding percentage of it immediately following their investments.
- (2) Calculated based on the currency conversion rate of US\$1:RMB6.5288.
- (3) Calculated on the basis of the [REDACTED] of HK\$[REDACTED], the [REDACTED] of the proposed range of the [REDACTED], and based on the currency conversion rate of RMB1:HK\$0.8406.
- (4) The valuation of our Company increased significantly during the period between our Series B-2 Investment and Series C Investment primarily because our Group has achieved several major R&D milestones during this period, demonstrating strong R&D and execution capabilities in our operations as compared to our peers. Such milestones include, among others, (i) our first participant was dosed with adjuvanted SCB-2019 in Phase 1 clinical trial; (ii) CEPI extended partnership with us to fund development of SCB-2019 (CpG 1018/Alum) through licensure; and (iii) we announced positive Phase 1 data for our adjuvanted SCB-2019.
- (5) Our anticipated post-money market capitalization immediately upon completion of the [REDACTED] has primarily taken into account (a) the post-money valuation of the Series C Investment, (b) the expected capital raising during the [REDACTED], (c) our business growth since completion of the Series C Investment in March 2021 such as (i) the initiation of SPECTRA, a global pivotal Phase 2/3 clinical trial for SCB-2019 (CpG 1018/Alum), (ii) our announcement of positive preclinical data from our second-generation, protein-based COVID-19 vaccine candidate, and (iii) the results from SPECTRA and with which we plan to submit conditional regulatory approval applications to the EMA, the NMPA and the WHO in the fourth quarter of 2021, and (d) the difference in risks undertaken by the Pre-[REDACTED] Investors investing in a private company vis-à-vis investors investing in a public company.

Special Rights Granted to the Pre-[REDACTED] Investors

Certain special rights were granted to some of the Pre-[REDACTED] Investors pursuant to the shareholders’ agreement (the “**Shareholders Agreement**”) entered into between, among others, the Pre-[REDACTED] Investors and the Articles of Association dated March 16, 2021. Pursuant to the Shareholders’ Agreement and the Articles of Association, all special rights granted to the Pre-[REDACTED] Investors will be terminated immediately prior to the [REDACTED] except for the redemption right, which will be terminated immediately prior to our submission of a [REDACTED] to the Stock Exchange.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Information regarding the Pre-[REDACTED] Investors

Our Pre-[REDACTED] Investors include certain Sophisticated Investors, such as dedicated healthcare funds and biotech funds as well as established funds with a focus on investments in the healthcare sector. The background information of our Pre-[REDACTED] Investors is set out below.

Name of the Pre-[REDACTED] Investors	Background
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Hillhouse Capital	
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	AUT-XXI is a limited company incorporated under the laws of Hong Kong, which is wholly owned by AUT-XXI Holdings Limited (“ AUT Holding ”), an exempted company incorporated in the Cayman Islands. The sole shareholder of AUT Holding is HH IMV Holdings, L.P. (“ HH IMV ”), an exempted limited partnership established in the Cayman Islands. The sole limited partner of HH IMV is Hillhouse Fund IV, L.P., which is managed and controlled by Hillhouse Capital Management, Ltd. (“ Hillhouse Capital ”), an exempted company incorporated in the Cayman Islands.
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JNRY V Holdings Limited (“**JNRY**”) is an exempted company incorporated under the laws of Cayman Islands and is engaged in investment holding. JNRY is ultimately managed and controlled by Hillhouse Capital.

Founded in 2005, Hillhouse Capital is a global firm of investment professionals and operating executives who are focused on building and investing in high quality business franchises that achieve sustainable growth. Independent proprietary research and industry expertise, in conjunction with world-class operating and management capabilities, are key to Hillhouse Capital’s investment approach. Hillhouse Capital partners with exceptional entrepreneurs and management teams to create value, often with a focus on enacting innovation and technological transformation. Hillhouse Capital invests in the healthcare, consumer, consumer technology, TMT, financials and business services sectors in companies across all equity stages. Hillhouse Capital and its group members manage assets on behalf of global institutional clients. Hillhouse Capital is a Sophisticated Investor and has made meaningful investment in our Company at least six months before the [REDACTED].

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Name of the
Pre-[REDACTED]
Investors

Background

**Chengdu Tianhe,
Sichuan Tianhe and
Shanghai Tianhe**

Chengdu Tianhe is a limited liability company established under the laws of the PRC. It is principally engaged in the incubation business of biomedical technology companies. As of the Latest Practicable Date, Chengdu Tianhe was owned by Ms. Shibi Wang, an individual investor and a former director of Sichuan Clover as to 78%, and Xinxin Cheng (程辛欣), an Independent Third Party, as to 22%.

Sichuan Tianhe is an investment fund established as a limited partnership under the laws of the PRC. Sichuan Tianhe has approximately RMB252,500,000 under its management and focuses on investing in biotech industry and other emerging industries. Sichuan Tianhe has six limited partners, of which none holds more than 30% of the share interest in Sichuan Tianhe but five hold more than 10%, namely Jiangsu Hantang International Trade Group Co., Ltd. (江蘇漢唐國際貿易集團有限公司), Chengdu Tianhe, Sichuan Development Equity Investment Fund Management Co., Ltd. (四川發展股權投資基金管理有限公司), State Development and Hi-tech Investment Co., Ltd. (國投高科技投資有限公司) and Chengdu Jingkai Technology Industrial Incubation Co., Ltd. (成都經開科技產業孵化有限公司), and it is managed by its general partner, Chengdu Ronghui Datong Equity Investment Fund Management Co., Limited (成都融匯大通股權投資基金管理有限公司) (“**Ronghui Datong**”), which is in turn controlled by Chengdu Tianhe.

Shanghai Tianhe Shengtai Enterprise Management Partnership (Limited Partnership) (上海天合生泰企業管理合夥企業(有限合夥)) (“**Shanghai Tianhe**”) is wholly controlled by Chengdu Tianhe. Chengdu Tianhe is the limited partner holding 99% of the equity interest in Shanghai Tianhe and indirectly wholly owns Chengdu Hejisheng Health Technology Co., Ltd. (成都和濟生健康科技有限公司), the general partner of Shanghai Tianhe.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Name of the
Pre-[REDACTED]
Investors

Background

Temasek

Aranda Investments Pte. Ltd. (“**Aranda**”) is an indirect wholly-owned subsidiary of Temasek Holdings (Private) Limited (“**Temasek**”). Incorporated in 1974, Temasek is an investment company with a net portfolio value of US\$306 billion (RMB1.52 trillion) portfolio as at 31 March 2020. Its investment philosophy is anchored around four key themes: Transforming Economies; Growing Middle Income Populations; Deepening Comparative Advantages; and Emerging Champions. Temasek actively seeks sustainable solutions to address present and future challenges, as it captures investment and other opportunities that help to bring about a better, smarter and more sustainable world. Headquartered in Singapore, it is supported by 11 offices around the work, and has investments in the life sciences sector include Wuxi Apptech, Celltrion, Inc., Gilead Sciences, Inc. and Thermos Fisher Scientific Inc.

Delos Capital

Elasa is an exempted company incorporated with limited liability under the laws of the Cayman Islands and is engaged in investment holding. Elasa is wholly owned by Delos Capital Fund II, LP (“**Delos Capital**”), an exempted limited partnership registered as a private fund under the Private Funds Law of the Cayman Islands, with Delos Capital GP II, LP, an exempted limited partnership registered under the laws of Cayman Islands, being its general partner. As of the Latest Practicable Date, Delos Capital had 7 limited partners while none of them held more than 30% share interest in Delos Capital except for Peng-Lin Investment Limited, a company controlled by Mr. Yin Chung-Yao, an Independent Third Party, holding approximately 50% share interest. Delos Capital is advised by Delos Capital Advisors LLC (“**Delos Advisors**”). Both Delos Capital GP II, LP and Delos Advisors are wholly-owned by Delos Capital Holdings Limited (“**Delos Holdings**”), an exempted company incorporated with limited liability under the laws of the Cayman Islands. Skye Capital Holdings Limited (“**Skye Capital**”) is the majority shareholder of Delos Holdings and Mr. Henry Chen, the founding partner of Delos Capital, is the sole shareholder of Skye Capital.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Name of the
Pre-[REDACTED]
Investors

Background

Since 2014, Delos Capital and its affiliates as healthcare-focused funds have been investing in growth platforms in Greater China and relevant innovation in the U.S. in both therapeutics and medical technology, such as Syndax Pharmaceuticals (NASDAQ: SNDX) and Tanvex Biologics (TPEX: 6541). Delos Advisors currently advises two funds with over US\$330 million in total capital under management. Delos Capital is a Sophisticated Investor and has made meaningful investment in our Company at least six months before the [REDACTED].

Lapam

Lapam Fund III is a limited partnership established under the laws of the PRC. As of the Latest Practicable Date, there were 24 limited partners while none of them held more than 30% share interest in Lapam Fund III. The general partner of Lapam Fund III is Tibet Lapam Yijing Chuangye Investment Center (Limited Partnership) (西藏龍磐怡景創業投資中心(有限合夥)) (“**Tibet Yijing**”), which is in turn managed by its general partner, Beijing Lapam Investment Management Consulting Center (General Partnership) (北京龍磐投資管理諮詢中心(普通合夥)) (“**Lapam Investment**”). The general partner of Lapam Investment is Mr. Zhihua Yu (余治華), who is also the founding and managing partner of Lapam Investment. The single largest limited partner of Lapam Investment who held more 99% share is Tibet Lapam Management Consulting Center (Limited Partnership) (西藏龍磐管理諮詢中心(有限合夥)) (“**Tibet Lapam Consulting**”) which is controlled by Mr. Zhihua Yu.

Lapam Fund IV is a limited partnership established under the laws of the PRC. As of the Latest Practicable Date, there were around 20 limited partners while the single largest limited partner and the only one holding more than 30% share interest in Lapam Fund IV is National Council for Social Security Fund (全國社會保障基金理事會), which is affiliated with the State Council of China. It held approximately 32.3% share interest in Lapam Fund IV. The general partner of Lapam Fund IV is Tibet Lapam Consulting that is controlled by Mr. Zhihua Yu.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

**Name of the
Pre-[REDACTED]
Investors**

Background

As of June 30, 2021, Lapam Investment has more than RMB3.6 billion under management. Lapam Investment targets start-up, early-stage and fast-growing companies that have innovative and disruptive healthcare technologies, including small-molecule therapies, biologics, and medical devices. Lapam Capital has invested in 38 biopharmaceutical companies and 13 medical device companies to date, including Beijing Continent Drugs Co., Ltd. (北京康蒂尼藥業有限公司), CANbridge Pharmaceuticals Inc. and Reme Gen Co., Ltd (stock code: 9995).

Both Lapam Fund III and Lapam Fund IV are Sophisticated Investors and have made meaningful investment in our Company at least six months before the [REDACTED].

Sichuan Health Care

Sichuan Health Care is a limited partnership established under the laws of the PRC. Sichuan Health Care has approximately RMB1.0858 billion under its management and is principally engaged in the investment in the healthcare industry. Sichuan Health Care is managed by Sichuan Juxin Development Equity Investment Fund Management Co., Ltd. (四川聚信發展股權投資基金管理有限公司) and Tao Capital Management (Beijing) Co., Ltd. (道遠資本管理(北京)有限公司). Sichuan Health Care has six partners with two of them holding more than 92.1% of the share interest, both of which are ultimately controlled by the Department of Finance of Sichuan Province and its subordinated bureaus.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Name of the
Pre-[REDACTED]
Investors

Background

Kaiyuan Hongdao

Kaiyuan Hongdao is a limited partnership established under the laws of the PRC. Kaiyuan Hongdao has RMB350 million under its management and is principally engaged in the investment of biomedicine industry. Kaiyuan Hongdao has seven limited partners with Beijing Zhongguancun Venture Capital Development Co., Ltd. (北京中關村創業投資發展有限公司), a state-controlled enterprise, as its single largest limited partner holding approximately 56.57% share interest in Kaiyuan Hongdao. The general partner of Kaiyuan Hongdao is Beijing Kaiyuan Zhengdao Chuangye Investment Center (Limited Partnership) (北京開元正道創業投資中心(有限合夥)), which is managed by its general partner, Beijing Zhonghui Xinyuan Management Consulting Center (Limited Partnership) (北京中慧鑫源管理諮詢中心(有限合夥)) (“**Zhonghui Xinyuan**”). Zhonghui Xinyuan is controlled by its general partner, Songhe Cui (崔松鶴), who also holds 40% of its equity interests and is an Independent Third Party.

Qianhai FoF

Qianhai FoF is a limited partnership established under the laws of the PRC with RMB28.5 billion under its management and is mainly engaged in parent fund and venture capital business. Qianhai FoF is managed by Qianhai Ark Asset Management Co., Ltd. (前海方舟資產管理有限公司) (“**Qianhai Ark**”). Qianhai Ark was owned as to approximately 64.5% by Shenzhen Qianhai Huaize Ark Venture Capital Enterprise (Limited Partnership) (深圳前海淮澤方舟創業投資企業(有限合夥)). Shenzhen Qianhai Huaize Ark Venture Capital Enterprise (Limited Partnership) was owned as to approximately 80% by Jiaozuo Huaihai Consultancy Services Center (焦作市淮海諮詢服務中心) which in turn was wholly owned by Haitao Jin (靳海濤), an Independent Third Party. Other than Qianhai Ark who manages Qianhai FoF and held approximately 1.05% of the interests as at the Latest Practicable Date, Qianhai FoF has 49 limited partners, each of which held less than 10% of the interests in Qianhai FoF.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Name of the
Pre-[REDACTED]
Investors

Background

Oceanpine

Oceanpine Investment Fund II LP (“**Oceanpine Fund II**”) is an exempted limited partnership registered in the Cayman Islands with its principal activity in private equity investment. The general partner of Oceanpine Fund II is Oceanpine Growth (Cayman) Limited (“**Oceanpine Growth**”), an exempted company incorporated in the Cayman Islands with limited liability. Oceanpine Growth is wholly owned by Dave Liguang Chenn, the founder, chief executive officer and managing partner of Oceanpine Capital. Oceanpine Growth manages assets on behalf of institutional investors, family offices, and high net-worth individuals.

Oceanpine Fund II is managed by veteran investment professionals of Oceanpine Growth, each of whom with in-depth industry insights in providing strategic resources and operational support to its portfolio companies, thus compounding their growth potentials. Oceanpine Growth is investing the Oceanpine Fund II in DeepTech-focused innovative companies in Semiconductor, artificial intelligence, 5G, IoT (internet of things), big data, enterprise software, as well as biotech companies. Oceanpine Fund II engages in early to late growth-oriented equity investment with underlying exposures in China and the United States.

Nanjing Deauville

Nanjing Deauville is a general partnership established under the laws of the PRC and is principally engaged in equity investment. As at the Latest Practicable Date, Nanjing Deauville was owned by Fang Tian (田方) and Yunming Liu (劉雲明), who are both Independent Third Parties, as to 58.57% and 41.43%, respectively.

Beixin Fund

Beixin Fund was established as a limited partnership on 29 December 2017, which is managed by Hangzhou Betta Capital Management Co., Ltd. (杭州貝加投資管理有限責任公司) and focused on the investment of life science industry with RMB200 million under its management. Hangzhou Betta Capital Management Co., Ltd (杭州貝加投資管理有限責任公司) is owned by Shizhe Ding (丁師哲) and Xiaoxuan Xing (邢小玄) as to 90% and 10%, respectively, both of whom are Independent Third Parties.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

**Name of the
Pre-[REDACTED]
Investors**

Background

OrbiMed

OrbiMed New Horizons Master Fund, L.P. (“**ONH**”) and OrbiMed Genesis Master Fund, L.P. (“**Genesis**”) are each exempted limited partnership established under the laws of Cayman Islands with OrbiMed Advisors LLC acting as the investment manager. The Biotech Growth Trust PLC (“**BIOG**”) is a publicly listed trust organized under the laws of England. OrbiMed Capital LLC is the portfolio manager of BIOG. OrbiMed Capital LLC and OrbiMed Advisors LLC exercise voting and investment power through a management committee comprising Carl L. Gordon, Sven H. Borho, and Jonathan T. Silverstein.

**Hangzhou Golden
Dragon**

Hangzhou Golden Dragon is a limited liability company established under the laws of the PRC and is principally engaged in commercial real estate management and investment. The largest shareholder of Hangzhou Golden Dragon is Along Yan (顏阿龍), who is an Independent Third Party.

C&D

C&D Emerging Industry International Investment Limited (“**C&D**”) is a limited company incorporated under the laws of Hong Kong and is wholly owned by Xiamen C&D Emerging Industry Equity Investment Co., Ltd. (廈門建發新興產業股權投資有限責任公司), a limited company established under the laws of the PRC and indirectly controlled by State-owned Assets Supervision and Administration Commission of Xiamen Municipal People’s Government. Xiamen C&D Emerging Industry Equity Investment Co., Ltd. is principally engaged in funds and equity investment business in medical health, advanced manufacturing and TMT & consumption industries with around RMB13 billion under its management.

Easter Lily

Easter Lily Global Limited (“**Easter Lily**”) is a limited company incorporated under the laws of British Virgin Islands that is principally engaged in investment holding. Easter Lily is wholly owned by Yuxiang Hou, an Independent Third Party.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Name of the
Pre-[REDACTED]
Investors

Background

Mindtouch

Mindtouch High Technology Co., Limited (“**Mindtouch**”) is a limited company incorporated under the laws of Hong Kong that is principally engaged in investment holding. Mindtouch is wholly owned by Min Wang (王旻), an Independent Third Party.

Score High

Score High Holdings Limited (“**Score High**”) is a limited company incorporated under the laws of British Virgin Islands that is principally engaged in investment holding. Score High is wholly owned by Feng Gao (高丰), an Independent Third Party.

Public Float

The Shares held by Hillhouse through AUT-XXI and JNRY will not be considered as part of the public float because they will be Substantial Shareholders and therefore core connected persons of our Company upon the [REDACTED].

To our Director’s best knowledge, save as disclosed above, Shares held by each of the other Pre-[REDACTED] Investors will be counted towards the public float for the purpose of Rule 8.08 of the Listing Rules after the [REDACTED].

Mr. Joshua Liang and Dr. Liang are entitled to exercise the voting rights attached to the Shares held by themselves, Dr. Xiaodong Wang, Dr. Jianwei Zhu, Mr. Zheng Ping and Mr. Pu Jiang pursuant to the Acting-in-concert Deed and the Voting Proxy Agreements. Furthermore, Mr. Joshua Liang is the adviser of the ESOP Trust and is entitled to exercise the voting rights attached to the Shares held by Super Novel. As such, approximately [REDACTED] of the total issued Shares held or controlled by Dr. Liang and Mr. Joshua Liang, as a group of Substantial Shareholders, will not count towards public float after the [REDACTED] without taking into account the Shares which may be allotted and issued under the [REDACTED] or the share options granted under the Pre-[REDACTED] Share Option Plan.

Save as disclosed above, to the best of our Directors’ knowledge, all other Shareholders of our Company are not core connected persons of our Company. As a result, these Shareholders will aggregately hold a total of approximately [REDACTED]% of the Shares (upon completion of the [REDACTED] without taking into account the Shares which may be allotted and issued under the [REDACTED] or the share options granted under the Pre-[REDACTED] Share Option Plan) with a market capitalization of approximately HK\$[REDACTED] (based on the [REDACTED] of HK\$[REDACTED], being the [REDACTED] of the [REDACTED] range), which will count towards the public float. As a result, over 25% of our Company’s total issued Shares with a market capitalization of at least HK\$375 million will be held by the public upon completion of the [REDACTED] and the [REDACTED] as required under Rule 8.08(1)(a) and Rule 18A.07 of the Listing Rules.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Compliance with Interim Guidance and Guidance Letters on Pre-[REDACTED] Investments

On the basis that (i) the considerations for the Pre-[REDACTED] Investments were irrevocably settled more than 28 clear days before the date of our first submission of the [REDACTED] to the Stock Exchange and (ii) the special rights granted to the Pre-[REDACTED] Investors have been terminated prior to such [REDACTED], the Joint Sponsors have confirmed that the Pre-[REDACTED] Investments are in compliance with the Interim Guidance on Pre-[REDACTED] Investment issued by the Stock Exchange on October 13, 2010 and as updated in March 2017, the Guidance Letter HKEX-GL43-12 issued by the Stock Exchange in October 2012 and as updated in July 2013 and March 2017 and the Guidance Letter HKEX-GL44-12 issued by the Stock Exchange in October 2012 and as updated in March 2017.

ADOPTION OF THE SHARE INCENTIVE PLANS

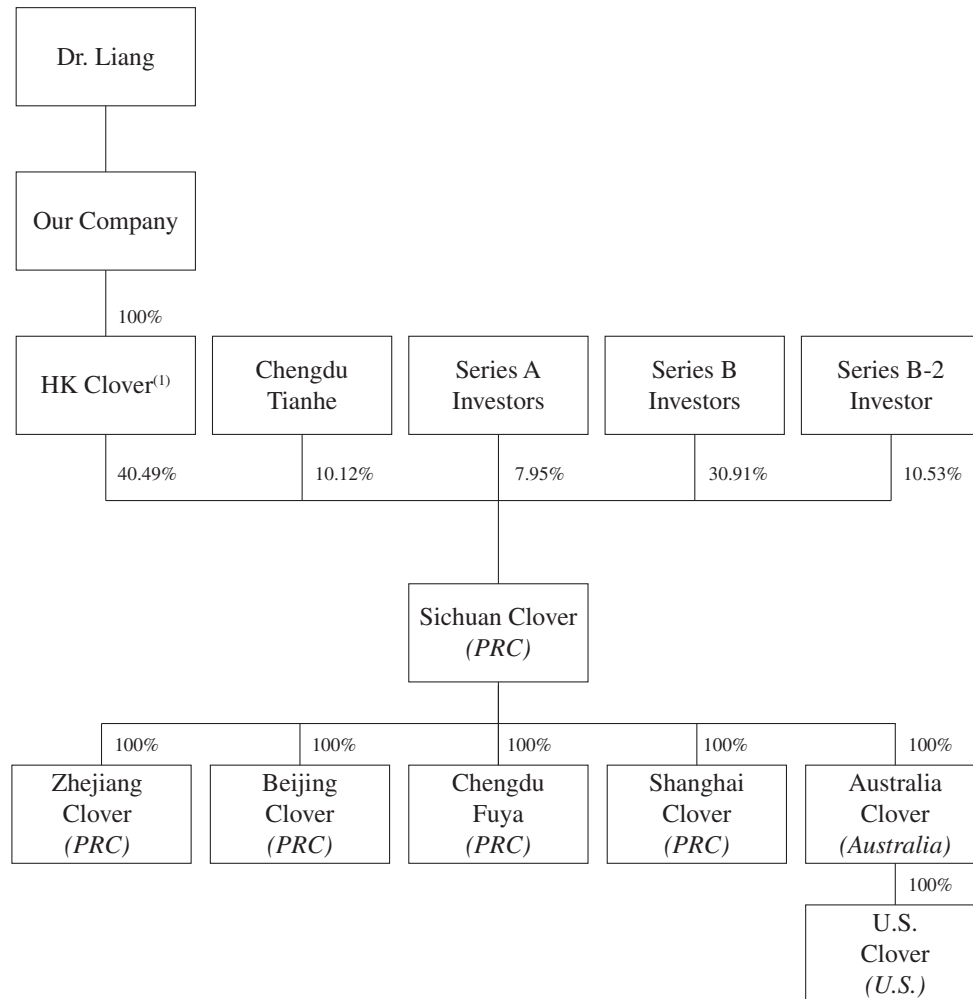
In order to reward or incentivize our Directors, employees and consultants for their contribution or potential contribution, our Company adopted the Pre-[REDACTED] Share Option Plan and the RSU Scheme on April 15, 2021, as amended from time to time, details and principal terms of which were set out in “Statutory and General Information – D. Share Incentive Plans” in Appendix IV to this document.

We have also conditionally adopted the Post-[REDACTED] Share Option Scheme, the principal terms of which are set out in “Statutory and General Information – D. Share Incentive Plans – 3. Post-[REDACTED] Share Option Plan in Appendix IV to this document.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

REORGANIZATION

The following chart sets forth the corporate structure of our Group immediately prior to our Reorganization:



Note:

- (1) Includes approximately 2.53%, 4.05%, 2.03%, 1.22% and 0.81% of the equity interest held as nominee for Mr. Joshua Liang, Dr. Xiaodong Wang, Dr. Jianwei Zhu, Mr. Zheng Ping and Mr. Pu Jiang, respectively, pursuant to the Trust Arrangements.

We have carried out the following Reorganization steps in preparation for the [REDACTED]:

Step 1. Incorporation of Our Company

On October 31, 2018, our Company was incorporated in the Cayman Islands as an exempted company with limited liability and has an authorized share capital of US\$50,000 divided into 500,000,000 Shares with a nominal value of US\$0.0001 each. Upon incorporation, one Share, representing the then issued share capital of our Company, was issued and transferred to Dr. Liang at nominal value.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Step 2. Allotment and Issue of Shares to Our Individual Shareholders

On February 10, 2021, our Company allotted and issued a total of 29,499,999 Shares to Dr. Liang. On March 16, 2021, our Company allotted and issued a total of 10,500,000 Shares to, Dr. Xiaodong Wang, Mr. Joshua Liang, Dr. Jianwei Zhu, Fine Well Investments Limited (康祥投資有限公司) (“PZ BVI”) and Shine Sino Global Limited (耀華環球有限公司) (“JP BVI”) being the offshore holding companies held by Mr. Zheng Ping and Mr. Pu Jiang, respectively, on a pro-rata basis with reference to their beneficial interests in Sichuan Clover and on the same date, Dr. Liang, HK Clover and the Nominators agreed to terminate the Trust Arrangements.

Step 3. Equity Transfer and Share Subscription by Certain Corporate Shareholders

On March 16, 2021, our Company allotted and issued a total of 58,796,254 Shares to the Series A Investors, the Series B Investors and the Series B-2 Investors or their affiliates (together the “**Reorganization Corporate Shareholders**”) on a pro-rata basis with reference to their respective shareholdings in Sichuan Clover. On the same date, the Reorganization Corporate Shareholders entered into an equity transfer agreement with HK Clover pursuant to which they agreed to transfer the entire equity interests they held in Sichuan Clover to HK Clover.

Step 4. Conversion of the Convertible Notes

On March 16, 2021, the Convertible Notes were fully converted into Series C Preferred Shares and the shareholding structure of our Company following such conversion was set forth below:

Name of Shareholders	Series of Shares	Number of Shares	Shareholding Percentage
Dr. Liang	Ordinary Share	29,500,000	22.19%
Dr. Xiaodong Wang	Ordinary Share	4,000,000	3.01%
Mr. Joshua Liang	Ordinary Share	2,500,000	1.88%
Dr. Jianwei Zhu	Ordinary Share	2,000,000	1.50%
PZ BVI	Ordinary Share	1,200,000	0.90%
JP BVI	Ordinary Share	800,000	0.60%
Shanghai Tianhe ⁽¹⁾	Ordinary Share	10,000,000	7.52%
Sichuan Tianhe	Series A Preferred Shares	4,380,000	3.29%
Diaowlan ⁽²⁾	Series A Preferred Shares	1,510,000	1.14%
Qianhai BVI ⁽³⁾	Series A Preferred Shares	1,961,413	1.48%

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Name of Shareholders	Series of Shares	Number of Shares	Shareholding Percentage
Elasa	Series B Preferred Shares	8,951,401	6.73%
Lapam Fund III	Series B Preferred Shares	5,021,824	3.78%
Lapam Fund IV	Series B Preferred Shares	7,030,554	5.29%
Bexin Capital ⁽⁴⁾	Series B Preferred Shares	1,506,547	1.13%
Kaiyuan Hongdao	Series B Preferred Shares	2,008,730	1.51%
Sichuan Health Care	Series B Preferred Shares	5,021,824	3.78%
Hangzhou Golden Dragon	Series B Preferred Shares	1,004,365	0.76%
AUT-XXI	Series B-2 Preferred Shares	10,399,596	7.82%
JNRY	Series C Preferred Shares	14,113,751	10.61%
Aranda	Series C Preferred Shares	14,113,751	10.61%
Oceanpine Fund II	Series C Preferred Shares	1,782,790	1.34%
BIOG	Series C Preferred Shares	1,039,960	0.78%
ONH	Series C Preferred Shares	297,132	0.22%
Genesis	Series C Preferred Shares	148,566	0.11%
Elasa	Series C Preferred Shares	1,485,658	1.12%
C&D	Series C Preferred Shares	742,829	0.56%
Easter Lily	Series C Preferred Shares	148,566	0.11%
Mindtouch	Series C Preferred Shares	148,566	0.11%
Score High	Series C Preferred Shares	148,566	0.11%
Total		132,966,389	100%

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Notes:

- (1) Shanghai Tianhe is wholly controlled by Chengdu Tianhe. Chengdu Tianhe is the limited partner holding 99% of the equity interest in Shanghai Tianhe and indirectly wholly owns Chengdu Hejisheng Health Technology Co., Ltd. (成都和濟生健康科技有限公司), the general partner of Shanghai Tianhe.
- (2) Diaowlan Co., Ltd (“**Diaowlan**”) is an offshore holding company incorporated in the BVI and is wholly owned by Nanjing Deauville.
- (3) Qianhai Ark (BVI) Investment Co., Limited (“**Qianhai BVI**”) is an offshore holding company incorporated in the BVI and is wholly owned by Qianhai FoF.
- (4) Bexin Capital Limited (“**Bexin Capital**”) is an offshore holding company incorporated in the BVI and is wholly owned by Bexin Fund.

Step 5. Transfer of Equity Interests in Australia Clover from Sichuan Clover to Our Company

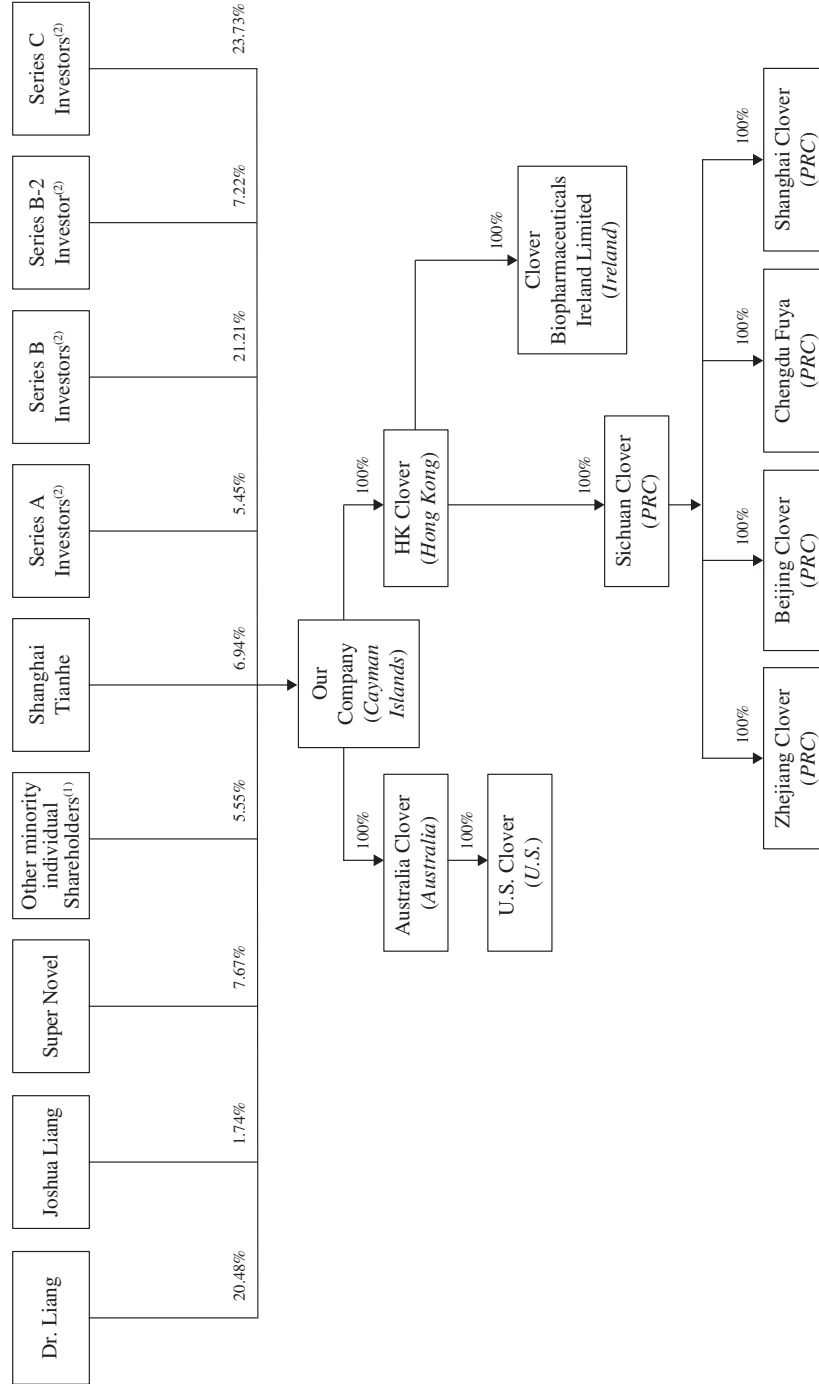
On March 16, 2021, Sichuan Clover entered into an equity transfer agreement with our Company, pursuant to which Sichuan Clover transferred the entire equity interests in Australia Clover to our Company.

[REDACTED]

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

CORPORATE STRUCTURE AFTER THE REORGANIZATION AND IMMEDIATELY PRIOR TO THE [REDACTED] AND THE [REDACTED]

Our corporate and shareholding structure after the Reorganization and immediately prior to the completion of the [REDACTED] and the [REDACTED] is as follows:



Notes:

- (1) Refer to Dr. Xiaodong Wang (as to 2.78%), Dr. Jianwei Zhu (as to 1.39%), Mr. Zheng Ping (as to 0.83%) and Mr. Pu Jiang (as to 0.56%).
- (2) For the shareholding of each of the Series A Investors, the Series B Investors, the Series B-2 Investor and the Series C Investors, please refer to “– Reorganization – Step 4. Conversion of the Convertible Notes” in this section.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

(2) Refer to Dr. Xiaodong Wang (as to [REDACTED]), Dr. Jianwei Zhu (as to [REDACTED]), Mr. Zheng Ping (as to [REDACTED]) and Mr. Pu Jiang (as to [REDACTED]).

(3) The shareholding of the Series A Investors, the Series B Investors, the Series B-2 Investor and the Series C Investors upon the completion of the [REDACTED] is set out below:

JNRY	Aranda	Elasa	AUT-XXI	Lapam Fund IV	Lapam Fund III	Sichuan Health Care	Sichuan Tianhe	Kaiyuan Hongdao	Qianhai FoF	Oceanpine Fund II
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Nanjing Deauville	Beixin Fund	BIOG		C&D	ONH	Genesis	Easter Lily	Mindtouch	Score High	
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

PRC LEGAL COMPLIANCE

Our PRC Legal Adviser have confirmed that (i) all relevant approvals or filings have been obtained or made, as applicable, for the equity transfers in the PRC in respect of the Reorganization; and (ii) the Reorganization has been properly and legally completed to the extent related to PRC laws and regulations and has complied with all relevant PRC laws and regulations in all material aspects.

SAFE and ODI Registration

Pursuant to the Circular 37 promulgated by SAFE which became effective on July 4, 2014, a PRC resident must register with the local branch of SAFE before he or she contributes legal assets or equity interests in an overseas special purpose vehicle, which is directly established or indirectly controlled by the PRC resident for the purpose of overseas investment or financing.

Pursuant to the Circular 13, promulgated by SAFE and which became effective on June 1, 2015, the power to accept SAFE registration was delegated from local SAFE to local banks where the assets or interest in the domestic entity was located.

As advised by our PRC Legal Adviser, Mr. Zheng Ping and Mr. Pu Jiang, as PRC residents, have completed the foreign exchange registrations in December 2020 pursuant to Circular 37 and Circular 13.

Pursuant to the Administrative Measures for the Overseas Investment of Enterprises (《企業境外投資管理辦法》) promulgated by the NDRC and Administrative Measures for Overseas Investment Management (《境外投資管理辦法》) promulgated by the MOFCOM (the “**ODI Rules**”), a domestic institution shall undergo registration procedure for foreign investment in accordance with the provisions of the ODI Rules, which require the domestic institution to register with relevant authorities prior to its overseas direct investment and obtain relevant recordation, approval, certificate or permit.

As advised by our PRC Legal Adviser, each of Chengdu Tianhe (through Shanghai Tianhe), Sichuan Tianhe, Nanjing Deauville, Qianhai FoF, Lapam Fund III, Lapam Fund IV, Bexin Fund, Kaiyuan Hongdao, Sichuan Health Care and Hangzhou Golden Dragon has completed the overseas direct investment registration with the local MOFCOM and NDRC in February, 2021 pursuant to the ODI Rules in relation to their offshore investments as domestic institutions.

BUSINESS

OVERVIEW

Founded in 2007, we are a global clinical-stage biotechnology company committed to developing novel vaccines and biologic therapeutic candidates for infectious diseases as well as cancer and autoimmune diseases. The indications for our lead product in each therapeutic area are COVID-19, malignant ascites and ankylosing spondylitis, respectively. From GenHunter, we in-licensed the Trimer-Tag™ technology platform, a product development platform for the creation of novel vaccines and biologic therapies. We have leveraged the Trimer-Tag™ technology platform to become a COVID-19 vaccine developer and created SCB-2019 (CpG 1018/Alum), one of our Core Products, to address COVID-19 which is caused by SARS-CoV-2. In September 2021, SCB-2019 (CpG 1018/Alum) met the primary efficacy endpoint and secondary efficacy endpoints in SPECTRA (Study Evaluating Protective-Efficacy and Safety of Clover’s Trimeric Recombinant Protein-based and Adjuvanted COVID-19 Vaccine), our global pivotal Phase 2/3 clinical trial. We will potentially become one of the first companies to commercialize a protein-based COVID-19 vaccine globally through the COVAX Facility. Leveraging our expertise in protein bioengineering, manufacturing capabilities, and in-house manufacturing facility, we developed another Core Product, SCB-808, for the treatment of rheumatic diseases. Our pipeline also consists of nine additional product candidates in development as of the Latest Practicable Date.

The Trimer-Tag™ technology platform can trimerize any protein of interest and target a broad spectrum of naturally trimerization-dependent disease and biologic targets. These include dozens of enveloped RNA viruses (e.g. coronaviruses, rabies, respiratory syncytial virus (RSV), influenza, human immunodeficiency virus (HIV), and Ebola) and the tumor necrosis factor (TNF) superfamily (TNFSF), which have diverse biological functions and are linked to serious diseases, such as certain cancers and autoimmune disorders. Globally, Trimer-Tag™ is the only trimerization technology platform for designing and producing recombinant, covalently-linked, trimeric fusion proteins (trimer-tagged proteins) exploiting a human-derived trimerization tag, according to Frost & Sullivan. The trimer-tagged proteins produced by the Trimer-Tag™ technology platform have high potency against trimerization-dependent disease targets and favorable safety profiles.

We have built our product pipeline by employing the Trimer-Tag™ technology platform and leveraging our in-house biologics manufacturing infrastructure and capabilities. As of the Latest Practicable Date, our product pipeline consisted of (i) six Trimer-Tag™ subunit vaccine candidates, including SCB-2019 (CpG 1018/Alum), for which we obtained SPECTRA results in September 2021, (ii) two Trimer-Tag™ oncology product candidates, including SCB-313 for which we are conducting five Phase 1 clinical trials in China and Australia, and (iii) three Fc-fusion product candidates, including SCB-808, for which we are conducting a pivotal Phase 3 clinical trial in China.

BUSINESS

Trimer-TagTM subunit vaccine candidates. With our COVID-19 vaccine candidate SCB-2019 (CpG 1018/Alum), we expect to commercialize one of the first protein-based COVID-19 vaccines globally, enabling us to potentially help address the global shortage of COVID-19 vaccines and capture a significant market share of the approximately 15 billion COVID-19 vaccine doses required through 2026. In addition, periodic booster shots or re-vaccination may be needed especially as new variants emerge, resulting in a significant global need for COVID-19 vaccines for years to come. Because SCB-2019 (CpG 1018/Alum) is expected to be stable under standard refrigeration (2-8°C) storage and transportation conditions, it is a potentially preferable and a more cost-effective solution for global distribution by leveraging existing and conventional infrastructure, a necessity when transporting to remote and low-resource regions. We announced that SPECTRA, our global pivotal Phase 2/3 clinical trial for SCB-2019 (CpG 1018/Alum), met the primary and secondary efficacy endpoints in September 2021. Based on the SPECTRA results, SCB-2019 (CpG 1018/Alum) demonstrated 100% efficacy against severe COVID-19, 100% efficacy against hospitalizations due to COVID-19, and 84% efficacy against moderate-to-severe COVID-19 caused by any strain of SARS-CoV-2 in SPECTRA. Against the globally dominant Delta variant, SCB-2019 (CpG 1018/Alum) demonstrated 79% efficacy against COVID-19 of any severity in SPECTRA. SCB-2019 (CpG 1018/Alum) also had a favorable safety profile in SPECTRA with no significant differences in systemic solicited adverse events or severe/serious adverse events compared to placebo. Moreover, SCB-2019 (CpG 1018/Alum) was the first COVID-19 vaccine candidate to demonstrate a significantly reduced risk of COVID-19 in previously infected individuals.

Having obtained data from SPECTRA in September 2021, we plan to submit conditional regulatory approval applications to the EMA, the NMPA and the WHO in the fourth quarter of 2021. We expect to obtain conditional approvals between the fourth quarter of 2021 and the middle of 2022. Post conditional approval, we expect to commence product launch which may occur as early as year end 2021. SCB-2019 (CpG 1018/Alum) is funded by the Coalition for Epidemic Preparedness Innovations (CEPI), and will be made available for procurement and allocation through the COVAX Facility. We also intend to supply additional SCB-2019 (CpG 1018/Alum) post conditional approval via bilateral negotiations and supply arrangements with global governments. We and investigators also plan to evaluate multiple clinical trials exploring SCB-2019 (CpG 1018/Alum) as a heterologous booster following primary vaccination and as a homologous booster for SCB-2019 (CpG 1018/Alum).

Leveraging the Trimer-TagTM technology platform, we will be able to rapidly develop second-generation COVID-19 vaccine candidates. Our pre-clinical immunogenicity study in mice indicated that a modified Beta Variant (B.1.351) protein-based COVID-19 vaccine candidate could potentially be protective against the original SARS-CoV-2 strains and certain variants of concern. We are also conducting additional vaccine discovery programs for various other indications, including rabies, RSV, influenza, and HIV, all of which are enveloped RNA viruses that display trimeric spike glycoproteins, a characteristic similar to the SARS-CoV-2 virus.

BUSINESS

Trimer-Tag™ oncology product candidates. We have successfully utilized the Trimer Tag™ technology platform to design and develop SCB-313 as a covalently-linked, native-like trimeric fusion protein which is structurally and functionally differentiated from the dimeric antibody-based structures and other native ligand-based candidates targeting this pathway. We believe SCB-313 has the potential to address the unmet global need for the treatment of intracavitary malignancies, including MA, MPE, and PC, as well as additional cancer indications. We are exploring other targets in the TNFSF for immuno-oncology and immunology indications. We are currently conducting discovery programs evaluating trimeric fusion protein candidates targeting the 4-1BB pathway, a member of the TNFSF.

Fc-fusion product candidates. Leveraging our expertise in protein bioengineering, manufacturing capabilities, and in-house manufacturing facility, we are developing Fc-fusion protein molecules and biosimilars. Our most advanced program is SCB-808 an Enbrel (etanercept) biosimilar in a ready-for-injection, pre-filled syringe formulation. Enbrel is indicated for the treatment of rheumatic diseases. We are conducting a pivotal Phase 3 clinical trial for SCB-808 in China, expect to submit an NDA to the NMPA in second half of 2023, and commence commercialization thereafter, if approved. In addition, we expect to initiate Phase 1 clinical trials in the fourth quarter of 2021 for SCB-420, an Eylea (aflibercept) biosimilar indicated for the treatment of certain large market ophthalmologic diseases, including wAMD, and in the second quarter of 2022 for SCB-219, a novel TPO-mimetic Fc-fusion protein being developed for CIT and ITP.

Manufacturing Facility. We have an in-house, commercial-ready biologics manufacturing facility in Changxing, Zhejiang province, China. This facility is prepared for the rapid scale-up and commercial production of SCB-2019. Our Changxing facility was designed to adhere to the cGMP standards of the U.S., EU, and China. The Changxing facility has received certification by a Qualified Person (QP), a requirement to achieve EU cGMP standards. We expect the NMPA, the EMA and the WHO to conduct GMP inspections on our Changxing facility in the second half of 2021 in connection with their regulatory review process for conditional approval.

We have assembled a seasoned, global senior management team with deep and complementary experience and capabilities in drug discovery, clinical operations, biomanufacturing, drug commercialization, and capital markets.

OUR VISION

Our vision is to deliver next-generation solutions to empower the global population with a healthier future.

OUR MISSION

Our mission is to leverage our cutting-edge Trimer-Tag™ technology platform and fully-integrated manufacturing capabilities for the discovery, development, and delivery of innovative and affordable medical solutions.

BUSINESS

OUR STRENGTHS

Differentiated Trimer-Tag™ technology platform accelerating the development of novel vaccines and biologic therapies

The Trimer-Tag™ technology platform is a product development platform for the creation of novel vaccines and biologic therapies. The Trimer-Tag™ technology platform can trimerize any protein of interest and target a broad spectrum of naturally trimerization-dependent disease and biologic targets. These include dozens of enveloped RNA viruses (e.g. coronaviruses, rabies, RSV, influenza, HIV, and Ebola) and the TNFSF, which have diverse biological functions and are linked to serious diseases, such as certain cancers and autoimmune disorders.

Globally, Trimer-Tag™ is the only trimerization technology platform for designing and producing recombinant, covalently-linked, trimeric fusion proteins (trimer-tagged proteins) exploiting a human-derived trimerization tag, according to Frost & Sullivan. Key advantages of the trimer-tagged proteins produced by the Trimer-Tag™ technology platform include:

- ***High potency against trimerization-dependent disease targets.*** The Trimer-Tag™ motif possesses structural flexibility enabling trimer-tagged virus spike proteins and TNFSF ligands to achieve native-like trimeric structures. In pre-clinical studies, trimer-tagged proteins demonstrated a high binding affinity to their targets and/or high potency compared to corresponding dimeric antibody-based structures and other native ligand-based candidates, a characteristic that may contribute to the biological activity of trimer-tagged proteins.
- ***Favorable safety profile.*** The trimerization motif of Trimer-Tag™ is based on a human amino acid sequence derived from human collagen (C-terminal domain of Type I procollagen). Collagen, the most abundant protein in the human body, is capable of self-assembly into covalently-linked trimers during its formation process via the C-propeptide domain. We believe trimer-tagged fusion proteins will have a low risk of inducing anti-Trimer-Tag™ antibodies in the human body, and thus contributing to a favorable safety profile.

We achieved initial S-Trimer™ antigen expression for SCB-2019 (CpG 1018/Alum) within 15 days of program initiation in early February 2020 and accomplished first-in-human dosing in June 2020, within 5 months of program initiation. These successes enabled us to become a COVID-19 vaccine developer and potentially one of the first companies to commercialize a protein-based COVID-19 vaccine globally through the COVAX Facility. In addition, the Trimer-Tag™ technology platform can be adapted quickly to address challenges from multiple variants of the SARS-CoV-2 virus, which have and are expected to continue to emerge around the globe. We completed initial antigen expression for a modified Beta Variant (B.1.351) in early February 2021 within a few weeks of program initiation. These achievements serve as a strong proof-of-concept for our ability to leverage the Trimer-Tag™ technology platform, rapidly develop new product candidates, and advance them quickly into the clinic.

BUSINESS

Our protein-based COVID-19 vaccine candidate SCB-2019 (CpG 1018/Alum) potentially launching by the end of 2021

We expect to address the significant global need for COVID-19 vaccines with our near-commercial protein-based COVID-19 vaccine candidate SCB-2019 (CpG 1018/Alum). We obtained data from SPECTRA, a global pivotal phase 2/3 clinical trial for SCB-2019 (CpG 1018/Alum), in September 2021. We subsequently plan to submit conditional regulatory approval applications to the EMA, the NMPA, and the WHO in the fourth quarter of 2021. We expect to obtain conditional approvals between the fourth quarter of 2021 and the middle of 2022. Post conditional approval, we expect to commence product launch which may occur as early as year end 2021. We expect to commercialize one of the first protein-based COVID-19 vaccines globally, enabling us to potentially help address the global shortage of COVID-19 vaccines and capture a significant market share of the approximately 15 billion COVID-19 vaccine doses required through 2026. In addition, periodic booster shots or re-vaccination may be needed especially as new variants emerge, resulting in a significant global need for COVID-19 vaccines for years to come.

Highly stable and well-suited for global storage and distribution. Based on our ongoing stability studies, SCB-2019 (CpG 1018/Alum) is expected to be stable under standard refrigeration (2-8°C) storage and transportation conditions. As such, SCB-2019 (CpG 1018/Alum) is a potentially preferable and a more cost-effective solution for global distribution by leveraging existing and conventional infrastructure, a necessity when transporting to remote and low-resource regions.

Strong immune responses potentially leading to protective immunity. SCB-2019 (CpG 1018/Alum) is adjuvanted to elicit strong immune responses. In SPECTRA, SCB-2019 (CpG 1018/Alum) demonstrated 100% efficacy against severe COVID-19, 100% efficacy against hospitalizations due to COVID-19, and 83.7% efficacy against moderate-to-severe COVID-19 cases caused by any strain of SARS-CoV-2. SCB-2019 (CpG 1018/Alum) was also the first COVID-19 vaccine candidate to demonstrate significantly reduced risk of COVID-19 in previously infected individuals. As published in *The Lancet*, SCB-2019 (CpG 1018/Alum) induced high neutralizing antibody titers and Th1-biased cell-mediated immune responses in our Phase 1 clinical trial, implying a balanced immune response. Neutralizing antibodies can prevent viruses from interacting with host cells and are part of humoral immunity. Virus-specific CD4⁺ T-cell immune responses were detected in patients who recovered from COVID-19, which were mainly associated with Th1 cytokines, suggesting that strong Th1-biased cell-mediated immune responses are likely to contribute to vaccine efficacy, according to Frost & Sullivan.

BUSINESS

Potentially differentiated and favorable safety profile. SCB-2019 (CpG 1018/Alum) demonstrated a favorable safety profile in SPECTRA, with no significant differences in systemic solicited adverse events or severe/serious adverse events compared to placebo. Moreover, in the Phase 1 clinical trial, SCB-2019 (CpG 1018/Alum) demonstrated weak or no Th2- and Th17- cellular immune responses, which are risk factors for vaccine associated enhanced respiratory disease (VAERD), according to Frost & Sullivan. Adjuvanted protein-based vaccines for a wide range of viruses have been approved and commercialized prior to the COVID-19 pandemic, unlike some other vaccine development platforms, such as mRNA, adenovirus, and DNA.

Well-characterized manufacturing processes at our in-house commercial-ready facility with large-scale production capacity. We are potentially able to produce more than one billion doses of SCB-2019 annually at peak capacity at our commercial-scale manufacturing facility located in Changxing, Zhejiang province, China. This facility is certified by a QP within the European Union (EU), a requirement to achieve EU current Good Manufacturing Practices (cGMP) standards. The manufacturing process for SCB-2019 is well-characterized and similar to that of other recombinant proteins. We are following these cGMP standards at our Changxing manufacturing facility to ensure a high level of quality control, allowing us to quickly scale up for mass vaccination. Moreover, we believe SCB-2019 (CpG 1018/Alum) could be a cost-effective vaccine product given the high productivity of the manufacturing process.

CEPI-funded development program with clear commercialization pathway. SCB-2019 (CpG 1018/Alum) will be made available for procurement and allocation through the COVAX Facility, which is a global initiative established by the WHO, the Global Alliance for Vaccines and Immunizations (GAVI), and CEPI that aims to procure and fairly distribute COVID-19 vaccines to participating countries. We also intend to supply additional SCB-2019 (CpG 1018/Alum) post conditional approval via bilateral negotiations and supply arrangements with global governments. We are proud to be the first company headquartered in China to receive funding and support from CEPI, which has agreed to provide up to US\$360.5 million in grant funding to support the development of SCB-2019 (CpG 1018/Alum) through global licensure.

Novel oncology TRAIL-Trimer fusion protein to address the unmet global need for the treatment of intracavitary malignancies

Binding of the TNF-related apoptosis-inducing ligand (TRAIL) to the death receptors leads to physiologic trimerization of the death receptors and potent activation of the extrinsic apoptosis (cell death) pathway. Dimeric antibody-based structures and other native ligand-based candidates targeting this pathway have failed to demonstrate significant anti-tumor efficacy due to an insufficient capacity of these agents to induce death receptor clustering, and/or caused adverse events such as liver toxicity. With the Trimer Tag[®] technology platform, we have successfully designed and developed SCB-313 as a covalently-linked, native-like trimeric fusion protein that is structurally and functionally differentiated from the dimeric antibody-based structures and other native ligand-based candidates targeting this pathway. In both *in vivo* and *in vitro* pre-clinical studies, SCB-313 demonstrated favorable pharmacodynamics and pharmacokinetics profiles with an extended intracavitary half-life, which results in greater drug exposure to target tumor cells locally, potentially translating to anti-tumor efficacy.

BUSINESS

We believe SCB-313 has the potential to address the unmet global need for the treatment of intracavitary malignancies, including MA, MPE, and PC, as well as additional cancer indications. Intracavitary malignancies are commonly observed in late-stage cancer patients. The total incidence of intracavitary malignancies, including MA, MPE and PC, worldwide amounted to 2.5 million in 2019 and is expected to reach 3.0 million in 2030. Despite the high incidence, the current standard of care fails to provide meaningful clinical benefit for most patients.

We are conducting five Phase 1 clinical trials for SCB-313 in China and Australia for the treatment of intracavitary malignancies. We expect to advance the development of SCB-313 for the treatment of MA to a Phase 2 clinical trial in the first half of 2022. In addition, we plan to initiate additional Phase 1 clinical trials for SCB-313 to explore new indications, such as bladder cancer, and combination approaches in 2022.

Robust pipeline with novel vaccines and biologic therapeutic candidates against infectious diseases as well as cancer and autoimmune diseases

Leveraging the Trimer-Tag™ technology platform and R&D capabilities, we have established a robust product pipeline with multiple promising innovative vaccine, novel immuno-oncology, and Fc-fusion product candidates. In addition to SCB-2019 (CpG 1018/Alum) and SCB-313 currently undergoing clinical development, we expect to advance multiple innovative candidates into the clinic.

Vaccine pipeline. We are developing innovative vaccine candidates, including second-generation COVID-19 vaccines. We completed candidate selection of a potential second-generation COVID-19 vaccine candidate in the first half of 2021. Concurrently, we are conducting additional vaccine discovery programs for various indications, including rabies, RSV, influenza and HIV, all of which are enveloped RNA viruses that display trimeric spike glycoproteins, a characteristic similar to the SARS-CoV-2 virus.

Oncology pipeline. We are exploring other targets in the TNFSF for immuno-oncology and immunology indications. We are currently conducting discovery programs evaluating trimeric fusion protein candidates targeting the 4-1BB pathway, a member of the TNFSF. Activation of the 4-1BB receptor, which requires trimerization to be activated, is an attractive candidate for applications in cancer immunotherapy and demonstrated potent cytotoxic immune cell activation and antitumor responses in multiple pre-clinical studies. Building on experience utilizing the Trimer-Tag™ technology platform and deep understanding of protein trimerization, we believe we will be able to design a native-like trimeric fusion protein to target the 4-1BB pathway. We expect to make a candidate selection and enter IND-enabling studies in the second half of 2021.

BUSINESS

Fc-fusion pipeline. Leveraging our expertise in protein bioengineering, manufacturing capabilities, and in-house manufacturing facility, we have established a program to develop and commercialize novel molecules and biosimilars in China. Our most advanced program is SCB-808, an Enbrel (etanercept) biosimilar in a ready-for-injection, pre-filled syringe formulation. Enbrel is indicated for the treatment of rheumatic diseases, including ankylosing spondylitis and rheumatoid arthritis. Currently, all approved Enbrel biosimilars in China are in a freeze-dried (lyophilized) powder formulation that require reconstitution by a trained medical professional prior to subcutaneous injection. SCB-808, as a pre-filled syringe, could potentially be self-administered by patients, which would improve patient adherence and address the significant unmet medical needs in China. SCB-808 demonstrated high similarity to Enbrel from a pharmacokinetic and safety profile in a Phase 1 clinical trial. We are conducting a pivotal Phase 3 clinical trial for SCB-808 in China, expect to submit an NDA to the NMPA in the second half of 2023, and commence commercialization thereafter, if approved.

SCB-420 is an Eylea (aflibercept) biosimilar indicated for the treatment of certain large market ophthalmologic diseases such as wet age-related macular degeneration (wAMD). We expect to initiate SCB-420 in a Phase 1 clinical trial in Australia in the fourth quarter of 2021.

SCB-219 is a novel TPO-mimetic Fc-fusion protein being developed for chemotherapy-induced thrombocytopenia (CIT) in China. We expect to initiate a Phase 1 clinical trial in China in the second quarter of 2022.

Established in-house cGMP biologics manufacturing infrastructure and capabilities, ready for commercial launch

We have an in-house, commercial-ready biologics manufacturing facility in Changxing, Zhejiang province, China. This facility is prepared for the rapid scale-up and commercial production of SCB-2019. Our Changxing facility was designed to adhere to the cGMP standards of the U.S., EU, and China. The Changxing facility has received certification by a QP, a requirement to achieve EU cGMP standards.

Our Changxing manufacturing facility is approximately 32,000 sq.m. The facility is equipped with a state-of-the-art, centrally automated, and flexible start-to-finish platform based on single-use technologies for the production of protein-based vaccines and therapeutics. We have four 2,000L bioreactors, multiple fill-finish lines, and will potentially be able to produce more than one billion doses of SCB-2019 annually at peak capacity.

We have established a strong chemistry, manufacturing, and controls (CMC) team with extensive industry expertise and experience in clinical, commercial production, and regulatory compliance. Dr. Michael Berry, Chief Technical Operations Officer, has 33 years of experience in CMC and biologics manufacturing. Dr. Berry held senior management positions at Dynavax, Portola Pharmaceuticals, and Novartis Vaccines & Diagnostics.

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Seasoned management team with decades of industry and scientific expertise, supported by our COVID-19 Scientific Advisory Board and global healthcare investors

We have assembled a seasoned, global senior management team with deep and complementary experience and capabilities in drug discovery, clinical operations, biomanufacturing, drug commercialization, and capital markets. Our senior management team and general management team average 23 years of experience from global biotechnology companies and research institutions.

- **Dr. Peng Liang**, founder, Chairman and Chief Scientific Officer, is the inventor of the Trimer-Tag™ technology platform. Dr. Liang is also the founder and president of GenHunter Corporation, from which we obtained an exclusive license to utilize the Trimer-Tag™ technology platform for the development of innovative product candidates. Dr. Liang is a prolific scientist, with other renowned scientific breakthroughs including his invention of Differential Display for systematic analysis of gene expression, which has been commercialized by GenHunter Corporation; discovery of Interleukin 24 (IL-24), a pro-inflammatory cytokine and its receptors, which was licensed to Wyeth (now Pfizer); and more than 75 original research papers published in peer-reviewed journals. Dr. Liang was a tenured associate professor in the department of Cancer Biology at Vanderbilt University from 2008 to 2009.
- **Mr. Joshua Liang**, Chief Executive Officer and executive Director, has a solid track record in both scientific research and capital markets. Trained in the field of biopharmaceutical research, Mr. Liang is a co-inventor of SCB-2019 and published nine research papers in peer-reviewed journals. Prior to joining us, Mr. Liang worked as an investment banker and executed deal transactions valued over US\$20 billion, in aggregate. Since joining us in 2016, Mr. Liang has raised more than US\$690 million in equity, grant, and non-dilutive financings.
- **Ms. Htay Htay Han**, Chief Medical Officer (Vaccine), has over 24 years of experience in vaccine research and development. Ms. Han was formerly head of early clinical development programs at Takeda. Prior to that, she served as a Senior Director and Clinical R&D Program Lead at GSK.
- **Dr. Philippe Bishop**, Chief Medical Officer (Oncology), has over 22 years of experience in oncology therapeutic development. Dr. Bishop founded Aratinga Bio, Inc. and acted as the Chief Medical Officer and Executive Vice President. Prior to that, he worked at Gilead Biosciences, Roche/Genentech, Johnson & Johnson, Sanofi-Aventis, the FDA, and NCI.

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- **Dr. Xiaobing Li**, Executive Vice President, has over 25 years of experience in biopharmaceutical development. Dr. Li served as a Vice President and Head of Program Leadership and therapeutic portfolio management at Voyager Therapeutics. Prior to that, she held various roles at SAGE Therapeutics, as the Senior Director and Head of Global Program Teams.
- **Dr. Michael Berry**, Chief Technical Operations Officer. Please see “– Established in-house cGMP biologics manufacturing infrastructure and capabilities, ready for commercial launch” for details.

In addition, we established a COVID-19 Scientific Advisory Board (COVID-19 SAB) comprised of esteemed key opinion leaders (KOLs), who provide valuable insights and guidance regarding our global COVID-19 vaccine development strategy. The COVID-19 SAB is comprised of vaccine industry veterans with vast expertise in the vaccine development life-cycle, including R&D, clinical trial design and development, regulatory affairs, and commercialization. The chairman of our COVID-19 SAB, Dr. Ralf Clemens, has over 30 years of experience in vaccine development and held executive positions in several world-renowned multinational corporations. He served as a Senior Vice President of Global Vaccine Development at Takeda, Head of Global Vaccine Development at Novartis, and Vice President of Worldwide Vaccine Clinical R&D at GSK. Dr. Clemens is currently a member of the Board of Trustees of the International Vaccine Institute, a leading global vaccinology organization initiated by the *United Nations Development Programme*.

Our team of exceptional global talent, located in over a dozen countries across China, the U.S., Europe, Latin America, South East Asia, and Australia, are the foundation of our innovation and successes. As of the Latest Practicable Date, among our 716 full-time employees, 38 and 126 held Ph.D. and M.D. degrees, respectively. Our international talent pool has robust expertise in drug discovery, clinical program development, manufacturing, and strengths in business development, corporate management, and project management.

Our shareholders consist of renowned institutional and strategic investors, including Hillhouse, Temasek, Lapam Capital, Delos Capital, Qianhai FoF, Oceanpine Capital, Betta Capital, and OrbiMed.

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OUR STRATEGIES

We have identified key near and long-term corporate strategies and objectives:

Accelerate the development and commercialize SCB-2019 (CpG 1018/Alum)

We obtained data from SPECTRA in September 2021 and plan to submit conditional regulatory approval applications to the EMA, the NMPA and the WHO in the fourth quarter of 2021. We expect to obtain conditional approvals between the fourth quarter of 2021 and the middle of 2022. Post conditional approval, we expect to commence product launch which may occur as early as year end 2021. SCB-2019 (CpG 1018/Alum) is anticipated to potentially be one of the first protein-based COVID-19 vaccines commercialized globally through the COVAX Facility.

Clover also expanded SPECTRA to evaluate adolescents and we plan to initiate various clinical trials for SCB-2019 (CpG 1018/Alum) in subpopulations of COVID-19 vaccine addressable populations, including immunocompromised patients and the pediatric population. We also plan to evaluate the possibility of utilizing SCB-2019 (CpG 1018/Alum) for heterologous booster following primary vaccination and as a homologous booster for SCB-2019 (CpG 1018/Alum).

We will continue to actively prepare for global licensure of SCB-2019 (CpG 1018/Alum) by establishing a commercial-ready manufacturing infrastructure. We executed an advance purchase agreement and committed up to 414 million vaccine doses to the COVAX Facility for global allocation. Please refer to “– Further enhance our research and development, manufacturing, and commercialization capabilities to build an integrated biotechnology company” for details.

Develop our second-generation COVID-19 vaccines

Multiple variants of the SARS-CoV-2 virus have emerged and are circulating globally, including but not limited to the Alpha Variant, Beta Variant, Delta Variant, and Gamma Variant. Given the error-prone nature of RNA virus replication, variants will inevitably emerge as the virus is transmitted. New information about the characteristics of these variants is rapidly emerging and concerns regarding the effectiveness of currently authorized vaccines against them have been raised. We will be able to rapidly develop second-generation COVID-19 vaccine candidates to address these emerging variants, leveraging the proprietary Trimer-Tag™ technology platform. In early 2021, we initiated the production of vaccine antigens against three variants of concern. We completed candidate selection for a potential second-generation COVID-19 vaccine candidate in the first half of 2021. Our pre-clinical immunogenicity study in mice indicated that a modified Beta Variant (B.1.351) protein-based COVID-19 vaccine candidate could potentially be protective against the original SARS-CoV-2 strains and certain variants of concern. We continue to monitor the emerging strains and plan to initiate development of new vaccine candidates as needed.

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Advance the development and commercialize SCB-313 and SCB-808

We plan to rapidly expand the development of SCB-313, an innovative TRAIL-Trimer fusion protein targeting the death receptors to activate the extrinsic cancer cell death pathway. We are conducting five Phase 1 clinical trials for SCB-313 for the treatment of intracavitary malignancies in China and Australia. We expect to advance development of SCB-313 for the treatment of MA to a Phase 2 clinical trial in the first half of 2022. In addition, we plan to initiate additional Phase 1 clinical trials for SCB-313 to explore new indications, such as bladder cancer, and combination approaches in 2022.

We also plan to rapidly advance our development of SCB-808 towards commercialization in China. We are conducting a pivotal Phase 3 clinical trial for SCB-808, expect to submit an NDA to the NMPA in the second half of 2023, and commence commercialization thereafter, if approved.

Expand and advance our product pipeline in vaccines and immuno-oncology

We are conducting various vaccine discovery programs in rabies, RSV, influenza, and HIV, all of which are enveloped RNA viruses that have trimeric spike glycoproteins, similar to the SARS-CoV-2 virus. We have achieved pre-clinical proof-of-concept for each of these vaccine candidates, and intend to continue our R&D efforts with an aim to advance them into clinical stages. We also plan to advance the development of our immuno-oncology product candidates, including an innovative 4-1BB agonist product candidate. In addition to our SCB-2019 (CpG 1018/Alum) and SCB-313 programs currently undergoing clinical development, we expect to advance multiple innovative candidates into the clinic in 2022.

We intend to continue to build our product pipeline based on the Trimer-Tag™ technology platform, which can effectively target a broad spectrum of naturally trimerization-dependent disease and biologic targets. These include dozens of enveloped RNA viruses (e.g. coronaviruses, rabies, RSV, influenza, HIV, and Ebola) and TNFSF, which have diverse biological functions and are linked to serious diseases, such as certain cancers and autoimmune disorders. We will identify and further expand our product pipeline in these two core areas of domain expertise.

Further enhance our research and development, manufacturing, and commercialization capabilities to build an integrated biotechnology company

To become a leading innovative biotechnology company with a diverse global team and unlock the full potential of our technology platform, we intend to further invest in our research and development, manufacturing capabilities and develop our commercialization infrastructure.

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Manufacturing capabilities

We have four 2,000L bioreactors and will potentially be able to produce more than one billion doses of SCB-2019 annually at peak capacity. We have also recently expanded our fill and finish area by adding two vial filling lines. To date, our Changxing facility has received certification by a QP, a requirement to achieve EU cGMP standards. Additional pre-approval GMP inspections are expected to occur as part of the global marketing authorization submission processes for SCB-2019 (CpG 1018/Alum) in 2021. In the third quarter of 2021, we received a Pharmaceutical Manufacturing Permit from the Zhejiang Medical Products Administration for the production of SCB-2019 (CpG 1018/Alum) at the Changxing manufacturing facility. We plan to build an intelligent manufacturing facility with integrated automation technologies, such as the system-wide deployment of digital tools for data-driven operations and streamlined functionalities to enhance production efficiency, accuracy, and accountability. We plan to continue to build our CMC and manufacturing team by recruiting seasoned management and qualified experts.

Commercialization strategy

During the pandemic period (as declared by the WHO), SCB-2019 (CpG 1018/Alum) will be purchased by and allocated through the COVAX Facility pursuant to the orders to be placed between us and GAVI, the United Nations International Children’s Emergency Fund (UNICEF), the Pan American Health Organization (PAHO), or other potential parties. We executed an advance purchase agreement to supply up to 414 million vaccine doses to the COVAX Facility for global allocation. We may also consider commercializing SCB-2019 (CpG 1018/Alum) post conditional approval via bilateral negotiations and supply arrangements with global governments.

During the post-pandemic period, we may sell up to 50% of our production capacity for SCB-2019 (CpG 1018/Alum) to the COVAX Facility if required, and we intend to sell the remaining amount through bilateral negotiations and supply arrangements with global governments. We plan to build an efficient commercial team with a presence in major countries around the globe that can support our efforts in providing an effective and safe COVID-19 vaccine during the post-pandemic period.

We plan to continue to evaluate and develop commercial infrastructure in anticipation of the launch of SCB-808, SCB-313, and other pipeline products. We intend to adopt a tailored commercialization strategy for each of our product candidates. We may explore the possibility of a strategic collaboration with one or multiple qualified organizations that have relevant branding and commercial capabilities to ensure a quick uptake of our product candidates and broad patient access in China and globally.

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Explore synergistic and collaborative opportunities to enhance our growth and increase our value as a global biotechnology company

We are an innovative biotechnology company that aims to deliver next-generation solutions to empower the global population with a healthier future. We plan to achieve our vision by strengthening relationships with our existing strategic partners and seeking opportunities to collaborate with new partners.

We are committed to partnering with leading global healthcare organizations to advance our breakthrough pipeline programs and deliver our therapeutics to the global population as safely and as quickly as possible. We have established partnerships with CEPI, Dynavax and GAVI with the aim to deliver a safe and effective COVID-19 vaccine to countries and regions around the world affected by the COVID-19 pandemic. In addition to our internal manufacturing capabilities, we have engaged multiple CMOs, including Wuxi Vaccines, to potentially produce hundreds of millions of additional doses of SCB-2019 (CpG 1018/Alum) starting in 2022. As of the Latest Practicable Date, technology transfer activities from Clover to WuXi Vaccines for the manufacturing of SCB-2019 (CpG 1018/Alum) have begun.

In addition, we expect to continue to explore additional or deepen strategic relationships with premiere global biopharmaceutical companies and/or academic institutions to derive further value from the Trimer-Tag™ technology platform, our innovative product pipeline, and our platform capabilities. We will also continue to engage with leading experts in our areas of interest and expand our scientific and clinical capabilities. We will remain agile in partnership engagement and explore co-discovery, out-licensing, in-licensing, strategic collaboration, and joint venture opportunities to realize synergistic value from our platform and pipeline, enhance our focus on our core competencies, and maximize the commercial potential of our pipeline products. We seek to establish valuable partnerships with the Trimer-Tag™ technology platform to help broaden and rapidly advance our R&D and commercialization efforts.

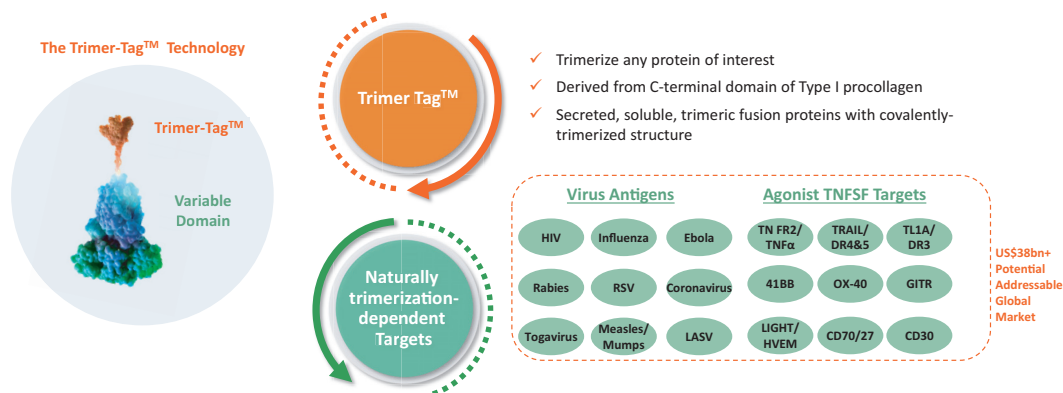
THE TRIMER-TAG™ TECHNOLOGY PLATFORM

Overview

The Trimer-Tag™ technology platform is a product development platform for the creation of novel vaccines and biologic therapies. The Trimer-Tag™ technology platform can trimerize any protein of interest and target a broad spectrum of naturally trimerization-dependent disease and biologic targets. By employing the Trimer-Tag™ technology platform, we are able to produce innovative, covalently-trimerized fusion proteins to effectively target previously difficult to target pathways. Globally, Trimer-Tag™ is the only trimerization technology platform for designing and producing recombinant, covalently-linked, trimeric fusion proteins (trimer-tagged proteins) exploiting a human-derived trimerization tag, according to the Frost & Sullivan Report. While there are various technologies to trimerize proteins of interest, the Trimer-Tag™ technology platform is the only technology platform that is based on a human amino acid sequence derived from human collagen (C-terminal domain of Type I procollagen). The Trimer-Tag™ technology platform is the foundation of our robust portfolio of product development programs, including novel vaccines and biologic therapeutic candidates to address infectious diseases as well as cancer and autoimmune diseases. From the Trimer-Tag™ technology platform, we developed a patent portfolio held by Clover that consists of one issued U.S. patent which will expire in 2038, and 22 patent applications, including 19 PCT patent applications in six patent families, and three U.S. patent applications, as of the Latest Practicable Date. The patents held by GenHunter for the Trimer-Tag™ technology platform will expire in 2024.

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The following diagram illustrates key features of the Trimer-Tag™ technology platform and naturally trimerization-dependent disease and biologic targets that could potentially be addressed by leveraging the Trimer-Tag™:



Key Features of Trimer-Tag™ Technology Platform

The Trimer-Tag™ technology platform can trimerize any protein of interest into covalently-trimerized structures. The trimerization motif of Trimer-Tag™ is based on a human amino acid sequence derived from human collagen (C-terminal domain of Type I procollagen). Collagen, the most abundant protein in the human body, is capable of self-assembly into covalently-linked trimers during its formation process via the C-propeptide domain. The Trimer-Tag™ motif possesses structural flexibility and mechanical properties that are ideal for enabling trimer-tagged virus spike proteins and TNFSF ligands to achieve native-like trimeric structures. The resulting fusion proteins are produced recombinantly in mammalian cells, secreted as soluble proteins in trimeric form, and covalently linked by inter-molecular disulfide bonds formed among the three C-terminal domains of Type I procollagen. Purification of trimer-tagged proteins is performed in-house by utilizing an affinity purification scheme directed to Trimer-Tag™ which allows us to achieve high levels of purity.

Key advantages the Trimer-Tag™ technology platform include:

Trimerizing Any Protein of Interest and Broad Application Potential

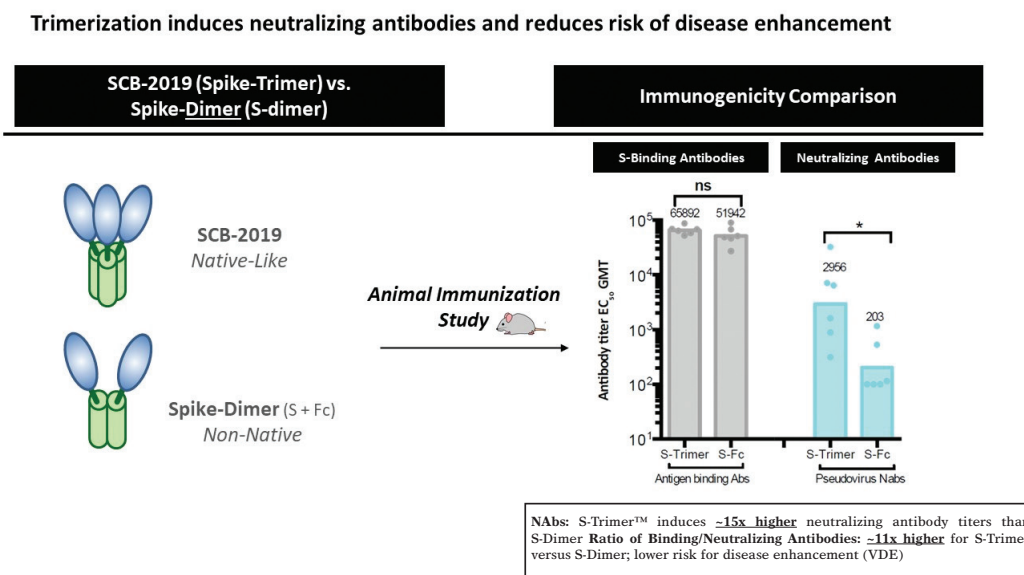
The Trimer-Tag™ technology platform can trimerize any protein of interest and target a broad spectrum of naturally trimerization-dependent disease and biologic targets. These include dozens of enveloped RNA viruses (e.g. coronaviruses, rabies, RSV, influenza, HIV, and Ebola) and the TNFSF, which have diverse biological functions and are linked to serious diseases, such as certain cancers and autoimmune disorders. According to Frost & Sullivan, the potential overall addressable market size of the Trimer-Tag™ technology platform, considering diseases caused by both enveloped RNA viruses and TNFSF, is estimated to be more than US\$38 billion globally.

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Antigens of Enveloped RNA Viruses

There are more than 20 known enveloped RNA viruses, including coronaviruses, rabies, RSV, influenza, HIV, and Ebola, that utilize naturally trimeric S proteins to bind to the host cell surface receptor ACE2 and subsequently enter the host cells. With the Trimer-Tag™ technology platform, we can develop novel vaccines using fusion proteins with a native-like trimeric structure. Protein-based vaccines deployed against the aforementioned viruses aim to preserve the native trimeric structure of the spike proteins to induce the desired and optimal neutralizing immune responses. Comparing pre-clinical mouse model vaccination data from SCB-2019 (Spike-Trimer) head-to-head with a Spike-Dimer (S-dimer), SCB-2019 induced approximately 15-fold higher neutralizing antibodies than the non-native-like S-dimer.

Trimer-Tag™ Technology Platform



Trimer-Tag™ technology platform enables the production of native-like viral spike antigens which mimic the trimeric spike antigens found on enveloped RNA viruses such as SARS-CoV-2. We achieved initial S-Trimer™ antigen expression for SCB-2019 (CpG 1018/Alum) within 15 days of program initiation in early February 2020 and accomplished first-in-human dosing in June 2020, within 5 months of program initiation. We also previously developed recombinant subunit-Trimer vaccines for RSV and influenza viruses utilizing the Trimer-Tag™ technology platform and demonstrated that these vaccine candidates evoke immune protection and/or neutralizing antibody responses in multiple animal models.

Tumor Necrosis Factor (TNF) Super family

The TNF superfamily is comprised of 19 ligands and 29 receptors, all of which require receptor trimerization for signal activation. These targets are involved in extrinsic apoptosis, immune co-stimulation, and inflammation and are linked to serious diseases, such as certain cancers and autoimmune disorders, according to Frost & Sullivan. The Trimer-Tag™ technology platform can be used to effectively design and produce ligands and receptors with a covalently-linked and native-like trimeric structure. Trimer-tagged proteins demonstrate a high binding affinity to their targets and/or high potency compared to corresponding dimeric antibody-based structures.

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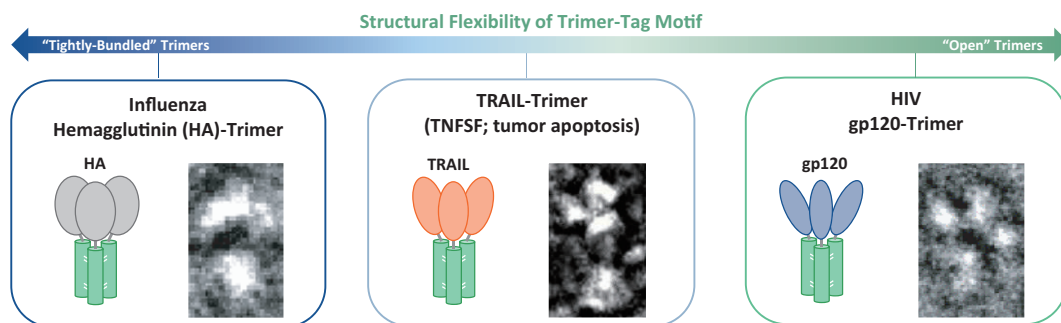
The majority of targets in the TNFSF have been traditionally difficult to effectively target, and the clinical development of novel agents such as recombinant human TRAIL ligand and dimeric agonist antibodies to death receptor 4 (DR4) and death receptor 5 (DR5), lacked the ability to potently activate the death receptor signaling pathways. Functional and structural studies have shown that DR4 and DR5 require trimerization on the cell membrane to drive receptor signaling to induce apoptosis. Trimerization of the receptor leads to clustering of intracellular domains that recruit and activate downstream signaling proteins for apoptosis to occur.

With the Trimer Tag™ technology platform, we have successfully designed and developed SCB-313 as a covalently-linked, native-like trimeric fusion protein, which is structurally and functionally differentiated from dimeric antibody-based structures and other native ligand-based candidates targeting this pathway. In both *in vivo* and *in vitro* pre-clinical studies, SCB-313 demonstrated favorable pharmacodynamics and pharmacokinetics profiles with an extended intracavitary half-life, which results in greater drug exposure to target tumor cells locally, potentially translating to anti-tumor efficacy. For details, see “– Our Product Candidates – Trimer-Tag™ Oncology Product Candidates – SCB-313.”

High Potency Against Covalently-trimerized Disease Targets

The Trimer-Tag™ motif possesses structural flexibility, enabling trimer-tagged virus spike proteins and TNFSF ligands to achieve stable, covalently-linked, and native-like trimeric structures. In a pre-clinical study, SCB-313 exhibited high binding affinity to their targets compared to corresponding dimeric antibody-based structures and other native ligand-based candidates, a characteristic that may contribute to the biological activity of trimer-tagged proteins.

The following diagram illustrates the structural flexibility of the Trimer-Tag™ motif, allowing the protein-of-interest to achieve its native-like trimeric structure:



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Human Amino Acid Sequence, Secreted Fusion Protein, and Favorable Safety Profile

The trimerization motif of Trimer-Tag™ is based on a human amino acid sequence derived from human collagen (C-terminal domain of Type I procollagen). Collagen, the most abundant protein in the human body, is capable of self-assembly into covalently-linked trimers during its formation process via the C-propeptide domain. The trimeric C-terminal domain of Type I procollagen circulates naturally in the blood of humans and is not known to be toxic to the human body. We believe trimer-tagged fusion proteins will have a low risk of inducing anti-Trimer-Tag™ antibodies in the human body, and thus contribute to having a favorable safety profile.

Beyond Proof-of-concept for Trimer-Tag™ Technology Platform

We achieved initial S-Trimer™ antigen expression for SCB-2019 (CpG 1018/Alum) within 15 days of program initiation in early February 2020 and accomplished first-in-human dosing in June 2020, within 5 months of program initiation. To date, we have successfully announced positive preclinical, Phase 1 and Phase 2/3 results for SCB-2019 (CpG 1018/Alum). After the Beta Variant was globally identified, we initiated our second-generation COVID-19 vaccine program and achieved initial antigen expression in February 2021 within a few weeks of program initiation and subsequently announced informative preclinical results. These achievements serve as a strong proof-of-concept for our ability to leverage the Trimer-Tag™ technology platform to rapidly develop new promising product candidates and advance them quickly into the clinic.

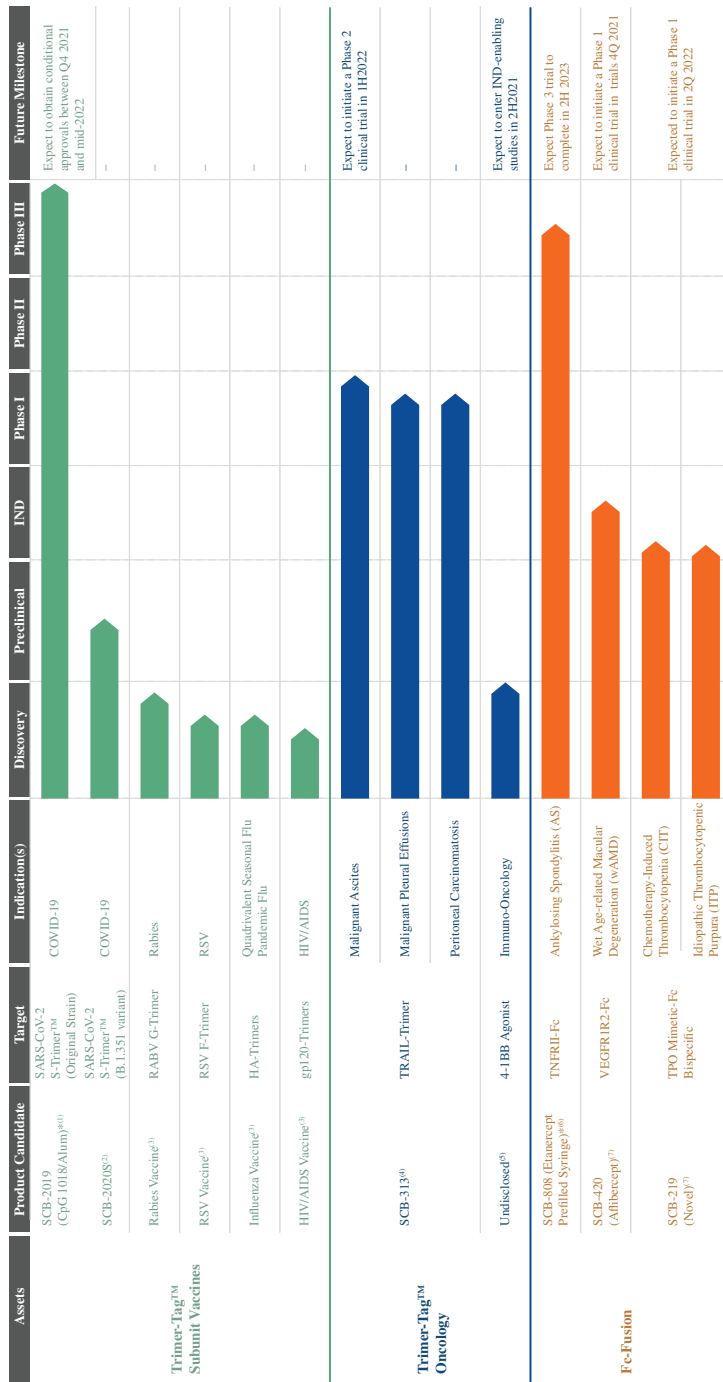
OUR PRODUCT CANDIDATES

Product Pipeline Overview

We have built our product pipeline by employing the Trimer-Tag™ technology platform and leveraging our in-house biologics manufacturing infrastructure and capabilities. As of the Latest Practicable Date, our product pipeline consisted of (i) six Trimer-Tag™ subunit vaccine candidates, including SCB-2019 (CpG 1018/Alum), a Core Product, for which we obtained SPECTRA results in September 2021, (ii) two Trimer-Tag™ oncology product candidates, including SCB-313 for which we are conducting five Phase 1 clinical trials in China and Australia, and (iii) three Fc-fusion product candidates, including SCB-808, a Core Product, for which we are conducting a pivotal Phase 3 clinical trial in China. In addition, we plan to submit the NDA for all of our product candidates except SCB-808 and SCB-420 to the NMPA for approval as Category I therapeutic products and all of our product candidates were developed in-house to date.

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The chart below summarizes the development status of our product candidates as of the Latest Practicable Date.



* Core Products

Notes:

- (1) Our Core Product and our COVID-19 vaccine candidate. We announced SPECTRA met the primary and secondary efficacy endpoints in September 2021. We expect to obtain conditional approvals between the fourth quarter of 2021 and the middle of 2022. Post conditional approval, we expect to commence product launch which may occur as early as year end 2021.
- (2) Our pre-clinical stage second-generation COVID-19 vaccine candidate designed with the NTD based on the original strain and RBD based on the Beta variant. This construct could potentially induce neutralization against multiple SARS-CoV-2 variants by including (a) anti-RBD antibodies targeting E484K and K417N mutations that can neutralize the Beta Variant and Gamma Variant and (b) anti-NTD antibodies that can neutralize the original strains.
- (3) Our vaccine candidates are in early stage development.
- (4) Our oncology product candidate for the treatment of malignant ascites (MA), malignant pleural effusions (MPE), and peritoneal carcinomatosis (PC) to address global unmet medical need of intracavitary malignancies. We are conducting five Phase 1 clinical trials for SCB-313 in China and Australia for the treatment of intracavitary malignancies. We expect to advance the development of SCB-313 for the treatment of MA to a Phase 2 clinical trial in the first half of 2022. We plan to initiate additional Phase 1 clinical trials for SCB-313 to explore new indications, such as bladder cancer, and combination approaches in 2022.
- (5) Our oncology product candidate is in early stage development and we are still assessing the target indication(s) for this product.
- (6) Our Core Product and Fc-Fusion product candidate is a biosimilar to Enbrel. In China, Enbrel was approved by the NMPA in February 2010 to treat RA and AS. We received the IND approval from NMPA in November 2017 and completed a Phase 1 clinical trial in January 2019. We are conducting a Phase 3 clinical trial, which is expected to complete in second half of 2023. To date, the NMPA did not raise any objections or material concerns with respect to the development of SCB-808.
- (7) Our Fc-Fusion product candidates are in early stage development.

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Our Pipeline Strategies

Leveraging the Trimer-Tag™ technology platform and R&D capabilities, we have established a robust product pipeline with multiple promising innovative vaccine, novel immuno-oncology, and Fc-fusion product candidates. We are committed to empowering the global population with a healthier future by delivering novel vaccines and biologic therapies. We believe that our pragmatic approach to product development, rooted in a foundation of agile, collaborative and visionary thinking, enables us to rapidly identify and create trimeric fusion proteins at scale, addressing vast populations in need. In early 2020, we quickly leveraged the Trimer-Tag™ technology platform to develop a COVID-19 vaccine candidate, and by September 2021, we obtained results from our global pivotal Phase 2/3 COVID-19 vaccine candidate clinical trial. In addition to the current acute need, we continue to leverage the Trimer-Tag™ technology platform by exploring vaccine development in rabies, RSV, influenza, and HIV.

We also remain committed to developing novel drugs to treat other diseases, such as certain cancers and autoimmune disorders. Through the Trimer-Tag™ technology platform, we are able to develop therapeutics aimed at naturally trimerization-dependent targets, such as TNFSF targets which are involved in extrinsic apoptosis, immune co-stimulation, and inflammation. Our Trimer-Tag™ oncology product candidates, SCB-313 and a 4-1BB agonist, have demonstrated pre-clinical efficacy and provide novel promising approaches with the potential to address significant unmet medical needs.

Our pipeline is further bolstered by leveraging our CMC expertise and capabilities in biologics manufacturing, which are also being utilized for the development of Fc-fusion product candidates, namely SCB-808, SCB-420, and SCB-219.

In addition to our current pipeline, we continue to evaluate additional trimerization-dependent disease targets by utilizing the Trimer-Tag™ technology platform, with a focus on indications with global unmet need.

Trimer-Tag™ Subunit Vaccine Candidates

SCB-2019 (CpG 1018/Alum)

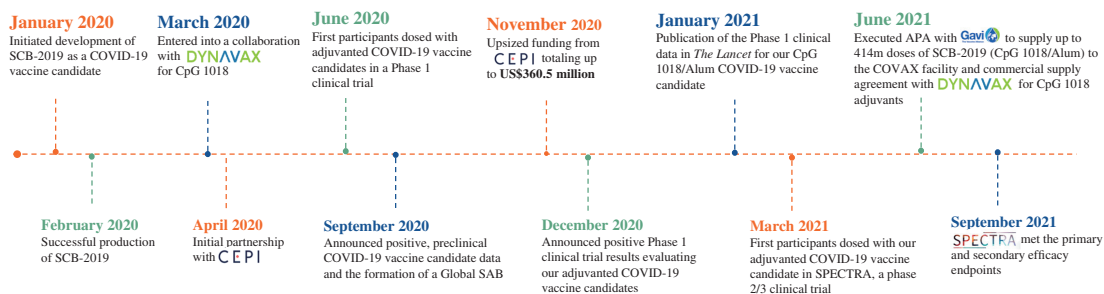
Summary

SCB-2019 (CpG 1018/Alum) consists of two key components, an antigen and an adjuvant. Employing the Trimer-Tag™ technology platform, we developed a SCB-2019 antigen, a stabilized trimeric form of the S-protein (S-Trimer™) based on the original strain of SARS-CoV-2. We created our COVID-19 vaccine candidate by combining SCB-2019 antigen (30 ug/dose) with Dynavax’s CpG 1018 advanced adjuvant and aluminum hydroxide (alum).

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We achieved initial S-Trimer™ antigen expression for SCB-2019 (CpG 1018/Alum) within 15 days of program initiation in early February 2020 and announced positive Phase 1 clinical data in December 2020. The encouraging immunogenicity data and safety/tolerability results were subsequently published in *The Lancet* in January 2021. We obtained and announced results from SPECTRA, a global, pivotal Phase 2/3 clinical trial, in September 2021. The following chart illustrates the key milestones for SCB-2019 (CpG 1018/Alum):

A Period of Meteoric Progress: SCB-2019 (CpG 1018/Alum) Milestones



We announced SPECTRA met the primary and secondary efficacy endpoints in September 2021. Based on the SPECTRA results, SCB-2019 (CpG 1018/Alum) demonstrated 100% efficacy against severe COVID-19, 100% efficacy against hospitalizations due to COVID-19, and 84% efficacy against moderate-to-severe COVID-19 caused by any strain of SARS-CoV-2 in SPECTRA. SCB-2019 (CpG 1018/Alum) also demonstrated 79% overall efficacy against COVID-19 of any severity caused by the globally dominant Delta variant, which currently comprises over 90% of all cases worldwide. Efficacy was 92% against the Gamma variant and 59% against the Mu variant, and collectively these three strains (Delta, Gamma and Mu) comprised 73% of all strains identified in SPECTRA. Overall efficacy was 67% against any strain in SPECTRA, successfully meeting the primary endpoint of the trial. SCB-2019 (CpG 1018/Alum) also had a favorable safety profile in SPECTRA with no significant differences in systemic solicited adverse events or severe/serious adverse events compared to placebo. Moreover, SCB-2019 (CpG 1018/Alum) was also the first COVID-19 vaccine candidate to demonstrate a significantly reduced risk of COVID-19 in previously infected individuals. We believe the data from SPECTRA indicate that SCB-2019 (CpG 1018/Alum) could be a compelling vaccine candidate to induce strong protective immunity against various strains of the SARS-CoV-2 virus to prevent COVID-19 disease.

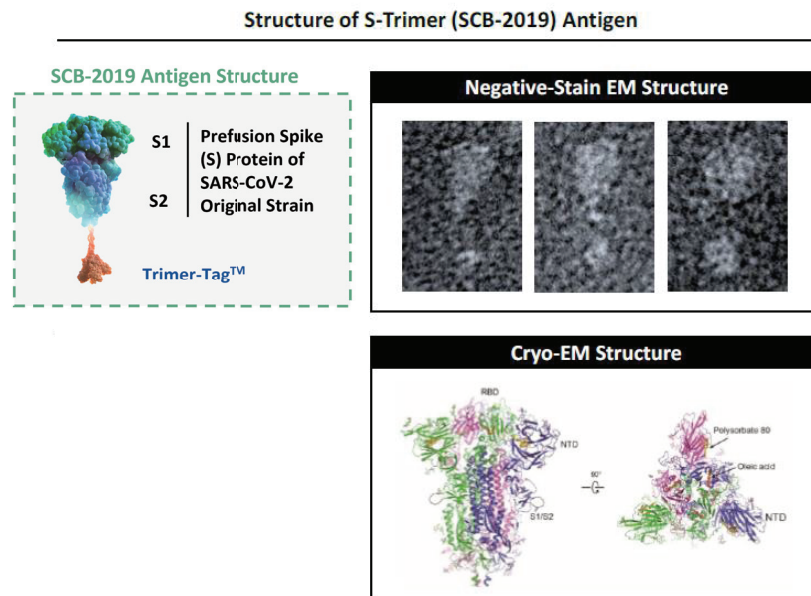
We plan to submit conditional regulatory approval applications to the EMA, the NMPA and the WHO in the fourth quarter of 2021. We expect to obtain conditional approvals between the fourth quarter of 2021 and the middle of 2022. Post conditional approval, we expect to commence product launch which may occur as early as year end 2021. We expect to commercialize SCB-2019 (CpG 1018/Alum) as one of the first protein-based COVID-19 vaccines globally.

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Mechanism of Action

SCB-2019 is a recombinant SARS-CoV-2 fusion protein developed by employing the Trimer-Tag™ technology platform. The main viral antigenic target of SCB-2019 is the spike (S) glycoprotein, a trimeric protein consisting of two subunits (S1 and S2) that are essential for viral binding, fusion, and uptake into mammalian cells. The S1 receptor binding domain (RBD) binds to human cell surface receptor ACE2 and, after proteolytic cleavage, the S2 subunit undergoes a major conformational change leading to fusion and intracellular uptake of viral mRNA for replication. Interference with this process is the basis of most immunological approaches to prevent COVID-19 infections, including vaccine technologies. The role of the S protein in binding with the host receptor ACE2 makes it an optimal target for vaccine and antiviral therapeutic development.

Engineered from the Trimer-Tag™ technology platform, SCB-2019 consists of two parts, namely the native trimeric S-protein and the Trimer-Tag™. When soluble receptors or biologically active proteins are fused into a Trimer-Tag™, the resulting fusion proteins expressed in mammalian cells are secreted as covalently-linked, native-like trimers. SCB-2019 preserves the native trimeric structure of the S-protein in the pre-fusion form, which is believed to be important for inducing antibodies against important viral neutralization epitopes. The following diagram illustrates the structure of SCB-2019:



Abbreviation(s): EM=electron microscopy.

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The major target for vaccine development for SARS-CoV-2 is the spike (S) protein of the virus, responsible for attachment and cell entry via the cellular receptor hACE2. Therefore, the goal for all COVID-19 vaccines is to induce high levels of neutralizing antibodies to the S protein. SCB-2019, the antigen we developed using the Trimer-Tag™ technology, is a native-like, stabilized form of the recombinant S-protein in a native trimeric prefusion conformation form. Injection of the SCB-2019 (the recombinant protein) mimics the contact process that would occur with the natural virus and stimulates an immune response against the S protein. Our vaccine candidate is adjuvanted to elicit strong immune responses. Adjuvants are pharmacological or immunological substances that can be added to a specific protein (antigen) in a vaccine to help boost the immune response triggered by the vaccine. The combination of stabilized S-protein with well-established adjuvant systems represents a promising vaccine candidate in terms of eliciting protective immunity against a broad spectrum of SARS-CoV-2 variants without inducing immunopathology.

We use an adjuvant system that contains aluminum hydroxide (Alum) and CpG 1018. Alum adsorbs the recombinant protein and associates with a slow release of antigen. In addition, alum promotes activation and trafficking of antigen-presenting cells to lymphoid tissues. Inclusion of Alum appears to promote high titers of neutralizing antibodies against the spike protein. The addition of CpG 1018 is associated with cell-mediated immune response by further increasing the antibody concentration and stimulating helper (CD4+) and cytotoxic (CD8+) T cell populations, generating robust T and B cell memory responses. These responses are important for long-term and broad protection against multiple variants of SARS-CoV-2.

Both adjuvants are proven technologies currently used in FDA- and EMA-approved and commercialized vaccines. These two adjuvants are produced at scale under cGMP conditions and have significant safety databases in clinical and post-marketing studies.

Market Opportunity and Competition

As of the Latest Practicable Date, the global COVID-19 pandemic caused by the SARS-CoV-2 virus has resulted in approximately 236 million infections and 4.8 million deaths globally. Infections are causing unprecedented numbers of cases of severe respiratory illness, with a substantial proportion of patients requiring intensive care, and in certain instances of unresolved cases, long-term respiratory and cognitive complications. COVID-19 is associated with high transmission rates and, without adequately acute effective treatment, a significant number of patients experience respiratory distress, threatening to overwhelm global healthcare capacity. Vaccines are widely considered to be the most effective solution to control the pandemic and reduce disease burden.

It is estimated that a total of approximately 15 billion COVID-19 vaccine doses will be required through 2026 worldwide, assuming a two-dose vaccine regimen and taking into consideration global government procurement and stockpiling, according to Frost & Sullivan. In addition, periodic booster shots or re-vaccination may be needed especially as new variants emerge, resulting in a significant global need for COVID-19 vaccines for years to come.

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Multiple vaccine technologies have entered into clinical trials, including mRNA and DNA vaccines, adenovirus-based viral vector vaccines, inactivated virus vaccines, and protein-based subunit vaccines. Please refer to “Industry Overview – COVID-19 Vaccine Market Globally” for the attributes of each development platform, essential characteristics for a successful COVID-19 vaccine, and advantages of protein-based COVID-19 vaccines.

On August 23, 2021, the U.S. FDA granted full approval for Pfizer-BioNTech’s COVID-19 vaccine. In addition, as of the Latest Practicable Date, three vaccines have been authorized for emergency use by the FDA and four vaccines have been conditionally approved by the EMA. The FDA has authorized two mRNA-based vaccines and one adenovirus-based viral vector vaccine for emergency use. The EMA conditionally approved two mRNA-based vaccines and two adenovirus-based viral vector vaccines. Please refer to “Industry Overview – COVID-19 Vaccine Market Globally” for details of the development and approval status of Phase 2/3 or later-stage COVID-19 vaccines globally as of the Latest Practicable Date.

Competitive Advantages of SCB-2019 (CpG 1018/Alum)

We believe SCB-2019 (CpG 1018/Alum) demonstrated the following advantages in SPECTRA, Phase 1 clinical trials, and pre-clinical studies, making it a promising COVID-19 vaccine candidate:

Highly Stable and Well-suited for Global Storage and Distribution

The stability profile of SCB-2019 (CpG 1018/Alum) makes it suitable for global distribution and mass vaccination campaigns. Based on our ongoing stability studies, SCB-2019 (CpG 1018/Alum) is stable for at least two months at room temperature and is expected to be stable for approximately 12 months in refrigeration conditions. In contrast, the two mRNA-based vaccines authorized for emergency use by the FDA and conditionally-approved by the EMA require minus 70 degrees Celsius and minus 20 Celsius conditions for long-term storage, according to Frost & Sullivan. Because SCB-2019 (CpG 1018/Alum) is stable for at least two months at room temperature and is expected to be stable for approximately 12 months in refrigeration conditions, it is a potentially preferable and a more cost-effective solution for global distribution by leveraging existing and conventional infrastructure, a necessity when transporting to remote and low-resource regions.

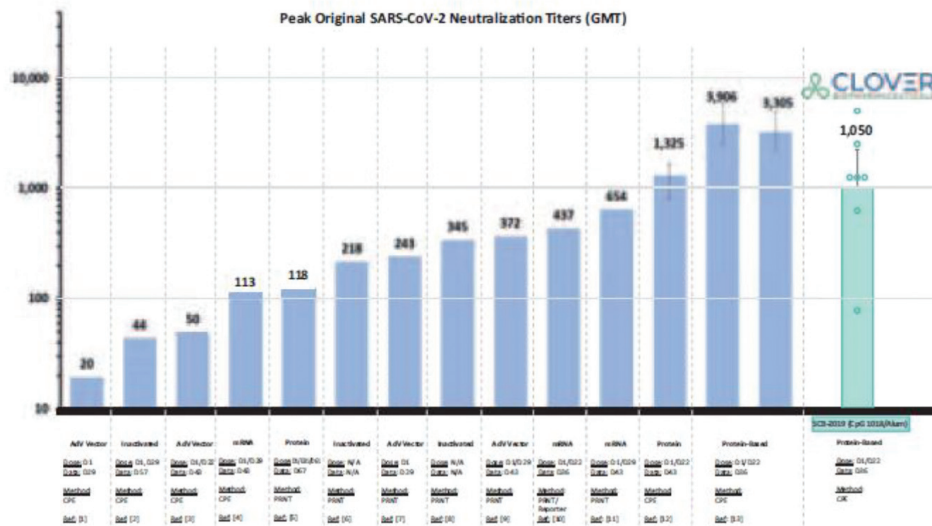
Strong Immune Responses Leading to Protective Immunity

Based on the SPECTRA results, SCB-2019 (CpG 1018/Alum) demonstrated 100% efficacy against severe COVID-19, 100% efficacy against hospitalizations due to COVID-19, and 84% efficacy against moderate-to-severe COVID-19 caused by any strain of SARS-CoV-2 in SPECTRA. SCB-2019 (CpG 1018/Alum) also demonstrated 79% overall efficacy against COVID-19 of any severity caused by the globally dominant Delta variant, which currently comprises over 90% of all cases worldwide. Efficacy was 92% against the Gamma variant and 59% against the Mu variant, and collectively these three strains (Delta, Gamma and Mu) comprised 73% of all strains identified in SPECTRA. Overall efficacy was 67% against any

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strain in the study, successfully meeting the primary endpoint of the trial. Moreover, SCB-2019 (CpG 1018/Alum) was also the first COVID-19 vaccine candidate to demonstrate significantly reduced risk of COVID-19 in previously infected individuals. Our Phase 1 clinical trial and pre-clinical studies also demonstrated SCB-2019 (CpG1018/Alum) induces Th1-biased cell-mediated immune responses. These results correlate to a strong immunogenicity profile, suggesting an optimal and balanced immune response:

- Strong immunogenicity evidenced by top-tier neutralizing antibody titers.* Neutralizing antibodies can prevent viruses from interacting with host cells and are part of humoral immunity. For COVID-19 vaccine candidates, a high level of neutralizing antibody titers, as measured by geometric mean titers (GMTs), is considered to be a strong biomarker of the potency and immunogenicity of the vaccine. In the Phase 1 clinical trial, SCB-2019 (CpG 1018/Alum) induced neutralizing antibodies in 100% of adult participants at the 30 µg S-Trimer dose with GMTs greater than 1:1,000, and seroconversion was observed in 88% (7 out of 8) of the elderly. The following diagram illustrates the peak GMTs of our SCB-2019 (CpG 1018/Alum) in Phase 1 clinical trial compared to other COVID-19 vaccines and vaccine candidates in adults in non-head-to-head trials:

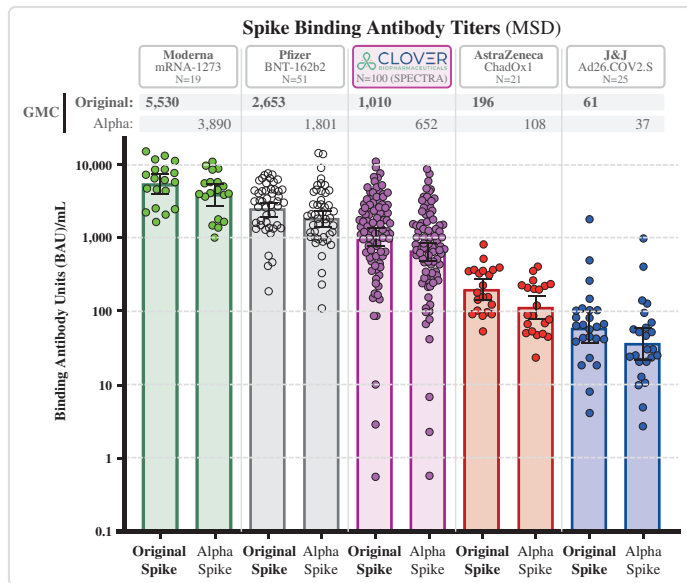


Note: Data in adults. Cross-study comparisons for illustrative purposes-only. Geometric mean titers ± 95% CI shown (where applicable). HCS (Human Convalescent Sera – Clover’s panel shown). [1] doi.org/10.1016/S0140-6736(20)31605-6, [2] doi.org/10.1016/S1473-3099(20)30843-4, [3] doi.org/10.1016/S0140-6736(20)31866-3, [4] doi.org/10.1101/2020.11.09.20228551, [5] doi.org/10.1016/S1473-3099(21)00127-4, [6] Industry reports, [7] doi.org/10.1101/2020.09.23.20199604, [8] Industry reports, [9] doi.org/10.1016/S0140-6736(20)31604-4, [10] doi.org/10.1038/s41586-020-2639-4, [11] doi.org/10.1056/NEJMoa2022483, [12] doi.org/10.1011/2020.11.04.20226282, [13] doi.org/10.1056/NEJMoa2026920.

A head-to-head assay comparison of binding antibody titers was conducted with 100 serum samples from participants vaccinated with 2 doses of SCB-2019 (CpG 1018/Alum) in Clover’s SPECTRA Phase 2/3 trial. These samples were sent to a central lab in the U.K. (David Goldblatt) for binding antibody testing. The serum was from baseline seronegative participants (SARS-CoV-2 naïve). The Median Age of the study samples was 35 years

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with a minimum age of 18 and a maximum age of 73. This study enabled Clover to perform a head-to-head comparison of serum antibody titers from participants administered with SCB-2019 (CpG 1018/Alum) in SPECTRA to the antibody titers of the four approved vaccines, namely Moderna, Pfizer, AstraZeneca, and J&J, specifically using the same assays in the same laboratory. SCB-2019 (CpG 1018/Alum) exhibited in-line or higher antibody titers compared to the four COVID-19 vaccines. This study suggests that SCB-2019 (CpG 1018/Alum)’s neutralizing antibody titers could be comparable with the COVID-19 mRNA vaccines, based on neutralizing/binding antibody ratios observed in previous studies. SCB-2019 (CpG 1018/Alum) showed approximately five to six times higher binding antibody titers versus ChadOx1 (AstraZeneca) COVID-19 vaccine in this study and approximately 16 to 18 times higher binding Ab titers versus Ad26.COVS.2.S (J&J) COVID-19 vaccine in this study. We also note that SCB-2019 (CpG 1018/Alum) also demonstrated an 81-94% efficacy against the original strain as predicted based on correlation analysis ($\rho = 0.94$) of binding antibody titers and vaccine efficacy^(1,3) “– Efficacy and Immunogenicity Data.” The following diagram illustrates the peak spike binding antibody titers of our SCB-2019 (CpG 1018/Alum) compared to other FDA or EMA conditionally approved COVID-19 vaccines:

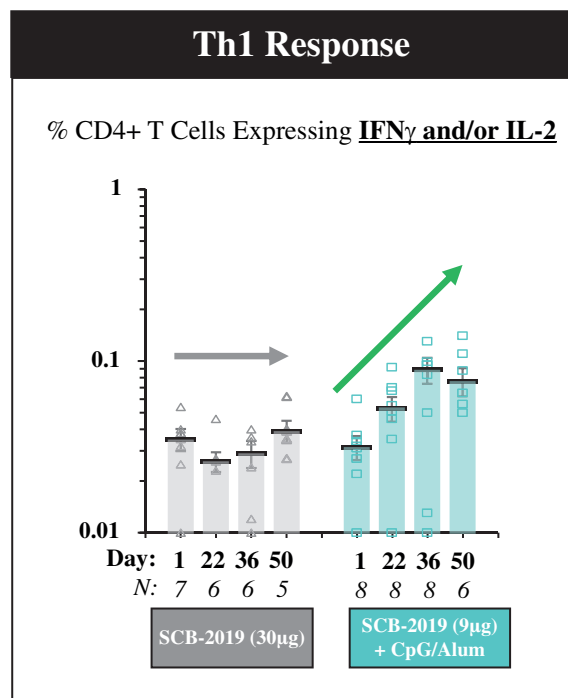


Note: Bars represent Geometric Mean Concentrations (GMC) of Spike IgG BAU/mL. Error bars represent 95% Confidence Intervals (95% CI). Data shown for 4 COVID-19 vaccines including Moderna mRNA-1273 vaccine (median age: 35; min-max: 20-55), Pfizer BNT-162b2 vaccine (median age: 43; min-max: 21-77), AstraZeneca ChadOx1 nCoV-19 vaccine (median age: 60; min-max: 23-70), J&J Ad26.COVS.2.S vaccine (median age: 48; min-max: 31-69).

- (1) DOI: 10.21203/rs.3.rs-902086/v1
- (2) Ratio of neutralizing antibodies (vaccine/HCS) to binding antibodies (vaccine/HCS) in prior clinical studies implies that adjuvanted protein-based vaccines (Clover and Novavax) induce approximately 3x higher ratio of neutralizing-to-binding antibodies compared to mRNA vaccines (Moderna and Pfizer). Clover (DOI: 10.1016/S0140-6736(21)00258-0); Novavax (DOI: 10.1056/NEJMoa2026920); Moderna (DOI: 10.1056/NEJMoa2022483), Pfizer (DOI: 10.1038/s41586-020-2639-4). HCS (human convalescent sera).

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- *Strong immunogenicity evidenced by strong Th1-biased cell-mediated immune responses.* Virus-specific T-cell immune responses were detected in patients who had recovered from COVID-19, including CD4+ T-cell immune responses. These are mainly associated with Th1 cytokines, suggesting that strong Th1-biased cell-mediated immune responses are likely to contribute to vaccine efficacy, according to Frost & Sullivan. SCB-2019 (CpG 1018/Alum) demonstrated the ability to elicit strong Th1-biased cell-mediated immune responses with weak or no Th2- and Th17- cell-mediated immune responses in our Phase 1 clinical trial. The following diagram illustrates the increase in percentage of CD4+ T cells differentiated to Th1 cells on day 1, 22, 36, and 50 post-administration of SCB-2019 (CpG 1018/Alum):



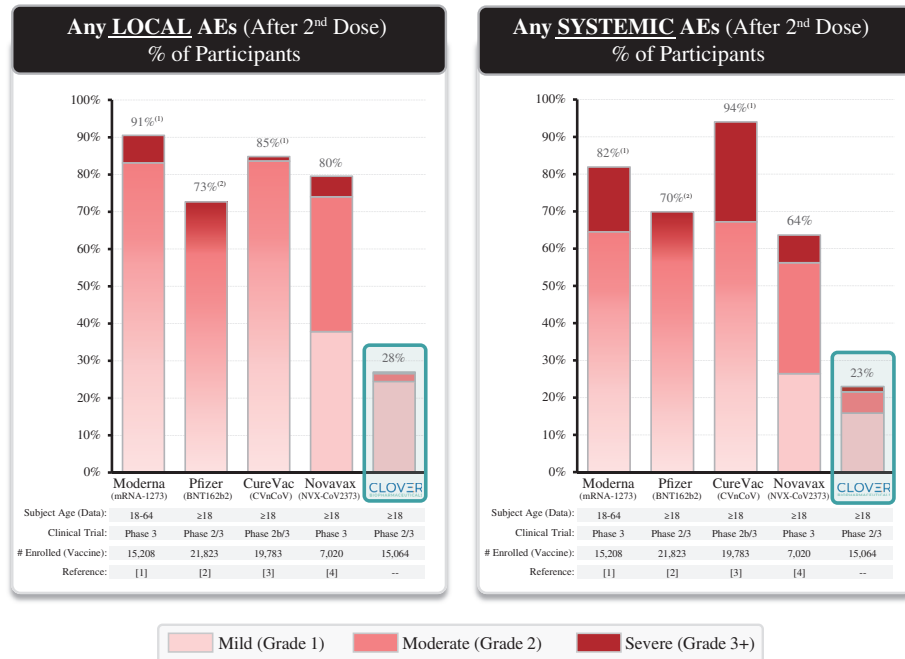
- *Proven adjuvants to enhance immune responses.* Our SCB-2019 (CpG 1018/Alum) is adjuvanted to elicit strong immune responses. The use of adjuvants is of particular importance in a pandemic since it may reduce the amount of antigen required per dose, allowing more vaccine doses to be produced quickly and therefore a potentially faster commercial ramp. CpG 1018 advanced adjuvant has been used in FDA- and European Commission (EC)-approved and commercialized vaccines, is produced at scale under cGMP conditions, and has significant safety databases in clinical and post-marketing studies, according to Frost & Sullivan.

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Potentially Differentiated and Favorable Safety Profile

SCB-2019 (CpG 1018/Alum) demonstrated a favorable safety profile with mass vaccination potential.

- Fewer local and systemic solicited adverse events.** In cross-trial, non-head-to-head studies, SCB-2019 (CpG 1018/Alum) demonstrated a favorable and potentially-differentiated safety profile in comparison to other COVID-19 vaccines. The SPECTRA safety results demonstrated that SCB-2019 (CpG 1018/Alum) has infrequent severe and serious adverse events, and no significant difference in comparison to placebo was observed. Overall, the reactogenicity profile of SCB-2019 (CpG 1018/Alum) compares favorably with those of the mRNA COVID-19 vaccines approved by or authorized for emergency use by the FDA and conditionally-approved by the EMA. Moreover, while Novavax’s COVID-19 vaccine is also an adjuvanted protein-based vaccine, the production process requires the addition of a nanoparticle in order to oligomerize the spike antigens, whereas Trimer-Tag™ enables SCB-2019 to be directly secreted as a native-like trimeric spike antigen. Additionally, Novavax utilizes the Matrix-M adjuvant which has never been approved previously by regulatory agencies for use in vaccines, whereas SCB-2019 utilizes CpG 1018 and Alum which have both been previously approved by FDA and EMA. The diagrams below illustrates a comparison of local and systemic solicited adverse event profiles between SCB-2019 (CpG 1018/Alum) and commercially available or development-stage COVID-19 vaccine candidates in non-head-to-head studies:



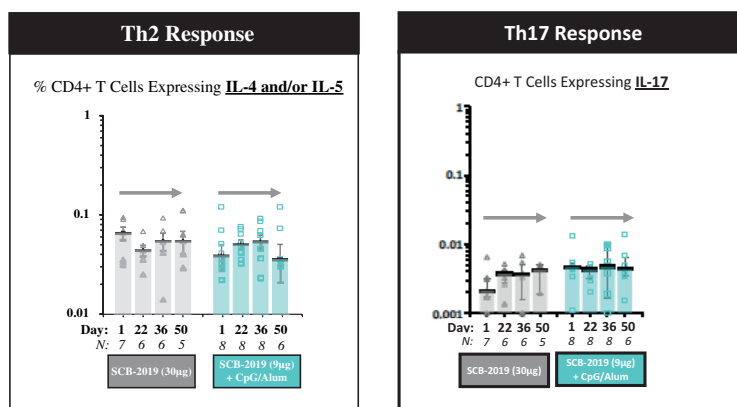
References: [1] Moderna FDA Briefing Document - VRBAC Meeting DEC 17, 2020, [2] Pfizer FDA Briefing Document – VRBAC Meeting DEC 10, 2020, [3] CureVac HERALD Study Final Analysis Presentation – JUL 01, 2021 and DOI: 10.2139/ssrn.3911826, [4] DOI: 10.1056/NEJMoa2107659.

Notes: CROSS-TRIAL COMPARISONS FOR ILLUSTRATIVE PURPOSES ONLY. Percentage of participants experiencing adverse events (AEs) are shown in figures.

- Data not disclosed separately for mild and moderate AEs. Shown in figure as combined mild-moderate AEs.
- Data not disclosed separately for mild, moderate and severe AEs. Shown in figure as combined mild-moderate-severe AE

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- Limited vaccine-enhanced disease risk.* In our Phase 1 clinical trial, SCB-2019 (CpG 1018/Alum) demonstrated weak or no Th2- and Th17- cell-mediated immune responses. Th2-biased cell-mediated immune responses are considered to be a risk factor for VAERD, according to the Frost & Sullivan Report. Th17 cells can contribute to the excessive inflammation, which makes Th17 another VAERD risk factor, according to the same source. The following diagram illustrates the low levels of Th2 and Th17 cell-mediated immune responses as demonstrated by low expression of IL-4/IL-5 and IL-17 in CD4+ T cells on day 1, 22, 36, and 50 post-administration of SCB-2019 (CpG 1018/Alum):



- Proven safe and effective vaccine development approach.* Recombinant proteins have long been proven as an effective and safe approach for vaccine development. Unlike new vaccine technologies, including mRNA-based, adenovirus-based and DNA-based vaccines, adjuvanted protein-based vaccines have been approved and commercialized for decades prior to the COVID-19 pandemic. Adjuvanted protein-based vaccines with regulatory approval include: influenza, hepatitis-B, HPV, and shingles. The historical success of protein-based vaccines validates their long-term safety, which is vital for global mass vaccination.

Well-characterized Manufacturing Processes at Our In-house Commercial-ready Facility with Large-Scale Production Capacity

We are potentially able to produce more than one billion doses of SCB-2019 annually at peak capacity at our commercial-scale manufacturing facility located in Changxing, Zhejiang province, China. This facility has received certification by a QP, a requirement to achieve EU cGMP standards. The manufacturing processes for SCB-2019 is well-characterized and similar to that of other recombinant proteins. This ensures a high level of quality control, allowing us to quickly scale up for mass production. Moreover, we believe SCB-2019 (CpG 1018/Alum) could be a cost-effective vaccine product, once approved, given the high productivity of the manufacturing process coupled with the low antigen dose requirement, See “– Manufacturing – Changxing Commercial Manufacturing Facility” for details.

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CEPI-funded Development Program with Clear Commercialization Pathway

We are proud to be the first company headquartered in China to receive funding and support from the Coalition for Epidemic Preparedness Innovations (CEPI). CEPI is the largest vaccine development initiative globally and a key player in the development of COVID-19 vaccines. CEPI has agreed to provide up to US\$360.5 million in grant funding to support the development of SCB-2019 (CpG 1018/Alum). SCB-2019 (CpG 1018/Alum) will be made available for procurement and allocation through the COVAX Facility, a global initiative established by WHO, GAVI, and CEPI that aims to accelerate the development and manufacture of COVID-19 vaccines, and to guarantee fair and equitable access for every country in the world. We executed an advanced purchase agreement to supply up to 414 million vaccine doses to the COVAX Facility for global allocation. We may also consider commercializing SCB-2019 (CpG 1018/Alum) post conditional approval via bilateral negotiations and supply arrangements with global governments.

Summary of Clinical Trial Data in SPECTRA – A Global Pivotal Phase 2/3 Clinical Trial

SPECTRA (Study Evaluating Protective-Efficacy and Safety of Clover's Trimeric Recombinant Protein-based and Adjuvanted COVID-19 Vaccine) is a global Phase 2/3 study to evaluate the efficacy, safety, and immunogenicity of SCB-2019 (CpG 1018/Alum). The SPECTRA trial initiated in March 2021, and in September 2021, we announced that SPECTRA met the primary and secondary efficacy endpoints. Based on the SPECTRA results, SCB-2019 (CpG 1018/Alum) demonstrated 100% efficacy against severe COVID-19, 100% efficacy against hospitalizations due to COVID-19, and 84% efficacy against moderate-to-severe COVID-19 caused by any strain of SARS-CoV-2 in SPECTRA. SCB-2019 (CpG 1018/Alum) also demonstrated 79% overall efficacy against COVID-19 of any severity caused by the globally dominant Delta variant, which currently comprises over 90% of all cases worldwide. Efficacy was 92% against the Gamma variant and 59% against the Mu variant, and collectively these three strains (Delta, Gamma and Mu) comprised 73% of all strains identified in SPECTRA. Overall efficacy was 67% against any strain in the study, successfully meeting the primary endpoint of the trial. SCB-2019 (CpG 1018/Alum) also had a favorable safety profile in SPECTRA with no significant differences in systemic solicited adverse events or severe/serious adverse events compared to placebo. Moreover, SCB-2019 (CpG 1018/Alum) was also the first COVID-19 vaccine candidate to demonstrate a significantly reduced risk of COVID-19 in previously infected individuals.

Trial Design and Status

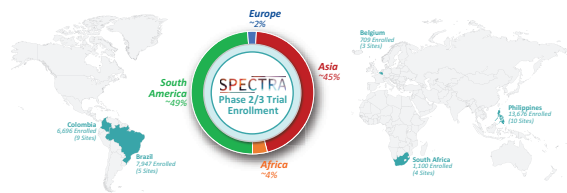
SPECTRA is a 1:1 randomized, double-blinded, placebo-controlled Phase 2/3 trial to evaluate the efficacy, safety and immunogenicity of SCB-2019 (CpG 1018/Alum) compared to placebo. 30,128 adult and elderly participants (≥ 18 years of age) were randomized and dosed with SCB-2019 (CpG 1018/Alum) or placebo administered in a two-dose regimen (21 days apart) as an intramuscular (IM) injection (0.5 mL/dose). The primary efficacy endpoint for SPECTRA was the prevention of PCR-confirmed symptomatic COVID-19 of any severity (mild, moderate, or severe) with onset ≥ 14 days after the second dose in adult and elderly

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participants (≤ 18 years of age) without evidence of prior SARS-CoV-2 infection (seronegative) at baseline. Primary safety endpoints include (i) solicited systemic and local adverse events within seven days after each dose, (ii) unsolicited adverse events up to day 43, and (iii) serious adverse events, medically attended adverse events and adverse events of special interest.

Predefined key secondary endpoints include (i) prevention of PCR-confirmed moderate-to-severe COVID-19, severe COVID-19, and hospitalization due to COVID-19, (ii) SARS-CoV-2 strain-specific prevention of any moderate-to-severe and severe COVID-19, (iii) efficacy in baseline seropositive participants, and (iv) immunogenicity, including neutralizing antibodies. Predefined key secondary endpoints with available results as of September 22, 2021 included prevention of PCR-confirmed moderate-to-severe COVID-19 and severe COVID-19 with onset ≥ 14 days after the second dose in adult and elderly participants (≥ 18 years of age) without evidence of prior SARS-CoV-2 infection (seronegative) at baseline. The statistical success criterion was lower bound 97.86% CI $> 0\%$.

SPECTRA randomized and dosed 30,128 adult and elderly (≥ 18 years of age) participants at 31 sites in five countries: the Philippines (13,676 participants at 10 sites), Brazil (7,947 participants at five sites), Colombia (6,696 participants at 9 sites), South Africa (1,100 participants at 4 sites), and Belgium (709 participants at three sites) across four continents. This resulted in SPECTRA being one of the most diverse COVID-19 vaccine clinical trials conducted to date. The following diagrams illustrate the diverse and balanced demographics of the participants enrolled in SPECTRA:



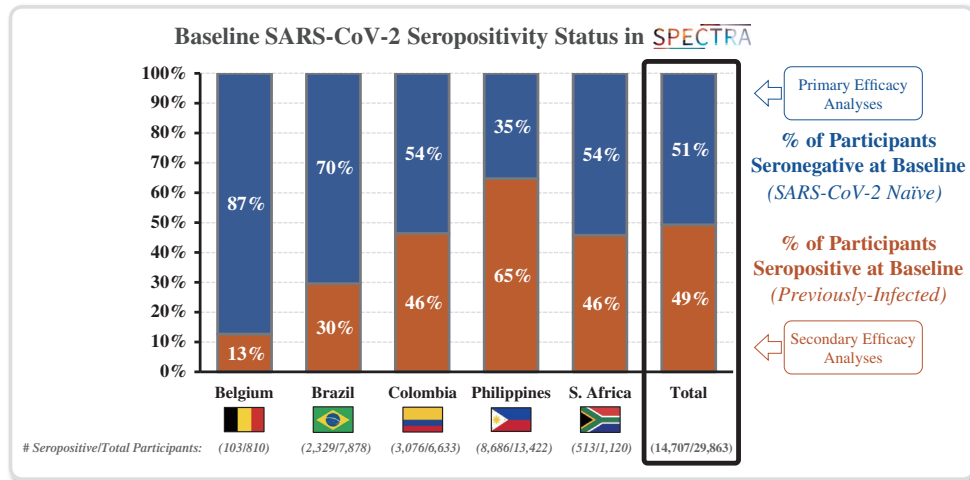
	SCB-2019 (CpG 1018/Alum)	Placebo
Participants ⁽¹⁾ (N)	15,064	15,064
Sex (%)		
Male	47.0%	46.7%
Female	53.0%	53.3%
Age (Years)		
Average Age (Min, Max)	32.1 Years (18 – 86)	32.0 Years (18 – 81)
Age 18-64	98.7%	98.6%
Age ≥ 65	1.3%	1.4%
Co-Morbidities ⁽²⁾ (%)	18.4%	17.9%
Race (%)		
Asian	45.5%	45.6%
White	20.1%	20.4%
Black	10.1%	9.7%
Other	22.4%	22.3%
Not Reported/Unknown	2.0%	2.0%
Ethnicity (%)		
Hispanic/Latino	45.5%	45.6%

Notes:

- (1) Number of participants randomized and dosed in trial.
- (2) Co-morbidities defined as participants at high risk for severe COVID-19 (U.S. CDC Recommendations, 2021).

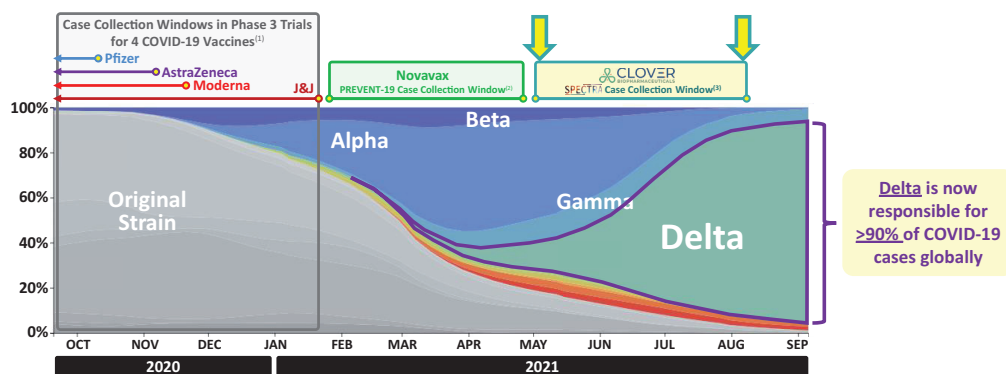
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SPECTRA enrollment included both baseline seronegative (SARS-CoV-2 naive individuals) and seropositive (previously infected individuals) which represents one of the first evaluations of this patient population in a randomized clinical trial. As SARS-CoV-2 continues to spread globally, the evaluation of vaccine efficacy and safety in baseline seropositive individuals is increasingly important. We observed that 51% of all participants in SPECTRA were SARS-CoV-2 naive, and 49% of all participants enrolled in SPECTRA were baseline seropositive, providing a basis for landmark analysis of vaccine efficacy in this population. The following chart illustrates the seropositivity status of our SPECTRA participants:



SPECTRA enabled Clover to evaluate efficacy against Delta Variant in a randomized clinical trial. During SPECTRA accrual of COVID-19 disease cases, which spanned the period from April 28, 2021 through August 10, 2021, the Delta Variant was the predominant circulating strain, while the original SARS-CoV-2 strain was the predominant strain during the case collection window for the Phase 3 trials for four FDA or EMA conditionally approved COVID-19 vaccines. No vaccine efficacy results against Delta Variant have been demonstrated by these vaccines in randomized clinical trials. The following diagram illustrates the overlay of SPECTRA and the strain distribution of SARS-CoV-2 since October 2020:

Global SARS-CoV-2 Strain Distribution (GISAID Database)



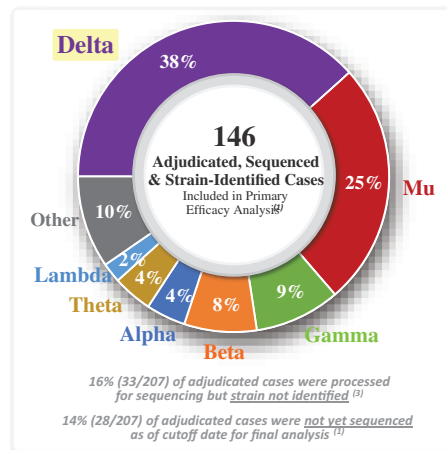
Source: Strain distribution data from Nextstrain.org (GISAID data) as of September 6, 2021

- (1) Case collection cutoff dates for primary efficacy endpoint used to support EUL/conditional approvals: Moderna (25-NOV-2020; DOI: 10.1056/NEJMoa2035389), Pfizer (09-OCT-2020; DOI: 10.1056/NEJMoa2034577), AstraZeneca (04-NOV-2020; DOI: 10.1016/S0140-6736(20)32661-1), J&J (22-JAN-2021; DOI: 10.1056/NEJMoa2101544).
- (2) Novavax case collection window for primary efficacy endpoint from 25-JAN-2021 to 30-APR-2021 (PREVENT-19 Final Data Announcement Presentation; 14-JUNE-2021).

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- (3) Clover case collection window for primary efficacy endpoint in SPECTRA from 28-APR-2021 to 10-AUG-2021.

In SPECTRA, a total of 207 cases of PCR-confirmed symptomatic COVID-19 of any severity occurring ≥ 14 days after the second dose in participants without evidence of prior SARS-CoV-2 infection (“SARS-CoV-2 naïve”) were adjudicated by an independent Endpoint Adjudication Committee (EAC) and included in the primary efficacy analysis. 179 of the 207 cases were adjudicated and sequenced by the cutoff date for final analysis (August 10, 2021). Of the 146 adjudicated, sequenced and strain-identified cases included in the primary efficacy analyses in baseline seronegative participants, 100% were variant strains, and no cases of the original SARS-CoV-2 strain were observed. The three most prevalent strains in the study comprising 73% of all sequenced cases were the Delta Variant, which was predominant and accounted for 38% (56 cases) of all sequenced strains, Mu Variant (37 cases) and Gamma Variant (13 cases). In terms of the specific mutations that are attributable to each variant, Gamma (P.1) harbors E484K escape mutation in RBD, and demonstrated high transmissibility in Brazil and other Latin American countries⁽¹⁾. The Mu Variant (B.1.621) is the predominant strain in Colombia⁽¹⁾, and believed to be ‘Beta-like’ based on spike protein mutation profile and cross-neutralization studies⁽²⁾. In a Phase 2b/3 clinical trial of an mRNA COVID-19 vaccine candidate demonstrated lowest efficacy against Mu Variant (41.5% vaccine efficacy) among all variant strains evaluated⁽³⁾. The following diagram illustrate the overall strain distribution in SPECTRA:



Notes:

- (1) Counting of cases for primary efficacy analyses begins at ≥ 14 days after second dose. Cutoff date for primary efficacy analyses was 10-AUG-2021 in all countries in SPECTRA.
- (2) 207 cases included in primary efficacy analyses in baseline seronegative participants were adjudicated by an independent endpoint adjudication committee (EAC). 41 additional cases in baseline seropositive participants were adjudicated and included for secondary efficacy analyses.
- (3) Samples processed for sequencing, but strains were not identified (e.g. lack of sufficient nasopharyngeal swab sample collected, unsuccessful RNA-sample extraction, etc.).

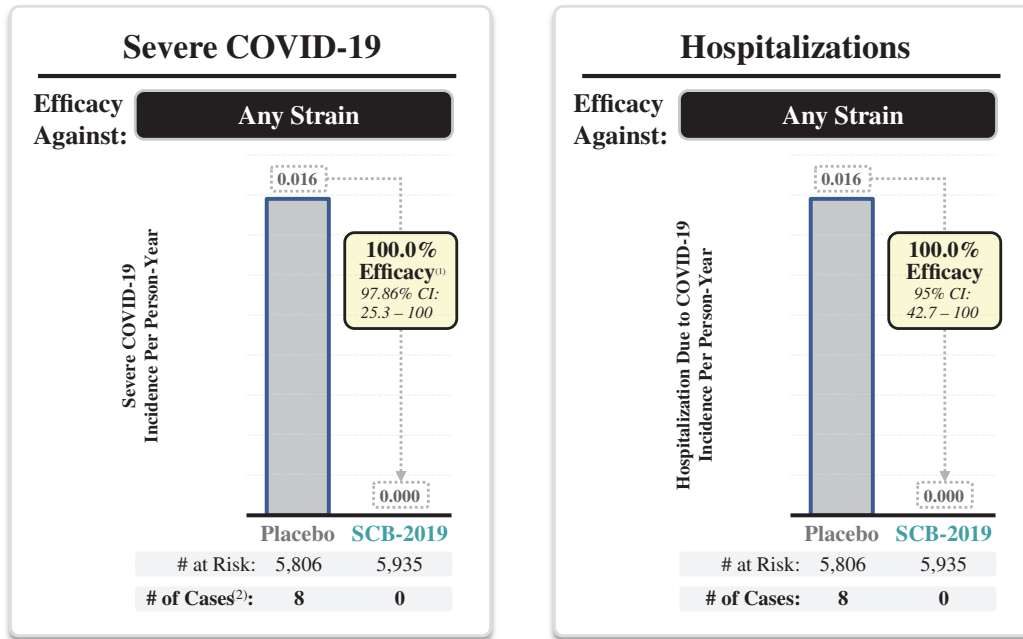
Notes:

- (1) NextStrain.org (GISAID database) as of 06-SEP-2021.
(2) DOI: 10.1101/2021.09.06.459005
(3) DOI: 10.2139/ssrn.3911826

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Efficacy and Immunogenicity Data

Based on the announced SPECTRA data, SCB-2019 (CpG 1018/Alum) demonstrated 100% efficacy (97.86% CI: 25.3, 100) against severe COVID-19 disease caused by any strain in the vaccine group, and 100% efficacy (95% CI: 42.7, 100) against hospitalization due to COVID-19, meeting the predefined success criteria in the protocol. All deaths due to COVID-19 (3 cases) occurred in the placebo group (none in the vaccine group), as illustrated in the following diagrams:

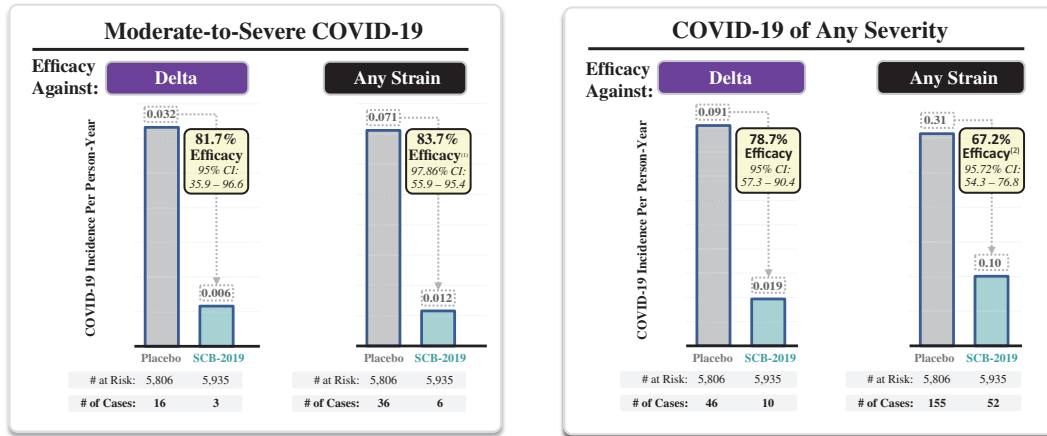


Notes:

- (1) Key secondary endpoint in SPECTRA protocol. Predefined success criteria is lower limit of 97.86% confidence interval exceeds 0%.
- (2) 8 total severe COVID-19 cases includes 4 cases caused by Delta, 1 Alpha, 1 Other (not identified), 2 Other (not sequenced at time of primary analysis cutoff).
- (3) 8 total severe COVID-19 cases includes 4 cases caused by Delta, 1 Alpha, 1 Other (not identified), 2 Other (not sequenced at time of primary analysis cutoff).

SCB-2019 (CpG 1018/Alum) showed significant overall efficacy against moderate-to-severe COVID-19 cases of any severity against any strain. Specifically, we observed an 83.7% efficacy (97.86% CI: 54.3, 76.8) against moderate-to-severe COVID-19 cases caused by any strain of SARS-CoV-2 and 81.7% (95% CI: 45.9, 96.6) efficacy against moderate-to-severe COVID-19 against the Delta Variant. SPECTRA demonstrated significant overall efficacy against COVID-19 disease of any severity caused by any strain was 67.2% (95.72% CI: 54.3, 76.8), successfully achieving the primary endpoint. The following diagrams illustrate the overall efficacy of SCB-2019 (CpG 1018/Alum):

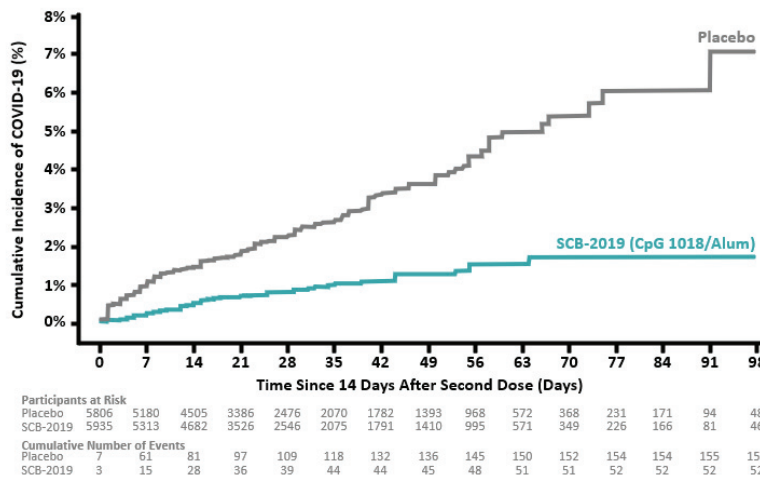
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Notes:

- (1) Key secondary endpoint in SPECTRA protocol. Predefined success criteria is lower limit of 97.86% confidence interval exceeds 0%.
- (2) Primary endpoint in SPECTRA protocol. Predefined success criteria is lower limit of 95.72% confidence interval exceeds 30%.

Vaccine efficacy evaluated in SPECTRA appears to show persistence through 112 days after the second dose in an environment dominated by the Delta Variant and other concerning variants, as shown in the following diagram:

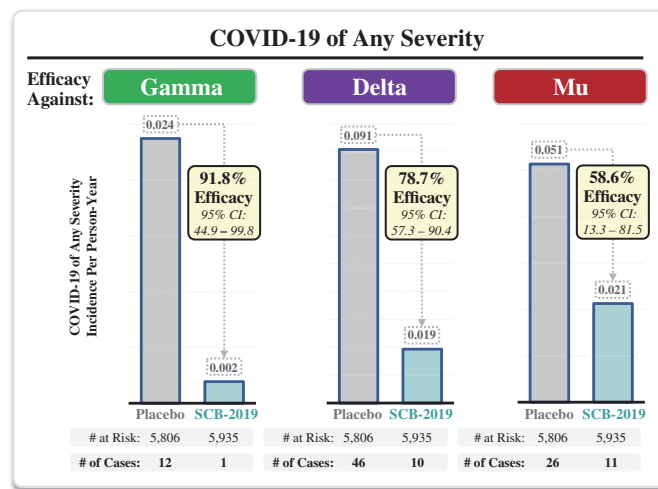


Notes: Figure shows data for PCR-confirmed COVID-19 of any severity (against any strain) at ≥14 days after second dose in participants without evidence of prior SARS-CoV-2 infection (baseline seronegative). Primary endpoint in protocol.

For the three most prevalent variants observed in SPECTRA, efficacy was 91.8% (95% CI: 44.9, 99.8) against Gamma Variant, 78.7% (95% CI: 57.3, 90.4) against Delta Variant and 58.6% (95% CI: 13.3, 81.5) against Mu. SCB-2019 (CpG 1018/Alum) is the first vaccine candidate to demonstrate significant efficacy against all three of these variants. SCB-2019 (CpG 1018/Alum) is also one of the first to demonstrate significant efficacy against all three

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of these variants in a double-blind, randomized clinical trial. Differences in vaccine efficacy across variant strains are driven by the unique mutation profiles of each variant, which can make some strains more transmissible and/or virulent than others and may enable immune escape. For the other variants observed in SPECTRA and not highlighted, which include Alpha, B.1.623, Beta, Lambda, Theta, Other and Not Identified, SCB-2019 (CpG 1018/Alum) demonstrated 90.2% efficacy (95% CI:31.2, 99.8) against moderate-to-severe COVID-19 and efficacy against COVID-19 of any severity was 55.0% (95% CI: 24.9%, 73.8%). No hospitalizations or severe COVID-19 cases were observed in the vaccine group (2 severe COVID-19 cases were observed in the placebo group). There was an insufficient number of cases of every observed variant strain in SPECTRA to enable statistical analyses of vaccine efficacy.

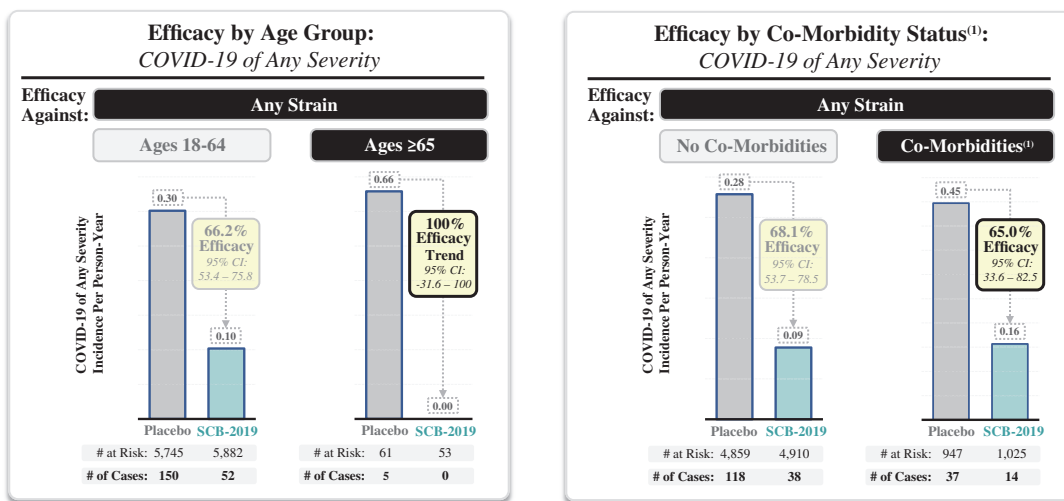


Notes:

- (1) NextStrain.org (GISAID database) as of 06-SEP-2021.
- (2) DOI: 10.1101/2021.09.06.459005
- (3) DOI: 10.2139/ssrn.3911826

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SPECTRA enrolled high risk participants, which include the elderly and those individuals with co-morbidities. While the enrollment of elderly was limited due to ongoing vaccination campaigns in countries where recruitment of SPECTRA was conducted, all 5 cases of COVID-19 in participants 65 years of age or older occurred in the placebo group (none in the vaccine group). The trend in efficacy observed for the elderly population indicate there is no age-dependent decline in efficacy. There were 18% of participants randomized in SPECTRA had co-morbidities for COVID-19 (i.e. participants at high risk for severe COVID-19), and no differences in vaccine efficacy were observed in participants with or without co-morbidities for COVID-19. SCB-2019 (CpG 1018/Alum) also demonstrated 100% efficacy trend and 65.0% efficacy in elderly populations and participants with co-morbidities, respectively, as shown in the following diagrams:

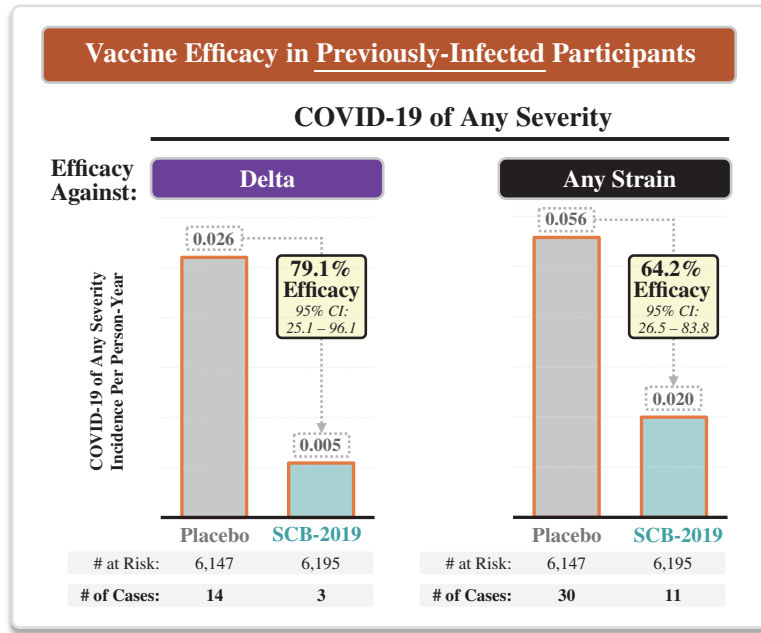


Note:

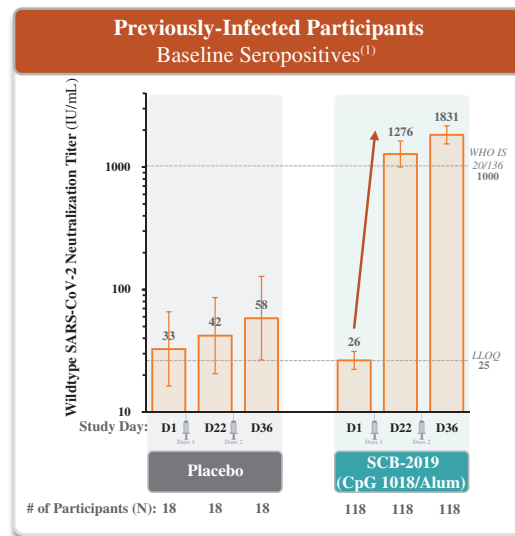
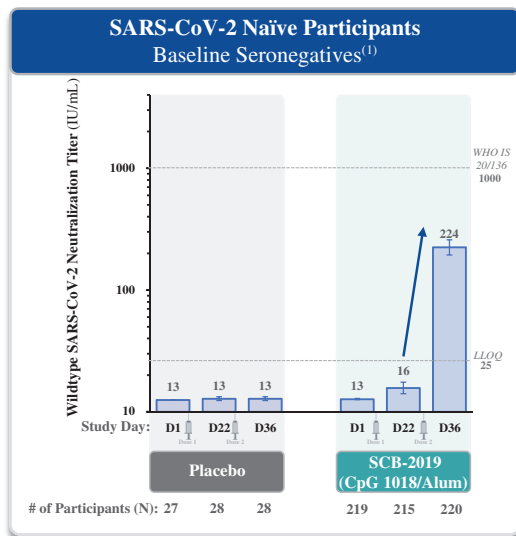
- (1) Co-morbidities defined as participants at high risk for severe COVID-19 (U.S. CDC Recommendations, 2021).

As SARS-CoV-2 continues to spread across the world, evaluating the efficacy and safety of COVID-19 vaccines in previously infected populations has become increasingly important. In SPECTRA, 49% of all participants randomized were seropositive (evidence of prior SARS-CoV-2 infection) at baseline prior to enrollment. The baseline seropositivity rate varied by country: 65% in the Philippines, 46% in Colombia, 46% in South Africa, 30% in Brazil and 13% in Belgium. There were 41 cases of PCR-confirmed symptomatic COVID-19 reinfections of any severity were accrued in baseline seropositive participants, of which 17 cases were caused by Delta Variant. Vaccination with SCB-2019 (CpG 1018/Alum) reduced the risk of symptomatic COVID-19 reinfection caused by any strain to 64.2% (95% CI: 26.5, 83.8) in previously infected participants. The risk of symptomatic COVID-19 reinfection caused by Delta was reduced to 79.1% (95% CI: 25.1, 96.1). SCB-2019 (CpG 1018/Alum) is the first COVID-19 vaccine candidate to successfully demonstrate significant incremental protection against COVID-19 in previously infected individuals in a randomized clinical trial.

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In addition, further analyses are conducted using serum collected from SPECTRA participants, neutralizing antibodies were evaluated with a wildtype SARS-CoV-2 neutralization assay at day 1, day 22 and day 36. The study demonstrated that SCB-2019 (CpG 1018/Alum) induced strong neutralizing immune responses in (i) SARS-CoV-2 naive participants after two doses, which is in line with Clover’s Phase 1 trial; and (ii) rapid and strong boosting effect in seropositive individuals after one dose, which further support Clover’s further evaluation of SCB-2019 (CpG 1018/Alum) as a booster vaccine candidate. The following diagrams illustrate the neutralizing antibodies induced by SCB-2018 (CpG 1018/Alum) in seronegative participants and seropositive participants:



Notes:

Bars represent Geometric Mean Concentrations (GMC) ± 95% confidence intervals (95% CI). Validated Wildtype and Pseudovirus neutralization assays against the original strain of SARS-CoV-2 (VisMederi). Titers expressed was international units/mL (IU/mL) based on WHO international standard sera (WHO IS 20/136). Samples with titers below LLOQ were assigned a value of 12.5.

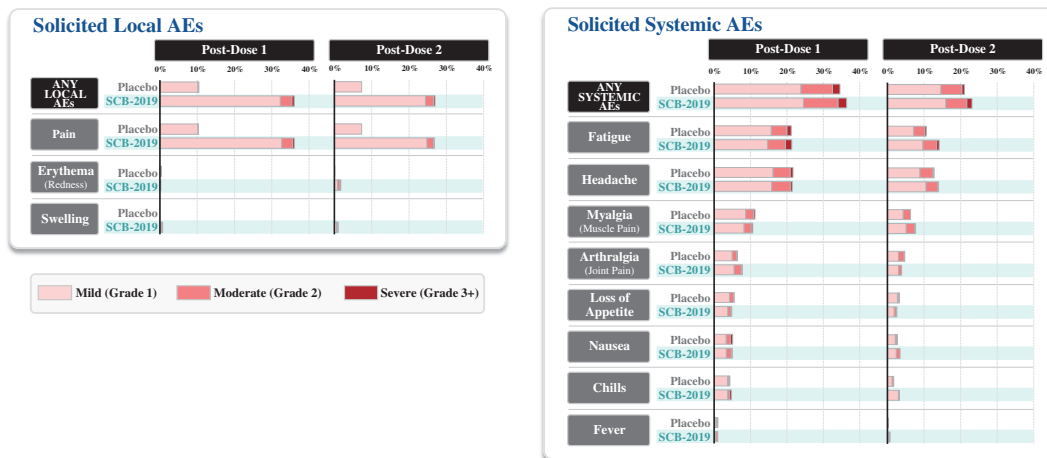
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- (1) Baseline seropositivity status determined by presence of antibodies binding to SARS-CoV-2 Spike (S) protein in Day 1 serum samples (Roche Elecsys® anti-S test).

Safety Results

The independent Data & Safety Monitoring Board (DSMB) has reviewed the safety data for SPECTRA on an ongoing basis, and no safety concerns have been identified warranting a pause or modification to the trial conduct to-date.

The SPECTRA safety results demonstrated that SCB-2019 (CpG 1018/Alum) has a favorable safety profile. Severe and serious adverse events (AEs) were infrequent and balanced between vaccine and placebo groups. Solicited local AEs were mostly mild and transient cases of pain at the injection site, and the most systematic solicited AEs mainly include fatigue, headache and myalgia. Moreover, solicited local AEs decreased in frequency following a second dose of SCB-2019 (CpG 1018/Alum). For all solicited systemic AEs monitored – fatigue, headache, muscle pain, joint pain, loss of appetite, nausea, chills and fever – no significant differences were observed between vaccine and placebo groups. The following charts illustrate the local AEs and systemic AEs in SPECTRA:



Based on non-head-to-head data, our SCB-2019 (CpG 1018/Alum) demonstrated a favorable and potentially differentiated safety profile compared to other COVID-19 vaccines. For details, see “Competitive Advantages of SCB-2019 (CpG 1018/Alum) – Potentially Differentiated and Favorable Safety Profile.”

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Summary of Clinical Trial Data in Our Phase 1 Clinical Trial

CLO-SCB-2019-001 is a Phase 1, randomized, double-blind, placebo-controlled study to assess safety, tolerability, and immunogenicity of our antigen, SCB-2019, at three dose levels (3 µg, 9 µg, and 30 µg) administered standalone and in combination with adjuvants, as two injections administered 21 days apart in 151 participants. The study was conducted in one study center in Australia.

We initiated this trial in June 2020 and completed dose escalation in October 2020. The interim results for this clinical trial were published in *The Lancet* in January 2021.

Trial Design and Status

The trial is a randomized, double-blind, placebo-controlled dose-escalation study with two trial arms. The first arm was in younger adults (aged 18–54 years) and the second arm in older adults (aged 55–75 years). Between June 19 and September 23, 2020, 329 healthy adult volunteers were screened, of whom 151 (91 younger adults and 60 older adults) were enrolled after testing negative for COVID-19.

After completion of the dose-escalation phase, the review of safety and immunogenicity data was performed. Based on the findings and continued collaboration with the adjuvant supplier, the dose level of 30 µg for SCB-2019 (CpG 1018/Alum) was selected for further evaluation in our global pivotal Phase 2/3 clinical trial.

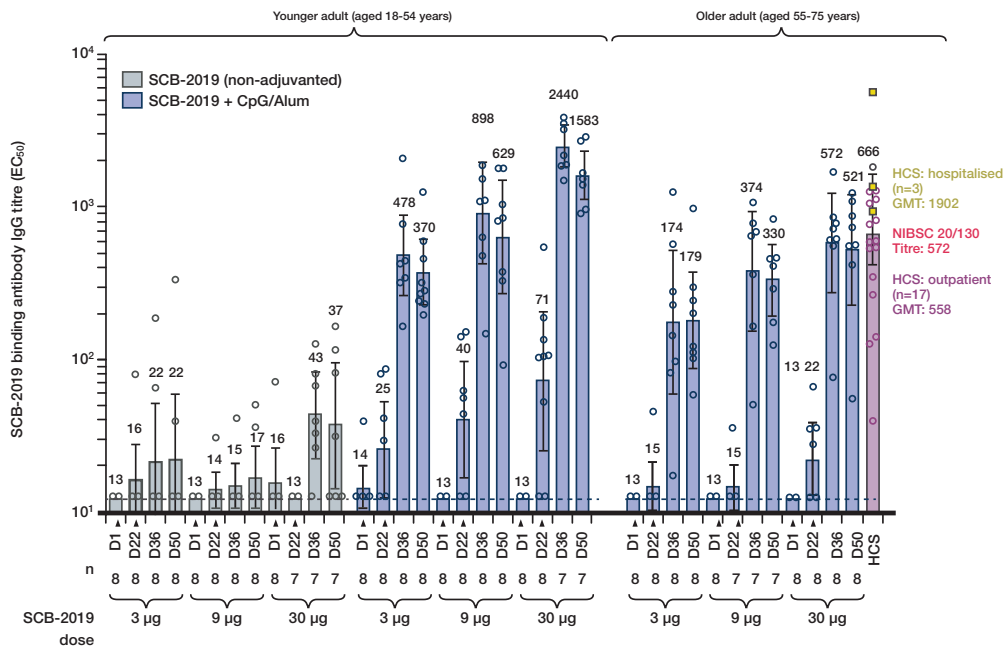
We also evaluated the long-term safety and immunogenicity of SCB-2019 (CpG 1018/Alum) in the extension portion of our Phase 1 clinical trial, which includes assessment of antibody persistence following a 2-dose regimen of our vaccine candidate, response to a booster dose of vaccine, and extended safety monitoring.

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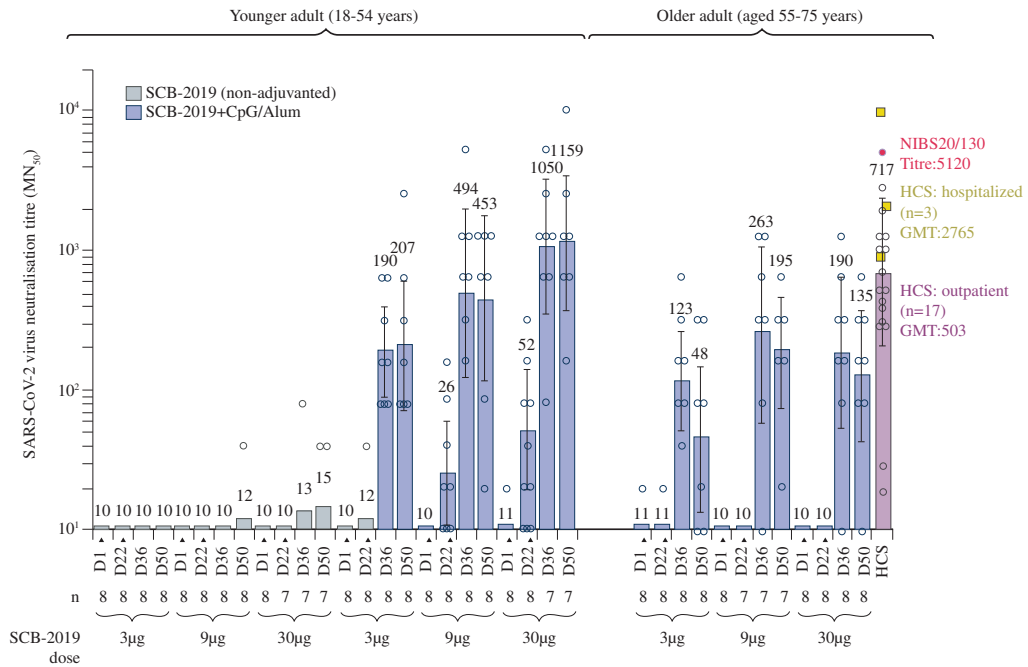
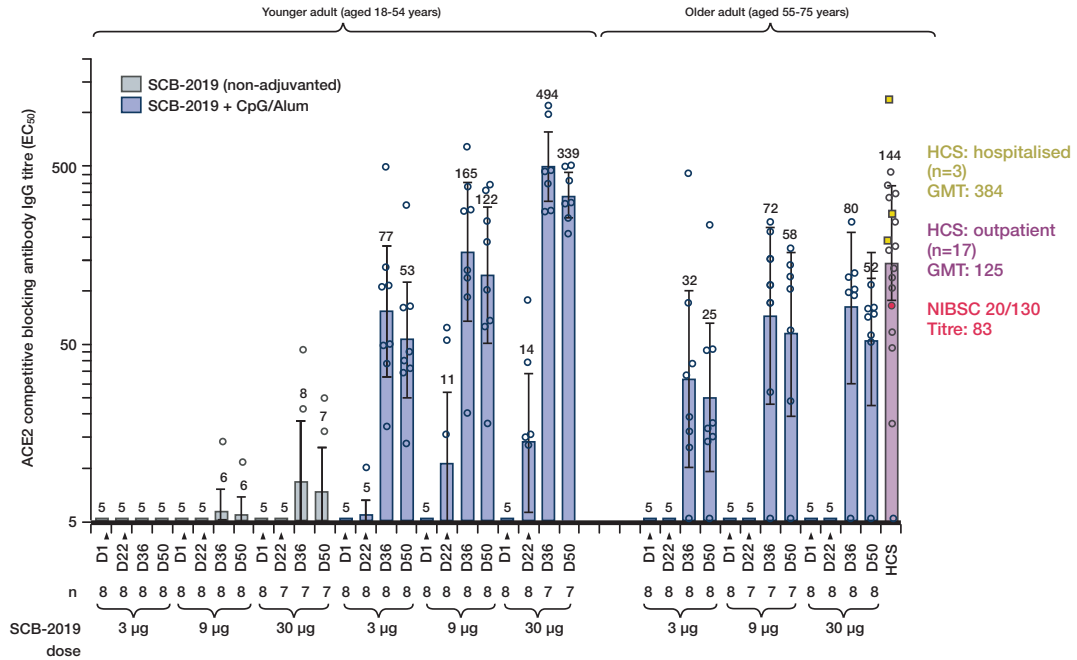
Efficacy and Immunogenicity Data

SCB-2019 (CpG 1018/Alum) demonstrated strong functional immune responses, as shown by SARS-CoV-2 neutralizing activity that correlated well with IgG antibodies against SCB-2019 or ACE2-competitive blocking antibodies.

Neutralizing responses were observed after just the first dose of SCB-2019 (CpG 1018/Alum). Highest responses were seen after completion of the two-dose series of SCB-2019 (CpG 1018/Alum). On day 36, GMTs levels peaked at rates similar or higher than those recorded in convalescent serum samples from patients hospitalized with COVID-19 and the National Institute for Biological Standards and Control (NIBSC) reference serum sample. High GMT levels persisted until the end of this interim analysis at day 50. The following charts illustrate the binding antibody IgG titers, ACE2-competitive blocking antibody IgG titers, and original SARS-CoV-2 strain neutralization titers of SCB-2019 (CpG 1018/Alum), each of which are believed to be important indicators for immunogenicity and efficacy of COVID-19 vaccines:

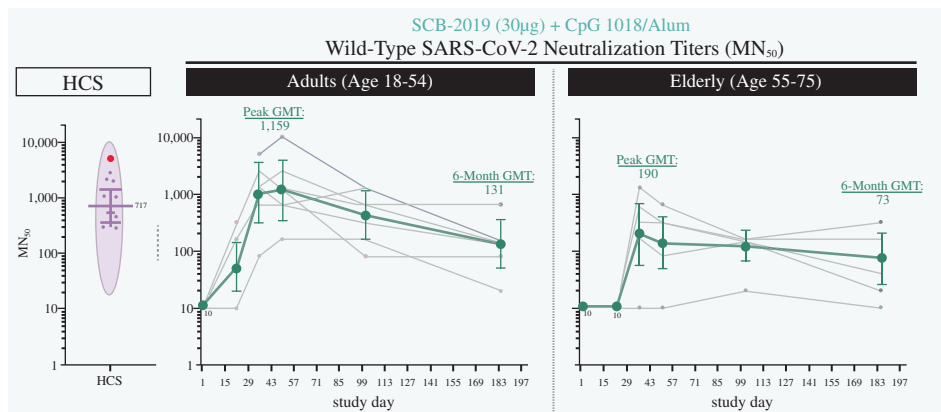


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The peak GMTs induced by SCB-2019 (CpG 1018/Alum) compares favorably with those of mRNA-based vaccines and adenovirus-based vaccines based on our cross study comparison, which is not considered as a head-to-head study comparison. Further investigation of the cell-mediated immune responses showed increases in Th1-biased activity after administration of both the first and second doses of SCB-2019 (CpG 1018/Alum). Our Phase I has shown SCB-2019 IgG antibodies, ACE2-competitive binding antibodies and neutralizing antibodies against wild type SARS-CoV-2 persisted at 25-35% of their observed peak levels at day 184, while titers waned from their peak normally at days 36-50. The following charts illustrate the neutralizing antibody durability of our SCB-2019 (CpG 1018/Alum):

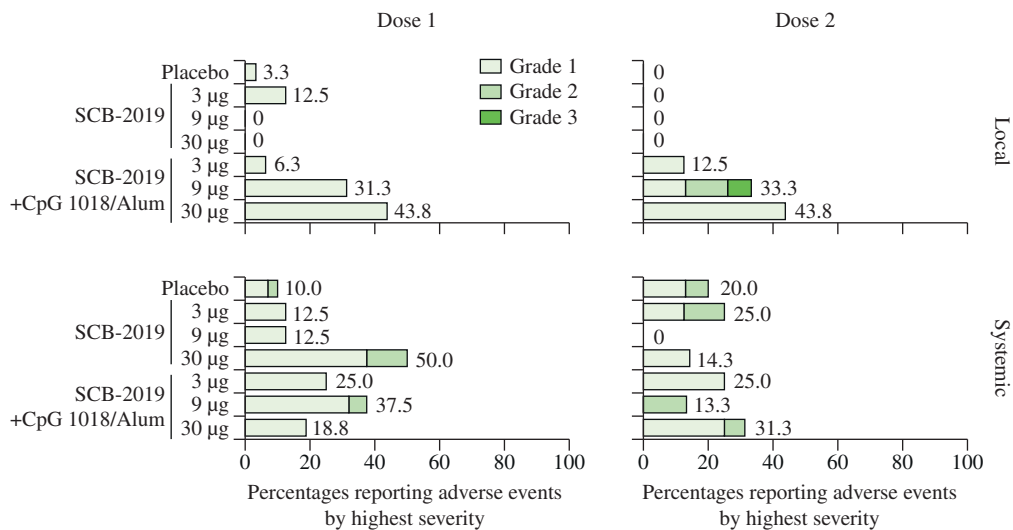


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Safety Data

The interim results of our Phase 1 clinical trial, SCB-2019 (CpG 1018/Alum) had a favorable safety profile and was well-tolerated with no vaccine-related serious adverse events or study withdrawals.

SCB-2019 (CpG 1018/Alum) showed acceptable reactogenicity with few grade 3 solicited adverse events. All local adverse events resolved within the reporting period of 7 days post-vaccination. When considering variation in the age of participants, no overall effect on safety or reactogenicity was seen. Although older adults (aged 55–75 years) had fewer local and systemic solicited adverse events than did younger adults (aged 18–54 years) after the first dose, the incidence of solicited adverse events was similar in both age groups after the second dose. The rates of solicited adverse events in participants administrated with SCB-2019 (CpG 1018/Alum) was relatively low and consistent with currently licensed CpG-adjuvanted and/or other adjuvanted protein-based vaccines. The diagram below illustrates incidence and severity of solicited local and systemic solicited adverse events in our clinical trial:



Summary of Pre-clinical Data

We conducted a series of *in vitro*, *in vivo*, and animal pre-clinical studies in order to characterize the pharmacodynamics, pharmacokinetic, and toxicology of SCB-2019 (CpG 1018/Alum).

In pre-clinical studies, SCB-2019 demonstrated high binding affinity to human ACE2. In addition, SCB-2019 (CpG 1018/Alum) exhibited high levels of binding and neutralizing antibodies in multiple animal immunogenicity studies and Th1-biased cell-mediated immune responses.

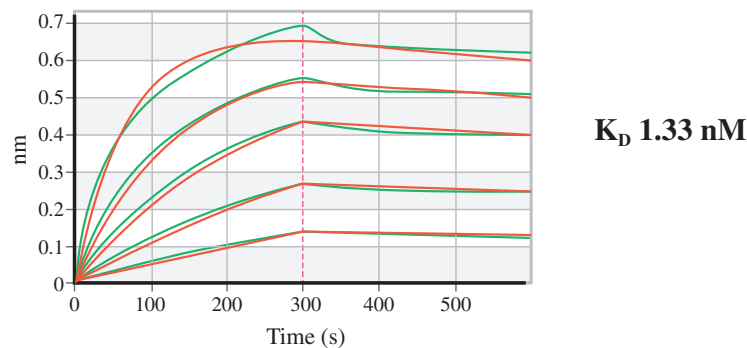
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Results from nonhuman primates (NHP) and hamster challenge studies demonstrated that SCB-2019 (CpG 1018/Alum) induced immune protection from SARS-CoV-2 challenge, with no signs of disease enhancement.

Pharmacodynamics

Data published in *Nature Communications* in March 2021 shows that we observed high binding affinity of approximately 1.3 nanomolar of SCB-2019. This is nearly one order of magnitude higher than what has been reported for other recombinant SARS-CoV-2 spike proteins, providing support that SCB-2019 has preserved a native-like antigen structure.

Human ACE2 Binding Affinity



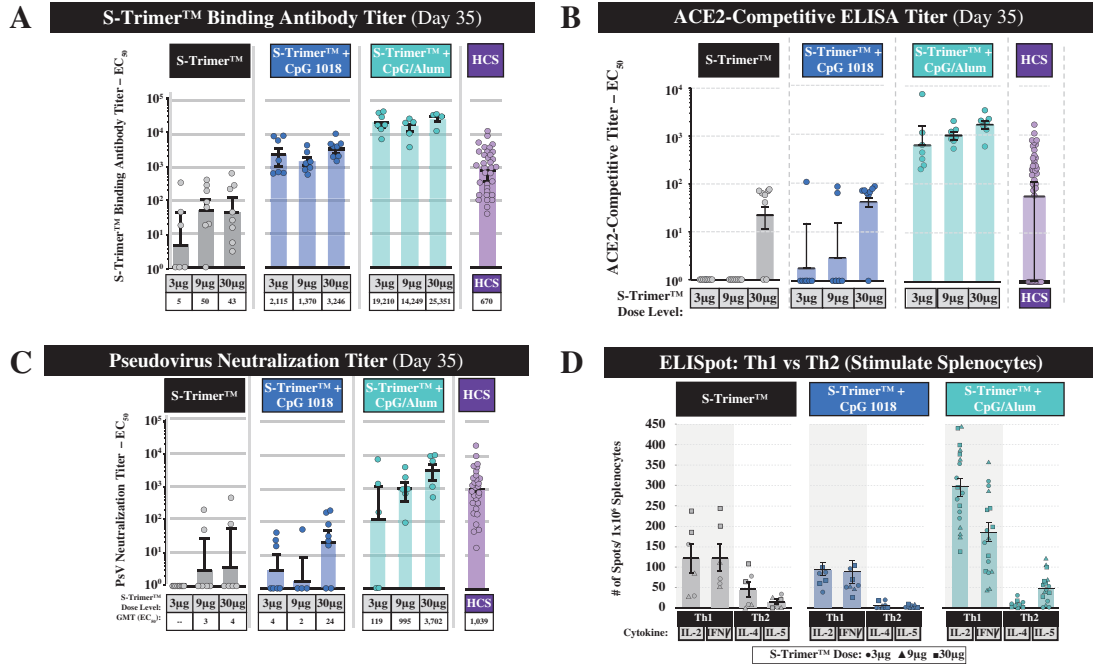
Note: HCS (Human Convalescent Sera)

- (1) J. Ma, et al. Cryo-EM structure of S-Trimer™, a subunit vaccine candidate for COVID-19. bioRxiv (2020). doi:10.1101/2020.09.21.306357
- (2) J.G. Liang, et al. S-Trimer™, a COVID-19 subunit vaccine candidate, induces protective immunity in nonhuman primates. bioRxiv (2020). doi:10.1101/2020.09.24.311027

The ability of SCB-2019 (CpG 1018/Alum) to induce immune responses (anti-SCB-2019 binding and SARS-CoV-2 neutralizing antibodies) was assessed in nonhuman primate models. When the SCB-2019 (CpG 1018/Alum) animal models were challenged on Day 35, they displayed high levels of anti-SCB-2019 binding antibody titers, ACE2-competitive titers, and neutralizing antibody titers at or above the range of human convalescent sera. All SCB-2019 dose levels (3 µg, 9 µg, or 30 µg) adjuvanted with CpG 1018/Alum were immunogenic.

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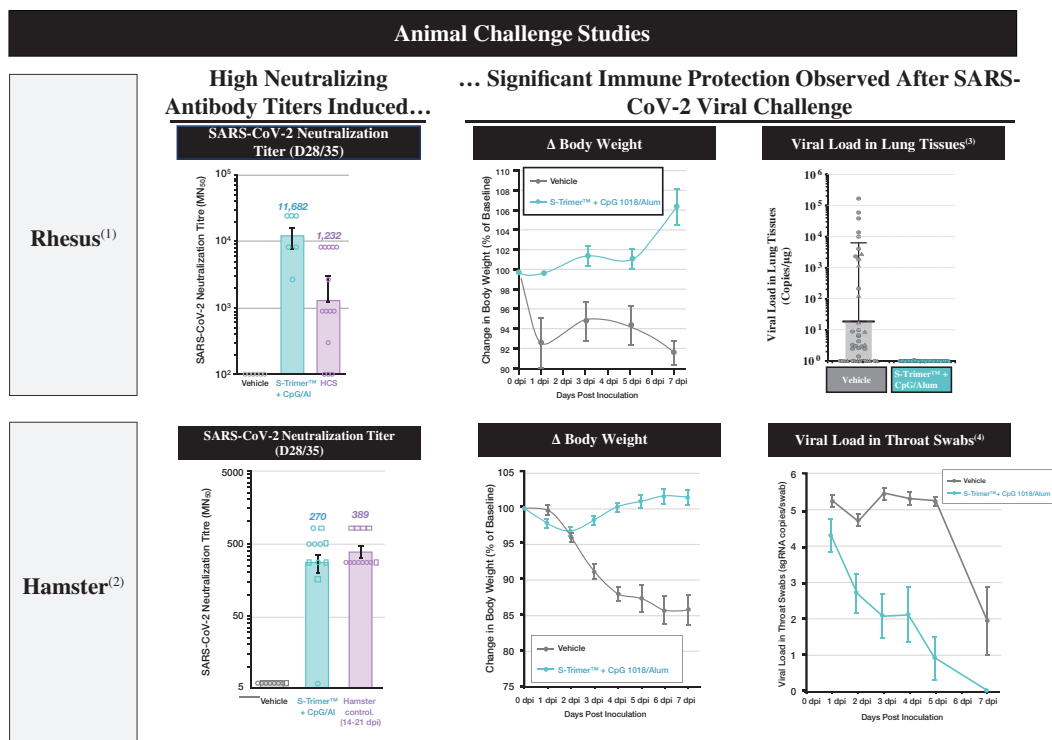
Cell-mediated immunity was also evaluated in a mouse immunogenicity study by evaluating Th1 versus Th2 responses using ELISpot. Th1-biased T-cell responses were observed across all vaccinated groups, suggesting a low risk of VAERD from vaccination with SCB-2019 (CpG 1018/Alum). The diagrams below illustrate such results:



Note: Geometric mean titers (GMT) for antibody titers and mean values for ELISpot are depicted. For all graphs, standard error margins (SEM) are depicted.

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SCB-2019 (CpG 1018/Alum) was evaluated in a NHP challenge study in rhesus macaques. Animals (n=6 per group) were vaccinated by intramuscular injection twice on Day 0 and Day 21 with 30 µg of SCB-2019 (CpG 1018/Alum) or a phosphate-buffered saline (PBS) vehicle control. SCB-2019 (CpG 1018/Alum) in NHPs was highly immunogenic, with binding and neutralizing antibody titers observed to be at or above the range of human convalescent sera. After NHPs were challenged on Day 35 with SARS-CoV-2, the animals were followed for clinical observations and viral loads. NHPs vaccinated with SCB-2019 (CpG 1018/Alum) appeared to be significantly protected from weight loss and increase in body temperature, compared to animals in the vehicle control group. Viral loads in lung tissues were also observed to be significantly reduced in SCB-2019 (CpG 1018/Alum) vaccinated animals. The diagrams below illustrate such results:



Note: HCS (Human Convalescent Sera). Geometric means titers (GMT) shown for neutralization titers.

- (1) Rhesus monkeys dosed on Day 0 + Day 21 (30 µg S-Trimer™ dose) and challenged on Day 35 with SARS-CoV-2 of 2.6 x 10⁶ TCID₅₀ both intranasally and intratracheally. [doi:10.1101/2020.09.24.311027]
- (2) Golden Syrian hamsters - doses on Day 0 + Day 21 (9 µg S-Trimer™ dose) and challenged on Day 35 with SARS-CoV-2 of 1.0 x 10^{4.7} TCID₅₀ intranasally.
- (3) Genomic (total) RNA.
- (4) sgRNA (indicating replicating virus). EOS (End of Study).

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Clinical Development Plan

We chose to conduct a Phase 1 clinical trial for SCB-2019 (CpG 1018/Alum) in Australia because we were able to leverage our prior experience of the regulatory process and conducting clinical trials in Australia for SCB-313, and the relatively fast initiation of clinical trials in Australia. For our Phase 2/3 clinical trial, we decided to conduct a global, multi-center trial to study our COVID-19 vaccine candidate in diverse populations and rapidly advance enrollment by accessing areas with larger patient populations. We initiated SPECTRA, a global pivotal Phase 2/3 clinical trial evaluating the efficacy, safety, and immunogenicity of SCB-2019 (CpG 1018/Alum), in March 2021 and announced that SPECTRA, a global pivotal Phase 2/3 clinical trial, met the primary and secondary efficacy endpoints in September 2021. We subsequently plan to submit conditional regulatory approval applications to the EMA, the NMPA and the WHO in the fourth quarter of 2021. Meanwhile, we are expecting GMP inspections from the NMPA, EMA, and WHO in the second half of 2021. We expect to obtain conditional approvals between the fourth quarter of 2021 and the middle of 2022. Post conditional approval, we expect to commence product launch which may occur as early as year end 2021. SCB-2019 (CpG 1018/Alum) is anticipated to potentially be one of the first protein-based COVID-19 vaccines commercialized globally through the COVAX Facility. For details of the latest development of COVID-19 outbreak, please see “Summary – Recent Development.”

Clover also expanded SPECTRA to evaluate adolescents and we plan to initiate various clinical trials for SCB-2019 (CpG 1018/Alum) in subpopulations of COVID-19 vaccine addressable populations, including but not limited to, immunocompromised patients and the pediatric population. We also plan to evaluate the possibility of utilizing SCB-2019 (CpG 1018/Alum) as a heterologous booster following primary vaccination and as a homologous booster for SCB-2019 (CpG 1018/Alum).

The first of these trials is an investigator-led, IDOR, heterologous booster study, expected to initiate in the second half of 2021. The purpose of this study is to compare the immunogenicity and safety of heterologous booster schedules in individuals who received ChAdOx1-S or CoronaVac vaccination previously. In addition, Clover plans to initiate an expansion of SPECTRA, by conducting a homologous booster study of SCB-2019 (CpG 1018/Alum). The purpose of this study will evaluate the immunogenicity and safety of a SCB-2019 (CpG 1018/Alum) booster dose following primary vaccination with SCB-2019 (CpG 1018/Alum).

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Material Communications and Next Steps

Material Communications with the EMA

Based on the scientific advice provided by EMA regarding our planned global pivotal phase 2/3 clinical trial design evaluating the efficacy, safety, and immunogenicity of SCB-2019 (CpG 1018/Alum), EMA had no objection for us to commence a Phase 2/3 clinical trial as planned. Consequently, we presented our Phase 1 clinical data of SCB-2019 (CpG 1018/Alum) for COVID-19 from Australia along with nonclinical study results and other supportive data to the Federal Agency for Medicines and Health Products (FAMHP) of Belgium and received FAMHP approval to conduct a portion of SPECTRA in Belgium, Federal Agency for Medicines and Health Products (FAMHP) of Belgium to conduct a portion of SPECTRA, in Belgium, a member country of the EU, and dosed the first participant in Belgium in April 2021.

While the EMA is responsible for evaluating the results of clinical trials to determine if a therapeutic candidate should be approved for use in the EU, the final authorization occurs at the national level, by individual member countries. In August 2020, we requested scientific advice for our SCB-2019 (CpG 1018/Alum) pursuant to Article 57(1)(n) of Regulation (EC) 726/2004 of the European Parliament. We provided the EMA/CHMP with the comments together with the supporting documents including quality development, pre-clinical development and clinical development to obtain their advice on advancing our COVID-19 vaccine candidate's clinical program. We then received written formal scientific advice response in September 2020 and November 2020. During the course of our communication with the EMA, they provided the scientific advice responses to ensure that we would conduct appropriately designed studies and associated tests, including pivotal clinical trials such as SPECTRA, so that favorable outcomes of these trials/studies can support marketing authorization application.

In September 2020, we received a Rapid Scientific Advice from the EMA on: (i) the design of SPECTRA in terms of population, endpoints, statistical analysis; (ii) plans for CMA and full Marketing Authorization Applications (MAA); and (iii) the applicability of data from non-EU/EEA countries for the EU setting, among other comments. In November 2020, we received (i) confirmations on the design of SPECTRA in terms of endpoints, statistical analysis, enhanced COVID-19 surveillance, and stratification factors; (ii) suggested approach on the data analysis and the associated study success criteria, such as the criteria for the lower bound of the confidence interval; (iii) confirmations on the adequacy of the data package required for a Conditional Marketing Authorization Application; and (iv) the agreement on a clinical development approach for use of our vaccine candidate in the pediatric population, among other comments. We have accommodated the responses from EMA in the design of our SPECTRA trial. In these confirmation and advisory documents, EMA reviewers expressed no objection for us to conduct SPECTRA. Separately, the FAMHP of Belgium independently approved SPECTRA's clinical trial study design and enrollment protocol of subjects in Belgium.

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We have also engaged the EMA in discussions regarding a potential conditional approval and have requested for rolling submissions. We held a pre-submission meeting with the EMA on September 23, 2021 and believe we are on track to complete regulatory submission during the fourth quarter of 2021.

Material Communications with the NMPA/CDE

We started the rolling submission to the CDE for the IND application for SCB-2019 (CpG 1018/Alum) in October 2020. On a rolling basis, we submitted data from our Phase 1 clinical trial in Australia to the CDE for review and responded to their questions from time to time regarding details of our studies on immunogenicity, safety, and dose level. In March 2021, we had a formal consultation meeting with the NMPA's Center for Drug Evaluation (CDE), when CDE confirmed on the acceptance of our Phase 1 clinical trial results of SCB-2019 (CpG 1018/Alum) for COVID-19 generated from Australia and indicated that they had no objection for our strategy to receive a conditional BLA (cBLA) approval based on SPECTRA's efficacy data. Data from the planned Phase 2 clinical trial evaluating SCB-2019 (CpG 1018/Alum) in China and additional data from SPECTRA can support a full BLA approval in China. Our IND application was formally approved by NMPA in June 2021, in which they indicated that they had no objection to our global Phase 2/3 clinical trial upon acceptance of data from our Phase 1 clinical trial. We initiated the Phase 2 clinical trial for SCB-2019 (CpG 1018/Alum) in China on August 10, 2021.

We have initiated rolling submission for cBLA with more CMC, nonclinical and clinical data other than those contained in our IND package after the IND approval. We completed the fourth round rolling submission during our latest communication with the NMPA in September 2021. We plan to conduct the final round of submission for cBLA for approval as a Category I-1 preventative biological product in China with final data from SPECTRA in the fourth quarter of 2021. We expect to obtain the conditional approval from the NMPA between the fourth quarter of 2021 and the middle of 2022.

Material Communications with the WHO

We submitted the expression of interest in July 2021 in relation to apply for WHO EUL for our SCB-2019 (CpG 1018/Alum). We initiated our first round rolling submission to the WHO on September 20, 2021.

We may not be able to ultimately develop and market SCB-2019 (CpG 1018/Alum) successfully.

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Selected Pre-clinical and Discovery-Stage Vaccine Candidates

We are developing recombinant subunit trimer vaccine candidates for multiple variants of the SARS-CoV-2 virus, rabies, RSV, influenza, and HIV employing the Trimer-Tag™ technology platform. These vaccine candidates have demonstrated that they evoke protective neutralizing antibody responses in multiple animal models.

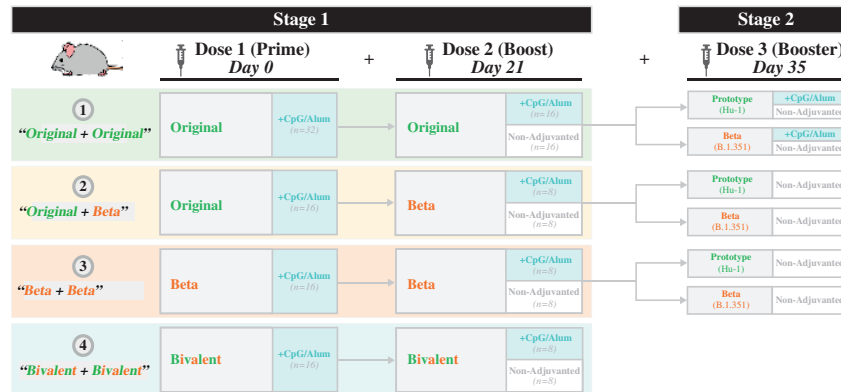
Second-generation COVID-19 Vaccine Candidates

Multiple variants of the SARS-CoV-2 virus have emerged and are circulating globally, including but not limited to the Alpha Variant, Beta Variant, Delta Variant, and Gamma Variant. Given the error-prone nature of RNA virus replication, variants will inevitably emerge as the virus is transmitted. New information about the characteristics of these variants is rapidly emerging and concerns regarding the effectiveness of currently authorized vaccines against them have been raised. We will continue to evaluate the efficacy of SCB-2019 (CpG 1018/Alum) against these variants and, if needed, intend to develop second-generation COVID-19 vaccine candidates to address emerging variants.

We are actively advancing our research and development for our second-generation COVID-19 vaccine candidates. In early 2021, we initiated the production of vaccine antigens against three variants of concern. We achieved initial S-Trimer™ antigen expression for the Beta Variant in February 2021 within a few weeks of program initiation. We completed candidate selection of a potential second-generation COVID-19 vaccine candidate in the first half of 2021. For details of the latest development of COVID-19 outbreak, please see “Summary – Recent Development.”

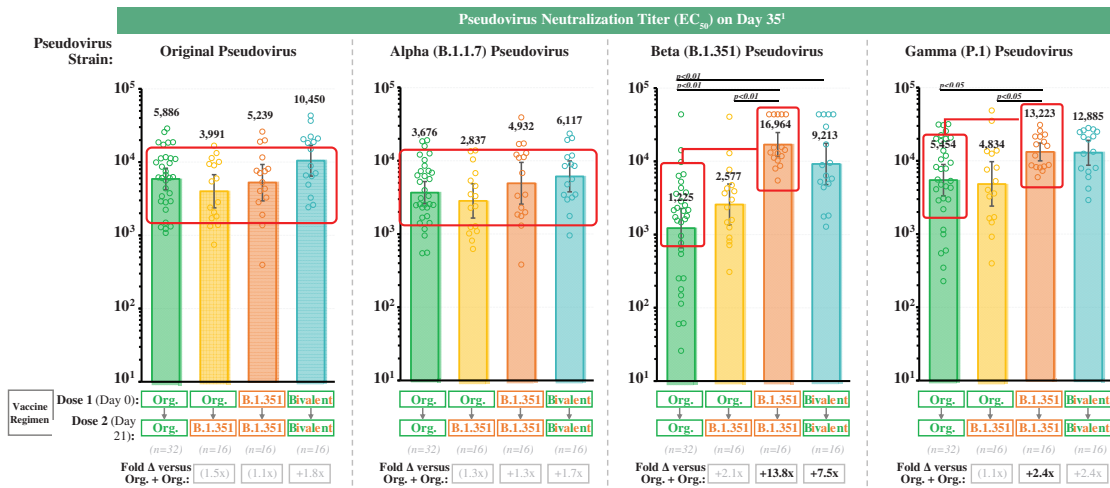
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Our pre-clinical mouse immunogenicity studies for a modified Beta Variant (B.1.351) protein-based COVID-19 vaccine candidate have produced informative preliminary results. The modified Beta Variant antigen construct is a chimera produced with Trimer-Tag™ and is comprised of the N-terminal domain (NTD) based on the original strain and an receptor-binding domain (RBD) based on the Beta Variant. The designs for immunogenicity studies for the Beta Variant are as follows: in the first stage of the study, the mouse models were administrated with (i) two doses of monovalent vaccine addressing the original strains of SARS-CoV-2 (i.e. SCB-2019), (ii) heterologous prime-boost with one dose of vaccine addressing the original strains of SARS-CoV-2 followed by a second dose of the Beta Variant-based vaccine candidate, (iii) two doses of monovalent Beta Variant based vaccine and/or (iv) two doses of bivalent vaccine candidate of both the vaccines addressing the original strains of SARS-CoV-2 and the Beta Variant, with the two doses given 21 days apart. All animals in the first stage of the study received a priming dose adjuvanted with CpG 1018 plus alum. For the second dose, half of the animals received a non-adjuvanted boost (antigen-only). In the second stage of the study, animals that received two doses of monovalent vaccine addressing the original strains of SARS-CoV-2 were randomized to receive a booster dose two weeks after the second dose with either vaccine addressing the original strains or a Beta Variant-based vaccine candidate (half adjuvanted and half non-adjuvanted). Animals in the heterologous prime-boost group and animals that received two doses of monovalent Beta Variant-based vaccine candidate were randomized to receive a booster dose with either non-adjuvanted vaccine addressing the original strains of SARS-CoV-2 or non-adjuvanted Beta Variant-based vaccine candidate. The four study groups, in the study are illustrated by the diagram below:

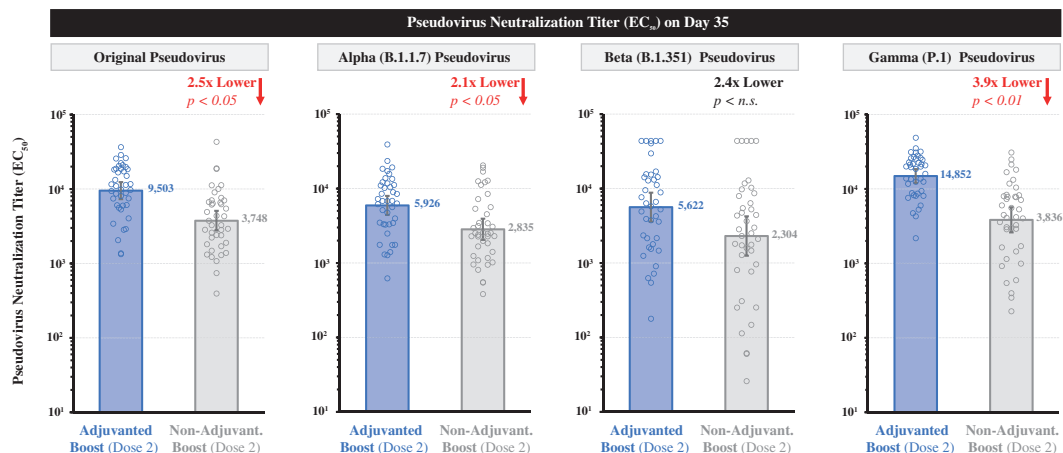


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Humoral immunogenicity analysis was conducted two weeks after the second dose on blood samples based on pseudovirus neutralization titers against the original strain and three variants of concern. The results demonstrate that neutralizing titers against the Beta and the Gamma Variant were highest in the groups receiving two doses of either Beta Variant-based vaccine or bivalent vaccine, with the former inducing the numerically highest titers. Neutralizing antibody titers for the original strain of SARS-CoV-2 and the variants of concern were similar across all groups and demonstrated that two doses of a Beta variant-based vaccine candidate was able to elicit were similar across all vaccine groups, demonstrating that two doses of Beta Variant-based vaccine candidate were able to elicit antibodies capable of fully back-neutralizing against the original strain and the three variants of concern tested in this study (Alpha Variant, Beta Variant, and Gamma Variant). The results indicate that our Beta Variant-based vaccine candidate could potentially be protective against the original strains of SARS-CoV-2 and certain variants of concern. The following diagram illustrates such preliminary results.

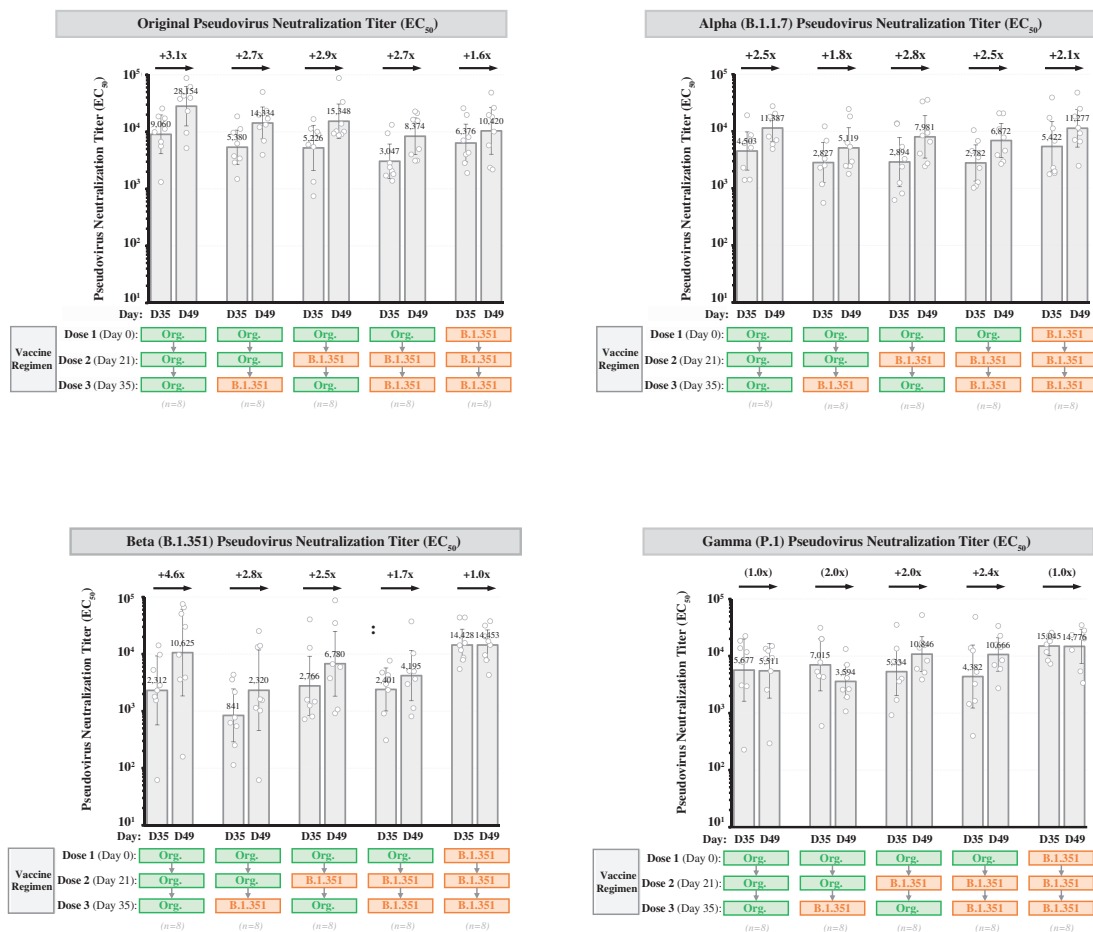


The effect of adjuvanted versus non-adjuvanted second doses was done via factorial analysis based on pseudovirus neutralization titers. Neutralizing antibody titers induced by the adjuvanted booster were two-to-four-fold higher than that of the non-adjuvanted booster, demonstrating the positive impact of adjuvants on immune response when utilized in the booster.



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Analysis for humoral and cellular immune responses for the booster doses were conducted two weeks after administration of the booster doses. Across all vaccine groups, receiving the booster dose neutralizing antibody titers increased by about 1.6- to 3.1- fold against the original strain and 1.8- to 2.8- fold against the Alpha Variant. In the groups receiving three doses of vaccine addressing the original strain of SARS-CoV-2, neutralizing antibody titers against the Beta Variant increased by 1.7- to 4.6- fold after the booster dose. In the group receiving three doses of the Beta Variant-based vaccine candidate, neutralizing antibody titers against the Beta Variant did not significantly increase after the booster dose, likely because titers were already at high biological levels after the first two doses. The following diagram illustrates such preliminary results.



Rabies Vaccine Candidate

Our rabies vaccine candidate (RABV G-Trimer) is currently in early-stage development. Currently approved rabies vaccines have limitations in their production capacities, required administration schedules, storage requirements, and cost. There continues to be a need for better rabies vaccines in certain countries, such as China, where animal immunization programs have been unsuccessful.

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RSV Vaccine Candidate

Our RSV vaccine candidate (Fusion F Antigen-Trimer) induced a strong neutralizing antibody response in a rat immunization model. This candidate demonstrated high binding affinity (sub-picomolar) to palivizumab. Currently, there are no approved vaccines for RSV, therefore our RSV vaccine candidate could potentially address the significant unmet need worldwide if approved.

Influenza Vaccine Candidate

Our influenza vaccine candidate (Hemagglutinin (HA)-Trimer) demonstrated proof-of-concept immunogenicity and viral-challenge results *in vivo* in mice (pandemic and seasonal). An adjuvanted protein-based seasonal flu vaccine may also be attractive to achieving stronger immune responses in elderly populations which traditionally have observed lower responses to traditional flu vaccines. A flu vaccine candidate could also potentially be developed to be used in a pandemic situation or as a universal (HA-stem) flu vaccine.

HIV/AIDS Vaccine Candidate

Our HIV/AIDS vaccine candidate (gp120-Trimer) demonstrated strong binding affinity to broadly-neutralizing antibodies (bNAbs), suggesting preservation of important antigenic epitopes. Preliminary data showed that gp120-trimers induced bNAb responses *in vivo* in a rabbit immunization model. Current progress made in HIV/AIDS vaccine research has revealed that native-like trimeric gp120 is the preferred antigen for eliciting broadly neutralizing antibodies (bNabs), and could hold promise for an effective prophylactic vaccine for the disease.

Trimer-Tag™ Oncology Product Candidates

SCB-313

Summary

SCB-313 is a novel, recombinant human TNF-related apoptosis-inducing ligand (TRAIL)-Trimer fusion protein engineered using the Trimer-Tag™ technology platform to target the extrinsic apoptosis pathway. Binding of SCB-313 to the death receptors leads to physiologic trimerization of the death receptors and potent activation of the extrinsic apoptosis (cell death) pathway, that is promising for cancer therapy.

TRAIL has long been a promising target for cancer therapy due to its ability to selectively kill cancer cells through activating DR4 and DR5 and inducing programmed cell death in a tumor-specific manner across many different tumor types. Functional and structural studies have shown that DR4 and DR5 require trimerization on the cell membrane to drive receptor signaling to induce apoptosis. Dimeric antibody-based structures and other native ligand-based

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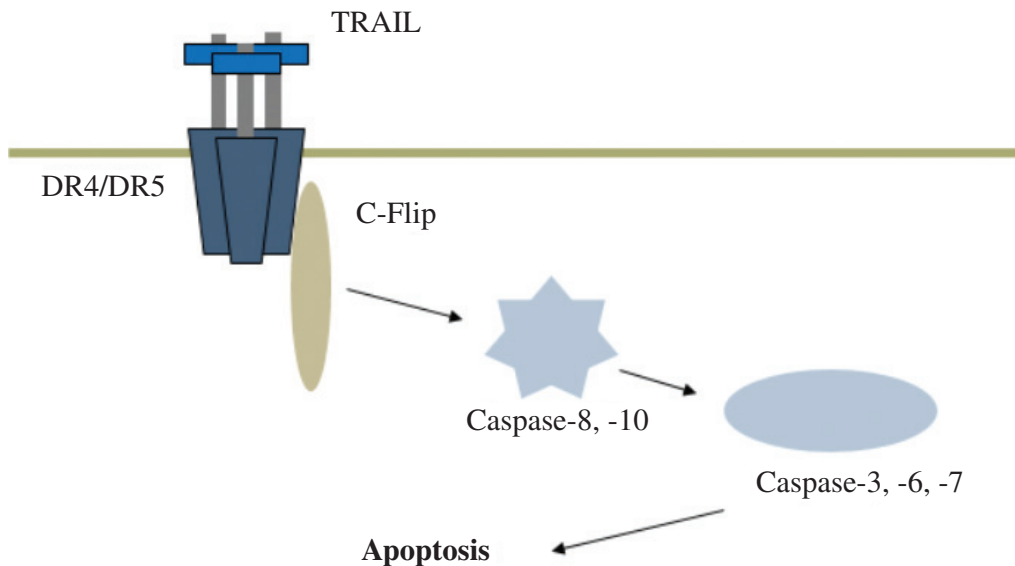
candidates targeting this pathway have failed to demonstrate significant anti-tumor efficacy due to an insufficient capacity of these agents to induce death receptor clustering, and/or adverse events such as liver toxicity.

SCB-313 is structurally and functionally differentiated from dimeric antibody-based and other native ligand-based candidates targeting the death receptor pathway. In both *in vivo* and *in vitro* pre-clinical studies, SCB-313 demonstrated favorable pharmacodynamic and pharmacokinetic profiles with an extended intracavitary half-life, which results in greater drug exposure to target tumor cells locally, potentially translating to anti-tumor efficacy.

We are conducting five Phase 1 clinical trials for SCB-313 in China and Australia for the treatment of intracavitary malignancies. We are focused on developing SCB-313 in MA, MPE and PC. We expect to advance the development of SCB-313 for the treatment of MA to a Phase 2 clinical trial in the first half of 2022. In addition, we plan to initiate additional Phase 1 clinical trials for SCB-313 to explore new indications, such as bladder cancer, and combination approaches in 2022.

Mechanism of Action

TRAIL, also known as Apo2 ligand, mediates activation of the extrinsic apoptosis pathway and is considered a promising target for cancer therapy. TRAIL is expressed as a naturally trimeric protein. TRAIL-binding induces DR4 and DR5 trimerization, the prerequisite for initiation of the apoptotic signaling pathway. Upon trimerization, DR4 and DR5 cytoplasmic domains serve as a docking site for adapter protein Fas-associated death domain (FADD), followed by recruitment of initiator procaspases 8 and 10. The resulting assembly of proteins comprise the death-inducing signaling complex. The activated caspases 8 and 10 then cleaves and activates downstream effector caspases 3, 6, and 7, culminating in apoptosis. The diagram below illustrates the mechanism of action of SCB-313:

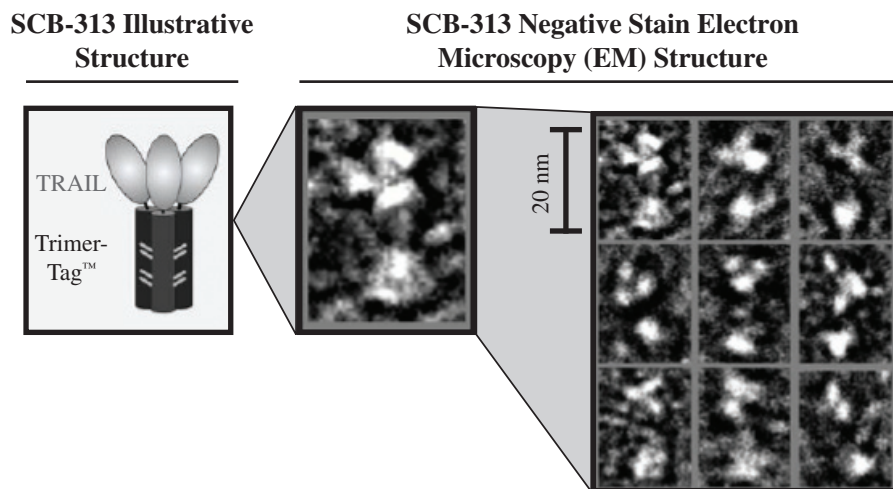


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Advantages of TRAIL-Trimer (SCB-313)

Historically, the TRAIL-DR4/DR5 pathway has been difficult to target due to insufficient activation of the TRAIL-receptor to induce apoptosis. Agonists of DR4 and DR5 have been studied previously, yet the development of a viable therapeutic candidate has proven to be challenging. None of the agents tested to date have induced sufficient anti-tumor activity to support further clinical development into pivotal trials.


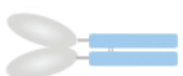

The Trimer-Tag™ motif possesses structural flexibility and mechanical properties that are ideal for enabling TNFSF ligands to achieve stable covalent bond-linkage and native-like trimeric structures of TRAIL, a requirement for biologic activity. Trimerization also increases the molecular weight extending TRAIL's half-life, a characteristic that yields improved antitumor efficacy when studied *in vivo*. The fusion proteins of SCB-313 are covalently linked by inter-molecular disulfide bonds formed among the C-terminal domains, therefore overcoming the previous stabilization, half-life, and efficacy challenges. The following diagram illustrates the structure of SCB-313:



Abbreviation(s): EM=electron microscopy.

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The following chart sets forth a summary of key attributes of SCB-313 compared to dimeric antibody-based structures and native ligand-based candidates:

		Illustrative Structure		Key Attributes
SCB-313 (TRAIL- Trimer)	~160kDa (Trimer-tagged protein)		✓	Natural, high potency for inducing apoptosis in tumor cells
			✓	Covalently-linked trimer, higher binding affinity to death receptors
			✓	Larger molecular weight, extends half-life and exposure to targeted tumor cells when administered within the peritoneum or pleural space
TRAIL-Fc	~96kDa (dimeric antibody-based structures)		×	Non-trimer structure
			×	Insufficient anti-tumor efficacy observed in clinical trials
Native TRAIL	~60kDa (native ligand)		×	Non-covalently associated trimer
			×	Small molecular weight, rapidly eliminated via renal filtration (i.e. short half-life in vivo)

SCB-313 retains the naturally potent bioactivity and high receptor binding kinetics of native TRAIL *in vitro*, which is four to five orders of magnitude higher than that of dimeric DR4 and DR5 agonists. SCB-313 also has a favorable pharmacokinetic and pharmacodynamic profiles *in vivo* compared to both native TRAIL and TRAIL-Fc, while preserving a favorable safety profile in pre-clinical studies.

Market Opportunity and Competition

SCB-313 has the potential to address significant unmet medical needs globally, with a focus on intracavitary malignancies. We are developing SCB-313 for the treatment of MA, MPE, and PC to address global unmet medical need. The indications that we are targeting for SCB-313 are diseases commonly observed in late-stage cancer patients.

According to Frost & Sullivan, the global intracavitary malignancies incidence reached 2.5 million in 2019 and is expected to grow to 2.8 million and 3.0 million by 2024 and 2030, respectively. Despite the high incidence, the current standard of care fails to provide meaningful clinical benefit for most patients.

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MA is the accumulation of significant amounts of exudate or fluid in the abdominal/peritoneal cavity, accompanied by the presence of malignant cells or tumor tissue. Patients who suffer from this are usually on the final stage of their cancer events. Currently, the standard of care involves therapies directed against the primary tumor and/or drainage to manage MA symptoms. Common treatments for the palliation of symptoms associated with MA, include: paracentesis, peritovenous shunts, direct intra-peritoneal administration of chemotherapy, and diuretics. Currently, no effective anti-tumor therapy or targeted medicines exist for the treatment of MA.

MPE is the accumulation of significant amounts of exudate or fluid in the pleural space, accompanied by the presence of malignant cells or tumor tissue. MPE is an indication that a primary tumor has metastasized and affects approximately 15% of lymphoma, breast, lung, and ovary cancer patients globally, according to Frost & Sullivan. Similar to the standard of care for MA, there are no explicit MPE treatment guidelines aside from the palliative management of disease symptoms, such as drainage, and therapies directed against the primary tumor. Commonly used therapies to alleviate the symptoms associated with MPE include chemical pleurodesis, indwelling pleural catheter, and hyperthermic intraperitoneal chemotherapy, all of which require hospitalization and are not able to effectively target the disease. Currently, there are no therapeutic options available for the treatment of MPE.

PC is the intraperitoneal dissemination of any form of cancer commonly seen as an advanced or late stage manifestation of malignancies. In PC tumors metastasize to and deposit on the peritoneal surface, thus it has historically been considered a terminal condition with a poor prognosis and median survival from five to twelve months, with proper palliative care. The current standard of care for the treatment of PC includes aggressive cytoreductive surgery, intraperitoneal hyperthermic chemotherapy, and systemic chemotherapy, all of which require hospitalization and are not able to effectively target the disease. Currently, there are no targeted therapies available globally for the treatment of PC.

There are very few drug candidates for intracavitary malignancies in clinical development. SCB-313 is the only drug candidate undergoing concurrent development for the treatment of MA, MPE, and PC. The following chart illustrates the competitive landscape of SCB-313 globally and in China, according to Frost & Sullivan:

Drug Code/ INN	Company	Indication	Status	Approval Date/ First Posted Date
BSG-001	BioSyngen Pte Ltd	Malignant Ascites; Malignant Pleural Effusion	Phase I/II in Australia (Not yet recruiting)	2018/11-08
SCB-313	Clover	Peritoneal Malignancies	Phase I in Australia	2018/02/23
		Peritoneal Carcinomatosis	Phase I in China	2019/08/09
		Malignant Ascites	Phase I in China	2019/07/24
		Malignant Pleural Effusion	Phase I in Australia	2019/03/11
			Phase I in China	2019/10/08
M701	Wuhan YZY Biopharma Co., Ltd.	Malignant Ascites	Phase I in China	2018/08/14

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Competitive Advantages of SCB-313

SCB-313 is a novel, covalently-linked, native-like trimer protein, that demonstrated an attractive profile for intracavitary malignancies, and the potential to overcome the obstacles encountered by dimeric TRAIL-Fc and native TRAILS. Previously, dimeric TRAIL-Fc exhibited low activity in inducing apoptosis, and while native TRAIL is highly potent, its molecular structure is trimerized via weak noncovalent interactions resulting in a short half-life and rapid elimination *in vivo*.

- *Potentially strong bioactivity.* Engineered using the Trimer Tag™ technology platform, SCB-313 consists of native TRAIL and Trimer Tag™, which is a human secreted protein that is capable to self-trimerization into a covalently-linked structure. SCB-313 has a high binding affinity for death receptors (DR4/DR5) and no presumed immunogenicity. In pre-clinical studies, SCB-313 demonstrated superior bioactivity and receptor-binding affinity compared to dimeric TRAIL-Fc. For example, SCB-313 was observed to have a binding affinity to its receptor DR5 that was over two orders of magnitude higher than that of native TRAIL and 4 orders of magnitude higher than a bivalent TRAIL-Fc.

In pre-clinical studies, SCB-313 demonstrated a longer *in vivo* half-life, increasing its potential exposure to targeted tumor cells compared to native TRAIL. It is hypothesized that this is due to SCB-313 covalently-linked structure and larger molecular weight. The half-life of SCB-313 was found to be over 3 times longer than native TRAIL (20 minutes versus 6 minutes). In mouse ascites, the half-life of SCB-313 (intraperitoneal injection) was around 3 hours, approximately 10-fold longer than the systemic half-life of SCB-313 (intravenous injection).

In pre-clinical mouse studies we achieved confirmation that the prolonged half-life of TRAIL-Trimer versus native TRAIL translated to superior antitumor efficacy. For pre-clinical studies of SCB-313 we showed that it induced rapid tumor apoptosis and regression in a dose-dependent fashion. In contrast, mice administered only formulation buffer had tumors that grew rapidly and continuously.

- *Potentially favorable safety profile.* SCB-313 is a secreted protein. In our pre-clinical studies, SCB-313 did not demonstrate any hepatocyte toxicity in both models (mice and cynomolgus monkeys) confirming the safety profile.

Given SCB-313's ability to induce tumor cell apoptosis, provide a significantly prolonged half-life, with extended exposure to target tumor cells, and favorable safety profile, we believe SCB-313 represents a potentially compelling first-in-class treatment for MA, MPE and PC, as well as other malignancies.

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Summary of Pre-clinical Data

We conducted a range of *in vitro*, *in vivo*, and animal pre-clinical studies to characterize the pharmacodynamics, pharmacokinetic, and toxicology of SCB-313. The anti-tumor activity of SCB-313 has been tested and demonstrated using multiple established human tumor cell lines. Data from a head-to-head pre-clinical study comparing the bioactivity *in vitro*, receptor binding activity *in vitro*, pharmacokinetic, antitumor activity, and safety of SCB-313 with a native TRAIL and TRAIL-Fc, was published in *Scientific Reports*, a peer-reviewed journal published by *Nature* in 2017.

Pharmacodynamic Studies: Efficacy Against Intracavitary Cancers

In pre-clinical pharmacology studies, SCB-313 demonstrated potent ability to induce apoptosis in *in vitro* tumor cell lines and *in vivo* tumor models. SCB-313 also showed superior antitumor activity *in vivo* compared to native TRAIL.

The *in vitro* anti-tumor activity of SCB-313 was assessed by measuring bioactivity (IC_{50}) using multiple human tumor cell lines, including those derived from MA and pleural effusion metastatic sites. In our pre-clinical studies, more than 70% of human cancer cell-lines tested were sensitive to SCB-313-induced apoptosis, with intracavitary cancers showing even greater sensitivity.

Additionally, *in vitro* functional receptor binding affinity was analyzed comparing SCB-313 (TRAIL-Trimer) to native TRAIL and TRAIL-Fc. SCB-313 was observed to have a binding affinity to receptor DR5 that was over two orders of magnitude higher than that of native TRAIL and 4 orders of magnitude higher than TRAIL-Fc. These results indicate that SCB-313 has strong bioactivity with significantly higher binding affinity and extended half-life as compared to native TRAIL and TRAIL-Fc. The table below demonstrates such results:

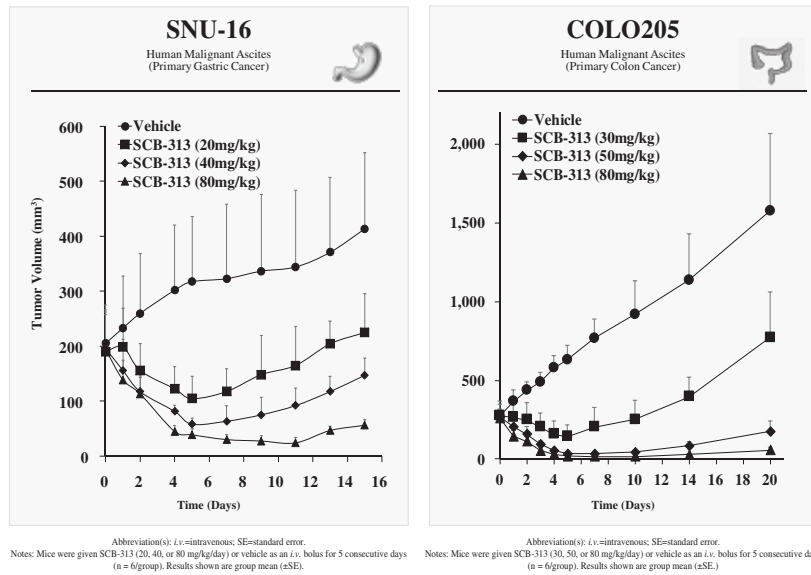
Analyte	Receptor	KD* (M)
TRAIL-Fc	DR5-Fc	1.85E-08
native TRAIL	DR5-Fc	2.63E-10
TRAIL-Trimer	DR5-Fc	<1.0E-12

Note: KD represents binding affinity.

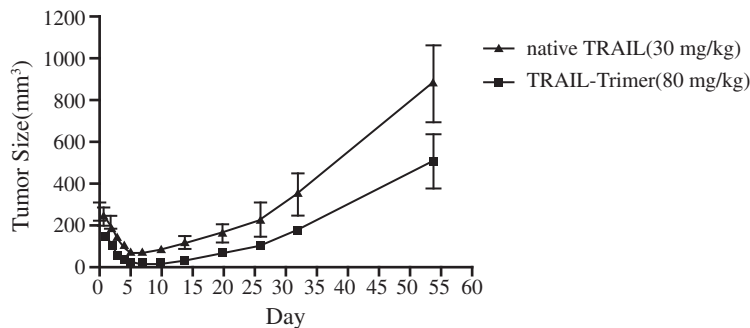
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The ability of SCB-313 to kill human tumor cells *in vivo* was assessed using a tumor xenograft model in nude mice. After subcutaneous tumors from inoculated SNU-16 and COLO205 cell lines grew to standard sizes of approximately 200 and 250 mm³, respectively, three doses (20mg/kg, 40mg/kg, 80mg/kg) of SCB-313 were administered by *intravenous infusion* once daily over the first 5 days of the study. The dosing regimen was based on prior studies of native TRAIL in similar mouse models. SCB-313 induced rapid tumor apoptosis and regression in a dose-dependent fashion. In contrast, tumors in mice that had been administered only with formulation buffer grew rapidly and continuously. The diagram below demonstrates such results:

Subcutaneous Tumor Xenografts in Nude Mice (BALB/c)



The observed dose-response of SCB-313 suggests that the best antitumor activity with this regimen is achieved with 80 mg/kg/day, when the longest sustained antitumor response was observed. As such, we compared the efficacy of SCB-313 (80 mg/kg/day) to an equimolar dose of native TRAIL (30 mg/kg/day), factoring in the approximately 2.7 fold difference in molecular weight between the two proteins. At every time point that tumor sizes were measured following dosing, tumors in mice treated with SCB-313 were smaller than in mice treated with native TRAIL. The diagram below demonstrates such results:

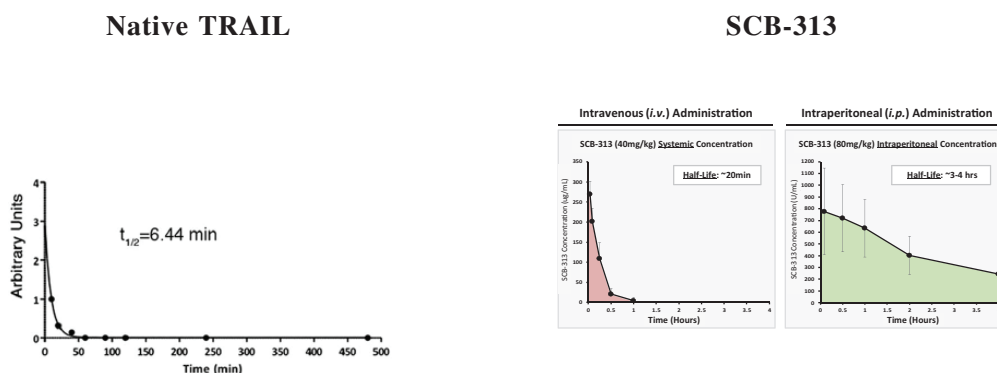


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Pharmacokinetic Studies: Extended Intracavitary Half-Life

There is a close and direct relationship between the half-life of TRAIL-based therapies and their anti-tumor pharmacodynamic effects *in vivo*. A key problem in previous studies of native TRAIL has been a very short half-life, due to its low molecular weight (approximately 60 kDa) and instability of its non-covalently linked trimeric structure leading to rapid elimination via renal filtration. In contrast to native TRAIL, SCB-313 exists as a stable covalently-linked trimer, and its larger molecular size (approximately 160 kDa) reduces elimination by rapid renal filtration.

The systemic half-life of SCB-313 in serum was compared with native TRAIL in nude mice when administered via intravenous injection and intraperitoneal injection. The half-life of SCB-313 was found to be over 3 times longer than native TRAIL (20 minutes versus 6 minutes). In addition, the half-life of SCB-313 via intraperitoneal injection in the mouse ascites was about 3 hours, which is approximately 10-fold longer than the systemic half-life of intravenous administered SCB-313. These data also suggest that SCB-313 can achieve optimal pharmacokinetics via intracavitary administration. The following three diagrams demonstrate these conclusions:



Due to a significantly prolonged half-life, SCB-313 demonstrated superior anti-tumor activity compared to native TRAIL *in vivo* in the COLO205 tumor xenograft model. These findings could be especially relevant in human cancers which exhibit significant numbers of tumor lesions, whereas the short half-life of native TRAIL would make it insufficient to extend beyond the perivascular space and penetrate the tumor bed before being eliminated via renal filtration. Thus, prolonged half-life is a critical attribute for TRAIL-based therapy because it results in favorable pharmacokinetics to target tumor cells and increased induction of apoptosis.

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Toxicology Studies: Potentially Favorable Safety Profile

Our pre-clinical toxicology studies of SCB-313 suggest a favorable safety profile. We evaluated the liver cytotoxicity in mice injected with SCB-313 and native TRAIL by using histological detection and neither SCB-313 nor native TRAIL showed any noticeable toxicities toward the mice liver cells. This apparent lack of hepatotoxicity was further confirmed in normal human liver cells exposed to high levels of SCB-313 *in vitro*. There were also no significant variations in body weights observed across nude mice treatment groups.

Additionally, in a separate study in cynomolgus monkeys evaluating various safety serum parameters following SCB-313 administration, no dose limiting toxic side effects, including those on the liver and kidney were observed, further confirming the safety profile of SCB-313.

Five Phase 1 Clinical Trials Ongoing for SCB-313

We are conducting five Phase 1 clinical trials for SCB-313 as a monotherapy in China and Australia for the treatment of intracavitary malignancies. We are focused on developing SCB-313 in MA, MPE and PC.

CLO-SCB-313-001

CLO-SCB-313-001 is the first in human Phase 1 clinical trial to evaluate the safety, tolerability, efficacy, pharmacodynamics, and pharmacokinetics of SCB-313 administered twice weekly for two weeks (on days 1, 4, 7 & 10) at 10 mg/day up to 160 mg/day via *IP* bolus injection for the treatment of patients with peritoneal malignancies, including but not limited to PC, MA, pseudomyxoma peritonei, and peritoneal mesothelioma.

This Phase 1 clinical trial is a multicenter, open label, uncontrolled, sequential dose escalation study. Patient accrual and the initiation of the second cohort will follow the principles of accelerated titration dosing (ATD) until the maximum tolerated dose (MTD) is reached, and the biological effective dose (BED) recommended for Phase 2 dose (RP2D) is established in at least 6 evaluable patients.

CLO-SCB-313-CHN-001

CLO-SCB-313-CHN-001 is a Phase 1, open-label, single-center, uncontrolled, sequential dose escalation study (ATD combined with 3+3 design) in patients with MA, to evaluate safety, tolerability, preliminary efficacy, and pharmacokinetics of SCB-313.

This clinical trial is comprised of 5 dose cohorts: 10 mg, 20 mg, 40 mg, 80 mg, and 160 mg. For dose cohorts 10 mg, 20 mg, and 40 mg, an ATD escalation will follow, while traditional "3+3" escalation will be applied for dose cohorts 80 mg and 160 mg. The primary endpoint is the incidence of dose limiting toxicity (DLT). SCB-313 will be administered as a single dose on the first day and then once daily over 3 consecutive days (Day 8-10) by *IP* bolus injection.

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CLO-SCB-313-002

CLO-SCB-313-002 is a Phase 1 clinical trial to evaluate the safety, tolerability, and immunogenicity of SCB-313 administered once via intrapleural injection as a single ascending dose (SAD) and once daily over 2 to 3 days as a multiple ascending dose (MAD) of a once daily *IP* administration and BED is established for the treatment of cancer patients with symptomatic MPE requiring drainage.

This Phase 1 clinical trial is a multicenter, open label, uncontrolled, sequential dose escalation study. Patients' accrual and the initiation of a second cohort will follow the principles of ATD for the SAD. In the SAD, patients will be enrolled in successive cohorts until the MTD or MAD is reached and BED is established in at least 6 evaluable patients. Therefore, if sufficient safety evidence is obtained in evaluable patients during the SAD phase, the MAD phase will be opened to further evaluate and confirm the MTD of SCB-313 administered at BED once daily over two to three days in MPE patients.

CLO-SCB-313-CHN-002

CLO-SCB-313-CHN-002 is a Phase 1, open-label, single-center, uncontrolled, sequential dose escalation study (ATD combined with "3+3" design) in patients with MPE, to evaluate safety, tolerability, preliminary efficacy, and pharmacokinetics of SCB-313 administered as a single dose on the first day (Day1) followed by once daily over 3 consecutive days (Day 8-10) via *IP* bolus injection.

This clinical trial comprises 5 dose cohorts, namely 5 mg, 10 mg, 20 mg, 40 mg, and 80 mg. For dose cohorts 5 mg to 20 mg, ATD escalation is followed, while traditional "3+3" escalation is applied for dose cohorts 40 mg and 80 mg. The primary endpoint is the incidence of DLT, while the secondary endpoints are occurrence of AE and immunogenicity, all of which are evaluated within 28 days after 1st dose of SCB-313.

CLO-SCB-313-CHN-003

CLO-SCB-313-CHN-003 is a Phase 1, open-label, single-center, uncontrolled, sequential dose escalation study (ATD combined with "3+3" design) in patients with PC, to evaluate safety, tolerability, preliminary efficacy, and pharmacokinetics of SCB-313.

This clinical trial is comprised of 5 dose cohorts: 10 mg, 20 mg, 40 mg, 80 mg and 160 mg. ATD escalation is applied for the 10 mg and 20 mg cohorts, while a traditional '3+3' escalation is applied for dose cohorts 40 mg, 80mg, and 160 mg. The primary endpoint is the incidence of DLT. SCB-313 will be administered at Day 1, 4, 7 by *IP* bolus injection.

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Interim Analysis of Safety and Activity

As of July 2021, all 5 of the SCB-313 clinical studies are ongoing. However, for the purpose of providing periodic safety updates to health authorities and planning for future studies we have conducted an interim analysis of safety and activity.

As of January 2021, a total of 32 patients with doses ranging from 10 mg to 160 mg were treated in phase I clinical trials in China and Australia (Interim Assessment of Safety from SCB-313 Development Safety Report) and as of May 2021, 19 patients enrolled in studies CLO-SCB-313-CHN-001 and CLO-SCB-313-001 were assessed together for activity (Interim Assessment of Activity from ongoing Malignant Ascites Trials). The interim analyses results are discussed together in the following sections and pooled where appropriate.

Overall patient demographics and baseline characteristics for each Interim Analysis cohorts is described in the table below.

Patients had a median age > 50 (range, 26-89) and nearly all had an Eastern Cooperative Oncology Group performance status of 1-2. Patients had a median of 2 (range, 1-5) prior lines of therapy. The histologic origin of cancers varied with the most common being ovarian, lung, and gastrointestinal/colorectal.

Patient Demographics and Baseline Disease Characteristics

Characteristic	Safety Evaluable Cohort (N=32)	Malignant Ascites Activity Evaluable Cohort (N=19)
Age, years		
Median	56	53
Range	26-89	38-77
Male sex, No. (%)	11 (34%)	7 (37%)
ECOG performance status, No. (%)		
0	1 (3%)	N/A
1	25 (78%)	17 (90%)
2	6 (19%)	2 (11%)
Histology subtype, No. (%)		
Ovarian	7 (22%)	4 (21%)
Lung Adeno	6 (19%)	N/A
Colon/Colorectal	5 (16%)	6 (32%)
Breast	3 (9%)	3 (16%)
Gastric	3 (9%)	2 (11%)
Mesothelioma	3 (9%)	1 (5%)
Appendix cancer	2 (6%)	N/A
Advance Uterus cancer	1 (3%)	1 (5%)
Genital	1 (3%)	N/A

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Characteristic	Safety Evaluable Cohort (N=32)	Malignant Ascites Activity Evaluable Cohort (N=19)
Mediastinal (Possibly neuro Endocrine)	1 (3%)	N/A
Liver	N/A	1 (5%)
prostate	N/A	1 (5%)
Prior lines of therapy, No.		
Unknown	1 (3%)	0 (0%)
1	6 (19%)	3 (16%)
2	11 (34%)	4 (21%)
3	3 (9%)	4 (21%)
4	5 (16%)	4 (21%)
5	5 (16%)	3 (16%)
6	1 (3%)	1 (5%)
Refractory to any prior therapy, No. (%)		
Unknown	25 (78%)	N/A
Refractory	7 (22%)	N/A

Safety Data

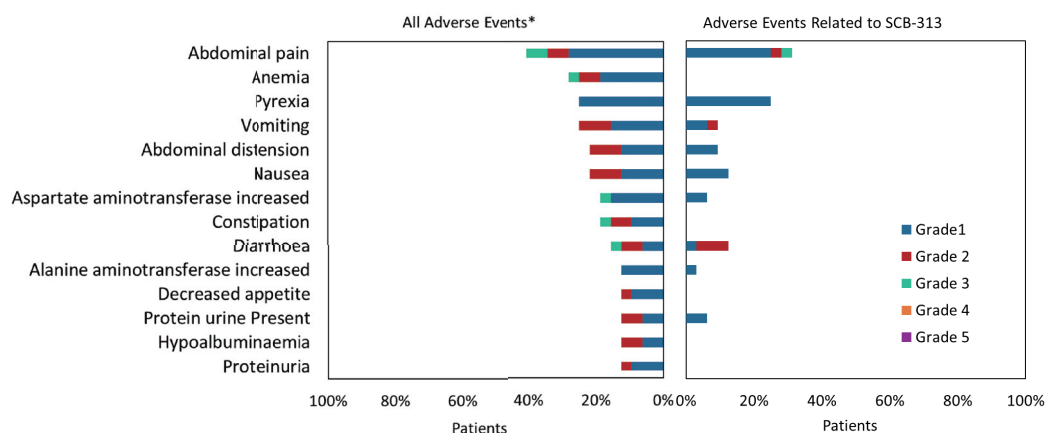
AEs were reported in 32 of 32 patients (100%); 19 (59%) had at least one AE considered related to SCB-313. The most common AE (reported in over 10% of patients) regardless of the relationship with SCB-313 included: abdominal pain, vomiting, pyrexia, nausea, anemia, constipation, abdominal distension, hypoalbuminemia, diarrhea, proteinuria, decreased appetite, and liver function test abnormalities. Most AEs were mild to moderate in severity (grade 1 or 2). No SCB-313 related SAEs or AEs leading to discontinuations were reported.

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Summary of Severe, Medically Significant, or Life-Threatening Adverse Events in Patients Receiving SCB-313 at Any Dose (Interim Results: Safety Evaluable Cohort)

	n (patients)	% (N=32 patients)
Patients with any grade 3-4 AE	15	47
Patients with any grade 3-4 Treatment Related AE	1	3
Patients with any Treatment Related SAE	0	0
Patients with any AE leading to permanent treatment discontinuation	0	0
Patients with any AE leading to death	0	0

Adverse Events per Preferred Term (PT)



* Adverse events with an incidence of $\geq 10\%$ or an NCI-CTCAE grade 5; all Phase I trials in Australia and China as of 28 January 2021; N=32 patients.

Efficacy Data

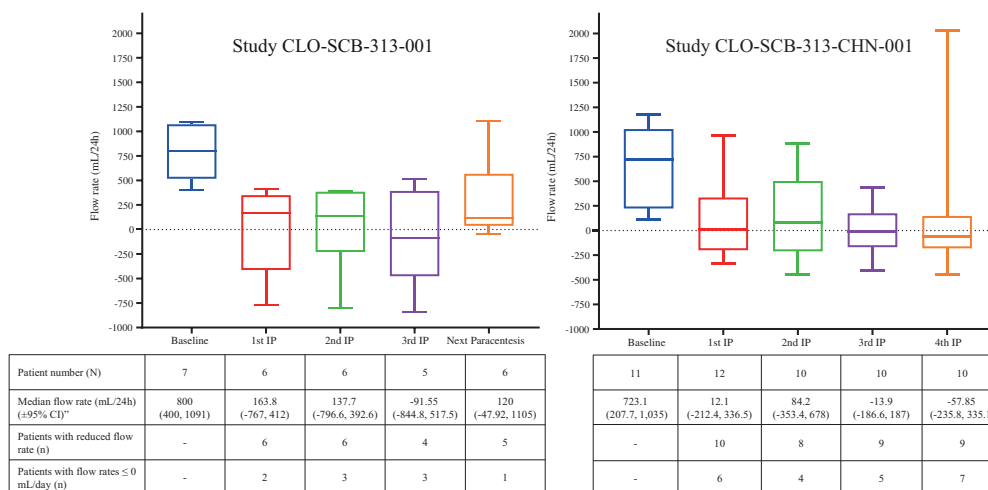
PK analyses revealed the terminal half-life for SCB-313 in ascites is ~3-4 hrs. Cmax and AUC shows a nonlinear dose-dependent increase and near complete elimination from the peritoneal fluid by 24 hrs. There was no accumulation after multiple administrations.

Clinical activity was observed at all SCB-313 doses administered.

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SCB-313 treatment resulted in measurable ascites flow rate decrease across all dose-levels (10, 20, 40, 80, and 160 mg). Measurement of apoptosis specific caspase cleaved CK18 (ccCK18) was analyzed in 4 patients and showed there was an SCB-313 administration dependent ccCK18 increase 4-8 hours following treatment.

Ascites Flow Rate



In summary, SCB-313 therapy presents an acceptable safety profile at all tested dose levels (10, 20, 40, 80, and 160 mg). Activity data are consistent with an anti-tumor effect and measurable clinical effect following SCB-313 treatment. Dose limiting toxicities and the maximum tolerated dose level have not been defined.

Clinical Development Plan

We expect to initiate a global Phase 2 clinical trial for SCB-313 for the treatment of malignant ascites in the first half of 2022. In addition, we plan to initiate additional Phase 1 clinical trials for SCB-313 to explore new indications such as bladder cancer and combination approaches in 2022. We plan to submit the NDA of SCB-313 to the NMPA for approval as a Category I therapeutic product.

We may not be able to ultimately develop and market SCB-313 successfully.

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Selected Discovery-Stage Immuno-oncology Product Candidate

4-1BB Agonist Product Candidate

We are conducting discovery programs evaluating trimeric fusion protein candidates targeting the 4-1BB pathway, a member of the TNFSF. Activation of the 4-1BB receptor, which requires trimerization to be activated, is an attractive candidate for applications in cancer immunotherapy and demonstrated potent cytotoxic immune cell activation and antitumor responses in multiple pre-clinical studies. Building on experience utilizing the Trimer-Tag™ technology platform and deep understanding of protein trimerization, we believe we will be able to design a native-like trimeric fusion protein to target the 4-1BB pathway. We expect to make a candidate selection and enter IND-enabling studies in the second half of 2021.

Fc-fusion Product Candidates

SCB-808

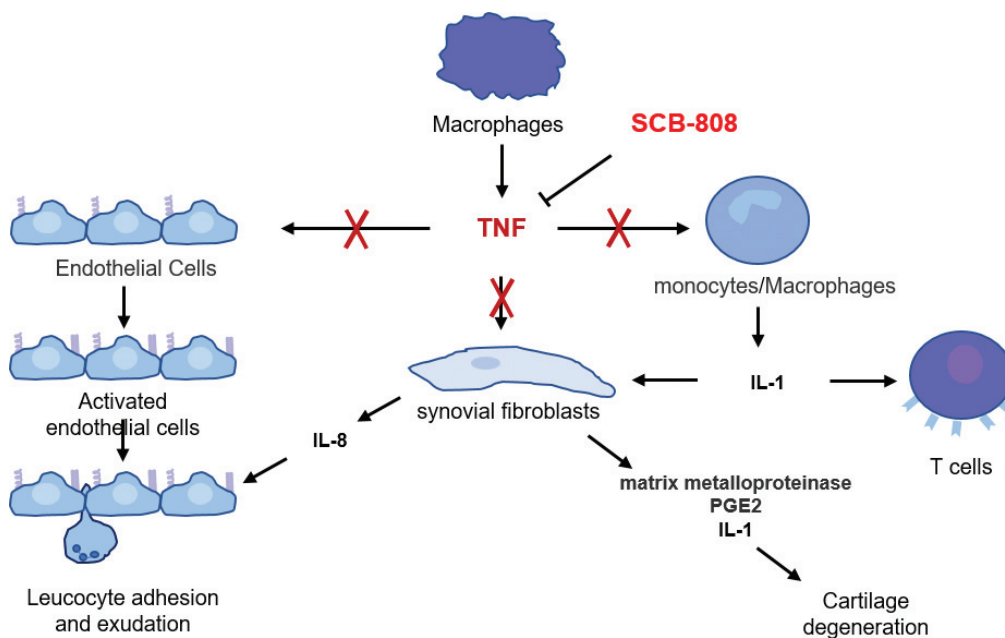
We are developing SCB-808 as a biosimilar to Enbrel (etanercept). Enbrel is a blockbuster TNF- α inhibitor marketed by Amgen, Pfizer, and Takeda Pharmaceuticals with global sales of US\$6.3 billion in 2020. Since the initial FDA approval in November 1998, Enbrel has been approved for various indications worldwide, including rheumatoid arthritis (RA), ankylosing spondylitis (AS), juvenile idiopathic arthritis, psoriatic arthritis, and psoriasis. In China, Enbrel was approved by the NMPA in February 2010 for the indications of RA and AS.

We completed a Phase 1 clinical trial in January 2019, which evaluated SCB-808's pharmacokinetics, safety, and immunogenicity as compared with Enbrel. We obtained the approval to conduct Phase 3 clinical trial for SCB-808 from the NMPA in March 2019 and initiated a Phase 3 clinical trial in December 2019 to evaluate SCB-808's efficacy, safety, and pharmacokinetics for the treatment of AS as compared with Enbrel. The Phase 3 clinical trial is currently ongoing and is expected to be completed in the second half of 2023.

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Mechanism of Action

Etanercept is a TNF- α inhibitor, which is an artificially engineered dimeric fusion protein that specifically binds to TNF- α in the human body and blocks the biological function of TNF- α . TNF- α is an endogenous cytokine in the human body and is involved in the normal inflammatory and immune responses of the body. TNF- α plays a critical role in the inflammatory process of RA, juvenile idiopathic arthritis, AS, and psoriasis, and its dysregulation leads to joint lesions. It is found that the level of TNF- α increases in the lesion tissues and body fluids of patients with the above diseases. The biological activity of TNF- α is dependent on its binding to the TNF- α receptors on the cell surface. Etanercept binds to the external domain of the cell membrane of a type of TNF- α receptor, namely, human tumor type II necrosis factor receptor, with the Fc segment of human type I immunoglobulin IgG1. By binding to TNF- α , etanercept blocks TNF- α 's biological functions, thereby inhibiting the inflammatory process in the diseases mentioned above. The diagram below illustrates the mechanism of action of SCB-808:



Background of Reference Drug: Enbrel

Since the initial FDA approval in November 1998, Enbrel has been approved for various indications worldwide, including RA, AS, juvenile idiopathic arthritis, psoriatic arthritis, and psoriasis. In China, Enbrel was approved by the NMPA in February 2010 for the indications of RA and AS. According to Frost & Sullivan, the total prevalence of RA and AS reached 9.9 million individuals in 2020 in China and is expected to reach 10.5 million by 2030. Access to Enbrel for eligible patients in China was significantly limited by high prices in the past decade. In 2021, the treatment cost for Enbrel in China is approximately RMB649.4/50 mg and nearly RMB16,884 per year. Approximately 75% of total treatment costs of Enbrel are covered by NRDL and patients pay out-of-pocket for the rest of treatment costs.

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Market Opportunity and Competition

In China, SCB-808 is expected to primarily compete with the reference drug Enbrel and other etanercept biosimilars that have been launched or currently under development. The following tables sets forth details of approved drugs and product candidates that may compete with SCB-808 in China as of the Latest Practicable Date.

Brand Name/Drug Code	Company	Indication	Dosage form	Status	CDE Processing Date/ Approval Date/First Published Date	NRDL Inclusion
Yi Sai Pu	Shanghai Cp Guojian	RA, AS, PS	Powder	Marketed	2005	List B
			Injection	BLA	2019/08/06	
Enbrel	Pfizer	RA, AS	Powder	Marketed	2010/02/26	List B
			Injection	Marketed	2018/05/17	List B
Qiang Ke	Shanghai Celgen Bio-Pharmaceutica	AS	Powder	Marketed	2011	List B
An Bai Nuo	Hisun Biological	RA, AS, PS	Powder	Marketed	2015/04/09	List B
			Injection	BLA	2020/07/04	N/A
QL0902	Qilu	RA, AS	Powder	BLA	2020/07/23	N/A
SCB-808	Clover	RA, AS	Injection	Clinical Trial Phase 3	2018/07/24	N/A
BF02	Genemen Biotech	AS	Injection	Clinical Trial Phase 1	2016/04/27	N/A

Note: CDE Processing Date refers to the date when application is accepted.

Competitive Advantages of SCB-808

We believe SCB-808 has the following advantages when compared to currently marketed etanercept biosimilars in China:

Potentially First-to-Market Ready-for-Injection Prefilled Syringe Formulation of Etanercept Biosimilar

Several etanercept biosimilars have been approved and marketed in China, although they are all in freeze-dried powder formulation. Such drugs must be reconstituted by trained medical personnel before injection. Similar to Enbrel, SCB-808 is being developed as a prefilled syringe formulation. The prefilled syringe formulation is expected to be more convenient for patients to self-administer the drug and is also expected to improve patient compliance.

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Potentially First Etanercept Biosimilar with Proven Bioequivalence to Enbrel in China

The currently marketed etanercept biosimilars in China were approved before the implementation of the Guidelines for the R&D and Evaluation of Biosimilar Drugs (for Trial Implementation) was promulgated by the NMPA in 2015. Therefore, none of the etanercept biosimilars released clinical trial results demonstrating bioequivalence data in comparison to Enbrel.

Summary of Clinical Trial Data

We completed a Phase 1 clinical trial which evaluated SCB-808's pharmacokinetics after a single escalating dose in healthy adult male Chinese subjects and evaluated the relative bioavailability of the intended clinical dose of 25 mg of SCB-808 and Enbrel.

Phase 1 Clinical Trial

Trial design. The Phase 1 clinical trial was a single-center, open-label, parallel trial to evaluate pharmacokinetics of SCB-808. A total of 48 healthy Chinese male subjects were divided into four cohorts, 12 subjects per cohort: a low dose group (SCB-808, 12.5 mg), a medium dose group (SCB-808, 25 mg), a high dose group (SCB-808, 50 mg), and a positive control group (Enbrel, 25 mg). Each subject in the low, medium, and high cohorts received a single dose of SCB-808. After subcutaneous administration, blood samples were collected at preset time points, and serum concentrations were tested by ELISA for pharmacokinetic profiling. The safety and immunogenicity of each dose group of SCB-808 and the Enbrel positive control group were observed after 28 days of administration.

Trial status. The Phase 1 clinical trial was initiated in August 2018 and was completed in January 2019.

Pharmacokinetic data. The trial demonstrated that in healthy male subjects, within the dose range of 12.5-50 mg of SCB-808, the serum exposure was linear with the dose. At the dose of 25 mg of SCB-808, the bioavailability of C_{max} , AUC_{0-t} and $AUC_{0-\infty}$ of SCB-808 relative to Enbrel was close to 100%.

Safety data. All observed AEs for SCB-808 and Enbrel were mild. The incidence of AEs was 16.67% for both SCB-808 and Enbrel at 25 mg, indicating that SCB-808 has good safety and is similar to Enbrel.

Immunogenicity data. With the dose escalation of SCB-808, the positive rate of immunogenicity decreased, and the positive rate of neutralizing antibody was 0%. At the dose of 25 mg of SCB-808, the positive rate of anti-drug antibody after 28 days of SCB-808 administration was lower than that of Enbrel, indicating that SCB-808 has good immunogenicity.

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Conclusion. SCB-808 has a favorable pharmacokinetic profile, good safety data and immunogenicity data, and is highly similar to Enbrel.

Ongoing Phase 3 Clinical Trial

Trial design. The Phase 3 clinical trial is a multi-center, randomized, controlled and double-blinded clinical trial to evaluate the effectiveness, pharmacokinetics, and safety of SCB-808 and as compared with Enbrel for the treatment of AS. The Phase 3 trial has two phases, namely the open-label phase and the randomized and double-blinded phase. In the open-label phase, a total of 60 patients were randomized into three cohorts, each comprised of 20 patients: SCB-808 (2x25 mg per week), SCB-808 (1x50 mg per week), and Enbrel (2x25 mg per week) each patient was administered one dose per week in a six-week period. During the treatment period, safety, preliminary effectiveness, immunogenicity, and pharmacokinetics were evaluated.

Trial status. The Phase 3 clinical trial was initiated in December 2019 and is expected to be completed in the second half of 2023. The open-label phase was completed in December 2020 with the double-blind comparative phase expected to initiate in the fourth quarter of 2021.

Summary of Pre-clinical Data

We achieved favorable pre-clinical testing results showing that SCB-808 has high similarity to Enbrel. The pre-clinical studies we conducted include:

- *in vitro* and *in vivo* testing of the pharmacodynamics;
- *in vivo* testing of the pharmacokinetics, toxicology and immunogenicity of SCB-808 in mammals; and
- extensive head-to-head comparisons on CMC quality attributes (including physical and chemical properties, biological activities, purity and impurity, and stability) of SCB-808 to those of Enbrel.

Material Communications and Next Steps

We received the IND approval for SCB-808 from the NMPA in November 2017, and are currently conducting the Phase 3 clinical trial. Since we are developing SCB-808 as a biosimilar to Enbrel (etanercept), we were able to initiate a Phase 3 clinical trial after we demonstrated bioequivalence relative to Enbrel in our Phase 1 trial based on our communication with CDE. We plan to complete the ongoing Phase 3 clinical trial in the second half of 2023 and submit the NDA to the NMPA for approval as a Category III therapeutic biological product. To date, the NMPA did not raise any objections or material concerns with respect to the development of SCB-808.

We may not be able to ultimately develop and market SCB-808 successfully.

BUSINESS

Selected Pre-clinical Fc-Fusion Product Candidates

SCB-420

SCB-420 is an aflibercept biosimilar currently in pre-clinical development for ophthalmologic diseases such as wAMD. Clinical trials are expected to initiate in the fourth quarter of 2021. We plan to register SCB-420 for approval as a Category III therapeutic biological product.

SCB-219

SCB-219 is a novel TPOR agonist currently in pre-clinical development for the treatment of CIT and ITP. Clinical trials are expected to initiate in the second quarter of 2022. We plan to register SCB-219 for approval as a Category I therapeutic biological product.

LICENSING AND COLLABORATION ARRANGEMENTS

License Agreement with GenHunter

In October 2019, we and GenHunter entered into a license agreement (the “GenHunter License Agreement”), which replaced the previous license agreement entered into between us and GenHunter in October 2013. GenHunter is a biopharmaceutical company headquartered in the United States and was founded by our Chairman and Chief Scientific Officer, Dr. Peng Liang. GenHunter is 100% wholly owned by Dr. Liang, and mainly engaged in research and development of innovative technologies in the field of biomedical and life sciences. See “Connected Transactions – Non-exempt Continuing Connected Transaction – License Agreement.” GenHunter’s business focuses on the early scientific research including DNA sequencing, protein identification and producing lab-use consumer products such as blot containers, pre-cut membranes and autoradiography film in the United States.

Pursuant to the GenHunter License Agreement, GenHunter granted us an exclusive worldwide license under relevant patents and patent applications, trademarks, and copyrights related to Trimer-Tag™ technology platform to develop, manufacture, and commercialize drug products, or the licensed products. Drug products developed by us shall be deemed and continue to be deemed as licensed products for the effective duration of this agreement if they fulfill the following criteria: (i) the biological drug product is a recombinant fusion protein containing Trimer-Tag™ as part of its primary amino acid sequence, (ii) the biological drug product has been successfully expressed and produced via a recombinant protein expression system, and (iii) we intend to develop, manufacture, commercialize, or sublicense such drug product.

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Under the GenHunter License Agreement, we shall pay GenHunter a low-single-digit royalty based on the net sales of the products engineered using the Trimer-Tag™ technology platform on a country-by-country and product-by-product basis. Other than the royalty payment, we do not have monetary obligations to GenHunter. We have the right to grant sublicenses to third-parties, subject to GenHunter's approval, which shall not be unreasonably withheld. For sublicenses, we shall pay GenHunter a low-double-digit percentage of the sublicense income. The royalty term shall run country-by-country and product-by-product from the date of first commercial sale of such licensed product in a particular country until the latest of (i) expiration of the last-to-expire valid claim in patents for such drug product under GenHunter's patent rights in such country; or (ii) ten calendar years.

Under the GenHunter License Agreement, we have the right to file and own patents for the licensed products, which may include but is not limited to composition of matter or method patents for the licensed products and composition of matter or methods patents related to the biomanufacturing process, drug administration methods or new variants of Trimer-Tag™ utilized for such licensed products.

The GenHunter License Agreement shall remain in effect until the latest of (i) the last patent or patent application related to Trimer-Tag™ technology platform that have been or will be filed and controlled by GenHunter has expired or been abandoned, or (ii) completion of the final royalty payment to GenHunter pursuant to the royalty payment arrangement set forth above. GenHunter may terminate this agreement for cause, such as our late payment of royalties, our failure to continue the development, manufacture, commercialization or sublicensing of the products, or our insolvency or conviction of felony relating to the manufacture, use, or sale of the products. We may terminate the agreement by giving 90 days advance written notice to GenHunter. Pursuant to the GenHunter License Agreement, Dr. Liang and GenHunter cannot terminate the agreement unilaterally. In the event of controversy or claim arising out of or relating to any provision of the license agreements or the breach thereof, GenHunter and us shall try to settle amicably between ourselves. If both parties are unable to resolve or settle promptly, parties shall be settled through arbitration conducted in accordance with the rules of American Arbitration Association and such arbitration shall be final and binding.

Agreements for SCB-2019 (CpG 1018/Alum)

Funding Agreements with CEPI

We and CEPI entered into two outbreak response funding agreements, including a step 1 agreement and a step 2 agreement (collectively, the "CEPI Funding Agreement"), pursuant to which CEPI agreed to provide funding for our development of adjuvanted SCB-2019. The step 1 agreement of the CEPI Funding Agreement was entered into in April 2020, which covers funding for our development activities up to the first subject enrolled in the Phase 1 clinical trial. We and CEPI entered into the step 2 agreement of the CEPI Funding Agreement in May 2020, which replaced the step 1 agreement. The step 2 agreement covers funding for the entire development process through global licensure of SCB-2019 (CpG 1018/Alum).

BUSINESS

Pursuant to the CEPI Funding Agreement and mutually agreed request, CEPI agreed to provide up to US\$360.5 million in total in funding for the development of adjuvanted SCB-2019, which shall be paid according to the payment schedule associated with the completion of various development milestones, including a pre-clinical study, CMC phase 1, toxicology study, Phase I clinical trial, CMC scale-up and validation, long term follow-up study, Phase II/III pivotal clinical trial and supporting studies. We and CEPI set a budget for each milestone based on estimated costs for major tasks and activities, such as salaries for research personnel, global travel to initiate clinical sites, and purchase of equipment and raw materials. The expenses are applicable to the respective time periods from April 2020 to December 2022. Both parties may mutually agree to adjust the budget based on development activity. Thus, funding from CEPI is paid according to actual spending on a period-to-period basis as opposed to a fixed amount. In addition, CEPI agreed to forego any share of potential commercial benefits that may arise from the commercial exploitation of the results of our COVID-19 vaccine development project. All rights for the adjuvanted SCB-2019 development project's results and intellectual properties shall vest in us. CEPI shall have no rights in the development project's results and/or intellectual properties other than those necessary to give effect to, and consistent with our obligations and the uses by CEPI as described in this agreement.

We and CEPI agreed that the pricing of SCB-2019 (CpG 1018/Alum) shall be of a reasonable nature to ensure equitable access for populations in need as well as an appropriate return on investment for us that makes on-going supply sustainable. We agreed to supply SCB-2019 (CpG 1018/Alum) order to the COVAX Facility in a separate order to be entered into during the pandemic period (as defined by WHO), which is expected to be constituted to purchase, allocate, and direct the distribution of COVID-19 vaccines globally. We may also consider commercializing SCB-2019 (CpG 1018/Alum) post conditional approval via bilateral negotiations and supply arrangements with global governments. After the pandemic period, we agree to continue supplying our SCB-2019 (CpG 1018/Alum) to the COVAX Facility, if required, at the amount of no more than 50% of our total supply. For details, see “– Commercialization – SCB-2019 (CpG 1018/Alum).”

We and CEPI shall establish a Joint Monitoring and Advisory Group (the “JMAG”), which shall facilitate communications between both parties, review the development process, and discuss substantial changes in the scope or conduct of applicable clinical and animal studies. The JMAG shall have two voting members comprised of our project lead and CEPI's project lead, and decisions of the JMAG shall be made by unanimity of the two voting members. Any difference or dispute that cannot be resolved by the JMAG shall be submitted to the chief executive officers or designees of JMAG, CEPI and us for resolution. If a difference or dispute remains unresolved within 60 days or such additional time as mutually agreed, the parties involved shall irrevocably submit to arbitration. If CEPI invokes its right under the CEPI Funding Agreement to exploit the project results or the intellectual property for the response to the COVID-19 pandemic, the parties shall resolve the dispute within 14 days before irrevocably submitting to arbitration.

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Our obligation to CEPI is to commercialize SCB-2019 (CpG 1018/Alum) through the COVAX Facility. There is no set timeframe nor penalty if we fail to achieve this obligation. The CEPI Funding Agreement remains effective until all the development activities as set forth in the agreement have been completed. The termination clause under the CEPI Funding Agreement provides that either party may terminate the agreement for (i) the other party's material breach of the agreement or the equitable access plan, and failure to rectify the breach within 30 days after notice from the terminating party; or (ii) the other party's insolvency. CEPI shall be entitled to terminate this agreement for certain other causes, such as the occurrence of material safety, regulatory or ethical issues. Upon the termination of the CEPI Funding Agreement, we shall return to CEPI any remaining funds we received within 30 days from the date of termination. We are required to make payments of interest earned on such funds if the termination was due to material breach by us of the CEPI Funding Agreement. CEPI shall reimburse us for the expenses incurred after the termination date in relation to the project activities which were authorized by CEPI and included in the project budget and cannot be refunded or cancelled.

In 2020 and for the four months ended April 30, 2021, we received RMB931.1 million and RMB233.7 million from CEPI pursuant to the CEPI Funding Agreement.

Adjuvant Collaboration and Supply Arrangements with Dynavax

Dynavax is a commercial stage biopharmaceutical company focused on developing and commercializing novel vaccines for the prevention of hepatitis B and also manufactures and sells CpG 1018, a vaccine adjuvant. We and Dynavax entered into a collaboration agreement in March 2020, pursuant to which Dynavax agreed to supply its CpG 1018 adjuvant to us for pre-clinical studies. The key terms of the collaboration agreement are summarized below:

- *Term.* The collaboration agreement will begin on March 13, 2020 and shall continue in effect for a period of five years, unless terminated earlier as provided or upon the completion of the studies therein.
- *Product supply.* We agree to receive CpG 1018 adjuvant from Dynavax, and Dynavax agrees to manufacture and supply the CpG 1018 adjuvant to us pursuant to the quantity specified therein.
- *Intellectual property.* In performing the studies specified therein, we will solely own all inventions developed or generated solely by ourselves except that any and all inventions that relate to the CpG 1018 adjuvant shall be jointly owned between Dynavax and us. We and Dynavax shall jointly own all jointly developed inventions not including our SCB-2019 (CpG 1018/Alum) and shall have good faith discussion regarding the protection of such inventions. We shall keep complete and accurate records of the results of studies specified therein and shall promptly and fully disclose to Dynavax.

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- *Scope of use.* The studies involve preclinical investigation of S-Trimer™ (recombinant SARS-CoV-2 Spike [S]-protein subunit-Trimer vaccine) and the CpG 1018 adjuvant for use as a potential prophylactic vaccine for SARS-CoV-2, including *in vitro*/CMC studies and animal studies set forth therein.
- *Undertakings.* We acknowledge that the CpG 1018 adjuvant may have unpredictable and unknown biological and/or chemical properties and should be used with caution, and that they are not to be used for testing in or treatment of humans. We shall use CpG 1018 adjuvant in compliance with applicable laws and regulations.
- *Liability.* Dynavax shall not be liable for our use of the CpG 1018 adjuvant. The Company agreed to indemnify, defend and hold harmless Dynavax, its officers, directors, employees, agents, independent contractors and affiliates from damages, costs, or expenses for any loss, claim, injury or liability of whatsoever kind or nature, which may arise from our use, handling or storage of CpG 1018 adjuvant.
- *Return of materials.* We shall return any remaining CpG 1018 adjuvant to Dynavax upon the completion of the studies specified therein or upon the expiration or termination of the collaboration agreement.
- *Termination.* Both we and Dynavax may terminate the agreement for any reason upon 30 days written notice.

Pursuant to a clinical collaboration and supply agreement we entered into with Dynavax in May 2020, which was supplemented by multiple amendments thereafter (together, the "Clinical Collaboration and Supply Agreement"), Dynavax agreed to supply its CpG 1018 adjuvant to us for our Phase 1 clinical trial and follow-up safety study, Phase 2/3 clinical trial and other development activities including formulation and stability for the development of SCB-2019 (CpG 1018/Alum). The key terms of the Clinical Collaboration and Supply Agreement and its amendments are summarized below:

- *Term.* The clinical collaboration and supply agreement shall be effective for a period of five years from the agreement date, unless terminated earlier as provided or upon the completion of the studies therein, whichever is earlier.
- *Product price.* For certain activities, we agree to purchase CpG 1018 adjuvant from Dynavax, and Dynavax agrees to manufacture and supply the CpG 1018 adjuvant to us pursuant to a price discussed between the parties.
- *Product supply.* We and Dynavax shall mutually agree on the quantity and timing for supply. Additional supply plans may be agreed upon from time to time and incorporated into the agreement as clinical studies progress.

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- *Scope of use.* We shall use the CpG 1018 adjuvant solely to perform the clinical trials set forth in the clinical collaboration and supply agreement collaboration and its amendments. We shall provide the protocol and any amendment thereto to Dynavax for review and comment. Additional clinical trials may be added by mutual agreement of the parties set forth therein.
- *Clinical trials.* We shall be solely responsible for the conduct of clinical trials, at our own cost and expense, and shall conduct the clinical trials in compliance with all applicable laws and regulations. Dynavax shall provide us with reasonable assistance in connection with regulatory activities for the use of the CpG 1018 adjuvant in clinical trials. If significant work needs to be done by Dynavax to support the clinical programs, the parties shall agree on reasonable compensation to Dynavax.
- *Indemnification.* Dynavax shall defend, indemnify and hold us, our affiliates and their officers, directors, employees and agents harmless from and against all third party claims, suits, proceedings, damages, expenses (including court costs and reasonable attorneys' fees and expenses) and recoveries to the extent such claims arise out of (a) any negligence or willful misconduct of Dynavax, its affiliates, or their officers, directors, employees or agents (b) any breach of any of Dynavax's covenants, obligations, representation or warranties therein, and (c) the manufacturing of CpG 1018 adjuvant by Dynavax. We shall defend, indemnify and hold Dynavax, its affiliates and their officers, directors, employees and agents harmless from and against all third party claims, suits, proceedings, damages, expenses (including court costs and reasonable attorneys' fees and expenses) and recoveries to the extent such claims arise out of (a) any negligence or willful misconduct of us, our affiliates, or their officers, directors, employees or agents (b) any breach of any of our covenants, obligations, representation or warranties therein, and (c) the conduct of the clinical trials, including the use of the CpG 1018 in filled vials.
- *Intellectual property.* Any intellectual property owned by a party under the agreement or licensed by a third party to a party under the agreement as of the effective date or during the term of the agreement but independently of this agreement shall remain the sole and absolute property of the party. The inventorship of new intellectual property shall be determined in accordance with U.S. patent laws. Dynavax shall solely own all inventions, discoveries and know-how, as well as intellectual property rights that solely relate to CpG 1018 used in the study together with any results related solely thereto. We shall solely own all inventions, discoveries and know-how as well as intellectual property rights in relation to SCB-2019 used in the study together with any results related solely thereto. Dynavax and us shall jointly own any inventions, discoveries and know-how as well as intellectual property rights arising during the conduct of studies that relate to the combined use of CpG 1018 and COVID-19 S-Trimer™ antigen. Dynavax and us shall promptly disclose to each other all inventions relation to the joint intellectual property in performing the study and shall have good faith discussion regarding the protection of such intellectual property.

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- *Termination.* Parties under the collaboration and supply agreement and its amendments may terminate the agreement immediately upon written notice to the other party if the other party materially breaches its material obligations set forth therein, and, after receiving written notice identifying such material breach in reasonable detail, fails to cure such material breach within 30 days from the date of such notice.

In June 2021, we entered into a supply agreement with Dynavax (the “Supply Agreement”) for the commercial supply of CpG 1018 adjuvants for the use with our SCB-2019 (CpG 1018/Alum). Pursuant to the supply agreement, we have committed to purchase, and Dynavax has agreed to manufacture and supply, specified quantities of its CpG 1018 adjuvant for use in our commercialization of SCB-2019 (CpG 1018/Alum) with mutually agreed delivery dates in 2021 and 2022. However, the specified quantities and timing of CpG 1018 adjuvant for delivery in 2021 are subject to modification by the CEPI in its sole discretion. The key terms of the Supply Agreement and its amendments are summarized below:

- *Term.* The supply agreement shall be effective from the effective date to December 31, 2022, unless terminated earlier as provided, subject to extension by mutual written agreement.
- *Product price.* We agree to purchase CpG 1018 adjuvants from Dynavax, and Dynavax agrees to manufacture and supply the CpG 1018 adjuvant to us pursuant to prices set out therein. Pricing for CpG 1018 adjuvants delivered in 2021 and 2022 is variable depending on (i) the ultimate destination country of SCB-2019 (CpG 1018/Alum), and (ii) whether SCB-2019 (CpG 1018/Alum) is sold in private markets in the ultimate destination country or is sold under the agreements entered into with the GAVI or the COVAX. Prices for the CpG 1018 adjuvant are determined on a tiered structure based on the income level of the ultimate destination countries of SCB-2019 (CpG 1018/Alum). Under our agreement, there are three income tiers, namely low and middle income countries, upper middle income countries and high income countries (i.e. countries that do not belong to the first two tiers). The price for low and middle income countries is set at the lowest and such price is slightly higher in upper middle income countries. It was set with the highest price for high income countries. The price of the CpG 1018 adjuvant for low and middle income countries is fixed before December 31, 2021, and the price starting in 2022 will be adjusted based on the total volume purchased in each calendar year.

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- *Royalties and payment.* Dynavax will issue initial invoice at the applicable base price(s) for CpG 1018 adjuvant for use in our COVID-19 vaccines for sale or distribution in low- and middle-income countries (other than SCB-2019 (CpG 1018/Alum) sold in private markets within such countries), with a true-up mechanism to cover the pricing for CpG 1018 adjuvant incorporated in SCB-2019 (CpG 1018/Alum) that ultimately ship to countries other than such low- and middle-income countries or are sold in private markets. In addition, if the net selling price of SCB-2019 (CpG 1018/Alum) sold to a customer other than the COVAX Facility (including GAVI or other COVAX participants) exceeds a threshold specified in the Supply Agreement, Dynavax is entitled to a royalty calculated as a percentage of the excess portion of such net selling price. Royalties shall be calculated and reported each quarter and shall be paid within 45 days of the end of the quarter. If any payment due under this supply agreement is not paid when due, such payment shall accrue at an interest rate per annum of 200 basis points above the then current prime rate quoted by Citibank in New York City for the period from the due for payment date until the date of actual payment, provided that in no event shall such rate exceed the maximum legal annual interest rate. For CpG 1018 adjuvants to be delivered in 2021, subject to certain exceptions, we are obligated to pay the purchase price of the quantity of CpG 1018 adjuvants set forth in a purchase order submitted by us and accepted by Dynavax, subject to certain exceptions as stated therein, upon the earliest of (i) the first available trueing-up exercise for SCB-2019 (CpG 1018/Alum) incorporating such CpG 1018 adjuvant, (ii) within a specified period after we deliver SCB-2019 (CpG 1018/Alum) to a customer, or (iii) our receipt of payment for SCB-2019 (CpG 1018/Alum) from a customer. For CpG 1018 adjuvants to be delivered in 2022, subject to certain exceptions, we are obligated to pay a specified percentage of the purchase price of the quantity of CpG 1018 adjuvant set forth in a purchase order submitted by us and accepted by Dynavax upon Dynavax's acceptance of such purchase order, and the remainder of the purchase price upon Dynavax's release of such CpG 1018 adjuvants.
- *Product supply.* We and Dynavax shall mutually agree on the quantity and timing for supply. However, the specified quantities and timing of CpG 1018 adjuvant for delivery in 2021 are subject to modification by the CEPI in its sole discretion. Subject to Dynavax's material compliance with its supply obligations thereunder, we shall purchase Dynavax's proprietary CpG 1018 adjuvants exclusively from Dynavax during the term of the agreement, and shall not develop or manufacture, or attempt to develop or manufacture Dynavax's proprietary CpG 1018 adjuvants or its bioequivalent version. In the event of a significant adjuvant supply shortage from Dynavax, we are entitled to a manufacturing technology transfer to enable us to make or have the CpG1018 adjuvant made by a designated contract manufacturer for SCB-2019 (CpG 1018/Alum). The manufacturing technology transfer will enable us to have the capability to manufacture CpG 1018 or engage CDMOs to manufacture CpG 1018. By adjusting our production schedule, we believe we will be able to manufacture CpG 1018 at our own facilities without significant additional capital investment.

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- *Delivery.* Dynavax shall ensure that the CpG 1018 adjuvants are properly packed and secured in a manner reasonably determined by Dynavax to be appropriate for shipping and deliver the goods within five business days of the delivery date specified in the order to the location specified in the order or as otherwise agreed by the parties before delivery. Dynavax shall not be responsible for any delay in delivery to the extent caused by a third party carrier.
- *Intellectual property.* We acknowledge that CpG 1018 adjuvants covered by this agreement are proprietary to Dynavax, and that Dynavax shall at all time remain the sole and exclusive owner of all intellectual property rights in and to CpG 1018 adjuvants, and we shall not obtain any right, ownership interest, or license in or to the CpG 1018 adjuvants as a result of our purchase, receipt or use of CpG 1018 adjuvants supplied by Dynavax, subject to the terms and conditions set out therein. Dynavax grants to us a limited non-exclusive, non-transferable, royalty-free license under Dynavax's intellectual property rights in and to the CpG 1018 adjuvants, solely to develop, make, have made, use, sell, have sold, offer for sale and import SCB-2019 (CpG 1018/Alum) during the term of the agreement, subject to the terms and conditions in the agreement.
- *Indemnity and Liability.* Dynavax shall indemnify and hold us harmless from all losses, liabilities, damages and expense, including reasonable attorneys' fees and costs incurred as a result of any claim, demand, action or other proceeding by a third party to the extent caused by (i) the negligence or willful misconduct of Dynavax, (ii) any breach by Dynavax of its covenants, representations, warranties or other obligations thereunder, or (iii) the infringement of the intellectual property rights of a third party arising from Dynavax's manufacture of CpG 1018 adjuvants or the use, sale, offer for sale or import of the CpG 1018 adjuvants by us or on our behalf as a component of the SCB-2019 (CpG 1018/Alum). We shall indemnify and hold Dynavax harmless from all losses, liabilities, damages and expense, including reasonable attorneys' fees and costs incurred as a result of any claim, demand, action or other proceeding by a third party to the extent caused by (i) the negligence or willful misconduct of us, (ii) any breach by us of our covenants, representations, warranties or other obligations hereunder, (iii) the infringement of the intellectual property rights of a third party arising out of the manufacture, use, sale, offer for sale or import of Clover's COVID-19 vaccines, including our SCB-2019 (CpG 1018/Alum) sold by us or on our behalf, (iv) the research, development, manufacture (excluding the manufacturing of SCB-2019 (CpG 1018/Alum)), use, marketing, promotion, distribution, handling, storage, sale or other disposition of SCB-2019 (CpG 1018/Alum) by or on our behalf; or (v) fill/finish and packaging activities, subject to the conditions and exceptions set out therein. Unless otherwise agreed by the parties in writing, Dynavax's maximum liability in aggregate to us arising out of the Supply Agreement shall not exceed 100% of the aggregate amounts paid by us under the Supply Agreement to Dynavax. Neither party shall be liable to the other Party for any loss of an indirect or consequential nature, nor for any loss of turnover, profits, business or goodwill, whether in contract, warranty, negligence, tort, strict liability or otherwise, arising out of any breach of or failure to perform any of the provisions of the Supply Agreement.

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- *Termination.* Without affecting any other right or remedy available to it, each party has the right to terminate the Supply Agreement for uncured material breach of the Supply Agreement by the other party, in the event of the liquidation or winding up, as provided therein, of, or threatened or suspension or cessation of all or a substantial part of the business of, the other party, or in the event the other party or any of its directors, employees or consultants is found to have violated applicable anti-corruption laws. In addition, we have the right to terminate the Supply Agreement if WHO denies our pre-qualification for SCB-2019 (CpG 1018/Alum), or if certain adverse regulatory events, as provided therein, occur. Notwithstanding the exercise of any termination right, subject to specified exceptions, payment or other obligations arising prior to any such termination would remain unchanged.

In addition, we and Dynavax entered into a pharmacovigilance agreement in June 2020, which sets forth mutually agreed safety and pharmacovigilance procedures, such as procedures of safety data collection and information exchange, and adverse events assessment. We and Dynavax agreed that (i) Dynavax shall be responsible for maintaining the central global safety database, maintaining and updating the Investigator Brochure, and ongoing review and analysis of all information that is pertinent to the safety profile of CpG 1018 containing products that is obtained from any source, and (ii) we shall be responsible for safety data collection from our sponsored clinical trials co-administering vaccine product containing CpG 1018 plus Alum Alhydrogel[®] and SCB-2019 covered under the pharmacovigilance agreement, responding to regulatory inquiry on safety information, and obtaining follow-up information and forwarding such information to Dynavax.

We and Dynavax also entered into a quality agreement in May 2020, which sets forth both parties' obligations and responsibilities for quality assurance and quality control requirements. Pursuant to the quality agreement, both Dynavax and us shall communicate quality issues through designated QA contacts, maintain an independent QA unit to carry out defined quality assurance responsibilities, ensure our personnels are trained and training documented, manufacture and/or handle CpG 1018 according to applicable laws, regulations, guidelines and standards, maintain product distribution records, recalls, shipment holds or returns CpG 1018 according to site procedure, store complaint samples, issue reports and corrective action for clinical complaints to agencies, notify relevant health authority of recall incidents, and conduct audit of the other party. In addition, Dynavax shall manufacture, conduct acceptance and release testing, handle, store, transport, warehouse and distribute CpG 1018 according to Clinical Collaboration and Supply Agreement, in compliance with GMP, GDP, other applicable laws and this agreement, provides us a certificate of compliance, certificate of analysis, CpG retest date and material safety data sheet for each batch of product supplied, among other obligations. We shall check incoming product upon receipt, identify suitable facility to perform secondary packaging, labeling and distribution, own release transport, warehouse and distribute the product upon receiving from Dynavax, and notify Dynavax QA within two business days upon discovery of a quality issue of CpG 1018, among other obligations. In January 2021, we entered into an amendment to the quality agreement with Dynavax, which expands the applicability of the quality agreement with Dynavax beyond Phase 1 clinical trials.

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We and Dynavax determine the price for CpG 1018 adjuvants based on arms length negotiation, taking into account the cost of producing the adjuvants and benchmark against the price which Dynavax sells to other vaccine companies. Pursuant to the abovementioned agreements, Dynavax supplied to us US\$4.5 million value of CpG 1018 adjuvants in the four months ended April 30, 2021, respectively.

Since we entered into the collaboration agreement in March 2020, we have maintained a cooperative relationship with Dynavax. We believe that the risk that the arrangement with Dynavax would be terminated or that we would not be able to obtain CpG 1018 from Dynavax as needed is low because the arrangement is in the best commercial interests of Dynavax. Adjuvants are pharmacological or immunological substances that can be added to a specific protein (antigen) in a vaccine to help boost the immune response triggered by the vaccine. As an optional ingredient in vaccines, the adjuvant market is highly dependent on the vaccine market. As such, the sales of CpG 1018 is reliant on the successful launch and global sales of our COVID-19 vaccine. Our SCB-2019 (CpG 1018/Alum) demonstrated positive results in pre-clinical studies, the Phase 1 clinical trials and in SPECTRA, the global pivotal Phase 2/3 clinical trial, showing promising commercial prospects. CEPI signed an agreement with Dynavax in February 2021 and amended in May 2021, pursuant to which CEPI promised to provide funding to Dynavax of up to US\$176 million for the manufacturing of CpG 1018 for CEPI partners with the potential to support hundreds of million doses of COVID-19 vaccine. As we are a CEPI partner, we are one of the partners who will potentially have the opportunity to procure CpG 1018 in 2021 from Dynavax. In the event of a significant adjuvant supply shortage from Dynavax, we are entitled to a manufacturing technology transfer to enable us to make or have the CpG1018 adjuvant made by a designated contract manufacturer for SCB-2019 (CpG 1018/Alum). We can potentially find alternative sources of adjuvants, including biosimilar products of CpG 1018 if such need arises. However, if we purchase adjuvants from other sources, there would be uncertainty in the regulatory pathway for SCB-2019 (CpG 1018/Alum), including potentially conducting additional clinical trials. However, the costs in relation to such additional clinical trials may be covered by the funding granted by CEPI. For details of the relevant risks, see "Risk Factors – Risks Relating to Manufacturing and Commercialization of Our Product Candidates – Reductions in available raw materials or product components, or increases in costs of our raw materials or product components, could have a negative impact on our business, financial condition and operations outcome."

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Advance Purchase Agreement with GAVI

We and GAVI entered into an advance purchase agreement (the “GAVI Advance Purchase Agreement”) in June 2021, pursuant to which we and GAVI shall collaborate to ensure fair allocation and distribution of our COVID-19 vaccine candidates around the world. Under the GAVI Advance Purchase Agreement, we shall manufacture and clinically evaluate our COVID-19 vaccine candidates and GAVI shall provide certainty to ensure the demand for COVID-19 vaccine candidates. The key terms of the GAVI Advance Purchase Agreement are summarized below:

- *Purchase Commitment.* GAVI shall procure the purchase of (i) 64.0 million doses of our SCB-2019 (CpG 1018/Alum), and (ii) up to an additional 350.0 million doses of our SCB-2019 (CpG 1018/Alum) pursuant to the options stated therein.
- *Vaccine Variation.* We shall regularly update GAVI on the development of any variant vaccine as stated therein and shall promptly notify GAVI of any submission we make for emergency use authorization or regulatory approval in respect of such variant vaccine. GAVI shall have the option to require that some or all of the doses which we have not yet begun manufacturing to be substituted with our such variant vaccine, subject to the terms and exceptions stated therein.
- *Allocation.* GAVI may allocate SCB-2019 (CpG 1018/Alum) doses to any COVAX participant. Decision as to how the vaccine doses is allocated between COVAX participants shall be made in accordance with the terms of the COVAX Facility and the WHO allocation framework. In addition to COVAX participants, GAVI may, in its sole discretion, allocate SCB-2019 (CpG 1018/Alum) doses to any organization or person that procures vaccine doses on behalf of refugees, asylum seekers or other vulnerable populations or missed communities, or other populations eligible to receive humanitarian buffer doses under the terms and conditions of the COVAX Facility.
- *Purchase Price and Payment.* GAVI shall procure the SCB-2019 (CpG 1018/Alum) doses at prices determined by the tier of the COVAX participant to whom the doses are delivered for use as listed in the schedule enclosed therein. There are three pricing tiers based on the income level of the COVAX participant, namely the low and middle income countries (i.e. the AMC92 Countries as listed therein), upper middle income countries (i.e. the UMIC COVAX Participants as defined therein) and high income countries (i.e. the HIC COVAX Participants as defined therein). A fixed price is assigned to each tier. The price ranges from the mid-single digit to low double digit US dollars across the tiers. Under the agreement, the pricing for low and middle income countries is set at the lowest and it was set at the highest for high income countries. The pricing for SCB-2019 (CpG 1018/Alum) in upper middle income countries is set in between the aforementioned two tiers. GAVI shall pay to us an advance payment within ten business days of signature of the GAVI Advance Purchase Agreement. As of the Latest Practicable Date, we have received an

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advance payment of US\$160 million from GAVI. Upon receipt of evidence satisfactory to GAVI that the interim analysis study report for SPECTRA meet the relevant WHO criteria and that we will then proceed with our filing application for emergency use listing, GAVI shall make a further payment within ten business days, subject to the conditions stated therein. The difference between the applicable purchase price and the advance payments made by GAVI shall be paid by buyers to us in accordance with relevant supply agreement separately between each buyer and us.

- *Refund.* Subject to the exceptions and conditions set out therein, the amount paid by GAVI are non-refundable and are non-transferable prepayment toward the purchase price for the purchase commitment made by GAVI and any additional doses purchased by GAVI. These exceptions and conditions include if (i) we cease to develop SCB-2019 (CpG 1018/Alum) other than due to a failure to obtain regulatory approval, (ii) we fail to comply with obligations relating to regulatory approval, such as taking all reasonable steps to obtain emergency use approval by December 31, 2021, (iii) CEPI, any other funding provider for our development of SCB-2019 (CpG 1018/Alum) or any buyer of SCB-2019 (CpG 1018/Alum) through COVAX terminates its agreement with us for default, (iv) doses of SCB-2019 (CpG 1018/Alum) are not available as expected after a certain period of time, and (v) GAVI terminates the agreement for cause. As such, the prepayment made by GAVI is non-refundable unless we failed to take all reasonable steps to develop and commercialize SCB-2019 (CpG 1018/Alum) per our obligations under the contract. The payments made by GAVI can be used to fund non-refundable payments to our suppliers to secure raw materials and services required to manufacture SCB-2019 (CpG 1018/Alum) doses for GAVI's purchase commitment or additional doses GAVI purchases by exercising the options set out therein.
- *Balancing Payment.* GAVI shall be entitled to give notice to us at any time that GAVI's committed SCB-2019 (CpG 1018/Alum) doses are not required for allocation under the COVAX Facility. On receipt of such notification, we shall use our best endeavor to sell the remaining doses outside the COVAX Facility, but will have no obligation to sell the remaining doses outside the COVAX Facility at a price lower than the prices agreed to therein. If we are unable to sell all of the remaining doses, despite using best endeavours to do so, and such remaining doses become wasted, we shall inform GAVI the number of wasted doses and GAVI shall pay us a balancing payment calculated according to the formula set out therein.

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- *Funding.* The parties therein acknowledge that we have received a commitment of US\$328.0 million dollar commitment from CEPI to support the development of SCB-2019 (CpG 1018/Alum). We shall provide GAVI with information in respect of such funding, or any further funding we receive or may receive from CEPI and any other third party who has provided funding to us to aid the development of vaccine. We acknowledge that CEPI has a right to require that all doses of the SCB-2019 (CpG 1018/Alum) we produce are sold to GAVI but has agreed to give a certain percentage of the doses of vaccine manufactured in 2021 to be allocated to the PRC government and a certain percentage of the doses manufactured in 2022 to be allocated to the PRC government or other third parties. Other than that, we shall not agree to supply any doses of vaccine in 2021 and 2022 to any person without GAVI's prior written approval.
- *Our Commitment.* We shall take all reasonable steps to seek to ensure that SCB-2019 (CpG 1018/Alum) shall receive initial approval, i.e. approval for use during a public health emergency by a competent authority and the WHO, by no later than December 31, 2021 and regulatory approval, i.e. the marketing authorization from a competent authority or WHO prequalification, by no later than October 31, 2022. We shall use our best endeavors to submit an application for emergency use listing simultaneously with our first application to a stringent regulatory authority for emergency use authorization. We shall make available SCB-2019 (CpG 1018/Alum) doses pursuant to the order and supply process set out there in. If we are unable to launch SCB-2019 (CpG 1018/Alum) by the end of 2021, the committed doses to supply to GAVI in the fourth quarter of 2021 will carry over till March 31, 2022.
- *Information.* We shall provide GAVI on an ongoing basis as reasonably requested by GAVI with information in relation to technical details and characteristics, clinical trial results as provided to a stringent regulatory authority, all information for the effective operation of the WHO no-fault compensation scheme (which may be shared with WHO), and any credible suspicions of any misappropriation, fraudulent practices, corrupt practice, coercive practice or other prohibited practices as set out therein, among other information.
- *Liability.* With the exception of wilful misconduct or otherwise for losses that cannot be excluded or limited at law, neither party shall be liable to the other or to any third party, as stated therein, whether in contract, in tort, under any statute or otherwise under or in connection with this agreement in respect of any loss of profit or loss of business, or indirect or consequential loss. GAVI's aggregate liability shall be limited to an amount equal to the aggregate of (i) the payments made by GAVI and (ii) payments paid in relation to additional doses.

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- *Indemnification.* We acknowledge that neither GAVI nor any COVAX partners will provide any indemnity in respect of claims which we may receive relating to the use or administration of the vaccine. We and Gavi have agreed a model indemnity provision to be entered into between us and any AMC92 Country and a standard indemnity provision to be entered into between us and any self financing participant receiving Clover's COVID-19 vaccine doses through the COVAX Facility, pursuant to which the COVAX Facility participant shall indemnify and hold harmless each indemnified person against all losses incurred by that indemnified person arising out of or in connection with any claim arising out of or in connection with a breach of the supply agreement, negligent or willful misconduct by such participant in the COVAX Facility and death or personal injury caused by the use or administration or the ineffectiveness of the vaccine.
- *Term and Termination.* The term of this agreement shall terminate by the later of December 31, 2022 and 30 days after the date on which the purchase orders have been placed for all SCB-2019 (CpG 1018/Alum) doses or a balancing payment has been made. Either party shall be entitled to terminate the agreement at any time pursuant to the conditions set out therein, including in the event of a material breach by the other party that is not capable of remedy or fails to be remedied within 30 days after being given written notice. GAVI shall be entitled to terminate the agreement if we have not submitted an application for emergency use listing for SCB-2019 (CpG 1018/Alum) by December 31, 2021, or if five million doses or more of the vaccine are not available for deliver before December 1, 2021, or we have not entered into a supply agreement with designated procurement agency by December 1, 2021, among other things. If GAVI terminates this agreement, we are required to refund any advance payment paid to us by GAVI (i) that has not been credited against the amounts of binding purchase orders made by a buyer through the COVAX Facility, and (ii) excluding any non-refundable payments we made to suppliers to secure raw materials and services required to manufacture the vaccine.
- *Dispute Resolution.* All dispute arising out of or in connection with this agreement shall be resolved by arbitration in accordance with the Rules of Arbitration of the International Chamber of Commerce.

BUSINESS

RESEARCH AND DEVELOPMENT

We are a science-based global biotechnology company focused on utilizing the Trimer-Tag™ technology platform to develop novel vaccines and biologic therapies targeting trimerization-dependent pathways. We believe research and development is critical to our future growth and our ability to remain competitive in the global biopharmaceutical market. We are dedicated to building an innovative product pipeline with a focus on vaccines, oncology, and autoimmune disorders by leveraging our in-house research and development capabilities, which span internal discovery, CMC, pre-clinical, and clinical development. Our research and development focus also includes biosimilars that leverage our well-established CMC capabilities.

We conduct our research and development activities through an in-house research and development team. Our drug discovery, pre-clinical, and clinical development teams work closely with each other to facilitate the development of our product candidates and have cross-disciplinary expertise in a variety of fields, including biology, pharmacology, chemistry, toxicology, structural biology, translational medicine, and clinical research. We have established a full range of in-house product discovery capabilities, including fusion protein design and optimization, amplification, cultivation, harvest, *in vivo* assessment of product efficacy and drug metabolism, and pharmacokinetics analysis. The clinical development unit of our platform manages all aspects of clinical trials, including clinical trial design, implementation, production of drug-candidate samples, and the collection and analysis of trial data.

Members of our R&D team have deep scientific talent and extensive experience at multinational pharmaceutical companies. Our R&D team consists of our drug discovery and pre-clinical team, clinical development team, and CMC team. In addition, we collaborate with external research partners, such as CROs.

Our research and development expenses mainly included clinical trial expenses, staff costs and costs of raw materials and consumables during the Track Record Period. For the years ended December 31, 2019 and 2020 and the four months ended April 30, 2021, our research and development expenses were RMB45.8 million, RMB228.2 million and RMB370.8 million, respectively. For details of our raw materials and consumables, please see “Financial Information – Description of Certain Key Items of Financial Position Items – Inventories.”

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Drug Discovery and Pre-clinical Development

Our drug discovery team is dedicated to product discovery, formulation development, process development, and pre-clinical research of novel vaccine and biologic therapeutic candidates. Leveraging the Trimer-Tag™ technology platform and deep understanding of protein trimerization, we are focused on building out an innovative discovery pipeline of novel vaccines and biologic therapies targeting a broad spectrum of naturally trimerization-dependent disease and biologic targets, including TNFSF and antigens of enveloped RNA viruses. See also “– The Trimer-Tag™ Technology Platform” for more information.

Our discovery and pre-clinical research team is led by Dr. Peng Liang, our Chairman and Chief Scientific Officer. Our multidisciplinary team has expertise in pharmacology, toxicology, drug metabolism, and pharmacokinetics (DMPK), vaccine, cancer biology, translational medicine, and biomarker discovery.

With respect to novel vaccine and biologics development, our internal research and development team takes a leading role in the design and management of the research projects and outsources daily execution tasks to multiple CROs. Our discovery, pre-clinical, clinical development, CMC, and business development groups interact closely with each other to advance our product development programs in an efficient manner. Our clinical development and CMC teams participate early in our research and development process, which helps us select attractive programs with market potential and reduce the risk of unanticipated obstacles in the clinical development and manufacturing stage.

At this R&D facility, we have research capabilities and engage in research activities such as screening, fusion protein generation and engineering, molecular and cellular biology and *in vitro* and *in vivo* pharmacology.

Clinical Development

Our clinical development team is led by Chief Medical Officer (Vaccine) Ms. Htay Htay Han and Chief Medical Officer (Oncology) Dr. Philippe Bishop. Ms. Han has over 24 years of experience in vaccine research and development. Ms. Han was formerly head of early clinical development programs at Takeda. Prior to that, she served as a Senior Director and Clinical R&D Program Lead at GSK. Dr. Bishop has over 22 years of experience in oncology therapeutic development. Dr. Bishop founded Aratinga Bio, Inc. and acted as the Chief Medical Officer and Executive Vice President. Prior to that, he worked at Gilead Biosciences, Roche/Genentech, Johnson & Johnson, Sanofi-Aventis, the FDA, and NCI.

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The clinical development unit of our platform manages all stages of clinical trials, including clinical trial design, implementation, drug supply, and the collection and analysis of trial data. Each of our clinical development programs is led by a program leader who (i) formulates a clinical development plan, (ii) designs the trial protocol and (iii) oversees the trial execution, all with support from relevant team members. We employ an adaptive clinical trial design strategy to achieve efficiency in product development processes and potentially accelerate approvals for our product candidates. Our clinical development unit is also responsible for the selection of trial sites. To maximize trial efficiency, we strategically select trial sites based on their location in proximity to major metropolitan cities, number of addressable patients, and principal investigators in order to optimize trial speed, cost-effectiveness, and cultural compatibility. We have entered into agreements with numerous hospitals and principal investigators located worldwide that can support our various stages of clinical trials and indications. We believe the size and geographic diversity of our selected facilities provides us with a significant advantage when initiating and running large-scale clinical trials for multiple indications. Utilizing a strategic approach to patient recruitment, we have been able to optimize the time from trial initiation to data availability.

Chemistry, Manufacturing and Controls (CMC)

Our CMC team is an integrated part of our R&D functions. CMC performs vital roles including process development, scale-up, optimization, characterization and validation, control method development and validation, and technology transfer and assessment. Our CMC team provides pre-clinical and clinical support throughout the product development process.

Our CMC capabilities include:

- *Pre-clinical support.* Seamlessly integrated into our R&D process, our CMC process development team supports our product discovery process by producing material for early-stage discovery, pre-clinical and IND-enabling studies, and is responsible for producing CMC-related regulatory documentation.
- *Clinical support.* For ongoing clinical trials, our CMC teams manage clinical trial material supply working cross-functionally with the internal clinical and regulatory teams as well as external supply.
- *Commercial manufacturing.* Our CMC team will lead the manufacturing process in the future for commercial manufacturing at our Changxing manufacturing facility and/or third-party CMOs.

Regulatory Affairs

Our regulatory affairs team is responsible for the regulatory approval process of our product candidates, including assembling application dossiers for INDs and NDAs, addressing inquiries from relevant regulatory authorities, and monitoring ongoing R&D projects to ensure compliance with relevant regulations. Our regulatory team members are deeply familiar with regulatory processes of relevant governmental agencies, such as the NMPA, the EMA and the FDA.

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Collaboration with Contract Research Organizations (CROs)

We perform core functions such as designing clinical development strategy and protocol in-house, and exercising control and oversight over key functions of clinical trial management, including data source validation. We use CROs and consultants to manage, conduct, and support our clinical trials and pre-clinical studies in Asia, Latin America, EU, and Australia. We selected our CROs weighing various factors, such as their qualifications, academic and professional experience (including global regulatory compliance experience), and industry reputation. The CROs provide us with an array of products and services necessary for complex clinical trials. In addition to the scope, depth, and quality of their service and product offerings, we place a high value on our CROs’ ability to facilitate optimal site selection, timely patient recruitment, and efficient conduct of complex clinical trials. Generally, we enter into a master service agreement with a CRO under which we execute a separate work order for each pre-clinical or clinical research project, or we enter into a research and development contract with a CRO for an individual project. We supervise these CROs to ensure that they perform their duties to us in a manner that complies with our protocols, applicable laws, and that protects the integrity of the data resulting from our trials and studies.

Below is a summary of the key terms for CRO engagement:

- *Services.* The CRO provides us with services related to a pre-clinical or clinical research project as specified in the agreement or a work order.
- *Term.* The CRO is required to complete the pre-clinical or clinical research project within the prescribed time limit.
- *Payments.* We are required to make payments to the CRO in accordance with the payment schedule agreed to by the parties.
- *Intellectual property rights.* We own all intellectual property rights arising from the pre-clinical or clinical research project.
- *Risk allocation.* Each party should indemnify the other party for losses caused by its fault or gross negligence. If the research fails due to unresolvable technical difficulties or otherwise due to circumstances beyond a party’s control, the parties should negotiate how to allocate the losses resulting from such failure.

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In 2019 and 2020 and the four months ended April 30, 2021, we engaged a total of 25, 36 and 28 CROs and consultants, respectively, to manage, conduct and support our clinical trials and pre-clinical studies and incurred a total expense of RMB18.9 million, RMB104.9 million and RMB262.1 million, respectively for fees to such CROs and consultants. We determine the service fee for each CRO or consultant based on the expected or actual work performed by the CRO or consultant as well as the estimated or actual cost incurred on an hourly, monthly or by project basis. Our major CROs and consultants during the Track Record Period include established providers of biopharmaceutical, medical device and healthcare services. Some of our CROs are our top five suppliers during the Track Record Period. See “–Suppliers” in this section. During the Track Record Period, none of our CROs and consultants, including their directors, shareholders and senior management, had any past or present relationship with us or our subsidiaries, shareholders, directors or senior management, or any of their respective associates.

Supported by our CROs and our geographically diverse hospital partners, we are able to recruit specialized patient populations for our clinical trials. We have the expertise and experience in recruiting for and conducting trials focused on vaccines, cancers, and autoimmune disorders.

COVID-19 Scientific Advisory Board (COVID-19 SAB)

Comprised of prominent vaccine and industry experts from around the world, our COVID-19 SAB advises and guides our global COVID-19 vaccine development strategy. Formed in September 2020, the COVID-19 SAB members have diverse backgrounds in the life sciences with specialty areas of expertise in vaccines, public health, and policy making to strategically advise our global vaccine candidate selection process, clinical development strategy, and commercialization of our COVID-19 vaccine candidates. These global KOLs share in our vision of developing and producing a safe, effective, and accessible vaccine to provide relief to communities around the world suffering from the COVID-19 pandemic.

The chairman of our COVID-19 SAB, Dr. Ralf Clemens, has over 30 years of experience in vaccine development and held executive positions in several world-renowned multinational corporations. Dr. Clemens is currently a member of the Board of Trustees of the International Vaccine Institute, a leading global vaccinology organization initiated by the *United Nations Development Programme*, a Member of the Scientific Committee of CEPI, a Member of the Selection Committee of Global Health Innovative Technology Fund, and an external Scientific Advisor to the Bill & Melinda Gates Foundation. Dr. Clemens is also the Principal and Founder of Grid Europe Ltd. Consulting (Global Research in Infectious Diseases) and has served as a Supervisory Director at CureVac N.V. (NYSE: CVAC) since 2015. He served as a Senior Vice President of Global Vaccine Development at Takeda, Head of Global Vaccine Development at Novartis, and Vice President of Worldwide Vaccine Clinical R&D at GSK. He graduated with an M.D. from the University of Mainz, Germany, and under the Wharton Advanced Management Program from the Wharton Business School in 1996.

BUSINESS

MANUFACTURING

Changxing Commercial Manufacturing Facility

We have an in-house, commercial-ready biologics manufacturing facility in Changxing, Zhejiang province, China which occupies approximately 50,000 sq.m. of land with a total gross building floor area of approximately 32,000 sq.m. Our Changxing manufacturing facility was designed to adhere to the cGMP standards of the U.S., EU, and China. The Changxing facility has received certification by a QP, a requirement to achieve EU cGMP standards. Additional pre-approval GMP inspections are expected during the review process for conditional regulatory approval for SCB-2019 (CpG 1018/Alum) in 2021. In the third quarter of 2021, we received a Pharmaceutical Manufacturing Permit from the Zhejiang Medical Products Administration for the production of SCB-2019 (CpG 1018/Alum) at the Changxing manufacturing facility. The initial construction of Changxing manufacturing facility was funded by an enterprise controlled by the Changxing local government.

Our Changxing manufacturing facility is well prepared for the rapid scale-up and commercial production of SCB-2019. Our Changxing manufacturing facility features a warehouse, two drug substance production floors, fill and finish areas, a utilities system, a water system, HVAC system, and waste-water treatment plant. The manufacturing facility covers the full functions across the biologics manufacturing process, including seed thawing, amplification, bioreactor cell culture, harvest, purification/chromatography, ultrafiltration/diafiltration, formulation, filling, packaging, and quality control testing. The facility is equipped with a state-of-the-art, centrally automated, and flexible start-to-finish platform based on single-use technologies for the production of protein-based vaccines and biologic therapeutics. We have four 2,000L bioreactors and multiple fill-finish lines, including ones for prefilled syringes, glass vials, and a lyophilizer. Our Changxing facility will potentially be able to produce more than one billion doses of our SCB-2019 antigen annually at peak capacity. We can also produce supply of our other pipeline products, such as SCB-808, at commercial scale. Under our current manufacturing process, our Changxing manufacturing facility can manufacture approximately a quarter of the peak capacity. We expect to finalize a more optimized manufacturing process in the near-term that will allow us to manufacture over one billion doses of SCB-2019 at peak annual capacity. We have expanded our fill and finish area in 2020 by adding two vial filling lines for our future demands, and the lines are operational as of the third quarter of 2021. We expect the NMPA, the EMA and the WHO to conduct GMP inspections on our Changxing facility in the second half of 2021 in connection with their regulatory review process for conditional approval. In addition to our internal manufacturing capabilities, we have engaged multiple CMOs, including Wuxi Vaccines, to potentially produce hundreds of millions of additional doses of SCB-2019 (CpG 1018/Alum) starting in 2022. As of the Latest Practicable Date, technology transfer activities from Clover to WuXi Vaccines for the manufacturing of SCB-2019 (CpG 1018/Alum) have begun. Utilizing our Changxing manufacturing facility, we have supplied materials for our pivotal global Phase 2/3 clinical trial for SCB-2019 (CpG 1018/Alum).

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Chengdu R&D and Pilot Manufacturing Facility

We have an R&D and pilot manufacturing facility located in Chengdu, Sichuan province, China to supply materials for our pre-clinical, IND, and early-stage clinical trials, which occupies approximately 3,300 sq.m. Our Chengdu manufacturing facility has a 200L single-use and 150L stainless steel bioreactor capacity as well as multiple pilot-scale drug product (DP) filling lines. Utilizing our Chengdu manufacturing facility, we have supplied materials for pre-clinical studies and early-stage clinical trials for our product candidates, including SCB-313, SCB-808 and SCB-2019 (CpG 1018/Alum). We are not planning to use this manufacturing facility to manufacture our vaccine related candidates.

COMMERCIALIZATION

Commercialization Strategies

We are in the process of executing our launch readiness plan and formulating our sales and marketing plans in anticipation of multiple potential product launches within the next few years. Our current launch readiness efforts are carried out by a cross-functional team, consisting of clinical, regulatory, CMC, market access/government affairs, as well as legal, compliance, business development, public relations, and investor relations. The focus will be on product readiness, market readiness, and organizational readiness. We intend to build our commercialization capabilities through a combination of efficient and specialized internal sales and marketing teams and external marketing and distribution partnerships, with the goal of achieving broad product access across the globe.

SCB-2019 (CpG 1018/Alum)

During the pandemic period (as declared by the WHO), our SCB-2019 (CpG 1018/Alum), after licensure, will be purchased by and allocated through the COVAX Facility pursuant to the orders placed by GAVI, UNICEF, PAHO, or other potential parties. We may also consider commercializing SCB-2019 (CpG 1018/Alum) post conditional approval via bilateral negotiations and supply arrangements with global governments.

COVAX is the vaccine pillar of the Access to COVID-19 Tools-Accelerator (the “ACT-Accelerator”). ACT-Accelerator is a global collaboration to accelerate the development, production, and equitable access to COVID-19 tests, treatments, and vaccines. The ACT-Accelerator brings together governments, scientists, businesses, civil society, and philanthropists, and global health organizations, including the Bill & Melinda Gates Foundation, CEPI, FIND, GAVI, The Global Fund, Unitaid, Wellcome Trust, the WHO, and the World Bank. These organizations have joined forces to support the development and equitable distribution of tests, treatments, and vaccines to reduce worldwide mortality and severe disease, restoration of full societal and economic activity globally in the near term, and the facilitation of high-level control of COVID-19 disease in the medium term. The ACT-Accelerator is comprised of four pillars: diagnostics, treatment, vaccines, and health system strengthening.

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We have negotiated and determined the price of SCB-2019 (CpG 1018/Alum) to COVAX participants procuring through the COVAX Facility in the GAVI Advance Purchase Agreement. The price of SCB-2019 (CpG 1018/Alum) in bilateral agreements will be negotiated in discussions with those parties before entering into an agreement.

During the post-pandemic period (as declared by the WHO), we may sell up to 50% of our production capacity for SCB-2019 (CpG 1018/Alum) to the COVAX Facility if required, and we intend to sell additional SCB-2019 (CpG 1018/Alum) through bilateral negotiations and supply arrangements with global governments.

SUPPLIERS

Our Suppliers

During the Track Record Period, our suppliers primarily consisted of (i) suppliers of raw materials and consumables for our drug and vaccine development, (ii) suppliers of equipment and devices for our manufacturing facility development, and (iii) CROs, who provide third-party contracting services for research and development.

We procure raw materials from numerous suppliers around the world according to our product development plans. Our raw materials for our product candidates primarily include biological and chemical materials. Most of our raw materials are widely available. We have established stable collaboration relationships with qualified suppliers for raw materials, which we believe have sufficient capacity to meet our demands. Nevertheless, we believe that adequate alternative sources for such supplies exist. To monitor the quality of supplies, we implemented a standardized operating system, setting out the procedures and guidelines for the procurement of raw materials, quality control inspection, warehousing, testing, and storage. During the Track Record Period, we did not experience any shortage or delays in the supply of raw materials. Please also refer to “– Research and Development – Clinical Development – Collaboration with Contract Research Organizations (CROs)” and “– Licensing and Collaboration Arrangements – Agreements for SCB-2019 (CpG 1018/Alum)” for details.

We select our suppliers by considering their qualifications, compliance with relevant regulations and industry standards, production facilities, production quality, prices, business scale, market share, reputation, and after-sales service quality. During the Track Record Period, we did not experience any material disputes with suppliers, difficulties during the procurement of raw materials, interruptions in our operations due to a shortage or delay of raw materials, or significant fluctuations in raw material prices.

For the years ended December 31, 2019 and 2020 and the four months ended April 30, 2021, our purchases from our five largest suppliers in aggregate accounted for 46.3%, 50.8% and 71.2% of our total purchases, respectively, and purchases from our largest supplier alone accounted for 14.0%, 22.3% and 40.1% of our total purchases, respectively.

BUSINESS

The following table sets forth details of our five largest suppliers during the Track Record Period.

Rank	Suppliers	Purchase amount <i>(RMB in thousands)</i>	% of total purchase <i>(%)</i>	Settlement terms	Commencement of business relationship	Supplier background	Business Scale	Country
For the four months ended April 30, 2021								
1	Supplier A	171,233	40.1	Settle according to milestones in the contract and settle expenses incurred by month.	2020	CRO	A subsidiary of a publicly listed company on the NYSE with an authorised share capital of US\$4 million	U.S.
2	Supplier B	49,614	11.6	Settle the raw material/research equipment costs and the customs clearance fee according to the milestones in the contract.	2017	Supplier of raw material and equipment	With a registered capital of RMB30 million	China
3	Supplier C	35,082	8.2	Settle according to milestones in the contract.	2020	CRO	With a registered capital of US\$10,000	The Republic of Panama
4	Supplier D	29,320	6.9	Settle within 30 days upon receiving payment invoice.	2020	Supplier of raw material	With a registered capital of US\$278,000	U.S.
5	Supplier E	18,604	4.4	Prepay 40% contract price upon signing the contract. Settle the remaining contract price within 30 days upon receiving payment invoice issued by the supplier each month.	2020	CRO	A subsidiary of a publicly listed company on the NYSE with an authorised share capital of US\$26.5 million	U.S.
	Total	<u>303,853</u>	<u>71.2</u>					

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<u>Rank</u>	<u>Suppliers</u>	<u>Purchase amount</u> <i>(RMB in thousands)</i>	<u>% of total purchase</u> <i>(%)</i>	<u>Settlement terms</u>	<u>Commencement of business relationship</u>	<u>Supplier background</u>	<u>Business Scale</u>	<u>Country</u>
For the year ended December 31, 2020								
1	Supplier B	64,788	22.3	Settle according to milestones in the contract.	2017	Supplier of raw materials and equipment	With a registered capital of RMB30 million	China
2	Supplier F	34,611	11.9	Settle according to milestones in the contract and settle expenses incurred by month.	2018	CRO	A subsidiary of a publicly listed company on the NYSE with an authorised share capital of US\$4 million	Australia
3	Supplier G	18,991	6.5	Settle according to milestones in the contract.	2020	Constructor of product lines	With a registered capital of RMB349 million	China
4	Supplier H	14,876	5.1	Settle for products within 30 days from the signing of contracts. Settle 90% of the service fee within 30 days after receiving the invoice and the remaining 10% within six months after the signing of contracts.	2020	Supplier of raw materials and equipment	With a registered capital of RMB1,283 million	China
5	Supplier I	14,531	5.0	Settle according to milestones in the contract.	2019	CRO	With a registered capital of RMB100 million	China
	Total	<u>147,797</u>	<u>50.8</u>					

BUSINESS

<u>Rank</u>	<u>Suppliers</u>	<u>Purchase amount</u>	<u>% of total purchase</u>	<u>Settlement terms</u>	<u>Commencement of business relationship</u>	<u>Supplier background</u>	<u>Business Scale</u>	<u>Country</u>
		<i>(RMB in thousands)</i>						
For the year ended December 31, 2019								
1	Supplier F	4,070	14.0	Settle according to milestones in the contract and settle expenses incurred by month.	2018	CRO	A subsidiary of a publicly listed company on the NYSE with an authorised share capital of US\$4 million	Australia
2	Supplier J	3,088	10.6	Settle within 30 days upon receiving invoice or payment notice.	2018	CRO	With a registered capital of US\$2 million	China
3	Supplier K	2,350	8.1	Settle according to milestones in the contract.	2019	Constructor of research and development facilities	With a registered capital of RMB20 million	China
4	Supplier L	2,342	8.1	Settle according to milestones in the contract.	2018	CRO	With a registered capital of RMB60 million	China
5	Supplier M	1,593	5.5	Settle according to milestones in the contract.	2018	CRO	Revenue for year 2020 amounted to US\$4,416 million	U.S.
	Total	<u>13,443</u>	<u>46.3</u>					

During the Track Record Period, we engaged various CROs with different qualifications and geographical location primarily based on the needs of our preclinical and clinical studies. Our procurement of CRO services will continue to depend on the cadence of our clinical and preclinical studies. Another one of our major suppliers was a supplier of raw materials during the Track Record Period, that mainly supply the raw material and equipment for the CMC activities for our SCB-2019 (CpG 1018/Alum). We generally procure our raw materials and consumables according to the progress of our clinical studies and its availability. We expect to purchase more raw materials in light of the advancement of our clinical trials and the commercialization of our SCB-2019 (CpG 1018/Alum). We also had suppliers of equipment and construction of production lines as we built our manufacturing facility and equipped our R&D facilities.

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All of our suppliers during the Track Record Period are Independent Third Parties. None of our Directors, their respective associates nor any shareholder who, to the knowledge of our Directors, owned more than 5% of our issued share capital as at the Latest Practicable Date, has any interest in any of our five largest suppliers during the Track Record Period.

COMPETITION

We face competition in several different forms. Product candidates engineered using the Trimer-Tag™ technology platform face actual or potential competition from various companies. The Trimer-Tag™ technology platform also faces actual or potential competition from other technology platforms.

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, competition, and a strong emphasis on proprietary products. While we believe the Trimer-Tag™ technology platform, well-established management team, and robust pipeline of clinical and pre-clinical stage product candidates will provide us with competitive advantages, we face actual or potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing products and new products that may become available in the future.

We operate in the segments of the pharmaceutical, biotechnology, and other related markets that develop vaccines, oncology, or autoimmune disorders. There are other companies working to develop similar vaccines or therapies in these fields. These companies include divisions of large pharmaceutical companies and biotechnology companies of various sizes. Many of these companies and institutions, either alone or together with their partners, have substantially greater financial resources and larger research and development divisions than we have. In addition, many of these competitors, either alone or together with their partners, have substantially greater experience than us in developing pharmaceutical products, undertaking pre-clinical testing and clinical trials, obtaining the relevant regulatory approvals of such products and the manufacturing and commercialization of such products. Accordingly, our competitors may succeed in obtaining patent protection, relevant marketing approval, and commercializing products more rapidly than us.

We face competition from companies developing or testing product candidates for the same or similar targets we are pursuing with our own pipeline. Please refer to “– Our Product Candidates” and “Industry Overview” for further details of our major competitors. In addition, there may be additional competitors working on the targets of our critical programs of whom we are currently unaware.

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Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more potent and effective, are safer and have fewer side effects, are more convenient, or are less expensive than any drugs that we may develop. Our competitors also may obtain the relevant regulatory approvals for their drugs or vaccines earlier than we obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of our product candidates, if approved, are likely to be their efficacy, safety, convenience and price, the effectiveness of companion diagnostics in guiding the use of related therapeutics, the level of generic competition, and the availability of reimbursement from government and other third-party payers.

INTELLECTUAL PROPERTY

Intellectual property rights are the basis towards the success of our business, and we are committed to the development and protection of our intellectual properties. Our success depends in part on our ability to: obtain and maintain patent and other intellectual property and proprietary protections for commercially important technologies, inventions and know-how related to our business, including for the Trimer-Tag™ technology platform and product candidates; defend and enforce our patents; preserve the confidentiality of our trade secrets; and operate without infringing, misappropriating or otherwise violating the valid, enforceable intellectual property rights of third parties.

As of the Latest Practicable Date, our owned patent portfolio consists of one issued U.S. patent, and 24 patent applications, including 20 PCT patent applications in seven patent families, three U.S. patent applications, and one China patent application. Our owned patents and patent applications primarily include compositions, methods and uses related to TNFSF and certain vaccines against enveloped RNA viruses, including SCB-2019 (CpG 1018/Alum). As of the Latest Practicable Date, we in-licensed the exclusive worldwide rights for the Trimer-Tag™ technology platform under twelve issued patents, including three issued U.S. patents and nine issued patents in other jurisdictions, namely PRC, Japan, and Europe (i.e. the U.K., France, Germany, Spain, Italy, the Netherlands, and Switzerland/Liechtenstein). Our in-licensed patents and patent applications primarily relate to methods and compositions for producing secreted trimeric fusion proteins employing the Trimer-Tag™ technology.

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The patent portfolios for our Core Products and SCB-313 as of the Latest Practicable Date are summarized below:

SCB-2019 (CpG 1018/Alum): We filed one PCT application for the SCB-2019 antigen in June 2020, and three additional PCT applications in April 2021, May 2021, and June 2021, in each case, claiming priority to the June 2020 PCT. On September 29, 2021, we filed an U.S. patent application claiming priority to the PCT applications. A patent that eventually issues in this patent family is expected to expire around June 2040. This estimate does not necessarily reflect all patent term adjustments, extensions, and disclaimers. We also filed one PCT application that covers an affinity purification method used in the manufacture of SCB-2019 in August 2020. We filed additional PCT applications in April 2021 and June 2021.

SCB-808: We filed one PRC patent application directed to methods for producing fusion proteins, and a patent that eventually issues is expected to expire around April 2041. This estimate does not necessarily reflect all patent term adjustments, extensions, and disclaimers.

SCB-313: We own one U.S. patent directed to methods for treating cancer which is expected to expire in March 2038. There are pending continuation-in-part applications in the U.S. patent family, and additional continuing applications directed to composition of matter can be filed.

In addition, we own the exclusive worldwide rights for twelve issued patents relating to the Trimer-Tag™ technology platform, including three issued U.S. patents and nine issued patents in other jurisdictions. Such patents are expected to expire in the fourth quarter of 2024.

We intend to pursue marketing exclusivity periods that are available under regulatory provisions in certain countries for our Core Products and SCB-313. As of the Latest Practicable Date, we were not aware of any concerns or issues raised by relevant authorities regarding the patent applications relating to our Core Products and SCB-313.

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The following table summarizes the details of our material granted patents and filed patent applications in connection with our clinical and pre-clinical candidates which were independently developed by us leveraging the Trimer-Tag™ technology platform as of the Latest Practicable Date:

Product	Scope of Patent Protection	Jurisdiction	Patent status	Applicant/ Patentee	Patent expiration
SCB-2019 (CpG 1018/Alum)	Composition of matter and methods of making and using the same can be pursued	PCT/U.S.	Applications filed	Sichuan Clover	No issued patent
SCB-2019 (CPG 1018/Alum)	Methods and compositions for affinity purification used in the manufacture of SCB-2019	PCT	Application Filed	Sichuan Clover	No issued patent
SCB-808	Methods of Producing TNFR-IG Fusion Proteins	PRC	Application Filed	Sichuan Clover	No issued patent
SCB-313	Method of treating cancer and composition of matter and methods of making and using the same can be achieved	U.S.	One issued patent, and pending applications	Sichuan Clover	March 9, 2038 for the issued patent

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The term of individual patents may vary based on the countries in which they are obtained. In most countries in which we file patent applications, including China and the U.S., the term of an issued patent is generally 20 years from the filing date of the earliest non-provisional patent application on which the patent is based in the applicable country. In the United States, a patent’s term may be lengthened in some cases by a patent term adjustment, which extends the term of a patent to account for administrative delays by the United States Patent and Trademark Office, (the “USPTO”), in excess of a patent applicant’s own delays during the prosecution process, or may be shortened if a patent is terminally disclaimed over a commonly owned patent having an earlier expiration date. The table below is a summary of our patent applications as of the Latest Practicable Date.

Type	Jurisdiction	Filing Date	Status	Scope	Patent title	Inventors
Invention	US	31-May-17	Granted	SCB-313	Method and Compositions for Producing Disulfide-Linked Trimeric TNF Family of Cytokines and Their Use	Dr. Liang
Invention	US	27-Feb-20	Pending		Method and Compositions for Producing Disulfide-Linked Trimeric TNF Family of Cytokines and Their Use	Dr. Liang
Invention	US	3-Mar-20	Pending	SCB-313	Method and Compositions for Producing Disulfide-Linked Trimeric TNF Family of Cytokines and Their Use	Dr. Liang
PCT	PCT	10-Jun-20*	Pending	SCB-2019	CORONAVIRUS VACCINE COMPOSITIONS, METHODS, AND USES THEREOF	
PCT	PCT	13-Apr-21*	Pending	SCB-2019	CORONAVIRUS VACCINE COMPOSITIONS, METHODS, AND USES THEREOF	Dr. Liang; Mr. Joshua Liang
PCT	PCT	14-May-21*	Pending	SCB-2019	CORONAVIRUS VACCINE COMPOSITIONS, METHODS AND USES THEREOF	
PCT	PCT	10-Jun-21	Pending	SCB-2019	CORONAVIRUS VACCINE COMPOSITIONS, METHODS AND USES THEREOF	
Invention	U.S.	29-Sep-21	Pending		CORONAVIRUS VACCINE COMPOSITIONS, METHODS, AND USES THEREOF	
PCT	PCT	10-Jun-20*	Pending		RSV VACCINE COMPOSITIONS, METHODS, AND USES THEREOF	Dr. Liang; Mr. Joshua Liang
PCT	PCT	13-Apr-21*	Pending		RSV VACCINE COMPOSITIONS, METHODS, AND USES THEREOF	
PCT	PCT	10-Jun-21	Pending		RSV VACCINE COMPOSITIONS, METHODS AND USES THEREOF	

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Type	Jurisdiction	Filing Date	Status	Scope	Patent title	Inventors
PCT	PCT	10-Jun-20*	Pending		INFLUENZA VACCINE COMPOSITIONS, METHODS, AND USES THEREOF	Dr. Liang;
PCT	PCT	13-Apr-21*	Pending		VACCINE COMPOSITIONS, METHODS, AND USES THEREOF	Mr. Joshua Liang
PCT	PCT	10-Jun-21	Pending		VACCINE COMPOSITIONS, METHODS AND USES THEREOF	
PCT	PCT	10-Jun-20*	Pending		HIV VACCINE COMPOSITIONS, METHODS, AND USES THEREOF	Dr. Liang;
PCT	PCT	13-Apr-21*	Pending		HIV VACCINE COMPOSITIONS, METHODS, AND USES THEREOF	Mr. Joshua Liang
PCT	PCT	10-Jun-21	Pending		HIV VACCINE COMPOSITIONS, METHODS AND USES THEREOF	
PCT	PCT	10-Jun-20*	Pending		CORONAVIRUS DIAGNOSTIC COMPOSITIONS, METHODS, AND USES THEREOF	Dr. Liang;
PCT	PCT	13-Apr-21*	Pending		CORONAVIRUS DIAGNOSTIC COMPOSITIONS, METHODS, AND USES THEREOF	Mr. Joshua Liang
PCT	PCT	10-Jun-21	Pending		CORONAVIRUS DIAGNOSTIC COMPOSITIONS, METHODS AND USES THEREOF	
PCT	PCT	31-Aug-20*	Pending	SCB-2019	METHODS AND COMPOSITIONS FOR PURIFICATION OF TRIMERIC FUSION PROTEINS	Dr. Liang;
PCT	PCT	13-Apr-21	Pending	SCB-2019	METHODS AND COMPOSITIONS FOR PURIFICATION OF TRIMERIC FUSION PROTEINS	Mr. Joshua Liang
PCT	PCT	30-Aug-21	Pending	SCB-2019	METHODS AND COMPOSITIONS FOR PURIFICATION OF TRIMERIC FUSION PROTEINS	
Invention	China	15-Apr-21	Pending	SCB-808	METHOD OF PRODUCING TNFR-IG FUSION PROTEINS	Dr. Liang
PCT	PCT	24-Sep-21	Pending		TPO MIMETIC FUSION PROTEINS AND METHODS OF USE	Dr. Liang

* Withdrew strategically after obtaining priority.

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The availability and eligibility requirements of patent term extension (PTE) or supplementary protection certificate (SPC) vary from jurisdiction to jurisdiction, and the actual term extension and scope of protection will be determined on a case by case basis. With respect to any issued patents in the U.S. and Europe, we may be entitled to obtain an extension of the patent’s term provided we meet the applicable requirements for obtaining such patent term extensions. For example, in the U.S., we may apply for a patent term extension of up to five years as compensation for the patent term lost during clinical trials and the FDA regulatory review process under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The exact duration of the extension depends on the time we spend in clinical studies, as well as getting an NDA approval from the FDA. However, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended, and only those claims covering the approved drug, a method for use, or a method for manufacturing may be extended. PTE provisions for China’s amended patent law came into effect on June 1, 2021, which, upon request from the patent holder, generally provide PTE capped at 5 years, and the resulting total effective patent term shall not exceed 14 years from the approval for marketing of the new drug. In certain other foreign jurisdictions, similar extensions as compensation for regulatory delays are also available.

The actual protection provided by a patent varies on a claim-by-claim and country-by-country basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of any patent term extensions or adjustments, the availability of legal remedies in a particular country, and the validity and enforceability of the patent. We cannot provide any assurance that patents will be issued with respect to any of our owned or licensed pending patent applications or any such patent applications that may be filed in the future, nor can we provide any assurance that any of our owned or licensed issued patents or any such patents that may be issued in the future will be commercially useful in protecting our product candidates and methods of manufacturing the same.

We performed due diligence on the intellectual property rights of GenHunter before entering into the GenHunter License Agreement, but we cannot guarantee that their rights will not be challenged, or that GenHunter will provide meaningful exclusivity or otherwise enable us to exploit the licensed product candidates should there be a challenge to their intellectual property rights. See “Risk Factors – Risks Relating to Our Intellectual Property Rights.” If we are unable to obtain and maintain patent protection for our product candidates or the Trimer-Tag™ technology platform, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and our ability to successfully commercialize any product or technology may be adversely affected.” For additional information about our license, please refer to “– Licensing and Collaboration Agreements – License Agreement with GenHunter.”

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We may rely, in some circumstances, on trade secret and/or confidential information to protect aspects of our technology. We seek to protect our technology and processes, in part, by entering into confidentiality agreements with consultants, scientific advisers and contractors, and invention assignment agreements with our employees. We have entered into confidentiality agreements and non-competition agreements with our senior management and certain key members of our R&D team and other employees who have access to trade secrets or confidential information about our business. Our standard employment contract, which we used to employ each of our employees, contains an assignment clause, under which we own all the rights to all inventions, technology, know-how and trade secrets derived during the course of such employee’s work.

These agreements may not provide sufficient protection of our trade secret and/or confidential information. These agreements may also be breached, resulting in the misappropriation of our trade secret and/or confidential information, and we may not have an adequate remedy for any such breach. In addition, our trade secret and/or confidential information may become known or be independently developed by a third party, or misused by any collaborator to whom we disclose such information. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to or successfully copy aspects of our products or obtain or use information that we regard as proprietary without our consent. As a result, we may be unable to sufficiently protect our trade secrets and proprietary information.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. Despite any measures taken to protect our data and intellectual property, unauthorized parties may attempt to or successfully gain access to and use information that we regard as proprietary. See “Risk Factors – Risk Relating to Our Intellectual Property Rights” for a description of risks related to our intellectual property.

We conduct our business under the brand name of “Clover Biopharmaceuticals”. As of the Latest Practicable Date, we had registered four trademarks and four copyrights in the PRC and we had four registered trademarks in Hong Kong. As of the same date, we had 31 trademark application that we consider material in the PRC, Hong Kong, U.S. and the EU, and we were the registered owner of one domain name that we consider material.

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During the Track Record Period and up to the Latest Practicable Date, we were not involved in any proceedings in respect of, and we had not received notice of any claims of infringement of, any intellectual property rights that may be threatened or pending, in which we may be a claimant or a respondent that may have a material adverse impact on us.

See “Appendix IV – Statutory and General Information – B. Further Information about Our Business – 2. Intellectual Property Rights” in this document for further information.

EMPLOYEES

The following table sets forth the details of our employees by function as of the Latest Practicable Date:

<u>Function</u>	<u>Number</u>	<u>% of Total</u>
Research and Development	124	17.3
Manufacturing and CMC	421	58.8
General and Administrative	171	23.9
Total	716	100.0

As of the Latest Practicable Date, 638 of our employees were located in China, and 78 were located in the U.S, Singapore, Mexico, Philippines, Colombia, Switzerland, Thailand, France, Brazil, Australia, Ireland, Netherland, UK, and Romania.

Employment Agreements with Key Management and Research Staff

We enter into employment agreements with our employees to cover matters such as wages, benefits, and grounds for termination. Further, we execute standard confidentiality and employment agreements with our key management and research staff. The contracts with our key personnel typically include a standard non-compete agreement that prohibits the employee from competing with us, directly or indirectly, during his or her employment and for one year after the termination of his or her employment. The contracts also typically include undertakings regarding assignment of inventions and discoveries made during the course of his or her employment. For further details regarding the terms of confidentiality and employment agreements with our key management, please refer to the section headed “Directors and Management” in this document.

None of our company or any of our subsidiaries are covered under a labor union. The PRC government requires us to provide work-related injury insurance for each of our employees who have entered into employment contracts with us. We believe that we maintain a good working relationship with our employees and we have not experienced any significant labor disputes or any significant difficulty in recruiting staff for our operations.

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Service Agreements with Recruitment Agents

In 2019 and 2020, we recruited a total number of 38 and 159 employees through third party recruiting agents, respectively. We normally enter into service agreements with these third party recruiting agents. Key terms of our service agreements are summarized as below:

- *Nature and Scope of the Service.* Third party recruiting service providers are responsible for searching for suitable candidates. These recruiting agents are responsible to conduct pre-selection and screening processes based on their analysis of industry data and trends before sending resumes to our human resource department.
- *Term.* The service agreement is usually effective for a term of 12 months which commences from a specified effective date to an expiration date.
- *Pricing.* We pay a fixed rate service fee which is a percentage of the annual salary of the candidate successfully placed.
- *Payments.* No fees are occurred till a candidate has been successfully placed in our Company. Typically, the service agreements requires payment within a designated period of time once the service is invoiced.
- *Guarantee Period.* The service agreement sets out a guarantee period, which usually begins from the starting date of the hired candidate, whereby our recruiting agents guarantee a replacement in case a candidate ceases employment within the guaranteed period.
- *Termination.* Each party has a right to terminate the contract with prior written notice.

Recruitment, Training and Development

We recruit our employees based on their qualification and potential. We provide new employee training to our employees and periodic on-the-job training to enhance the skills and knowledge of our employees.

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Employee Benefits

Our employees’ remuneration includes salaries, bonuses, employee provident fund and social security insurance contributions and other welfare payments, which are determined based on their qualifications, industry experience, position, and performance. In accordance with the relevant laws and regulations, we have made contributions to social security insurance funds (including pension plans, medical insurance, work-related injury insurance, unemployment insurance and maternity insurance), and housing funds for our employees. As of the Latest Practicable Date, except as otherwise disclosed in the document, we complied with statutory social security insurance fund and housing fund obligations in all material aspects. See “Risk Factors – Risks Relating to Our Operation – Failure to pay the social insurance and housing provident funds for any on behalf of our employees in accordance with the Labor Contract Law or comply with other PRC regulations may have an adverse impact on our financial conditions and results of operation.” In addition, we have granted and plan to continue to grant share-based incentive awards to our employees in the future to incentivize their contribution to our growth and development.

LAND AND PROPERTIES

Our headquarters are located in Chengdu, Sichuan province, China. The leases for our headquarters expire from 2021 to 2023. As of the Latest Practicable Date, we did not own any properties and we leased a number of properties with an aggregate gross floor area of over 6,400 square meters in Chengdu, Beijing, Shanghai and Boston for various functions.

As of the Latest Practicable Date, we had not completed lease registrations for all of our leases with the relevant regulatory authorities. As advised by our PRC Legal Adviser, the non-registration of lease agreements will not affect the validity of such lease agreements, but the relevant local housing administrative authorities can require us to complete registrations within a specified timeframe and we may be subject to a fine between RMB1,000 and RMB10,000 per lease for any delay in making these registrations. Therefore, we have the right to use such properties in accordance with the lease agreement but we may be subject to the risks of fines if the lease registration is not completed as required by the relevant local housing administrative authorities. The maximum penalty that we may be liable in relation to the failure of registering lease agreements during the Track Record Period was approximately RMB270 thousand. As of the Latest Practicable Date, we were not subject to any penalties arising from the non-registration of the lease agreements. See “Risk Factors – Risks Relating to Doing Business in China – Our leasehold interests in leased properties have not been registered with the relevant PRC governmental authorities as required by relevant PRC laws. The failure to register leasehold interests may expose us to potential fines.”

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We do not engage in any property activities as defined in Rule 5.01 of the Listing Rules. As of April 30, 2021, no single property interest had a carrying value exceeding 15% of our total assets. Accordingly, we are not required by Chapter 5 of the Listing Rules to value or include in this document any valuation report of our property interests, and, pursuant to section 6(2) of the Companies Ordinance (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong), this document is exempted from compliance with the requirements of section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance and paragraph 34(2) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

LICENSES, PERMITS AND APPROVALS

During the Track Record Period and up to the Latest Practicable Date, we believe that we had obtained all requisite licenses, approvals and permits from relevant authorities that are material to our operations.

LEGAL PROCEEDINGS AND REGULATORY COMPLIANCE

As of the Latest Practicable Date, we had not been a party to any actual or threatened material legal or administrative proceedings, and our Directors had not been involved in any such proceedings. We are committed to maintaining the highest standards of compliance with the laws and regulations applicable to our business. However, we may from time to time be subject to various legal or administrative claims and proceedings arising in the ordinary course of business.

INSURANCE

We maintain property insurance covering our production facilities and equipment that we believe are sufficient in accordance with customary industry practice, as well as social welfare insurance in accordance with the relevant laws and regulations in China. In line with industry practice in the PRC, we have elected not to maintain certain types of insurances, such as business interruption insurance or product liability insurance. See “Risk Factors – Risks Relating to Our Operations – We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.” for further details of risks relating to our current insurance coverage. Our Directors are of the view that our current insurance coverage is in line with industry practice and is adequate for our operations.

HEALTH, SAFETY AND ENVIRONMENTAL MATTERS

We strive to operate our facilities in a manner that protects the environment and the health and safety of our employees, patients, and communities. We have implemented company-wide environmental, health and safety (EHS) manuals, policies, and standard operating procedures in relation to air pollution, wastewater treatment, biological solid waste management, and emergency response and practices. We periodically provide EHS trainings to our employees.

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Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. To further ensure our compliance with applicable environmental protection and health and safety laws and regulations, we (i) have established various guidelines governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes to ensure such guidelines are strictly enforced for the disposal of laboratory materials and wastes; (ii) inspect our equipment and facilities regularly to identify and eliminate safety hazards; (iii) provide regular safety awareness training to our employees; (iv) keep health records for all employees and conduct health examinations before, during and after their time at the company, especially for employees engaged in work involving occupational hazards; and (v) conduct regular fire safety inspections, maintenance of fire-fighting equipment and regular emergency drills.

Our EHS department is responsible for monitoring and enforcing the compliance of our operations with environment, health and safety laws and regulations. This responsibility is executed through formulation and implementation of EHS policies and procedures, EHS inspections, and incident response planning. We have not had any significant workplace accidents in the history of our Company.

We believe we have maintained good relationships with the communities surrounding our production facilities. During the Track Record Period and up to the Latest Practicable Date, we complied with the relevant environmental and occupational health and safety laws and regulations in all material aspects, and we did not have any incidents or complaints which had a material and adverse effect on our business, financial condition or impact on the operations of our business during the period. For the years ended December 31, 2019, 2020 and the four months ended April 30, 2021, our expenses in relation to environmental protection amounted to RMB77.0 thousand and RMB0.5 million and RMB0.2 million, respectively. We expect our costs of complying with current and future environmental protection laws to increase in the future, as we further our research and development efforts and commence commercial manufacturing of our products after regulatory approval.

Governance of Environmental and Social Matters

We incorporate a sustainable development approach in our daily business operation decisions. Our EHS department is responsible for establishing, adopting and reviewing our ESG policies, vision and goals to evaluate, determine and address our ESG-related risks once a year.

We are subject to environmental-related and social related risks and climate-related issues. See “Risk Factors – If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business” and “Risk Factors – Risks Relating to Our Operations – We face risks related to natural disasters, health epidemics, civil and social disruption and other outbreaks, which could significantly disrupt our operations. In particular, the COVID-19 outbreak in China and worldwide has adversely affected, and may continue to adversely affect, our business, results of operations and financial condition” We may adopt more ESG policies relating to social responsibility and internal governance as our EHS

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department deems fit. Our EHS department takes full responsibility to our ESG strategy and reporting. Our EHS department may assess or engage independent third party advisory companies to evaluate the ESG risks and review our existing strategy, target and internal controls. Necessary improvements will then be implemented to mitigate the risks. At the same time, each of our business unit is responsible for promoting and implementing various sustainable development measures and providing disclosure information relevant to sustainable development measures.

Environmental Matters

We are concerned about the impact of our business on climate and environment. We strive to take measures to protect the ecological environment during our business operation, so as to minimize adverse environmental impact. The projects under our management are subject to PRC environmental laws and regulations as well as environmental regulations promulgated by local governments including, but not limited to the PRC Environmental Protection Law (《中華人民共和國環境保護法》), the PRC Prevention and Control of Noise Pollution Law (《中華人民共和國環境噪聲污染防治法》), the PRC Environmental Impact Appraisal Law (《中華人民共和國環境影響評價法》), the Administration Rules on Environmental Protection of Construction Projects (《建設項目環境保護管理條例》), and the Regulation on Pollutant Discharge Permit Administration (《排污許可管理條例》).

Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. We have implemented company-wide EHS manuals, policies and standard operation procedures and periodically provide EHS trainings to our employees to ensure the compliance with applicable environmental protection and health and safety laws and regulations. See “– Health, Safety and Environmental Matters” in this section. We continuously use quantitative metrics to evaluate, assess and manage our pollutants emission and resource consumption. During the Track Record Period and after the establishment of our Changxing manufacturing facility, we periodically engaged third-party professional environmental testing agencies to evaluate our pollutants emission, including wastewater and waste gas, soil and underground water of our plant and ambient noise around our plant. During the Track Record Period, our pollutants emission in environmental testing generally met relevant national and industry environmental standards. For example, during the Track Record Period, the nonmethane hydrocarbons contained in the exhaust and the hydrogen sulfide emission rate did not exceed 80mg/m³ and 0.33kg/h, respectively. In addition, the Ph values of the wastewater were within the range of 6 to 9 and the Chemical Oxygen Demand (COD) waste water did not exceed 500 mg/L. During the Track Record Period, we actively monitored our resource consumption for our manufacturing function. For the year ended December 31, 2020 and the four months ended April 30, 2021, our consumption of water and electricity amounted to 83.1 thousand ton and 9,979 thousand Kilowatt-hour and 38.5 thousand ton and 2,188.7 thousand Kilowatt-hours, respectively.

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While there is no virus used in the manufacturing process of our vaccine-related products, the manufacturing process of our potential commercialized products may involve the use of non-biodegradable raw materials, mainly include mixing plastic bag, and may produce hazardous waste products. Under our ESG policies, we have established stringent guidelines in relation to the manufacturing procedures and the handling, use, storage, treatment and disposal of non-biodegradable materials. We provide periodic training on these guidelines and procedures to our employees as part of our employee-training program to ensure such procedures are strictly enforced. In addition, we monitor the implementation of our ESG policies through our EHS department for each stage of the manufacturing process. Our Directors (who are responsible for monitoring the corporate governance of our Group), with help from our legal advisors, will also periodically review our compliance status with ESG policies after the [REDACTED]. We will continue to use quantitative metrics to evaluate, assess and manage our pollutants emission and resource consumption after the commercialization of our product candidates. We are currently negotiating with certain insurance companies and plan to purchase the compulsory liability insurance for the manufacturing of our vaccines under the PRC law in the fourth quarter of 2021 prior to our commercial launch of SCB-2019 (CpG 1018/Alum). For details, please see “Regulatory Overview – Regulations Relating to Vaccines – Vaccine Administration.”

We pay close attention to the global trend and China’s national strategy of addressing climate change and ecological environment protection, and will actively enhance our ability to address climate change and cope with China’s initiatives and action plans regarding future carbon dioxide emission. In terms of major climate change-related initiatives or action plans that may affect us, we plan to formulate policies after our [REDACTED] to systematically identify, assess and manage climate change-related risks, and formulate relevant response strategies.

Social Matters

We have policies on compensation and dismissal, equal opportunities, diversity and anti-discrimination. We are proud to be an equal opportunity employer with a dedicated workforce, and do not discriminate based on gender, gender identity, religion, race, ethnicity or disability. If our employees encounter any unequal discrimination, they should seek immediate assistance from either their department head, human resources department or our management team. We will immediately follow up, investigate, and, if necessary, report to the law enforcement authorities. Our Directors confirmed that during the Track Record Period and up to the Latest Practicable Date, there had been no violation of any applicable social laws, rules and regulations and no claim or penalty imposed upon us as a result of such laws, rules and regulations.

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We have adopted and maintained a series of rules, standard operating procedures and measures to maintain a healthy and safe environment for our employees. We have relevant internal policies in place to ensure safe storage and handling of flammable and corrosive materials used in our manufacturing process. We also have safety equipment and instruments in place. Additionally, we have established an EHS department in charge of safety and emergency issues consisting of four employees mainly responsible for identifying and mitigating safety risks, improving the safety production policies and procedures, supervising the implementation of such policies and procedures, making emergency plans and providing trainings in respect of production safety to our employees. In addition, we provide our employees with training in various areas to improve their knowledge and skills.

RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

We recognize that risk management is critical to our long-term development and success. Key operational risks faced by us include changes in the general market conditions and the regulatory environment of the PRC and global pharmaceutical markets, our ability to develop, manufacture and commercialize our drug and vaccine candidates, and our ability to compete with other vaccine, immuno-oncology and biotechnology companies. See “Risk Factors” for a more detailed discussion on various risks we may subject to. In particular, we are exposed to credit, liquidity and currency risks that arise in the normal course of our business. See “Financial Information – Quantitative and Qualitative Disclosure about Market Risk” for details on the above-mentioned market risks.

We have adopted a consolidated set of risk management policies which set out a risk management framework to identify, assess, evaluate, and monitor key risks associated with our strategic objectives on an ongoing basis. Our senior management, and ultimately our Directors, supervise the implementation of our risk management policies. Risks identified by management will be analyzed on the basis of likelihood and impact, and will be properly followed up and mitigated and rectified by our Group and reported to our Directors.

The following key principles outline our Group’s approach to risk management and internal control we plan to implement:

- Our senior management oversees and manages the overall risks associated with our business operations, including (i) reviewing and approving our risk management policy to ensure that it is consistent with our corporate objectives; (ii) monitoring the most significant risks associated with our business operations and our management’s handling of such risks; and (iii) ensuring the appropriate application of our risk management framework across our Group;

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- Our Chief Executive Officer, Mr. Joshua Liang, is responsible for (i) formulating and updating our risk management policy; (ii) reviewing and approving major risk management issues of our company; (iii) promulgating risk management measures; (iv) providing guidance on our risk management approach to the relevant departments in our company; (v) reviewing the relevant departments’ reporting on key risks and providing feedback; (vi) supervising the implementation of our risk management measures by the relevant departments; (vii) ensuring that the appropriate structure, processes and competencies are in place across our company; and (viii) reporting to our audit committee on our material risks;
- The relevant departments in our Company, including but not limited to the finance department, the legal department, and the human resources department, are responsible for implementing our risk management policy and carrying out our day-to-day risk management practice. In order to formalize risk management across our Group and set a common level of transparency and risk management performance, the relevant departments will (i) gather information about the risks relating to their operation or function; (ii) conduct risk assessments, which include the identification, prioritization, measurement and categorization of all key risks that could potentially affect their objectives; (iii) prepare a risk management report annually for our chief executive officer’s review; (iv) continuously monitor the key risks relating to their operation or function; (v) implement appropriate risk responses where necessary; and (vi) develop and maintain an appropriate mechanism to facilitate the application of our risk management framework.

We consider that our Directors and members of our senior management possess the necessary knowledge and experience in providing good corporate governance oversight in connection with risk management and internal control.

Internal Control

Our Board is responsible for establishing our internal control system and reviewing its effectiveness. During the Track Record Period, we regularly reviewed and enhanced our internal control system. Below is a summary of the internal control policies, measures, and procedures we have implemented or plan to implement:

- We have adopted various measures and procedures regarding each aspect of our business operation, such as related party transaction, risk management, protection of intellectual property, environmental protection and occupational health and safety. For more information, see “– Intellectual Property” and “– Health, Safety and Environment Matters.” We have also adopted various measures and procedures regarding our business operation, for example. Our internal audit department conducts audit field work to monitor the implementation of our internal control policies, reports any weaknesses identified to our management and audit committee, and follows up on the rectification actions.

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- We provide various training programs to keep our employees updated on relevant laws, regulations, and policies. Our new employees are required to attend compliance training programs soon after on-boarding, and must pass tests which examine their understanding of the compliance issues addressed by the training programs. Our employees are also required to regularly attend on-site and online training sessions to keep them informed of recent updates in the relevant laws and regulations.
- Our Directors (who are responsible for monitoring the corporate governance of our Group), with help from our legal advisers, will also periodically review our compliance status with all relevant laws and regulations after the [REDACTED].
- We have established an audit committee which (i) makes recommendations to our Directors on the appointment and removal of external auditors; and (ii) reviews the financial statements and renders advice in respect to financial reporting as well as oversees internal control procedures of our Group.
- We have engaged Somerley Capital Limited as our compliance adviser to provide advice to our Directors and management team until the end of the first fiscal year after the [REDACTED] regarding matters relating to the Listing Rules. Our compliance adviser is expected to ensure our use of funding complies with the sections entitled "Future Plans and Use of [REDACTED]" in this document after the [REDACTED], as well as to provide support and advice regarding requirements of relevant regulatory authorities in a timely fashion.
- We have engaged a PRC law firm to advise us on and keep us informed on PRC laws and regulations after the [REDACTED]. We will continue to arrange various trainings to be provided by external legal advisers from time to time when necessary and/or any appropriate accredited institution to update our Directors, senior management, and relevant employees on the latest PRC laws and regulations.
- We maintain strict anti-corruption policies and we believe we will therefore be less affected by the increasingly stringent measures taken by the PRC government to correct corruptive practices in the pharmaceutical industry.

In addition, as part of our risk management measures, we have implemented specific measures against corruption and bribery, including providing anti-corruption and anti-bribery compliance training for our Directors and senior management to enhance their knowledge and compliance of applicable laws and regulations. We require our employees, especially those involved in procurement, sales and marketing and other business functions which are more susceptible to bribery and corruptions, to abide by our compliance requirements, and make necessary representations and warranties to the Company. We also have established a system of supervision that allows complaints and reports to be submitted to management regarding non-compliant behavior of our internal employees.

During the Track Record Period, we have regularly reviewed and enhanced our internal control system. We consider that our Directors and members of our senior management possess the necessary knowledge and experience in providing good corporate governance oversight in connection with risk management and internal control.

DIRECTORS AND MANAGEMENT

BOARD OF DIRECTORS

Our Board of Directors comprises nine Directors, including two executive Directors, three non-executive Directors and four independent non-executive Directors. Our Directors are elected to serve a term of three years, which is renewable upon reelection and/or reappointment.

The following table sets out information in respect of our Directors:

Name	Age	Position	Date of joining our Group	Date of appointment as a Director	Roles and responsibilities
Dr. Peng LIANG ⁽¹⁾	60	Executive Director and chairman of the Board	June 4, 2007	October 31, 2018	Overall management of the business strategy, corporate development and research and development of our Group
Mr. Joshua LIANG ⁽¹⁾	29	Executive Director	April 11, 2016	December 25, 2020	Leading the management and operation of all functional departments and supervising product strategy of our Group
Dr. Xiaodong WANG	58	Non-executive Director	December 20, 2011	March 16, 2021	Providing guidance and advice on the corporate and business strategies of our Group

DIRECTORS AND MANAGEMENT

Name	Age	Position	Date of joining our Group	Date of appointment as a Director	Roles and responsibilities
Mr. Ting XIAO (肖汀)	34	Non-executive Director	October 17, 2019	March 16, 2021	Providing guidance and advice on the corporate and business strategies of our Group
Mr. Dong LYU (呂東)	46	Non-executive Director	March 16, 2020	March 16, 2021	Providing guidance and advice on the corporate and business strategies of our Group
Dr. Xiaobin WU	59	Independent non-executive Director	September 26, 2021	September 26, 2021	Supervising and providing independent judgement to our Board
Mr. Xiang LIAO	56	Independent non-executive Director	September 26, 2021	September 26, 2021	Supervising and providing independent judgement to our Board
Mr. Jeffrey FARROW	59	Independent non-executive Director	September 26, 2021	September 26, 2021	Supervising and providing independent judgement to our Board
Mr. Thomas LEGGETT	44	Independent non-executive Director	September 26, 2021	September 26, 2021	Supervising and providing independent judgement to our Board

Note:

(1) Dr. Peng Liang is the father of Mr. Joshua Liang.

DIRECTORS AND MANAGEMENT

Executive Directors

Dr. Peng LIANG, aged 60, was appointed as an executive Director on October 31, 2018. Dr. Liang is primarily responsible for overall management of the business strategy, corporate development and research and development of our Group. Dr. Liang founded our Group by establishing Sichuan Clover in June 2007 as the chairman of Sichuan Clover.

In addition to our Company and Sichuan Clover, Dr. Liang is also serving the following positions in our Group:

- the chairman of Zhejiang Clover since August 2016;
- the president of U.S. Clover since April 2020;
- a director of Australia Clover since June 2017; and
- a director of HK Clover since November 2018.

Dr. Liang has over 25 years of experience in both practical and academic fields of pharmaceutical industry. Prior to founding our Group, Dr. Liang founded GenHunter Corporation in October 1992 and has served as the chairman since its incorporation. From July 2008 to June 2009, he served as an associate professor of Vanderbilt University. From November 2007, Dr. Liang once served as a guest professor in Sichuan University (四川大學). From July 2021, Dr. Liang serves as a member of the scientific advisory committee of Shandong Boan Biotech Co., Ltd. (山東博安生物技術股份有限公司).

Dr. Liang received his doctor of philosophy in biochemistry from University of Illinois in May 1990, after which he was a postdoctoral fellow in biochemistry in Harvard Medical School until August 1995 in the U.S. He obtained his bachelor’s degree in biochemistry from Peking University (北京大學) in July 1982 in the PRC. In 1997 and 1998, Dr. Liang was respectively awarded the Innovative Technology Award by the Society of Chinese Bioscientists in America and the Prize Molecular Bioanalytics by the German Society of Biochemistry and Molecular Biology.

Mr. Joshua LIANG, aged 29, was appointed as an executive Director on December 25, 2020. Mr. Liang is primarily responsible for leading the management and operation of all functional departments and supervising product strategy of our Group. Mr. Liang joined our Group in April 2016 as the chief strategy officer of Sichuan Clover.

DIRECTORS AND MANAGEMENT

In addition to the positions in our Company, Mr. Liang is serving the following positions in our Group:

- a director and the chief executive officer of Sichuan Clover since September 2017 and since June 2020, respectively;
- a director and the general manager of Zhejiang Clover since August 2016;
- the executive director and general manager of Beijing Clover since August 2020;
- the executive director and general manager of Shanghai Clover since February 2021;
- the chief executive officer of U.S. Clover since April 2020;
- the executive director and chief executive officer of Australia Clover since December 2020; and
- the director of HK Clover since December 2020.

Prior to joining our Group, Mr. Liang served as an analyst at Centerview Partners from July 2014 to February 2016, where he was mainly responsible for assisting in analyzing industry dynamics, competitive positioning and business strategies.

Mr. Liang obtained his bachelor’s degrees in both economics and biology from the University of Pennsylvania in May 2014 in the U.S.

Non-executive Directors

Dr. Xiaodong WANG, aged 58, was appointed as a non-executive Director on March 16, 2021. Dr. Wang is primarily responsible for providing guidance and advice on the corporate and business strategies of our Group. Dr. Wang joined our Group in December 2011 as a director of Sichuan Clover.

Dr. Wang is concurrently serving the following positions outside our Group:

- a director at Beigene Inc., a pharmaceutical company whose shares are listed on both NASDAQ (ticker symbol: BGNE) and the Stock Exchange (stock code: 6160), since February 2016; and
- a director at National Institute of Biological Sciences, Beijing (北京生命科學研究所) since October 2009.

DIRECTORS AND MANAGEMENT

Prior to joining our Group, Dr. Wang served as a chair professor of Biomedical Sciences at the University of Texas Southwestern Medical Center from 2001 to 2010 and an investigator at Howard Hughes Medical Institute from 1997 to 2010 in the U.S.

Dr. Wang received his doctor of philosophy in biochemistry from University of Texas Southwestern Medical Center in May 1991 in the U.S. and bachelor degree of biology from Beijing Normal University (北京師範大學) in July 1984 in the PRC. Dr. Wang was awarded many prizes in his professional field, including the Shaw Prize in Life Science and Medicine by the Shaw Prize Foundation (邵逸夫基金會) in September 2006, the Qiu Shi Science and Technologies Prize by the Qiu Shi Science and Technologies Foundation (求是科技基金會) in August 2013, and the King Faisal Prize in Science by the King Faisal Foundation, Saudi Arabia in 2020.

Mr. Ting XIAO (肖汀), aged 34, was appointed as a non-executive Director on March 16, 2021. He is primarily responsible for providing guidance and advice on the corporate and business strategies of our Group. Mr. Xiao joined our Group on October 17, 2019 as a director of Sichuan Clover.

Mr. Xiao has worked at Delos Advisors Limited, a venture capital investment fund, as the principal since January 2017 and as an investment professional from June 2015 to January 2017. From December 2010, he once worked in Goldman Sachs as an associate. From July 2008 to December 2010, Mr. Xiao worked at China International Capital Corporation Limited (中國國際金融股份有限公司) as an analyst.

Mr. Xiao obtained his bachelor’s degree in international economy and trade from Shanghai Jiao Tong University (上海交通大學) in July 2008. Mr. Xiao is a Chartered Financial Analyst (CFA) and a Financial Risk Manager (FRM), and he obtained the qualifications from the Chartered Financial Analyst Institute in September 2018 and the Global Association of Risk Professionals in March 2014, respectively.

Mr. Dong LYU (呂東), aged 46, was appointed as a non-executive Director on March 16, 2021. He is primarily responsible for providing guidance and advice on the corporate and business strategies of our Group.

From July 2011 to July 2016, Mr. Lyu worked at Shanghai Panxin Equity Investment Management Co., Ltd. (上海磐信股權投資管理有限公司) as a vice president. From September 2016 to September 2020, he served as a managing director at PAG Growth (Zhuhai) Holding Investment Management Co., Ltd (太盟成長(珠海)股權投資管理有限公司). Subsequently, in September 2020, Mr. Lyu joined Zhuhai Hillhouse Investment Management Holding Co., Ltd (珠海高瓴股權投資管理有限公司), where he currently serves as a managing director. He has also been a non-executive director at Jacobio Pharmaceuticals Group Co., Ltd. (加科思藥業集團有限公司), a company whose shares are listed on the Stock Exchange (stock code: 01167), since November 2020.

DIRECTORS AND MANAGEMENT

Mr. Lyu obtained his bachelor’s degree in pharmacy from Beijing Medical University (北京醫科大學) (currently known as the Peking University Health Science Center (北京大學醫學部)) in July 1996 in the PRC, his master’s degree in pharmaceutics from Peking University (北京大學) in June 2003 in the PRC, and his doctor degree in social and administrative pharmacy from China Pharmaceutical University (中國藥科大學) in June 2010 in the PRC.

Independent Non-executive Directors

Dr. Xiaobin WU, aged 59, was appointed as an independent non-executive Director on April 19, 2021 with effect from September 26, 2021. He is primarily responsible for supervising and providing independent judgement to our Board.

Dr. Wu has more than 25 years of rich experience in the pharmaceutical industry, including 17 years leading China operations of multinational companies, with expertise in integrated research and development, strategy, commercialization and general management. Prior to joining our Group, Dr. Wu took the role of global president and general manager of BeiGene, Ltd. (“**BeiGene**”), a Stock Exchange listed company (stock code: 6160), since May 2018. Before joining BeiGene, Dr. Wu served as the country manager of Pfizer China; and regional president of Pfizer Essential Health in Greater China Region from October 2009 to April 2018. Dr. Wu has led Pfizer China business with focus and integrity, building an incredible business and establishing a strong culture of compliance. Under his leadership, Pfizer China experienced a significant growth, developed a clear vision and strategy, which transformed the business and organization to new heights, and established its position as a leading multinational pharmaceutical company in China, also becomes a significant contributor to China’s healthcare system. Dr. Wu is widely recognized as an industry opinion leader in China, he actively worked with industry associations, helped to shape and influence the environment to ensure Chinese patients have access to high-quality medicines and vaccines.

Prior to Pfizer, Dr. Wu served as president and managing director of Wyeth China and Hong Kong from 2004 to 2009. Before joining Wyeth, Dr. Wu served as the general manager of Bayer Healthcare in China from 2001 to 2004. He started his career in 1992 in sales & marketing, also in headquarters’ functions with Bayer in Germany.

Dr. Wu was elected as the vice chairman of China Pharmaceutical industry Research and Development Association since 2019. He is also a research fellow at Research Center of National Drug Policy and Ecosystem. Dr. Wu served as the vice chairman of the R&D Based Pharmaceutical Association Committee (RDPAC) in China from 2008 to 2018. In addition to his duties in industrial associations, Dr. Wu is frequently awarded with industry awards, including being voted as “Person of the Year” in Healthy China Award 2017, won the award of “2017 Top 10 Most Influential Person in Chinese Healthcare Industry” and “2017 Social Responsibility Eminent Person Award”

Dr. Wu obtained Ph.D. in biochemistry and pharmacology in April 1993 and a master’s degree in molecular biology in January 1990 from the University of Konstanz in Germany.

DIRECTORS AND MANAGEMENT

Mr. Xiang LIAO, aged 56, was appointed as an independent non-executive Director on April 19, 2021 with effect from September 26, 2021. He is primarily responsible for supervising and providing independent judgement to our Board.

In addition to his position in our Company, Mr. Liao has served as the chief executive officer of NovaStream Biotech Co., Ltd. (北京欣生禾生物科技有限公司) since March 2012. From January 2008 to January 2012, he worked for Novartis Vaccines. From May 1992 to December 2007, he worked for Sanofi Pasteur, a biotechnology company, where he served various positions with last one being a corporate development director.

Mr. Liao obtained his bachelor’s degree in medicine from West China University of Medical Sciences (華西醫科大學) in July 1987 in the PRC and his master’s degree in biochemistry from the University of Scranton in August 1992 in the U.S. He obtained his master in business administration in Columbia University in October 2003 in the U.S.

Mr. Jeffrey FARROW, aged 59, was appointed as an independent non-executive Director on April 19, 2021 with effect from September 26, 2021. He is primarily responsible for supervising and providing independent judgement to our Board.

In addition to his position in our Company, Mr. Farrow also serves as the chief financial officer of Global Blood Therapeutics, Inc., a company whose shares are listed on the NASDAQ (ticker symbol: GBT). From June 2015 to March 2016, he worked for ZS Pharma, Inc., a biotechnology company, as its chief financial officer. From November 2009 to May 2015, he first worked as the vice president of finance and then the chief financial officer of Hyperion Therapeutics, Inc. From May 2008 to December 2009, he served as the vice president of finance of Evotec, a biotechnology company listed on Frankfurt Stock Exchange (ticker symbol: EVT), where he was mainly responsible for US finance operations and SEC filings. From January 2004 to July 2007, he first worked as the senior director of finance and then the vice president of finance and chief accounting officer at Renovis Health Corp. (a company acquired by Evotec in 2008). From July 1996 to January 2004, he worked for KPMG with his last position being a senior manager.

Mr. Farrow obtained his bachelor’s degree in business administration with a concentration in finance from California State University of Fullerton in June 1993 in the U.S. Mr. Farrow obtained the Certified Public Accountant license from California Board of Accountancy in May 2002 in the U.S.

DIRECTORS AND MANAGEMENT

Mr. Thomas LEGGETT, aged 44, was appointed as an independent non-executive Director on April 19, 2021 with effect from September 26, 2021. He is primarily responsible for supervising and providing independent judgement to our Board.

In addition to his position in our Company, Mr. Leggett also serves as the chief financial officer of Black Diamond Therapeutics, Inc., a company whose shares are listed on the NASDAQ (ticker symbol: BDTX). By August 2019, he once worked for a NASDAQ listed company, Axcella Health, Inc. (ticker symbol: AXLA) as its chief financial officer. From May 2015, he once worked as the treasurer & head of business development finance of Purdue Pharma L.P., a pharmaceuticals company. From November 2009 to May 2015, he first served as a director and then as an executive director of UBS Securities, where he was mainly responsible for providing corporate finance and strategic advisory services to life sciences clients. From January 2007, he worked at Lazard Freres & Co., an investment bank. From August 2004 to January 2007, he worked for J.P. Morgan Securities as an associate.

Mr. Leggett obtained his bachelor’s degree in economics from Columbia University in May 1999 and his master of business administration from the Wharton School of the University of Pennsylvania in May 2004 in the U.S.

SENIOR MANAGEMENT

Mr. Joshua LIANG, aged 29, was appointed as our chief executive officer on December 25, 2020. Please refer to the section headed “– Board of Directors – Executive Directors” for his biography.

OTHER MANAGEMENT

Name	Age	Position	Date of joining our Group	Date of appointment as a management	Roles and responsibilities
Ms. Htay Htay HAN	53	Chief medical officer (vaccine)	February 3, 2021	February 3, 2021	Responsible for the clinical development of our vaccine candidates of our Group

DIRECTORS AND MANAGEMENT

Name	Age	Position	Date of joining our Group	Date of appointment as a management	Roles and responsibilities
Dr. Philippe BISHOP	56	Chief medical officer (oncology)	December 28, 2020	December 28, 2020	Responsible for the clinical development of our oncology and Fc-fusion product candidates of our Group
Dr. Xiaobing LI	53	Executive vice president	July 27, 2020	July 27, 2020	Leading product development and program & portfolio management of our Group
Dr. Michael BERRY	56	Chief technical operation officer	March 15, 2021	March 15, 2021	Responsible for manufacturing, supply chain, and quality of our Group
Mr. Phillip Eric LEE	34	Chief financial officer and chief business officer	January 7, 2021	January 7, 2021	Responsible for finance and accounting, corporate strategy, business development, human resources, information technology and investor relations of our Group
Mr. Brian KREX	54	General counsel	February 3, 2021	February 3, 2021	Legal affairs of our Group

DIRECTORS AND MANAGEMENT

Ms. Htay Htay HAN, aged 53, was appointed as our chief medical officer (vaccine) in February 2021. She is primarily responsible for the clinical development of our vaccine candidates of our Group.

Prior to joining our Group, from December 1992 to June 2016, Ms. Han served at GSK Vaccines as a project level, clinical research and development lead, where she mainly responsible for global clinical development of vaccine programs. From June 2016 to August 2020, she worked at Takeda Pharmaceuticals Inc. as a senior medical director (early programs).

Ms. Han obtained her bachelor of medicine and bachelor of surgery degrees in March 1987 from Institute of Medicine (1), Rangoon University in Myanmar.

Dr. Philippe BISHOP, aged 56, was appointed as our chief medical officer (oncology) in December 2020. He is primarily responsible for the clinical development of our oncology and Fc-fusion product candidates of our Group.

Prior to joining our Group, Dr. Bishop worked at National Cancer Institute of National Institutes of Health as a medical oncologist and associate investigator from June 1999 to February 2003. He also worked at U.S. Food and Drug Administration as a medical officer from December 1999 to February 2003. From February 2003 to January 2005, Dr. Bishop served at Sanofi-aventis, a pharmaceutical company in the U.S., as a global clinical director, where he mainly responsible for product development. From January 2005, he served as a senior director at Johnson & Johnson Pharmaceutical Research & Development, L.L.C. From December 2007, he worked at Genentech, Inc., a biotechnology company, as a vice president responsible for development of oncology. From December 2014, he worked at Gilead Sciences, Inc. as a senior vice president responsible for heading hematology/oncology in Research & Development Executive Administrative department. From May 2017, he served as the executive vice president and chief medical officer of ARATINGA.BIO, INC.

Dr. Bishop obtained his bachelor's degree of science in biology from Loyola Marymount University in May 1985 in the U.S. and doctor of medicine in May 1993 from University of Nevada School of Medicine in the U.S.

Dr. Xiaobing LI, aged 53, was appointed as our executive vice president in July 2020. She is the head of product development and program & portfolio management of our Group.

DIRECTORS AND MANAGEMENT

Prior to joining our Group, Dr. Li served several positions in Janssen Pharmaceuticals, Inc., a pharmaceutical company whose shares are listed on the New York Stock Exchange (stock symbol: JNJ), including scientist and director from October 1996 to September 2010. From September 2010 to July 2014, she worked at Alkermes Plc, a pharmaceutical company whose shares are listed on the NASDAQ (stock symbol: ALKS), where she was mainly responsible for global program lead and execution as a director. From July 2014 to March 2016, she worked at Ironwood Pharmaceuticals, Inc., a pharmaceutical company whose shares are listed on the NASDAQ (stock symbol: IRWD) as a senior director. From April 2016 to May 2018, Dr. Li served as a senior director and development team lead of SAGE Therapeutics Inc, a pharmaceutical company whose shares are listed on the NASDAQ (stock symbol: SAGE). From May 2019, she served as a vice president of program management at Voyager Therapeutics Inc, a pharmaceutical company whose shares are listed on the NASDAQ (stock symbol: VYGR).

Dr. Li obtained her bachelor’s degree in chemistry from Nankai University (南開大學) in July 1989 in the PRC, Ph.D. in organic chemistry from Princeton University in January 1994 in the U.S., and the master of business administration from Colorado State University in May 2012 in the U.S. Dr. Li obtained the project management professional certificate from Project Management Institute in July 2005 in the U.S.

Dr. Michael BERRY, aged 56, was appointed as our chief technical operation officer in March 2021. He is primarily responsible for manufacturing, supply chain, and quality of our Group.

Prior to joining our Group, Dr. Berry served as a director in ARCA Bio Pharma Inc., where he was engaged in managing process development, technology transfer and scale-up and manufacturing of drug substance, from April 2005 to May 2009. From April 2010 to September 2013, he worked in Novartis Diagnostics as a director of manufacturing sciences and technology. From October 2013 to February 2015, he worked at Portola Pharmaceuticals as a senior director of bioprocess development. From February 2015 to August 2017, he worked at Dynavax Technologies as a vice president responsible for development and manufacturing sciences.

Dr. Berry obtained his bachelor’s degree of science in life sciences from Leicester Polytechnic in June 1985 in the U.K., his master’s degree in chemical engineering, applied biochemistry and molecular biology of science from Victoria University of Manchester in July 1987 in the U.K., and his Ph.D. in microbiology from University of Manitoba in May 1996 in Canada.

Mr. Phillip Eric LEE, aged 34, was appointed as our chief financial officer and chief business officer in January 2021. He is primarily responsible for finance and accounting, corporate strategy, business development, human resources, information technology and investor relations of our Group.

DIRECTORS AND MANAGEMENT

Prior to joining our Group, Mr. Lee served at Merrill Lynch as an analyst from July 2008 to May 2009, where he mainly advised the biotech industry. From June 2009 to July 2015, he served in positions of increasing responsibility at Centerview Partners LLC, an investment bank, with his last position being a principal. From August 2015 to January 2016, he worked at Avalanche Biotech, a NASDAQ listed company (stock symbol: ADVM), as an associate director, where he was mainly responsible for financial planning and analysis. From December 2015 to March 2018, he joined Cytokinetics, Inc., a pharmaceutical company whose shares are listed on the NASDAQ (stock symbol: CYTK), as a director and was subsequently promoted to senior director since November 2017. From April 2018 to January 2021, he served as a senior director and was subsequently promoted to vice president at 4D Molecular Therapeutics, Inc., a biotech company whose shares are listed on the NASDAQ (stock symbol: FDMT), where he was mainly responsible for overseeing the finance function.

Mr. Lee obtained his bachelor’s degrees in business administration and electrical engineering computer science from University of California, Berkeley in May 2008 in the U.S.

Mr. Brian KREX, aged 54, was appointed as our general counsel in February 2021. He is primarily responsible for legal affairs of our Group.

Prior to joining our Group, Mr. Krex worked at Moses & Singer LLP, a law firm, as an associate from November 2000 to March 2006. From April 2006 to March 2015, he worked at Pfizer Inc, serving in a variety of positions of increasing seniority, with a final position as chief counsel of the U.S. Innovative Business Unit. From April 2015 to March 2019, he served as the head of commercial and regulatory law department for Alexion Pharmaceuticals, Inc. From March 2019 to September 2020, he served as the general counsel of AGTC.

Mr. Krex obtained his bachelor degree in American history from Bard College in May 1990 in the U.S and his juris doctor degree in law from Seton Hall University School of Law in June 1996 in the U.S.

JOINT COMPANY SECRETARIES

Mr. Brian KREX, aged 54, one of our joint company secretaries, was appointed on April 19, 2021, Mr Krex is also our general counsel. For details, please see “– Management Team” above.

Ms. Po Ting FUNG (馮寶婷), was appointed as the joint company secretary of the Company on April 19, 2021. Ms. Fung currently serves as an assistant manager of corporate services of Vistra Corporate Services (HK) Limited. She has over 11 years of experience in providing company secretarial services to a portfolio of clients including public listed companies and private companies.

Ms. Fung has been an associate member of The Hong Kong Institute of Chartered Secretaries and an associate member of The Chartered Governance Institute in United Kingdom since November 2020.

DIRECTORS AND MANAGEMENT

Ms. Fung obtained her master’s degree in Corporate Governance and her bachelor’s degree in Corporate Administration of Business Administration from The Open University of Hong Kong in 2020 and 2016, respectively.

BOARD COMMITTEES

Our Company has established three committees under the Board pursuant the corporate governance practice requirements under the Hong Kong Listing Rules, including the Audit Committee, the Remuneration Committee and the Nomination Committee.

Audit Committee

We have established the Audit Committee in compliance with Rule 3.21 of the Listing Rules and the Corporate Governance Code set out in Appendix 14 to the Listing Rules. The primary duties of the Audit Committee are to review and supervise the financial reporting process and internal controls system of the Group, review and approve connected transactions and to advise the Board. The Audit Committee comprises three independent non-executive Directors, namely Mr. Thomas Leggett, Mr. Jeffrey Farrow and Mr. Ting Xiao. Mr. Jeffrey Farrow is appropriately qualified as required under Rules 3.10(2) and 3.21 of the Listing Rules.

Remuneration Committee

We have established the Remuneration Committee in compliance with Rule 3.25 of the Listing Rules and the Corporate Governance Code set out in Appendix 14 to the Listing Rules. The primary duties of the Remuneration Committee are to review and make recommendations to the Board regarding the terms of remuneration packages, bonuses and other compensation payable to our Directors and senior management. The Remuneration Committee comprises two independent non-executive Directors and one non-executive Director, namely Dr. Xiaobin Wu, Mr. Xiang Liao and Dr. Xiaodong Wang. Dr. Xiaobin Wu is the chairman of the committee.

Nomination Committee

We have established the Nomination Committee in compliance with the Code on Corporate Governance set out in Appendix 14 to the Listing Rules. The primary duties of the Nomination Committee are to make recommendations to our Board regarding the appointment of Directors and Board succession. The Nomination Committee comprises one executive Director and two independent non-executive Directors, namely Dr. Peng Liang, Mr. Thomas Leggett and Dr. Xiaobin Wu. Dr. Peng Liang is the chairman of the committee.

BOARD DIVERSITY POLICY

In order to enhance the effectiveness of our Board and to maintain the high standard of corporate governance, we have adopted the board diversity policy (the “**Board Diversity Policy**”) which sets out the objective and approach to achieve and maintain diversity of our Board. Pursuant to the Board Diversity Policy, we seek to achieve the diversity of the Board

DIRECTORS AND MANAGEMENT

through the consideration of a number of factors when selecting the candidates to our Board, including but not limited to gender, skills, age, professional experience, knowledge, cultural, education background, ethnicity and length of service. The ultimate decision of the appointment will be based on merit and the contribution which the selected candidates will bring to our Board.

We have taken, and will continue to take, steps to promote gender diversity at all levels of our Company, including but not limited to our Board and the senior management levels. In particular, Ms. Htay Htay Han, our chief medical officer (vaccine) responsible for the clinical development of our vaccine candidates of our Group, and Dr. Xiaobing Li, our executive vice president responsible for product development and program & portfolio management of our Group, are female and form part of our management team. Going forward, we will continue to work to enhance gender diversity of our Board. Our Board will use its best endeavors to appoint female directors to our Board after [REDACTED] (keeping in mind the importance of management continuity and the timeline for retirement and reappointment of Directors under the Articles) and our Nomination Committee will use its best endeavors and on suitable basis to identify and recommend multiple suitable female candidates to our Board for its consideration on appointment of a Director after the [REDACTED]. We will also continue to ensure that there is gender diversity when recruiting staff at mid to senior level so that we will have a pipeline of female management and potential successors to our Board in due time to ensure gender diversity of our Board. Our Group will continue to emphasize training of female talent and providing long-term development opportunities for our female staff.

Our Directors have a balanced mix of knowledge and skills, including in biochemistry, pharmaceuticals, business development, research and development, investment management and corporate finance. They obtained degrees in various majors including biology, pharmaceuticals, economics and business development, among others. We have four independent non-executive Directors with different industry backgrounds, representing more than one third of the members of our Board.

Our Nomination Committee is responsible for ensuring the diversity of our Board members. After the [REDACTED], our Nomination Committee will monitor the implementation of the Board Diversity Policy and review the Board Diversity Policy from time to time to ensure its continued effectiveness and we will disclose in our corporate governance report about the implementation of the Board Diversity Policy on an annual basis.

KEY TERMS OF EMPLOYMENT CONTRACTS

We normally enter into employment contracts, confidentiality agreements and noncompetition agreements with our senior management members and other key personnel. Below sets forth the key terms of these contracts we enter into with our senior management and other key personnel.

DIRECTORS AND MANAGEMENT

Non-competition

Within 24 months from the date of the employee’s departure (the “**Non-compete Period**”) and during the course of employment by our Group, he/she shall not, among others, (i) be engaged by, hold equity or beneficiary interests in, receive services or benefit from, provide services or consultation to, or cooperate with any entity that (a) competes with us or (b) is invested or controlled, directly or indirectly, by the entities that compete with us, (ii) engage in any business that competes with us, or (iii) directly or indirectly, in any other entity, hold positions that are the same or similar to the position held by the employee in our Group. In addition, the employee shall not have any business connection with any our customer during the Non-compete Period.

We will pay monthly compensation to the relevant employee during the Non-compete Period.

Confidentiality

The employee shall keep in confidence and shall not disclose our trade secrets, including but not limited to our technical information and operational information in confidence during the term of their employment and thereafter.

Service Invention

The intellectual property rights in any invention, work or non-patent technical result that is (i) resulted from performing employee duties or (ii) developed mainly using our material, technologies and information shall belong to us.

COMPLIANCE ADVISER

We have appointed Somerley Capital Limited as our compliance adviser (the “**Compliance Adviser**”) pursuant to Rule 3A.19 of the Listing Rules. Our Compliance Adviser will provide us with guidance and advice as to compliance with the Listing Rules and applicable Hong Kong laws. Pursuant to Rule 3A.23 of the Listing Rules, our Compliance Adviser will advise our Company in certain circumstances including:

- (a) before the publication of any regulatory announcement, circular, or financial report;
- (b) where a transaction, which might be a notifiable or connected transaction, is contemplated, including share issues and share repurchases;
- (c) where we propose to use the [REDACTED] of the [REDACTED] in a manner different from that detailed in this document or where the business activities, development or results of our Group deviate from any forecast, estimate or other information in this document; and

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- (d) where the Stock Exchange makes an inquiry to our Company regarding unusual movements in the price or trading volume of its listed securities or any other matters in accordance with Rule 13.10 of the Listing Rules.

The term of appointment of our Compliance Adviser shall commence on the [REDACTED] and is expected to end on the date on which we comply with Rule 13.46 of the Listing Rules in respect of our financial results for the first full financial year commencing after the [REDACTED].

DIRECTORS’ REMUNERATION

For details on the service contracts and appointment letters signed between the Company and our Directors, please refer to the section “Statutory and General Information – C. Further Information about Our Directors – 1. Particulars of Directors’ Service Contracts and Appointment Letters” in Appendix IV to this document.

For the years ended December 31, 2019, 2020 and the four months ended April 30, 2021, the total amount paid by us for payments of emoluments, salaries, allowances, discretionary bonus, defined contribution retirement plans and other benefits in kind (if applicable) to Directors were approximately RMB3.0 million, RMB7.3 million and RMB2.4 million, respectively. For remuneration details of all Directors during the Track Record Period, please refer to Note 8 to the Accountants’ Report as set out in Appendix I to this document.

According to existing effective arrangements, the total amount of remuneration (excluding any possible payment of discretionary bonus) shall be paid by us to Directors for the financial year ending December 31, 2021 is expected to be approximately RMB5.0 million.

The remuneration of Directors has been determined with reference to the salaries of comparable companies and their experience, duties and performance.

For each of the years ended December 31, 2019, 2020 and the four months ended April 30, 2021, the five highest remunerated individuals of our Company included two, two and nil Directors, whose remunerations were included in the total amount paid by us for the emoluments, salaries, allowances, discretionary bonus, defined contribution retirement plans and other benefits in kind (if applicable) of the relevant Directors. For the years ended December 31, 2019, 2020 and the four months ended April 30, 2021, the total amount of remuneration and benefits in kind (if applicable) paid by us to the five highest remunerated individuals were approximately RMB8.0 million, RMB17.3 million and RMB11.6 million, respectively.

During the Track Record Period, no remuneration was paid by us nor receivable by Directors or the five highest remunerated individuals as incentives for joining or as rewards upon joining our Company. During the Track Record Period, no remuneration was paid by us nor receivable by Directors, past Directors or the five highest remunerated individuals as compensation for leaving positions relating to management affairs in any subsidiary of the Company.

DIRECTORS AND MANAGEMENT

During the Track Record Period, none of our Directors has waived any remuneration. Save as disclosed above, during the Track Record Period, no other amounts shall be paid or payable by us or any of our subsidiaries to the Directors or the five highest remunerated individuals. Certain of our Directors were granted with restricted share unites under the RSU Scheme. For details of the restricted share units granted, please see “Appendix IV – Statutory and General Information – D. Share Incentive Plans – 2. RSU Scheme.”

Save as disclosed above, no Director is entitled to receive other special benefits from the Company.

CONNECTED TRANSACTIONS

OVERVIEW

Prior to the [REDACTED], our Group has entered into certain transactions with parties who will, upon the [REDACTED], become connected persons of the Company. Details of such one-off connected transaction and continuing connected transactions of our Company following the [REDACTED] are set out below.

RELEVANT CONNECTED PERSONS

Connected Persons	Connected relationship
Chengdu Tianhe	<p>Ms. Shibi Wang, who resigned as the director of Sichuan Clover on March 23, 2021 and thus a former director of Sichuan Clover within the 12 months prior to the Latest Practicable Date, holds 78% of the equity interests in Chengdu Tianhe. Therefore, Chengdu Tianhe is an associate of Ms. Shibi Wang.</p> <p>Ms. Shibi Wang resigned as the director of Sichuan Clover due to personal reasons and unrelated to the Pre-[REDACTED] Investments in the Company. She has confirmed that she has no dispute with the Group during the Track Record Period and up to the Latest Practicable Date. The Group is not aware of any other matters on Ms. Wang’s resignation that needs to be brought to the attention of the Company’s shareholders and the Stock Exchange.</p>
GenHunter	<p>Dr. Liang, our executive Director and Substantial Shareholder, wholly owns GenHunter. Therefore, GenHunter is an associate of Dr. Liang.</p>

ONE-OFF CONNECTED TRANSACTION

Property Lease Agreement

Description of the Transaction

Our Company entered into property lease agreements (the “**Property Lease Agreements**”) with Chengdu Tianhe, pursuant to which, our Group has leased properties with a total gross area of approximately 3,300 sq.m. located at Chengdu Life and Pharmaceutical Industrial Incubator, Chengdu, Sichuan, PRC (the “**Properties**”) from Chengdu Tianhe primarily for its use as offices and pre-clinical laboratories. The Property Lease Agreements were entered into (i) in the ordinary and usual course of business of our Group, (ii) on arm’s length basis, and (iii) on normal commercial terms with the rents being agreed with reference to the prevailing markets rates. The value of the lease liabilities which includes the present value of the lease payments recognized by our Company according to IFRS 16 as at December 31, 2020 amounted to RMB9.0 million.

The lease and utility fees attributable to Chengdu Tianhe in relation to the leasing of properties for the two years ended December 31, 2019 and 2020 and the four months ended April 30, 2021 amounted to approximately RMB1.4 million, 2.7 million and RMB1.1 million, respectively.

CONNECTED TRANSACTIONS

Reasons and benefits of the transaction

It is a common practice in the pharmaceutical industry that a pre-profit biotech company, like us, operates by leasing properties instead of constructing its own properties, so as to input a substantial part of its cash flow into research and development activities.

We have been leasing the Properties from Chengdu Tianhe for operation and research and development during the Track Record Period. Given any relocation of facility or change of the current arrangements under the Property Lease Agreements may cause disruption to our business operation and incur additional relocation costs, it is cost efficient and beneficial to our operations to continue to lease the Properties from Chengdu Tianhe. In light of the above, our Directors are of the view that such arrangement is fair and reasonable and in the best interest of our Group and our Shareholders as a whole.

Listing Rules Implications

In accordance with IFRS 16 “Leases” (which became effective from 1 January 2019), the Company recognised a right-of-use asset on its balance sheet in connection with the lease of the properties from Chengdu Tianhe. Therefore, the entering into of the Property Lease Agreements by the Company will be regarded as an acquisition of a capital asset and a one-off connected transaction of the Company for the purposes of the Listing Rules. Accordingly, the reporting, announcement, annual review and independent shareholders’ approval requirements in Chapter 14A of the Listing Rules will not be applicable.

NON-EXEMPT CONTINUING CONNECTED TRANSACTION

Following the [REDACTED], the following transaction will be regarded as a continuing connected transaction subject to the reporting, annual review, announcement, circular and independent shareholders’ approval requirements under Chapter 14A of the Listing Rules.

License Agreement

Principal Terms

Pursuant to the license agreement entered into between GenHunter, being the licensor, and Sichuan Clover, being the licensee, dated October 14, 2019 (the “**License Agreement**”), GenHunter agreed to grant to Sichuan Clover, and Sichuan Clover agreed to accept, worldwide (the “**Territory**”) and in the field (the “**Field**”) of all biological drug products and research & development applications an exclusive license under relevant patents and patent applications, trademarks, and copyrights related to Trimer-Tag™ technology platform (together the “**GenHunter IP Rights**”) to develop, manufacture and commercialize drug products (including the right to grant sublicense subject to GenHunter’s approval). In consideration, Sichuan Clover agreed to pay GenHunter (i) a royalty of 2% on net sales of drug products (the “**Products**”) developed by the Group using the GenHunter IP Rights (the “**Net Sales Royalty**”) and (ii) a royalty of 20% of sublicense income (the “**Sublicense Income Royalty**”).

CONNECTED TRANSACTIONS

Reasons for and Benefits of the Transaction

As disclosed in the section headed “Business – Licensing and Collaboration Arrangements – License Agreement with GenHunter” of this document, GenHunter and Sichuan Clover entered into the License Agreement to ensure that the GenHunter IP Rights could be fully utilized by Sichuan Clover in development, manufacture and commercialization of the Products. As a result of the License Agreement, our Group held all of the relevant intellectual property rights to carry out our principal businesses and GenHunter would be able to benefit from the potential Net Sales Royalty and Sublicense Income Royalty generated thereunder. Therefore, our role and the role of GenHunter are complementary and beneficial to each other. As confirmed by Frost & Sullivan, the License Agreement (including the Net Sales Royalty and the Sublicense Income Royalty contemplated thereunder) is in line with the industry prevailing practice. Therefore, our Directors are of the view that such arrangements are in the best interest of our Group and our Shareholders as a whole.

Term of the License Agreement

Pursuant to the License Agreement, unless terminated under the provisions therein, it shall remain in the effect until the later of (i) the last patent or patent application related to Trimer-Tag™ technology platform that have been or will be filed and controlled by GenHunter has expired or been abandoned; or (ii) receipt of the final royalty payment to GenHunter from Sichuan Clover pursuant to the royalty payment arrangement under the License Agreement, details of which are set forth under the section “Business – Licensing and Collaboration Arrangements – License Agreement with GenHunter” of this document. Under Rule 14A.52 of the Listing Rules, the period of an agreement for a continuing connected transaction must be fixed. However, the term of the License Agreement is for an unspecified term since it will, unless terminated in accordance with its terms, continue in full force.

The Joint Sponsors are of the view that, based on the due diligence they have conducted and taking into consideration (i) the reasons for entering into the License Agreement as set out above; (ii) the market practice in the biotech industry for similar license agreement, and the confirmation from Frost & Sullivan; and (iii) the fact that the relevant arrangements were negotiated on an arm’s length basis, it is reasonable for the License Agreement to be entered into for a term which will continue until terminated in accordance with their respective terms, and it is normal business practice for agreements of this type to be of such duration.

We have applied for, and the Stock Exchange [has granted], a waiver from strict compliance with Rule 14A.52 of the Listing Rules such that the term of the License Agreement can be of an unspecified term based on the grounds that (a) the License Agreement allows our Group to leverage our ability to develop, manufacture and commercialize biological drug products and GenHunter to benefit from the royalty generated from the net sales of Products and sublicense income, both of which are long term in nature. Imposing a restriction on the term of the License Agreement for a period of three years would deviate from the market prevailing practice and be contrary to the business intention of the parties; (b) such a unspecified term of cooperation is in the interest of our Company and the Shareholders as a whole; and (c) we can terminate the License Agreement by giving prior written notice to GenHunter within a prescribed period of time.

CONNECTED TRANSACTIONS

Such waiver is subject to the following conditions: (a) the Company will disclose in this document the major reasons for the License Agreement to be for an unspecified term and details of the waiver; and (b) the Company will re-comply with the applicable requirements of the Listing Rules for setting the annual caps for the transactions under the License Agreement before the expiry of the initial term of three years, during which a waiver in relation to the reporting, announcement and independence shareholders' approval requirements under Chapter 14A of the Listing Rules in respect of the transactions under the License Agreement has been applied for.

Historical Transaction Amounts

As (i) no Product has been approved for commercialization by the relevant authorities and (ii) Sichuan Clover has not granted any sublicense pursuant to the License Agreement, there was no historical amount paid by our Group to GenHunter pursuant to the License Agreement.

Annual Caps

We have set the annual caps for (i) the Net Sales Royalty and (ii) the Sublicense Income Royalty based on the formulas below.

(i) Net Sales Royalty

The amount of the Net Sales Royalty to be paid by Sichuan Clover to GenHunter will be determined in accordance with the following formula:

$$\text{Amount of Net Sales Royalty} = 2\% \times \text{net sales of Products}$$

The above formula is fair and reasonable and in the interest of our Company and the Shareholders as a whole because (i) the terms of the License Agreement, including the formula set out above, were determined after arm's length negotiation between GenHunter and Sichuan Clover and in the ordinary and usual course of our business; (ii) as advised by Frost & Sullivan, it is a common practice in the pharmaceutical industry that licensors share with licensees a part of the profit generated from the sales of products developed under licenced intellectual property; and (iii) taking into account the cost of the developing, manufacturing and commercialization of the Products, the percentage of the net sales of Products to be enjoyed by GenHunter is in line with the industry average for arrangement of similar nature, as advised by Frost & Sullivan.

CONNECTED TRANSACTIONS

(ii) *Sublicense Income Royalty*

The amount of the Sublicense Income Royalty to be paid by Sichuan Clover to GenHunter will be determined in accordance with the following formula:

$$\text{Amount of Sublicense Income Royalty} = 20\% \times \text{sublicense income}$$

The above formula is fair and reasonable and in the interest of our Company and the Shareholders as a whole because (i) the terms of the License Agreement, including the formula set out above, were determined after arm's length negotiation between GenHunter and Sichuan Clover and in the ordinary and usual course of our business; (ii) as advised by Frost & Sullivan, it is a common practice in the pharmaceutical industry that licensors share with licensees a part of the profit generated from sublicense; and (iii) the percentage of the sublicense income to be enjoyed by GenHunter is in line with the industry average for arrangement of similar nature, as advised by Frost & Sullivan.

We have applied for a waiver from strict compliance with the requirement under Rule 14A.53 of the Listing Rules so as to allow the Company to set the annual caps in relation to continuing connected transactions under the License Agreement as formulas in accordance with the terms as set out in the License Agreement for an initial term of three years for the following reasons:

- (i) There was no historical amount and sufficient data for us to establish a model to estimate the future sales volume and amount for the Product as none of the Products has been commercialized. It is impractical for the Company to accurately estimate the amount of the royalty to be paid by Sichuan Clover to GenHunter pursuant to the License Agreement as (i) the amount of the net sales of the Products depends on the actual addressable market of the Products, which will in turn depend on various factors including the acceptance by the medical community and patient access, drug pricing, reimbursement and the number of affordable patients and (ii) our Company did not have plans for granting sublicense under the License Agreement as at the Latest Practicable Date. Even if we are able to set up a projection model for calculation purpose, such a model will only present hypothetical predictions, which is not based on scientific analysis using historical data, and could be inaccurate, unreliable and even misleading;
- (ii) Imposing an arbitrary cap on the potential sales volume of the Product and/or the sublicense income does not demonstrate commercial reasonableness and would be counter-productive as far as the interests of our Group, GenHunter as well as their respective shareholders are concerned. In the absence of a factually and mathematically reliable model to estimate the annual net sales of the Products and/or sublicense income, imposing an arbitrary monetary cap may become an arbitrary ceiling on the transaction amount under the License Agreement. In addition, a fixed annual cap is not helpful to incentivize our Group to generate more revenue and profit from selling the Products and/or granting sublicense, and will restrict business

CONNECTED TRANSACTIONS

growth of the two groups, which would go against the commercial objective of the License Agreement. Also, if the actual Net Sales Royalty/Sublicense Income Royalty exceeds the cap, the Group would be suspended from selling the Products and/or granting sublicenses until relevant shareholder approval is obtained, which will affect not only the business of the two groups but also the patients who need the Product for treatment, and further affect the two groups' market recognition among the doctors and hospitals because they are not able to sustain a stable supply of the Products. As far as the transactions are on normal commercial terms, and the percentages prescribed in the formulas for the calculation of the Net Sales Royalty and/or the Sublicense Income Royalty are commercially reasonable and in line with market standards, the interests of our Group, GenHunter and their respective shareholders are protected, and there is no reason or benefit for the two groups to impose such fixed cap.

- (iii) The disclosure of the annual caps in monetary terms would in effect provide Shareholders and investors as well as competitors of our Company with an indication of our Company's estimated revenue. The disclosure of such information is highly sensitive and would therefore put our Company in disadvantageous position in relation to its business operation and competition with other market players; and
- (iv) Instead of setting a fixed annual cap on the Net Sales Royalty and/or the Sublicense Income Royalty, if there is any material change to the percentage prescribed in the formulas for the calculation of the Net Sales Royalty and/or the Sublicense Income Royalty, we will re-comply with the applicable rules under Chapter 14A of the Listing Rules, including seeking independent shareholders' approval where the case may so require, so as to further ensure the interest of the shareholders of both our Company and GenHunter.

The Stock Exchange [has granted] the waiver from strict compliance with the requirement under Rule 14A.53 of the Listing Rules in respect of the continuing connected transactions under the License Agreement subject to the following conditions:

- (i) our Company will comply with the announcement, circular and independent Shareholders' approval requirements under Chapter 14A of the Listing Rules if there is any material change to the terms of the License Agreement;
- (ii) our Company will designate a team to execute and ensure that the transactions in relation to the License Agreement are undertaken in accordance with the terms of the License Agreements;
- (iii) our chief executive officer will use his best endeavours to supervise the compliance with the terms of the License Agreement and applicable Listing Rules requirements to the extent not waived by the Stock Exchange on a regular basis;

CONNECTED TRANSACTIONS

- (iv) the independent non-executive Directors and the auditors of the Company will review the transactions in relation to the License Agreement on an annual basis and confirm in our annual reports the matters set out in Rules 14A.55 and 14A.56 of the Listing Rules, respectively;
- (v) the Company will disclose in the document the background for entering into the License Agreement, the terms of the License Agreement, the grounds for the waiver sought and the Directors' and Joint Sponsors' views on the fairness and reasonableness of the transactions under the License Agreement; and
- (vi) in the event of any future amendments to the Listing Rules imposing more stringent requirements than those as at the date of this document on the above continuing connected transactions, the Company will take immediate steps to ensure compliance with such new requirements.

The waiver set out above is for a term of [three] years ending on December 31, [2023]. The Company will, after taking into account, among other things, the addressable market, the drug pricing and the historical transaction amount of the relevant products, re-assess whether a further waiver is required at the expiry of such initial term.

Independence from GenHunter

Our Directors believe that the risk of Dr. Liang or GenHunter terminating the License Agreement is remote as (i) neither Dr. Liang nor GenHunter has the right to terminate the License Agreement unilaterally; (ii) GenHunter only has limited termination rights under the License Agreement, for example, Sichuan Clover defaults in the performance of its obligations under the License Agreement, becomes insolvent or has a petition in bankruptcy filed for or against it, or is convicted of a felony; and (iii) the termination would not be in the commercial interest of GenHunter given the License Agreement was entered into in its ordinary business and GenHunter would benefit from potential Net Sales Royalty and Sublicense Income Royalty generated thereunder.

Dr. Liang confirms that he does not have any intention to terminate the License Agreement and will not recklessly do so in the future.

Corporate Governance Measures

During the ordinary and usual course of business of our Company, we review potential intellectual property licensing opportunities from time to time. During due diligence, we would request the potential strategic partner to provide information on, including but not limited to, intellectual property, products that are protected by or could be developed under such intellectual property, clinical development and regulatory pathway of such products, and competitive landscape and commercialization plan of such products. In parallel, prior to entering into an intellectual property license agreement, our business development team would perform in-house analyses of the prospect of the products that could be developed under such

CONNECTED TRANSACTIONS

intellectual property and the potential competitive landscape for the territory of interest. Furthermore, our business development team will benchmark the terms of any potential term sheet to third-party licensing arrangements.

In addition, the commercial negotiations with potential licensing partners are led by our chief executive officer, chief business officer, chief financial officer and certain senior management as needed of our Company, who are not interested in the License Agreement and will independently evaluate the terms taking into account all relevant factors as we consider necessary. A decision on whether to enter into license arrangements with another company will be made purely based on commercial considerations and whether we consider it is in the best interest of our Company and Shareholders to enter into such licensing arrangement.

Listing Rules Requirements

As the highest of the applicable percentage ratios (other than the profit ratio) calculated for the purpose of Chapter 14A of the Listing Rules is expected to exceed 5%, the transactions under the License Agreement will constitute a continuing connected transaction subject to reporting, annual review, announcement, circular and independent Shareholders’ approval requirements under Chapter 14A of the Listing Rules.

WAIVER APPLICATION FOR THE NON-EXEMPT CONTINUING CONNECTED TRANSACTION

As the transactions contemplated under the License Agreement are expected to continue on a continuing basis, our Directors consider that compliance with the announcement, circular and independent shareholders’ approval requirements under Chapter 14A of the Listing Rules would be impractical, would add unnecessary administrative costs to us and would be unduly burdensome to us. Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted], a waiver to us under Rule 14A.105 of the Listing Rules from compliance with the announcement, circular and independent shareholders’ approval requirements in respect of the above non-exempt continuing connected transaction. In the event of any future amendments to the Listing Rules imposing more stringent requirements than those applicable as of the Latest Practicable Date on the non-exempt continuing connected transaction referred to above, our Company will take immediate steps to ensure compliance with such new requirements within a reasonable time.

We have applied for, and the Stock Exchange [has granted], a waiver from strict compliance with the requirement under Rule 14A.52 of the Listing Rules such that the term of the License Agreement can be of an unspecified term.

For reasons set out in the paragraph headed “– Non-exempt Continuing Connected Transaction – License Agreement – Annual Caps” above, our Company has applied for, and the Stock Exchange [has granted], a waiver from strict compliance with Rule 14A.53 of the Listing Rules.

CONNECTED TRANSACTIONS

CONFIRMATION FROM OUR DIRECTORS

Our Directors (including our independent non-executive Directors) are of the opinion that (i) the non-exempt continuing connected transaction as set out above has been entered into, and will be carried out, in the ordinary and usual course of business of our Company and on normal commercial terms or better to us and is fair and reasonable and is in the interest of our Company and our Shareholders as a whole; and (ii) the proposed caps in formula are fair and reasonable and in the interest of our Company and our Shareholders as a whole.

CONFIRMATION FROM THE JOINT SPONSORS

The Joint Sponsors are of the view that (i) the non-exempt continuing connected transaction described above, and for which waiver has been sought, has been entered into in the ordinary and usual course of business of our Company on normal commercial terms or better to our Company, and is fair and reasonable and in the interest of the Company and the Shareholders as a whole, and (ii) the proposed caps in formula are fair and reasonable and in the interest of the Company and the Shareholders as a whole.

SUBSTANTIAL SHAREHOLDERS

So far as our Directors are aware, immediately following the completion of the [REDACTED] and the [REDACTED] and assuming that the [REDACTED] and the share options granted under the Pre-[REDACTED] Share Option Plan are not exercised, the following persons will have interests and/or short positions (as applicable) in the Shares or underlying Shares of our Company, which would be required to be disclosed to us and the Stock Exchange pursuant to the provisions of Divisions 2 and 3 of Part XV of the SFO or will, directly or indirectly, be interested in 5% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at the general meetings of the Company or any other members of the Group:

LONG POSITIONS IN THE SHARES OF THE COMPANY

Name of Substantial Shareholder	Nature of interest	Shares held as of the date of this document		Shares held immediately following the completion of the [REDACTED] and [REDACTED]	
		Number of Shares	Approximate percentage	Number of Shares	Approximate percentage
Dr. Liang	Beneficial owner	29,500,000	20.48%	[REDACTED]	[REDACTED]
	Beneficial owner ⁽¹⁾	297,132	0.21%	[REDACTED]	[REDACTED]
	Interest of a party to an agreement ⁽²⁾	2,500,000	1.74%	[REDACTED]	[REDACTED]
	Interest of a party to agreements ⁽³⁾	8,000,000	5.55%	[REDACTED]	[REDACTED]
Mr. Joshua Liang	Beneficial owner	2,500,000	1.74%	[REDACTED]	[REDACTED]
	Beneficial owner ⁽⁴⁾	519,981	0.36%	[REDACTED]	[REDACTED]
	Interest of a party to an agreement ⁽²⁾	29,500,000	20.48%	[REDACTED]	[REDACTED]
	Adviser of a trust ⁽⁵⁾	11,050,000	7.67%	[REDACTED]	[REDACTED]
JNRY ⁽⁶⁾	Beneficial owner	14,113,751	9.80%	[REDACTED]	[REDACTED]
AUT-XXI ⁽⁶⁾	Beneficial owner	10,399,596	7.22%	[REDACTED]	[REDACTED]
Aranda ⁽⁷⁾	Beneficial owner	14,113,751	9.80%	[REDACTED]	[REDACTED]
Shanghai Tianhe ⁽⁸⁾	Beneficial owner	10,000,000	6.94%	[REDACTED]	[REDACTED]
Ms. Shibi Wang ⁽⁸⁾	Interest in controlled corporation	14,380,000	9.98%	[REDACTED]	[REDACTED]
Elasa ⁽⁹⁾	Beneficial owner	10,437,059	7.25%	[REDACTED]	[REDACTED]

SUBSTANTIAL SHAREHOLDERS

Name of Substantial Shareholder	Nature of interest	Shares held as of the date of this document		Shares held immediately following the completion of the [REDACTED] and [REDACTED]	
		Number of Shares	Approximate percentage	Number of Shares	Approximate percentage
Lapam Fund IV ⁽¹⁰⁾	Beneficial owner	7,030,554	4.88%	[REDACTED]	[REDACTED]
Lapam Fund III ⁽¹⁰⁾	Beneficial owner	5,021,824	3.49%	[REDACTED]	[REDACTED]

Notes:

- (1) Referring to the Shares underlying the restricted share units granted to Dr. Liang under the RSU Scheme.
- (2) Pursuant to the Acting-in-concert Deed entered, Dr. Liang and Mr. Joshua Liang agreed to act in concert by aligning their votes at Shareholders’ meetings of the Company. Therefore, they are deemed to be jointly interested in the aggregate number of Shares held by each other.
- (3) Pursuant to the voting proxy agreements entered into on March 16, 2021 by each of Dr. Xiaodong Wang, Mr. Jianwei Zhu, Mr. Pu Jiang and Mr. Zheng Ping (the “Grantors”) and Dr. Liang separately, each of the Grantors granted the voting right of the Shares held by them to Dr. Liang. Therefore, Dr. Liang was deemed to be interested in the Shares held by the Grantors under the SFO.
- (4) Referring to the Shares underlying the restricted share units granted to Mr. Joshua Liang under the RSU Scheme.
- (5) The Core Trust Company Limited is the trustee for the RSU Scheme. Under the trust deed, Mr. Joshua Liang is able to exercise voting rights attached to the Shares held by the Super Novel.
- (6) AUT-XXI is wholly owned by AUT-XXI Holdings Limited (“AUT Holding”). The sole shareholder of AUT Holding is HH IMV Holdings, L.P. (“HH IMV”). The sole limited partner of HH IMV is Hillhouse Fund IV, L.P. (“Hillhouse Fund”), which is managed and controlled by Hillhouse Capital Management, Ltd. (“Hillhouse Capital”). Therefore, each of AUT Holding, HH IMV, Hillhouse Fund, Hillhouse Capital and HH IMV Holdings GP, Ltd. was deemed to be interested in the Shares held by AUT under the SFO.

JNRY is ultimately managed and controlled by Hillhouse Capital. Therefore, each of Hillhouse Capital and HH IMV Holdings GP, Ltd. was deemed to be interested in the Shares held by JNRY under the SFO.
- (7) Aranda Investments Pte. Ltd. (“Aranda”) is a wholly owned subsidiary of Temasek Holdings (Private) Limited (“Temasek Holdings”). As such, Temasek Holdings was deemed to be interested in the Shares held by Aranda under the SFO.
- (8) Chengdu Tianhe is a limited partner and holds 99% of the equity interest in Shanghai Tianhe Shengtai Enterprise Management Partnership (Limited Partnership) (上海天合生泰企業管理合夥企業(有限合夥)) (“Shanghai Tianhe”). Chengdu Tianhe was controlled by Ms. Shibi Wang as to 78% of the equity interests. (成都和濟生健康科技有限公司) (“Chengdu Heji”) is the general partner of Shanghai Tianhe. Chengdu Heji is wholly controlled by (成都標匯檢測技術有限公司) (“Chengdu Biaohui”). Chengdu Biaohui is wholly controlled by Chengdu Tianhe. Therefore, each of Chengdu Tianhe, Chengdu Heji, Chengdu Biaohui and Ms. Shibi Wang was deemed to be interested in the Shares in which Shanghai Tianhe was interested under the SFO.

Sichuan Tianhe is managed by its general partner, Chengdu Ronghui Datong Equity Investment Fund Management Co., Limited (成都融匯大通股權投資基金管理有限公司) (“Ronghui Datong”). Ronghui Datong was controlled by Chengdu Tianhe which held 70% equity interests in Ronghui Datong. Therefore, each of Ronghui Datong and Ms. Shibi Wang was deemed to be interested in the Shares in which Sichuan Tianhe was interested under the SFO.

SUBSTANTIAL SHAREHOLDERS

- (9) Elasa is an exempted company wholly owned by Delos Capital Fund II, LP (“**Delos Capital**”), an exempted limited partnership registered as private fund under the Private Funds Law of the Cayman Islands. Delos Capital is managed by Delos Capital Advisors LLC (“**Delos Advisors**”). Therefore, each of Delos Fund and Delos Advisors was deemed to be interested in the Shares in which Elasa was interested under the SFO.
- (10) Lapam Fund III is a limited partnership established under the laws of the PRC. The general partner of Lapam Fund III is Tibet Lapam Yijing Chuangye Investment Center (Limited Partnership) (西藏龍磐怡景創業投資中心(有限合夥)) (“**Tibet Yijing**”), which is in turn managed by its general partner, Beijing Lapam Investment Management Consulting Center (General Partnership) (北京龍磐投資管理諮詢中心(普通合夥)) (“**Lapam Investment**”). The general partner of Lapam Investment is Mr. Zhihua Yu (余治華). The single largest limited partner of Lapam Investment is Tibet Lapam Management Consulting Center (Limited Partnership) (西藏龍磐管理諮詢中心(有限合夥)) (“**Tibet Lapam Consulting**”) which is controlled by Mr. Zhihua Yu.

Lapam Fund IV is a limited partnership established under the laws of the PRC. The general partner of Lapam Fund IV is Tibet Lapam Consulting that is controlled by Mr. Zhihua Yu. The single largest limited partner of Lapam Fund IV is National Council for Social Security Fund (全國社會保障基金理事會), which is controlled by the State Council of China.

Save as otherwise disclosed herein, our Directors are not aware of any persons who will, immediately following completion of the [REDACTED] and the [REDACTED] (assuming the [REDACTED] and the share options granted under the Pre-[REDACTED] Share Option Plan are not exercised), have any interests and/or short positions in the Shares or underlying shares of our Company which would fall to be disclosed to the Company and the Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO or, will be, directly or indirectly, interested in 5% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of our Company or any other member of our Group.

SHARE CAPITAL

AUTHORIZED AND ISSUED SHARE CAPITAL

The following is a description of the authorized and issued share capital of our Company immediately following the completion of the [REDACTED] and the [REDACTED] (assuming the [REDACTED] and the share options granted under the Pre-[REDACTED] Share Option Plan are not exercised, and each Preferred Share in the Company held by the Pre-[REDACTED] Investors will be redesignated and reclassified into one ordinary Share upon the [REDACTED] becoming unconditional):

Authorized Share Capital

Number of Shares	Nominal Value
<i>As of the date of this document⁽¹⁾:</i>	
2,000,000,000 of US\$0.0001 each	US\$200,000

Issued Share Capital

Number of Shares	Nominal Value
<i>Ordinary Shares in issue as of the date of this document</i>	
61,050,000 of US\$0.0001 each	US\$6,105
<i>Preferred Shares to be converted to Shares on a one-for-one basis</i>	
82,966,389 of US\$0.0001 each	US\$8,296.64
<i>Shares to be issued pursuant to the [REDACTED]:</i>	
[REDACTED] of US\$0.0001 each	US\$[REDACTED]
<i>Shares to be issued pursuant to the [REDACTED]:</i>	
[REDACTED] of US\$0.0001 each	US\$[REDACTED]
<i>Total</i>	
[REDACTED] of US\$0.0001 each	US\$[REDACTED]

Note:

- (1) The Preferred Shares will be converted into Shares on a one to one basis by way of re-designation to Shares on the [REDACTED].

SHARE CAPITAL

ASSUMPTIONS

The above table assumes that the [REDACTED] becomes unconditional and Shares are issued pursuant to the [REDACTED] and the [REDACTED] and that the Shares held by the Pre-[REDACTED] Investors are re-designated into ordinary Shares on a one-to-one basis. It takes no account of any Shares which may be issued or repurchased by our Company pursuant to the general mandates granted to our Directors to issue or repurchase Shares as referred to below or any additional Shares which may be issued pursuant to the Pre-[REDACTED] Share Option Plan.

RANKING

The [REDACTED] will rank *pari passu* in all respects with all Shares currently in issue or to be issued as mentioned in this document, and will qualify and rank in full for all dividends or other distributions declared, made or paid on the Shares in respect of a record date which falls after the date of this document.

CIRCUMSTANCES UNDER WHICH GENERAL MEETINGS ARE REQUIRED

Our Company will have only one class of Shares, namely ordinary Shares, and each ranks *pari passu* with the other Shares upon completion of the [REDACTED] and the [REDACTED].

Pursuant to the Cayman Companies Act and the terms of the Memorandum of Association and Articles of Association, our Company may from time to time by ordinary resolution of Shareholders (i) increase its capital; (ii) consolidate and divide its capital into shares of larger amount; (iii) divide its shares into several classes; (iv) subdivide its shares into shares of smaller amount; and (v) cancel any shares which have not been taken or agreed to be taken. In addition, our Company may subject to the provisions of the Cayman Companies Act reduce its share capital or capital redemption reserve by its shareholders passing a special resolution.

See the section headed “Appendix III – Summary of the Constitution of Our Company and Cayman Islands Company Law” to this document for further details.

SHARE OPTION PLANS

The Company has adopted the Pre-[REDACTED] Share Option Plan and the Post-[REDACTED] Share Option Plan, details of which are set out in “Statutory and General Information – D. Share Incentive Plans” in Appendix IV to this document.

SHARE CAPITAL

GENERAL MANDATE TO ISSUE SHARES

Subject to the [REDACTED] becoming unconditional, our Directors have been granted a general unconditional mandate to allot, issue and deal with Shares with a total number of not more than the sum of:

- 20% of the total number of the Shares in issue immediately following completion of the [REDACTED] and the [REDACTED] (excluding the Shares which may be allotted and issued pursuant to the exercise of the [REDACTED], if any); and
- the total number of Shares repurchased by us under the authority referred to in the paragraph headed “– General Mandate to Repurchase Shares” in this section.

This general mandate to issue Shares will expire at the earliest of:

- the conclusion of the next annual general meeting of our Company unless otherwise renewed by an ordinary resolution of our Shareholders in a general meeting, either unconditionally or subject to conditions;
- the expiration of the period within which our Company’s next annual general meeting is required by the Memorandum of Association and Articles of Association or any other applicable laws to be held; or
- the date on which it is varied or revoked by an ordinary resolution of our Shareholders passed in a general meeting.

See the section headed “Statutory and General Information – A. Further Information about our Group – 4. Written Resolutions Passed by Our Shareholders on [REDACTED], 2021” in Appendix IV to this document for further details of this general mandate to allot, issue and deal with Shares.

GENERAL MANDATE TO REPURCHASE SHARES

Subject to the [REDACTED] becoming unconditional, our Directors have been granted a general unconditional mandate to exercise all the powers of our Company to repurchase our own securities with nominal value of up to 10% of the total number of our Shares in issue immediately following the completion of the [REDACTED] and the [REDACTED] (excluding the Shares which may be allotted and issued pursuant to the exercise of the [REDACTED], if any).

The repurchase mandate only relates to repurchases made on the Stock Exchange, or on any other stock exchange on which our Shares are [REDACTED] (and which are recognized by the SFC and the Stock Exchange for this purpose), and which are in accordance with the Listing Rules. A summary of the relevant Listing Rules is set out in the section headed “Statutory and General Information – A. Further Information about Our Group – 5. Repurchase of Our Own Securities – Provision of the Listing Rules” in Appendix IV to this document.

SHARE CAPITAL

This general mandate to repurchase Shares will expire at the earliest of:

- the conclusion of the next annual general meeting of our Company unless otherwise renewed by an ordinary resolution of our Shareholders in a general meeting, either unconditionally or subject to conditions; or
- the expiration of the period within which our Company’s next annual general meeting is required by the Memorandum of Association and Articles of Association or any other applicable laws to be held; or
- the date on which it is varied or revoked by an ordinary resolution of our Shareholders passed in a general meeting.

See “Statutory and General Information – A. Further Information about our Group – 5. Repurchase of our own securities” in Appendix IV to this document for further details of the repurchase mandate.

FINANCIAL INFORMATION

You should read the following discussion and analysis in conjunction with our audited consolidated information, including the notes thereto, included in the Accountants’ Report set out in Appendix I to this document. Our audited consolidated information has been prepared in accordance with IFRS.

The following discussion and analysis contain forward-looking statements that reflect our current views with respect to future events and financial performance that involve risks and uncertainties. These statements are based on assumptions and analysis made by us in light of our experience and perception of historical events, current conditions and expected future developments, as well as other factors we believe are appropriate under the circumstances. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this document, including those set forth in “Risk Factors” and “Forward-Looking Statements” in this document.

OVERVIEW

Founded in 2007, we are a global clinical-stage biotechnology company committed to developing novel vaccines and biologic therapeutic candidates for infectious diseases as well as cancer and autoimmune diseases. The indications for our lead product in each therapeutic area are COVID-19, malignant ascites and ankylosing spondylitis, respectively. From GenHunter, we in-licensed the Trimer-Tag™ technology platform, a product development platform for the creation of novel vaccines and biologic therapies. We have leveraged the Trimer-Tag™ technology platform to become a COVID-19 vaccine developer and created SCB-2019 (CpG 1018/Alum), one of our Core Products, to address COVID-19 which is caused by SARS-CoV-2. We will potentially become one of the first companies to commercialize a protein-based COVID-19 vaccine globally through the COVAX facility. Leveraging our expertise in protein bioengineering, manufacturing capabilities, and in-house manufacturing facility, we developed another Core Product, SCB-808, for the treatment of rheumatic diseases. Our pipeline also consists of nine additional product candidates in development as of the Latest Practicable Date.

We have built our product pipeline by employing the Trimer-Tag™ technology platform and leveraging our in-house biologics manufacturing infrastructure and capabilities. As of the Latest Practicable Date, our product pipeline consisted of (i) six Trimer-Tag™ subunit vaccine candidates, including SCB-2019 (CpG 1018/Alum), for which we obtained data from SPECTRA, a global pivotal Phase 2/3 clinical trial in September 2021, (ii) two Trimer-Tag™ oncology product candidates, including SCB-313 for which we are conducting five Phase 1 clinical trials in China and Australia, and (iii) three Fc-fusion product candidates, including SCB-808, a Core Product, for which we are conducting a pivotal Phase 3 clinical trial in China. In addition to our existing product pipeline, we will also continue to research and develop innovative biologic therapeutics and vaccines utilizing the Trimer-Tag™ technology platform. For more information, please refer to “Business – Our Product Candidates.”

FINANCIAL INFORMATION

KEY FACTORS AFFECTING OUR RESULTS OF OPERATIONS

Our Ability to Successfully Develop and Commercialize Our Product Candidates

Our business and results of operations depend on our ability to successfully advance development of our product candidates. Factors including the safety and efficacy clinical trial results of our product candidates, the efficacy and safety profile of products generated from the Trimer-Tag™ technology platform, and our ability to obtain the requisite regulatory approvals for our product candidates in time, are crucial for our business and results of operations.

We announced SPECTRA, a global pivotal phase 2/3 clinical trial evaluating the efficacy, safety, and immunogenicity of SCB-2019 (CpG 1018/Alum) met the primary and secondary efficacy endpoints in September 2021. We plan to submit conditional regulatory approval applications for SCB-2019 (CPG 1018/Alum) to the EMA, the NMPA and the WHO in the fourth quarter of 2021. We expect to obtain conditional approvals between the fourth quarter of 2021 and the middle of 2022. Post conditional approval, we expect to commence product launch which may occur as early as year end 2021. We are conducting a pivotal Phase 3 clinical trial for SCB-808, we expect to submit an NDA to the NMPA in the second half of 2023 for SCB-808 and commence commercialization thereafter if approved. We also expect to advance multiple additional products into the clinic in the near-term. These products may require significant marketing efforts before we generate any revenue from product sales. If they fail to achieve a sufficient degree of market acceptance, we may not be able to generate revenue as expected. See “Business – Our Product Candidates” and “Risk Factors – Risks Relating to Our Business and Industry – Risks Relating to Pre-clinical and Clinical Development of Our Product Candidates.”

Operating Expenses

Our business and results of operations are significantly affected by our cost structure, which comprised primarily research and development expenses and administrative expenses during the Track Record Period.

Research and development activities are critical to our business. Our current research and development activities mainly relate to product discovery, preclinical studies and clinical trials of our product candidates. As a result, our research and development expenses primarily consist of clinical trial expenses, staff costs, costs of raw materials and consumables, R&D consultation and service fees and depreciation and amortization in relation to our research and development equipment and facilities. For the years ended December 31, 2019 and 2020 and the four months ended April 30, 2020 and 2021, our research and development expenses accounted for 61.3%, 67.2%, 69.6% and 80.6%, respectively, of our total operating expenses (being research and development expenses, administrative expenses, other expenses and finance costs). We expect our research and development expenses to continue to increase in the foreseeable future as we advance product candidates and programs.

FINANCIAL INFORMATION

Our administrative expenses primarily consist of staff costs, professional service fees, consulting fees, depreciation and amortization, office expenses and [REDACTED] expenses. For the years ended December 31, 2019 and 2020 and the four months ended April 30, 2020 and 2021, our administrative expenses accounted for 22.8%, 22.5%, 28.9% and 17.2%, respectively, of our total operating expenses. We expect our administrative expenses to increase in the future to support our business expansion. We also anticipate increasing legal, compliance, accounting, insurance and investor and public relations expenses associated with being a public company.

Fair Value Changes of Convertible Redeemable Preferred Shares

We raised private equity financings through the issuance of convertible redeemable preferred shares to a group of investors. We adopted the option-pricing method and equity allocation model to determine the fair value of the redeemable preferred shares. The preferred shares we issued are redeemable preferred shares designated as financial liabilities at FVTPL, the fair value gain was RMB9.2 million in 2019 and the fair value loss was RMB597.7 million, RMB119.9 million and RMB454.8 million for the year ended December 31, 2019 and the four months ended April 30, 2020 and 2021, respectively. For details, see “– Significant Accounting Policies, Judgments and Estimates – Significant Accounting Policies – Estimation of the Fair Value of Financial Liabilities.” Our convertible redeemable preferred shares will be converted into Shares upon the [REDACTED], after which point we will no longer recognize any changes in fair value. The redemption right attached to our convertible redeemable preferred shares has been terminated. See Note 21 of “Appendix I – Accountants’ Report” to this document.

Funding for Our Operations

During the Track Record Period, we funded our operations primarily through equity financing. Going forward, with the continuing expansion of our business and our product pipeline, we may require further funding from our existing shareholders, through public or private offerings, debt financing, collaborations, and licensing arrangements or other sources. In the event of successful commercialization of one or more of our product candidates, we expect to fund our operations in part with revenue generated from sales of our products. Any fluctuation in our ability to fund our operations will impact our cash flow and our results of operations.

BASIS OF PRESENTATION

We were incorporated in the Cayman Islands on October 31, 2018. Our Company, as the holding company of our business, indirectly owns subsidiaries in the PRC, Hong Kong, Australia and the United States that are principally engaged in research and development of biopharmaceutical products. See “History, Reorganization and Corporate Structure” for more details. Our consolidated statements have been prepared on the historical cost basis except for certain financial instruments which are measured at fair value. All intragroup assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of our Group are eliminated in full on combination.

FINANCIAL INFORMATION

Our consolidated information has been prepared in accordance with IFRSs, which comprise all standards and interpretations approved by the IASB. All IFRSs effective for the accounting period commencing from January 1, 2019, together with the relevant transitional provisions, have been early adopted by our Company in preparation of the consolidated information throughout the Track Record Period.

International Financial Reporting Standards (“IFRS”) effective for the accounting period commencing from January 1, 2021, together with the relevant transitional provisions, have been early adopted by our Group in the preparation of the historical financial information consistently throughout the relevant periods. The historical financial information has been prepared under the historical cost convention, except for certain financial liabilities which have been measured at fair value through profit or loss. For further details please see note 2.2 to the Accountants’ Report in Appendix I to this document.

SIGNIFICANT ACCOUNTING POLICIES, JUDGMENTS AND ESTIMATES

Our significant accounting policies which are important for an understanding of our financial condition and results of operations are set forth in detail in notes 2 and 3 to the Accountants’ Report set out in Appendix I of this document. Some of the accounting policies involve subjective assumptions and estimates, as well as complex judgements relating to accounting items. In each case, the determination of these items requires management judgment based on information and financial data that may change in future periods. When reviewing our financial statements, you should consider (i) our selection of critical accounting policies, (ii) the judgment and other uncertainties affecting the application of such policies, and (iii) the sensitivity of reported results to changes in conditions and assumptions.

Critical accounting judgments and estimates are those that are most important to the portrayal of our financial conditions and results of operations and require our management to make judgments, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities and their accompanying disclosures and the disclosure of contingent liabilities during the Track Record Period, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods.

We continually evaluate these estimates based on our own historical experience, knowledge and assessment of current business and other conditions, our expectations regarding the future based on available information and our best assumptions, which together form our basis for making judgments about matters that are not readily apparent from other sources. Since the use of estimates is an integral component of the financial reporting process, our actual results could differ from those estimates and expectations. Some of our accounting policies require a higher degree of judgment than others in their application.

FINANCIAL INFORMATION

Significant Accounting Policies

We believe the following critical accounting policies involve the most significant judgments and estimates used in the preparation of our financial statements.

Research and Development Costs

We recognize research costs as expenses to the statement of profit or loss in the period in which they are incurred. We capitalize development costs only when we can demonstrate (i) the technical feasibility of completing the development project so that the product candidates will be available for use or sale, (ii) our intention and ability to complete the development project to use or sell the product candidate, (iii) how the development project will generate future economic benefits, and (iv) the availability of resources to complete the development project and the ability to measure reliably the expenditures attributable to the development project. We record development costs which do not meet these criteria as expenses when incurred. During the Track Record Period, we recorded all research and development costs as expenses in our consolidated statements of profit or loss.

Intangible Assets

For intangible assets acquired separately, we initially recognize them at cost. The cost of intangible assets acquired in a business consolidation is recognized with the fair value at the date of acquisition. We further categorize such intangible assets as either with finite or indefinite useful lives. For intangible assets with finite lives, we amortize them over their useful economic lives, and we assess it for impairment whenever there is an indication that the intangible asset may be impaired. For intangible assets with indefinite useful lives, or intangible assets with finite useful lives but are not available for use, we do not amortize them but test them for impairment annually either individually or at the cash generating unit level.

Fair Value Measurement

We measure our derivative financial instruments at fair value at the end of each Track Record Period. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability, or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be accessible by us. The fair value of an asset or a liability is measured under the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

We use valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximizing the use of relevant observable inputs and minimizing the use of unobservable inputs.

FINANCIAL INFORMATION

All assets and liabilities for which fair value is measured or disclosed in our consolidated statements are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

Level 1 – based on quoted prices (unadjusted) in active markets for identical assets or liabilities;

Level 2 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is observable, either directly or indirectly; and

Level 3 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable.

For assets and liabilities that are recognized in our consolidated financial statements on a recurring basis, we determine whether transfers have occurred between levels in the hierarchy by reassessing categorization (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each period.

Our financial liabilities at fair value through profit or loss categorized within level 3 of fair value measurement were convertible redeemable preferred shares.

In respect of the assessment of fair value of the convertible redeemable preferred shares, with reference to the guidance under the “Guidance Note on Directors’ Duties in the Context of Valuations in Corporate Transactions” issued by the SFC in May 2017 applicable to directors of companies listed on the Stock Exchange, the Directors have undertaken the following key actions: (i) considering available information in assessing the financial forecast and assumptions including but not limited to the historical financial performance, market prospects, comparable companies’ conditions, economic, political and industry conditions; (ii) engaging an independent external valuer to assist our management to assess the fair value; (iii) considering the independence, reputation, capabilities and objectivity of the external valuer to ensure the suitability of such valuer; (iv) reviewing and discussing with our management and the external valuer on the valuation models and approaches; and (v) reviewing the valuation work papers and results prepared by the valuer. Valuation techniques are verified by the independent and recognized international business valuer before being implemented for valuation and are calibrated to ensure that outputs reflect market conditions. In respect of the valuation of our convertible redeemable preferred shares, details and the quantitative information about the significant unobservable inputs used in level 3 fair value measurements are set forth in Note 30 to the Accountants’ Report in Appendix I.

The Reporting Accountants have performed relevant procedures in accordance with Hong Kong Standard on Auditing (“HKSA”) 540 (Revised) “Auditing Accounting Estimates and Related Disclosures” and Hong Kong Auditing Practice Guidance 1000 “Special Considerations in Auditing Financial Instruments” to assess the valuation of the convertible redeemable preferred shares.

FINANCIAL INFORMATION

In relation to the financial liabilities recognized at fair value through profit or loss categorized within level 3 of fair value measurement or auditing standards for the Reporting Accountants or other valuation standards, the Joint Sponsors have taken due diligence steps including (i) conducting financial due diligence with the Company and the Reporting Accountants covering the basis of the relevant valuation; (ii) conducting an interview with the independent external valuer in relation to the methodology adopted to determine the valuation; (iii) reviewing the valuation report prepared by independent external valuer; and (iv) considering the qualification, independence and credentials of the independent external valuer. There is nothing that comes to the attention of the Joint Sponsors that indicates that the Directors have not undertaken independent and sufficient investigation and due diligence to determine the valuation of aforementioned level 3 financial liabilities.

Lease Term of Contracts

We have several lease contracts that include extension and termination options. We apply judgement in evaluating whether to exercise the option to renew or terminate the lease. We consider all relevant factors that create an economic incentive for it to exercise either the renewal or termination. After the commencement date, we reassess the lease term if there is a significant event or change in circumstances that is within our control and affect our ability to exercise the option to renew or to terminate (e.g., construction of significant leasehold improvements or significant customization to the leased asset).

We include the renewal period as part of the lease term for leases of building due to the significance of these assets to our operation. These leases have a short non-cancellable period (i.e., three to five years) and there will be a significant negative effect on production if a replacement is not readily available.

Impairment of Non-Financial Assets (Other Than Goodwill)

We assess whether there are any indicators of impairment for all non-financial assets at the end of each Track Record Period. Intangible assets not yet available for intended use are tested for impairment annually and at other times when such an indicator exists. Other non-financial assets are tested for impairment when there are indicators that the carrying amounts may not be recoverable. An impairment exists when the carrying value of an asset or a cash-generating unit exceeds its recoverable amount, which is the higher of its fair value less costs of disposal and its value in use. The calculation of the fair value less costs of disposal is based on available data from binding sales transactions in an arm’s length transaction of similar assets or observable market prices less incremental costs for the disposal of the asset. When value-in-use calculations are undertaken, management must estimate the expected future cash flows from the asset or cash-generating unit and choose a suitable discount rate in order to calculate the present value of those cash flows.

FINANCIAL INFORMATION

Development Costs

Development costs are capitalized in accordance with the accounting policy for research and development costs. Determining the amounts to be capitalized requires our management to make assumptions regarding the expected future cash generation of the assets, discount rates to be applied and the expected period of benefits. For further details please see note 2.4 to the Accountants' Report set out in Appendix I of this document.

Provision for Inventories

We review the carrying amounts of the inventories at the end of each Track Record Periods to determine whether the inventories are carried at lower of cost and net realizable value. The net realizable value is estimated based on current market situation and historical experience. Any change in the assumptions would increase or decrease the amount of inventories written-down or the related reversals of write-down and affect our financial position.

Useful Lives of Property, Plant and Equipment

Our management determines the estimated useful lives and the related depreciation charge for the property, plant and equipment. This estimate is based on the historical experience of the actual useful lives of property, plant and equipment of similar nature and functions. Our management will increase the depreciation charge where useful lives are less than previously estimated lives, or will write off or write down technically obsolete or non-strategic assets that have been abandoned or sold. Actual economic lives may differ from estimated useful lives. Periodic review could result in a change in depreciable lives and therefore depreciation charge in the future periods.

Estimation of the Fair Value of Financial Liabilities

Certain financial liabilities are measured at fair value at the end of each of the Track Record Periods. For further details please see note 29 to the Accountants' Report set out in Appendix I of this document.

The convertible redeemable preferred shares issued by our Company are not traded in an active market and the respective fair value is determined by using valuation techniques. We applied the Back-solve Approach to determine the underlying equity value of our Company and adopted the option-pricing method and equity allocation model to determine the fair value of the convertible redeemable preferred shares. Key assumptions such as the timing of the liquidation, redemption or the event as well as the probability of the various scenarios were based on our best estimates. For further details please see note 21 to the Accountants' Report set out in Appendix I of this document.

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Leases – Estimating the Incremental Borrowing Rate

We cannot readily determine the interest rate implicit in a lease, and therefore, it uses an incremental borrowing rate to measure lease liabilities. The incremental borrowing rate is the rate of interest that we would have to pay to borrow over a similar term, and with a similar security, the funds necessary to obtain an asset of a similar value to the right-of-use asset in a similar economic environment. The incremental borrowing rate therefore reflects what we “would have to pay”, which requires estimation when no observable rates are available (such as for subsidiaries that do not enter into financing transactions) or when we need to be adjusted to reflect the terms and conditions of the lease (for example, when leases are not in the subsidiary’s functional currency). We estimate the incremental borrowing rate using observable inputs (such as market interest rates) when available and are required to make certain entity-specific estimates (such as the subsidiary’s stand-alone credit rating).

FINANCIAL INFORMATION

DESCRIPTION OF CERTAIN KEY ITEMS OF THE CONSOLIDATED STATEMENTS OF PROFIT OR LOSS

The following table sets forth a summary of our consolidated statements of profit or loss for the periods indicated. Our historical results presented below are not necessarily indicative of the results that may be expected for any future period.

	Year Ended December 31,		Four Months Ended April 30,	
	2019	2020	2020	2021
	<i>(RMB in thousands except loss for share)</i>			
	(Unaudited)			
Other income and gains	16,908	24,341	13,152	5,491
Administrative expenses	(17,035)	(76,429)	(11,983)	(78,989)
Research and development expenses	(45,799)	(228,219)	(28,857)	(370,815)
Fair value changes of convertible redeemable preferred shares	9,245	(597,659)	(119,870)	(454,770)
Other expenses	(1,570)	(31,959)	(13)	(3,660)
Finance costs	(10,332)	(2,973)	(585)	(6,444)
Loss before tax	(48,583)	(912,898)	(148,156)	(909,187)
Income tax expense	—	—	—	—
Loss for the year/period	(48,583)	(912,898)	(148,156)	(909,187)
Attributable to:				
Owners of the parent	(48,583)	(912,898)	(148,156)	(909,187)
Loss per share attributable to ordinary equity holders of the parent (RMB)				
Basic	(0.97)	(18.26)	(2.96)	(18.18)
Diluted	(0.97)	(18.26)	(2.96)	(18.18)

Other Income and Gains

Other income and gains primarily consists of (i) government grants, which represents grants we received from government for the research and development for our product candidates, (ii) bank interest income, (iii) financial assets at FVTPL, which represented our foreign currency forward contracts, and (iv) others.

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The following table sets forth a breakdown of our other income and gains for the periods indicated:

	Year Ended December 31,		Four Months Ended April 30,	
	2019	2020	2020	2021
	<i>(RMB in thousands)</i>			
	(Unaudited)			
Government grants ⁽¹⁾	15,909	20,359	11,131	3,215
Bank interest income	783	3,408	558	2,021
Foreign exchange differences, net	84	–	889	–
Fair value gains, net:				
Financial assets at FVTPL	–	–	–	167
Others	132	574	574	88
Total	16,908	24,341	13,152	5,491

Note:

- (1) Government grants represented the subsidies received from the PRC local government authorities to support our research and development activities and the purchase of certain items of property, plant and equipment. As of the Latest Practicable Date, there are no unfulfilled conditions related to these government grants.

Administrative Expenses

Our administrative expenses mainly consist of (i) staff costs, representing wages, benefits and bonuses for our administrative staff, (ii) consulting fees, mainly in relation to the commercialization of our SCB-2019 (CpG 1018/Alum) and the establishment of our Pre-[REDACTED] Share Option Plan and RSU Scheme, (iii) [REDACTED] expenses, (iv) professional service fees, which mainly include recruitment agent fees, (v) office expenses, (vi) share based compensation, and (vii) depreciation and amortization charges in relation to our properties, leasehold buildings and office equipment.

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The following table summarizes a breakdown of our administrative expenses for the periods indicated:

	Year Ended December 31,				Four Months Ended April 30,			
	2019	2020		2020		2021		
	<i>(RMB in thousands, except for percentage)</i>							
	(Unaudited)							
Staff costs	8,672	51.4%	32,967	43.1%	6,991	58.3%	29,585	37.5%
Professional								
service fees	2,500	14.7	19,822	25.9	2,152	18.0	16,543	20.9
[REDACTED]								
expenses	–	–	1,991	2.6	–	–	15,113	19.1
Consulting fees	1,058	6.2	7,154	9.4	763	6.4	6,120	7.8
Office expenses	829	4.9	2,931	3.8	460	3.8	2,603	3.3
Share based								
compensation	–	–	–	–	–	–	1,833	2.3
Depreciation and								
amortization	1,070	6.3	4,544	5.9	1,091	9.1	1,670	2.1
Others ⁽¹⁾	2,816	16.5	7,020	9.3	526	4.4	5,522	7.0
Total	17,035	100.0%	76,429	100.0%	11,983	100.0%	78,989	100.0%

Note:

- (1) Others mainly include software expenses, travel expenses, delivery expenses, property management expenses and repair and maintenance fees.

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Research and Development Expenses

Our research and development expenses mainly consist of (i) clinical trial expenses, primarily including payments to CROs, hospitals and other medical institutions and testing fees incurred for clinical trials, (ii) staff costs, including salaries, bonus and welfare for research and development personnel, (iii) costs of raw materials and consumables used for research and development of our product candidates, (iv) R&D consultation and service fees, mainly representing certain preclinical study costs for SCB-2019 (CPG 1018/Alum), (v) depreciation and amortization in relation to our leasehold buildings and machinery and equipment, and (vi) share based compensation, representing the awards to our employees.

The following table summarizes a breakdown of our research and development expenses for the periods indicated:

	Year Ended December 31,		Four Months Ended April 30,	
	2019	2020	2020	2021
	<i>(RMB in thousands)</i>			
	(Unaudited)			
Clinical trial expenses	15,400	76,321	5,188	266,547
Staff costs	19,609	66,418	12,548	61,886
Costs of raw materials and consumables	4,168	39,655	1,764	25,363
R&D consultation and service fees	2,549	29,473	6,335	4,790
Depreciation and amortization	1,398	2,316	704	2,660
Share based compensation	–	–	–	1,566
Others ⁽¹⁾	2,675	14,036	2,318	8,003
Total	45,799	228,219	28,857	370,815

Note:

(1) Others mainly include utility expenses, property management fees, and office fees.

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Fair Value Changes of Convertible Redeemable Preferred Shares

We recorded fair value changes of convertible redeemable preferred shares of RMB9.2 million, RMB(597.7) million, RMB(119.9) million and RMB(454.8) million for the years ended December 31, 2019 and 2020 and the four months ended April 30, 2020 and 2021, respectively. Our fair value changes of convertible redeemable preferred shares represented changes in fair value of the convertible redeemable preferred shares that we issued to Pre-[REDACTED] Investors. We designated all convertible redeemable preferred shares as financial liabilities at fair value through profit or loss. Subsequent to initial recognition, the fair value change of convertible redeemable preferred shares is recognized in profit or loss except for the portion attributable to credit risk change which will be recognized to other comprehensive income, if any. The convertible redeemable preferred shares will be converted into the Shares upon the [REDACTED], after which we do not expect to recognize any further loss or gain on fair value changes from the convertible redeemable preferred shares.

Other Expenses

Our other expenses consisted of the exchange losses due to fluctuation in exchange rates. We had other expenses of RMB1.6 million, RMB32.0 million, RMB13,000 and RMB3.7 million in 2019 and 2020 and the four months ended April 30, 2020 and 2021, respectively.

Finance Costs

Our finance costs primarily consist of (i) transaction costs for the issuance of our Series B, B-2 and C Preferred Shares, mainly comprised of consulting fees, and (ii) interest on lease liabilities, mainly in relation to the leasehold building for our operations. The table below summarizes a breakdown of our finance costs for the periods indicated:

	Years Ended December 31,		Four Months Ended April 30,	
	2019	2020	2020	2021
	<i>(RMB in thousands)</i>			
	(Unaudited)			
Transaction costs for issuance of our Company’s convertible redeemable preferred shares	9,788	1,316	123	5,770
Interest on lease liabilities	544	1,657	462	674
Total	10,332	2,973	585	6,444

FINANCIAL INFORMATION

Income Tax Expense

We are subject to income tax on an entity basis on profits arising in or derived from the jurisdictions in which members of our Group are domiciled and operate.

Cayman Islands

Under the current laws of the Cayman Islands, our Company is not subject to tax on income or capital gains. In addition, upon payments of dividends by our Company to the shareholders, no Cayman Islands withholding tax is imposed.

Hong Kong

Our subsidiary incorporated in Hong Kong is subject to Hong Kong profits tax at the rate of 16.5% on the estimated assessable profit arising in Hong Kong. No provision for Hong Kong profits tax has been made as the Group has no assessable profits derived from or earned in Hong Kong during the Track Record Period.

The PRC

Pursuant to the Corporate Income Tax Law of the PRC and the respective regulations, our subsidiaries which operate in the PRC are subject to corporate income tax at a rate of 25% on the taxable income.

Australia

Our subsidiary incorporated in Australia was subject to Australian income tax. During the Track Record Period, Australia corporate income tax has been provided at the rate of 30% on the estimated assessable profits arising in Australia.

U.S.

Our subsidiary incorporated in Delaware, United States was subject to statutory United States federal corporate income tax at a rate of 21% during the Track Record Period.

Ireland

Our subsidiary incorporated in the Ireland is subject to Ireland income tax. Ireland corporate income tax has been provided at the rate of 12.5% on the estimated assessable profits arising in Ireland during the Track Record Period.

FINANCIAL INFORMATION

RESULTS OF OPERATIONS

Four Months Ended April 30, 2021 Compared to Four Months Ended April 30, 2020

Other Income and Gains

Our other income and gains decreased from RMB13.2 million for the four months ended April 30, 2020 to RMB5.5 million for the four months ended April 30, 2021. This decrease was primarily because we have met certain criteria for government grants and the deferred government grants have been transferred to other income in 2020 already.

Administrative Expenses

Our administrative expenses increased significantly from RMB12.0 million for the four months ended April 30, 2020 to RMB79.0 million for the four months ended April 30, 2021. This increase was primarily attributable to (i) an increase of RMB22.6 million in staff costs due to the significant increase in the number of our management and administrative staff in line with our rapid business expansion, (ii) we incurred RMB15.1 million [REDACTED] expenses due to our proposed [REDACTED], (iii) an increase of RMB14.4 million in professional service fees mainly paid to our third party recruitment agencies as we recruited 75 staff from such agencies during the four months ended April 30, 2021 comparing to 27 during the four months ended April 30, 2020, and (iv) an increase of RMB5.4 million consulting fees primarily in relation to the commercialization of SCB-2019 (CpG 1018/Alum) and the establishment of our Pre-[REDACTED] Share Option Plan and the RSU Scheme.

Research and Development Expenses

Our research and development expenses increased by 1,185.0% from RMB28.9 million for the four months ended April 30, 2020 to RMB370.8 million for the four months ended April 30, 2021. This increase was primarily attributable to (i) an significant increase in clinical trial expenses of RMB261.4 million, as our SCB-2019 (CpG 1018/Alum) has entered Phase II/III clinical trial in four countries in early 2021, (ii) an increase in staff costs of RMB49.3 million as we engaged more R&D staff mainly in charge of clinical operations, vaccine registration and project management in light our commercialization of our SCB-2019 (CPG 1018/Alum), (iii) an increase of RMB23.6 million in costs of raw materials and consumables due to the initiation of the Phase II/III clinical trial in four countries for our SCB-2019 (CPG 1018/Alum).

Fair Value Changes of Convertible Redeemable Preferred Shares

The fair value loss of our convertible redeemable preferred shares increased from RMB119.9 million for the four months ended April 30, 2020 to RMB454.8 million for the four months ended April 30, 2021, as we issued Series C Preferred Shares in 2021 and the fair value changes of our convertible redeemable preferred shares was in relation to an increase in our valuation.

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Other Expenses

We recorded an amount of RMB13,000 and RMB3.7 million for our other expenses for the four months ended April 30, 2020 and 2021, respectively. The increase in our other expenses mainly represented the exchange loss due to fluctuation in exchange rate.

Finance Costs

Our finance costs increased from RMB0.6 million for the four months ended April 30, 2020 to RMB6.4 million for the four months ended April 30, 2021. This increase in finance costs was primarily due to the higher transaction costs for the issuance of our Series C Preferred Shares in 2021 compare to which for the issuance of our Series B-2 Preferred Shares in 2020.

Loss for the Period

As a result of the above, we recorded a loss of RMB148.2 million for the four months ended April 30, 2020, as compared to a loss of RMB909.2 million for the four months ended April 30, 2021.

Year Ended December 31, 2020 Compared to Year Ended December 31, 2019

Other Income and Gains

Our other income and gains increased from RMB16.9 million in 2019 to RMB24.3 million in 2020. This increase was primarily attributable to an increase in grants we received from the PRC local government authorities to support our research and development activities.

Administrative Expenses

Our administrative expenses increased significantly from RMB17.0 million in 2019 to RMB76.4 million in 2020. This increase was primarily attributable to (i) an increase of RMB24.2 million in staff costs as a result of the increase in the number of administrative personnel to support our business growth, (ii) an increase of RMB17.3 million in professional service fees from third party recruitment agencies due to the employees we recruited through recruitment agents increased from 38 in 2019 to 159 in 2020 which is also in line with our business expansion, and (iii) an increase of RMB6.1 million consulting fees, mainly in relation to the consultation and application for grants for our product candidates.

FINANCIAL INFORMATION

Research and Development Expenses

Our research and development expenses increased by 398.3% from RMB45.8 million in 2019 to RMB228.2 million in 2020. This increase was primarily attributable to (i) an increase in clinical trial expenses of RMB60.9 million, as we incurred significant expenses for the clinical trials of SCB-2019 (CPG 1018/Alum) and SCB-313 in 2020, (ii) an increase in staff costs of RMB46.8 million as a result of the increase in our R&D staff for the development of SCB-2019 (CPG 1018/Alum), (iii) an increase of RMB35.5 million in costs of raw materials and consumables due to the initiation of research and development program of SCB-2019 (CPG 1018/Alum) in early 2020, and (iv) an increase of RMB26.9 million in R&D consultation and service fees, which was mainly attributable to the costs for preclinical study activities of our SCB-2019 (CPG 1018/Alum), such as pharmacodynamics research and pharmacokinetics and toxicological research costs.

Fair Value Changes of Convertible Redeemable Preferred Shares

The fair value gain of convertible redeemable preferred shares was RMB9.2 million in 2019 and the fair value loss was RMB597.7 million in 2020, as we issued Series B-2 Preferred Shares in 2020 and the fair value changes of our convertible redeemable preferred shares was in relation to an increase in our valuation.

Other Expenses

Our other expenses were RMB1.6 million in 2019 and RMB32.0 million in 2020, which represented the exchange loss due to fluctuation in exchange rate.

Finance Costs

Our finance costs decreased from RMB10.3 million in 2019 to RMB3.0 million in 2020. This decrease in finance costs was primarily due to the lower transaction costs for the issuance of our Series B-2 Preferred Shares in 2020 compare to which for the issuance of our Series B Preferred Shares in 2019.

Income Tax Expense

We did not incur any income tax expense in 2019 and 2020.

Loss for the Year

As a result of the above, we recorded a loss of RMB48.6 million in 2019, as compared to a loss of RMB912.9 million in 2020.

FINANCIAL INFORMATION

DESCRIPTION OF CERTAIN CONSOLIDATED STATEMENTS OF FINANCIAL POSITION ITEMS

The following table sets forth a summary of our consolidated statements of financial position as of the dates indicated.

	As of December 31,		As of
	2019	2020	April 30, 2021
	<i>(RMB in thousands)</i>		
Non-current assets			
Property, plant and equipment	4,991	65,897	112,741
Right-of-use assets	12,437	21,090	27,982
Intangible assets	294	277	6,481
Other non-current assets	4,148	51,839	28,125
Total non-current assets	<u>21,870</u>	<u>139,103</u>	<u>175,329</u>
Current assets			
Inventories	393	50,881	146,717
Prepayments, other receivables and other assets	5,259	191,032	173,990
Financial assets at FVTPL	–	–	167
Time deposits and restricted cash	10,000	290,328	245,126
Cash and cash equivalents	148,694	516,184	1,828,780
Total current assets	<u>164,346</u>	<u>1,048,425</u>	<u>2,394,780</u>
Current liabilities			
Trade payables	7,165	33,820	98,831
Other payables and accruals	18,512	28,655	51,451
Lease liabilities	1,810	4,259	7,763
Total current liabilities	<u>27,487</u>	<u>66,734</u>	<u>158,045</u>
Net current assets	<u>136,859</u>	<u>981,691</u>	<u>2,236,735</u>
Total assets less current liabilities	<u>158,729</u>	<u>1,120,794</u>	<u>2,412,064</u>
Non-current liabilities			
Lease liabilities	10,645	18,057	21,336
Convertible redeemable preferred shares	198,736	1,127,306	[REDACTED]
Deferred income	17,170	958,172	1,210,881
Total non-current liabilities	<u>226,551</u>	<u>2,103,535</u>	<u>4,295,560</u>
Net liabilities	<u>(67,822)</u>	<u>(982,741)</u>	<u>(1,883,496)</u>

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Property, Plant and Equipment

Our property, plant and equipment primarily consisted of machinery, electronic and other equipment, vehicles, leasehold improvements and construction in progress. Our property, plant and equipment increased significantly from RMB5.0 million as of December 31, 2019 to RMB65.9 million as of December 31, 2020, which is mainly due to the increase of machinery and electronic and other equipment in 2020 in line with our business expansion and the construction of our production lines and installation of manufacturing equipment. Our property, plant and equipment increased from RMB65.9 million as of December 31, 2020 to RMB112.7 million as of April 30, 2021 primarily due to the construction of our production lines in preparation of the commercialization of SCB-2019 (CPG 1018/Alum).

Right-of-Use Assets

Our right-of-use assets mainly relate to our leasehold buildings and other equipment. Our right-of-use assets increased significantly from RMB12.4 million as of December 31, 2019 to RMB21.1 million as of December 31, 2020 primarily attributable to the newly leased offices in Shanghai and Chengdu in 2020. Our right-of-use assets further increased to RMB28.0 million as of April 30, 2021 due to the increased offices we leased mainly in Chengdu, Beijing and Boston in line with our business expansion.

Intangible Assets

Our intangible assets mainly include softwares. Our intangible assets remained stable as of December 31, 2019 and 2020. It increased from RMB0.3 million as of December 31, 2020 to RMB6.5 million as of April 30, 2021 mainly because we adopted the new management Systems Applications and Products (SAP) system due to our business expansion. Such system is considered to have longer period of economic benefits to our Company.

Other Non-Current Assets

Our non-current assets mainly represent the prepayments relating to the purchase of equipment. Our other non-current assets increased significantly from RMB4.1 million as of December 31, 2019 to RMB51.8 million as of December 31, 2020, which is mainly due to the purchase of equipment in 2020 in relation to our Changxing manufacturing facility. Our other non-current assets decreased from RMB51.8 million as of December 31, 2020 to RMB28.1 million as of April 30, 2021 upon the delivery and inspection of certain equipment we purchased which subsequently increased our property, plant and equipment.

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Lease Liabilities

Our lease liabilities include the properties we lease for business operations, which mainly include our office premises. We recorded lease liabilities of RMB12.5 million, RMB22.3 million and RMB29.1 million as of December 31, 2019 and 2020 and April 30, 2021, respectively. The following table sets forth the carrying amount of our lease liabilities as of the dates indicated:

	As of December 31,		As of
	2019	2020	April 30, 2021
	<i>(RMB in thousands)</i>		
Current portion	1,810	4,259	7,763
Non-current portion	10,645	18,057	21,336
 Total	 12,455	 22,316	 29,099

Convertible Redeemable Preferred Shares

Our convertible redeemable preferred shares increased significantly from RMB198.7 million as of December 31, 2019 to RMB1,127.3 million as of December 31, 2020 as a result of our issuance of Series B-2 Preferred Shares in 2020 as well as the increase of valuation of the Company. Our convertible redeemable preferred share increased from RMB1,127.3 million as of December 31, 2020 to RMB3,063.3 million as of April 30, 2021 mainly issuance of Series C Preferred Shares in early 2021 as well as the increase of valuation of Company.

FINANCIAL INFORMATION

The following table sets forth the movements of carrying amount of our convertible redeemable preferred shares as of the dates indicated:

	Series A Preferred Shares	Series B Preferred Shares	Series B-2 Preferred Shares	Series C Preferred Shares	Total
At January 1, 2019	62,981	–	–	–	62,981
Issue	–	145,000	–	–	145,000
Changes in fair value	(9,669)	424	–	–	(9,245)
At December 31, 2019 and at January 1, 2020	53,312	145,424	–	–	198,736
Issue	–	159,125	171,786	–	330,911
Changes in fair value	114,520	401,367	81,772	–	597,659
At December 31, 2020 and at January 1, 2021	167,832	705,916	253,558	–	1,127,306
Issue	–	–	–	1,487,456	1,487,456
Changes in fair value	85,561	327,734	109,205	(67,730)	454,770
Currency translation differences	(921)	(3,876)	(1,392)	–	(6,189)
At April 30, 2021	<u>252,472</u>	<u>1,029,774</u>	<u>361,371</u>	<u>1,419,726</u>	<u>[REDACTED]</u>

Deferred Income

Our deferred income increased significantly from RMB17.2 million as of December 31, 2019 to RMB958.2 million as of December 31, 2020, and further increased to RMB1,210.9 million as of April 30, 2021 due to the deferred revenue that we received from CEPI for the continuous research and development of our SCB-2019 (CpG 1018/Alum). There is no unmet performance obligations that deter the Company from using the funding received. The deferred income is recognized as other income upon we fulfill our future commercial obligation under the contract with GAVI. We also expect to recognize the amount of government grant upon achieving certain milestones for the research and development of certain drug candidates in the next two years. For details, see “Risk Factors – Risks Relating to Our Financial Position And

FINANCIAL INFORMATION

Need For Additional Capital – We may not be able to fulfil our obligation in respect of deferred revenue, which may have impact on our liquidity position.” The following table sets forth the breakdown of our deferred income as of the dates indicated:

	As of December 31,		As of
	2019	2020	April 30, 2021
	<i>(RMB in thousands)</i>		
Deferred revenue	–	931,005	1,183,764
Deferred government grant	17,170	27,117	27,117
Total	17,170	958,172	1,210,881

As of the Latest Practicable Date, there are no unmet performance obligations that would deter us from using the funding received.

Inventories

Our inventories primarily consist of raw materials for our research and development activities and the future commercialization for certain product candidates. Our inventories increased significantly from RMB0.4 million as of December 31, 2019 to RMB50.9 million as of December 31, 2020, and further increased to RMB146.7 million as of April 30, 2021. The increase in inventories during the Track Record Period was mainly because we increased our purchase of raw materials for the research and development of SCB-2019 (CpG 1018/Alum) as we advanced clinical trials in 2020 and we also scaled up our CMC activities in 2021 in light of its NDA filing.

For the years ended December 31, 2019 and 2020 and the four months ended April 30, 2021, our inventory turnover days are 17, 236 and 467, respectively. Our inventory turnover days represented the turnovers days for our raw materials and we had no finished goods during the Track Record Period. Our turnovers for raw materials increased significantly during the same period because we purchased more raw material inventories as we advance the clinical development of our SCB-2019 (CpG 1018/Alum) and further prepare for its commercialization.

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As of April 30, 2021, our inventories which mainly include raw material and consumables amounted to RMB146.7 million. The following table sets forth the breakdown of our inventories and their respective shelf life by categories as of April 30, 2021:

	Amount as of April 30, 2021	Shelf life
	<i>(RMB in million)</i>	
Mixing plastic bags*	27.6	2~3 years
Dynavax’s CpG 1018 adjuvant	27.5	1 year
Vials	19.5	5 years
Chromatography packing	16.9	5 years
Membrane package	15.7	3 years
Cell booster	13.2	2 years
Alum adjuvant	4.2	2 years
Other raw materials	22.1	Over 3 years
	146.7	
Total	146.7	

* Mixing plastic bags mainly include cell mixing bag and nanofiltration membrane package.

As of August 31, 2021, approximately RMB39.82 million of our inventories, or 27.1% of our inventories as of April 30, 2021, were subsequently utilized. Our inventory is primarily comprised of raw materials in anticipation of the commercialization of our SCB-2019 (CpG 1018/Alum). As we are on track in developing SCB-2019 (CpG 1018/Alum), we do not expect any recoverability issues for our inventories.

Prepayments, Other Receivables and Other Assets

Our prepayments, other receivables and other assets primarily consist of (i) prepayments to suppliers for machinery and raw materials, (ii) value-added tax recoverable, representing value-added taxes paid with respect to our procurement that can be credited against future value-added tax payables, and (iii) other receivables, representing security deposits mainly related to human resource agency service fees. The following table sets forth components of our prepayments, other receivables and other assets as of the dates indicated:

	As of December 31,		As of April 30,
	2019	2020	2021
	<i>(RMB in thousands)</i>		
Prepayments	5,084	220,165	168,628
Value-added tax recoverable	3,727	18,423	27,500
Other receivables	596	4,283	5,987
	5,259	191,032	173,990
<i>Analyzed into:</i>			
Current portion	5,259	191,032	173,990
Non-current portion	4,148	51,839	28,125
	9,407	242,871	202,115
Total	9,407	242,871	202,115

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Our prepayments, other receivables and other assets increased from RMB9.4 million as of December 31, 2019 to RMB242.9 million as of December 31, 2020. The increase was mainly due to (i) an increase in prepayments due to our increased procurement for machinery for our Changxing manufacturing facility and raw materials to be used in our research and development activities, (ii) an increase in value-added tax recoverable due to an increase in value-added tax paid with respect to such procurement, and (iii) an increase in other receivables mainly relating to the security deposits for our human resource agency service fees.

Our prepayments, other receivables and other assets decreased from RMB242.9 million as of December 31, 2020 to RMB202.1 million as of April 30, 2021. The decrease was mainly due to the significant decrease in prepayments to CROs due to advancement of our Phase III SCB-2019 (CPG 1018/Alum) clinical trial.

As of August 31, 2021, approximately RMB137.9 million, or 81.8% of our prepayments as of April 30, 2021 have been utilized.

Time Deposits and Restricted Cash

Our time deposits and restricted cash represented the balances we pledged for the bank deposits over three months. Our time deposits and restricted cash increased from RMB10.0 million as of December 31, 2019 to RMB290.3 million as of December 31, 2020, primarily because the increase in bank deposits over three months mainly relate to the proceeds from financings we received in 2020. Our time deposits and restricted cash decreased from RMB290.3 million as of December 31, 2020 to RMB245.1 million as of April 30, 2021 mainly due to the matured time deposit at bank and the release of certain restricted cash from local government as we have met specific requirements.

Cash and Cash Equivalents

Our cash and cash equivalents increased from RMB148.7 million as of December 31, 2019 to RMB516.2 million as of December 31, 2020, primarily attributable to (i) proceeds we received from our Series B-2 financing, and (ii) subsidies we received from CEPI and the local government for the research and development of SCB-2019 (CPG 1018/Alum) and SCB-808 in 2020.

Our cash and cash equivalents increased from RMB516.2 million as of December 31, 2020 to RMB1,828.8 million as of April 30, 2021, primarily attributable to (i) proceeds we received from our Series C financing, and (ii) funding from CEPI we received for the continuous research and development of SCB-2019 (CPG 1018/Alum) in early 2021.

FINANCIAL INFORMATION

Trade Payables

Our trade payables primarily arise from our purchase of raw materials and CRO services. Our trade payables increased from RMB7.2 million as of December 31, 2019 to RMB33.8 million as of December 31, 2020, primarily attributable to an increase in the purchase of raw materials and CRO services, which was in line with our increased research and development activities in 2020. We recorded trade payables of RMB98.8 million as of April 30, 2021 as compared to RMB33.8 million as of December 31, 2020, which is primarily attributable to the increase in the purchase of raw materials mainly for the phase II/III clinical trials for our SCB-2019 (CPG 1018/Alum) and the scale up of our CMC activities in light of its NDA filing. Our trade payables are non-interest-bearing and normally settled on terms of 30 to 60 days. Our Directors confirm that we had no material defaults in payment of trade payables during the Track Record Period and up to the Latest Practicable Date.

The following table sets forth an aging analysis of our trade payables as of the dates indicated:

	As of December 31,		As of
	2019	2020	April 30,
			2021
	<i>(RMB in thousands)</i>		
Within 6 months	5,164	33,102	98,831
6 to 12 months	1	183	–
Over 1 year	2,000	535	–
Total	7,165	33,820	98,831

As of August 31, 2021, approximately RMB93.4 million, or 94.5% of our trade payables as of April 30, 2021 have been settled.

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Other Payables and Accruals

The following table sets forth our other payables and accruals, which consist of (i) service fee payable, which primarily represent fees payable to our legal consultation service providers in relation to the issuance of our Series B and Series B-2 Preferred Shares and the fees payable to professional service providers in relation to the [REDACTED], (ii) payroll payable, due to the increased employees in line with our business expansion, and (iii) payables for property, plant and equipment, primarily attributable to our continuous purchase of machinery and equipment to support our business expansion. The following table sets forth components of our other payables and accruals as of the dates indicated:

	As of December 31,		As of
	2019	2020	April 30,
			2021
	<i>(RMB in thousands)</i>		
Service fee payable	8,750	5,141	17,977
Payroll payable	8,007	19,128	16,447
Payables for property, plant and equipment	613	1,186	12,853
Taxes other than income tax	83	1,422	3,056
Amounts due to related parties	928	938	–
Other payables	131	840	1,118
Total	18,512	28,655	51,451

Other payables and accruals increased from RMB18.5 million as of December 31, 2019 to RMB28.7 million as of December 31, 2020, primarily attributable to an increase of RMB11.1 million payroll payables as we hired more staff to support our business expansion, and further offset by a decrease of RMB3.6 million in service fee payable due to the settlement of consultation fees incurred in 2019 mainly relating to our Series B financing.

Our other payables and accruals increased from RMB28.7 million as of December 31, 2020 to RMB51.5 million as of April 30, 2021, primarily attributable to an increase of RMB12.8 million service fee payable mainly due to the settlement of our auditing and consultation service in relation to our Series C financing and proposed [REDACTED] and an increase of RMB11.7 million in payable for property, plant and equipment because we purchased more machinery and equipment in line with our business expansion.

FINANCIAL INFORMATION

LIQUIDITY AND CAPITAL RESOURCES

Overview

Our primary uses of cash relate to the research and development of our Core Products and the purchase of equipment and machinery. During the Track Record Period, we primarily funded our working capital requirement through equity financing. We monitor and maintain a level of cash and cash equivalents deemed adequate to finance our operations and mitigate the effects of fluctuations in cash flows. As our business develops and expands, we expect to generate more cash from our operating activities through launching new products. Going forward, we believe our liquidity requirements will be satisfied by using funds from a combination of cash from operations, bank balances and cash and net [REDACTED] from the [REDACTED]. As of April 30, 2021, our cash and cash equivalents amounted to RMB1,828.8 million.

Current Assets and Liabilities

The following table sets forth our current assets and current liabilities as of the dates indicated:

	<u>As of December 31,</u>		<u>As of</u>	<u>As of</u>
	<u>2019</u>	<u>2020</u>	<u>April 30,</u>	<u>August 31,</u>
			<u>2021</u>	<u>2021</u>
	<i>(RMB in thousands)</i>			
	(Unaudited)			
Current assets				
Inventories	393	50,881	146,717	522,937
Prepayments, other receivables and other assets	5,259	191,032	173,990	408,090
Financial assets at FVTPL	–	–	167	323
Time deposits and restricted cash	10,000	290,328	245,126	74,831
Cash and cash equivalents	<u>148,694</u>	<u>516,184</u>	<u>1,828,780</u>	<u>2,445,108</u>
Total current assets	<u>164,346</u>	<u>1,048,425</u>	<u>2,394,780</u>	<u>3,451,289</u>
Current liabilities				
Trade payables	7,165	33,820	98,831	172,842
Other payables and accruals	18,512	28,655	51,451	70,852
Lease liabilities	1,810	4,259	7,763	8,298
Contract liabilities	–	–	–	1,031,685
Total current liabilities	<u>27,487</u>	<u>66,734</u>	<u>158,045</u>	<u>1,283,677</u>
Net current assets	<u><u>136,859</u></u>	<u><u>981,691</u></u>	<u><u>2,236,735</u></u>	<u><u>2,167,612</u></u>

FINANCIAL INFORMATION

We had net current assets of RMB981.7 million as of December 31, 2020, as compared to net current assets of RMB136.9 million as of December 31, 2019. The increase was mainly due to (i) an increase of RMB367.5 million in our cash and cash equivalents, primarily attributable to the proceeds we received from the issuance of Series B-2 Preferred Shares in 2020, (ii) an increase of RMB280.3 million in our time deposits and restricted cash, primarily consisted of the proceeds from financings we received in 2020, and (iii) an increase of RMB185.8 million in prepayments, other receivables and other assets, primarily attributable to the prepayments made to our CROs.

We had net current assets of RMB2,236.7 million as of April 30, 2021, as compared to net current assets of RMB981.7 million as of December 31, 2020. The increase was mainly due to (i) an increase of RMB1,312.6 million in our cash and cash equivalents, primarily attributable to the proceeds we received from our Series C financing in early 2021, and (ii) an increase RMB95.8 million in our inventories primarily consisted of raw materials for the Phase II/III clinical trials and its near-term commercialization for our SCB-2019 (CPG 1018/Alum).

Our net current assets decreased to RMB2,167.6 million as of August 31, 2021, primarily because of an increase in our contract liabilities in relation to the prepaid vaccine payment we received in light of the commercialization of our SCB-2019 (CpG 1018/Alum). For further details, please see “Summary – Recent Development”.

FINANCIAL INFORMATION

Cash Operating Costs

The following table provides information regarding our cash operating costs for the periods indicated:

	As of December 31,		As of
	2019	2020	April 30,
			2021
	<i>(RMB in thousands)</i>		
<i>Research and Development costs for</i>			
<i>Core Products (SCB-2019 (CpG</i>			
<i>1018/Alum) and SCB-808)⁽¹⁾</i>			
Clinical trial expenses	5	44,375	207,129
Raw material costs	42	104,824	26,290
Testing expenses	4	6,685	3,910
Salaries and benefits	2,916	55,642	43,039
Others ⁽²⁾	1,132	19,849	8,492
	4,099	231,375	288,860
<i>Subtotal</i>			
 <i>Research and development costs for</i>			
<i>other product candidates⁽³⁾</i>			
Clinical trial expenses	8,448	13,769	75,411
Raw material costs	8,418	7,524	2,370
Testing expenses	162	10,529	593
Salaries and benefits	8,731	4,223	18,847
Others ⁽²⁾	3,115	1,506	85
	28,874	37,551	97,307
<i>Subtotal</i>			
Workforce employment	14,992	16,055	29,585
Non-income taxes, royalties and other			
government charges	86	105	–
Prepaid item ⁽⁴⁾	–	167,390	684
Other	11,315	48,161	2,396

Notes:

- (1) We recorded an amount of RMB4.1 million, RMB231.4 million and RMB288.9 million of research and development costs of our Core Products for the years ended December 31, 2019 and 2020 and the four months ended April 30, 2021, respectively. The research and development costs we allocated to our Core Products in 2019 were related to SCB-808, and the amounts recorded for the year ended December 31, 2020 and the four months ended April 30, 2021 were primarily related to SCB-2019 (CpG 1018/Alum) because we initiated the research and development activities of our SCB-2019 (CpG 1018/Alum) in 2020.
- (2) Others mainly consisted of professional fees, office and travel expenses.
- (3) Research and developments costs for other product candidates, primarily including clinical expenses and raw material costs incurred in relation to the development of SCB-313.
- (4) Prepaid item primarily represents our advance payment to CROs in relation to the development of SCB-2019 (CpG 1018/Alum).

FINANCIAL INFORMATION

Cash Flows

The following table sets forth the components of our consolidated statement of cash flows for the periods indicated:

	Year Ended December 31,		Four Months Ended April 30,	
	2019	2020	2020	2021
	<i>(RMB in thousands)</i>			
	(Unaudited)			
Cash flows from operating activities before movement in working capital	(45,966)	(277,988)	(27,565)	(439,155)
Changes in working capital	19,349	754,915	11,300	249,613
Net cash flows (used in)/from operating activities	(26,617)	476,927	(16,265)	(189,542)
Net cash flows (used in)/from investing activities	(2,598)	(394,120)	(63,987)	28,779
Net cash flows from financing activities	142,050	316,847	47,873	1,474,261
Net increase in cash and cash equivalents	<u>112,835</u>	<u>399,654</u>	<u>(32,379)</u>	<u>1,313,498</u>
Cash and cash equivalents at beginning of year/period	35,744	148,694	148,694	516,184
Effects of foreign exchange rate changes, net	115	(32,164)	(137)	(902)
Cash and cash equivalents at end of year/period	<u>148,694</u>	<u>516,184</u>	<u>116,178</u>	<u>1,828,780</u>

Operating Activities

Since inception, we have incurred negative cash flows from our operations. Substantially all of our operating cash outflows have resulted from research and development expenses and administrative expenses.

FINANCIAL INFORMATION

For the four months ended April 30, 2021, our net cash used in operating activities was RMB189.5 million, primarily reflecting loss before tax of RMB909.2 million and operating cash flows before movement in working capital of RMB439.2 million, positively adjusted by fair value changes of redeemable preferred shares of RMB454.8 million, finance costs of RMB6.4 million, net foreign exchange differences of RMB3.6 million, share-based payment expenses of RMB3.4 million, depreciation of property, plant and equipment of RMB2.1 million and depreciation of right-of-use assets of RMB1.8 million negatively adjusted by interest income of RMB2.0 million.

In 2020, our net cash from operating activities was RMB476.9 million. This net cash from operating activities was primarily reflecting loss before tax of RMB912.9 million and operating cash flows before movement in working capital of RMB278.0 million, positively adjusted by fair value changes of redeemable preferred shares of RMB597.7 million, net foreign exchange differences of RMB31.9 million and depreciation of right-of-use assets of RMB4.0 million.

In 2019, our net cash used in operating activities was RMB26.6 million, primarily reflecting loss before tax of RMB48.6 million and operating cash flows before movement in working capital of RMB46.0 million, positively adjusted by RMB10.3 million of finance costs, and RMB1.2 million of right-of-use assets, and negatively adjusted by RMB9.2 million of fair value changes of convertible redeemable preferred shares.

Investing Activities

Our cash outflow from investing activities were primarily related to increase in time deposits and restricted cash and purchases of items of property, plant and equipment.

For the four months ended April 30, 2021, our net cash from investing activities was RMB28.8 million, which was primarily attributable to RMB45.2 million in decrease in time deposit and restricted deposits, and RMB13.7 million in purchase of property, plant and equipment.

In 2020, our net cash used in investing activities was RMB394.1 million, which was primarily attributable to (i) RMB280.3 million in increase in time deposits and restricted deposits, and (ii) RMB113.6 million in purchases of items of property, plant and equipment.

In 2019, our net cash used in investing activities was RMB2.6 million, which was primarily attributable to RMB6.8 million in purchases of property, plant and equipment, partially offset by RMB4.2 million in decrease in time deposits and restricted deposits.

Financing Activities

Our net cash received from financing activities was primarily proceeds from the issuance of convertible redeemable preferred shares.

FINANCIAL INFORMATION

For the four months ended April 30, 2021, our net cash from financing activities was RMB1,474.3 million, which was primarily attributable to RMB1,487.5 million in proceeds from issue of convertible redeemable preferred shares, partially offset by RMB6.1 million in transaction cost for issuance of our convertible redeemable preferred shares.

In 2020, our net cash generated from financing activities was RMB316.8 million, which was primarily attributable to the RMB330.9 million in proceeds from the issuance of convertible redeemable preferred shares, partially offset by RMB9.3 million in transaction cost for issuance of our convertible redeemable preferred shares.

In 2019, our net cash generated from financing activities was RMB142.1 million, which was mainly the proceeds from the issuance of convertible redeemable preferred shares.

WORKING CAPITAL CONFIRMATION

We believe our liquidity requirements will be mainly satisfied by using funds from a combination of our existing cash, net [REDACTED] from the [REDACTED]. As of August 31, 2021, being the latest practicable date for determining our indebtedness, we had capital resources of RMB2,519.9 million, consisting of cash and cash equivalents and time deposits and restricted cash. The Directors are of the opinion that, taking into account (i) the financial resources available to our Group, including cash and cash equivalents of RMB1,828.8 million as of April 30, 2021, cash flows from operating activities and the estimated net [REDACTED] based on the [REDACTED] of the [REDACTED] from the [REDACTED], and (ii) our cash burn rate, which is our cash and cash equivalents balance divided by average monthly net cash used in operating activities plus payments for property, plant and equipment, we have sufficient working capital to cover at least 125% of our costs, including research and development expenses, general and administrative expenses, finance costs and other expenses for at least the next 12 months from the date of this document. Without taking into account the estimated net [REDACTED] from the [REDACTED], our Directors believe that we have sufficient working capital for at least 12 months from the date of this document.

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INDEBTEDNESS

As of December 31, 2019 and 2020, April 30 and August 31, 2021, except as disclosed in the table below, we did not have any material mortgages, charges, debentures, loan capital, debt securities, loans, unutilized banking facilities, bank overdrafts or other similar indebtedness, finance lease or hire purchase commitments, liabilities under acceptances (other than normal trade bills), acceptance credits, which are either guaranteed, unguaranteed, secured or unsecured, or guarantees or other contingent liabilities.

	As of December 31,		As of April 30,	As of August 31,
	2019	2020	2021	2021
	<i>(RMB in thousands)</i>			(Unaudited)
Current				
Lease liabilities	1,810	4,259	7,763	8,298
Non-current				
Convertible redeemable preferred shares	198,736	1,127,306	3,063,343	3,394,750
Lease liabilities	10,645	18,057	21,336	19,351
Total	211,191	1,149,622	3,092,442	3,422,399

CAPITAL EXPENDITURES

Our capital expenditures primarily consist of (i) construction in progress, (ii) electronic and other equipment, (iii) leasehold improvements, (iv) building, (v) machinery and (vi) vehicles. During the Track Record Period, our capital expenditure was primarily in relation to the construction of our production lines and installation of manufacturing equipment. The following table sets forth our capital expenditures for the periods indicated.

	Year Ended December 31,		Four Months Ended April 30,
	2019	2020	2021
	<i>(RMB in thousands)</i>		
Construction in progress	–	58,354	9,262
Electronic and other equipment	393	102	4,486
Buildings	–	–	25,321
Machinery	1,097	8	8,833
Vehicles	–	173	–
Leasehold improvements	1,792	3,841	1,016
Total	3,282	62,478	48,918

FINANCIAL INFORMATION

QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Foreign Currency Risk

Foreign currency risk is the risk of loss resulting from changes in foreign currency exchange rates. The fluctuations in the exchange rate between RMB and other currencies in which we conduct business may affect our results of operations. We seek to limit our exposures to foreign currency risk by minimizing our net foreign currency position. See note 31 to the Accountants’ Report set out in Appendix I.

Credit Risk

The carrying amounts of cash and bank balances and other receivables represent our maximum exposure equal to credit risk in relation to the financial assets.

We expect that there is no significant credit risk associated with cash and bank balances since they are substantially held in reputable state-owned banks and other medium or large-sized listed banks. Our Directors does not expect that there will be any significant losses from on-performance by these counterparties.

We trade only with recognized and creditworthy third parties. It is our Group’s policy that all customers who wish to trade on credit terms are subject to credit verification procedures. In addition, receivable balances are monitored on an ongoing basis and our Directors are of the view that our exposure to bad debts is not significant.

The credit risk of our other financial assets, which comprise cash and cash equivalents and other receivables, arises from default of the counterparty, with a maximum exposure equal to the carrying amounts of these instruments.

Since we only trade only with recognized and creditworthy third parties, there is no requirement for collateral. Concentrations of credit risk are managed by customer/counterparty, by geographical region and by industry sector. There are no significant concentrations of credit risk within our Group as the customer bases of our Group’s trade receivables are widely dispersed in different sectors and industries.

Our Directors are of the view that our exposure to credit risk arising from other receivables is not significant since counterparties to these financial assets have no history of default. See note 31 to the Accountants’ Report set out in Appendix I.

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Liquidity Risk

Liquidity risk is the risk that we will encounter difficulty in meeting financial obligations due to shortage of funds. Our exposure to liquidity risk arises primarily from operations. We monitor and maintain a level of cash and cash equivalents deemed adequate by the management of our Group to finance the operations and mitigate the effects of fluctuations in cash flows. Our objective is to maintain a balance between continuity of funding and flexibility. We aim to maintain sufficient cash and cash equivalents to meet our liquidity requirements. See note 31 to the Accountants’ Report set out in Appendix I.

KEY FINANCIAL RATIOS

	As of December 31,		As of April 30,
	2019	2020	2021
Current Ratio ⁽¹⁾	6.0	15.7	15.2

Note:

(1) Current ratio is calculated using current assets divided by current liabilities as of the same date.

Current ratio increased from 6.0 as of December 31, 2019 to 15.7 as of December 31, 2020 due to an increase in current assets in relation to our cash and cash equivalents and time deposits and restricted cash. We recorded a relatively stable current ratio of 15.2 as of April 30, 2021.

TRANSACTIONS WITH RELATED PARTIES

We had the following transactions during the Track Record Period with related parties:

Name of Related Company	Nature of Transaction	Year Ended December 31,		Four Months Ended April 30,	
		2019	2020	2020	2021
				<i>(Unaudited)</i>	
Chengdu Tianhe	Office lease and utility fees	1,374	2,716	669	1,118
	Entrusted loan ⁽²⁾	–	–	–	99,021
GenHunter Corporation	Service fees	138	171	79	62
Peng Liang	Individual income tax payments ⁽¹⁾	1,570	–	–	–

Note:

- (1) It represented the settlement of the shareholders bearing individual tax incurred in relation to our equity financing.
- (2) We entered into a entrusted loan contract with Chengdu Tianhe and a commercial bank on 4 February 2021, pursuant to which we entrusted the commercial bank to provide a loan to Chengdu Tianhe. As of April 30, 2021, all loans under the entrusted loan contract have been repaid in accordance with the contract.

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	As of December 31,		As of
	2019	2020	April 30, 2021
	<i>(RMB in thousands)</i>		
Amount due from a related party:			
Chengdu Tianhe	72	113	134
Amount due to a related party:			
Chengdu Clover Biotechnology Co., Ltd. (“ Chengdu Clover ”)	2,928	1,473	–

Chengdu Clover is a biotechnology company established under the laws of PRC in September 2008 and has a registered capital of RMB1.0 million. Chengdu Clover is controlled by the sister of our founder, Dr. Liang, and Chengdu Tianhe holds 20% of the equity interests in it. It is primarily engaged in research and development of biotechnology and the sales of chemical reagents mainly in Chengdu. It engaged with small scale of business since inception and does not actively engage with business activities during the Track Record Period.

Prior to the Track Record Period, we entered into transactions with Chengdu Clover in which Chengdu Clover provided research and development in relation to the pre-clinical studies of SCB-313. After Chengdu Clover completed the pre-clinical studies, we purchased the property, plant and equipment used in the pre-clinical studies from Chengdu Clover. Amounts due to Chengdu Clover represent the research and development service fees and the considerations to purchase property, plant and equipment in the aforementioned transactions. We have settled the outstanding balances as of the Latest Practicable Date. We currently do not plan to engage Chengdu Clover to provide research and development services going forward.

We entered into the Entrusted Loan Agreement in February 2021 to entrust a commercial bank to provide a loan of an amount of RMB99.0 million to Chengdu Tianhe. The proceeds of such loan were subsequently advanced to Chengdu Tianhe to assist their planned renovation and reconstruction process. We provided the entrusted loan to Chengdu Tianhe because it needed short-term capital for business purposes and we had idle cash at the time and considered such arrangement to be low risk considering our relationship with Chengdu Tianhe. The annual interest rate for the Entrusted Loan Agreement is fixed at 3%. The Entrusted Loan Agreement was terminated upon full repayment of principal and interest by Chengdu Tianhe in March 2021. We do not intend to provide similar entrusted loans to other shareholders, independent third parties or other related parties going forward.

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It is the view of our Directors that each of the above transactions (i) was conducted in the ordinary and usual course of business and on normal commercial terms between the relevant parties, and (ii) does not distort our Track Record Period results or make our historical results not reflective of future performance. See note 28 to the Accountant’s Report as set out in Appendix I for a detailed information of transactions with related parties.

DIVIDENDS

We did not declare or pay dividends on our Shares during the Track Record Period. We currently expect to retain all future earnings for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. The declaration and payment of any dividends in the future will be determined by our Board of Directors, in its discretion, and will depend on a number of factors, including our earnings, capital requirements, overall financial condition and contractual restrictions. In addition, our Shareholders may by ordinary resolution declare a dividend, but no dividend may exceed the amount recommended by our Board of Directors. If we pay dividends in the future, in order for us to distribute dividends to our Shareholders, we will rely to some extent on any dividends distributed by our PRC subsidiaries. Any dividend distributions from our PRC subsidiaries to us will be subject to PRC withholding tax. In addition, regulations in the PRC currently permit payment of dividends of a PRC company only out of accumulated distributable after-tax profits as determined in accordance with its articles of association and the accounting standards and regulations in China. See “Risk Factors – Risks Relating to Doing Business in China.” In the future, we may rely to some extent on dividends and other distributions on equity from our principal operating subsidiaries to fund offshore cash and financing requirements.

DISTRIBUTABLE RESERVES

As of April 30, 2021, we did not have any distributable reserves.

[REDACTED] EXPENSES

[REDACTED] expenses to be borne by us are estimated to be approximately HK\$[REDACTED] (including [REDACTED] commission, assuming an [REDACTED] of HK\$[REDACTED] per Share, being the [REDACTED] of the [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per Share), assuming no Shares are issued pursuant to the [REDACTED]. No such expenses were recognized and charged to our consolidated statements of profit or loss in 2019. In 2020, the [REDACTED] expenses charged to profit or loss were RMB[REDACTED] (approximately HK\$[REDACTED]) and the issue costs capitalized to deferred issue costs were RMB[REDACTED] (approximately HK\$[REDACTED]). After December 31, 2020, approximately HK\$[REDACTED] is expected to be charged to our consolidated statements of profit or loss, and approximately HK\$[REDACTED] is expected to be accounted for as a deduction from equity upon the [REDACTED]. The [REDACTED] expenses above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

FINANCIAL INFORMATION

UNAUDITED PRO FORMA ADJUSTED CONSOLIDATED NET TANGIBLE ASSETS

The following unaudited pro forma adjusted consolidated net tangible assets has been prepared in accordance with paragraph 4.29 of the Rules Governing the Listing of Securities on the Stock Exchange of Hong Kong Limited and with reference to Accounting Guideline 7 “Preparation of Pro Forma Financial Information for inclusion in Investment Circulars” issued by the Hong Kong Institute of Certified Public Accountants (“HKICPA”) for illustration purpose only, and is set out below to illustrate the effect of the [REDACTED] on our consolidated net tangible liabilities as of April 30, 2021 as if it had taken place on that date.

The unaudited pro forma adjusted consolidated net assets attributed to the owners of the Company has been prepared for illustrative purposes only and because of its hypothetical nature, it may not give a true picture of the financial position of the Group had the [REDACTED] been completed as of April 30, 2021 or any future date. It is prepared based on the consolidated net tangible liabilities as at April 30, 2021 as set out in the Accountants’ Report, the text of which is set forth in Appendix I to this document, and adjusted as described below. The unaudited pro forma adjusted consolidated net tangible assets does not form part of the Accountants’ Report, the text of which is set out in Appendix I to this document.

[REDACTED]

FINANCIAL INFORMATION

[REDACTED]

NO MATERIAL ADVERSE CHANGE

Save as disclosed in this document, our Directors have confirmed, after performing all the due diligence work which our Directors consider appropriate, that, as of the date of this document, there has been no material adverse change in our financial or trading position or prospects since April 30, 2021 and up to the date of this document.

DISCLOSURE UNDER RULES 13.13 TO 13.19 OF THE LISTING RULES

Our Directors have confirmed that, as of the Latest Practicable Date, they were not aware of any circumstance that would give rise to a disclosure requirement under Rules 13.13 to 13.19 of the Listing Rules.

FUTURE PLANS AND USE OF [REDACTED]

FUTURE PLANS AND PROSPECTS

See “Business – Our Strategies” for a detailed description of our future plans.

USE OF [REDACTED]

We estimate that we will receive net [REDACTED] from the [REDACTED] of approximately HK\$[REDACTED], after deducting [REDACTED] commissions, fees and estimated expenses payable by us in connection with the [REDACTED], and assuming an [REDACTED] of HK\$[REDACTED] per Share, being the [REDACTED] of the [REDACTED] range stated in this Document. If the [REDACTED] is set at HK\$[REDACTED] per Share, being the [REDACTED] of the [REDACTED] range, the net [REDACTED] from the [REDACTED] will increase by approximately HK\$[REDACTED]. If the [REDACTED] is set at HK\$[REDACTED] per Share, being the [REDACTED] of the [REDACTED], the net [REDACTED] from the [REDACTED] will decrease by approximately HK\$[REDACTED].

Assuming an [REDACTED] at the [REDACTED] of the [REDACTED] range, we currently intend to apply these net [REDACTED] for the following purposes:

- Approximately [REDACTED], or HK\$[REDACTED], will be used for the research and development, manufacturing and commercialization of our Core Products and related products;
 - approximately [REDACTED], or HK\$[REDACTED], to be used for regulatory submission, commercial preparation and launch, and post-marketing studies of SCB-2019 (CpG 1018/Alum). Of these [REDACTED], we expect to allocate (i) approximately [REDACTED] for further CMC development, optimization scale-up and commercial production of SCB-2019 (CpG 1018/Alum), (ii) approximately [REDACTED] for regulatory submission associated costs and post-marketing studies, and (iii) approximately [REDACTED] to engage CMOs to develop certain manufacturing processes of SCB-2019 (CpG 1018/Alum) to supplement our own manufacturing capabilities. See “Business – Our Product Candidates – Trimer-Tag™ Subunit Vaccine Candidates – SCB-2019 (CpG 1018/Alum);”
 - approximately [REDACTED], or HK\$[REDACTED], will be used for the research and development and regulatory submission for our second-generation COVID-19 vaccine candidates. See “Business – Our Product Candidates – Trimer-Tag™ Subunit Vaccine Candidates – Selected Pre-clinical and Discovery-Stage Vaccine Candidates – Second-generation COVID-19 vaccine candidates;”
 - approximately [REDACTED], or HK\$[REDACTED], will be used for the research and development and commercial preparation and launch of SCB-808. Of these [REDACTED], we expect to allocate approximately [REDACTED] to complete the Phase 3 clinical trial and approximately [REDACTED] to prepare for the commercial launch of SCB-808. See “Business – Our Product Candidates – Fc Fusion Product Candidates – SCB-808;”

FUTURE PLANS AND USE OF [REDACTED]

- Approximately [REDACTED]%, or HK\$[REDACTED], will be used for the research and development, manufacturing and commercialization of other products in our pipeline;
 - approximately [REDACTED]%, or HK\$[REDACTED], will be used for the research and development of SCB-313. We expect to allocate approximately [REDACTED]% of the [REDACTED] intended for this purpose for developing SCB-313 for the treatment of MA, MPE and PC. We expect to allocate approximately [REDACTED]% of the [REDACTED] intended for this purpose for Phase 1 clinical trials for other indications. See “Business – Our Product Candidates – Trimer-Tag™ Oncology Product Candidates – SCB-313;”
 - approximately [REDACTED]%, or HK\$[REDACTED], will be used for the research and development of other product candidates, including (i) the phase 1 clinical trial of our SCB-420 candidate, (ii) preclinical development and Phase 1 clinical trials of vaccine candidates for rabies, RSV and influenza, and (iii) preclinical development and Phase 1 clinical trials for a 4-1BB agonist product candidate in oncology;
- Approximately [REDACTED]%, or HK\$[REDACTED], will be used for working capital and other general corporate purposes.

The above allocation of the net [REDACTED] from the [REDACTED] will be adjusted on a pro rata basis in the event that the [REDACTED] is fixed at a higher or lower level compared to the [REDACTED] of the [REDACTED] range stated in this Document.

If the [REDACTED] is exercised in full, the net [REDACTED] that we will receive will be approximately HK\$[REDACTED], assuming an [REDACTED] of HK\$[REDACTED] per Share (being the [REDACTED] of the [REDACTED] range). In the event that the [REDACTED] is exercised in full, we intent to apply the additional net [REDACTED] to the above purposes in the proportions stated above.

To the extent that the net [REDACTED] from the [REDACTED] are not immediately used for the purposes described above and to the extent permitted by the relevant laws and regulations, they will be placed in short-term demand deposits with authorized and licensed commercial banks or financial institutions.

We will issue an appropriate announcement if there is any material change to the above proposed use of [REDACTED].

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

STRUCTURE OF THE [REDACTED]

[REDACTED]

STRUCTURE OF THE [REDACTED]

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STRUCTURE OF THE [REDACTED]

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STRUCTURE OF THE [REDACTED]

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STRUCTURE OF THE [REDACTED]

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STRUCTURE OF THE [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED]

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APPENDIX I

ACCOUNTANTS’ REPORT

[To insert the firm’s letterhead]

ACCOUNTANTS’ REPORT ON HISTORICAL FINANCIAL INFORMATION TO THE DIRECTORS OF CLOVER BIOPHARMACEUTICALS LTD. AND GOLDMAN SACHS (ASIA) L.L.C. AND CHINA INTERNATIONAL CAPITAL CORPORATION HONG KONG SECURITIES LIMITED

Introduction

We report on the historical financial information of Clover Biopharmaceuticals Ltd. (the “Company”) and its subsidiaries (together, the “Group”) set out on pages [I-4] to [I-46], which comprises the consolidated statements of profit or loss, statements of comprehensive income, statements of changes in equity and statements of cash flows of the Group for each of the years ended 31 December 2019 and 2020 and the four months ended 30 April 2021 (the “Relevant Periods”), and the consolidated statements of financial position of the Group as at 31 December 2019 and 2020 and 30 April 2021 and the statement of financial position of the Company as at 31 December 2019 and 2020 and 30 April 2021 and a summary of significant accounting policies and other explanatory information (together, the “Historical Financial Information”). The Historical Financial Information set out on pages [I-4] to [I-46] forms an integral part of this report, which has been prepared for inclusion in the document of the Company dated [Date] (the “Document”) in connection with the initial [REDACTED] of the shares of the Company on the Main Board of The Stock Exchange of Hong Kong Limited (the “Stock Exchange”).

Directors’ responsibility for the Historical Financial Information

The directors of the Company are responsible for the preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of presentation and the basis of preparation set out in notes 2.1 and 2.2 to the Historical Financial Information, respectively, and for such internal control as the directors determine is necessary to enable the preparation of the Historical Financial Information that is free from material misstatement, whether due to fraud or error.

Reporting accountants’ responsibility

Our responsibility is to express an opinion on the Historical Financial Information and to report our opinion to you. We conducted our work in accordance with Hong Kong Standard on Investment Circular Reporting Engagements 200 *Accountants’ Reports on Historical Financial Information in Investment Circulars* issued by the Hong Kong Institute of Certified Public Accountants (“HKICPA”). This standard requires that we comply with ethical standards and plan and perform our work to obtain reasonable assurance about whether the Historical Financial Information is free from material misstatement.

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Our work involved performing procedures to obtain evidence about the amounts and disclosures in the Historical Financial Information. The procedures selected depend on the reporting accountants’ judgement, including the assessment of risks of material misstatement of the Historical Financial Information, whether due to fraud or error. In making those risk assessments, the reporting accountants consider internal control relevant to the entity’s preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of presentation and the basis of preparation set out in notes 2.1 and 2.2 to the Historical Financial Information, respectively, in order to design procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity’s internal control. Our work also included evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors, as well as evaluating the overall presentation of the Historical Financial Information.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Opinion

In our opinion, the Historical Financial Information gives, for the purposes of the accountants’ report, a true and fair view of the financial position of the Group as at 31 December 2019 and 2020 and 30 April 2021, and the financial position of the Company as at 31 December 2019 and 2020 and 30 April 2021 and of the financial performance and cash flows of the Group for each of the Relevant Periods in accordance with the basis of presentation and the basis of preparation set out in notes 2.1 and 2.2 to the Historical Financial Information, respectively.

Review of interim financial information

We have reviewed the interim comparative financial information of the Group which comprises the consolidated statement of profit or loss, statement of comprehensive income, statement of changes in equity and statement of cash flows of the Group for the four months ended 30 April 2020 and other explanatory information (the “Interim Comparative Financial Information”). The directors of the Company are responsible for the preparation of the Interim Comparative Financial Information in accordance with the basis of presentation and the basis of preparation set out in notes 2.1 and 2.2 to the Historical Financial Information, respectively. Our responsibility is to express a conclusion on the Interim Comparative Financial Information based on our review. We conducted our review in accordance with Hong Kong Standard on Review Engagements 2410 *Review of Interim Financial Information Performed by the Independent Auditor of the Entity* issued by the HKICPA. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Hong Kong Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion. Based on our review,

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nothing has come to our attention that causes us to believe that the Interim Comparative Financial Information, for the purposes of the accountants' report, is not prepared, in all material respects, in accordance with the basis of presentation and the basis of preparation set out in notes 2.1 and 2.2 to the Historical Financial Information, respectively.

Report on matters under the Rules Governing the Listing of Securities on the Main Board of the Stock Exchange and the Companies (Winding Up and Miscellaneous Provisions) Ordinance

Adjustments

In preparing the Historical Financial Information, no adjustments to the Underlying Financial Statements as defined on page [I-4] have been made.

Dividends

We refer to note 11 to the Historical Financial Information which states that no dividends have been paid by the Company in respect of the Relevant Periods.

No historical financial statements for the Company

As at the date of this report, no statutory financial statements have been prepared for the Company since its date of incorporation.

[●]

Certified Public Accountants

Hong Kong

[Date]

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HISTORICAL FINANCIAL INFORMATION

Preparation of Historical Financial Information

Set out below is the Historical Financial Information which forms an integral part of this accountants’ report.

The financial statements of the Group for the Relevant Periods, on which the Historical Financial Information is based, were audited by Ernst & Young in accordance with Hong Kong Standards on Auditing issued by the Hong Kong Institute of Certified Public Accountants (the “HKICPA”) (the “Underlying Financial Statements”).

The Historical Financial Information is presented in Renminbi (“RMB”) and all values are rounded to the nearest thousand (RMB’000) except when otherwise indicated.

CONSOLIDATED STATEMENTS OF PROFIT OR LOSS

		Year ended 31 December		Four months ended 30 April	
	Notes	2019	2020	2020	2021
		RMB’000	RMB’000	RMB’000	RMB’000
				(Unaudited)	
Other income and gains	5	16,908	24,341	13,152	5,491
Administrative expenses		(17,035)	(76,429)	(11,983)	(78,989)
Research and development expenses		(45,799)	(228,219)	(28,857)	(370,815)
Fair value changes of convertible redeemable preferred shares	21	9,245	(597,659)	(119,870)	(454,770)
Other expenses		(1,570)	(31,959)	(13)	(3,660)
Finance costs	7	(10,332)	(2,973)	(585)	(6,444)
LOSS BEFORE TAX	6	(48,583)	(912,898)	(148,156)	(909,187)
Income tax expense	10	–	–	–	–
LOSS FOR THE YEAR/PERIOD		<u>(48,583)</u>	<u>(912,898)</u>	<u>(148,156)</u>	<u>(909,187)</u>
Attributable to:					
Owners of the parent		<u>(48,583)</u>	<u>(912,898)</u>	<u>(148,156)</u>	<u>(909,187)</u>
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT (EXPRESSED IN RMB PER SHARE)					
Basic	12	<u>(0.97)</u>	<u>(18.26)</u>	<u>(2.96)</u>	<u>(18.18)</u>
Diluted	12	<u>(0.97)</u>	<u>(18.26)</u>	<u>(2.96)</u>	<u>(18.18)</u>

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CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

	Year ended 31 December		Four months ended 30 April	
	2019 <i>RMB'000</i>	2020 <i>RMB'000</i>	2020 <i>RMB'000</i> (Unaudited)	2021 <i>RMB'000</i>
LOSS FOR THE YEAR/PERIOD	<u>(48,583)</u>	<u>(912,898)</u>	<u>(148,156)</u>	<u>(909,187)</u>
OTHER COMPREHENSIVE INCOME				
Other comprehensive income that will not be reclassified to profit or loss in subsequent periods:				
Exchange differences on translation of the Company	<u>—</u>	<u>—</u>	<u>—</u>	<u>5,825</u>
Other comprehensive income that may be reclassified to profit or loss in subsequent periods:				
Exchange differences on translation of foreign operations	<u>114</u>	<u>(2,021)</u>	<u>(272)</u>	<u>453</u>
OTHER COMPREHENSIVE INCOME FOR THE YEAR/PERIOD, NET OF TAX	<u>114</u>	<u>(2,021)</u>	<u>(272)</u>	<u>6,278</u>
TOTAL COMPREHENSIVE INCOME FOR THE YEAR/PERIOD	<u>(48,469)</u>	<u>(914,919)</u>	<u>(148,428)</u>	<u>(902,909)</u>
Attributable to:				
Owners of the parent	<u>(48,469)</u>	<u>(914,919)</u>	<u>(148,428)</u>	<u>(902,909)</u>

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CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	Notes	As at 31 December		As at
		2019	2020	30 April
		RMB'000	RMB'000	2021
				RMB'000
NON-CURRENT ASSETS				
Property, plant and equipment	13	4,991	65,897	112,741
Right-of-use assets	14	12,437	21,090	27,982
Intangible assets	15	294	277	6,481
Other non-current assets	17	4,148	51,839	28,125
Total non-current assets		21,870	139,103	175,329
CURRENT ASSETS				
Inventories	16	393	50,881	146,717
Prepayments, other receivables and other assets	17	5,259	191,032	173,990
Financial assets at fair value through profit or loss		–	–	167
Time deposits and restricted cash	18	10,000	290,328	245,126
Cash and cash equivalents	18	148,694	516,184	1,828,780
Total current assets		164,346	1,048,425	2,394,780
CURRENT LIABILITIES				
Trade payables	19	7,165	33,820	98,831
Other payables and accruals	20	18,512	28,655	51,451
Lease liabilities	14	1,810	4,259	7,763
Total current liabilities		27,487	66,734	158,045
NET CURRENT ASSETS		136,859	981,691	2,236,735
TOTAL ASSETS LESS CURRENT LIABILITIES		158,729	1,120,794	2,412,064
NON-CURRENT LIABILITIES				
Lease liabilities	14	10,645	18,057	21,336
Convertible redeemable preferred shares	21	198,736	1,127,306	3,063,343
Deferred income	22	17,170	958,172	1,210,881
Total non-current liabilities		226,551	2,103,535	4,295,560
NET LIABILITIES		(67,822)	(982,741)	(1,883,496)
EQUITY				
Share capital	23	–	–	33
Reserves	25	(67,822)	(982,741)	(1,883,529)
Total equity		(67,822)	(982,741)	(1,883,496)

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CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

Year ended 31 December 2019

	Attributable to owners of the parent				Total equity RMB’000
	Share capital RMB’000 (note 23)	Merger reserve* RMB’000 (note 25)	Exchange fluctuation reserve* RMB’000 (note 25)	Accumulated losses* RMB’000	
At 1 January 2019	–	52,981	(292)	(72,042)	(19,353)
Loss for the year	–	–	–	(48,583)	(48,583)
Other comprehensive income for the year:					
Exchange differences on translation of foreign operations	–	–	114	–	114
Total comprehensive income for the year	–	–	114	(48,583)	(48,469)
At 31 December 2019	–	52,981	(178)	(120,625)	(67,822)

Year ended 31 December 2020

	Attributable to owners of the parent				Total equity RMB’000
	Share capital RMB’000 (note 23)	Merger reserve* RMB’000 (note 25)	Exchange fluctuation reserve* RMB’000 (note 25)	Accumulated losses* RMB’000	
At 1 January 2020	–	52,981	(178)	(120,625)	(67,822)
Loss for the year	–	–	–	(912,898)	(912,898)
Other comprehensive income for the year:					
Exchange differences on translation of foreign operations	–	–	(2,021)	–	(2,021)
Total comprehensive income for the year	–	–	(2,021)	(912,898)	(914,919)
At 31 December 2020	–	52,981	(2,199)	(1,033,523)	(982,741)

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Four months ended 30 April 2021

	Attributable to owners of the parent					Total equity RMB'000
	Share capital RMB'000 (note 23)	Share-based payments reserve* RMB'000 (note 24)	Merger reserve* RMB'000 (note 25)	Exchange fluctuation reserve* RMB'000 (note 25)	Accumulated losses* RMB'000	
At 1 January 2021	–	–	52,981	(2,199)	(1,033,523)	(982,741)
Loss for the period	–	–	–	–	(909,187)	(909,187)
Other comprehensive income for the period:						
Exchange differences on translation of the Company	–	–	–	5,825	–	5,825
Exchange differences related to foreign operations	–	–	–	453	–	453
Total comprehensive income for the period	–	–	–	6,278	(909,187)	(902,909)
Issue of shares	33	–	99,312	–	–	99,345
Deemed distribution to a shareholder**	–	–	(100,590)	–	–	(100,590)
Share-based payments	–	3,399	–	–	–	3,399
At 30 April 2021	<u>33</u>	<u>3,399</u>	<u>51,703</u>	<u>4,079</u>	<u>(1,942,710)</u>	<u>(1,883,496)</u>

Four months ended 30 April 2020

	Attributable to owners of the parent					Total equity RMB'000
	Share capital RMB'000 (note 23)	Merger reserve* RMB'000 (note 25)	Exchange fluctuation reserve* RMB'000 (note 25)	Accumulated losses* RMB'000		
At 1 January 2020	–	52,981	(178)	(120,625)		(67,822)
Loss for the period (unaudited)	–	–	–	(148,156)		(148,156)
Other comprehensive income for the period: (unaudited)	–	–	–	–		–
Exchange differences on translation of foreign operations (unaudited)	–	–	(272)	–		(272)
Total comprehensive income for the period (unaudited)	–	–	(272)	(148,156)		(148,428)
At 30 April 2020 (unaudited)	<u>–</u>	<u>52,981</u>	<u>(450)</u>	<u>(268,781)</u>		<u>(216,250)</u>

* These reserve accounts comprise the consolidated reserves of RMB(67,822,000), RMB(982,741,000) and RMB(1,883,529,000) in the consolidated statements of financial position as at 31 December 2019 and 2020 and 30 April 2021, respectively.

** The deemed distribution arose from the Reorganisation completed during the four months ended 30 April 2021, pursuant to which, a cash consideration of RMB100,590,000 was paid by the Group to Chengdu Tianhe Conventional Chinese and Medicine Technology Nurture Co., Ltd. (“Chengdu Tianhe”), the then ordinary shareholder of Sichuan Clover Biopharmaceuticals, Inc. (“Clover Sichuan”), for the acquisition of Clover Sichuan which was consolidated as a subsidiary in the Group’s consolidated financial statements under the basis that the current group structure had been in existence throughout the Relevant Periods.

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CONSOLIDATED STATEMENTS OF CASH FLOWS

	Notes	Year ended 31 December		Four months ended 30 April	
		2019 RMB'000	2020 RMB'000	2020 RMB'000 (Unaudited)	2021 RMB'000
CASH FLOWS FROM OPERATING ACTIVITIES					
Loss before tax		(48,583)	(912,898)	(148,156)	(909,187)
Adjustments for:					
Interest income	5	(783)	(3,408)	(558)	(2,021)
Finance costs	7	10,332	2,973	585	6,444
Depreciation of property, plant, and equipment	13	1,073	1,566	430	2,074
Depreciation of right-of-use assets	14	1,177	4,023	1,093	1,781
Amortisation of intangible assets	15	147	195	54	124
Loss on disposal of property, plant and equipment		–	6	6	–
Share-based payment expenses	6, 24	–	–	–	3,399
Foreign exchange differences, net	6	(84)	31,896	(889)	3,628
Fair value changes of financial assets at fair value through profit or loss	5	–	–	–	(167)
Fair value changes of convertible redeemable preferred shares	6	(9,245)	597,659	119,870	454,770
		(45,966)	(277,988)	(27,565)	(439,155)
Increase in inventories		(393)	(50,488)	(2,697)	(95,836)
Decrease/(increase) in prepayments, other receivables and other assets		(1,690)	(182,001)	(5,395)	14,816
Increase in trade payables		6,768	24,902	3,732	64,477
Increase/(decrease) in other payables and accruals		4,072	18,092	(2,775)	11,426
Increase in deferred income		9,809	941,002	17,877	252,709
Cash (used in)/generated from operations		(27,400)	473,519	(16,823)	(191,563)
Interest received		783	3,408	558	2,021
Net cash flows (used in)/from operating activities		(26,617)	476,927	(16,265)	(189,542)

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	Notes	Year ended 31 December		Four months ended 30 April	
		2019 RMB'000	2020 RMB'000	2020 RMB'000 (Unaudited)	2021 RMB'000
CASH FLOWS FROM INVESTING ACTIVITIES					
Purchases of items of property, plant and equipment		(6,816)	(113,614)	(1,112)	(13,692)
Additions to intangible assets		–	(178)	(178)	(2,731)
Decrease/(increase) in time deposits and restricted deposits	18	4,218	(280,328)	(62,697)	45,202
Net cash flows (used in)/from investing activities		(2,598)	(394,120)	(63,987)	28,779
CASH FLOWS FROM FINANCING ACTIVITIES					
Payment of transaction costs for issuance of the Company’s convertible redeemable preferred shares		(1,224)	(9,265)	(2,554)	(6,064)
Proceeds from issuance of convertible redeemable preferred shares	21	145,000	330,911	51,346	1,487,456
Lease payments	14	(1,726)	(4,472)	(919)	(2,564)
Payment of [REDACTED]		–	(327)	–	(1,219)
Issue of shares		–	–	–	99,345
Cash received from holders of preferred shares due to Reorganisation		–	–	–	528,076
Cash paid to holders of preferred shares due to Reorganisation		–	–	–	(530,179)
Deemed distribution to a shareholder		–	–	–	(100,590)
Net cash flows from financing activities		142,050	316,847	47,873	1,474,261
NET INCREASE IN CASH AND CASH EQUIVALENTS					
Cash and cash equivalents at beginning of year/period		35,744	148,694	148,694	516,184
Effect of foreign exchange rate changes, net		115	(32,164)	(137)	(902)
CASH AND CASH EQUIVALENTS AT END OF YEAR/PERIOD		148,694	516,184	116,178	1,828,780
ANALYSIS OF BALANCES OF CASH AND CASH EQUIVALENTS					
Cash and bank balances	18	158,694	806,512	188,875	2,073,906
Time deposits and restricted cash	18	(10,000)	(290,328)	(72,697)	(245,126)
Cash and cash equivalents as stated in the consolidated statements of cash flows		148,694	516,184	116,178	1,828,780

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STATEMENT OF FINANCIAL POSITION OF THE COMPANY

		As at 31 December		As at 30 April
	<i>Notes</i>	2019	2020	2021
		<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
NON-CURRENT ASSETS				
Investments in subsidiaries		–	–	637,167
CURRENT ASSETS				
Prepayments, other receivables and other assets		–	–	598,096
Cash and cash equivalents	18	–	–	1,471,977
Total current assets		–	–	2,070,073
CURRENT LIABILITIES				
Other payables and accruals		–	–	32,078
Total current liabilities		–	–	32,078
NET CURRENT ASSETS		–	–	2,037,995
TOTAL ASSETS LESS CURRENT LIABILITIES		–	–	2,675,162
NON-CURRENT LIABILITIES				
Convertible redeemable preferred shares	21	–	–	3,063,343
NET LIABILITIES		–	–	(388,181)
EQUITY				
Share capital	23	–	–	33
Reserves	25	–	–	(388,214)
Total equity		–	–	(388,181)

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II NOTES TO THE HISTORICAL FINANCIAL INFORMATION

1. CORPORATE INFORMATION

The Company is a limited liability company incorporated in the Cayman Islands on 31 October 2018. The registered address of the Company is PO Box 309, Ugland House, Grand Cayman, KYI-1104, Cayman Islands.

The Company is an investment holding company. During the Relevant Periods, the Company’s subsidiaries were principally engaged in the research and development of biopharmaceutical products.

The Company and its subsidiaries now comprising the Group underwent the Reorganisation as set out in the paragraph headed “Reorganisation” in the section headed “History and Development” in the Document. Apart from the Reorganisation, the Company has not commenced any business or operation since its incorporation.

As at the date of this report, the Company had direct and indirect interests in its subsidiaries, all of which are private limited liability companies (or, if incorporated outside Hong Kong, have substantially similar characteristics to a private company incorporated in Hong Kong), the particulars of which are set out below:

Name	Place and date of incorporation/ registration and place of operations	Nominal value of ordinary/ registered share capital	Percentage of equity attributable to the Company		Principal activities
			Direct	Indirect	
Clover Biopharmaceuticals (Hong Kong) Co., Limited (“Clover HK”) <i>(note (a))</i>	Hong Kong 30 November 2018	HKD1	100%	–	Investment holding
Sichuan Clover Biopharmaceuticals, Inc. (“Clover Sichuan”) 四川三葉草生物製藥有限公司 <i>(note (b))</i>	People’s Republic of China (“PRC”)/ Mainland China 4 June 2007	RMB98,796,254	–	100%	Research and development
Clover Biopharmaceuticals AUS Pty Ltd. (“Clover AUS”) <i>(note (a))</i>	Australia 6 June 2017	AUD4,305,489.28	100%	–	Research and development
Zhejiang Clover Biopharmaceuticals, Inc. (“Clover Zhejiang”)* 浙江三葉草生物製藥有限公司 <i>(note (b))</i>	PRC/Mainland China 23 August 2016	RMB70,000,000	–	100%	Research and development
Clover Biopharmaceuticals (Beijing) Co., Ltd. (“Clover Beijing”)* 克洛菲生物製藥(北京)有限公司 <i>(note (b))</i>	PRC/Mainland China 1 September 2020	RMB1,000,000	–	100%	Research and development
Clover Biopharmaceuticals USA, Inc. (“Clover USA”) <i>(note (a))</i>	the United States 6 March 2020	USD1	–	100%	Research and development
Chengdu Fuya Enterprise Management Co., Ltd. (“Chengdu Fuya”)* 成都福雅企業管理有限公司 <i>(note (b))</i>	PRC/Mainland China 30 October 2020	RMB100,000	–	100%	Counselling
Clover Biopharmaceuticals (Shanghai) Co., Ltd. (“Clover Shanghai”)* 愷洛菲生物製藥(上海)有限公司 <i>(note (a))</i>	PRC/Mainland China 9 February 2021	RMB1,000,000	–	100%	Research and development
Clover biopharmaceuticals Ireland limited (“Clover Ireland”) <i>(note (a))</i>	Ireland 14 April 2021	EUR1	–	100%	Research and development

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Notes:

- (a) As at the date of this report, no audited financial statements have been prepared for these entities since the date of incorporation as these entities were not subject to any statutory audit requirements under the relevant rules and regulations in the jurisdictions of their incorporation.
- (b) The statutory financial statements of these entities for the years ended 31 December 2019 and 2020 were audited by Zhejiang Zhonghe Lianhe Public Accountants LLP (浙江中和聯合會計師事務所(特殊普通合夥)) and Zhongxingcai Guanghua Certified Public Accountants LLP (中興財光華會計師事務所(特殊普通合夥)), respectively, certified public accountants registered in the PRC.
- * The English names of the companies registered in PRC represent the best efforts made by management of the Company to translate the Chinese names of the companies as they do not have official English names.

2.1 BASIS OF PRESENTATION

Pursuant to the Reorganisation, as more fully explained in the paragraph headed “Reorganisation” in the section headed “History and Development” in the Document, the Company became the holding company of the companies now comprising the Group on 16 March 2021. As the Reorganisation mainly involved inserting new holding companies and has not resulted in any change of economic substance, the Historical Financial Information for the Relevant Periods has been presented as a continuation of the existing companies using the pooling of interest method as if the Reorganisation had been completed at the beginning of the Relevant Periods.

Accordingly, the consolidated statements of profit or loss, statements of comprehensive income, statements of changes in equity and statements of cash flows of the Group for the Relevant Periods and the four months ended 30 April 2020 include the consolidated results and cash flows of Sichuan Clover Biopharmaceuticals, Inc. and its subsidiaries and the results and cash flows of the other companies now comprising the Group as if the current group structure had been in existence throughout the Relevant Periods and the four months ended 30 April 2020. The consolidated statements of financial position of the Group as at 31 December 2019 and 2020 and 30 April 2021 include the consolidated assets and liabilities of Sichuan Clover Biopharmaceuticals, Inc. and its subsidiaries and the assets and liabilities of the other companies now comprising the Group as if the current group structure had been in existence throughout the Relevant Periods and the four months ended 30 April 2020. No adjustments are made to reflect fair values, or recognise any new assets or liabilities as a result of the Reorganisation.

All intra-group transactions and balances have been eliminated on consolidation.

2.2 BASIS OF PREPARATION

The Historical Financial Information has been prepared in accordance with International Financial Reporting Standards (“IFRSs”) issued by the International Accounting Standards Board (the “IASB”), which comprise all standards and interpretations approved by the IASB. All IFRSs effective for the accounting period commencing from 1 January 2021, together with the relevant transitional provisions, have been early adopted by the Group in the preparation of the Historical Financial Information throughout the Relevant Periods and the four months ended 30 April 2020.

The Historical Financial Information has been prepared under the historical cost convention, except for certain financial assets and financial liabilities which have been measured at fair value through profit or loss.

Basis of consolidation

The consolidated financial statements include the financial statements of the Company and its subsidiaries (collectively referred to as the “Group”). A subsidiary is an entity (including a structured entity), directly or indirectly, controlled by the Company. Control is achieved when the Group is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee (i.e., existing rights that give the Group the current ability to direct the relevant activities of the investee).

When the Company has, directly or indirectly, less than a majority of the voting or similar rights of an investee, the Group considers all relevant facts and circumstances in assessing whether it has power over an investee, including:

- (a) the contractual arrangement with the other vote holders of the investee;
- (b) rights arising from other contractual arrangements; and
- (c) the Group’s voting rights and potential voting rights.

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The financial statements of the subsidiaries are prepared for the same reporting period as the Company, using consistent accounting policies. The results of subsidiaries are consolidated from the date on which the Group obtains control, and continue to be consolidated until the date that such control ceases.

Profit or loss and each component of other comprehensive income are attributed to the owners of the parent of the Group and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

The Group reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control described above. A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction. If the Group loses control over a subsidiary, it derecognises (i) the assets (including goodwill) and liabilities of the subsidiary, (ii) the carrying amount of any non-controlling interest and (iii) the cumulative translation differences recorded in equity; and recognises (i) the fair value of the consideration received, (ii) the fair value of any investment retained and (iii) any resulting surplus or deficit in profit or loss. The Group’s share of components previously recognised in other comprehensive income is reclassified to profit or loss or retained profits, as appropriate, on the same basis as would be required if the Group had directly disposed of the related assets or liabilities.

2.3 ISSUED BUT NOT YET EFFECTIVE IFRSs

The Group has not applied the following new and revised IFRSs, that have been issued but are not yet effective, in this Historical Financial Information. The Group intends to adopt them, if applicable, when they become effective.

IFRS 17	<i>Insurance Contracts</i> ²
Amendments to IAS 1	<i>Classification of Liabilities as Current or Non-current</i> ²
Amendments to IAS 1	<i>Disclosure of Accounting Policies</i> ²
Amendments to IFRS 3	<i>Reference to the Conceptual Framework</i> ¹
Amendments to IAS 16	<i>Property, Plant and Equipment: Proceeds before Intended Use</i> ¹
Amendments to IAS 37	<i>Onerous Contracts – Costs of Fulfilling a Contract</i> ¹
<i>Annual Improvements to IFRS Standards 2018-2020 Cycle</i>	<i>Amendments to IFRS 1, IFRS 9, IFRS 16 and IAS 41</i> ¹
Amendments to IFRS 17	<i>Insurance Contracts</i> ^{2, 4}
Amendments to IAS 28 and IFRS 10	<i>Sale or Contribution of Assets between an Investor and its Associate or Joint Venture</i> ³
Amendments to IAS 8	<i>Definition of Accounting Estimates</i> ²
Amendments to IAS 12	<i>Deferred Tax related to Assets and Liabilities arising from a Single Transaction</i> ²
Amendments to IFRS 16	<i>Covid-19-Related Rent Concessions beyond 30 June 2021</i> ⁵

¹ Effective for annual periods beginning on or after 1 January 2022

² Effective for annual periods beginning on or after 1 January 2023

³ No mandatory effective date yet determined but available for adoption

⁴ As a consequence of the amendments to IFRS 17 issued in June 2020, IFRS 4 was amended to extend the temporary exemption that permits insurers to apply IAS 39 rather than IFRS 9 for annual periods beginning before 1 January 2023

⁵ Effective for annual periods beginning on or after 1 April 2021

The Group is in the process of making an assessment of the impact of these new and revised IFRSs upon initial application and has concluded that the adoption of them will not have material impact on the Group’s financial position and financial performance.

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2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Fair value measurement

The Group measures its derivative financial instruments at fair value at the end of each reporting period. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability, or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be accessible by the Group. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

A fair value measurement of a non-financial asset takes into account a market participant’s ability to generate economic benefits by using the asset in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use.

The Group uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximising the use of relevant observable inputs and minimising the use of unobservable inputs.

All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorised within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

Level 1 – based on quoted prices (unadjusted) in active markets for identical assets or liabilities

Level 2 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is observable, either directly or indirectly

Level 3 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable

For assets and liabilities that are recognised in the financial statements on a recurring basis, the Group determines whether transfers have occurred between levels in the hierarchy by reassessing categorisation (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each reporting period.

Impairment of non-financial assets

Where an indication of impairment exists, or when annual impairment testing for an asset is required (other than inventories and financial assets), the asset’s recoverable amount is estimated. An asset’s recoverable amount is the higher of the asset’s or cash-generating unit’s value in use and its fair value less costs of disposal, and is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets, in which case the recoverable amount is determined for the cash-generating unit to which the asset belongs.

An impairment loss is recognised only if the carrying amount of an asset exceeds its recoverable amount. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. An impairment loss is charged to the statement of profit or loss in the period in which it arises in those expense categories consistent with the function of the impaired asset.

An assessment is made at the end of each reporting period as to whether there is an indication that previously recognised impairment losses may no longer exist or may have decreased. If such an indication exists, the recoverable amount is estimated. A previously recognised impairment loss of an asset other than goodwill is reversed only if there has been a change in the estimates used to determine the recoverable amount of that asset, but not to an amount higher than the carrying amount that would have been determined (net of any depreciation/amortisation) had no impairment loss been recognised for the asset in prior years. A reversal of such an impairment loss is credited to the statement of profit or loss in the period in which it arises in those expense categories consistent with the function of the impaired asset.

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Related parties

A party is considered to be related to the Group if:

- (a) the party is a person or a close member of that person’s family and that person
 - (i) has control or joint control over the Group;
 - (ii) has significant influence over the Group; or
 - (iii) is a member of the key management personnel of the Group or of a parent of the Group;

or

- (b) the party is an entity where any of the following conditions applies:
 - (i) the entity and the Group are members of the same group;
 - (ii) one entity is an associate or joint venture of the other entity (or of a parent, subsidiary or fellow subsidiary of the other entity);
 - (iii) the entity and the Group are joint ventures of the same third party;
 - (iv) one entity is a joint venture of a third entity and the other entity is an associate of the third entity;
 - (v) the entity is a post-employment benefit plan for the benefit of employees of either the Group or an entity related to the Group;
 - (vi) the entity is controlled or jointly controlled by a person identified in (a);
 - (vii) a person identified in (a)(i) has significant influence over the entity or is a member of the key management personnel of the entity (or of a parent of the entity); and
 - (viii) the entity, or any member of a group of which it is a part, provides key management personnel services to the Group or to the parent of the Group.

Property, plant and equipment and depreciation

Property, plant and equipment, other than construction in progress, are stated at cost less accumulated depreciation and any impairment losses. The cost of an item of property, plant and equipment comprises its purchase price and any directly attributable costs of bringing the asset to its working condition and location for its intended use.

Expenditure incurred after items of property, plant and equipment have been put into operation, such as repairs and maintenance, is normally charged to the statement of profit or loss in the period in which it is incurred. In situations where the recognition criteria are satisfied, the expenditure for a major inspection is capitalised in the carrying amount of the asset as a replacement. Where significant parts of property, plant and equipment are required to be replaced at intervals, the Group recognises such parts as individual assets with specific useful lives and depreciates them accordingly.

Depreciation is calculated on the straight-line basis to write off the cost of each item of property, plant and equipment to its residual value over its estimated useful life. The principal annual rates used for this purpose are as follows:

Buildings	5%
Machinery	10%
Electronic and other equipment	19% to 32%
Vehicles	24%
Leasehold improvements	Over the shorter of the residual useful life and lease terms

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Where parts of an item of property, plant and equipment have different useful lives, the cost of that item is allocated on a reasonable basis among the parts and each part is depreciated separately. Residual values, useful lives and the depreciation method are reviewed, and adjusted if appropriate, at least at each financial year end.

An item of property, plant and equipment including any significant part initially recognised is derecognised upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss on disposal or retirement recognised in the statement of profit or loss in the year the asset is derecognised is the difference between the net sales proceeds and the carrying amount of the relevant asset.

Construction in progress represents a building under construction, which is stated at cost less any impairment losses, and is not depreciated. Cost comprises the direct costs of construction and capitalised borrowing costs on related borrowed funds during the period of construction. Construction in progress is reclassified to the appropriate category of property, plant and equipment when completed and ready for use.

Intangible assets (other than goodwill)

Intangible assets acquired separately are measured on initial recognition at cost. The cost of intangible assets acquired in a business consolidation is the fair value at the date of acquisition. The useful lives of intangible assets are assessed to be either finite or indefinite. Intangible assets with finite lives are subsequently amortised over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortisation period and the amortisation method for an intangible asset with a finite useful life are reviewed at least at each financial year end.

Intangible assets with indefinite useful lives or not yet available for use are tested for impairment annually either individually or at the cash-generating unit level. Such intangible assets are not amortised. The useful life of an intangible asset with an indefinite life is reviewed annually to determine whether the indefinite life assessment continues to be supportable. If not, the change in the useful life assessment from indefinite to finite is accounted for on a prospective basis.

Know-how

Know-how is stated at cost less any impairment losses and is amortised on the straight-line basis over its estimated useful life of 5 years.

Software

Software is stated at cost less any impairment losses and is amortised on the straight-line basis over the estimated useful life of 3 to 10 years.

The estimated useful life of software is determined by considering the period of the economic benefits to the Group as well as by referring to the industry practice.

Research and development costs

All research costs are charged to the statement of profit or loss as incurred.

Expenditure incurred on projects to develop new products is capitalised and deferred only when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and the ability to measure reliably the expenditure during the development. Product development expenditure which does not meet these criteria is expensed when incurred.

Deferred development costs are stated at cost less any impairment losses and are amortised using the straight-line basis over the commercial lives of the underlying products not exceeding five to seven years, commencing from the date when the products are put into commercial production.

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Leases

The Group assesses at contract inception whether a contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

Group as a lessee

The Group applies a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. The Group recognises lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

(a) Right-of-use assets

Right-of-use assets are recognised at the commencement date of the lease (that is the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and any impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognised, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Right-of-use assets are depreciated on a straight-line basis over the shorter of the lease terms and the estimated useful lives of the assets as follows:

Categories	Estimated useful lives
Leasehold buildings	2 to 7 years
Office equipment	3 years

If ownership of the leased asset transfers to the Group by the end of the lease term or the cost reflects the exercise of a purchase option, depreciation is calculated using the estimated useful life of the asset.

(b) Lease liabilities

Lease liabilities are recognised at the commencement date of the lease at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Group and payments of penalties for termination of a lease, if the lease term reflects the Group exercising the option to terminate the lease. The variable lease payments that do not depend on an index or a rate are recognised as an expense in the period in which the event or condition that triggers the payment occurs.

In calculating the present value of lease payments, the Group uses its incremental borrowing rate at the lease commencement date because the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in lease payments (e.g., a change to future lease payments resulting from a change in an index or rate) or a change in assessment of an option to purchase the underlying asset.

(c) Short-term leases and leases of low-value assets

The Group applies the short-term lease recognition exemption to its short-term leases of machinery and equipment (that is those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option). It also applies the recognition exemption for leases of low-value assets to leases of office equipment that is considered to be of low value.

Lease payments on short-term leases and leases of low-value assets are recognised as an expense on a straight-line basis over the lease term.

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Investments and other financial assets

Initial recognition and measurement

Financial assets are classified, at initial recognition, as subsequently measured at amortised cost, fair value through other comprehensive income, and fair value through profit or loss.

The classification of financial assets at initial recognition depends on the financial asset’s contractual cash flow characteristics and the Group’s business model for managing them. With the exception of trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient of not adjusting the effect of a significant financing component, the Group initially measures a financial asset at its fair value plus in the case of a financial asset not at fair value through profit or loss, transaction costs. Trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient are measured at the transaction price determined under IFRS 15 in accordance with the policies set out for “Revenue recognition” below.

In order for a financial asset to be classified and measured at amortised cost or fair value through other comprehensive income, it needs to give rise to cash flows that are solely payments of principal and interest (“SPPI”) on the principal amount outstanding. Financial assets with cash flows that are not SPPI are classified and measured at fair value through profit or loss, irrespective of the business model.

The Group’s business model for managing financial assets refers to how it manages its financial assets in order to generate cash flows. The business model determines whether cash flows will result from collecting contractual cash flows, selling the financial assets, or both. Financial assets classified and measured at amortised cost are held within a business model with the objective to hold financial assets in order to collect contractual cash flows, while financial assets classified and measured at fair value through other comprehensive income are held within a business model with the objective of both holding to collect contractual cash flows and selling. Financial assets which are not held within the aforementioned business models are classified and measured at fair value through profit or loss.

All regular way purchases and sales of financial assets are recognised on the trade date, that is, the date that the Group commits to purchase or sell the asset. Regular way purchases or sales are purchases or sales of financial assets that require delivery of assets within the period generally established by regulation or convention in the marketplace.

Subsequent measurement

The subsequent measurement of financial assets depends on their classification as follows:

Financial assets at amortised cost (debt instruments)

Financial assets at amortised cost are subsequently measured using the effective interest method and are subject to impairment. Gains and losses are recognised in the statement of profit or loss when the asset is derecognised, modified or impaired.

Financial assets at fair value through other comprehensive income (debt instruments)

For debt investments at fair value through other comprehensive income, interest income, foreign exchange revaluation and impairment losses or reversals are recognised in the statement of profit or loss and computed in the same manner as for financial assets measured at amortised cost. The remaining fair value changes are recognised in other comprehensive income. Upon derecognition, the cumulative fair value change recognised in other comprehensive income is recycled to the statement of profit or loss.

Financial assets designated at fair value through other comprehensive income (equity investments)

Upon initial recognition, the Group can elect to classify irrevocably its equity investments as equity investments designated at fair value through other comprehensive income when they meet the definition of equity under IAS 32 *Financial Instruments: Presentation* and are not held for trading. The classification is determined on an instrument-by-instrument basis.

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Gains and losses on these financial assets are never recycled to the statement of profit or loss. Dividends are recognised as other income in the statement of profit or loss when the right of payment has been established, it is probable that the economic benefits associated with the dividend will flow to the Group and the amount of the dividend can be measured reliably, except when the Group benefits from such proceeds as a recovery of part of the cost of the financial asset, in which case, such gains are recorded in other comprehensive income. Equity investments designated at fair value through other comprehensive income are not subject to impairment assessment.

Financial assets at fair value through profit or loss

Financial assets at fair value through profit or loss are carried in the statement of financial position at fair value with net changes in fair value recognised in the statement of profit or loss.

This category includes derivative instruments and equity investments which the Group had not irrevocably elected to classify at fair value through other comprehensive income. Dividends on equity investments classified as financial assets at fair value through profit or loss are also recognised as other income in the statement of profit or loss when the right of payment has been established, it is probable that the economic benefits associated with the dividend will flow to the Group and the amount of the dividend can be measured reliably.

A derivative embedded in a hybrid contract, with a financial liability or non-financial host, is separated from the host and accounted for as a separate derivative if the economic characteristics and risks are not closely related to the host; a separate instrument with the same terms as the embedded derivative would meet the definition of a derivative; and the hybrid contract is not measured at fair value through profit or loss. Embedded derivatives are measured at fair value with changes in fair value recognised in the statement of profit or loss. Reassessment only occurs if there is either a change in the terms of the contract that significantly modifies the cash flows that would otherwise be required or a reclassification of a financial asset out of the fair value through profit or loss category.

A derivative embedded within a hybrid contract containing a financial asset host is not accounted for separately. The financial asset host together with the embedded derivative is required to be classified in its entirety as a financial asset at fair value through profit or loss.

Derecognition of financial assets

A financial asset (or, where applicable, a part of a financial asset or part of a group of similar financial assets) is primarily derecognised (i.e., removed from the Group’s consolidated statement of financial position) when:

- the rights to receive cash flows from the asset have expired; or
- the Group has transferred its rights to receive cash flows from the asset or has assumed an obligation to pay the received cash flows in full without material delay to a third party under a “pass-through” arrangement; and either (a) the Group has transferred substantially all the risks and rewards of the asset, or (b) the Group has neither transferred nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset.

When the Group has transferred its rights to receive cash flows from an asset or has entered into a pass-through arrangement, it evaluates if, and to what extent, it has retained the risk and rewards of ownership of the asset. When it has neither transferred nor retained substantially all the risks and rewards of the asset nor transferred control of the asset, the Group continues to recognise the transferred asset to the extent of the Group’s continuing involvement. In that case, the Group also recognises an associated liability. The transferred asset and the associated liability are measured on a basis that reflects the rights and obligations that the Group has retained.

Continuing involvement that takes the form of a guarantee over the transferred asset is measured at the lower of the original carrying amount of the asset and the maximum amount of consideration that the Group could be required to repay.

Impairment of financial assets

The Group recognises an allowance for expected credit losses (“ECLs”) for all debt instruments not held at fair value through profit or loss. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that the Group expects to receive, discounted at an approximation of the original effective interest rate. The expected cash flows will include cash flows from the sale of collateral held or other credit enhancements that are integral to the contractual terms.

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General approach

ECLs are recognised in two stages. For credit exposures for which there has not been a significant increase in credit risk since initial recognition, ECLs are provided for credit losses that result from default events that are possible within the next 12 months (a 12-month ECL). For those credit exposures for which there has been a significant increase in credit risk since initial recognition, a loss allowance is required for credit losses expected over the remaining life of the exposure, irrespective of the timing of the default (a lifetime ECL).

At each reporting date, the Group assesses whether the credit risk on a financial instrument has increased significantly since initial recognition. When making the assessment, the Group compares the risk of a default occurring on the financial instrument as at the reporting date with the risk of a default occurring on the financial instrument as at the date of initial recognition and considers reasonable and supportable information that is available without undue cost or effort, including historical and forward-looking information.

The Group considers a financial asset in default when contractual payments are 90 days past due. However, in certain cases, the Group may also consider a financial asset to be in default when internal or external information indicates that the Group is unlikely to receive the outstanding contractual amounts in full before taking into account any credit enhancements held by the Group. A financial asset is written off when there is no reasonable expectation of recovering the contractual cash flows.

Debt investments at fair value through other comprehensive income and financial assets at amortised cost are subject to impairment under the general approach and they are classified within the following stages for measurement of ECLs except for trade receivables and contract assets which apply the simplified approach as detailed below.

Stage 1 – Financial instruments for which credit risk has not increased significantly since initial recognition and for which the loss allowance is measured at an amount equal to 12-month ECLs

Stage 2 – Financial instruments for which credit risk has increased significantly since initial recognition but that are not credit-impaired financial assets and for which the loss allowance is measured at an amount equal to lifetime ECLs

Stage 3 – Financial assets that are credit-impaired at the reporting date (but that are not purchased or originated credit-impaired) and for which the loss allowance is measured at an amount equal to lifetime ECLs

Simplified approach

For trade receivables that do not contain a significant financing component or when the Group applies the practical expedient of not adjusting the effect of a significant financing component, the Group applies the simplified approach in calculating ECLs. Under the simplified approach, the Group does not track changes in credit risk, but instead recognises a loss allowance based on lifetime ECLs at each reporting date. The Group has established a provision matrix that is based on its historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment.

Financial liabilities

Initial recognition and measurement

Financial liabilities are classified, at initial recognition, as financial liabilities at fair value through profit or loss, loans and borrowings, payables, or as derivatives designated as hedging instruments in an effective hedge, as appropriate.

All financial liabilities are recognised initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs.

The Group’s financial liabilities include trade and other payables, amounts due to related parties, lease liabilities, and convertible redeemable preferred shares.

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Subsequent measurement

The subsequent measurement of financial liabilities depends on their classification as follows:

Financial liabilities at fair value through profit or loss

Financial liabilities at fair value through profit or loss include financial liabilities held for trading and financial liabilities designated upon initial recognition as at fair value through profit or loss.

Financial liabilities are classified as held for trading if they are incurred for the purpose of repurchasing in the near term. This category also includes derivative financial instruments entered into by the Group that are not designated as hedging instruments in hedge relationships as defined by IFRS 9. Separated embedded derivatives are also classified as held for trading unless they are designated as effective hedging instruments. Gains or losses on liabilities held for trading are recognised in the statement of profit or loss. The net fair value gain or loss recognised in the statement of profit or loss does not include any interest charged on these financial liabilities.

Financial liabilities at amortised cost (loans and borrowings)

After initial recognition, interest-bearing loans and borrowings are subsequently measured at amortised cost, using the effective interest rate method unless the effect of discounting would be immaterial, in which case they are stated at cost. Gains and losses are recognised in the statement of profit or loss when the liabilities are derecognised as well as through the effective interest rate amortisation process.

Amortised cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest rate. The effective interest rate amortisation is included in finance costs in the statement of profit or loss.

Derecognition of financial liabilities

A financial liability is derecognised when the obligation under the liability is discharged or cancelled, or expires.

When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as a derecognition of the original liability and a recognition of a new liability, and the difference between the respective carrying amounts is recognised in the statement of profit or loss.

Offsetting of financial instruments

Financial assets and financial liabilities are offset and the net amount is reported in the statement of financial position if there is a currently enforceable legal right to offset the recognised amounts and there is an intention to settle on a net basis, or to realise the assets and settle the liabilities simultaneously.

Inventories

Inventories are stated at the lower of cost and net realisable value. Cost is determined on the weighted average basis and comprises all cost of purchase and other costs incurred in bringing the inventories to their present location and condition. Net realisable value is based on estimated selling prices less any estimated costs to be incurred to completion and disposal.

Cash and cash equivalents

For the purpose of the consolidated statement of cash flows, cash and cash equivalents comprise cash on hand and demand deposits, and short-term highly liquid investments that are readily convertible into known amounts of cash, are subject to an insignificant risk of changes in value, and have a short maturity of generally within three months when acquired, less bank overdrafts which are repayable on demand and form an integral part of the Group’s cash management.

For the purpose of the consolidated statement of financial position, cash and cash equivalents comprise cash on hand and at banks, including term deposits, and assets similar in nature to cash, which are not restricted as to use.

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Income tax

Income tax comprises current and deferred tax. Income tax relating to items recognised outside profit or loss is recognised outside profit or loss, either in other comprehensive income or directly in equity.

Current tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of the Relevant Periods, taking into consideration interpretations and practices prevailing in the countries in which the Group operates.

Deferred tax is provided, using the liability method, on all temporary differences at the end of each of the Relevant Periods between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes.

Deferred tax liabilities are recognised for all taxable temporary differences, except:

- when the deferred tax liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business consolidation and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; and
- in respect of taxable temporary differences associated with investments in subsidiaries when the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future.

Deferred tax assets are recognised for all deductible temporary differences, and the carryforward of unused tax credits and any unused tax losses. Deferred tax assets are recognised to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, and the carryforward of unused tax credits and unused tax losses can be utilised, except:

- when the deferred tax asset relating to the deductible temporary differences arises from the initial recognition of an asset or liability in a transaction that is not a business consolidation and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; and
- in respect of deductible temporary differences associated with investments in subsidiaries, deferred tax assets are only recognised to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilised.

The carrying amount of deferred tax assets is reviewed at the end of each reporting period and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilised. Unrecognised deferred tax assets are reassessed at the end of each reporting period and are recognised to the extent that it has become probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the period when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of the Relevant Periods.

Deferred tax assets and deferred tax liabilities are offset if and only if the Group has a legally enforceable right to set off current tax assets and current tax liabilities and the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same taxation authority on either the same taxable entity or different taxable entities which intend either to settle current tax liabilities and assets on a net basis, or to realise the assets and settle the liabilities simultaneously, in each future period in which significant amounts of deferred tax liabilities or assets are expected to be settled or recovered.

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Government grants

Government grants are recognised at their fair value where there is reasonable assurance that the grant will be received and all attaching conditions will be complied with. When the grant relates to an expense item, it is recognised as income on a systematic basis over the periods that the costs, for which it is intended to compensate, are expensed.

Where the grant relates to an asset, the fair value is credited to a deferred income account and is released to the statement of profit or loss over the expected useful life of the relevant asset by equal annual instalments or deducted from the carrying amount of the asset and released to the statement of profit or loss by way of a reduced depreciation charge.

Revenue recognition

Other income

Interest income is recognised on an accrual basis using the effective interest method by applying the rate that exactly discounts the estimated future cash receipts over the expected life of the financial instrument or a shorter period, when appropriate, to the net carrying amount of the financial asset.

Share-based payments

The Company operates a share option scheme for the purpose of providing incentives and rewards to eligible participants who contribute to the success of the Group's operations. Employees (including directors) of the Group receive remuneration in the form of share-based payments, whereby employees render services as consideration for equity instruments ("equity-settled transactions").

The cost of equity-settled transactions with employees for grants is measured by reference to the fair value at the date at which they are granted. The fair value is determined by an external valuer using a binomial model, further details of which are given in note 24 to the Historical Financial Statements.

The cost of equity-settled transactions is recognised in employee benefit expense, together with a corresponding increase in equity, over the period in which the service conditions are fulfilled. The cumulative expense recognised for equity-settled transactions at the end of each of the Relevant Periods until the vesting date reflects the extent to which the vesting period has expired and the Group's best estimate of the number of equity instruments that will ultimately vest. The charge or credit to the statement of profit or loss for a period represents the movement in the cumulative expense recognised as at the beginning and end of that period.

Service and non-market performance conditions are not taken into account when determining the grant date fair value of awards, but the likelihood of the conditions being met is assessed as part of the Group's best estimate of the number of equity instruments that will ultimately vest. Market performance conditions are reflected within the grant date fair value. Any other conditions attached to an award, but without an associated service requirement, are considered to be non-vesting conditions. Non-vesting conditions are reflected in the fair value of an award and lead to an immediate expensing of an award unless there are also service and/or performance conditions.

For awards that do not ultimately vest because non-market performance and/or service conditions have not been met, no expense is recognised. Where awards include a market or non-vesting condition, the transactions are treated as vesting irrespective of whether the market or non-vesting condition is satisfied, provided that all other performance and/or service conditions are satisfied.

Where the terms of an equity-settled award are modified, as a minimum an expense is recognised as if the terms had not been modified, if the original terms of the award are met. In addition, an expense is recognised for any modification that increases the total fair value of the share-based payments, or is otherwise beneficial to the employee as measured at the date of modification.

Where an equity-settled award is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognised for the award is recognised immediately. This includes any award where non-vesting conditions within the control of either the Group or the employee are not met. However, if a new award is substituted for the cancelled award, and is designated as a replacement award on the date that it is granted, the cancelled and new awards are treated as if they were a modification of the original award, as described in the previous paragraph.

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The dilutive effect of outstanding options is reflected as additional share dilution in the computation of earnings per share.

Other employee benefits

Pension scheme

The employees of the Group’s subsidiaries which operate in Mainland China are required to participate in a central pension scheme operated by the local municipal government. These subsidiaries are required to contribute a certain percentage of their payroll costs to the central pension scheme. The contributions are charged to statement of profit or loss as they become payable in accordance with the rules of the central pension scheme.

Dividends

Dividends are recognised as a liability when they are approved by the shareholders in a general meeting. Proposed dividends are disclosed in the notes to the Historical Financial Information.

Foreign currencies

The Historical Financial Information is presented in RMB. Each entity in the Group determines its own functional currency and items included in the financial statements of each entity are measured using that functional currency. Foreign currency transactions recorded by the entities in the Group are initially recorded using their respective functional currency rates prevailing at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency rates of exchange ruling at the end of each of the Relevant Periods. Differences arising on settlement or translation of monetary items are recognised in the statement of profit or loss.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the initial transactions. Non-monetary items measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was measured. The gain or loss arising on translation of a non-monetary item measured at fair value is treated in line with the recognition of the gain or loss on change in fair value of the item (i.e., translation difference on the item whose fair value gain or loss is recognised in other comprehensive income or profit or loss is also recognised in other comprehensive income or profit or loss, respectively).

In determining the exchange rate on initial recognition of the related asset, expense or income on the derecognition of a non-monetary asset or non-monetary liability relating to an advance consideration, the date of initial transaction is the date on which the Group initially recognise the non-monetary asset or non-monetary liability arising from the advance consideration. If there are multiple payments or receipts in advance, the Group determine the transaction date for each payment or receipt of the advance consideration.

The functional currencies of the Company and certain overseas subsidiaries are currencies other than RMB. The functional currency of the Company is the United States Dollar (“US\$”). As at the end of each of the Relevant Periods, the assets and liabilities of these entities are translated into RMB at the exchange rates prevailing at the end of each of the Relevant Periods and their statements of profit or loss are translated into RMB at the weighted average exchange rates for the year or period.

The resulting exchange differences are recognised in other comprehensive income and accumulated in the exchange fluctuation reserve. On disposal of a foreign operation, the component of other comprehensive income relating to that particular foreign operation is recognised in the statement of profit or loss.

Any goodwill arising on the acquisition of a foreign operation and any fair value adjustments to the carrying amounts of assets and liabilities arising on acquisition are treated as assets and liabilities of the foreign operation and translated at the closing rate.

For the purpose of the consolidated statement of cash flows, the cash flows of overseas subsidiaries are translated into RMB at the exchange rates ruling at the dates of the cash flows. Frequently recurring cash flows of overseas subsidiaries which arise throughout the year are translated into RMB at the weighted average exchange rates for the year or period.

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3. SIGNIFICANT ACCOUNTING JUDGEMENTS AND ESTIMATES

The preparation of the Group’s financial statements requires management to make judgements, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and their accompanying disclosures, and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that could require a material adjustment to the carrying amounts of the assets or liabilities affected in the future.

Judgements

In the process of applying the Group’s accounting policies, management has made the following judgements, apart from those involving estimations, which have the most significant effect on the amounts recognised in the financial statements:

Significant judgement in determining the lease term of contracts with renewal options

The Group has several lease contracts that include extension and termination options. The Group applies judgement in evaluating whether or not to exercise the option to renew or terminate the lease. That is, it considers all relevant factors that create an economic incentive for it to exercise either the renewal or termination. After the commencement date, the Group reassesses the lease term if there is a significant event or change in circumstances that is within its control and affects its ability to exercise or not to exercise the option to renew or to terminate (e.g., construction of significant leasehold improvements or significant customisation to the leased asset).

The Group includes the renewal period as part of the lease term for leases of building due to the significance of these assets to its operations. These leases have a short non-cancellable period (i.e., three to five years) and there will be a significant negative effect on production if a replacement is not readily available.

Estimation uncertainty

The key assumptions concerning the future and other key sources of estimation uncertainty at the end of the reporting period, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are described below.

Impairment of non-financial assets (other than goodwill)

The Group assesses whether there are any indicators of impairment for all non-financial assets at the end of each of the Relevant Periods. Intangible assets not yet available for intended use are tested for impairment annually and at other times when such an indicator exists. Other non-financial assets are tested for impairment when there are indicators that the carrying amounts may not be recoverable. An impairment exists when the carrying value of an asset or a cash-generating unit exceeds its recoverable amount, which is the higher of its fair value less costs of disposal and its value in use. The calculation of the fair value less costs of disposal is based on available data from binding sales transactions in an arm’s length transaction of similar assets or observable market prices less incremental costs for disposing of the asset. When value-in-use calculations are undertaken, management must estimate the expected future cash flows from the asset or cash-generating unit and choose a suitable discount rate in order to calculate the present value of those cash flows.

Development costs

Development costs are capitalised in accordance with the accounting policy for research and development costs in note 2.4 to the Historical Financial Information. Determining the amounts to be capitalised requires management to make assumptions regarding the expected future cash generation of the assets, discount rates to be applied and the expected period of benefits.

Provision for inventories

The Group reviews the carrying amounts of the inventories at the end of each of the Relevant Periods to determine whether the inventories are carried at lower of cost and net realisable value. The net realisable value is estimated based on current market situation and historical experience. Any change in the assumptions would increase or decrease the amount of inventories written-down or the related reversals of write-down and affect the Group’s financial position.

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Useful lives of property, plant and equipment

The Group’s management determines the estimated useful lives and the related depreciation charge for the Group’s property, plant and equipment. This estimate is based on the historical experience of the actual useful lives of property, plant and equipment of similar nature and functions. Management will increase the depreciation charge where useful lives are less than previously estimated lives, or will write off or write down technically obsolete or non-strategic assets that have been abandoned or sold. Actual economic lives may differ from estimated useful lives. Periodic review could result in a change in depreciable lives and therefore depreciation charge in the future periods.

Estimation of the fair value of financial liabilities through profit or loss

Certain financial liabilities are measured at fair value at the end of each of the Relevant Periods as disclosed in note 29 to the Historical Financial Information.

The convertible redeemable preferred shares issued by the Company are not traded in an active market and the respective fair value is determined by using valuation techniques. The Group applied the Back-solve Approach to determine the underlying equity value of the Company and adopted the option-pricing method and equity allocation model to determine the fair value of the convertible redeemable preferred shares. Key assumptions such as the timing of the liquidation, redemption or the event as well as the probability of the various scenarios were based on the Group’s best estimates. Further details are included in notes 21 to the Historical Financial Information.

Fair value measurement of share-based payments

The Group has set up the share option scheme and granted options to the Company’s directors, the Group’s employees and consultants. The fair value of the options is determined by the binomial option-pricing model at the grant dates for options granted to directors and employees, and at the service provision dates for the consultants. Significant estimates on assumptions, including the underlying equity value, discount rate, expected volatility, and dividend yield, are made by management. Further details are included in note 24 to the Historical Financial Information.

Leases – Estimating the incremental borrowing rate

The Group cannot readily determine the interest rate implicit in a lease, and therefore, it uses an incremental borrowing rate (“IBR”) to measure lease liabilities. The IBR is the rate of interest that the Group would have to pay to borrow over a similar term, and with a similar security, the funds necessary to obtain an asset of a similar value to the right-of-use asset in a similar economic environment. The IBR therefore reflects what the Group “would have to pay”, which requires estimation when no observable rates are available (such as for subsidiaries that do not enter into financing transactions) or when it needs to be adjusted to reflect the terms and conditions of the lease (for example, when leases are not in the subsidiary’s functional currency). The Group estimates the IBR using observable inputs (such as market interest rates) when available and is required to make certain entity-specific estimates (such as the subsidiary’s stand-alone credit rating).

4. OPERATING SEGMENT INFORMATION

The Group has only one operating segment, which is the research and development of biopharmaceutical products.

No operating segments have been aggregated to form the above reportable operating segment.

Geographical information

(a) *Non-current assets*

	As at 31 December		As at 30 April
	2019	2020	2021
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Mainland China	21,870	139,103	172,017
Other countries/regions	–	–	3,312
	21,870	139,103	175,329

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The non-current asset information above is based on the locations of the assets and excludes financial instruments and deferred tax assets.

5. OTHER INCOME AND GAINS

	Year ended 31 December		Four months ended 30 April	
	2019 <i>RMB'000</i>	2020 <i>RMB'000</i>	2020 <i>RMB'000</i> <i>(Unaudited)</i>	2021 <i>RMB'000</i>
Bank interest income	783	3,408	558	2,021
Government grants*	15,909	20,359	11,131	3,215
Foreign exchange differences, net	84	–	889	–
Fair value gains, net:				
Financial assets at fair value through profit or loss	–	–	–	167
Others	132	574	574	88
	<u>16,908</u>	<u>24,341</u>	<u>13,152</u>	<u>5,491</u>

* Government grants have been received from the PRC local government authorities to support the subsidiaries’ research and development activities and the purchase of certain items of property, plant and equipment. There are no unfulfilled conditions related to these government grants.

6. LOSS BEFORE TAX

The Group’s loss before tax is arrived at after charging/(crediting):

	<i>Notes</i>	Year ended 31 December		Four months ended 30 April	
		2019 <i>RMB'000</i>	2020 <i>RMB'000</i>	2020 <i>RMB'000</i> <i>(Unaudited)</i>	2021 <i>RMB'000</i>
Research and development costs		24,222	159,485	15,589	304,401
Depreciation of property, plant and equipment	13	1,073	1,566	430	2,074
Depreciation of right-of-use assets	14	1,177	4,023	1,093	1,781
Amortisation of intangible assets	15	147	195	54	124
Lease payments not included in the measurement of lease liabilities	14	570	–	–	302
Fair value changes of convertible redeemable preferred shares [REDACTED] (including reporting accountants’ remuneration)	21	(9,245)	597,659	119,870	454,770
Employee benefit expense (including directors’ and chief executive’s remuneration (<i>note 8</i>)):			1,991	–	15,113
Wages, salaries and welfare		25,405	98,748	18,626	69,082
Pension scheme contributions		1,848	1,191	491	4,068
Share-based payment expenses	24	–	–	–	3,399
Subtotal of employee benefit expenses		<u>27,253</u>	<u>99,939</u>	<u>19,117</u>	<u>76,549</u>
Foreign exchange difference, net		(84)	31,896	(889)	3,628

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7. FINANCE COSTS

An analysis of finance costs is as follows:

	Year ended 31 December		Four months ended 30 April	
	2019 <i>RMB’000</i>	2020 <i>RMB’000</i>	2020 <i>RMB’000</i> <i>(Unaudited)</i>	2021 <i>RMB’000</i>
Transaction cost for issuance of the Group’s convertible redeemable preferred shares	9,788	1,316	123	5,770
Interest on lease liabilities (<i>note 14</i>)	544	1,657	462	674
	<u>10,332</u>	<u>2,973</u>	<u>585</u>	<u>6,444</u>

8. DIRECTORS’ AND CHIEF EXECUTIVE’S REMUNERATION

Certain directors received remuneration from the subsidiaries now comprising the Group for their appointment as directors of these subsidiaries. The aggregate amount of remuneration of the directors and chief executives for the Relevant Periods and the four months ended 30 April 2020 is set out below:

	Year ended 31 December		Four months ended 30 April	
	2019 <i>RMB’000</i>	2020 <i>RMB’000</i>	2020 <i>RMB’000</i> <i>(Unaudited)</i>	2021
Salaries, allowances and benefits in kind	3,023	7,307	1,460	2,406
Share-based payment expenses	–	–	–	38
	<u>3,023</u>	<u>7,307</u>	<u>1,460</u>	<u>2,444</u>

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(a) Independent non-executive directors

There were no other emoluments payable to the independent non-executive directors during the Relevant Periods and the four months ended 30 April 2020.

(b) Executive directors, non-executive directors and the chief executive

	Salaries, allowances and benefits in kind <i>RMB’000</i>	Share-based payment expenses <i>RMB’000</i>	Total remuneration <i>RMB’000</i>
Year ended 31 December 2019			
Executive directors:			
Peng Liang	1,041	–	1,041
Joshua Liang	1,982	–	1,982
	<u> </u>	<u> </u>	<u> </u>
Non-executive directors:			
Xiaodong Wang	–	–	–
Ting Xiao	–	–	–
Guangyu Xu	–	–	–
	<u> </u>	<u> </u>	<u> </u>
Year ended 31 December 2020			
Executive directors:			
Peng Liang	3,247	–	3,247
Joshua Liang	4,060	–	4,060
	<u> </u>	<u> </u>	<u> </u>
Non-executive directors:			
Xiaodong Wang	–	–	–
Ting Xiao	–	–	–
Guangyu Xu	–	–	–
	<u> </u>	<u> </u>	<u> </u>
Four months ended 30 April 2021			
Executive directors:			
Peng Liang	1,070	–	1,070
Joshua Liang	1,336	38	1,374
	<u> </u>	<u> </u>	<u> </u>
Non-executive directors:			
Xiaodong Wang	–	–	–
Ting Xiao	–	–	–
Guangyu Xu	–	–	–
Dong Lyu	–	–	–
	<u> </u>	<u> </u>	<u> </u>
Four months ended 30 April 2020 (unaudited)			
Executive directors:			
Peng Liang	582	–	582
Joshua Liang	878	–	878
	<u> </u>	<u> </u>	<u> </u>

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	Salaries, allowances and benefits in kind RMB’000	Share-based payment expenses RMB’000	Total remuneration RMB’000
Non-executive directors:			
Xiaodong Wang	–	–	–
Ting Xiao	–	–	–
Guangyu Xu	–	–	–
	<u> </u>	<u> </u>	<u> </u>

There was no arrangement under which a director or the chief executive waived or agreed to waive any remuneration during the Relevant Periods and the four months ended 30 April 2020.

9. FIVE HIGHEST PAID EMPLOYEES

The five highest paid employees included two directors during the years ended 31 December 2019 and 2020, one director during four months ended 30 April 2020, details of whose remuneration are set out in note 8 above. The five highest paid employees during four months ended 2021 did not include any director. Details of the remuneration for the Relevant Periods and the four months ended 30 April 2020 of the five highest paid employees who are neither a director nor chief executive of the subsidiaries are as follows:

	Year ended 31 December		Four months ended 30 April	
	2019 RMB’000	2020 RMB’000	2020 RMB’000 (unaudited)	2021 RMB’000
Salaries, allowances and benefits in kind	4,878	9,734	3,653	10,883
Pension scheme contributions	105	275	14	508
Share-based payment expenses	–	–	–	177
	<u>4,983</u>	<u>10,009</u>	<u>3,667</u>	<u>11,568</u>

The numbers of non-director and non-chief executive highest paid employees whose remuneration fell within the following bands are as follows:

	Year ended 31 December		Four months ended 30 April	
	2019	2020	2020 (unaudited)	2021
Nil to HKD2,000,000	2	–	4	1
HKD2,000,001 to HKD4,000,000	1	1	–	3
HKD4,000,001 to HKD6,000,000	–	2	–	1

10. INCOME TAX

The Group is subject to income tax on an entity basis on profits arising in or derived from the jurisdictions in which members of the Group are domiciled and operate.

Cayman Islands

Under the current laws of the Cayman Islands, the Company is not subject to tax on income or capital gains. In addition, upon payments of dividends by the Company to its shareholders, no Cayman Islands withholding tax is imposed.

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Hong Kong

The subsidiary incorporated in Hong Kong is subject to Hong Kong profits tax at the rate of 16.5% on the estimated assessable profits arising in Hong Kong. No provision for Hong Kong profits tax has been made as the Group has no assessable profits derived from or earned in Hong Kong during the Relevant Periods and the four months ended 30 April 2020.

Mainland China

Pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the “CIT Law”), the subsidiaries which operate in Mainland China are subject to CIT at a rate of 25% on the taxable income.

Australia

The subsidiary incorporated in the Australia is subject to Australia income tax. Australia corporate income tax has been provided at the rate of 30% on the estimated assessable profits arising in Australia during the Relevant Periods and the four months ended 30 April 2020.

United States of America

The subsidiary incorporated in Delaware, United States was subject to statutory United States federal corporate income tax at a rate of 21% during the Relevant Periods and the four months ended 30 April 2020.

Ireland

The subsidiary incorporated in the Ireland is subject to Ireland income tax. Ireland corporate income tax has been provided at the rate of 12.5% on the estimated assessable profits arising in Ireland during the Relevant Periods and the four months ended 30 April 2020.

A reconciliation of the tax expense applicable to loss before tax at the statutory rate for the jurisdictions in which the majority of the Group’s subsidiaries are domiciled to the tax expense at the effective tax rates are as follows:

	Year ended 31 December		Four months ended 30 April	
	2019 RMB’000	2020 RMB’000	2020 RMB’000 (unaudited)	2021 RMB’000
Loss before tax	(48,583)	(912,898)	(148,156)	(909,187)
Tax at the statutory tax rate of 25%	(12,146)	(228,225)	(37,039)	(227,297)
Effect of tax rate differences in other jurisdictions	(270)	(4,267)	(154)	107,255
Expenses not deductible for tax	410	39	22	2
Additional deductible allowance for qualified research and development costs	(3,953)	(17,929)	(2,669)	(3,598)
Tax losses utilised from previous periods	–	–	–	(63,210)
Deductible temporary differences not recognised	173	152,235	28,363	145,465
Tax losses not recognised	15,786	98,147	11,477	41,383
Tax charge at the Group’s effective tax rate	–	–	–	–

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The Group had tax losses of RMB108,025,000, RMB483,329,000, RMB153,316,000 and RMB400,508,000 for the years ended 31 December 2019 and 2020 and the four months ended 30 April 2020 and 2021, respectively, out of which the tax losses in PRC are available for a maximum of ten years for offsetting against future taxable profits of the companies in which the losses arose, while the tax losses incurred by overseas entities can be carried forward permanently to offset against the future taxable profits of these companies in which the losses arose. The Group in PRC had tax losses of RMB95,866,000, RMB347,287,000, RMB138,067,000 and RMB210,431,000 for the years ended 31 December 2019 and 2020 and the four months ended 30 April 2020 and 2021, respectively. The Group’s overseas entities had tax losses of RMB12,159,000, RMB136,042,000, RMB15,249,000 and RMB190,077,000 for the years ended 31 December 2019 and 2020 and the four months ended 30 April 2020 and 2021, respectively.

Deferred tax assets have not been recognised in respect of these losses as they have arisen in subsidiaries that have been loss-making for some time and it is not considered probable that taxable profits will be available against which the tax losses can be utilised.

11. DIVIDENDS

No dividends have been declared and paid by the Company in respect of the Relevant Periods and the four months ended 30 April 2020.

12. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

The calculation of the basic loss per share amounts is based on the loss for the year/period attributable to ordinary equity holders of the parent of loss of RMB48,583,000, loss of RMB912,898,000, loss of RMB148,156,000 and loss of RMB909,187,000 and the weighted average number of ordinary shares. The weighted average number of shares is determined based on 50,000,000 shares issued pursuant to the Reorganisation had been in issue throughout the Relevant Periods.

The calculation of the diluted loss per share amounts is based on the loss for the year/period attributable to ordinary equity holders of the parent. The weighted average number of ordinary shares used in the calculation is the number of ordinary shares in issue during the year/period, as used in the basic loss per share calculation, and the weighted average number of ordinary shares assumed to have been issued at no consideration on the deemed exercise or conversion of all dilutive potential ordinary shares into ordinary shares.

No adjustment has been made to the basic loss per share amounts presented for the years ended 31 December 2019 and 2020 and the four months ended 30 April 2020 and 2021 as the impact of the convertible redeemable preferred share and share options and restricted share units outstanding had an anti-dilutive effect on the basic loss per share amounts presented.

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13. PROPERTY, PLANT AND EQUIPMENT

	Machinery <i>RMB'000</i>	Electronic and other equipment <i>RMB'000</i>	Leasehold improvements <i>RMB'000</i>	Total <i>RMB'000</i>
31 December 2019				
At 1 January 2019:				
Cost	5,780	1,021	429	7,230
Accumulated depreciation	(3,383)	(823)	(242)	(4,448)
Net carrying amount	<u>2,397</u>	<u>198</u>	<u>187</u>	<u>2,782</u>
At 1 January 2019, net of accumulated depreciation				
Additions	1,097	393	1,792	3,282
Depreciation provided during the year (<i>note 6</i>)	(508)	(151)	(414)	(1,073)
At 31 December 2019, net of accumulated depreciation	<u>2,986</u>	<u>440</u>	<u>1,565</u>	<u>4,991</u>
At 31 December 2019:				
Cost	6,877	1,414	2,221	10,512
Accumulated depreciation	(3,891)	(974)	(656)	(5,521)
Net carrying amount	<u>2,986</u>	<u>440</u>	<u>1,565</u>	<u>4,991</u>

	Machinery <i>RMB'000</i>	Electronic and other equipment <i>RMB'000</i>	Vehicles <i>RMB'000</i>	Leasehold improvements <i>RMB'000</i>	Construction in progress <i>RMB'000</i>	Total <i>RMB'000</i>
31 December 2020						
At 31 December 2019 and at 1 January 2020:						
Cost	6,877	1,414	–	2,221	–	10,512
Accumulated depreciation	(3,891)	(974)	–	(656)	–	(5,521)
Net carrying amount	<u>2,986</u>	<u>440</u>	<u>–</u>	<u>1,565</u>	<u>–</u>	<u>4,991</u>

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	Machinery	Electronic and other equipment	Vehicles	Leasehold improvements	Construction in progress	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
At 1 January 2020, net of accumulated depreciation	2,986	440	–	1,565	–	4,991
Additions	8	102	173	3,841	58,354	62,478
Disposals	(3)	(3)	–	–	–	(6)
Transfers	14,408	5,656	–	–	(20,064)	–
Depreciation provided during the year (note 6)	(485)	(253)	(37)	(791)	–	(1,566)
At 31 December 2020, net of accumulated depreciation	<u>16,914</u>	<u>5,942</u>	<u>136</u>	<u>4,615</u>	<u>38,290</u>	<u>65,897</u>
At 31 December 2020: Cost	21,221	7,089	173	6,062	38,290	72,835
Accumulated depreciation	(4,307)	(1,147)	(37)	(1,447)	–	(6,938)
Net carrying amount	<u>16,914</u>	<u>5,942</u>	<u>136</u>	<u>4,615</u>	<u>38,290</u>	<u>65,897</u>

	Buildings	Machinery	Electronic and other equipment	Vehicles	Leasehold improvements	Construction in progress	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
30 April 2021							
At 31 December 2020 and at 1 January 2021: Cost	–	21,221	7,089	173	6,062	38,290	72,835
Accumulated depreciation	–	(4,307)	(1,147)	(37)	(1,447)	–	(6,938)
Net carrying amount	<u>–</u>	<u>16,914</u>	<u>5,942</u>	<u>136</u>	<u>4,615</u>	<u>38,290</u>	<u>65,897</u>
At 1 January 2021, net of accumulated depreciation	–	16,914	5,942	136	4,615	38,290	65,897
Additions	–	–	463	–	–	50,225	50,688
Transfers	25,321	8,833	4,023	–	1,016	(40,963)	(1,770)
Depreciation provided during the period (note 6)	–	(791)	(607)	(14)	(662)	–	(2,074)
At 30 April 2021, net of accumulated depreciation	<u>25,321</u>	<u>24,956</u>	<u>9,821</u>	<u>122</u>	<u>4,969</u>	<u>47,552</u>	<u>112,741</u>

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	Buildings RMB’000	Machinery RMB’000	Electronic and other equipment RMB’000	Vehicles RMB’000	Leasehold improvements RMB’000	Construction in progress RMB’000	Total RMB’000
At 30 April 2021:							
Cost	25,321	30,054	11,575	173	7,078	47,552	121,753
Accumulated depreciation	–	(5,098)	(1,754)	(51)	(2,109)	–	(9,012)
Net carrying amount	<u>25,321</u>	<u>24,956</u>	<u>9,821</u>	<u>122</u>	<u>4,969</u>	<u>47,552</u>	<u>112,741</u>

14. LEASES

The Group as a lessee

The Group has lease contracts for various items of buildings and office equipment used in its operations. Leases of buildings generally have lease terms between 2 and 7 years and leases of office equipment generally have lease terms of 3 years. Generally, the Group is restricted from assigning and subleasing the leased assets outside the Group. There are several lease contracts that include extension options, which are further discussed below.

(1) Right-of-use assets

The carrying amounts of the Group’s right-of-use assets and the movements during the Relevant Periods are as follows:

	Leasehold buildings RMB’000	Office equipment RMB’000	Total RMB’000
31 December 2019			
At 1 January 2019	4,082	–	4,082
Additions	9,532	–	9,532
Depreciation charge (note 6)	<u>(1,177)</u>	<u>–</u>	<u>(1,177)</u>
At 31 December 2019	<u>12,437</u>	<u>–</u>	<u>12,437</u>
31 December 2020			
At 1 January 2020	12,437	–	12,437
Additions	12,625	51	12,676
Depreciation charge (note 6)	<u>(4,018)</u>	<u>(5)</u>	<u>(4,023)</u>
At 31 December 2020	<u>21,044</u>	<u>46</u>	<u>21,090</u>
30 April 2021			
At 1 January 2021	21,044	46	21,090
Additions	15,815	–	15,815
Reassessment of a lease term arising from a decision not to exercise the extension option	(7,142)	–	(7,142)
Depreciation charge (note 6)	<u>(1,778)</u>	<u>(3)</u>	<u>(1,781)</u>
At 30 April 2021	<u>27,939</u>	<u>43</u>	<u>27,982</u>

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(2) Lease liabilities

The carrying amount of lease liabilities and the movements during the Relevant Periods are as follows:

	As at 31 December		As at 30 April
	2019 RMB’000	2020 RMB’000	2021 RMB’000
Carrying amount at beginning of year/period	4,105	12,455	22,316
New leases	9,532	12,676	15,815
Accretion of interest recognised during the year/period	544	1,657	674
Reassessment of a lease term arising from a decision not to exercise the extension option	–	–	(7,142)
Payments	(1,726)	(4,472)	(2,564)
Carrying amount at end of year/period	<u>12,455</u>	<u>22,316</u>	<u>29,099</u>
Analysed into:			
Current portion	1,810	4,259	7,763
Non-current portion	<u>10,645</u>	<u>18,057</u>	<u>21,336</u>

The maturity analysis of lease liabilities is disclosed in note 31 to the Historical Financial Information.

(3) The amounts recognised in profit or loss in relation to leases are as follows:

	Year ended 31 December		Four months ended 30 April	
	2019 RMB’000	2020 RMB’000	2020 RMB’000 (Unaudited)	2021 RMB’000
Interest on lease liabilities (note 7)	544	1,657	462	674
Depreciation charge of right-of-use assets (note 6)	1,177	4,023	1,093	1,781
Expense relating to short-term leases and leases of low-value assets (note 6)	<u>570</u>	<u>–</u>	<u>–</u>	<u>302</u>
Total amount recognised in profit or loss	<u>2,291</u>	<u>5,680</u>	<u>1,555</u>	<u>2,757</u>

(4) Extension options

Most of the leases across the Group contained extension options. These terms were used to maximise operational flexibility in terms of managing contracts and have been reflected in measuring lease liabilities in all these cases because the options have been reasonably certain to be exercised. This is generally the case when the underlying assets have been allocated for use after the exercise date of an extension option. The lease liabilities arising from the potential future rental payments relating to periods following the exercise dates of extension options were RMB6,760,000, RMB14,192,000 and RMB14,139,000 as at 31 December 2019 and 2020 and 30 April 2021, respectively.

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Set out below are the undiscounted potential future rental payments relating to periods following the exercise date of extension and termination options that are not included in the lease terms:

	Payable within five years RMB’000
Four months ended 30 April 2021	
Extension options expected not to be exercised	3,595
	<u>3,595</u>
2020	
Extension options expected not to be exercised	–
	<u>–</u>
2019	
Extension options expected not to be exercised	–
	<u>–</u>

(5) The total cash outflow for leases is disclosed in note 26(c) to the Historical Financial Information.

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15. INTANGIBLE ASSETS

	Know-how <i>RMB’000</i>	Software <i>RMB’000</i>	Total <i>RMB’000</i>
31 December 2019			
Cost at 1 January 2019, net of accumulated amortisation	–	–	–
Additions	–	441	441
Amortisation provided during the year (<i>note 6</i>)	–	(147)	(147)
At 31 December 2019	<u>–</u>	<u>294</u>	<u>294</u>
At 31 December 2019:			
Cost	35,805	441	36,246
Accumulated amortisation	(35,805)	(147)	(35,952)
Net carrying amount	<u>–</u>	<u>294</u>	<u>294</u>
31 December 2020			
Cost at 1 January 2020, net of accumulated amortisation	–	294	294
Additions	–	178	178
Amortisation provided during the year (<i>note 6</i>)	–	(195)	(195)
At 31 December 2020	<u>–</u>	<u>277</u>	<u>277</u>
At 31 December 2020:			
Cost	35,805	619	36,424
Accumulated amortisation	(35,805)	(342)	(36,147)
Net carrying amount	<u>–</u>	<u>277</u>	<u>277</u>
30 April 2021			
Cost at 1 January 2021, net of accumulated amortisation	–	277	277
Additions	–	6,328	6,328
Amortisation provided during the period (<i>note 6</i>)	–	(124)	(124)
At 30 April 2021	<u>–</u>	<u>6,481</u>	<u>6,481</u>
At 30 April 2021:			
Cost	35,805	6,947	42,752
Accumulated amortisation	(35,805)	(466)	(36,271)
Net carrying amount	<u>–</u>	<u>6,481</u>	<u>6,481</u>

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16. INVENTORIES

	<u>As at 31 December</u>		<u>As at 30 April</u>
	2019	2020	2021
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Raw materials	393	50,881	146,717
	<u>393</u>	<u>50,881</u>	<u>146,717</u>

17. PREPAYMENTS, OTHER RECEIVABLES AND OTHER ASSETS

	<u>As at 31 December</u>		<u>As at 30 April</u>
	2019	2020	2021
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Prepayments	5,084	220,165	168,628
Value-added tax recoverable	3,727	18,423	27,500
Other receivables	596	4,283	5,987
	<u>9,407</u>	<u>242,871</u>	<u>202,115</u>
Analysed into:			
Non-current portion	4,148	51,839	28,125
Current portion	5,259	191,032	173,990
	<u>9,407</u>	<u>242,871</u>	<u>202,115</u>

Prepayments primarily consisted of advance payments to suppliers for raw materials, research and development services and machinery.

Value-added tax recoverable represented the value-added tax that can be used for future deduction.

The financial assets included in the above balances are other receivables that primarily consisted of deposits relating to office lease or services, which are non-interest-bearing, unsecured and repayable on demand. Other receivables had no history of default and were categorized in stage 1 at the end of each of the Relevant Periods.

To measure the expected credit losses, other receivables have been grouped based on shared credit risk characteristics and the ageing. In calculating the expected credit loss rate, the Company considers the historical loss rate and adjusts for forward-looking macroeconomic data. During the Relevant Periods, the Company estimated that the expected credit loss rate for other receivables is minimal, as there was no history of default of other receivables and there is no significant change in the economic factors based on the assessment of the forward-looking information. The directors of the Company are of the opinion that the ECL in respect of these balances is minimal.

18. CASH AND CASH EQUIVALENTS

The Group

	<u>As at 31 December</u>		<u>As at 30 April</u>
	2019	2020	2021
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Cash and cash equivalents	148,694	516,184	1,828,780
Time deposits and restricted cash	10,000	290,328	245,126
	<u>158,694</u>	<u>806,512</u>	<u>2,073,906</u>

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	As at 31 December		As at 30 April
	2019	2020	2021
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Less:			
Time deposits with original maturity more than three months	(10,000)	(270,328)	(227,976)
Restricted cash*	–	(20,000)	(17,150)
Cash and cash equivalents	<u>148,694</u>	<u>516,184</u>	<u>1,828,780</u>
Denominated in:			
RMB	138,420	48,448	134,973
US\$	8,603	461,200	1,690,950
AUS\$	1,671	6,536	2,853
HK\$	–	–	4
Cash and cash equivalents	<u>148,694</u>	<u>516,184</u>	<u>1,828,780</u>

* The restricted cash at 31 December 2020 and 30 April 2021 was government funding received by Clover Sichuan, the withdrawal of which is subject to the approval of the government authority.

The Company

	As at 31 December		As at 30 April
	2019	2020	2021
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Cash and bank balances	–	–	1,471,977
Denominated in:			
US\$	–	–	1,471,975
HK\$	–	–	2
Cash and cash equivalents	<u>–</u>	<u>–</u>	<u>1,471,977</u>

The RMB is not freely convertible into other currencies, however, under Mainland China’s Foreign Exchange Control Regulations and Administration of Settlement, Sale and Payment of Foreign Exchange Regulations, the Group is permitted to exchange RMB for other currencies through banks authorised to conduct foreign exchange business. The remittance of funds out of Mainland China is subject to exchange restrictions imposed by the PRC government.

Cash at banks earns interest at floating rates based on daily bank deposit rates. Time deposits are made for varying periods of between six months and twelve months depending on the immediate cash requirements of the Group, and earn interest at the respective short-term time deposit rates. The bank balances are deposited with creditworthy banks with no recent history of default.

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19. TRADE PAYABLES

An ageing analysis of the trade payables as at the end of each of the Relevant Periods, based on the invoice date, is as follows:

	As at 31 December		As at 30 April
	2019 <i>RMB’000</i>	2020 <i>RMB’000</i>	2021 <i>RMB’000</i>
Within 6 months	5,164	33,102	98,831
6 to 12 months	1	183	–
Over 1 years	2,000	535	–
	<u>7,165</u>	<u>33,820</u>	<u>98,831</u>

The trade payables are non-interest-bearing and are normally settled on terms of 30 to 60 days.

20. OTHER PAYABLES AND ACCRUALS

	As at 31 December		As at 30 April
	2019 <i>RMB’000</i>	2020 <i>RMB’000</i>	2021 <i>RMB’000</i>
Payroll payable	8,007	19,128	16,447
Service fee payable	8,750	5,141	17,977
Amounts due to related parties	928	938	–
Payables for property, plant and equipment	613	1,186	12,853
Other payables	131	840	1,118
Taxes other than income tax	83	1,422	3,056
	<u>18,512</u>	<u>28,655</u>	<u>51,451</u>

Other payables and accruals are non-interest-bearing and have no fixed terms of settlement. The balances of amounts due to related parties as at 31 December 2019 and 2020 were trade in nature and have been settled during the four months ended 30 April 2021.

21. CONVERTIBLE REDEEMABLE PREFERRED SHARES

Convertible redeemable preferred shares issued by the Group are convertible redeemable upon occurrence of certain future events. These instruments can also be converted into ordinary shares of the Company at any time at the option of the holders, or automatically upon occurrence of an [REDACTED] of the Company’ shares, or when agreed by the holders of ordinary shares and the holders of each class of the preferred shares.

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The Group has completed several rounds of financing arrangements by issuing preferred shares, details of which are included below:

	Date of issuance	Purchase price per share <i>USD</i>	Number of Preferred Shares	Total consideration <i>Denominated in RMB’000</i>
Series A Preferred Shares	13 September 2017	1.20539	4,380,000	35,000
Series A Preferred Shares	25 December 2017	1.20539	1,510,000	12,070
Series A Preferred Shares	24 January 2018	1.20539	1,961,413	15,690
Series B Preferred Shares	9 December 2019	1.40480	30,545,245	304,125
Series B-2 Preferred Shares	5 June 2020	2.31751	10,399,596	171,786
Series C Preferred Shares	16 March 2021	6.73102	34,170,135	1,487,456
			<u>82,966,389</u>	<u>2,026,127</u>

In March 2021, the Company issued 34,170,135 Series C Preferred Shares at a price of US\$6.73102 per share for a total consideration of US\$230,000,000. According to the Memorandum of Association of the Company revised in March 2021, the key terms of the Series A Preferred Shares, Series B Preferred Shares, and Series C Preferred Shares (collectively, “Preferred Shares”) are summarised as follows:

Dividend rights

Subject to the provisions of the Company’s Second Amended and Restated Articles of Association of the Company (“Articles of Association”), as originally framed or amended and restated from time to time, the board of director may from time to time declare dividends on the issued and outstanding shares of the Company and authorize payment of the same out of the funds of the Company legally available therefor. No dividend, whether in cash, in property or in shares of the capital of the Company, shall be paid on or declared and set aside for any ordinary shares or any other class or series of shares of the Company unless and until (a) all declared but unpaid dividends on the Preferred Shares have been paid in full (calculated on as-converted basis), and (b) a distribution in like amount is likewise declared, paid, set aside or made, respectively, at the same time with respect to each issued and outstanding Preferred Share such that the distribution declared, paid, set aside or made to the holder thereof shall be equal to the distribution that such holder would have received if such Preferred Share had been converted into ordinary shares immediately prior to the record date for such distribution, or if no such record date is established, the date such distribution is made.

Conversion rights

Unless converted earlier pursuant to the Automatic Conversion as defined below, each holder of Preferred Shares shall have the right, at such holder’s sole discretion, to convert all or any portion of its Preferred Shares into ordinary shares at any time prior to the consummation of a qualified [REDACTED] of the Company, without the payment of any additional consideration.

The conversion ratios of each class of the Preferred Shares, shall be respectively determined by dividing their respective issue price, by the conversion price then in effect at the date of the conversion with respect to such particular series of Preferred Shares.

The initial conversion prices of each class of the Preferred Shares will be their respective issue price, each of which will be subject to adjustments to reflect share dividends, share splits, recapitalization and other events.

Each class or series of Preferred Shares shall automatically be converted into ordinary shares at the then applicable conversion price without the payment of any additional consideration upon the earlier of (i) the consummation of a qualified [REDACTED], and (ii) the prior written approval of the holders of at least two-thirds (2/3) of such class or series of Preferred Shares (on an as-converted basis, “Automatic Conversion”).

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Liquidation preferences

In the event of any liquidation, dissolution or winding up of the Company, either voluntary or involuntary (each, a "Liquidation Event") or the consummation of a Deemed Liquidation Event (see the definition below), all assets and funds of the Company legally available for distribution to the Members (after satisfaction of all creditors' claims and claims that may be preferred by the applicable laws) shall be distributed to the Members in the following sequence:

- (a) First, the holders of the Series C Preferred Shares shall receive, for each Series C Preferred Share held by such holder, on parity with each other and prior and in preference to any distribution Share held by such holder, on parity with each other and prior and in preference to any distribution Share held by such holder, on parity with each other and prior and in preference to any distribution equal to the Series C Issue Price with a simple interest of eight percent (8%) per annum return accruing from the Series C Original Issue Date, plus all declared but unpaid dividends thereon (the "Series C Preference Amount"). If the assets and funds thus distributed among the holders of the Series C Preferred Shares shall be insufficient to permit the payment to such holders of the full Series C Preference Amount, then the entire assets and funds of the Company legally available for distribution shall be distributed ratably among the holders of the Series C Preferred Shares in proportion to the aggregate Series C Preference Amount each such holder is otherwise entitled to receive pursuant to this clause (a);
- (b) If there are any assets or funds remaining after the aggregate Series C Preference Amount has been distributed or paid in full to the holders of Series C Preferred Shares pursuant to clause (a) above, the holders of the Series B Preferred Shares and Series B-2 Preferred Shares (being treated as a single class) shall receive, for each Series B Preferred Share or Series B-2 Preferred Share, as applicable, held by such holder, on parity with each other and prior and in preference to any distribution of any of the assets or funds of the Company to the holders of the Series A Preferred Shares and the Ordinary Shares, the amount equal to the Series B Issue Price or Series B-2 Issue Price, as applicable, with a simple interest of eight percent (8%) per annum return accruing from the Series B Original Issue Date or the Series B-2 Original Issue Date, as applicable, plus all declared but unpaid dividends thereon (the "Series B Preference Amount"). If the assets and funds thus distributed among the holders of the Series B Preferred Shares and Series B-2 Preferred Shares shall be insufficient to permit the payment to such holders of the full Series B Preference Amount, then the entire assets and funds of the Company legally available for distribution shall be distributed ratably among the holders of the Series B Preferred Shares and Series B-2 Preferred Shares in proportion to the aggregate Series B Preference Amount each such holder is otherwise entitled to receive pursuant to this clause (b); and;
- (c) If there are any assets or funds remaining after the aggregate Series C Preference and the Series B Preference Amount have been distributed or paid in full to the holders of Series B Preferred Shares and Series B-2 Preferred Shares pursuant to clauses (a) above, the remaining assets and funds of the Company legally available for distribution to the Members shall be distributed ratably among all Members on an as-converted basis (treating for this Article 135(c) all the Preferred Shares as if they had been converted to Ordinary Shares at the then applicable Conversion Price in effect immediately prior to such Liquidation Event or Deemed Liquidation Event).

The following events shall be deemed a liquidation, dissolution or winding up of the Company (each a "Deemed Liquidation Event"):

- (a) any consolidation, amalgamation, or merger of the Company with or into any other corporation or other entity or person, or any other corporate reorganization in which the shareholders of the Company immediately prior to such consolidation, amalgamation, merger or reorganisation own less than fifty percent (50%) of the Company's voting power in the aggregate immediately after such consolidation, amalgamation, merger or reorganisation; and
- (b) a sale, transfer, lease or other disposition of all or substantially all of the assets of the Company, or the exclusive licensing of all or substantially all of the Company's assets (including intellectual property) to a third party.

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Redemption feature

Unless prohibited by the applicable laws, if

- (a) there is any material breach or violation of, or inaccuracy or misrepresentation in any representation or warranty made by any companies of the Group, the founder or key personnel in the transaction warranty made by any companies of the Group, the founder or key personnel in the transaction documents or any material breach or violation of any undertaking, covenant or obligation by any companies of the Group, the founder or key personnel contained in the transaction documents and such breach, if curable, is not cured to the satisfaction of the majority holders of the Preferred Shares within ninety (90) days following written notice served by any holder of Preferred Shares to the Company,
- (b) the Company has not consummated a qualified [REDACTED] on or prior to 10 February 2027, or
- (c) any holder of the Preferred Shares, requires the Company to redeem its Preferred Shares,

at any time thereafter, any holder of the Preferred Shares, may require the Company to redeem its Preferred Shares.

In such event, if a redemption is requested by a holder of certain series Preferred Shares, the relevant Preferred Shares shall be redeemed by the Company at a price per share equal to its issue price of a simple rate of eight percent (8%) per annum return calculating from that the original issue date of the certain series of Preferred Shares to the applicable redemption date, plus all declared but unpaid dividends thereon.

Accounting for Preferred Shares

The Company does not bifurcate any embedded derivatives from the host instruments and has designated the entire instruments as financial liabilities at fair value through profit or loss. Any directly attributable transaction costs are recognised as finance costs in profit or loss. Subsequent to initial recognition, the fair value change of the Preferred Shares is recognised in profit or loss except for the portion attributable to credit risk change which shall be recognised in other comprehensive income, if any. The directors of the Company considered that there is no material credit risk change during the Relevant Periods.

The convertible redeemable preferred shares were classified as non-current liabilities unless the preferred shareholders demand the Company to redeem the preferred shares within 12 months after the end of each of the Relevant Periods.

The movements of the convertible redeemable preferred shares are set out below:

	Series A Preferred Shares	Series B Preferred Shares	Series B-2 Preferred Shares	Series C Preferred Shares	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
At 1 January 2019	62,981	–	–	–	62,981
Issue	–	145,000	–	–	145,000
Changes in fair value	(9,669)	424	–	–	(9,245)
At 31 December 2019 and at 1 January 2020	53,312	145,424	–	–	198,736
Issue	–	159,125	171,786	–	330,911
Changes in fair value	114,520	401,367	81,772	–	597,659
At 31 December 2020 and at 1 January 2021	167,832	705,916	253,558	–	1,127,306
Issue	–	–	–	1,487,456	1,487,456
Changes in fair value	85,561	327,734	109,205	(67,730)	454,770
Currency translation differences	(921)	(3,876)	(1,392)	–	(6,189)
At 30 April 2021	<u>252,472</u>	<u>1,029,774</u>	<u>361,371</u>	<u>1,419,726</u>	<u>3,063,343</u>

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The Group applied the Back-solve Approach method to determine the underlying equity value of the Group based on recent transactions in the Company’s shares, and then adopted the option-pricing method in equity allocation model to determine the fair value of the convertible redeemable preferred shares. Key assumptions are set out below:

	As at 31 December		As at 30 April
	2019	2020	2021
Risk-free interest rate	1.74%	0.07%	0.05%
Lack of marketability discount	10.08%-26.24%	5.76%-11.23%	2.77%-14.13%
Volatility	49.63%	54.81%	59.44%

22. DEFERRED INCOME

	As at 31 December		As at 30 April
	2019	2020	2021
	RMB’000	RMB’000	RMB’000
Deferred revenue (a)	–	931,055	1,183,764
Deferred government grant (b)	17,170	27,117	27,117
	<u>17,170</u>	<u>958,172</u>	<u>1,210,881</u>

- (a) Deferred revenue represented the amount of funding received from Coalition for Epidemic Preparedness Innovations (“CEPI”) by the end of 2020. Clover Sichuan and Clover AUS signed Outbreak Response Funding Agreement (the “Agreement”) with CEPI in 2020, pursuant to which CEPI is to provide funding to Clover Sichuan and Clover AUS to support the Group’s research and development of COVID-19 vaccine under the project of “Outbreak Response To Novel Coronavirus (COVID-19)” (the “Project”).

According to the Agreement, ownership of all data, assays, protocols, and materials made under the Project (“Project Results”), including vaccines (“Products”), as well as all intellectual property rights, including for inventions, know-how, patents, trademarks arising in relation to the Project Results or otherwise under the Project (“Project IP”) shall vest in the Company from creation. CEPI is committed to achieving equitable access to the results of all CEPI-supported programmes pursuant to the “Equitable Access Policy”, which means that any form or dosage of pharmaceutical composition or preparation made or developed under the Project (“Project Vaccine”) is first available to populations when and where it is needed to end an outbreak or contain an epidemic, regardless of whose ability to pay. A global allocation and purchasing mechanism (the “Global Allocation Mechanism”) is to be constituted subsequent to the Agreement to purchase, allocate, and direct the distribution of COVID-19 vaccines including Project Vaccine.

According to the Agreement, the Group agrees to (i) supply all doses of the Project Vaccine up to the capacity as may be required by the Global Allocation Mechanism during the Pandemic Period (the period of time between the date that World Health Organization (“WHO”) declared COVID-19 to be a Public Health Emergency of International Concern (“PHEIC”, that is, 30 January 2020) and the date that WHO declares the PHEIC to have ended); and, (ii) during the period of five years after the Pandemic Period ends, supply the Project Vaccine pursuant as may be required by the Global Allocation Mechanism for use in LMICs (Low and Middle Income Countries as defined by the Organisation for Economic Co-operation and Development), not to exceed 50% of the Project Vaccine unless mutually agreed to.

As such, the funding received from CEPI is for the Group’s commitment to supply the Project Vaccine as agreed in the Agreement after the commercialisation of the Project Vaccine in the future, and, therefore, should be recognised in income in line with the Group’s fulfilment of its obligation to supply the Project Vaccine as required by the Global Allocation Mechanism. As such, the amount received by the end of 2020 and the four months ended 30 April 2021 was recorded as deferred revenue.

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(b) The movements in government grants during the year/period are as follows:

	As at 31 December		As at 30 April
	2019	2020	2021
	RMB'000	RMB'000	RMB'000
At beginning of year/period	7,361	17,170	27,117
Grants received during the year/period	25,718	30,306	–
Amount recognised in profit or loss	(15,909)	(20,359)	–
	<u>17,170</u>	<u>27,117</u>	<u>27,117</u>

23. SHARE CAPITAL

The Company was incorporated on 31 October 2018 under the laws of the Cayman Islands as an exempted company with authorised share capital of US\$50,000 divided into 500,000,000 ordinary shares of a par value of US\$0.0001 each. The Company became the holding company of the Group on 16 March upon the completion of the Reorganisation.

	As at 31 December		As at 30 April
	2019	2020	2021
	RMB'000	RMB'000	RMB'000
Issued and fully paid:			
50,000,000 ordinary shares of US\$0.0001 each	–	–	33
	<u>–</u>	<u>–</u>	<u>33</u>

A summary of movement in the Company’s issued share capital is as follows:

	Number of ordinary shares	Share capital
		RMB'000
As at 1 January 2019, 2020 and 2021	1	–
Issue of ordinary shares during the period	49,999,999	33
	<u>50,000,000</u>	<u>33</u>

24. SHARE-BASED PAYMENTS

The Company operates a share-based payment scheme (the “Scheme”) for the purpose of providing incentives and rewards to eligible participants who contribute to the success of the Group’s operations. Eligible participants of the Scheme include the Company’s directors, the Group’s employees and non-employee consultants.

The Plan

A share incentive plan (the “Plan”) became effective in April 2021 when the board of directors of the Company approved the Plan. The maximum aggregate number of shares that may be issued under this Plan is 10,956,728 ordinary shares of the Company.

Share options

In April 2021, the Company granted 2,773,470 options under the Plan to various employees. The vesting schedule of the options granted would be subject to both a [REDACTED]-based vesting condition (the “[REDACTED] Condition”) and a service-based vesting condition (the “Service Condition”). The [REDACTED] Condition would be satisfied the day after the first-half anniversary of the date when the Company get [REDACTED] (“[REDACTED]”). Subject to the satisfaction of the [REDACTED] Condition, the Service Condition would be satisfied over a 4-year term. The options granted to employees are accounted for as equity awards and measured at their grant date fair values.

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The exercise prices and exercise periods of the share options outstanding as at the end of the Relevant Period is as follows:

	Number of share options	Average exercise price per share option USD
At 1 January 2021	–	–
Granted during the period	2,773,470	0.001
Forfeited during the period	–	–
Exercised during the period	–	–
Expired during the period	–	–
	<u>2,773,470</u>	<u>0.001</u>
At 30 April 2021	<u>2,773,470</u>	<u>0.001</u>

Four months ended 30 April 2021

Number of options	Exercise price USD	Exercise period
<u>2,773,470</u>	<u>0.001</u>	<u>2022-2031</u>

The fair value of equity-settled share options granted was estimated as at the date of grant using a binomial model, taking into account the terms and conditions upon which the options were granted. The following table lists the key assumptions that the model used.

	As at 30 April 2021
Expected volatility (%)	57.59%
Risk-free interest rate (%)	1.26%
Expected life of options (year)	9.99
Weighted average share price (RMB per share)	4.96

The Group recognised share-based payment expenses of RMB1,190,000 for the four months ended 30 April 2021.

Restricted share units

In April 2021, the Company granted 6,044,983 restricted share units under the Plan to various employees. The vesting schedule of the restricted share units granted would be subject to both the [REDACTED] Condition and the Service Condition. The [REDACTED] Condition would be satisfied the day after the first-half anniversary of the [REDACTED]. Subject to the satisfaction of the [REDACTED] Condition, the Service Condition would be satisfied over a 4-year term. The restricted share units granted to employees are accounted for as equity awards and measured at their grant date fair values. The Group recognised share-based payment expenses of RMB2,164,000 for the four months ended 30 April 2021.

In April 2021, the Company granted 261,474 restricted share units under the Plan to non-employee consultants. The vesting schedule of the restricted share units granted would be subject to both the [REDACTED] Condition and the Service Condition. The [REDACTED] Condition would be satisfied the day after the first-half anniversary of the [REDACTED]. Subject to the satisfaction of the [REDACTED] Condition, the Service Condition would be satisfied over a 4-year term. The restricted share units granted to non-employee consultants are accounted for as equity awards and measured at the fair values of the equity at the dates on which the services rendered. The Group recognised share-based payment expenses of RMB45,000 for the four months ended 30 April 2021.

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25. RESERVES

The amounts of the Group’s reserves and the movements therein for the Relevant Periods are presented in the consolidated statements of changes in equity.

(a) Merger reserve

Merger reserve comprises contributions by the shareholders.

(b) Exchange fluctuation reserve

The exchange fluctuation reserve comprises all foreign exchange differences arising from the translation of the financial statements of companies of which the functional currencies are not RMB. The reserve is dealt with in accordance with the accounting policy set out in note 2.4.

(c) Reserve movements of the Company

	At 30 April 2021				
	Capital reserve	Share- based payments reserve	Accumulated losses	Exchange fluctuation reserve	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
As at 1 January 2019, 2020 and 2021	–	–	–	–	–
Loss for the period	–	–	(475,660)	–	(475,660)
Exchange differences on translation of the Company	–	–	–	5,825	5,825
Total comprehensive income for the period	–	–	(475,660)	5,825	(469,835)
Issue of shares	99,312	–	–	–	99,312
Business combinations involving entities under common control	(21,090)	–	–	–	(21,090)
Share-based payments	–	3,399	–	–	3,399
At 30 April 2021	<u>78,222</u>	<u>3,399</u>	<u>(475,660)</u>	<u>5,825</u>	<u>(388,214)</u>

26. NOTES TO THE CONSOLIDATED STATEMENTS OF CASH FLOWS

(a) Major non-cash transactions

During the years ended 31 December 2019 and 2020 and the four months ended 30 April 2020 and 2021, the Group had non-cash additions to right-of-use assets and lease liabilities of RMB9,532,000 and RMB12,676,000, RMB11,163,000 and RMB15,815,000, respectively, in respect of lease arrangements for buildings and office equipment.

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(b) Changes in liabilities arising from financing activities

	Convertible redeemable preferred shares	Lease liabilities
	<i>RMB'000</i>	<i>RMB'000</i>
At 1 January 2019	62,981	4,105
Changes from financing cash flows	145,000	(1,726)
Change in fair value	(9,245)	–
New leases	–	9,532
Interest expense (<i>note 7</i>)	–	544
	<u>198,736</u>	<u>12,455</u>
At 31 December 2019	<u>198,736</u>	<u>12,455</u>
At 1 January 2020	198,736	12,455
Changes from financing cash flows	330,911	(4,472)
Change in fair value	597,659	–
New leases	–	12,676
Interest expense	–	1,657
	<u>1,127,306</u>	<u>22,316</u>
At 31 December 2020	<u>1,127,306</u>	<u>22,316</u>
At 1 January 2021	1,127,306	22,316
Changes from financing cash flows	1,487,456	(2,564)
Change in fair value	454,770	–
Currency translation differences	(6,189)	–
New leases	–	15,815
Reassessment of a lease term arising from a decision not to exercise the extension option	–	(7,142)
Interest expense	–	674
	<u>3,063,343</u>	<u>29,099</u>
At 30 April 2021	<u>3,063,343</u>	<u>29,099</u>
At 1 January 2020	198,736	12,455
Changes from financing cash flows	51,346	(919)
Change in fair value	119,870	–
New leases	–	11,163
Interest expense	–	462
	<u>369,952</u>	<u>23,161</u>
At 30 April 2020	<u>369,952</u>	<u>23,161</u>

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(c) **Total cash outflow for leases**

The total cash outflow for leases included in the statements of cash flows is as follows:

	Year ended 31 December		Four months ended 30 April	
	2019 <i>RMB’000</i>	2020 <i>RMB’000</i>	2020 <i>RMB’000</i>	2021 <i>RMB’000</i>
Within operating activities	570	–	–	302
Within financing activities	1,726	4,472	919	2,564
	<u>2,296</u>	<u>4,472</u>	<u>919</u>	<u>2,866</u>

27. COMMITMENTS

The Group had the following capital commitments at the end of each of the Relevant Periods:

	As at 31 December		As at 30 April
	2019 <i>RMB’000</i>	2020 <i>RMB’000</i>	2021 <i>RMB’000</i>
Contracted, but not provided for:			
Property, plant and equipment	745	27,841	21,537
Intangible assets	–	4,833	13,306
	<u>745</u>	<u>32,674</u>	<u>34,843</u>

28. RELATED PARTY TRANSACTIONS

(a) **Name and relationship**

The directors of the Group are of the view that the following parties are related parties that had transactions or balances with the Group during the Relevant Periods and the four months ended 30 April 2020.

Name of related parties	Relationship with the Group
Chengdu Tianhe	A shareholder of Clover Sichuan and an entity controlled by a director of Clover Sichuan
Chengdu Clover Biotechnology Co., Ltd. (“Chengdu Clover”)	An entity controlled by the sister of the founder
GenHunter Corporation	An entity controlled by the founder of the Company
Peng Liang	Founder of the Company

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(b) Transactions with related parties

	Year ended 31 December		Four months ended 30 April	
	2019 RMB'000	2020 RMB'000	2020 RMB'000 (Unaudited)	2021 RMB'000
Office lease and utility fees:				
Chengdu Tianhe (i)	1,374	2,716	669	1,118
Entrusted Loan				
Chengdu Tianhe (ii)	–	–	–	99,021
Purchase of services:				
GenHunter Corporation	138	171	79	62
Settlement of individual income tax for the founder:				
Peng Liang	1,570	–	–	–

Notes:

- (i) The Group entered into a set of property leasing agreements with Chengdu Tianhe, and accordingly recognised lease liabilities of RMB7,136,000 and RMB9,001,000 and RMB11,642,000 as at 31 December 2019 and 2020 and 30 April 2021, respectively.
- (ii) The Group entered into an entrusted loan contract with Chengdu Tianhe and China Zheshang Bank on 4 February 2021, pursuant to which the Group entrusted China Zheshang Bank to provide a loan of RMB99,021,000 to Chengdu Tianhe. As at 30 April 2021, all loans under the aforesaid entrusted loan contract have been repaid in accordance with the contract.

(c) Outstanding balances with related parties

	As at 31 December		As at 30 April
	2019 RMB'000	2020 RMB'000	2021 RMB'000
Amount due from a related party:			
Chengdu Tianhe	72	113	134
Amount due to a related party:			
Chengdu Clover	2,928	1,473	–

All the balances above are unsecured and interest-free.

All the balances of amounts due from/to related parties as at 31 December 2019 and 2020 and 30 April 2021 were trade in nature.

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(d) **Compensation of key management personnel of the Group:**

	Year ended 31 December		Four months 30 April	
	2019 <i>RMB’000</i>	2020 <i>RMB’000</i>	2020 <i>RMB’000</i>	2021 <i>RMB’000</i>
Short term employee benefits	5,970	19,139	2,575	15,475
Share-based payment expenses	–	–	–	241
Post-employment benefits	52	354	4	587
Total compensation paid to key management personnel	6,022	19,493	2,579	16,303

Further details of directors’ and the chief executive’s emoluments are included in note 8 to the Historical Financial Information.

29. FINANCIAL INSTRUMENTS BY CATEGORY

The carrying amounts of each of the categories of financial instruments as at the end of each of the Relevant Periods are as follows:

31 December 2019

Financial assets

	Financial assets at amortised cost <i>RMB’000</i>
Financial assets included in prepayments, other receivables and other assets	568
Time deposits and restricted cash	10,000
Cash and cash equivalents	148,694
	159,262

Financial liabilities

	Financial liabilities at amortised cost <i>RMB’000</i>	Financial liabilities at fair value through profit or loss (Designated as such upon initial recognition) <i>RMB’000</i>	Total <i>RMB’000</i>
Trade payables	7,165	–	7,165
Convertible redeemable preferred shares	–	198,736	198,736
Financial liabilities included in other payables and accruals	10,299	–	10,299
	17,464	198,736	216,200

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31 December 2020

Financial assets

	Financial assets at amortised cost <i>RMB’000</i>
Financial assets included in prepayments, other receivables and other assets	1,480
Time deposits and restricted cash	290,328
Cash and cash equivalents	516,184
	<u>807,992</u>

Financial liabilities

	Financial liabilities at amortised cost <i>RMB’000</i>	Financial liabilities at fair value through profit or loss (Designated as such upon initial recognition) <i>RMB’000</i>	Total <i>RMB’000</i>
Trade payables	33,820	–	33,820
Convertible redeemable preferred shares	–	1,127,306	1,127,306
Financial liabilities included in other payables and accruals	7,273	–	7,273
	<u>41,093</u>	<u>1,127,306</u>	<u>1,168,399</u>

30 April 2021

Financial assets

	Financial assets at amortised cost <i>RMB’000</i>	Financial assets at fair value through profit or loss (Mandatorily designated as such) <i>RMB’000</i>
Financial assets included in prepayments, other receivables and other assets	5,838	–
Foreign currency forward contract	–	167
Time deposits and restricted cash	245,126	–
Cash and cash equivalents	1,828,780	–
	<u>2,079,744</u>	<u>167</u>

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Financial liabilities

	Financial liabilities at amortised cost	Financial liabilities at fair value through profit or loss (Designated as such upon initial recognition)	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Trade payables	98,831	–	98,831
Convertible redeemable preferred shares	–	3,063,343	3,063,343
Financial liabilities included in other payables and accruals	30,904	–	30,904
	<u>129,735</u>	<u>3,063,343</u>	<u>3,193,078</u>

30. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS

Management has assessed that the fair values of cash and cash equivalents, time deposits, restricted deposits, trade payables, financial assets included in prepayments, other receivables and other assets and financial liabilities included in other payables and accruals, approximate to their carrying amounts largely due to the short term maturities of these instruments.

The Group’s finance department headed by the finance manager is responsible for determining the policies and procedures for the fair value measurement of financial instruments. The finance manager reports directly to the chief financial officer. At each reporting date, the finance department analyses the movements in the values of financial instruments and determines the major inputs applied in the valuation. The valuation is reviewed and approved by the chief financial officer.

The fair values of the financial assets and liabilities are included at the amount at which the instrument could be exchanged in a current transaction between willing parties, other than in a forced or liquidation sale.

Financial instruments in Level 3

As the Company’s convertible redeemable preferred shares are not traded in an active market, the fair values of these financial instruments have been determined by using back-solve method to determine the underlying equity value of the Company and option-pricing method in equity allocation model, based on assumptions that are not supported by observable market prices or rates. One of the major assumptions used in the valuation for convertible redeemable preferred shares is volatility, which was estimated based on annualised standard deviation of daily stock price return of comparable companies for a period from the respective valuation date and with similar span as time to expiration. The valuation requires the directors to determine comparable public companies based on industry, size, leverage and strategy, and to calculate the volatility for each comparable company identified. The volatility parameter adopted in the option-pricing method is based on the median value of volatility calculated for each comparable company. The directors believe that the estimated fair values resulting from the valuation technique, which are recorded in the consolidated statements of financial position, and the related changes in fair values, which are recorded in profit or loss, are reasonable, and that they were the most appropriate values at the end of each of the Relevant Periods.

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Below is a summary of significant unobservable inputs to the valuation of financial instruments together with a quantitative sensitivity analysis as at 31 December 2019 and 2020 and 30 April 2021:

31 December 2019

	Valuation technique	Significant unobservable inputs	Range of inputs	Increase/ (decrease) in the inputs (%)	Sensitivity of fair value to the input RMB’000
Convertible redeemable preferred shares	Back-solved method and option-pricing method	Volatility	49.63%	1/(1)	151/(145)

31 December 2020

	Valuation technique	Significant unobservable inputs	Range of inputs	Increase/ (decrease) in the inputs (%)	Sensitivity of fair value to the input RMB’000
Convertible redeemable preferred shares	Back-solved method and option-pricing method	Volatility	54.81%	1/(1)	(1,702)/1,709

30 April 2021

	Valuation technique	Significant unobservable inputs	Range of inputs	Increase/ (decrease) in the inputs (%)	Sensitivity of fair value to the input RMB’000
Convertible redeemable preferred shares	Back-solved method and option-pricing method	Volatility	59.44%	1/(1)	(3,868)/3,847

Fair value hierarchy

The following tables illustrate the fair value measurement hierarchy of the Group’s financial instruments:

Assets measured at fair value

As at 30 April 2021

	Fair value measurement using			Total RMB’000
	Quoted prices in active markets (Level 1) RMB’000	Significant observable inputs (Level 2) RMB’000	Significant unobservable inputs (Level 3) RMB’000	
Financial assets at fair value through profit or loss:				
Foreign currency forward contracts	–	167	–	167

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Liabilities measured at fair value:

As at 31 December 2019

	Fair value measurement using			Total RMB’000
	Quoted prices in active markets (Level 1) RMB’000	Significant observable inputs (Level 2) RMB’000	Significant unobservable inputs (Level 3) RMB’000	
Financial liabilities at fair value through profit or loss:				
Convertible redeemable preferred shares	–	–	198,736	198,736

As at 31 December 2020

	Fair value measurement using			Total RMB’000
	Quoted prices in active markets (Level 1) RMB’000	Significant observable inputs (Level 2) RMB’000	Significant unobservable inputs (Level 3) RMB’000	
Financial liabilities at fair value through profit or loss:				
Convertible redeemable preferred shares	–	–	1,127,306	1,127,306

As at 30 April 2021

	Fair value measurement using			Total RMB’000
	Quoted prices in active markets (Level 1) RMB’000	Significant observable inputs (Level 2) RMB’000	Significant unobservable inputs (Level 3) RMB’000	
Financial liabilities at fair value through profit or loss:				
Convertible redeemable preferred shares	–	–	3,063,343	3,063,343

During the Relevant Periods, there were no transfers of fair value measurements between Level 1 and Level 2 and no transfers into or out of Level 3 for both financial assets and financial liabilities.

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31. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES

The Group’s principal financial instruments, comprise cash and cash equivalents and preferred shares. The main purpose of these financial instruments is to raise finance for the Group’s operations. The Group has various other financial assets and liabilities such as trade payables, which arise directly from its operations.

The main risks arising from the Group’s financial instruments are foreign currency risk, credit risk and liquidity risk. The board of directors reviews and agrees policies for managing each of these risks and they are summarised below.

Foreign currency risk

Foreign currency risk is the risk of loss resulting from changes in foreign currency exchange rates. Fluctuations in exchange rates between RMB and other currencies in which the Group conducts business may affect the Group’s financial condition and results of operations. The Group seeks to limit its exposure to foreign currency risk by minimising its net foreign currency position.

The Group has transactional currency exposures. Such exposures arise from sales or purchases by operating units in currencies other than the units’ functional currencies.

The following table demonstrates the sensitivity at the end of each of the Relevant Periods to a reasonably possible change in the US\$ exchange rate, with all other variables held constant, of the Group’s profit before tax (due to changes in the fair value of monetary assets and liabilities).

Increase/(decrease) in loss before tax

	Year ended 31 December		Four months ended 30 April
	2019	2020	2021
	RMB’000	RMB’000	RMB’000
Increase in the US\$ rate by 5%	(427)	(23,468)	(10,999)
Decrease in the US\$ rate by 5%	427	23,468	10,999

Credit risk

The carrying amounts of cash and bank balances and other receivables represent the Group’s maximum exposure equal to credit risk in relation to the financial assets.

The Group expects that there is no significant credit risk associated with cash and bank balances since they are substantially held in reputable state-owned banks and other medium or large-sized listed banks. Management does not expect that there will be any significant losses from non-performance by these counterparties.

The Group trades only with recognised and creditworthy third parties. It is the Group’s policy that all customers who wish to trade on credit terms are subject to credit verification procedures. In addition, receivable balances are monitored on an ongoing basis and the Group’s exposure to bad debts is not significant.

The credit risk of the Group’s other financial assets, which comprise cash and cash equivalents and other receivables, arises from default of the counterparty, with a maximum exposure equal to the carrying amounts of these instruments.

Since the Group trades only with recognised and creditworthy third parties, there is no requirement for collateral. Concentrations of credit risk are managed by customer/counterparty, by geographical region and by industry sector. There are no significant concentrations of credit risk within the Group as the customer bases of the Group’s trade receivables are widely dispersed in different sectors and industries.

The Group also expects that there is no significant credit risk associated with other receivables since counterparties to these financial assets have no history of default.

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Maximum exposure and year-end staging

The tables below show the credit quality and the maximum exposure to credit risk based on the Group’s credit policy, which is mainly based on past due information unless other information is available without undue cost or effort, and year-end staging classification as at 31 December and period-end staging classification as at 30 April. The amounts presented are gross carrying amounts for financial assets and the exposure to credit risk for the financial guarantee contracts.

As at 31 December 2019

	12-month ECLs	Lifetime ECLs			Total RMB’000
	Stage 1 RMB’000	Stage 2 RMB’000	Stage 3 RMB’000	Simplified approach RMB’000	
Financial assets included in prepayments, other receivables and other assets – Normal*	568	–	–	–	568
Time deposits	10,000	–	–	–	10,000
Cash and cash equivalents – Not yet past due	148,694	–	–	–	148,694
	159,262	–	–	–	159,262

As at 31 December 2020

	12-month ECLs	Lifetime ECLs			Total RMB’000
	Stage 1 RMB’000	Stage 2 RMB’000	Stage 3 RMB’000	Simplified approach RMB’000	
Financial assets included in prepayments, other receivables and other assets – Normal*	1,480	–	–	–	1,480
Time deposits	270,328	–	–	–	270,328
Restricted cash	20,000	–	–	–	20,000
Cash and cash equivalents	516,184	–	–	–	516,184
	807,992	–	–	–	807,992

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As at 30 April 2021

	12-month	Lifetime ECLs			Total
	ECLs			Simplified	
	Stage 1	Stage 2	Stage 3	approach	
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
Financial assets included in prepayments, other receivables and other assets					
– Normal*	5,838	–	–	–	5,838
Time deposits	227,976	–	–	–	227,976
Restricted cash	17,150	–	–	–	17,150
Cash and cash equivalents	1,828,780	–	–	–	1,828,780
	<u>2,079,744</u>	<u>–</u>	<u>–</u>	<u>–</u>	<u>2,079,744</u>

* The credit quality of the financial assets included in prepayments, other receivables and other assets is considered to be “normal” when they are not past due and there is no information indicating that the financial assets had a significant increase in credit risk since initial recognition. Otherwise, the credit quality of the financial assets is considered to be “doubtful”.

Liquidity risk

The Group monitors and maintains a level of cash and cash equivalents deemed adequate by the management of the Group to finance the operations and mitigate the effects of fluctuations in cash flows.

The maturity profile of the Group’s financial liabilities as at the end of each of the Relevant Periods, based on the contractual undiscounted payments, is as follows:

	As at 31 December 2019				
	On demand	With 1 year	1 to 5 years	Over 5 years	Total
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
Lease liabilities	–	2,746	12,624	–	15,370
Trade payables	7,165	–	–	–	7,165
Financial liabilities included in other payables and accruals	10,299	–	–	–	10,299
Convertible redeemable preferred shares (note a)	–	–	351,596	–	351,596
	<u>17,464</u>	<u>2,746</u>	<u>364,220</u>	<u>–</u>	<u>384,430</u>

APPENDIX I

ACCOUNTANTS’ REPORT

As at 31 December 2020

	On demand	With 1 year	1 to 5 years	Over 5 years	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Lease liabilities	–	5,893	20,834	–	26,727
Trade payables	33,820	–	–	–	33,820
Financial liabilities included in other payables and accruals	7,273	–	–	–	7,273
Convertible redeemable preferred shares (<i>note a</i>)	–	–	864,126	–	864,126
	<u>41,093</u>	<u>5,893</u>	<u>884,960</u>	<u>–</u>	<u>931,946</u>

As at 30 April 2021

	On demand	With 1 year	1 to 5 years	Over 5 years	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Lease liabilities	–	9,664	24,331	–	33,995
Trade payables	98,831	–	–	–	98,831
Financial liabilities included in other payables and accruals	30,904	–	–	–	30,904
Convertible redeemable preferred shares (<i>note b</i>)	–	–	–	2,984,484	2,984,484
	<u>129,735</u>	<u>9,664</u>	<u>24,331</u>	<u>2,984,484</u>	<u>3,148,214</u>

Notes:

- (a) The liquidity risk of convertible redeemable preferred shares is the original issue price of Preferred Shares plus the respective predetermined interest (the “redemption amount”), assuming that no consummation of public [REDACTED] of the Company’s shares before 31 December 2024, and the holders of the Preferred Shares request the Company to redeem all of the Preferred Shares.
- (b) According to Memorandum of Association adopted on 16 March 2021, the redemption date regarding [REDACTED] consummation has been changed to 10 February 2027.

Capital management

The primary objectives of the Group’s capital management are to safeguard the Group’s ability to continue as a going concern and to maintain healthy capital ratios in order to support its business and maximise shareholders’ value.

The Group manages its capital structure and makes adjustments to it in light of changes in economic conditions and the risk characteristics of the underlying assets. To maintain or adjust the capital structure, the Group may adjust the dividend payment to shareholders, return capital to shareholders or issue new shares. The Group is not subject to any externally imposed capital requirements. No changes were made in the objectives, policies or processes for managing capital during the Relevant Periods.

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ACCOUNTANTS’ REPORT

32. EVENTS AFTER THE RELEVANT PERIODS

On 1 July 2021, the Board of Directors of the Company passed a resolution, pursuant to which the Company shall issue 7,250,000 ordinary shares with a par value of USD0.0001 each to Super Novel International Limited for it to hold ordinary shares of the Company underlying the restricted share unit scheme adopted by the Company on 15 April 2021.

33. SUBSEQUENT FINANCIAL STATEMENTS

No audited financial statements have been prepared by the Group or any of its subsidiaries in respect of any period subsequent to 30 April 2021.

APPENDIX II

UNAUDITED PRO FORMA FINANCIAL INFORMATION

[REDACTED]

[REDACTED]

APPENDIX II

UNAUDITED PRO FORMA FINANCIAL INFORMATION

[REDACTED]

APPENDIX II

UNAUDITED PRO FORMA FINANCIAL INFORMATION

[REDACTED]

[REDACTED]

APPENDIX III

**SUMMARY OF THE CONSTITUTION OF
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SUMMARY OF THE CONSTITUTION OF THE COMPANY

1 Memorandum of Association

The Memorandum of Association of the Company was conditionally adopted on September 26, 2021 and states, inter alia, that the liability of the members of the Company is limited, that the objects for which the Company is established are unrestricted and the Company shall have full power and authority to carry out any object not prohibited by the Companies Act or any other law of the Cayman Islands.

The Memorandum of Association is available for inspection at the address specified in Appendix V in the section headed "Documents on Display".

2 Articles of Association

The Articles of Association of the Company were conditionally adopted on September 26, 2021 and include provisions to the following effect:

2.1 *Classes of Shares*

The share capital of the Company consists of ordinary shares. The capital of the Company at the date of adoption of the Articles is US\$200,000 divided into 2,000,000,000 shares of US\$0.0001 each.

2.2 *Directors*

(a) Power to allot and issue Shares

Subject to the provisions of the Companies Act and the Memorandum and Articles of Association, the unissued shares in the Company (whether forming part of its original or any increased capital) shall be at the disposal of the Directors, who may offer, allot, grant options over or otherwise dispose of them to such persons, at such times and for such consideration, and upon such terms, as the Directors shall determine.

Subject to the provisions of the Articles of Association and to any direction that may be given by the Company in general meeting and without prejudice to any special rights conferred on the holders of any existing shares or attaching to any class of shares, any share may be issued with or have attached thereto such preferred, deferred, qualified or other special rights or restrictions, whether in regard to dividend, voting, return of capital or otherwise, and to such persons at such times and for such consideration as the Directors may determine. Subject to the Companies Act and to any special rights conferred on any shareholders or attaching to any class of shares, any share may, with the sanction of a special resolution, be issued on terms that it is, or at the option of the Company or the holder thereof, liable to be redeemed.

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(b) Power to dispose of the assets of the Company or any subsidiary

The management of the business of the Company shall be vested in the Directors who, in addition to the powers and authorities by the Articles of Association expressly conferred upon them, may exercise all such powers and do all such acts and things as may be exercised or done or approved by the Company and are not by the Articles of Association or the Companies Act expressly directed or required to be exercised or done by the Company in general meeting, but subject nevertheless to the provisions of the Companies Act and of the Articles of Association and to any regulation from time to time made by the Company in general meeting not being inconsistent with such provisions or the Articles of Association, provided that no regulation so made shall invalidate any prior act of the Directors which would have been valid if such regulation had not been made.

(c) Compensation or payment for loss of office

Payment to any Director or past Director of any sum by way of compensation for loss of office or as consideration for or in connection with his retirement from office (not being a payment to which the Director is contractually entitled) must first be approved by the Company in general meeting.

(d) Loans to Directors

There are provisions in the Articles of Association prohibiting the making of loans to Directors or their respective close associates which are equivalent to the restrictions imposed by the Companies Ordinance.

(e) Financial assistance to purchase Shares

Subject to all applicable laws, the Company may give financial assistance to Directors and employees of the Company, its subsidiaries or any holding company or any subsidiary of such holding company in order that they may buy shares in the Company or any such subsidiary or holding company. Further, subject to all applicable laws, the Company may give financial assistance to a trustee for the acquisition of shares in the Company or shares in any such subsidiary or holding company to be held for the benefit of employees of the Company, its subsidiaries, any holding company of the Company or any subsidiary of any such holding company (including salaried Directors).

(f) Disclosure of interest in contracts with the Company or any of its subsidiaries

No Director or proposed Director shall be disqualified by his office from contracting with the Company either as vendor, purchaser or otherwise nor shall any such contract or any contract or arrangement entered into by or on behalf of the Company with any person, company or partnership of or in which any Director shall be a member or otherwise interested be capable on that account of being avoided, nor shall any Director so contracting or being any member or so interested be liable to account to the Company for

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any profit so realised by any such contract or arrangement by reason only of such Director holding that office or the fiduciary relationship thereby established, provided that such Director shall, if his interest in such contract or arrangement is material, declare the nature of his interest at the earliest meeting of the board of Directors at which it is practicable for him to do so, either specifically or by way of a general notice stating that, by reason of the facts specified in the notice, he is to be regarded as interested in any contracts of a specified description which may be made by the Company.

A Director shall not be entitled to vote on (nor shall be counted in the quorum in relation to) any resolution of the Directors in respect of any contract or arrangement or any other proposal in which the Director or any of his close associates (or, if required by the Listing Rules, his other associates) has any material interest, and if he shall do so his vote shall not be counted (nor is he to be counted in the quorum for the resolution), but this prohibition shall not apply to any of the following matters, namely:

- (i) the giving to such Director or any of his close associates of any security or indemnity in respect of money lent or obligations incurred or undertaken by him or any of them at the request of or for the benefit of the Company or any of its subsidiaries;
- (ii) the giving of any security or indemnity to a third party in respect of a debt or obligation of the Company or any of its subsidiaries for which the Director or any of his close associates has himself/themselves assumed responsibility in whole or in part and whether alone or jointly under a guarantee or indemnity or by the giving of security;
- (iii) any proposal concerning an offer of shares, debentures or other securities of or by the Company or any other company which the Company may promote or be interested in for subscription or purchase where the Director or any of his close associates is/are or is/are to be interested as a participant in the underwriting or sub-underwriting of the offer;
- (iv) any proposal or arrangement concerning the benefit of employees of the Company or any of its subsidiaries including:
 - (A) the adoption, modification or operation of any employees' share scheme or any share incentive scheme or share option scheme under which the Director or any of his close associates may benefit; or
 - (B) the adoption, modification or operation of a pension or provident fund or retirement, death or disability benefits scheme which relates both to Directors, their close associates and employees of the Company or any of its subsidiaries and does not provide in respect of any Director or any of his close associates, as such any privilege or advantage not generally accorded to the class of persons to which such scheme or fund relates; and

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- (v) any contract or arrangement in which the Director or any of his close associates is/are interested in the same manner as other holders of shares or debentures or other securities of the Company by virtue only of his/their interest in shares or debentures or other securities of the Company.

(g) Remuneration

The Directors shall be entitled to receive by way of remuneration for their services such sum as shall from time to time be determined by the Directors, or the Company in general meeting, as the case may be, such sum (unless otherwise directed by the resolution by which it is determined) to be divided amongst the Directors in such proportions and in such manner as they may agree, or failing agreement, equally, except that in such event any Director holding office for less than the whole of the relevant period in respect of which the remuneration is paid shall only rank in such division in proportion to the time during such period for which he has held office. Such remuneration shall be in addition to any other remuneration to which a Director who holds any salaried employment or office in the Company may be entitled by reason of such employment or office.

The Directors shall also be entitled to be paid all expenses, including travel expenses, reasonably incurred by them in or in connection with the performance of their duties as Directors including their expenses of travelling to and from board meetings, committee meetings or general meetings or otherwise incurred whilst engaged on the business of the Company or in the discharge of their duties as Directors.

The Directors may grant special remuneration to any Director who shall perform any special or extra services at the request of the Company. Such special remuneration may be made payable to such Director in addition to or in substitution for his ordinary remuneration as a Director, and may be made payable by way of salary, commission or participation in profits or otherwise as may be agreed.

The remuneration of an executive Director or a Director appointed to any other office in the management of the Company shall from time to time be fixed by the Directors and may be by way of salary, commission or participation in profits or otherwise or by all or any of those modes and with such other benefits (including share option and/or pension and/or gratuity and/or other benefits on retirement) and allowances as the Directors may from time to time decide. Such remuneration shall be in addition to such remuneration as the recipient may be entitled to receive as a Director.

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(h) Retirement, appointment and removal

The Directors shall have power at any time and from time to time to appoint any person to be a Director, either to fill a casual vacancy or as an addition to the existing Directors. Any Director so appointed shall hold office only until the next general meeting of the Company and shall then be eligible for re-election at that meeting, but shall not be taken into account in determining the number of Directors and which Directors are to retire by rotation at such meeting.

The Company may by ordinary resolution remove any Director (including a Managing Director or other executive Director) before the expiration of his period of office notwithstanding anything in the Articles of Association or in any agreement between the Company and such Director (but without prejudice to any claim for compensation or damages payable to him in respect of the termination of his appointment as Director or of any other appointment of office as a result of the termination of this appointment as Director). The Company may also by ordinary resolution appoint another person in his place. Any Director so appointed shall hold office during such time only as the Director in whose place he is appointed would have held the same if he had not been removed.

The Company may also by ordinary resolution elect any person to be a Director, either to fill a casual vacancy or as an addition to the existing Directors. No person shall, unless recommended by the Directors, be eligible for election to the office of Director at any general meeting unless, during the period, which shall be at least seven days, commencing no earlier than the day after the despatch of the notice of the meeting appointed for such election and ending no later than seven days prior to the date of such meeting, there has been given to the Secretary of the Company notice in writing by a member of the Company (not being the person to be proposed) entitled to attend and vote at the meeting for which such notice is given of his intention to propose such person for election and also notice in writing signed by the person to be proposed of his willingness to be elected.

There is no shareholding qualification for Directors nor is there any specified age limit for Directors.

The office of a Director shall be vacated:

- (i) if he resigns his office by notice in writing to the Company at its registered office or its principal office in Hong Kong;
- (ii) if an order is made by any competent court or official on the grounds that he is or may be suffering from mental disorder or is otherwise incapable of managing his affairs and the Directors resolve that his office be vacated;

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- (iii) if, without leave, he is absent from meetings of the Directors (unless an alternate Director appointed by him attends) for 12 consecutive months, and the Directors resolve that his office be vacated;
- (iv) if he becomes bankrupt or has a receiving order made against him or suspends payment or compounds with his creditors generally;
- (v) if he ceases to be or is prohibited from being a Director by law or by virtue of any provision in the Articles of Association;
- (vi) if he is removed from office by notice in writing served upon him signed by not less than three-fourths in number (or, if that is not a round number, the nearest lower round number) of the Directors (including himself) for the time being then in office; or
- (vii) if he shall be removed from office by an ordinary resolution of the members of the Company under the Articles of Association.

At every annual general meeting of the Company one-third of the Directors for the time being, or, if their number is not three or a multiple of three, then the number nearest to, but not less than, one-third, shall retire from office by rotation, provided that every Director (including those appointed for a specific term) shall be subject to retirement by rotation at least once every three years. A retiring Director shall retain office until the close of the meeting at which he retires and shall be eligible for re-election thereat. The Company at any annual general meeting at which any Directors retire may fill the vacated office by electing a like number of persons to be Directors.

(i) Borrowing powers

The Directors may from time to time at their discretion exercise all the powers of the Company to raise or borrow or to secure the payment of any sum or sums of money for the purposes of the Company and to mortgage or charge its undertaking, property and assets (present and future) and uncalled capital or any part thereof.

(j) Proceedings of the Board

The Directors may meet together for the despatch of business, adjourn and otherwise regulate their meetings and proceedings as they think fit in any part of the world. Questions arising at any meeting shall be determined by a majority of votes. In the case of an equality of votes, the chairperson of the meeting shall have a second or casting vote.

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2.3 *Alteration to constitutional documents*

No alteration or amendment to the Memorandum or Articles of Association may be made except by special resolution.

2.4 *Variation of rights of existing shares or classes of shares*

If at any time the share capital of the Company is divided into different classes of shares, all or any of the rights attached to any class of shares for the time being issued (unless otherwise provided for in the terms of issue of the shares of that class) may, subject to the provisions of the Companies Act, be varied or abrogated either with the consent in writing of the holders of not less than three-fourths in nominal value of the issued shares of that class or with the sanction of a special resolution passed at a separate meeting of the holders of the shares of that class. To every such separate meeting all the provisions of the Articles of Association relating to general meetings shall *mutatis mutandis* apply, but so that the quorum for the purposes of any such separate meeting and of any adjournment thereof shall be a person or persons together holding (or representing by proxy or duly authorised representative) at the date of the relevant meeting not less than one-third in nominal value of the issued shares of that class.

The special rights conferred upon the holders of shares of any class shall not, unless otherwise expressly provided in the rights attaching to or the terms of issue of such shares, be deemed to be varied by the creation or issue of further shares ranking *pari passu* therewith.

2.5 *Alteration of capital*

The Company may, from time to time, whether or not all the shares for the time being authorised shall have been issued and whether or not all the shares for the time being issued shall have been fully paid up, by ordinary resolution, increase its share capital by the creation of new shares, such new capital to be of such amount and to be divided into shares of such respective amounts as the resolution shall prescribe.

The Company may from time to time by ordinary resolution:

- (a) consolidate and divide all or any of its share capital into shares of a larger amount than its existing shares. On any consolidation of fully paid shares and division into shares of larger amount, the Directors may settle any difficulty which may arise as they think expedient and in particular (but without prejudice to the generality of the foregoing) may as between the holders of shares to be consolidated determine which particular shares are to be consolidated into each consolidated share, and if it shall happen that any person shall become entitled to fractions of a consolidated share or shares, such fractions may be sold by some person appointed by the Directors for that purpose and the person so appointed may transfer the shares so sold to the purchaser thereof and the validity of such transfer shall not be questioned, and so

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that the net proceeds of such sale (after deduction of the expenses of such sale) may either be distributed among the persons who would otherwise be entitled to a fraction or fractions of a consolidated share or shares rateably in accordance with their rights and interests or may be paid to the Company for the Company's benefit;

- (b) cancel any shares which at the date of the passing of the resolution have not been taken or agreed to be taken by any person, and diminish the amount of its share capital by the amount of the shares so cancelled subject to the provisions of the Companies Act; and
- (c) sub-divide its shares or any of them into shares of smaller amount than is fixed by the Memorandum of Association, subject nevertheless to the provisions of the Companies Act, and so that the resolution whereby any share is sub-divided may determine that, as between the holders of the shares resulting from such sub-division, one or more of the shares may have any such preferred or other special rights, over, or may have such deferred rights or be subject to any such restrictions as compared with the others as the Company has power to attach to unissued or new shares.

The Company may by special resolution reduce its share capital or any capital redemption reserve in any manner authorised and subject to any conditions prescribed by the Companies Act.

2.6 Special resolution – majority required

A "special resolution" is defined in the Articles of Association to have the meaning ascribed thereto in the Companies Act, for which purpose, the requisite majority shall be not less than three-fourths of the votes of such members of the Company as, being entitled to do so, vote in person or, in the case of corporations, by their duly authorised representatives or, where proxies are allowed, by proxy at a general meeting of which notice specifying the intention to propose the resolution as a special resolution has been duly given and includes a special resolution approved in writing by all of the members of the Company entitled to vote at a general meeting of the Company in one or more instruments each signed by one or more of such members, and the effective date of the special resolution so adopted shall be the date on which the instrument or the last of such instruments (if more than one) is executed.

In contrast, an "ordinary resolution" is defined in the Articles of Association to mean a resolution passed by a simple majority of the votes of such members of the Company as, being entitled to do so, vote in person or, in the case of corporations, by their duly authorised representatives or, where proxies are allowed, by proxy at a general meeting held in accordance with the Articles of Association and includes an ordinary resolution approved in writing by all the members of the Company aforesaid.

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2.7 *Voting rights*

Subject to any special rights, privileges or restrictions as to voting for the time being attached to any class or classes of shares, at any general meeting on a poll every member present in person (or, in the case of a member being a corporation, by its duly authorised representative) or by proxy shall have one vote for each share registered in his name in the register of members of the Company.

Where any member is, under the Listing Rules, required to abstain from voting on any particular resolution or restricted to voting only for or only against any particular resolution, any votes cast by or on behalf of such member in contravention of such requirement or restriction shall not be counted.

In the case of joint registered holders of any share, any one of such persons may vote at any meeting, either personally or by proxy, in respect of such share as if he were solely entitled thereto; but if more than one of such joint holders be present at any meeting personally or by proxy, that one of the said persons so present being the most or, as the case may be, the more senior shall alone be entitled to vote in respect of the relevant joint holding and, for this purpose, seniority shall be determined by reference to the order in which the names of the joint holders stand on the register in respect of the relevant joint holding.

A member of the Company in respect of whom an order has been made by any competent court or official on the grounds that he is or may be suffering from mental disorder or is otherwise incapable of managing his affairs may vote by any person authorised in such circumstances to do so and such person may vote by proxy.

Save as expressly provided in the Articles of Association or as otherwise determined by the Directors, no person other than a member of the Company duly registered and who shall have paid all sums for the time being due from him payable to the Company in respect of his shares shall be entitled to be present or to vote (save as proxy for another member of the Company), or to be reckoned in a quorum, either personally or by proxy at any general meeting.

At any general meeting a resolution put to the vote of the meeting shall be decided by way of a poll save that the chairperson of the meeting may allow a resolution which relates purely to a procedural or administrative matter as prescribed under the Listing Rules to be voted on by a show of hands.

If a recognised clearing house (or its nominee(s)) is a member of the Company it may authorise such person or persons as it thinks fit to act as its proxy(ies) or representative(s) at any general meeting of the Company or at any general meeting of any class of members of the Company provided that, if more than one person is so authorised, the authorisation shall specify the number and class of shares in respect of which each such person is so authorised. A person authorised pursuant to this provision shall be entitled to exercise the same rights and

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powers on behalf of the recognised clearing house (or its nominee(s)) which he represents as that recognised clearing house (or its nominee(s)) could exercise as if it were an individual member of the Company holding the number and class of shares specified in such authorisation, including, where a show of hands is allowed, the right to vote individually on a show of hands.

2.8 Annual general meetings and extraordinary general meetings

The Company shall hold a general meeting as its annual general meeting each year, within a period of not more than 15 months after the holding of the last preceding annual general meeting (or such longer period as the Stock Exchange may authorise). The annual general meeting shall be specified as such in the notices calling it.

The board of Directors may, whenever it thinks fit, convene an extraordinary general meeting. General meetings shall also be convened on the written requisition of any one or more members holding together, as at the date of deposit of the requisition, shares representing not less than one-tenth of the paid up capital of the Company which carry the right of voting at general meetings of the Company. The written requisition shall be deposited at the principal office of the Company in Hong Kong or, in the event the Company ceases to have such a principal office, the registered office of the Company, specifying the objects of the meeting and the resolutions to be added to the meeting agenda, and signed by the requisitionist(s). If the Directors do not within 21 days from the date of deposit of the requisition proceed duly to convene the meeting to be held within a further 21 days, the requisitionist(s) themselves or any of them representing more than one-half of the total voting rights of all of them, may convene the general meeting in the same manner, as nearly as possible, as that in which meetings may be convened by the Directors provided that any meeting so convened shall not be held after the expiration of three months from the date of deposit of the requisition, and all reasonable expenses incurred by the requisitionist(s) as a result of the failure of the Directors shall be reimbursed to them by the Company.

2.9 Accounts and audit

The Directors shall cause to be kept such books of account as are necessary to give a true and fair view of the state of the Company's affairs and to show and explain its transactions and otherwise in accordance with the Companies Act.

The Directors shall from time to time determine whether, and to what extent, and at what times and places and under what conditions or regulations, the accounts and books of the Company, or any of them, shall be open to inspection by members of the Company (other than officers of the Company) and no such member shall have any right of inspecting any accounts or books or documents of the Company except as conferred by the Companies Act or any other relevant law or regulation or as authorised by the Directors or by the Company in general meeting.

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The Directors shall, commencing with the first annual general meeting, cause to be prepared and to be laid before the members of the Company at every annual general meeting a profit and loss account for the period, in the case of the first account, since the incorporation of the Company and, in any other case, since the preceding account, together with a balance sheet as at the date to which the profit and loss account is made up and a Director's report with respect to the profit or loss of the Company for the period covered by the profit and loss account and the state of the Company's affairs as at the end of such period, an auditor's report on such accounts and such other reports and accounts as may be required by law. Copies of those documents to be laid before the members of the Company at an annual general meeting shall not less than 21 days before the date of the meeting, be sent in the manner in which notices may be served by the Company as provided in the Articles of Association to every member of the Company and every holder of debentures of the Company provided that the Company shall not be required to send copies of those documents to any person of whose address the Company is not aware or to more than one of the joint holders of any shares or debentures.

2.10 Auditors

The Company shall at every annual general meeting appoint an auditor or auditors of the Company who shall hold office until the next annual general meeting. The removal of an auditor before the expiration of his period of office shall require the approval of an ordinary resolution of the members in general meeting. The remuneration of the auditors shall be fixed by the Company at the annual general meeting at which they are appointed provided that in respect of any particular year the Company in general meeting may delegate the fixing of such remuneration to the Directors.

2.11 Notice of meetings and business to be conducted thereat

An annual general meeting shall be called by not less than 21 days' notice in writing and any extraordinary general meeting shall be called by not less than 14 days' notice in writing. The notice shall be exclusive of the day on which it is served or deemed to be served and of the day for which it is given, and shall specify the time, place and agenda of the meeting, particulars of the resolutions and the general nature of the business to be considered at the meeting. The notice convening an annual general meeting shall specify the meeting as such, and the notice convening a meeting to pass a special resolution shall specify the intention to propose the resolution as a special resolution. Notice of every general meeting shall be given to the auditors and all members of the Company (other than those who, under the provisions of the Articles of Association or the terms of issue of the shares they hold, are not entitled to receive such notice from the Company).

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Notwithstanding that a meeting of the Company is called by shorter notice than that mentioned above, it shall be deemed to have been duly called if it is so agreed:

- (a) in the case of a meeting called as an annual general meeting, by all members of the Company entitled to attend and vote thereat or their proxies; and
- (b) in the case of any other meeting, by a majority in number of the members having a right to attend and vote at the meeting, being a majority together holding not less than 95% in nominal value of the shares giving that right.

If, after the notice of a general meeting has been sent but before the meeting is held, or after the adjournment of a general meeting but before the adjourned meeting is held (whether or not notice of the adjourned meeting is required), the Directors, in their absolute discretion, consider that it is impractical or unreasonable for any reason to hold a general meeting on the date or at the time and place specified in the notice calling such meeting, it may change or postpone the meeting to another date, time and place.

The Directors also have the power to provide in every notice calling a general meeting that in the event of a gale warning or a black rainstorm warning is in force at any time on the day of the general meeting (unless such warning is cancelled at least a minimum period of time prior to the general meeting as the Directors may specify in the relevant notice), the meeting shall be postponed without further notice to be reconvened on a later date.

Where a general meeting is postponed:

- (a) the Company shall endeavour to cause a notice of such postponement, which shall set out the reason for the postponement in accordance with the Listing Rules, to be placed on the Company's website and published on the Stock Exchange's website as soon as practicable, but failure to place or publish such notice shall not affect the automatic postponement of a general meeting due to a gale warning or black rainstorm warning being in force on the day of the general meeting;
- (b) the Directors shall fix the date, time and place for the reconvened meeting and at least seven clear days' notice shall be given for the reconvened meeting; and such notice shall specify the date, time and place at which the postponed meeting will be reconvened and the date and time by which proxies shall be submitted in order to be valid at such reconvened meeting (provided that any proxy submitted for the original meeting shall continue to be valid for the reconvened meeting unless revoked or replaced by a new proxy); and
- (c) only the business set out in the notice of the original meeting shall be transacted at the reconvened meeting, and notice given for the reconvened meeting does not need to specify the business to be transacted at the reconvened meeting, nor shall any accompanying documents be required to be recirculated. Where new business is to be transacted at such reconvened meeting, the Company shall give a fresh notice for such reconvened meeting in accordance with the Articles of Association.

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2.12 Transfer of shares

Transfers of shares may be effected by an instrument of transfer in the usual common form or in such other form as the Directors may approve which is consistent with the standard form of transfer as prescribed by the Stock Exchange.

The instrument of transfer shall be executed by or on behalf of the transferor and, unless the Directors otherwise determine, the transferee, and the transferor shall be deemed to remain the holder of the share until the name of the transferee is entered in the register of members of the Company in respect thereof. All instruments of transfer shall be retained by the Company.

The Directors may refuse to register any transfer of any share which is not fully paid up or on which the Company has a lien. The Directors may also decline to register any transfer of any shares unless:

- (a) the instrument of transfer is lodged with the Company accompanied by the certificate for the shares to which it relates (which shall upon the registration of the transfer be cancelled) and such other evidence as the Directors may reasonably require to show the right of the transferor to make the transfer;
- (b) the instrument of transfer is in respect of only one class of shares;
- (c) the instrument of transfer is properly stamped (in circumstances where stamping is required);
- (d) in the case of a transfer to joint holders, the number of joint holders to whom the share is to be transferred does not exceed four;
- (e) the shares concerned are free of any lien in favour of the Company; and
- (f) a fee of such amount not exceeding the maximum amount as the Stock Exchange may from time to time determine to be payable (or such lesser sum as the Directors may from time to time require) is paid to the Company in respect thereof.

If the Directors refuse to register a transfer of any share they shall, within two months after the date on which the transfer was lodged with the Company, send to each of the transferor and the transferee notice of such refusal.

The registration of transfers may, on 10 business days' notice (or on 6 business days' notice in the case of a rights issue) being given by advertisement published on the Stock Exchange's website, or, subject to the Listing Rules, by electronic communication in the manner in which notices may be served by the Company by electronic means as provided in the Articles of Association or by advertisement published in the newspapers, be suspended and

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the register of members of the Company closed at such times for such periods as the Directors may from time to time determine, provided that the registration of transfers shall not be suspended or the register closed for more than 30 days in any year (or such longer period as the members of the Company may by ordinary resolution determine provided that such period shall not be extended beyond 60 days in any year).

2.13 Power of the Company to purchase its own shares

The Company is empowered by the Companies Act and the Articles of Association to purchase its own shares subject to certain restrictions and the Directors may only exercise this power on behalf of the Company subject to the authority of its members in general meeting as to the manner in which they do so and to any applicable requirements imposed from time to time by the Stock Exchange and the Securities and Futures Commission of Hong Kong. Shares which have been repurchased will be treated as cancelled upon the repurchase.

2.14 Power of any subsidiary of the Company to own shares

There are no provisions in the Articles of Association relating to the ownership of shares by a subsidiary.

2.15 Dividends and other methods of distribution

Subject to the Companies Act and the Articles of Association, the Company in general meeting may declare dividends in any currency but no dividends shall exceed the amount recommended by the Directors. No dividend may be declared or paid other than out of profits and reserves of the Company lawfully available for distribution, including share premium.

Unless and to the extent that the rights attached to any shares or the terms of issue thereof otherwise provide, all dividends shall (as regards any shares not fully paid throughout the period in respect of which the dividend is paid) be apportioned and paid pro rata according to the amounts paid up on the shares during any portion or portions of the period in respect of which the dividend is paid. For these purposes no amount paid up on a share in advance of calls shall be treated as paid up on the share.

The Directors may from time to time pay to the members of the Company such interim dividends as appear to the Directors to be justified by the profits of the Company. The Directors may also pay half-yearly or at other intervals to be selected by them any dividend which may be payable at a fixed rate if they are of the opinion that the profits available for distribution justify the payment.

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The Directors may retain any dividends or other monies payable on or in respect of a share upon which the Company has a lien, and may apply the same in or towards satisfaction of the debts, liabilities or engagements in respect of which the lien exists. The Directors may also deduct from any dividend or other monies payable to any member of the Company all sums of money (if any) presently payable by him to the Company on account of calls, instalments or otherwise.

No dividend shall carry interest against the Company.

Whenever the Directors or the Company in general meeting have resolved that a dividend be paid or declared on the share capital of the Company, the Directors may further resolve: (a) that such dividend be satisfied wholly or in part in the form of an allotment of shares credited as fully paid up on the basis that the shares so allotted are to be of the same class as the class already held by the allottee, provided that the members of the Company entitled thereto will be entitled to elect to receive such dividend (or part thereof) in cash in lieu of such allotment; or (b) that the members of the Company entitled to such dividend will be entitled to elect to receive an allotment of shares credited as fully paid up in lieu of the whole or such part of the dividend as the Directors may think fit on the basis that the shares so allotted are to be of the same class as the class already held by the allottee. The Company may upon the recommendation of the Directors by ordinary resolution resolve in respect of any one particular dividend of the Company that notwithstanding the foregoing a dividend may be satisfied wholly in the form of an allotment of shares credited as fully paid without offering any right to members of the Company to elect to receive such dividend in cash in lieu of such allotment.

Any dividend, interest or other sum payable in cash to a holder of shares may be paid by cheque or warrant sent through the post addressed to the registered address of the member of the Company entitled, or in the case of joint holders, to the registered address of the person whose name stands first in the register of members of the Company in respect of the joint holding or to such person and to such address as the holder or joint holders may in writing direct. Every cheque or warrant so sent shall be made payable to the order of the holder or, in the case of joint holders, to the order of the holder whose name stands first on the register of members of the Company in respect of such shares, and shall be sent at his or their risk and the payment of any such cheque or warrant by the bank on which it is drawn shall operate as a good discharge to the Company in respect of the dividend and/or bonus represented thereby, notwithstanding that it may subsequently appear that the same has been stolen or that any endorsement thereon has been forged. The Company may cease sending such cheques for dividend entitlements or dividend warrants by post if such cheques or warrants have been left uncashed on two consecutive occasions. However, the Company may exercise its power to cease sending cheques for dividend entitlements or dividend warrants after the first occasion on which such a cheque or warrant is returned undelivered. Any one of two or more joint holders may give effectual receipts for any dividends or other monies payable or property distributable in respect of the shares held by such joint holders.

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Any dividend unclaimed for six years from the date of declaration of such dividend may be forfeited by the Directors and shall revert to the Company.

The Directors may, with the sanction of the members of the Company in general meeting, direct that any dividend be satisfied wholly or in part by the distribution of specific assets of any kind, and in particular of paid up shares, debentures or warrants to subscribe securities of any other company, and where any difficulty arises in regard to such distribution the Directors may settle it as they think expedient, and in particular may disregard fractional entitlements, round the same up or down or provide that the same shall accrue to the benefit of the Company, and may fix the value for distribution of such specific assets and may determine that cash payments shall be made to any members of the Company upon the footing of the value so fixed in order to adjust the rights of all parties, and may vest any such specific assets in trustees as may seem expedient to the Directors.

2.16 Proxies

Any member of the Company entitled to attend and vote at a meeting of the Company shall be entitled to appoint another person who must be an individual as his proxy to attend and vote instead of him and a proxy so appointed shall have the same right as the member to speak at the meeting. A proxy need not be a member of the Company.

Instruments of proxy shall be in common form or in such other form as the Directors may from time to time approve provided that it shall enable a member to instruct his proxy to vote in favour of or against (or in default of instructions or in the event of conflicting instructions, to exercise his discretion in respect of) each resolution to be proposed at the meeting to which the form of proxy relates. The instrument of proxy shall be deemed to confer authority to vote on any amendment of a resolution put to the meeting for which it is given as the proxy thinks fit. The instrument of proxy shall, unless the contrary is stated therein, be valid as well for any adjournment of the meeting as for the meeting to which it relates provided that the meeting was originally held within 12 months from such date.

The instrument appointing a proxy shall be in writing under the hand of the appointor or his attorney authorised in writing or if the appointor is a corporation either under its seal or under the hand of an officer, attorney or other person authorised to sign the same.

The instrument appointing a proxy and (if required by the Directors) the power of attorney or other authority (if any) under which it is signed, or a notarially certified copy of such power or authority, shall be delivered at the registered office of the Company (or at such other place as may be specified in the notice convening the meeting or in any notice of any adjournment or, in either case, in any document sent therewith) not less than 48 hours before the time appointed for holding the meeting or adjourned meeting at which the person named in the instrument proposes to vote or, in the case of a poll taken subsequently to the date of a meeting or adjourned meeting, not less than 48 hours before the time appointed for the taking of the poll and in default the instrument of proxy shall not be treated as valid. No instrument

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appointing a proxy shall be valid after the expiration of 12 months from the date named in it as the date of its execution. Delivery of any instrument appointing a proxy shall not preclude a member of the Company from attending and voting in person at the meeting or poll concerned and, in such event, the instrument appointing a proxy shall be deemed to be revoked.

2.17 Calls on shares and forfeiture of shares

The Directors may from time to time make calls upon the members of the Company in respect of any monies unpaid on their shares (whether on account of the nominal amount of the shares or by way of premium or otherwise) and not by the conditions of allotment thereof made payable at fixed times and each member of the Company shall (subject to the Company serving upon him at least 14 days' notice specifying the time and place of payment and to whom such payment shall be made) pay to the person at the time and place so specified the amount called on his shares. A call may be revoked or postponed as the Directors may determine. A person upon whom a call is made shall remain liable on such call notwithstanding the subsequent transfer of the shares in respect of which the call was made.

A call may be made payable either in one sum or by instalments and shall be deemed to have been made at the time when the resolution of the Directors authorising the call was passed. The joint holders of a share shall be jointly and severally liable to pay all calls and instalments due in respect of such share or other monies due in respect thereof.

If a sum called in respect of a share shall not be paid before or on the day appointed for payment thereof, the person from whom the sum is due shall pay interest on the sum from the day appointed for payment thereof to the time of actual payment at such rate, not exceeding 15% per annum, as the Directors may determine, but the Directors shall be at liberty to waive payment of such interest wholly or in part.

If any call or instalment of a call remains unpaid on any share after the day appointed for payment thereof, the Directors may at any time during such time as any part thereof remains unpaid serve a notice on the holder of such shares requiring payment of so much of the call or instalment as is unpaid together with any interest which may be accrued and which may still accrue up to the date of actual payment.

The notice shall name a further day (not being less than 14 days from the date of service of the notice) on or before which, and the place where, the payment required by the notice is to be made, and shall state that in the event of non-payment at or before the time and at the place appointed, the shares in respect of which such call was made or instalment is unpaid will be liable to be forfeited.

If the requirements of such notice are not complied with, any share in respect of which such notice has been given may at any time thereafter, before payment of all calls or instalments and interest due in respect thereof has been made, be forfeited by a resolution of

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the Directors to that effect. Such forfeiture shall include all dividends and bonuses declared in respect of the forfeited shares and not actually paid before the forfeiture. A forfeited share shall be deemed to be the property of the Company and may be re-allotted, sold or otherwise disposed of.

A person whose shares have been forfeited shall cease to be a member of the Company in respect of the forfeited shares but shall, notwithstanding the forfeiture, remain liable to pay to the Company all monies which at the date of forfeiture were payable by him to the Company in respect of the shares, together with (if the Directors shall in their discretion so require) interest thereon at such rate not exceeding 15% per annum as the Directors may prescribe from the date of forfeiture until payment, and the Directors may enforce payment thereof without being under any obligation to make any allowance for the value of the shares forfeited, at the date of forfeiture.

2.18 Inspection of register of members

The register of members of the Company shall be kept in such manner as to show at all times the members of the Company for the time being and the shares respectively held by them. The register may, on 10 business days' notice (or on 6 business days' notice in the case of a rights issue) being given by advertisement published on the Stock Exchange's website, or, subject to the Listing Rules, by electronic communication in the manner in which notices may be served by the Company by electronic means as provided in the Articles of Association or by advertisement published in the newspapers, be closed at such times and for such periods as the Directors may from time to time determine either generally or in respect of any class of shares, provided that the register shall not be closed for more than 30 days in any year (or such longer period as the members of the Company may by ordinary resolution determine provided that such period shall not be extended beyond 60 days in any year).

Any register of members kept in Hong Kong shall during normal business hours (subject to such reasonable restrictions as the Directors may impose) be open to inspection by any member of the Company without charge and by any other person on payment of a fee of such amount not exceeding the maximum amount as may from time to time be permitted under the Listing Rules as the Directors may determine for each inspection.

2.19 Quorum for meetings and separate class meetings

No business shall be transacted at any general meeting unless a quorum is present when the meeting proceeds to business, but the absence of a quorum shall not preclude the appointment, choice or election of a chairperson which shall not be treated as part of the business of the meeting.

Two members of the Company present in person or by proxy shall be a quorum provided always that if the Company has only one member of record the quorum shall be that one member present in person or by proxy.

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A corporation being a member of the Company shall be deemed for the purpose of the Articles of Association to be present in person if represented by its duly authorised representative being the person appointed by resolution of the directors or other governing body of such corporation or by power of attorney to act as its representative at the relevant general meeting of the Company or at any relevant general meeting of any class of members of the Company.

The quorum for a separate general meeting of the holders of a separate class of shares of the Company is described in paragraph 2.4 above.

2.20 Rights of minorities in relation to fraud or oppression

There are no provisions in the Articles of Association concerning the rights of minority shareholders in relation to fraud or oppression.

2.21 Procedure on liquidation

If the Company shall be wound up, and the assets available for distribution amongst the members of the Company as such shall be insufficient to repay the whole of the paid-up capital, such assets shall be distributed so that, as nearly as may be, the losses shall be borne by the members of the Company in proportion to the capital paid up, or which ought to have been paid up, at the commencement of the winding up on the shares held by them respectively. If in a winding up the assets available for distribution amongst the members of the Company shall be more than sufficient to repay the whole of the capital paid up at the commencement of the winding up, the excess shall be distributed amongst the members of the Company in proportion to the capital paid up at the commencement of the winding up on the shares held by them respectively. The foregoing is without prejudice to the rights of the holders of shares issued upon special terms and conditions.

If the Company shall be wound up, the liquidator may with the sanction of a special resolution of the Company and any other sanction required by the Companies Act, divide amongst the members of the Company in specie or kind the whole or any part of the assets of the Company (whether they shall consist of property of the same kind or not) and may, for such purpose, set such value as he deems fair upon any property to be divided as aforesaid and may determine how such division shall be carried out as between the members or different classes of members of the Company. The liquidator may, with the like sanction, vest the whole or any part of such assets in trustees upon such trusts for the benefit of the members of the Company as the liquidator, with the like sanction and subject to the Companies Act, shall think fit, but so that no member of the Company shall be compelled to accept any assets, shares or other securities in respect of which there is a liability.

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2.22 Untraceable members

The Company shall be entitled to sell any shares of a member of the Company or the shares to which a person is entitled by virtue of transmission on death or bankruptcy or operation of law if: (a) all cheques or warrants, not being less than three in number, for any sums payable in cash to the holder of such shares have remained uncashed for a period of 12 years; (b) the Company has not during that time or before the expiry of the three month period referred to in (d) below received any indication of the whereabouts or existence of the member; (c) during the 12 year period, at least three dividends in respect of the shares in question have become payable and no dividend during that period has been claimed by the member; and (d) upon expiry of the 12 year period, the Company has caused an advertisement to be published in the newspapers or subject to the Listing Rules, by electronic communication in the manner in which notices may be served by the Company by electronic means as provided in the Articles of Association, giving notice of its intention to sell such shares and a period of three months has elapsed since such advertisement and the Stock Exchange has been notified of such intention. The net proceeds of any such sale shall belong to the Company and upon receipt by the Company of such net proceeds it shall become indebted to the former member for an amount equal to such net proceeds.

SUMMARY OF CAYMAN ISLANDS COMPANY LAW AND TAXATION

1 Introduction

The Companies Act is derived, to a large extent, from the older Companies Acts of England, although there are significant differences between the Companies Act and the current Companies Act of England. Set out below is a summary of certain provisions of the Companies Act, although this does not purport to contain all applicable qualifications and exceptions or to be a complete review of all matters of corporate law and taxation which may differ from equivalent provisions in jurisdictions with which interested parties may be more familiar.

2 Incorporation

The Company was incorporated in the Cayman Islands as an exempted company with limited liability on 31 October 2018 under the Companies Act. As such, its operations must be conducted mainly outside the Cayman Islands. The Company is required to file an annual return each year with the Registrar of Companies of the Cayman Islands and pay a fee which is based on the size of its authorised share capital.

3 Share Capital

The Companies Act permits a company to issue ordinary shares, preference shares, redeemable shares or any combination thereof.

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The Companies Act provides that where a company issues shares at a premium, whether for cash or otherwise, a sum equal to the aggregate amount of the value of the premia on those shares shall be transferred to an account called the "share premium account". At the option of a company, these provisions may not apply to premia on shares of that company allotted pursuant to any arrangement in consideration of the acquisition or cancellation of shares in any other company and issued at a premium. The Companies Act provides that the share premium account may be applied by a company, subject to the provisions, if any, of its memorandum and articles of association, in such manner as the company may from time to time determine including, but without limitation:

- (a) paying distributions or dividends to members;
- (b) paying up unissued shares of the company to be issued to members as fully paid bonus shares;
- (c) in the redemption and repurchase of shares (subject to the provisions of section 37 of the Companies Act);
- (d) writing-off the preliminary expenses of the company;
- (e) writing-off the expenses of, or the commission paid or discount allowed on, any issue of shares or debentures of the company; and
- (f) providing for the premium payable on redemption or purchase of any shares or debentures of the company.

No distribution or dividend may be paid to members out of the share premium account unless immediately following the date on which the distribution or dividend is proposed to be paid the company will be able to pay its debts as they fall due in the ordinary course of business.

The Companies Act provides that, subject to confirmation by the Grand Court of the Cayman Islands, a company limited by shares or a company limited by guarantee and having a share capital may, if so authorised by its articles of association, by special resolution reduce its share capital in any way.

Subject to the detailed provisions of the Companies Act, a company limited by shares or a company limited by guarantee and having a share capital may, if so authorised by its articles of association, issue shares which are to be redeemed or are liable to be redeemed at the option of the company or a shareholder. In addition, such a company may, if authorised to do so by its articles of association, purchase its own shares, including any redeemable shares. The manner of such a purchase must be authorised either by the articles of association or by an ordinary resolution of the company. The articles of association may provide that the manner of purchase may be determined by the directors of the company. At no time may a company

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redeem or purchase its shares unless they are fully paid. A company may not redeem or purchase any of its shares if, as a result of the redemption or purchase, there would no longer be any member of the company holding shares. A payment out of capital by a company for the redemption or purchase of its own shares is not lawful unless immediately following the date on which the payment is proposed to be made, the company shall be able to pay its debts as they fall due in the ordinary course of business.

There is no statutory restriction in the Cayman Islands on the provision of financial assistance by a company for the purchase of, or subscription for, its own or its holding company's shares. Accordingly, a company may provide financial assistance if the directors of the company consider, in discharging their duties of care and to act in good faith, for a proper purpose and in the interests of the company, that such assistance can properly be given. Such assistance should be on an arm's-length basis.

4 Dividends and Distributions

With the exception of section 34 of the Companies Act, there are no statutory provisions relating to the payment of dividends. Based upon English case law which is likely to be persuasive in the Cayman Islands in this area, dividends may be paid only out of profits. In addition, section 34 of the Companies Act permits, subject to a solvency test and the provisions, if any, of the company's memorandum and articles of association, the payment of dividends and distributions out of the share premium account (see paragraph 3 above for details).

5 Shareholders' Suits

The Cayman Islands courts can be expected to follow English case law precedents. The rule in *Foss v. Harbottle* (and the exceptions thereto which permit a minority shareholder to commence a class action against or derivative actions in the name of the company to challenge (a) an act which is *ultra vires* the company or illegal, (b) an act which constitutes a fraud against the minority where the wrongdoers are themselves in control of the company, and (c) an action which requires a resolution with a qualified (or special) majority which has not been obtained) has been applied and followed by the courts in the Cayman Islands.

6 Protection of Minorities

In the case of a company (not being a bank) having a share capital divided into shares, the Grand Court of the Cayman Islands may, on the application of members holding not less than one-fifth of the shares of the company in issue, appoint an inspector to examine into the affairs of the company and to report thereon in such manner as the Grand Court shall direct.

Any shareholder of a company may petition the Grand Court of the Cayman Islands which may make a winding up order if the court is of the opinion that it is just and equitable that the company should be wound up.

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Claims against a company by its shareholders must, as a general rule, be based on the general laws of contract or tort applicable in the Cayman Islands or their individual rights as shareholders as established by the company's memorandum and articles of association.

The English common law rule that the majority will not be permitted to commit a fraud on the minority has been applied and followed by the courts of the Cayman Islands.

7 Disposal of Assets

The Companies Act contains no specific restrictions on the powers of directors to dispose of assets of a company. As a matter of general law, in the exercise of those powers, the directors must discharge their duties of care and to act in good faith, for a proper purpose and in the interests of the company.

8 Accounting and Auditing Requirements

The Companies Act requires that a company shall cause to be kept proper books of account with respect to:

- (a) all sums of money received and expended by the company and the matters in respect of which the receipt and expenditure takes place;
- (b) all sales and purchases of goods by the company; and
- (c) the assets and liabilities of the company.

Proper books of account shall not be deemed to be kept if there are not kept such books as are necessary to give a true and fair view of the state of the company's affairs and to explain its transactions.

9 Register of Members

An exempted company may, subject to the provisions of its articles of association, maintain its principal register of members and any branch registers at such locations, whether within or without the Cayman Islands, as its directors may from time to time think fit. There is no requirement under the Companies Act for an exempted company to make any returns of members to the Registrar of Companies of the Cayman Islands. The names and addresses of the members are, accordingly, not a matter of public record and are not available for public inspection.

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10 Inspection of Books and Records

Members of a company will have no general right under the Companies Act to inspect or obtain copies of the register of members or corporate records of the company. They will, however, have such rights as may be set out in the company's articles of association.

11 Special Resolutions

The Companies Act provides that a resolution is a special resolution when it has been passed by a majority of at least two-thirds of such members as, being entitled to do so, vote in person or, where proxies are allowed, by proxy at a general meeting of which notice specifying the intention to propose the resolution as a special resolution has been duly given, except that a company may in its articles of association specify that the required majority shall be a number greater than two-thirds, and may additionally so provide that such majority (being not less than two-thirds) may differ as between matters required to be approved by a special resolution. Written resolutions signed by all the members entitled to vote for the time being of the company may take effect as special resolutions if this is authorised by the articles of association of the company.

12 Subsidiary Owning Shares in Parent

The Companies Act does not prohibit a Cayman Islands company acquiring and holding shares in its parent company provided its objects so permit. The directors of any subsidiary making such acquisition must discharge their duties of care and to act in good faith, for a proper purpose and in the interests of the subsidiary.

13 Mergers and Consolidations

The Companies Act permits mergers and consolidations between Cayman Islands companies and between Cayman Islands companies and non-Cayman Islands companies. For these purposes, (a) "merger" means the merging of two or more constituent companies and the vesting of their undertaking, property and liabilities in one of such companies as the surviving company, and (b) "consolidation" means the combination of two or more constituent companies into a consolidated company and the vesting of the undertaking, property and liabilities of such companies to the consolidated company. In order to effect such a merger or consolidation, the directors of each constituent company must approve a written plan of merger or consolidation, which must then be authorised by (a) a special resolution of each constituent company and (b) such other authorisation, if any, as may be specified in such constituent company's articles of association. The written plan of merger or consolidation must be filed with the Registrar of Companies of the Cayman Islands together with a declaration as to the solvency of the consolidated or surviving company, a list of the assets and liabilities of each constituent company and an undertaking that a copy of the certificate of merger or consolidation will be given to the members and creditors of each constituent company and that notification of the merger or consolidation will be published in the Cayman Islands Gazette.

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Dissenting shareholders have the right to be paid the fair value of their shares (which, if not agreed between the parties, will be determined by the Cayman Islands court) if they follow the required procedures, subject to certain exceptions. Court approval is not required for a merger or consolidation which is effected in compliance with these statutory procedures.

14 Reconstructions

There are statutory provisions which facilitate reconstructions and amalgamations approved by a majority in number representing 75% in value of shareholders or creditors, depending on the circumstances, as are present at a meeting called for such purpose and thereafter sanctioned by the Grand Court of the Cayman Islands. Whilst a dissenting shareholder would have the right to express to the Grand Court his view that the transaction for which approval is sought would not provide the shareholders with a fair value for their shares, the Grand Court is unlikely to disapprove the transaction on that ground alone in the absence of evidence of fraud or bad faith on behalf of management and if the transaction were approved and consummated the dissenting shareholder would have no rights comparable to the appraisal rights (i.e. the right to receive payment in cash for the judicially determined value of his shares) ordinarily available, for example, to dissenting shareholders of United States corporations.

15 Take-overs

Where an offer is made by a company for the shares of another company and, within four months of the offer, the holders of not less than 90% of the shares which are the subject of the offer accept, the offeror may at any time within two months after the expiration of the said four months, by notice require the dissenting shareholders to transfer their shares on the terms of the offer. A dissenting shareholder may apply to the Grand Court of the Cayman Islands within one month of the notice objecting to the transfer. The burden is on the dissenting shareholder to show that the Grand Court should exercise its discretion, which it will be unlikely to do unless there is evidence of fraud or bad faith or collusion as between the offeror and the holders of the shares who have accepted the offer as a means of unfairly forcing out minority shareholders.

16 Indemnification

Cayman Islands law does not limit the extent to which a company's articles of association may provide for indemnification of officers and directors, except to the extent any such provision may be held by the Cayman Islands courts to be contrary to public policy (e.g. for purporting to provide indemnification against the consequences of committing a crime).

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17 Liquidation

A company may be placed in liquidation compulsorily by an order of the court, or voluntarily (a) by a special resolution of its members if the company is solvent, or (b) by an ordinary resolution of its members if the company is insolvent. The liquidator's duties are to collect the assets of the company (including the amount (if any) due from the contributories (shareholders)), settle the list of creditors and discharge the company's liability to them, rateably if insufficient assets exist to discharge the liabilities in full, and to settle the list of contributories and divide the surplus assets (if any) amongst them in accordance with the rights attaching to the shares.

18 Stamp Duty on Transfers

No stamp duty is payable in the Cayman Islands on transfers of shares of Cayman Islands companies except those which hold interests in land in the Cayman Islands.

19 Taxation

Pursuant to section 6 of the Tax Concessions Act (As Revised) of the Cayman Islands, the Company may obtain an undertaking from the Financial Secretary of the Cayman Islands:

- (a) that no law which is enacted in the Cayman Islands imposing any tax to be levied on profits, income, gains or appreciations shall apply to the Company or its operations; and
- (b) in addition, that no tax to be levied on profits, income, gains or appreciations or which is in the nature of estate duty or inheritance tax shall be payable:
 - (i) on or in respect of the shares, debentures or other obligations of the Company;
or
 - (ii) by way of the withholding in whole or in part of any relevant payment as defined in section 6(3) of the Tax Concessions Act (As Revised).

The Cayman Islands currently levy no taxes on individuals or corporations based upon profits, income, gains or appreciations and there is no taxation in the nature of inheritance tax or estate duty. There are no other taxes likely to be material to the Company levied by the Government of the Cayman Islands save certain stamp duties which may be applicable, from time to time, on certain instruments executed in or brought within the jurisdiction of the Cayman Islands. The Cayman Islands are not party to any double tax treaties that are applicable to any payments made by or to the Company.

APPENDIX III

**SUMMARY OF THE CONSTITUTION OF
OUR COMPANY AND CAYMAN ISLANDS COMPANY LAW**

20 Exchange Control

There are no exchange control regulations or currency restrictions in the Cayman Islands.

21 General

Maples and Calder (Hong Kong) LLP, the Company's legal advisers on Cayman Islands law, have sent to the Company a letter of advice summarising aspects of Cayman Islands company law. This letter, together with a copy of the Companies Act, is available for inspection as referred to in the section headed "Documents on Display" in Appendix V. Any person wishing to have a detailed summary of Cayman Islands company law or advice on the differences between it and the laws of any jurisdiction with which he/she is more familiar is recommended to seek independent legal advice.

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STATUTORY AND GENERAL INFORMATION

A. FURTHER INFORMATION ABOUT OUR GROUP

1. Incorporation

Our Company is an exempted company with limited liability incorporated in the Cayman Islands on October 31, 2018. Our registered office address is at PO Box 309, Ugland House, Grand Cayman, KY1-1104, Cayman Islands. Accordingly, our Company’s corporate structure and Memorandum and Articles are subject to the relevant laws of the Cayman Islands, a summary of which is set out in “Summary of the Constitution of Our Company and Cayman Islands Company Law” in Appendix III to this document.

Our registered place of business in Hong Kong is at Room 1901, 19/F, Lee Garden One, 33 Hysan Avenue, Causeway Bay, Hong Kong. We were registered as a non-Hong Kong company under Part 16 of the Companies Ordinance on June 25, 2021. Ms. Po Ting Fung has been appointed as the authorized representative of our Company for the acceptance of service of process in Hong Kong. The address for service of process in Hong Kong is at Room 1901, 19/F, Lee Garden One, 33 Hysan Avenue, Causeway Bay, Hong Kong.

2. Changes in the Share Capital of Our Company

Our Company was incorporated in the Cayman Islands as an exempted company with limited liability on October 31, 2018. As of the date of our Company’s incorporation, the authorized share capital of our Company was US\$50,000 divided into 500,000,000 Shares with a par value of US\$0.0001 each. Upon its incorporation, one fully-paid Share of US\$0.0001 was allotted and issued to an initial subscriber who is an Independent Third Party on October 31, 2018, which was then transferred to Dr. Liang on the same date.

Pursuant to the written resolutions of the sole Shareholder of our Company passed on February 10, 2021, our authorized share capital was changed to US\$50,000 divided into 500,000,000 Shares of a par value of US\$0.0001 each, of which: (i) 465,829,865 are designated as ordinary Shares of a nominal or par value of US\$0.0001 each, and (ii) 34,170,135 are designated as Series C Preferred Shares of a nominal or par value of US\$0.0001 each.

On February 10, 2021 our Company allotted and issued a total of 29,499,999 ordinary Shares to Dr. Liang. On March 16, 2021 our Company allotted and issued a total of 10,500,000 ordinary Shares to (i) Dr. Xiaodong Wang (4,000,000 ordinary Shares), Mr. Joshua Liang (2,500,000 ordinary Shares) and Dr. Jianwei Zhu (2,000,000 ordinary Shares); and (ii) Fine Well Investments Limited (康祥投資有限公司) (1,200,000 ordinary Shares) and Shine Sino Global Limited (耀華環球有限公司) (800,000 ordinary Shares).

Pursuant to the written resolutions of the sole Shareholder of the Company passed on March 16, 2021, our authorized share capital was changed to US\$50,000 divided into 500,000,000 Shares of a par value of US\$0.0001 each, of which: (i) 417,033,611 are designated as ordinary Shares of a nominal or par value of US\$0.0001 each, (ii) 7,851,413 are designated as Series A Preferred Shares of a par value of US\$0.0001 each, (iii) 30,545,245 are designated as Series B Preferred Shares of a par value of US\$0.0001 each, (iv) 10,399,596 are designated as Series B-2 Preferred Shares of a par value of US\$0.0001 each, and (v) 34,170,135 are designated as Series C Preferred Shares of a nominal or par value of US\$0.0001 each.

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On March 16, 2021 our Company allotted and issued a total of 58,796,254 Shares.

On March 16, 2021, the Convertible Notes were fully converted and our Company allotted and issued a total of 34,170,135 Series C Preferred Shares to the Investors.

On July 1, 2021, our Company allotted 7,250,000 ordinary Shares to Super Novel.

On October 8, 2021, our Company allotted 3,800,000 ordinary Shares to Super Novel.

Pursuant to the written resolutions of our Shareholders passed on September 26, 2021, our authorized share capital was increased from US\$50,000 to US\$200,000 by the creation of additional 1,500,000,000 Shares, and following such increase, the authorized share capital of our Company was US\$200,000 divided into 2,000,000,000 Shares of US\$0.0001 each.

For details on our Company’s authorized and issued share capital and the Pre-[REDACTED] Reorganization, see “History, Development and Corporate Structure – Reorganization”, and “Share Capital – Authorized and Issued Share Capital.”

Save as disclosed above, there has been no alteration in our share capital within two years immediately preceding the date of this document.

3. Changes in the Share Capital of Our Subsidiaries

A summary of the corporate information and the particulars of our subsidiaries are set out in Note 1 to the Accountants’ Report as set out in Appendix I to this document.

The following sets out the alterations in the registered capital of our subsidiaries that took place within two years preceding the date of this document.

Sichuan Clover

On November 27, 2019, the registered capital of Sichuan Clover was increased from RMB57,851,413 to RMB88,396,658.

On May 29, 2020, the registered capital of Sichuan Clover was increased from RMB88,396,658 to RMB98,796,254.

Zhejiang Clover

On June 27, 2020, the registered capital of Zhejiang Clover was increased from RMB50,000,000 to RMB70,000,000.

Beijing Clover

On September 1, 2020, Beijing Clover was established under the laws of the PRC with limited liability and registered capital of RMB1,000,000.

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Shanghai Clover

On February 9, 2021, Shanghai Clover was established under the laws of the PRC with limited liability and registered capital of RMB1,000,000.

U.S. Clover

On March 30, 2020, U.S. Clover was established under the laws of the U.S. with limited liability and 50,000,000 authorized shares of US\$0.001 each.

Clover Biopharmaceuticals Ireland Limited

On April 22, 2021, Clover Biopharmaceuticals Ireland Limited was established under the laws of Ireland as a private company limited by shares with the share capital divided into ordinary shares of €1.00 each.

4. Written Resolutions Passed by Our Shareholders on September 26, 2021

Written resolutions of the Shareholders of our Company were passed on September 26, 2021, pursuant to which, among others:

- (a) our Company approved and conditionally adopted the Memorandum and Articles of Association with effect from the [REDACTED];
- (b) our authorized share capital was increased from US\$50,000 to US\$200,000 by the creation of additional 1,500,000,000 Shares, following which, the authorized share capital of our Company was US\$200,000 divided into 2,000,000,000 Shares of US\$0.0001 each; and
- (c) conditional on (1) the Listing Committee granting [REDACTED] of, and permission to [REDACTED], the Shares in issue and to be issued as stated in this document and such [REDACTED] and permission not subsequently having been revoked prior to the commencement of [REDACTED] the Shares on the Stock Exchange; (2) the [REDACTED] having been determined and (3) the obligations of the [REDACTED] under the [REDACTED] becoming unconditional and the [REDACTED] not being terminated in accordance with their terms or otherwise, in each case on or before such dates as may be specified in the [REDACTED]:
 - (i) all the issued Preferred Shares, of a par value of US\$0.0001, be redesignated and reclassified into ordinary Shares, on a one-to-one basis, following which:
 - (A) our authorized share capital be redesignated and reclassified to US\$200,000 divided into 2,000,000,000 ordinary Shares, with par value of US\$0.0001 each; and

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- (B) all the ordinary Shares of a par value of US\$0.0001 in issue to remain as ordinary Shares.
- (ii) the [REDACTED] and the [REDACTED] was approved, and the proposed allotment and issue of the [REDACTED] under the [REDACTED] and the [REDACTED] were approved, and the Board was authorized to determine the [REDACTED] for, and to allot and issue the [REDACTED];
- (iii) the [REDACTED] was approved and the Directors were authorized to effect the same and to allot and issue up to [REDACTED] Shares upon the exercise of the [REDACTED];
- (iv) a general mandate was given to our Directors to exercise all powers of our Company to allot, issue and deal with Shares or securities convertible into Shares and to make or grant offers, agreements or options (including any warrants, bonds, notes and debentures conferring any rights to subscribe for or otherwise receive Shares) which might require Shares to be allotted and issued or dealt with subject to the requirement that the aggregate nominal value of our Shares so allotted and issued or agreed conditionally or unconditionally to be allotted and issued, otherwise than by way of the [REDACTED], rights issue or pursuant to the exercise of any subscription rights attaching to any warrants which may be allotted and issued by the Company from time to time or allotment and issue of Shares in lieu of the whole or part of a dividend on Shares in accordance with the Articles of Association on a specific authority granted by our Shareholders in a general meeting, shall not exceed the sum of (i) 20% of the aggregate nominal value of our Shares in issue immediately following the completion of the [REDACTED] and the [REDACTED] (but excluding any Shares which may be issued pursuant to the exercise of the [REDACTED]); and (ii) the aggregate nominal amount of the share capital of the Company purchased by the Company pursuant to the authority granted to the Directors as referred to in (c)(v) below;
- (v) a general mandate (the "**Repurchase Mandate**") was given to our Directors to exercise all powers of our Company to repurchase its own Shares on the Stock Exchange or on any other stock exchange on which the securities of our Company may be listed and which is recognized by the SFC and the Stock Exchange for this purpose, in accordance with all applicable laws and the requirement of the Listing Rules such number of Shares as will represent up to 10% of the aggregate nominal value of our Shares in issue immediately following the completion of the [REDACTED] and the [REDACTED]; and

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- (vi) the general mandate as mentioned in paragraph (iii) above was extended by the addition to the aggregate nominal value of our Shares which may be allotted and issued or agreed to be allotted and issued by our Directors pursuant to such general mandate of an amount representing the aggregate nominal value of our Shares purchased by our Company pursuant to the mandate to purchase Shares referred to in paragraph (iv) above (up to 10% of the aggregate nominal value of our Shares in issue immediately following the completion of the [REDACTED] and the [REDACTED]).

Each of the general mandates referred to in paragraphs (c)(iv), (c)(v), and (c)(vi) above will remain in effect until whichever is the earliest of:

- the conclusion of the next annual general meeting of our Company;
- the expiration of the period within which the next annual general meeting of our Company;
- is required to be held by any applicable law or the Articles; or
- the time when such mandate is revoked or varied by an ordinary resolution of the Shareholders in a general meeting.

5. Repurchase of Our Own Securities

The following paragraphs include, among others, certain information required by the Stock Exchange to be included in this document concerning the repurchase of our own securities.

(a) Provision of the Listing Rules

The Listing Rules permit companies with a primary listing on the Stock Exchange to repurchase their own securities on the Stock Exchange subject to certain restrictions, the most important of which are summarized below:

(i) Shareholder's Approval

All proposed repurchases of securities (which must be fully paid up in the case of shares) by a company with a primary listing on the Stock Exchange must be approved in advance by an ordinary resolution of the shareholders in a general meeting, either by way of general mandate or by specific approval of a particular transaction.

Pursuant to a resolution passed by our Shareholders on September 26, 2021, the Repurchase Mandate was given to our Directors authorizing them to exercise all powers of our Company to repurchase Shares on the Stock Exchange, or on any other stock exchange on which the securities of our Company may be listed and which is recognized

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by the SFC and the Stock Exchange for this purpose, with a total nominal value up to 10% of the aggregate nominal value of our Shares in issue immediately following the completion of the [REDACTED] and the [REDACTED] with such mandate to expire at the earliest of (i) the conclusion of the next annual general meeting of our Company (unless otherwise renewed by an ordinary resolution of our Shareholders in a general meeting, either unconditionally or subject to conditions), (ii) the expiration of the period within which our Company's next annual general meeting is required by the Articles of Association or any other applicable laws to be held, and (iii) the date on which it is varied or revoked by an ordinary resolution of our Shareholders in a general meeting.

(ii) Source of Funds

Purchases must be funded out of funds legally available for the purpose in accordance with the Memorandum and Articles and the applicable laws and regulations of Hong Kong and the Cayman Islands. A listed company may not purchase its own securities on the Stock Exchange for a consideration other than cash or for settlement otherwise than in accordance with the trading rules of the Stock Exchange from time to time. As a matter of Cayman law, any purchases by our Company may be made out of profits or out of the proceeds of a new issue of shares made for the purpose of the purchase or from sums standing to the credit of our share premium account or out of capital, if so authorized by the Articles and subject to the Cayman Companies Act. Any premium payable on the purchase over the par value of the shares to be purchased must have been provided for out of profits or from sums standing to the credit of our share premium account or out of capital, if so authorized by the Articles and subject to the Cayman Companies Act.

(iii) Trading Restrictions

The total number of shares which a listed company may repurchase on the Stock Exchange is the number of shares representing up to a maximum of 10% of the aggregate number of shares in issue.

A company may not issue or announce a proposed issue of new securities for a period of 30 days immediately following a repurchase (other than an issue of securities pursuant to an exercise of warrants, share options or similar instruments requiring the company to issue securities which were outstanding prior to such repurchase) without the prior approval of the Stock Exchange. In addition, a listed company is prohibited from repurchasing its shares on the Stock Exchange if the purchase price is 5% or more than the average closing market price for the five preceding trading days on which its shares were traded on the Stock Exchange. The Listing Rules also prohibit a listed company from repurchasing its securities if the repurchase would result in the number of listed securities which are in the hands of the public falling below the relevant prescribed minimum percentage as required by the Stock Exchange. A listed company is required to procure that the broker appointed by it to effect a repurchase of securities discloses to the Stock Exchange such information with respect to the repurchase as the Stock Exchange may require.

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(iv) Status of Repurchased Shares

The listing of all purchased securities (whether on the Stock Exchange or otherwise) is automatically canceled and the relative certificates must be canceled and destroyed. Under the laws of the Cayman Islands, unless, prior to the purchase the directors of our Company resolve to hold the shares purchased by our Company as treasury shares, shares purchased by our Company shall be treated as canceled and the amount of our Company's issued share capital shall be diminished by the nominal value of those shares. However, the purchase of shares will not be taken as reducing the amount of the authorized share capital under Cayman Islands laws.

(v) Suspension of Repurchase

A listed company may not make any repurchase of securities after a price sensitive development has occurred or has been the subject of a decision until such time as the price sensitive information has been made publicly available. In particular, during the period of one month immediately preceding the earlier of (a) the date of the board meeting (as such date is first notified to the Stock Exchange in accordance with the Listing Rules) for the approval of a listed company's results for any year, half-year, quarterly or any other interim period (whether or not required under the Listing Rules) and (b) the deadline for publication of an announcement of a listed company's results for any year or half-year under the Listing Rules, or quarterly or any other interim period (whether or not required under the Listing Rules), the listed company may not repurchase its shares on the Stock Exchange other than in exceptional circumstances. In addition, the Stock Exchange may prohibit a repurchase of securities on the Stock Exchange if a listed company has breached the Listing Rules.

(vi) Reporting Requirements

Certain information relating to repurchases of securities on the Stock Exchange or otherwise must be reported to the Stock Exchange not later than 30 minutes before the earlier of the commencement of the morning trading session or any pre-opening session on the following business day. In addition, a listed company's annual report is required to disclose details regarding repurchases of securities made during the year, including a monthly analysis of the number of securities repurchased, the purchase price per share or the highest and lowest price paid for all such repurchases, where relevant, and the aggregate prices paid.

(vii) Core Connected Persons

The Listing Rules prohibit a company from knowingly purchasing securities on the Stock Exchange from a "core connected person", that is, a director, chief executive or substantial shareholder of the company or any of its subsidiaries or a close associate of any of them (as defined in the Listing Rules) and a core connected person shall not knowingly sell his securities to the company.

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(b) Reasons for Repurchases

Our Directors believe that it is in the best interests of our Company and Shareholders for our Directors to have a general authority from the Shareholders to enable our Company to repurchase Shares in the market. Such repurchases may, depending on market conditions and funding arrangements at the time, lead to an enhancement of the net asset value per Share or earnings per Share and will only be made where our Directors believe that such repurchases will benefit our Company and Shareholders.

(c) Funding of Repurchases

Repurchase of the Shares must be funded out of funds legally available for such purpose in accordance with the Articles of Association and the applicable laws of the Cayman Islands.

Our Directors may not repurchase the Shares on the Stock Exchange for a consideration other than cash or for settlement otherwise than in accordance with the trading rules of the Stock Exchange. Subject to the foregoing, our Directors may make repurchases out of profits of the Company, out of the share premium account of the Company or out of the proceeds of a new issuance of shares made for the purpose of the repurchase or, if authorized by the Articles and subject to the Cayman Companies Act, out of capital and, in the case of any premium payable on the repurchase, out of profits of our Company or from sums standing to the credit of the share premium account of our Company or, if authorized by the Articles and subject to the Cayman Companies Act, out of capital.

However, our Directors do not propose to exercise the general mandate to such an extent as would, in the circumstances, have a material adverse effect on the working capital requirements of our Company or its gearing levels which, in the opinion of our Directors, are from time to time appropriate for our Company.

(d) General

The exercise in full of the Repurchase Mandate, on the basis of [REDACTED] Shares in issue immediately following the completion of the [REDACTED] and the [REDACTED], excluding any Shares which may be issued pursuant to the exercise of the [REDACTED] and the share options granted under the Pre-[REDACTED] Share Option Scheme, could accordingly result in up to approximately [REDACTED] Shares being repurchased by our Company during the period prior to the earliest of:

- the conclusion of the next annual general meeting of our Company unless renewed by an ordinary resolution of our Shareholders in a general meeting, either unconditionally or subject to conditions;
- the expiration of the period within which our Company's next annual general meeting is required by the Articles of Association or any other applicable laws to be held; or

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- the date on which it is varied or revoked by an ordinary resolution of our Shareholders in a general meeting.

None of our Directors nor, to the best of their knowledge having made all reasonable enquiries, any of their associates currently intends to sell any Shares to our Company.

Our Directors have undertaken to the Stock Exchange that, so far as the same may be applicable, they will exercise the Repurchase Mandate in accordance with the Listing Rules and the applicable laws in the Cayman Islands.

If, as a result of any repurchase of Shares, a Shareholder's proportionate interest in the voting rights of our Company increases, such increase will be treated as an acquisition for the purposes of the Takeovers Code. Accordingly, a Shareholder or a group of Shareholders acting in concert could obtain or consolidate control of our Company and become obliged to make a mandatory offer in accordance with Rule 26 of the Takeovers Code. Save as aforesaid, our Directors are not aware of any consequences which would arise under the Takeovers Code as a consequence of any repurchases pursuant to the Repurchase Mandate.

Any repurchase of Shares that results in the number of Shares held by the public being reduced to less than 25% of the Shares then in issue could only be implemented if the Stock Exchange agreed to waive the Listing Rules requirements regarding the public shareholding referred to above. It is believed that a waiver of this provision would not normally be granted other than in exceptional circumstances.

No core connected person of our Company has notified our Company that he or she has a present intention to sell Shares to our Company, or has undertaken not to do so, if the Repurchase Mandate is exercised.

B. FURTHER INFORMATION ABOUT OUR BUSINESS

1. Summary of Material Contract

The following contract (not being contracts entered into in the ordinary course of business) has been entered into by members of our Group within the two years preceding the date of this document and is or may be material:

[REDACTED]

APPENDIX IV STATUTORY AND GENERAL INFORMATION




2. Intellectual Property Rights

(a) Trademarks

As of the Latest Practicable Date, we had registered the following trademarks which we consider to be or may be material to our business:

Trademark	Category	Owner	Place of Registration	Registration No.	Registration date	Expiry Date
	Class 5	Sichuan Clover	PRC	6690187	June 21, 2010; renewal application filed on July 2, 2019	2030.06.20
	Class 35	Sichuan Clover	PRC	38040645	December 28, 2019	2029.12.27
	Class 5	Sichuan Clover	PRC	38036382	December 28, 2019	2029.12.27
	Class 42	The Company	Hong Kong	305503806	May 31, 2021	2031.01.11
	Class 42	The Company	Hong Kong	305503798	May 31, 2021	2031.01.11
	Class 42, 44	The Company	Hong Kong	305503789	May 31, 2021	2031.01.11
	Class 42, 44	The Company	Hong Kong	305503770	May 31, 2021	2031.01.11
Clover biopharma	Class 5	Sichuan Clover	PRC	52301380	August 21, 2021	2031.08.20

As of the Latest Practicable Date, we had applied for the registration of the following trademarks which we consider to be or may be material to our business:

Trademark	Place of Application	Application Number	Applicant	Application Date
三叶草	PRC	52288139	Sichuan Clover	December 18, 2020
	PRC	50953568	Sichuan Clover	November 3, 2020
	PRC	50944318	Sichuan Clover	November 3, 2020
	PRC	50939744	Sichuan Clover	November 3, 2020

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Trademark	Place of Application	Application Number	Applicant	Application Date
	PRC	50921965	Sichuan Clover	November 2, 2020
	PRC	50904542	Sichuan Clover	November 2, 2020
CLOVER	PRC	58067980	Sichuan Clover	July 29, 2021
三叶草	PRC	58087184	Sichuan Clover	July 29, 2021
Clover biopharma	PRC	58913965	Sichuan Clover	September 1, 2021
Clover biopharma	PRC	58922355	Sichuan Clover	September 1, 2021
Clover biopharma	PRC	58931761	Sichuan Clover	September 1, 2021
Clover biopharma	PRC	58936388	Sichuan Clover	September 1, 2021
Clover biopharma	PRC	58938754	Sichuan Clover	September 1, 2021
CLOVER	PRC	58923150	Sichuan Clover	September 1, 2021
CLOVER	PRC	58935404	Sichuan Clover	September 1, 2021
CLOVER	PRC	58935792	Sichuan Clover	September 1, 2021
	PRC	58923221	Sichuan Clover	September 1, 2021
	PRC	58931795	Sichuan Clover	September 1, 2021
三叶草	PRC	58923537	Sichuan Clover	September 1, 2021
三叶草	PRC	58929869	Sichuan Clover	September 1, 2021
三叶草	PRC	58933411	Sichuan Clover	September 1, 2021
	Hong Kong	305751423	Clover Biopharmaceuticals Ireland Limited	September 20, 2021
	Hong Kong	305751405	Clover Biopharmaceuticals Ireland Limited	September 20, 2021
	Hong Kong	305751432	Clover Biopharmaceuticals Ireland Limited	September 20, 2021

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Trademark	Place of Application	Application Number	Applicant	Application Date
	Hong Kong	305751414	Clover Biopharmaceuticals Ireland Limited	September 20, 2021
	Hong Kong	305751496	Clover Biopharmaceuticals Ireland Limited	September 20, 2021
	Hong Kong	305751487	Clover Biopharmaceuticals Ireland Limited	September 20, 2021
S-TRIMER	U.S.	90207852	Sichuan Clover	September 24, 2020
CLOVER	EU	18527309	Clover Biopharmaceuticals Ireland Limited	August 5, 2021
	EU	18561366	Clover Biopharmaceuticals Ireland Limited	September 17, 2021
	EU	18561372	Clover Biopharmaceuticals Ireland Limited	September 17, 2021

(b) Patents

As of the Latest Practicable Date, we owned the following registered patent which we consider to be or may be material to our business:

No.	Type	Patent	Place of Registration	Patent Number	Owner	Expiration Date
1.	Invention	Methods and Compositions for Producing Disulfide-Linked Trimeric TNF Family of Cytokines and Their Use	U.S.	US10618949B2	Sichuan Clover	2038-03-09

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As of the Latest Practicable Date, we filed the following patent applications which we consider to be or may be material to our business:

No.	Type	Patent	Place of Registration	Application Number	Owner	Application Date
1.	Invention	Methods and Compositions for Producing Disulfide-Linked Trimeric TNF Family of Cytokines and Their Use	U.S.	US20200190181A	Sichuan Clover	2020-02-27
2.	Invention	Methods and Compositions for Producing Disulfide-Linked Trimeric TNF Family of Cytokines and Their Use	U.S.	US20200199187A1	Sichuan Clover	2020-03-03
3.	Invention	Coronavirus Diagnostic Compositions, Methods, and Uses Thereof	PCT	PCT/CN 2020/095332	Sichuan Clover	2020-06-10
4.	Invention	Methods and Compositions for Purification of Trimeric Fusion Proteins	PCT	PCT/CN 2020/112439	Sichuan Clover	2020-08-31

(c) Domain Names

As of the Latest Practicable Date, we owned the following domain name which we consider to be or may be material to our business:

No.	Domain Name	Registration Number	Owner	Registered Date	Expiry Date
1.	cloverbiopharma.com	蜀ICP備08004531號-1	Sichuan Clover	2007.06.25	2023.06.25

(d) Copyrights

As of the Latest Practicable Date, we owned the following copyrights which we consider to be or may be material to our business:

No.	Name/Description	Record Owner	Registration Number	Registration Date
1.	Clover Marks (i)	Sichuan Clover	2020-F-00026752	December 24, 2020
2.	Clover Marks (ii)	Sichuan Clover	2020-F-00026753	December 24, 2020
3.	Clover Marks (i)	Sichuan Clover	2020-F-00026750	December 24, 2020
4.	Clover Marks (ii)	Sichuan Clover	2020-F-00026751	December 24, 2020

Save as aforesaid, as of the Latest Practicable Date, there were no other intellectual property rights which the Company considers to be or may be material to our business.

C. FURTHER INFORMATION ABOUT OUR DIRECTORS

1. Particulars of Directors' Service Contracts and Appointment Letters

(a) Executive Director

Each of our executive Director has entered into a service contract with our Company on September 26, 2021. The initial term of their service contracts shall commence from the date of his/her appointment as a Director and continue for a period of three years after or until the third annual general meeting of the Company since the [REDACTED], whichever is earlier, and shall be automatically renewed for successive periods of three years (subject always to re-election as and when required under the Articles), until terminated in accordance with the terms and conditions of the service contract or by either party giving to the other not less than three months' prior notice in writing.

(b) Non-executive Directors and Independent Non-executive Directors

Each of our non-executive Directors and independent non-executive Directors has entered into an appointment letter with our Company on September 26, 2021. The initial term for their appointment letters shall commence from the date of his/her appointment as a Director and continue for a period of three years after or until the third annual general meeting of the Company since the [REDACTED], whichever is earlier, and shall be automatically renewed for successive periods of three years (subject always to re-election as and when required under the Articles), until terminated in accordance with the terms and conditions of the appointment letter or by either party giving to the other not less than three months' prior notice in writing.

2. Remuneration of Directors

Remuneration and benefits in kind of approximately RMB3.0 million, RMB7.3 million and RMB2.4 million in aggregate were paid and granted by our Group to our Directors in respect of the years ended December 31, 2019 and 2020 and the four months ended April 30, 2021.

Under the arrangements currently in force, our Directors will be entitled to receive remuneration and benefits in kind which, for the year ending December 31, 2021, is expected to be approximately RMB5.0 million in aggregate (excluding discretionary bonus).

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3. Disclosure of Interests

(a) *Interests and Short Positions of Our Directors and the Chief Executive of Our Company in the Share Capital of our Company and Its Associated Corporations Following Completion of the [REDACTED] and the [REDACTED]*

Immediately following completion of the [REDACTED] and the [REDACTED] (assuming the [REDACTED] and the share options granted under the Pre-[REDACTED] Share Option Plan are not exercised), the interests or short positions of our Directors and chief executives in the Shares, underlying shares and debentures of our Company and its associated corporations, within the meaning of Part XV of the SFO, which will have to be notified to our Company and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions which he/she is taken or deemed to have under such provisions of the SFO), or which will be required, pursuant to section 352 of the SFO, to be recorded in the register referred to therein, or which will be required to be notified to our Company and the Stock Exchange pursuant to the Model Code for Securities Transactions by Directors of Listed Companies contained in the Listing Rules, will be as follows:

Name of Director or chief executive	Nature of Interest	Shares held as of the Latest Practicable Date		Shares held immediately following the completion of the [REDACTED] and the [REDACTED] (assuming that the [REDACTED] and the share options granted under the Pre-[REDACTED] Share Option Plan are not exercised)	
		Number	Approximate percentage	Number	Approximate percentage
Dr. Peng Liang	Beneficial owner	29,500,000	20.48%	[REDACTED]	[REDACTED]
	Beneficial owner ⁽¹⁾	297,132	0.21%	[REDACTED]	[REDACTED]
	Interest of a party to an agreement ⁽²⁾	2,500,000	1.74%	[REDACTED]	[REDACTED]
	Interest of a party to an agreement ⁽³⁾	8,000,000	5.55%	[REDACTED]	[REDACTED]
Mr. Joshua Liang	Beneficial owner	2,500,000	1.74%	[REDACTED]	[REDACTED]
	Beneficial owner ⁽⁴⁾	519,981	0.36%	[REDACTED]	[REDACTED]
	Interest of a party to an agreement ⁽²⁾	29,500,000	20.48%	[REDACTED]	[REDACTED]
	Adviser of a trust ⁽⁵⁾	11,050,000	7.67%	[REDACTED]	[REDACTED]
Dr. Xiaodong Wang	Beneficial owner ⁽⁶⁾	59,500	0.04%	[REDACTED]	[REDACTED]
Dr. Xiaobin Wu	Beneficial owner ⁽⁶⁾	59,500	0.04%	[REDACTED]	[REDACTED]
Mr. Xiang Liao	Beneficial owner ⁽⁶⁾	59,500	0.04%	[REDACTED]	[REDACTED]
Mr. Jeffrey Farrow	Beneficial owner ⁽⁶⁾	59,500	0.04%	[REDACTED]	[REDACTED]
Mr. Thomas Leggett	Beneficial owner ⁽⁶⁾	59,500	0.04%	[REDACTED]	[REDACTED]

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Notes:

- (1) Referring to the Shares underlying the restricted share units granted to Dr. Liang under the RSU Scheme.
- (2) Pursuant to the Acting-in-concert Deed, Dr. Liang and Mr. Joshua Liang agreed to act in concert by aligning their votes at Shareholders’ meetings of the Company. Therefore, they are deemed to be jointly interested in the aggregate number of Shares held by each other.
- (3) Pursuant to the voting proxy agreements entered into on March 16, 2021 by each of Dr. Xiaodong Wang, Mr. Jianwei Zhu, Mr. Pu Jiang and Mr. Zheng Ping (the “Grantors”) and Dr. Liang separately, each of the Grantors granted the voting right of the Shares held by them to Dr. Liang. Therefore, Dr. Liang was deemed to be interested in the Shares held by the Grantors under the SFO.
- (4) Referring to the Shares underlying the restricted share units granted to Mr. Joshua Liang under the RSU Scheme.
- (5) The Core Trust Company Limited is the trustee for the RSU Scheme. Under the trust deed, Mr. Joshua Liang is able to exercise voting rights attached to the Shares held by Super Novel.
- (6) Referring to the Shares underlying the restricted share units granted to each of the Directors under the RSU Scheme.

(b) Interests and Short Positions Discloseable under Divisions 2 and 3 of Part XV of the SFO

For information on the persons who will, immediately following the completion of the [REDACTED] and the [REDACTED] (assuming the [REDACTED] and the share options granted under the Pre-[REDACTED] Share Option Plan are not exercised), having or be deemed or taken to have beneficial interests or short position in our Shares or underlying shares which would fall to be disclosed to our Company under the provisions of 2 and 3 of Part XV of the SFO, or directly or indirectly be interested in 5% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of any other member of our Company, see the section headed “Substantial Shareholders” in this document.

Save as set out above, as of the Latest Practicable Date, our Directors were not aware of any persons who would, immediately following the completion of the [REDACTED] and the [REDACTED], be interested, directly or indirectly, in 5% or more of the nominal of any class of share capital carrying rights to vote in all circumstances at general meetings of any member of our Group or had option in respect of such capital.

4. Disclaimers

Save as disclosed in this document:

- (a) there are no existing or proposed service contracts (excluding contracts expiring or determinable by the employer within one year without payment of compensation (other than statutory compensation)) between the Directors and any member of the Group;

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- (b) none of the Directors or the experts named in the paragraph headed “– E. Other Information – 4. Qualifications and consents of Experts” in this Appendix has any direct or indirect interest in the promotion of, or in any assets which have been, within the two years immediately preceding the date of this document, acquired or disposed of by or leased to any member of the Group, or are proposed to be acquired or disposed of by or leased to any member of the Group;
- (c) save as in connection with the [REDACTED], none of our Directors nor any of the experts named in the paragraph headed “– E. Other Information – 4. Qualifications and consents of experts” in this Appendix is materially interested in any contract or arrangement subsisting at the date of this document which is significant in relation to the business of our Group as a whole;
- (d) taking no account of any Shares which may be taken up under the [REDACTED] and the [REDACTED], so far as is known to any Director or chief executive of the Company, no other person (other than a Director or chief executive of the Company) will, immediately following completion of the [REDACTED] and the [REDACTED], have interests or short positions in the Shares and underlying Shares which would fall to be disclosed to the Company and the Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO or (not being a member of the Group), be interested, directly or indirectly, in 5% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of any member of the Group;
- (e) none of the Directors or chief executive of the Company has any interests or short positions in the Shares, underlying shares or debentures of the Company or its associated corporations (within the meaning of Part XV of the SFO) which will have to be notified to the Company and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions which he is taken or deemed to have under such provisions of the SFO) or which will be required, pursuant to section 352 of the SFO, to be entered into the register referred to therein, or will be required, pursuant to the Model Code for Securities Transaction by Directors of Listed Issuers, to be notified to the Company and the Stock Exchange once the Shares are [REDACTED] thereon;
- (f) save in connection with the [REDACTED], none of the experts named in the paragraph headed “– E. Other Information – 4. Qualifications and consents of experts” in this Appendix: (i) is interested legally or beneficially in any of our Shares or any shares in any of our subsidiaries; or (ii) has any right (whether legally enforceable or not) to subscribe for or to nominate persons to subscribe for securities in any member of our Group; and
- (g) none of our Directors or their respective close associates or any Shareholders of our Company (who to the knowledge of our Directors owns more than 5% of the number of our issued shares) has any interest in our five largest suppliers or our five largest customers.

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D. SHARE INCENTIVE PLANS

1. Pre-[REDACTED] Share Option Plan

Summary of Key Terms

The following is a summary of the principal terms of the Pre-[REDACTED] Share Option Plan of the Company as approved and adopted by the resolution of the Board dated April 15, 2021 (“**Adoption Date**”) and by the resolutions of the shareholders of the Company dated April 15, 2021. The terms of the Pre-[REDACTED] Share Option Plan are not subject to the provisions of Chapter 17 of the Listing Rules.

(a) Purpose

The purpose of the Pre-[REDACTED] Share Option Plan is to enable the Company to grant options to eligible participants as incentives or rewards for their contribution or potential contribution to the Group.

(b) Who May Join

Eligible participants (“**Eligible Participants**”) means any person belonging to any of the following classes of persons:

- (i) any full-time employees of the Group or any of the company in which the Company or any subsidiary has any equity interest (“**Invested Entity**”);
- (ii) any non-executive directors of the Group or any of the Invested Entities but excluding any independent non-executive directors;
- (iii) consultants and advisors, provided that such consultants and advisors render bono fide services and that such services are not in connection with the offer and sale of securities in a capital-raising transaction; and
- (iv) general partners. The options under this Scheme can be granted to any company wholly owned by one or more Eligible Participants, or any discretionary trust where any Eligible Participant is a discretionary object;

The options under this Pre-[REDACTED] Share Option Plan can be granted to any company wholly owned by one or more eligible participants, or any discretionary trust where any eligible participant is a discretionary object.

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(c) Duration and Control of the Pre-[REDACTED] Share Option Plan

The Pre-[REDACTED] Share Option Plan shall be valid and effective for a period commencing on the Adoption Date and ending immediately prior to the [REDACTED] (both dates inclusive). Any option granted under this scheme shall become exercisable after the [REDACTED] after which no further options shall be granted under this scheme but the provisions of this scheme shall in all other respects remain in full force and effect to the extent necessary to give effect to the exercise of any options granted prior thereto or otherwise as may be required in accordance with the provisions of this scheme and options granted prior thereto but not yet exercised shall continue to be valid and exercisable in accordance with this scheme.

In respect of an option, the period to be notified by the Board to each grantee within which the option may be exercisable (“**Option Period**”) shall not exceed a period of 10 years commencing on the date upon which such option is deemed to be granted and accepted in accordance with paragraph (d) (“**Commencement Date**”).

This scheme shall be subject to the administration of the Board, or Mr. Joshua Liang or other officer or director designated by the Board (the “**Administrator**”), whose decision as to all matters arising in relation to this scheme or its interpretation or effect (save as otherwise provided herein) shall be final and binding on all parties subject to the prior receipt of a statement in writing from the auditors or the approved independent financial adviser if and as required by paragraph (i) below.

Subject to applicable laws and the provisions of this scheme (including any other powers given to the Administrator hereunder), and except as otherwise provided by the Board, the Administrator shall have the authority, in its discretion:

- (i) to construe and interpret the terms of the scheme and options granted pursuant to the scheme; and
- (ii) to take such other action, not inconsistent with the terms of the scheme, as the Administrator deems appropriate.

(d) Options

The Board shall, subject to and in accordance with the provisions of this scheme and the Listing Rules, be entitled, but shall not be bound, at any time, to offer to grant an option to any eligible participant whom the Board may in its absolute discretion select and subject to such conditions (including, without limitation, any minimum period for which an option must be held before it can be exercised and/or any performance targets which must be achieved before an option can be exercised) as it may think fit.

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If the Board determines to offer an option to an eligible participant, the Company shall deliver a written offer notice (including, for the avoidance of doubt, by way of an e-mail) (the "**Offer Notice**") to the relevant eligible participant in such form as the Company may deem appropriate.

An option shall be deemed to have been granted to and accepted by the grantee and to have taken effect when (a) the Offer Notice has been duly delivered to the Eligible Participant; and (b) the option to which the Offer Notice related has been duly accepted by the Eligible Participant in writing (including, for the avoidance of doubt, by way of an e-mail), provided that a remittance or payment in favor of the Company of US\$0.001 (or in an equivalent amount in RMB) by way of consideration for the grant thereof is received by the Company on or before the relevant acceptance date (or such other later time agreed by the Company). Such remittance or payment shall in no circumstances be refundable.

Any offer to grant an option may be accepted in respect of less than the number of Shares for which it is offered provided that it must be accepted in respect of one board lot for [REDACTED] in Shares on the Stock Exchange or an integral multiple thereof or such other number as agreed by the Board and such number is clearly stated in the written response constituting acceptance of the option in the manner as set out in the previous paragraph. To the extent that the offer to grant an option is not accepted by the acceptance date, it shall be deemed to have been irrevocably declined unless otherwise agreed by the Company.

The options shall not be listed or dealt with on the Stock Exchange.

An option and an offer to grant an option shall be personal to the grantee and shall not be transferable or assignable, save and except for any transfer of option pursuant to paragraph (f) of this scheme or any transfer of option which is otherwise approved by the Board. Save as otherwise provided in this paragraph, no grantee shall in any way sell, transfer, charge, mortgage, encumber or create any interest (legal or beneficial) in favor of any third party over or in relation to any option held by him/her or any offer relating to the grant of an option made to him/her or attempt to do so (save that the grantee may nominate a nominee in whose name the Shares issued pursuant to this scheme may be registered). If the grantee under this scheme is a company or a discretionary trust, such grantee shall undertake to the Company that it will not permit any change of the ultimate beneficial ownership of such option. Any breach of the foregoing shall entitle the Company to cancel any outstanding options or any part thereof granted to such Grantee.

For the avoidance of doubt, any holder of options transferred pursuant to the terms of this scheme shall be subject to the same terms and conditions of the offer to grant an option extended to the initial grantee including but not limited to the exercise price of the option.

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(e) Exercise Price

The exercise price in relation to each option offered to an eligible participant shall, subject to the adjustments referred to in paragraph (i), be a price that is set out in the Offer Notice representing not less than the par value of a Share.

Subject to applicable laws, the grantee is entitled to choose the following type of consideration to be paid for the Shares to be issued upon exercise of options under the scheme:

- (i) cash;
- (ii) payment through a broker-dealer sale and remittance procedure pursuant to which the grantee (a) shall provide written instructions to a Company designated brokerage firm to effect the immediate sale of some or all of the purchased Shares and remit to the Company sufficient funds to cover the aggregate exercise price payable for the purchased Shares and (b) shall provide written directives to the Company to deliver the certificates for the purchased Shares directly to such brokerage firm in order to complete the sale transaction; or
- (iii) any combination of the foregoing methods of payment.

(f) Exercise of Options

Subject to the paragraphs below, an option shall be personal to the grantee and shall not be assignable and no grantee shall in any way sell, transfer, charge, mortgage, encumber or create any interest (legal or beneficial) in favor of any third party over or in relation to any option or attempt so to do, and shall be exercised in whole or in part and, other than where it is exercised to the full extent outstanding, shall be exercised in one board lot for [REDACTED] in Shares on the Stock Exchange or an integral multiple thereof or such other number as agreed by the Board, by the grantee by giving notice in writing to the Company stating that the option is thereby exercised and the number of Shares in respect of which it is exercised. Each such notice must be accompanied by a remittance or payment and/or such other written instructions and directives as provided under paragraph (e) (where applicable) for the full amount of the exercise price for the Shares in respect of which the notice is given. Within 10 business days after receipt of the notice and the remittance or payment and/or such other written instructions and directives as provided under paragraph (e) (where applicable), and, where appropriate, receipt of the certificate by the auditors or the approved independent financial adviser as the case may be pursuant to paragraph (i), the Company shall allot and issue the relevant number of Shares to the grantee credited as fully paid and issue to the grantee certificates in respect of the Shares so allotted.

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Unless otherwise provided hereof, each of the grantees to whom an option has been granted under this scheme shall be entitled to exercise his/her option in the manner set forth in the Offer Notice (unless otherwise agreed by the Board in writing, in no event can any option granted be exercised earlier than the day after the first half-year anniversary of the [REDACTED]). The exercise of any option shall be subject to the shareholders of the Company in general meeting approving any necessary increase in the authorized share capital of the Company (if applicable).

Subject to as hereinafter provided, an option may be exercised by a grantee at any time during the Option Period provided that:

- (i) in the event of the grantee ceasing to be an eligible participant for any reason other than on his/her death, ill-health, injury, disability or the termination of his/her relationship with the Company and/or any of the subsidiaries and/or any of the Invested Entities on one or more of the grounds specified in paragraph (g), the grantee may exercise the option up to his/her entitlement at the date of cessation of being an eligible participant (to the extent not already exercised, excluding the options which have not become exercisable pursuant to this paragraph (f) hereof) (such options, the "**Non-exercisable Options**") within the period of three months (or such longer period as the Board may determine) following the date of such cessation (which date shall be, in relation to a grantee who is an eligible participant by reason of his/her employment with the Company or any of the subsidiaries, the last actual working day with the Company or the relevant subsidiary or the relevant Invested Entity whether salary is paid in lieu of notice or not) and upon expiry of the said three-month period (or such longer period as the Board may determine), any outstanding options (including any Non-exercisable options, if applicable) granted to the grantee to the extent not already exercised shall be automatically lapsed, or be transferred, if otherwise decided by the Board, to any other eligible participant designated by the Board from time to time at US\$0.001 (or in an equivalent amount in RMB);
- (ii) in the case of the grantee ceasing to be an eligible participant by reason of death and none of the events which would be a ground for termination of his/her relationship with the Company and/or any of the subsidiaries and/or any of the Invested Entities under paragraph (g) has occurred, the personal representative(s) of the grantee shall be entitled within a period of 12 months (or such longer period as the Board may determine) from the date of his/her death or such other period to be determined by the Board from time to time to exercise the options in full (to the extent not already exercised, excluding any Non-exercisable Options and upon expiry of the said 12-month period (or such longer period as the Board may determine), all outstanding options (including any Non-exercisable Options, if applicable) granted to the grantee to the extent not already exercised shall be automatically lapsed or be transferred, if otherwise decided by the Board, to any other eligible participant designated by the Board from time to time at US\$0.001 (or in an equivalent amount in RMB);

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Notwithstanding the above or paragraph (g)(iii) hereof, the Board shall, upon occurrence of any events mentioned in paragraph above or paragraph (g)(iii) hereof, have the sole discretion to determine (a) whether or not to retain (in full or in part) the Non-exercisable Options of any Grantee (such retained options, the "**Retained Options**"); and/or (b) the manner in accordance with which the outstanding options (including the Retained Options, if applicable) held by such Grantee shall be exercised, provided that paragraph (e) and the Scheme Limit (as defined below) will continue to be complied with.

No dividends shall be payable in relation to the Shares that are the subject of options that have not been exercised. The Shares to be allotted upon the exercise of an option shall not carry voting rights until completion of the registration of the grantee (or such other person nominated by the grantee) as the holder thereof. Subject to as aforesaid, the Shares to be allotted upon the exercise of an option shall be subject to all the provisions of the Articles and shall rank *pari passu* in all respects with and shall have the same voting, dividend, transfer and other rights, including those arising on liquidation of the Company as attached to the fully-paid Shares in issue on the date of issue, in particular but without prejudice to the generality of the foregoing, in respect of voting, transfer and other rights including those arising on a liquidation of the Company and rights in respect of any dividend or other distributions paid or made on or after the date of issue. Shares issued on the exercise of an option shall not rank for any rights attaching to Shares by reference to a record date preceding the date of allotment.

(g) Lapse of Option

Except as otherwise agreed to between the Company and a Grantee, or as otherwise approved by the Board, an option shall lapse automatically and not be exercisable (to the extent not already exercised) on the earliest of:

- (i) the expiry date relevant to that option;
- (ii) the date of commencement of the winding-up of the Company (as determined in accordance with the Cayman Companies Act);
- (iii) the date on which the grantee ceases to be an eligible participant for any reason including his/her resignation, ill-health, injury, disability or by reason of the termination of his/her relationship with the Company and/or any of the subsidiaries and/or any of the Invested Entities on any one or more of the following grounds:
 - (a) that he/she has been guilty of serious misconduct;
 - (b) that he/she has been convicted of any criminal offense involving his/her integrity or honesty or in relation to an employee of the Company and/or any of the subsidiaries and/or any of the Invested Entities;

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(c) that he/she has become insolvent, bankrupt or has made arrangements or compositions with his/her creditors generally; or

(d) on any other ground as determined by the Board that would warrant the termination of his/her employment at common law or pursuant to any applicable laws or under the grantee's service contract with the Company or the relevant subsidiary or the relevant Invested Entity. A resolution of the Board or the board of directors of the relevant subsidiary or the relevant Invested Entity to the effect that the relationship of a grantee has or has not been terminated on one or more of the grounds specified in this paragraph shall be conclusive; and

(iv) the date on which the Board shall exercise the Company's right to cancel the option at any time after the Grantee commits a breach of the provisions of paragraph (d) or the options are canceled in accordance with paragraph (1).

(h) Maximum Number of Shares

The maximum number of Shares in respect of which options may be granted is [REDACTED] Shares as adjusted after the [REDACTED] ("Scheme Limit"). Option lapsed and/or canceled in accordance with the terms of this scheme shall not be counted for the purpose of calculating the Scheme Limit, and the number of Shares in respect of which options may be granted under this scheme shall be increased by the same number of options lapsed and/or canceled.

Subject to the above, the number of option and Shares subject to this scheme can be adjusted according to paragraph (i) in case that the auditors or the approved independent financial adviser, which shall act as experts and not arbitrators, shall certify in writing to the Board that any such alterations, in their opinion, are fair and reasonable.

(i) Capital Restructuring

In the event of any capitalization issue, rights issue, open offer (if there is a price dilutive element), sub-division, consolidation of shares, or reduction of capital of the Company in accordance with applicable laws and regulatory requirements, such corresponding alterations (if any) shall be made (except on an issue of securities of the Company as consideration in a transaction which shall not be regarded as a circumstance requiring alteration or adjustment) in:

(i) the number of Shares subject to any outstanding options so far as unexercised;

(ii) the exercise price; and/or

(iii) the Scheme Limit.

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as the auditors or the approved independent financial adviser shall at the request of the Company or any grantee, certify in writing either generally or as regards any particular grantee, to be in their opinion fair and reasonable, provided that any such alterations shall be made on the basis that a grantee shall have the same proportion of the equity capital of the Company (as interpreted in accordance with the Guidance Letters) as that to which he/she was entitled to subscribe had he/she exercised all the options held by him/her immediately before such adjustments and the aggregate exercise price payable by a grantee on the full exercise of any option shall remain as nearly as possible the same as (but shall not be greater than) it was before such event and that no such alterations shall be made if the effect of such alterations would be to enable a Share to be issued at less than its nominal value. The capacity of the auditors or the approved independent financial adviser, as the case may be, in this paragraph is that of experts and not arbitrators and their certificate shall, in the absence of manifest error, be final and conclusive and binding on the Company and the grantees. Any adjustment to be made in accordance with this paragraph shall comply with the Listing Rules, the Guidance Letters and any future guidance/interpretation of the Listing Rules issued by the Stock Exchange from time to time.

In respect of any adjustments required by paragraph above, other than any made on a capitalization issue, the auditors or the approved independent financial adviser, as the case may be, shall confirm to the Board in writing that the adjustments satisfy the requirements set out in the Listing Rules and the note thereto and the Guidance Letters and/or such other requirement prescribed under the Listing Rules from time to time (as applicable).

(j) Alteration of the Pre-[REDACTED] Share Option Plan

The terms and conditions of this scheme and the regulations for the administration and operation of this scheme (provided that the same are not inconsistent with this scheme and the Listing Rules) may be altered in any respect by resolution of the shareholders of the Company except that:

- (i) any alteration to the advantage of the grantees or the eligible participants (as the case may be) in respect of the key terms of this scheme; or
- (ii) any material alteration to the terms and conditions of this scheme or any change to the terms of options granted (except any alterations which take effect automatically under the terms of this scheme),

must be made with the prior approval of the shareholders of the Company in general meeting at which any persons to whom or for whose benefit the Shares may be issued under this Scheme and their respective associates shall abstain from voting provided that

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no alteration shall operate to affect adversely the terms of issue of any option granted or agreed to be granted prior to such alteration or to reduce the proportion of the equity capital to which any person was entitled pursuant to such option prior to such alteration except with:

- (i) the consent in writing of grantees holding in aggregate options which if exercised in full on the date immediately preceding that on which such consent is obtained would entitle them to the issue of three-fourths in nominal value of all Shares which would fall to be issued upon the exercise of all options outstanding on that date; or
- (ii) the sanction of a special resolution passed at a meeting of the grantees (being only those grantees holding options, all or any part of which is unexercised as at the time of the meeting at which the resolution is proposed).

Written notice of any alterations made in accordance with this paragraph shall be given to all grantees.

In respect of any meeting of grantees referred to in paragraph above, all the provisions of Articles as to general meetings of the Company shall mutatis mutandis apply as though the options were a class of shares forming part of the capital of the Company except that:

- (i) not less than seven days' notice of such meeting shall be given;
- (ii) a quorum at any such meeting shall be two grantees present in person or by proxy and holding options entitling them to the issue of one-tenth in nominal value of all Shares which would fall to be issued upon the exercise of all options then outstanding unless there is only one grantee holding all options then outstanding, in which case the quorum shall be one grantee;
- (iii) every grantee present in person or by proxy at any such meeting shall be entitled on a show of hands to one vote, and on a poll, to one vote for each Share to which he/she would be entitled upon exercise in full of his/her options then outstanding;
- (iv) any grantee present in person or by proxy may demand a poll; and
- (v) if any such meeting is adjourned for want of a quorum, such adjournment shall be to such date and time, not being less than seven or more than fourteen days thereafter, and to such place as may be appointed by the chairman of the meeting. At any adjourned meeting those grantees who are then present in person or by proxy shall form a quorum and at least seven days' notice of any adjourned meeting shall be given in the same manner as for an original meeting and such notice shall state that those grantees who are then present in person or by proxy shall form a quorum.

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(k) Termination of the Pre-[REDACTED] Share Option Plan

The Shareholders of the Company or the Board may at any time resolve to terminate the operation of this scheme and in such event no further options shall be offered but the provisions of this scheme shall remain in force to the extent necessary to give effect to the exercise of any option granted prior to the termination or otherwise as may be required in accordance with the provisions of this scheme and options granted prior to such termination shall continue to be valid and exercisable in accordance with this scheme.

Details of the options granted, including options exercised or outstanding, under this scheme shall be disclosed in the circular to shareholders of the Company seeking approval of the new scheme established after the termination of this scheme.

(l) Cancellation of Options

Any cancellation of options granted but not exercised must be approved by the grantees of the relevant options in writing. For the avoidance of doubt, such approval is not required in the event any option is canceled pursuant to paragraph 4.6 above.

Outstanding Options

As of the date of this document, the aggregate number of underlying Shares pursuant to the outstanding share options granted under the Pre-[REDACTED] Share Option Plan is [REDACTED] ([REDACTED] as adjusted after the [REDACTED]). Immediately following completion of the [REDACTED] and the [REDACTED] (assuming the [REDACTED] is not exercised and the share options granted under the Pre-[REDACTED] Share Option Plan are not exercised), the aggregate number of Shares underlying all share options granted represents approximately [REDACTED]% of the issued Shares immediately following the completion of the [REDACTED] and the [REDACTED]. No options under the Pre-[REDACTED] Share Option Plan shall be granted after the [REDACTED].

Assuming full exercise of options under the Pre-[REDACTED] Share Option Plan, the shareholding of our Shareholders immediately following the [REDACTED] and the [REDACTED] will be diluted by approximately [REDACTED]% if calculated on the basis of [REDACTED] Shares in issue immediately following completion of the [REDACTED] and the [REDACTED] and assuming that the [REDACTED] is not exercised and without taking into account any additional Shares to be issued pursuant to any Pre-[REDACTED] Share Options. The options granted did not have consequent impact on the earnings per Share for the two years ended December 31, 2020 and the four months ended April 30, 2021.

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As of the date of this document, the outstanding share options which have been granted under the Pre-[REDACTED] Share Option Plan for an aggregate of [REDACTED] ([REDACTED] as adjusted after the [REDACTED]) Shares have been granted to a total of 141 Eligible Participants, none of which is Director or member of the senior management of the Company. The outstanding share options granted under the Pre-[REDACTED] Share Option Plan were granted at a consideration of US\$0.001 to each of the relevant Eligible Participant with an exercise price of US\$0.001 per Share. The exercise period of the share options granted is ten years commencing from the date upon which the share options are deemed to be granted and accepted pursuant to the terms of the Pre-[REDACTED] Share Option Plan.

The table below shows the details of share options granted to connected person(s) of our Company under the Pre-[REDACTED] Share Option Plan that are outstanding as of the Latest Practicable Date.

Name	Address	Position/ Connected relationship	Exercise price	Total Number of Shares underlying the outstanding options as adjusted after the [REDACTED]	Date of grant	Vesting period	Approximate percentage of equity interest in our Company underlying the outstanding options upon the [REDACTED] ⁽¹⁾
Mr. Yuting Jiang (江宇霆)	Building No.9, South Garden, No. 24 South One Lane, First Ring Road, Wuhou District, Chengdu, Sichuan Province, PRC	IT Supervisor/ Nephew of Dr. Liang, our executive Director and Substantial Shareholder	US\$0.001	[REDACTED]	August 6, 2021	Please refer to <i>Note (2)</i> below.	[REDACTED]

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The table below sets out the details of share options granted to our employees that are not connected persons of our Company under the Pre-[REDACTED] Share Option Plan that are outstanding as of the date of this document.

Batch No.	Total number of grantees	Total number of Shares underlying the outstanding options as adjusted after the [REDACTED]	Exercise price	Date of Grant	Vesting period	Approximately percentage of equity interests in the Company underlying the outstanding options upon the [REDACTED] ⁽¹⁾
1	44	[REDACTED]	US\$0.001	April 18, 2021	Please refer to Note (2) below.	[REDACTED]
2	1	[REDACTED]	US\$0.001	April 18, 2021	Please refer to Note (3) below.	[REDACTED]
3	8	[REDACTED]	US\$0.001	July 23, 2021	Please refer to Note (2) below.	[REDACTED]
4	83	[REDACTED]	US\$0.001	August 6, 2021	Please refer to Note (2) below.	[REDACTED]
5	2	[REDACTED]	US\$0.001	August 20, 2021	Please refer to Note (2) below.	[REDACTED]
6	2	[REDACTED]	US\$0.001	October [●], 2021	Please refer to Note (2) below.	[REDACTED]

Notes:

- (1) Based on the assumption that the [REDACTED] is not exercised and without taking into account any Shares to be issued upon the exercise of share options granted under the Pre-[REDACTED] Share Option Plan.
- (2) 25% of the share options granted under the Pre-[REDACTED] Share Option Plan will vest on the 1st anniversary of the vesting commencement date as contemplated in the notice of grant, and 25% of the share options granted under the Pre-[REDACTED] Share Option Plan shall vest upon each anniversary after that during a three-year term. In addition, all the share options shall only be vested subject to the satisfaction of [REDACTED]-based condition on the date after the first half-year anniversary of the [REDACTED].
- (3) 25% of the share options granted under the Pre-[REDACTED] Share Option Plan will vest on the 1st anniversary of the vesting commencement date as contemplated in the notice of grant, and forty-eighth (1/48th) of the share options granted under the Pre-[REDACTED] Share Option Plan shall vest upon each month after that during a 36-month term. In addition, all the share options shall only be vested subject to the satisfaction of [REDACTED]-based condition on the date after the first half-year anniversary of the [REDACTED].

Application has been made to the Listing Committee for the [REDACTED] of and permission to [REDACTED] the Shares to be issued pursuant to the Pre-[REDACTED] Share Option Plan.

Our Company has applied for and [has been] granted (i) a waiver from the Stock Exchange from strict compliance with the disclosure requirements under Rule 17.02(1)(b) and paragraph 27 of Appendix IA to the Listing Rules; and (ii) an exemption from the SFC from

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strict compliance with the disclosure requirements of paragraph 10(d) of Part I of the Third Schedule to the Companies Ordinance. See “Waivers from Strict Compliance with the Listing Rules and Exemption from Strict Compliance with the Companies (Winding Up and Miscellaneous Provisions) Ordinance” for details.

2. RSU Scheme

The Company has granted certain restricted share units (“**RSUs**”) pursuant to the RSU Scheme, details and principal terms of which are set forth below.

Summary of Key Terms

The following is a summary of the principal terms of the RSU Scheme of the Company as approved and adopted by the resolution of the Board dated April 15, 2021 (“**Adoption Date**”) and by the resolutions of the Shareholders dated April 15, 2021, as amended from time to time. The terms of the RSU Scheme are not subject to the provisions of Chapter 17 of the Listing Rules.

(a) Purpose

The purpose of the RSU Scheme is to enable the Company to grant RSUs to eligible participants as incentives or rewards for their contribution or potential contribution to the Group.

This scheme shall be subject to the administration of the Board or Mr. Joshua Liang designated by the Board, whose decision as to all matters arising in relation to this scheme or its interpretation or effect (save as otherwise provided herein) shall be final and binding on all parties. The Board shall have the right to (i) interpret and construe the provisions of this scheme, (ii) determine the persons who will be granted Awards under the scheme, the terms on which Awards are granted and when the RSUs granted pursuant to this scheme may vest, (iii) make such appropriate and equitable adjustments to the terms of the Awards granted under the Scheme as it deems necessary, (iv) appoint and/or authorize one or more persons and/or contractors, as the Board deems appropriate, to assist in the administration of this scheme and delegate such powers and/or functions relating to the administration of this scheme, and (v) make such other decisions or determinations as it shall deem appropriate in the administration of the scheme.

(b) Who May Join

Eligible participants (“**Eligible Participants**”) means any person belonging to any of the following classes of persons:

- (i) any full-time employees of the Group or any of the company in which the Company or any subsidiary has any equity interest (“**Invested Entity**”);
- (ii) any non-executive directors of the Group or any of the Invested Entities;

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- (iii) consultants and advisors, provided that such consultants and advisors render bona fide services and that such services are not in connection with the offer and sale of securities in a capital-raising transaction; and
- (iv) general partners.

The RSUs under this Scheme can be granted to any company wholly owned by one or more Eligible Participants, or any discretionary trust where any Eligible Participant is a discretionary object.

(c) Duration and Control of the RSU Scheme

The RSU Scheme shall be valid and effective commencing on the Adoption Date and shall remain in effect for a period of 10 years from such date which may be refreshed from time to time in the sole discretion of the Board ("**Term**"), after which period no further awards will be granted, but the provisions of this Scheme shall in all other respects remain in full force and effect and Awards that are granted during the Term may continue to be exercisable in accordance with their terms of issue.

No member of the Board shall be personally liable by reason of any contract or other instrument executed by such member or on his behalf in his capacity as a member of the Board nor for any mistake of judgment made in good faith, and the Company shall indemnify and hold harmless each employee, officer or director of the Company to whom any duty or power relating to the administration or interpretation of the scheme may be allocated or delegated, against any cost or expense (including counsel fees) or liability (including any sum paid in settlement of a claim with the approval of the Board) arising out of any act or omission to act in connection with the Scheme unless arising out of such person's own fraud or bad faith.

An Eligible Participant may be granted an Award under this scheme provided that such participation will be subject to such limits and conditions as the Board may determine in its absolute discretion.

All decisions, determinations and interpretations made by the Board shall be final, binding and conclusive upon all Eligible Participants for all purposes.

The Company may appoint trustee ("**Trustee**") to assist with the administration and vesting of RSUs granted pursuant to this scheme. The Company may (i) allot and issue Shares to the Trustee to be held by the Trustee and which will be used to satisfy the RSUs upon exercise and/or (ii) direct and procure the Trustee to receive existing Shares from any Shareholder of the Company or purchase existing Shares (either on-market or off-market) to satisfy the RSUs upon exercise. The Company shall procure that sufficient funds are provided to the Trustee by whatever means as the Board may in its absolute

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discretion determine to enable the Trustee to satisfy its obligations in connection with the administration of this Scheme. All Shares underlying the RSUs granted and to be granted under this Scheme will be transferred, allotted or issued to the Trustee.

(d) Awards

On and subject to the terms of this scheme and the terms and conditions that the Board imposes pursuant to paragraph (a), the Board shall be entitled at any time during the term of the scheme to make a grant to any Eligible Participant, as the Board may in its absolute discretion determine.

Awards may be granted on such terms and conditions (e.g. by linking the vesting of their RSU to the attainment or performance of milestones by any member of the Group, the grantee or any group of Eligible Participants) as the Board may determine, provided such terms and conditions shall not be inconsistent with any other terms and conditions of this Scheme.

A grant shall be made to an Eligible Participant by a letter and/or any such notice or document in such form as the Board may from time to time determine ("**Notice of Grant**") and such grant shall be subject to the terms as specified in this Scheme and the Notice of Grant shall be substantially in the form set out in the RSU Scheme. The Eligible Participant shall undertake to hold the Award on the terms on which it is granted and be bound by the provisions of this Scheme and the terms set forth in the Notice of Grant. Such Award shall remain open for acceptance by the Eligible Participant to whom a grant is made for a period to be determined by the Board, provided that no such grant shall be open for acceptance after the expiry of the Term or after this Scheme has been terminated in accordance with the provisions hereof. To the extent that the Award is not accepted within the period determined by the Board, it will be deemed to have been irrevocably declined and shall immediately lapse.

If the Eligible Participant accepts the offer of grant of RSUs, he/she is required to sign a acceptance notice ("**Acceptance Notice**") and return it to the Company within the period specified and in a manner prescribed in the Notice of Grant. Upon the receipt from the Eligible Participant of a duly executed Acceptance Notice, the RSUs are granted to such Eligible Participant, who becomes a grantee in this Scheme.

No grant shall be made to, nor shall any grant be capable of acceptance by, any Eligible Participant at a time when the Eligible Participant would or might be prohibited from dealing in the Shares by any applicable rules, regulations or laws.

In the event that the Company is [REDACTED] on the Stock Exchange, no grant shall be made to, nor shall any grant be capable of acceptance by, any Eligible Participant after an event which would constitute inside information pursuant to the SFO has occurred or an inside information event has been the subject of a decision until such

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inside information has been announced in accordance with the requirements of the Listing Rules, the SFO or any other applicable laws and regulations. In particular during the period commencing one month immediately preceding the earlier of:

- (i) the date of the meeting of the Board (as such date is first notified to the Stock Exchange in accordance with the Listing Rules) for the approval of the Company's results for any year, half-year, quarterly or any other interim period (whether or not required under the Listing Rules); and
- (ii) the deadline for the Company to publish an announcement of its results for any year or half-year under the Listing Rules, or quarterly or any other interim period (whether or not required under the Listing Rules),

and ending on the date of the results announcement, no Award may be granted. Such period will cover any period of delay in the publication of a results announcement.

In the event that the Company is [REDACTED] on the Stock Exchange, where any Award is proposed to be granted to a director or any employee of the Group, who because of his/her office or employment in the Group, is likely to possess inside information in relation to the Shares, it shall not be granted on any day on which the financial results of the Company are published and during the period of:

- (i) 60 days immediately preceding the publication date of the annual results or, if shorter, the period from the end of the relevant financial year up to the publication date of the results; and
- (ii) 30 days immediately preceding the publication date of the quarterly results (if any) and half-year results or, if shorter, the period from the end of the relevant quarterly or half-year period up to the publication date of the results.

In the event that the Company is [REDACTED] on The Stock Exchange of Hong Kong Limited, any grant of an Award to any Director, chief executive or Substantial Shareholder of any member of the Group, or any of their respective associates (as defined in the Listing Rules), shall be subject to compliance with the requirements of the Listing Rules.

The Board may not grant any Awards to any Eligible Participants in any of the following circumstances:

- (i) the requisite approvals for that grant from any applicable regulatory authorities have not been obtained;
- (ii) the securities laws or regulations require that a document or other offering documents be issued in respect of the grant of the Awards or in respect this Scheme, unless the Board determines otherwise;

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- (iii) where granting the Award would result in a breach by the Group or any of the Directors of any applicable securities laws, rules or regulations; or
- (iv) where such grant of Award would result in a breach of the limits of this Scheme.

The Board shall, after any RSUs have been granted and duly accepted by the Eligible Participant(s), inform the Trustee of the name(s) of the Eligible Participant(s), the number of RSUs and the number of underlying Shares that can be acquired by each Eligible Participant upon exercise of the RSUs granted to each such Eligible Participant, the vesting schedule of RSUs (if any) and other terms and conditions (if any) that RSUs are subject to as determined by the Board.

(e) Vesting

Unless otherwise provided hereof, the RSUs granted under this Scheme shall be vested to grantees in the manner set forth in the Notice of Grant (unless otherwise agreed by the Board in writing, in no event can any RSU granted be vested earlier than the day after the first half-year anniversary of the [REDACTED]).

Upon fulfillment or waiver of the vesting period and vesting conditions (if any) applicable to each of the grantees, a vesting notice ("**Vesting Notice**") will be sent to the grantee by the Board confirming (a) the extent to which the vesting period and vesting conditions (if any) have been fulfilled or waived and, (b) the number of Shares (and, if applicable, the cash or non-cash income, dividends or distributions and/or the sale proceeds of non-cash and non-scrip distributions in respect of these Shares) or the amount of cash the grantee will receive.

RSUs held by a grantee that are vested as evidenced by the Vesting Notice may be exercised (in whole or in part) by the grantee serving an exercise notice ("**Exercise Notice**") in writing on the Trustee and copied to the Company. Any exercise of RSUs must be in respect of a board lot for dealing in Shares on the Stock Exchange or an integral multiple thereof (except where the number of Shares underlying the RSUs which remains unexercised is less than one board lot). In an Exercise Notice, the grantee shall, subject to the paragraph below, request the Trustee to, and the Board shall direct and procure the Trustee to within five (5) business days, transfer the Shares underlying the RSUs exercised (and, if applicable, the cash or non-cash income, dividends or distributions and/or the sale proceeds of non-cash and non-scrip distributions in respect of those Shares) to the grantee which the Company has allotted and issued to the Trustee as fully paid up Shares or which the Trustee has either acquired by purchasing existing Shares or by receiving existing Shares from any Shareholder of the Company, subject to the grantee paying all tax, stamp duty, levies and charges applicable to such transfer to the Trustee or as the Trustee directs.

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The grantee acknowledges that, at least three months in advance of the vesting of any installment of the RSUs held by him, the Company will instruct the Trustee to, promptly after such RSUs vest, sell certain number of Shares (being in a board lot or an integral multiple thereof except where the number of Shares underlying the RSUs which remains unexercised is less than one board lot) underlying such RSUs and Shares that have been vested but not yet transferred by the Trustee to him on the open market following the trading method designated by the grantee. The Trustee will remit cash proceeds of such sale to the Company sufficient to satisfy such tax withholding obligations. The Company will then pay the required tax withholding obligations to the appropriate taxing authorities. The Trustee will remit the remaining funds to the grantee.

If the vesting conditions are not satisfied and no waiver of such condition is granted, the RSUs shall be cancelled according to conditions as determined by the Board in its absolute discretion.

In the event that the grantee fails to execute the required documents within fourteen (14) days after receiving the Vesting Notice, the vested RSUs will lapse.

Notwithstanding the foregoing, if any relevant parties of this Scheme would or might be prohibited from dealing in the Shares by the Listing Rules or by any other applicable laws, regulations or rules within the period specified above, the date on which the relevant Shares shall be allotted and issued or transferred (as the case may be) to the grantee shall occur as soon as possible after the date when such dealing is permitted by the Listing Rules or by any other applicable laws, regulations or rules.

The grantee shall be solely liable to pay all taxes and other levies that may be assessed or assessable on any payments made by the Company hereunder and all payments required to be made hereunder and all payments required to be made hereunder by the Company shall be subject to the deduction or withholding of such amounts as the Board may reasonably determine is necessary or desirable by reason of any liability to tax or obligation to account for tax or loss of any relief from tax that may fall on the Company or any subsidiary in respect of, or by reason of such delivery of Shares underlying an RSU, and the grantee agrees to indemnify and keep the Group indemnified in respect of any such liability, obligation or loss and accepts any claim in respect of such indemnity may be satisfied by set-off against any sums due from the Group to such grantee from time to time. Subject to paragraph above, and unless the grantee requests otherwise, upon vesting of the RSUs, the Company, on behalf of the grantee, will instruct the Trustee to sell a number of the Shares underlying the vested RSUs to satisfy any tax withholding obligations of the Company, and the Trustee will remit cash proceeds of such sale to the Company sufficient to satisfy such tax withholding obligations. The Company will then pay the required tax withholding obligations to the appropriate taxing authorities.

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For the avoidance of doubt, the RSUs shall only vest onto the grantee upon the completion of transfer of the Shares underlying RSUs into the account designated by the grantee if the grantee chooses to Shares or a combination of Shares and equivalent value in cash with reference to the market value of the Shares. However, the grantee shall be entitled to the economic benefit of such Shares, including but not limited to, any dividend, income or any other right for which the record date is prior to the date on which the Shares are completely and actually transferred into the grantee's account but on or after the date of the Vesting Notice.

In the event a general offer by way of voluntary offer, takeover or otherwise (other than by way of scheme of arrangement pursuant to the paragraph below) is made to all the Shareholders (or all such Shareholders other than the offeror and/or any person controlled by the offeror and/or any person acting in association or concert with the offeror) and such offer becomes or is declared unconditional prior to the vesting date of any RSU, the Board shall, prior to the offer becoming or being declared unconditional, determine at its absolute discretion whether such RSU shall vest and the period within which such RSU shall vest. If the Board determines that such RSU shall vest, it shall notify the grantee that the RSU shall vest and the period within which such RSU shall vest.

In the event a general offer for Shares by way of scheme of arrangement is made to all the Shareholders and has been approved by the necessary number of Shareholders at the requisite meetings prior to the vesting of any RSU, the Board shall, prior to such meetings, determine at its absolute discretion whether such RSU shall vest and the period within such RSU shall vest. If the Board determines that such RSU shall vest, it notify the grantee that the RSU shall vest and the period within which such RSU shall vest.

In the event a notice is given by the Company to its Shareholders to convene a Shareholders' meeting for the purpose of considering and, if thought fit, approving a resolution to voluntarily wind-up the Company prior to the vesting date of any RSU, the Board shall determine at its discretion whether such RSU shall vest, and the period when such RSU shall vest and in the latter case, the unvested RSUs must be vested and effected by no later than two business days before the day of the proposed Shareholders' meeting. If the Board determines that such RSU shall vest, it shall notify the grantee that the RSU shall vest and the period within which such RSU shall vest.

In the event of a compromise or arrangement, other than a scheme of arrangement contemplated in the paragraph above, between the Company and its members and/or creditors being proposed in connection with a scheme for the reconstruction or amalgamation of the Company, the Board shall determine at its discretion whether such RSU shall vest, and the period when such RSU shall vest. If the Board determines that such RSU shall vest, it shall notify the grantee that the RSU shall vest and the period within which such RSU shall vest.

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In the event of the grantee ceasing to be an Eligible Participant for any reason other than on his resignation, death, ill-health, injury, disability or the termination of his relationship with the Group and/or any of the Invested Entities on one or more of the grounds specified in paragraph (h), the RSU shall vest up to his/her entitlement at the date of cessation of being an Eligible Participant (to the extent not already vested, excluding the RSUs which have not vested pursuant to paragraph (e) hereof) within the period of three months (or such longer period as the Board may determine) following the date of such cessation (which date shall be, in relation to a grantee who is an Eligible Participant by reason of his/her employment with the Group, the last actual working day with the Group or the relevant Invested Entity whether salary is paid in lieu of notice or not) and upon expiry of the said three-month period (or such longer period as the Board may determine), any outstanding RSUs granted to the grantee to the extent not already vested shall be automatically lapsed, or be transferred, if otherwise decided by the Board, to any other Eligible Participant designated by the Board from time to time.

In the case of the grantee ceasing to be an Eligible Participant by reason of death and none of the events which would be a ground for termination of his relationship with the Group and/or any of the Invested Entities under paragraph (h) has occurred, the personal representative(s) of the grantee shall be entitled within a period of 12 months (or such longer period as the Board may determine) from the date of his/her death or such other period to be determined by the Board from time to time to vest the RSUs in full (to the extent not already vested, excluding the RSUs which have not vested pursuant to paragraph (e) hereof) and upon expiry of the said 12-month period (or such longer period as the Board may determine), all outstanding RSUs granted to the grantee to the extent not already vested shall be automatically lapsed or be transferred, if otherwise decided by the Board, to any other Eligible Participant designated by the Board from time to time.

The Shares to be issued upon the vesting of RSUs granted pursuant to this Scheme shall be subject to all the provisions of the memorandum and Articles of Association of the Company for the time being in force and shall rank *pari passu* in all respects with the existing fully paid Shares in issue on the date on which those Shares are issued. Once the name of a RSU holder has been recorded in the register of members of the Company, such holder shall be entitled to participate in all dividends or other distributions of the Company.

(f) Underlying Shares

No Award shall be granted pursuant to this Scheme if as a result of such grant (assumed accepted), the aggregate number of Shares (being in a board lot or an integral multiple thereof) (or, where cash is awarded in lieu of Shares, the aggregate number of Shares as are equivalent to the amount of cash so awarded) underlying all grants made pursuant to this Scheme (excluding the Awards that have lapsed or been cancelled in accordance with the rules of this Scheme) will exceed [REDACTED] Shares as adjusted after the [REDACTED] ("RSU Scheme Limit").

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The RSU Scheme Limit may be refreshed from time to time subject to prior Board approval, but in any event, the total number of Shares that underlie the RSUs to be granted following the date of approval of the refreshed limit (“**New Approval Date**”) must not exceed [REDACTED] Shares as adjusted after the [REDACTED]. Shares underlying the RSUs granted pursuant to this Scheme (including those outstanding, forfeited or vested Shares) prior to the New Approval Date will not be counted for the purpose of determining the maximum aggregate number of Shares that may underlie the RSUs to be granted following the New Approval Date under the limit as refreshed.

The Company shall disclose in its annual reports an analysis or reference of the fair value of the Awards granted for the preceding financial year and the employee costs arising from such grants.

(g) Transferability

Subject to paragraphs (e), unless otherwise approved by the Company in writing (to the extent permitted by law), an Award shall be personal to the grantee and shall not be assignable or transferable by the grantee. Save as otherwise provided in this paragraph, no grantee shall in any way sell, transfer, charge, mortgage, encumber or create any interests (legal or beneficial) in favour of any third party over or in relation to any unvested RSU.). If the grantee under this Scheme is a company or a discretionary trust, such grantee shall undertake to the Company that it will not permit any change of the ultimate beneficial ownership of such RSUs. Any breach of the foregoing shall entitle the Company to cancel any outstanding RSUs or any part thereof granted to such grantee.

For the avoidance of doubt, any holder of RSUs transferred pursuant to the terms of this Scheme shall be subject to the same terms and conditions of the offer to grant RSUs extended to the initial grantee.

(h) Lapse and Cancellation

Except as otherwise agreed to between the Company and a grantee, or as otherwise approved by the Board, an unvested RSU shall be lapsed and cancelled automatically upon the earliest of:

- (i) the expiry of the RSUs as may be determined by the Board which shall not be later than the last day of the Term relevant to that RSU;
- (ii) the date on which the grantee ceases to be an Eligible Participant for any reason including his/her resignation, ill-health, injury, disability, dismissal, or by reason of the termination of his/her relationship with the Group and/or any of the Invested Entities on any one or more of the following grounds:
 - (1) that he/she has been guilty of serious misconduct;

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- (2) that he/she has been convicted of any criminal offence involving his/her integrity or honesty or in relation to an employee of the Group and/or any of the Invested Entities;
 - (3) that he/she has become insolvent, bankrupt or has made arrangements or compositions with his/her creditors generally; or
 - (4) on any other ground as determined by the Board that would warrant the termination of his/her employment at common law or pursuant to any applicable laws or under the grantee's service contract with the Group or the relevant Invested Entity. A resolution of the Board or the board of directors of the relevant subsidiary of the Company or the relevant Invested Entity to the effect that the relationship of a grantee has or has not been terminated on one or more of the grounds specified in this paragraph shall be conclusive;
- (iii) the date on which the offer (or, as the case may be, revised offer) referred to in paragraph (e) closes;
 - (iv) the record date for determining entitlements under the scheme of arrangement referred to in paragraph (e);
 - (v) the date of the commencement of the winding-up of the Company;
 - (vi) the date on which the grantee commits a breach of paragraph (g);
 - (vii) the date on which it is no longer possible to satisfy any outstanding conditions to vesting.

Except as otherwise agreed to between the Company and a grantee, or as otherwise approved by the Board, RSUs that have been vested but not exercised by a grantee shall be lapsed and cancelled automatically after three months from the termination of his relationship with the Group and/or any of the Invested Entities.

Except for the conditions set forth in paragraph (g) above and this paragraph, the Board may at any time cancel any unvested RSUs granted to a grantee subject to consent by the grantee in writing. Where the Company cancels unvested RSUs and makes a grant of new RSUs to the same grantee, such grant may only be made with available RSUs to the extent not yet granted within the limits prescribed by paragraph (f) above.

(i) Reorganisation of Capital Structure

In the event of an alteration in the capital structure of the Company whilst any RSU has not vested by way of capitalization of profits or reserves, bonus issue, rights issue, open offer, subdivision or consolidation of shares, reduction of the share capital of the

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Company or otherwise howsoever in accordance with legal requirements and requirements of the Stock Exchange (other than an issue of Shares as consideration in respect of a transaction to which the Company or the subsidiary is a party or in connection with any share option, restricted share or other equity incentive schemes of the Group or in the event of any distribution of the Company's capital assets to the Shareholders on a pro rata basis (whether in cash or in specie) (other than dividends paid out of the net profits attributable to the Shareholders for each financial year of the Company), such corresponding alterations (if any) shall be made to the number or nominal amount of Shares subject to the RSU so far as unvested as the auditors or an approved independent financial adviser shall certify in writing, either generally or as regard any particular grantee, to have in their opinion, fairly and reasonably satisfied the requirement that such adjustments give an Eligible Participant the same proportion (or rights in respect of the same proportion) of the share capital of the Company as that to which that grantee was previously entitled, but that no such adjustments be made to the extent that a Share would be issued at less than its nominal value. The capacity of the auditors or the approved independent financial adviser in this paragraph is that of experts and not of arbitrators and their certification shall, in absence of manifest error, be final and binding on the Company and the grantees. The costs of the auditors or the approved independent financial adviser shall be borne by the Company.

(j) Share Capital

The unvested RSUs do not carry any right to vote at general meetings of the Company. No Eligible Participant shall enjoy any of the rights of a Shareholder by virtue of the grant of an Award pursuant to this Scheme, unless and until such Shares underlying the RSUs are actually issued or transferred (as the case may be) to the Eligible Participant upon the vesting of the RSUs and the Eligible Participant's name has been entered in the register of members of the Company as holder of such Shares. Unless otherwise specified by the Board in its entire discretion in the Notice of Grant, the Eligible Participants do not have any rights to any cash or non-cash income, dividends or distributions and/or the sale proceeds of non-cash and non-scrip distributions from any Shares underlying an Award.

(k) Alteration of the RSU Scheme

The terms and conditions of this scheme and the regulations for the administration and operation of this scheme (provided that the same are not inconsistent with this scheme and the Listing Rules) may be altered in any respect by resolution of the Shareholders except that:

- (i) any alteration to the advantage of the grantees or the eligible participants (as the case may be) in respect of the key terms of this scheme; or
- (ii) any material alteration to the terms and conditions of this Scheme (except any alterations which take effect automatically under the terms of this Scheme),

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must be made with the prior approval of the Shareholders in general meeting at which any persons to whom or for whose benefit the Shares may be issued under this Scheme and their respective associates shall abstain from voting provided that no alteration shall operate to affect adversely the terms of issue of any RSU granted or agreed to be granted prior to such alteration or to reduce the proportion of the equity capital to which any person was entitled pursuant to such RSUs prior to such alteration except with:

- (i) the consent in writing of grantees holding in aggregate RSUs which if vested in full on the date immediately preceding that on which such consent is obtained would entitle them to the issue of three-fourths in nominal value of all Shares which would fall to be issued upon the vesting of all RSUs outstanding on that date; or
- (ii) the sanction of a Special Resolution.

Written notice of any alterations made in accordance with this paragraph shall be given to all grantees.

In respect of any meeting of grantees referred to in paragraph above, all the provisions of Articles as to general meetings of the Company shall *mutatis mutandis* apply as though the RSUs were a class of shares forming part of the capital of the Company except that:

- (i) not less than seven days' notice of such meeting shall be given;
- (ii) a quorum at any such meeting shall be two grantees present in person or by proxy and holding RSUs entitling them to the issue of one-tenth in nominal value of all Shares which would fall to be issued upon the exercise of all RSUs then outstanding unless there is only one grantee holding all RSUs then outstanding, in which case the quorum shall be one grantee;
- (iii) every grantee present in person or by proxy at any such meeting shall be entitled on a show of hands to one vote, and on a poll, to one vote for each Share to which he/she would be entitled upon exercise in full of his/her RSUs then outstanding;
- (iv) any grantee present in person or by proxy may demand a poll; and
- (v) if any such meeting is adjourned for want of a quorum, such adjournment shall be to such date and time, not being less than seven or more than fourteen days thereafter, and to such place as may be appointed by the chairman of the meeting. At any adjourned meeting those grantees who are then present in person or by proxy shall form a quorum and at least seven days' notice of any adjourned meeting shall be given in the same manner as for an original meeting and such notice shall state that those grantees who are then present in person or by proxy shall form a quorum.

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(l) Termination of the RSU Scheme

The Shareholders or the Board may at any time resolve to terminate the operation of this scheme and in such event no further RSUs shall be offered but the provisions of this scheme shall remain in force to the extent necessary to give effect to the exercise of any RSU granted prior to the termination or otherwise as may be required in accordance with the provisions of this scheme and RSUs granted prior to such termination shall continue to be valid and exercisable in accordance with this scheme.

Details of the RSUs granted, including RSUs exercised or outstanding, under this scheme shall be disclosed in the circular to Shareholders seeking approval of the new scheme established after the termination of this scheme.

Outstanding RSUs

The overall limit on the number of underlying Shares to be granted under the RSU Scheme is [REDACTED] ([REDACTED]) as adjusted after the [REDACTED]) Shares. No additional Shares will be issued by the Company under the RSU Scheme in the [REDACTED].

As of the Latest Practicable Date, 65 grantees were granted with RSUs with a total of 6,595,628 ([REDACTED]) as adjusted after the [REDACTED]) underlying Shares under the RSU Scheme. The table below shows the details of RSUs granted to Directors that are outstanding as at the Latest Practicable Date. Director and connect person (under the definition of the Listing Rules) of the Company has been identified to be the grantees under the RSU Scheme prior to the [REDACTED].

Name	Position	Number of Shares underlying the outstanding RSUs as adjusted after the [REDACTED]	Date of grant	Approximate percentage of equity interest in the Company underlying the outstanding options^(note)
Mr. Joshua Liang	Executive Director and chief executive officer	[REDACTED]	April 18, 2021	[REDACTED]
Dr. Liang	Executive Director and chief scientific officer	[REDACTED]	April 18, 2021	[REDACTED]
Dr. Xiaodong Wang	Non-executive Director	[REDACTED]	October [●], 2021	[REDACTED]

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Name	Position	Number of Shares underlying the outstanding RSUs as adjusted after the [REDACTED]	Date of grant	Approximate percentage of equity interest in the Company underlying the outstanding options^(note)
Dr. Xiaobin Wu	Independent non-executive Director	[REDACTED]	October [●], 2021	[REDACTED]
Mr. Xiang Liao	Independent non-executive Director	[REDACTED]	October [●], 2021	[REDACTED]
Mr. Jeffrey Farrow	Independent non-executive Director	[REDACTED]	October [●], 2021	[REDACTED]
Mr. Thomas Leggett	Independent non-executive Director	[REDACTED]	October [●], 2021	[REDACTED]

Note: Based on the assumption that all Preferred Shares will automatically be converted into Shares on a 1:1 basis on the [REDACTED] and that the [REDACTED] is not exercised and without taking into account any Shares to be issued upon the exercise of share options granted under the Pre-[REDACTED] Share Option Plan.

3. Post-[REDACTED] Share Option Plan

The following is a summary of principal terms of the Post-[REDACTED] Share Option Plan conditionally approved by a resolution of the then shareholder of our Company passed on September 26, 2021 and adopted by a resolution of the Board on the same date (the “**Adoption Date**”). The terms of the Post-[REDACTED] Share Option Plan are in compliance with the provisions of Chapter 17 of the Listing Rules.

(a) Purpose

The purpose of the Post-[REDACTED] Share Option Plan is to provide incentive or reward to Eligible Persons (as defined below) for their contribution to, and continuing efforts to promote the interests of, the Group, and to incentivize them to remain with the Group, as well as for such other purposes as the Board may approve from time to time.

(b) Who May Join

Eligible persons (“**Eligible Persons**”) include:

- (i) any employee (whether full-time or part-time) of the Company or any of its subsidiaries who has contributed to the Group’s innovative projects, including but not limited to innovation committee member, project leader, engineer and technician;

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- (ii) any staff, advisor (professional or otherwise), consultant, agent or business partner that the Company deems important to provide support to the Group;
- (iii) any director (including executive, non-executive and independent non-executive directors) of the Group; and
- (iv) any shareholder or any member of the Group or any holder of any securities issued by any member of the Group.

The basis of eligibility of any of the above classes of Eligible Persons to the grant of any option under the Post-[REDACTED] Share Option Plan ("**Option**") shall be determined by the Board from time to time on the basis of their contribution to the development and growth of the Group.

(c) Duration of the Post-[REDACTED] Share Option Plan

The Post-[REDACTED] Share Option Plan shall be valid and effective for a period of 10 years commencing on the date on which it is adopted by ordinary resolution of the Shareholders in general meeting, after which period no further Options shall be granted. Subject to the above, in all other respects, in particular, in respect of Options remaining outstanding on the expiry of the 10-year period referred to in this paragraph, the provisions of the Post-[REDACTED] Share Option Plan shall remain in full force and effect.

(d) Maximum Number of Shares Available for Subscription

At the time of adoption by the Company of the Post-[REDACTED] Share Option Plan or any new share option scheme (the "**New Scheme**"), the aggregate number of Shares which may be issued upon exercise of all Options to be granted under the Post-[REDACTED] Share Option Plan, the New Scheme and all schemes existing at such time (the "**Existing Scheme(s)**") of the Company must not in aggregate exceed 10% of the total number of Shares in issue as of the date the Shares commence [REDACTED] on the Stock Exchange or the date of adoption of the New Scheme (as the case may be) (the "**Scheme Mandate Limit**"). For the purposes of calculating the Scheme Mandate Limit, Shares which are the subject matter of any Options that have already lapsed in accordance with the terms of the relevant Existing Scheme(s) shall not be counted. The Scheme Mandate Limit may be refreshed by ordinary resolution of the Shareholders in general meeting, provided that:

- (i) the Scheme Mandate Limit so refreshed shall not exceed 10% of the total number of Shares in issue as of the date of Shareholders' approval of the refreshing of the Scheme Mandate Limit;
- (ii) options previously granted under any Existing Scheme(s) (including options outstanding, cancelled, or lapsed in accordance with the rules of the Post-[REDACTED] Share Option Scheme (as amended from time to time) or exercised options) shall not be counted for the purpose of calculating the limit as refreshed; and

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- (iii) a circular regarding the proposed refreshing of the Scheme Mandate Limit has been dispatched to the Shareholders in a manner complying with, and containing the matters specified in, the relevant provisions of Chapter 17 of the Listing Rules in force from time to time. In accordance with the current Listing Rules, the circular must contain the information which comply with the relevant provisions of Chapter 17 of the Listing Rules in force from time to time.

The Company may seek separate approval from the Shareholders in the general meeting for granting Options which will result in the Scheme Mandate Limit being exceeded, provided that:

- (i) the grant is to Eligible Persons specifically identified by the Company before the approval is sought; and
- (ii) a circular regarding the grant has been dispatched to the Shareholders in a manner complying with, and containing the matters specified in, the relevant provisions of Chapter 17 of the Listing Rules in force from time to time. In accordance with the current Listing Rules, the circular must contain a generic description of the specified participants who may be granted such Options, the number and terms of the Options to be granted, the purpose of granting Options to the specified participants with an explanation as to how the terms of the Options serve such purpose and the other information which comply with the relevant provisions of Chapter 17 of the Listing Rules in force from time to time.

Notwithstanding the foregoing, the maximum aggregate number of Shares which may be issued upon exercise of all outstanding Options granted and yet to be exercised under the Post-[REDACTED] Share Option Plan and any other share option schemes of the Company, must not, in aggregate, exceed 30% of the total number of Shares in issue from time to time. No options may be granted under the Post-[REDACTED] Share Option Plan and any other share option schemes of the Company if this will result in such limit being exceeded.

(e) Maximum Entitlement of Each Eligible Person

No Option shall be granted to any Eligible Person (the "**Relevant Eligible Person**") if, at the relevant time of grant, the total number of Shares issued and to be issued upon exercise of all Options and options under any other share option schemes of the Company (including those options granted and proposed to be granted, whether exercised, canceled or outstanding) to the Relevant Eligible Person in the 12-month period up to and including the date of such grant would exceed 1% of the total number of Shares in issue at such time, within any 12-month period unless:

- (i) such grant has been duly approved, in the manner prescribed by the relevant provisions of Chapter 17 of the Listing Rules in force from time to time, by ordinary resolution of the Shareholders in general meeting, at which the Relevant Eligible Person and his close associates (or his associates if the Relevant Eligible Person is a Connected Person) abstained from voting;

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- (ii) a circular regarding the grant has been dispatched to the Shareholders in a manner complying with, and containing the information specified in, the relevant provisions of Chapter 17 of the Listing Rules in force from time to time. In accordance with the current Listing Rules, the circular must disclose the identity of the participant, the number and terms of the Options to be granted (and options previously granted to such participant under the Pre-[REDACTED] Share Option Plan, the Post-[REDACTED] Share Option Plan and any other share option schemes of our Company), the information required under Rule 17.02(2)(d) of the Listing Rules and the disclaimer required under Rule 17.02(4) of the Listing Rules; and
- (iii) the number and terms (including the Subscription Price (as defined below)) of such Options are fixed before the general meeting of the Company at which the same are approved and the date of Board meeting for proposing such further grant should be taken as the date of grant for the purpose of calculating the Subscription Price.

(f) Grant of Options

Each offer of an Option (the “**Offer**”) shall be in writing made to an Eligible Person by letter in such form as the Board may from time to time determine at its discretion (the “**Offer Letter**”). The Offer Letter shall state, among others, the period during which the Option may be exercised (the “**Option Period**”), which period is to be determined and notified by the Board but shall expire in any event not later than the last day of the 10-year period after the date of grant of the Option. The Board may specify in the Offer Letter any conditions which must be satisfied before the Option may be exercised, including without limitation such performance targets (if any) and minimum periods for which an Option must be held before it can be exercised and any other terms in relation to the exercise of the Option, including without limitation such percentages of the Options that can be exercised during a certain period of time, as the Board may determine from time to time.

The Board shall specify in the Offer Letter a date by which the grantee (“**Grantee**”) must accept the Offer or be deemed to have declined it, being a date no later than 14 days after (i) the date on which the Option is offered (the “**Offer Date**”), or (ii) the date on which the conditions for the Offer are satisfied, if any, whichever is earlier.

(g) Subscription Price

The price at which each Share subject to an Option may be subscribed for on the exercise of that Option (the “**Subscription Price**”) shall be a price solely determined by the Board and notified to an Eligible Person and shall be at least the highest of:

- (i) the closing price of the Shares as stated in the Stock Exchange’s daily quotations sheet on the Offer Date, which must be a Business Day;
- (ii) the average of the closing price of the Shares as stated in the Stock Exchange’s daily quotations sheets for the five Business Days immediately preceding the Offer Date; and

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(iii) the nominal value of the Shares.

(h) Grant of Options to Core Connected Persons

Where an Option is to be granted to a Director, chief executive or Substantial Shareholder of the Company, or any of their respective associates, the grant shall not be valid unless it has been approved by the independent non-executive Directors, excluding any independent non-executive Director who is also a proposed Grantee of the Option.

Where an Option is to be granted to a Substantial Shareholder (as defined in the Listing Rules) or an independent non-executive Director (or any of their respective associates), and the grant will, in the 12-month period up to and including the date of such grant, result in the number and value of the Shares issued and to be issued upon exercise of all options (granted and proposed to be granted, whether exercised, cancelled or outstanding) to the relevant Eligible Person exceeding the following:

- (i) 0.1% of the total number of Shares in issue at the relevant time of grant; and
- (ii) an aggregate value (based on the closing price of the Shares as stated in the daily quotations sheets issued by the Stock Exchange on the date of each grant) in excess of HK\$5 million or such other sum as may be from time to time provided under the Listing Rules,

such grant shall not be valid unless:

- (i) a circular containing the details of the grant has been dispatched to the Shareholders in a manner complying with, and containing the matters specified in, the relevant provisions of Chapter 17 of the Listing Rules in force from time to time. In accordance with the current Listing Rules, the circular must contain (1) details of the number and terms of the Options (including the Subscription Price and other information required under Rules 17.03(5) to 17.03(10)) to be granted to each participant, which must be fixed before the Shareholders' meeting, and the date of board meeting for proposing such further grant is to be taken as the date of grant for the purpose of calculating the Subscription Price; (2) a recommendation from the independent non-executive Directors (excluding independent non-executive Director who is also a proposed Grantee of the Options) to the independent Shareholders as to voting; (3) the information required under Rules 17.02(2)(c) and (d) and the disclaimer required under Rule 17.02(4); and (4) the information required under Rule 2.17; and
- (ii) the grant has been approved by the Shareholders in general meeting (taken on a poll), at which the proposed Grantee, his associate, and all core connected persons (has the meaning ascribed thereto under the Listing Rules) abstained from voting in favor.

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(i) Ranking of Shares

The Shares to be allotted and issued upon the exercise of an Option shall be subject to the Articles of Association and the laws of the Cayman Islands for the time being in force and shall rank *pari passu* in all respects with other fully-paid Shares in issue as of the date of allotment and will entitle the holders to the same rights of the holders of other fully-paid Shares in issue, including voting, dividend, transfer and any other rights. In particular, the Shares to be allotted and issued upon the exercise of an Option will entitle the holders to participate in all dividends or other distributions paid or made on or after the date of allotment other than any dividend or other distribution previously declared or recommended or resolved to be paid or made if the record date therefor shall be on or before the date of allotment and issue. The Option itself (before exercise) will not entitle the Grantee to any of aforementioned Shareholder's rights.

(j) Restrictions on the Time of Grant of Options

The grant of Options shall be subject to restrictions under the Listing Rules. No Offer shall be made after any inside information (as defined in the Listing Rules) has come to the knowledge of the Company, until such information has been announced by the Company pursuant to the requirements of the Listing Rules. In particular, during the period commencing one month immediately preceding the earlier of (1) the date of the meeting of the Board (as such date is first notified by the Company to the Stock Exchange in accordance with the Listing Rules) for the approval of the Company's results for any year, half-year, quarterly or any other interim period (whether or not required under the Listing Rules); and (2) the deadline for the Company to publish an announcement of its results for any year or half-year under the Listing Rules, or quarterly or any other interim period (whether or not required under the Listing Rules), and ending on the date of actual publication of the results announcement, no Option may be granted. The period during which no Option may be granted will cover any period of delay in the publication of results announcement.

(k) Rights on Ceasing to Be an Eligible Person

- (i) where the Grantee is a director or an employee of the Group and his/her employment ceases for any reason other than death or becoming permanently disabled as described in paragraph (iii) below, the Option may not be exercised after the date of such cessation, which date shall be his last actual working day with the Company or any subsidiary whether salary is paid in lieu of notice or not;
- (ii) where the Grantee is a director or an employee of the Group and the Board at its absolute discretion determines that he is unable to pay or to have no reasonable prospect of being able to pay his debts, or has become insolvent, or has made any arrangements or composition with his creditors generally or on which he has been convicted of any criminal offence involving his integrity or honesty, the Option granted to such Grantee may not be exercised on or after the date on which the Board has so determined;

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- (iii) where the Grantee of an outstanding Option dies or becomes permanently disabled before exercising the Option in full or at all, the Option may not be exercised after the date of his death or permanent disability. However, if the Board issues a written consent to his personal representatives after the date of his death or permanent disability, only the vested Option may be transferred to the personal representative as soon as practicable. For the avoidance of doubt, all vesting conditions previously imposed on such Option shall still apply; and
- (iv) if the Board at its absolute discretion determines that the Grantee (other than an employee of the Group) or his associate has committed any breach of any contract entered into between the Grantee or his associate on one part and the Group on the other part or that the Grantee has committed any act of bankruptcy or has become insolvent or is subject to any winding-up, liquidation or analogous proceedings or has made any arrangement or composition with his creditors generally, the Option granted to such Grantee may not be exercised on or after the date on which the Board has so determined.

(l) Rights on General Offer

If a general offer (whether by way of a take-over, share repurchase offer, scheme of arrangement or otherwise in like manner) is made to all the Shareholders (or all such Shareholders other than the offeror and/or any person controlled by the offeror and/or any person acting in association or concert with the offeror) and such offer, having been approved in accordance with applicable laws and regulatory requirements, becomes or is declared unconditional, all the Grantees and any Grantee (or his personal representatives) may by notice in writing to the Company within 21 days after such offer becoming or being declared unconditional exercise the Option to its full extent or to the extent specified in such notice.

(m) Rights on Compromise or Other Arrangement

Other than a general offer or a scheme of arrangement, if a compromise or arrangement between the Company and its Shareholders or creditors is proposed for the purposes of or in connection with a scheme for the reconstruction of the Company or its amalgamation with any other company or companies, the Company shall give notice thereof to the Grantee (together with a notice of the existence of the provisions of this paragraph) on the same date or soon after it dispatches the notice to each member or creditor of the Company summoning the meeting to consider such a compromise or arrangement, and thereupon the Grantee (or his personal representatives) may forthwith and until the expiry of the period commencing with such date and ending with the earlier of 2 months thereafter and the date on which such compromise or arrangement is sanctioned by the court of competent jurisdiction, exercise any of his Options in full or in part, but the aforesaid exercise of an Option shall be conditional upon such compromise or arrangement being sanctioned by the court of competent jurisdiction and becoming effective. Upon such compromise or arrangement becoming effective, all outstanding Options shall lapse except insofar as previously exercised under the Post-[REDACTED] Share Option Plan. The Company may require the Grantee (or his

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personal representatives) to transfer or otherwise deal with the Shares issued as a result of the exercise of Options in these circumstances so as to place the Grantee in the same position as nearly as would have been the case had such Shares been subject to such compromise or arrangement.

(n) Rights on Winding-up

In the event a notice is given by the Company to its Shareholders to convene a general meeting for the purposes of considering, and if thought fit, approving a resolution to voluntarily wind-up the Company other than for the purposes of a reconstruction, amalgamation or scheme of arrangement, the Company shall on the same date as or soon after it dispatches such notice to each member of the Company give notice thereof to all Grantees (together with a notice of the existence of the provisions of this paragraph) and thereupon, each Grantee (or his personal representatives) shall be entitled to exercise all or any of his Options at any time no later than four Business Days prior to the proposed general meeting of the Company by giving notice in writing to the Company, accompanied by a remittance for the full amount of the aggregate Subscription Price for the Shares in respect of which the notice is given whereupon the Company shall as soon as possible and, in any event, no later than one Business Day immediately prior to the date of the proposed general meeting referred to above, allot the relevant Shares to the Grantee credited as fully paid.

(o) Lapse of Option

The right to exercise an Option (to the extent not already exercised) shall terminate immediately upon the earliest of:

- (i) the expiry of the Option Period;
- (ii) the date referred to in paragraph (k)(i);
- (iii) the date referred to in paragraph (k)(ii);
- (iv) the expiry of the 60-day period referred to in paragraph (k)(iii);
- (v) the date referred to in paragraph (k)(iv);
- (vi) the expiry of the period referred to in paragraphs (l);
- (vii) subject to the compromise or arrangement becoming effective, the expiry of the period referred to in paragraph (m);
- (viii) subject to paragraph (n), the date of the commencement of the winding-up of the Company; or
- (ix) the non-fulfilment of any condition to the Post-[REDACTED] Share Option Plan on or before the date stated therein.

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The Company shall owe no liability to any Grantee for the lapse of any Option under this paragraph.

(p) Cancellation of Options Granted

The Board may cancel an Option granted but not exercised with the approval of the Grantee of such Option. For the avoidance of doubt, such approval is not required in the event any Option is cancelled pursuant to paragraph (r) below.

No Options may be granted to an Eligible Person in place of his cancelled Options unless there are available unissued Options (excluding the cancelled Options) within the Scheme Mandate Limit from time to time.

(q) Termination of the Post-[REDACTED] Share Option Plan

The Company, by ordinary resolution in general meeting, or the Board may at any time terminate the operation of the Post-[REDACTED] Share Option Plan and in such event no further Option will be offered but the provisions of the Post-[REDACTED] Share Option Plan shall remain in full force and effect in all other respects and Options granted prior to such termination shall continue to be valid and exercisable in accordance with the Post-[REDACTED] Share Option Plan.

(r) Transferability of Options

An Option shall be personal to the Grantee and shall not be assignable nor transferable, and no Grantee shall in any way sell, transfer, charge, mortgage, encumber or create any interest (legal or beneficial) in favor of any third party over or in relation to any Option. Any breach of the foregoing shall entitle the Board to cancel any outstanding Options or any part thereof granted to such Grantee.

(s) Effect of Alterations to Share Capital

In the event of any alteration to the capital structure of the Company whilst any Option remains exercisable, arising from capitalization issue, rights issue, consolidation, subdivision or reduction of the share capital of the Company in accordance with the legal requirements or requirements of the Stock Exchange, other than any alteration in the capital structure of the Company as a result of an issue of Shares as consideration in a transaction to which the Company is a party, adjustment (if any) shall be made to:

- (i) the number of Shares subject to the Option so far as unexercised; and/or
- (ii) the Subscription Price for the Shares subject to the Option so far as unexercised; and/or
- (iii) any combination thereof.

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In the event of any adjustment as described in this paragraph (s), the auditors of the Company (the “**Auditors**”) or the independent financial adviser to the Company (acting as expert not arbitrator) shall at the request of the Company certify in writing to the Board either generally or as regards any particular Grantee that the adjustments are in compliance with the requirements under the note to Rules 17.03(13) of the Listing Rules.

Any such adjustments must give a Grantee the same proportion of the equity capital of the Company as to which that Grantee was previously entitled, and any adjustments so made shall be in compliance with the Listing Rules and such applicable guidance and/or interpretation of the Listing Rules from time to time issued by the Stock Exchange (including, without limitation, the “Supplemental Guidance on Main Board Listing Rule 17.03(13) and the Notice immediately after the Rule” attached to the letter of the Stock Exchange dated September 5, 2005 to all issuers relating to share option scheme as well as the Frequently Asked Questions on Adjustments of the Exercise Price of Share Options issued on November 6, 2020) but no such alterations shall be made the effect of which would be to enable a Share to be issued at less than its nominal value.

The capacity of the Auditors or the independent financial adviser to the Company in this paragraph is that of experts and not of arbitrators and their certification shall, in the absence of manifest error, be final and binding on the Company and the Grantees. The costs of the Auditors or the independent financial adviser to the Company shall be borne by the Company.

Notice of such adjustment shall be given to the Grantees by the Company.

(t) Alteration of the Post-[REDACTED] Share Option Plan

The Post-[REDACTED] Share Option Plan may be altered in any respect by resolution of the Board except that the provisions of the Post-[REDACTED] Share Option Plan as to:

- (i) the definitions of “Eligible Person” and “Grantee”; and
- (ii) the provisions relating to the matters set out in Rule 17.03 of the Listing Rules,

shall not be altered to the advantage of Grantees except with the prior approval of the Shareholders in general meeting (with participants and their respective associates abstaining from voting). No such alterations shall operate to affect adversely the terms of issue of any Option granted or agreed to be granted prior to such alterations except with the consent or sanction in writing of such majority of the Grantees as would be required of the Shareholders under the Articles for the time being of the Company for a variation of the rights attached to the Shares.

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Any change to the authority of the Board in relation to any alterations to the terms of the Post-[REDACTED] Share Option Plan must be approved by the Shareholders in general meeting.

Any alterations to the provisions of the Post-[REDACTED] Share Option Plan which are of a material nature or any change to the terms of Options granted must be approved by the Shareholders in general meeting except where the alterations take effect automatically under the existing provisions of the Post-[REDACTED] Share Option Plan.

The amended terms of the Post-[REDACTED] Share Option Plan or the Options must comply with Chapter 17 of the Listing Rules.

E. OTHER INFORMATION

1. Estate Duty

Our Directors have been advised that no material liability for estate duty is likely to fall on our Company or any of our subsidiaries.

2. Litigation

As of the Latest Practicable Date, the Directors were not aware of any pending or threatened litigation, arbitration or administrative proceedings against us or our Directors which may have a material adverse impact on our business, financial condition or results of operations.

3. Joint Sponsors

The Joint Sponsors have made an application on our behalf to the Listing Committee for the [REDACTED] of, and permission to [REDACTED], the Shares in issue (including the Shares to be converted from the Preferred Shares), the Shares to be issued pursuant to the [REDACTED] and the [REDACTED] (including the additional Shares which may fall to be issued pursuant to exercise of the [REDACTED] (if any) and the share options granted under the Pre-[REDACTED] Share Option Plan. All necessary arrangements have been made to enable such Shares to be admitted into [REDACTED].

Each of the Joint Sponsors will be paid by our Company a fee of US\$500,000 to act as a sponsor to the Company in connection with the [REDACTED].

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

4. Qualifications and Consents of Experts

The following experts have each given and have not withdrawn their respective written consents to the issue of this document with copies of their reports, letters, opinions or summaries of opinions (as the case may be) and the references to their names included herein in the form and context in which they are respectively included.

Name	Qualification
Goldman Sachs (Asia) L.L.C.	Licensed corporation to conduct Type 1 (dealing in securities), Type 4 (advising on securities), Type 5 (advising on futures contracts), Type 6 (advising on corporate finance) and Type 9 (asset management) regulated activities as defined under the SFO
China International Capital Corporation Hong Kong Securities Limited	Licensed corporation to conduct Type 1 (dealing in securities), Type 2 (dealing in futures contracts), Type 4 (advising on securities), Type 5 (advising on futures contracts) and Type 6 (advising on corporate finance) regulated activities as defined under the SFO
Tian Yuan Law Firm	Legal adviser as to PRC law
Maples and Calder (Hong Kong) LLP	Legal adviser as to Cayman Islands laws
Ernst & Young	Certified public accountants Registered public interest entity auditor
Frost & Sullivan	Independent industry consultant

As of the Latest Practicable Date, none of the experts named above had any shareholding interest in our Company or any of our subsidiaries or the right (whether legally enforceable or not) to subscribe for or to nominate persons to subscribe for securities in any member of our Group.

5. Binding Effect

This document shall have the effect, if an application is made in pursuance hereof, of rendering all persons concerned bound by all the provisions (other than the penal provisions) of sections 44A and 44B of the Companies Ordinance so far as applicable.

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

6. No Material and Adverse Change

Our Directors confirm that, save as disclosed in the document, as far as they are aware, there had been no material adverse change in our financial, trading position or prospects since April 30, 2021, being the date of our consolidated statements as set out in “Appendix I – Accountants’ Report” of this document, up to the date of this document.

7. Bilingual Document

The English language and Chinese language versions of this document are being published separately in reliance upon the exemption provided by section 4 of Companies (Exemption of Companies and prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong).

8. Preliminary Expenses

The preliminary expenses of the Company were approximately RMB30,000.

9. Promoters

We have no promoter for the purpose of the Listing Rules. Save as disclosed in this document, within the two years immediately preceding the date of this document, no cash, securities or other benefit has been paid, allotted or given nor are any proposed to be paid, allotted or given to any promoters in connection with the [REDACTED] and the related transactions described in this document.

10. Disclaimers

- (a) Save as disclosed in this document:
- (i) within the two years immediately preceding the date of this document, neither we nor any of our subsidiaries has issued or agreed to issue any share or loan capital fully or partly paid up either for cash or for a consideration other than cash;
 - (ii) no share or loan capital of our Company or any of our subsidiaries is under option or is agreed conditionally or unconditionally to be put under option;
 - (iii) within the two years immediately preceding the date of this document, no commissions, discounts, brokerage or other special terms have been granted in connection with the issue or sale of any shares or loan capital of any member of the Group;

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

- (iv) within the two years immediately preceding the date of this document, no commission has been paid or payable to any persons for subscription, agreeing to subscribe, procuring subscription or agreeing to procure subscription of any shares of the Company or any of its subsidiaries;
 - (v) no founder, management or deferred shares of the Company or any of its subsidiaries have been issued or agreed to be issued;
 - (vi) the Company has no outstanding convertible debt securities or debentures;
 - (vii) there is no arrangement under which future dividends are waived or agreed to be waived or is agreed conditionally or unconditionally to be put under option; and
 - (viii) there has not been any interruption in the business of the Group which may have or have had a significant effect on the financial position of the Group in the 12 months immediately preceding the date of this document.
- (b) The principal register of members of our Company will be maintained by our [REDACTED], in the Cayman Islands and our Hong Kong register of members will be maintained by our [REDACTED], in Hong Kong. Unless the Directors otherwise agree, all transfer and other documents of title of Shares must be lodged for registration with and registered by our [REDACTED] and may not be lodged in the Cayman Islands.
- (c) No company within the Group is presently listed on any stock exchange or traded on any trading system and no listing or permission to deal is being or is proposed to be sought.

**APPENDIX V DOCUMENTS DELIVERED TO THE REGISTRAR OF
COMPANIES AND ON DISPLAY**

DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES IN HONG KONG

The documents attached to the copy of this document and delivered to the Registrar of Companies in Hong Kong for registration were:

- (a) a copy of the [REDACTED];
- (b) the written consents referred to in the section headed “Statutory and General Information – E. Other Information – 4. Qualifications and Consents of Experts” in Appendix IV to this document; and
- (c) a copy of each of the material contracts referred to in the section headed “Statutory and General Information – B. Further Information about our business – 1. Summary of material contracts” in Appendix IV to this document.

DOCUMENTS ON DISPLAY

Copies of the following documents will be published on the Stock Exchange’s website at www.hkexnews.hk and our Company’s website at <https://www.cloverbiopharma.com>:

- (a) the Memorandum of Association and the Articles of the Company;
- (b) the Accountants’ Report and the report on the unaudited pro forma financial information of our Group prepared by Ernst & Young, the texts of which are set out in Appendix I and II to this document, respectively;
- (c) the audited financial statements of the companies comprising our Group for the years ended December 31, 2019 and 2020 and the four months ended April 30, 2021;
- (d) the legal opinion issued by Tian Yuan Law Firm, our PRC Legal Adviser in respect of general matters and property interests of our Group in the PRC;
- (e) the letter of advice from Maples and Calder (Hong Kong) LLP, our legal advisor as to the law of the Cayman Islands, summarizing certain aspects of the Cayman Islands company law referred to in Appendix III to this document;
- (f) the industry report prepared by Frost & Sullivan;
- (g) the material contracts referred to in the section entitled “B. Further Information about Our Business – 1. Summary of Material Contracts” in Appendix IV to this document;

**APPENDIX V DOCUMENTS DELIVERED TO THE REGISTRAR OF
COMPANIES AND ON DISPLAY**

- (h) the written consents referred to in the section entitled "E. Other Information – 4. Qualifications and Consents of Experts" in Appendix IV to this document;
- (i) the service contracts or letters of appointment referred to in the section headed "C. Further Information about Our Directors – 1. Particulars of Directors' Service Contracts" in Appendix IV to this document;
- (j) the Cayman Companies Act;
- (k) the terms of the Pre-[REDACTED] Share Option Plan and a list of grantees under the Pre-[REDACTED] Share Option Plan, containing all details as required under the Listing Rules and the Companies (Winding Up and Miscellaneous Provisions) Ordinance;
- (l) the terms of the RSU Scheme; and
- (m) the terms of the Post-[REDACTED] Share Option Plan.