
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM F-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

I-MAB

(Exact name of Registrant as specified in its charter)

Not Applicable

(Translation of Registrant's name into English)

Cayman Islands
(State or other jurisdiction of
incorporation or organization)

2834
(Primary Standard Industrial
Classification Code Number)

Not Applicable
(I.R.S. Employer
Identification No.)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933. Emerging growth company.

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 7(a)(2)(B) of the Securities Act.

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price(2)(3)	Amount of registration fee
Ordinary shares, par value US\$0.0001 per share(1)	US\$	US\$
(1) American depository shares issuable upon deposit of ordinary shares registered hereby will be registered under a separate registration statement on Form F-6 (Registration No. 333-). Each American depository share represents ordinary shares.		
(2) Includes ordinary shares that are issuable upon the exercise of the underwriters' over-allotment option. Also includes ordinary shares initially offered and sold outside the United States that may be resold from time to time in the United States either as part of their distribution or within 40 days after the later of the effective date of this registration statement and the date the shares are first bona fide offered to the public. These ordinary shares are not being registered for the purpose of sales outside the United States.		
(3) Estimated solely for the purpose of determining the amount of registration fee in accordance with Rule 457(o) under the Securities Act of 1933.		

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and we are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion. Dated _____, 2019.

American Depositary Shares

[LOGO]

I-MAB

Representing Ordinary Shares

This is an initial public offering of _____ American depositary shares (the “ADSs”), by I-Mab. Each ADS represents _____ of our ordinary shares, par value US\$0.0001 per share.

Prior to this offering, there has been no public market for the ADSs or our shares. We anticipate that the initial public offering price will be between US\$ _____ and US\$ _____ per ADS. We intend to apply to list the ADSs on [the Nasdaq Global Market] under the symbol “IMAB.”

We are an “emerging growth company” under applicable U.S. federal securities laws and are eligible for reduced public company reporting requirements.

Investing in our ADSs involves risks. See “[Risk Factors](#)” beginning on page 16 for factors you should consider before buying the ADSs.

Neither the United States Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

PRICE US\$ PER ADS

	Per ADS	Total
Initial public offering price	US\$ _____	US\$ _____
Underwriting discounts and commissions	US\$ _____	US\$ _____
Proceeds, before expenses, to us	US\$ _____	US\$ _____

(1) For a description of compensation payable to the underwriters, see “Underwriting.”

We have granted the underwriters an option to purchase up to an additional _____ ADSs within 30 days from the date of this prospectus at the initial public offering price, less the underwriting discounts and commissions.

The underwriters expect to deliver the ADSs against payment in U.S. dollars in New York, New York on or about _____, 2019.

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Prospectus dated _____, 2019.

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You should rely only on the information contained in this prospectus or in any related free writing prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus or in any related free writing prospectus. We are offering to sell, and seeking offers to buy the ADSs, only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of the ADSs.

Neither we have nor any of the underwriters has taken any action to permit a public offering of the ADSs outside the United States or to permit the possession or distribution of this prospectus or any filed free writing prospectus outside the United States. Persons outside the United States who come into possession of this prospectus or any filed free writing prospectus must inform themselves about and observe any restrictions relating to the offering of the ADSs and the distribution of this prospectus or any filed free writing prospectus outside the United States.

Until _____, 2019 (the 25th day after the date of this prospectus), all dealers that buy, sell or trade ADSs, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

PROSPECTUS SUMMARY

The following summary is qualified in its entirety by, and should be read in conjunction with, the more detailed information and financial statements appearing elsewhere in this prospectus. In addition to this summary, we urge you to read the entire prospectus carefully, especially the risks of investing in our ADSs discussed under “Risk Factors,” before deciding whether to invest in our ADSs. This prospectus contains information from an industry report commissioned by us and prepared by Frost & Sullivan, an independent research firm, to provide information regarding our industry and our market position. We refer to this report as the Frost & Sullivan Report.

Overview

We are a clinical stage biopharmaceutical company committed to the discovery, development and commercialization of first-in-class and best-in-class biologics to treat diseases with significant unmet medical needs, particularly cancers and autoimmune disorders. Our mission is to bring transformational medicines to patients through innovation.

We were founded to capture the opportunities presented by the confluence of two major developments—the emergence of an attractive and growing biologics market in China, and the revolutionary scientific breakthroughs in cancer and autoimmune disease medicines. We believe we are well-positioned to become a biotech leader in China because of our innovative discovery expertise, fit-for-purpose technology platforms, biomarker-enabled translational medicine capabilities, and clinical development capabilities. These integrated capabilities are further enhanced by our deep understanding of China’s biologics regulatory framework and our direct access to extensive pre-clinical and clinical trial resources in China. To date, we have developed an innovative pipeline of more than 10 clinical and pre-clinical stage assets through our internal research and development efforts and in-licensing arrangements with global pharmaceutical and biotech companies.

Commercial Opportunities in China and Our Unique Position

We see vast commercial opportunities for immuno-oncology and autoimmune biologics therapies in China. First, both the incidence and mortality of cancers in China have been increasing in recent years and are outpacing those in the United States and the rest of the world. Second, many innovative biologics approved to treat cancer and autoimmune diseases in the United States and Europe are not yet available in China. Third, the Chinese government has implemented new policies and regulations to simplify the review and approval cycle of clinical trials and new drug applications to encourage biologics innovation. Fourth, there has been a continuous and rapid increase in personal disposable income in China coupled with ongoing improvement in basic national health insurance coverage, making innovative biologics more accessible to more Chinese patients. According to the Frost & Sullivan Report, China’s biologics market is growing faster than the global biologics market and is expected to reach approximately RMB1.3 trillion (US\$189.1 billion) by 2030 in terms of sales revenue.

We believe we are uniquely positioned as a China-based global player to tap into these vast commercial opportunities. This is best demonstrated by our short journey in becoming one of the top clinical stage innovative biotech companies in China. Through December 31, 2018, we had raised approximately US\$330 million of cash in equity financing from our dedicated group of investors, including leading healthcare-focused funds. To date, our research and development capabilities encompass discovery, biologics CMC development, pre-clinical development and clinical development with footprints in Shanghai, Beijing and the United States. We are now at a critical juncture to transition from a clinical stage biotech company into a fully integrated end-to-end global biopharmaceutical company in the next few years.

Our Unique Business Model

To achieve our mission and capitalize on these commercial opportunities, we have developed a business model built on two pillars: a fast-to-market China approach and a fast-to-PoC (proof of concept) global approach.

Fast-to-Market China Approach

Our fast-to-market China approach focuses on seeking opportunities to in-license the development and commercialization rights of investigational drugs from global biopharmaceutical companies for Greater China. We only select investigational drugs with favorable clinical safety and preliminary efficacy data that have the potential to become first-in-class and best-in-class medicines. Through our substantial in-house research and development efforts, we build additional data packages to meet the requirements of the National Medical Products Administration (the “NMPA”) to ensure programs are ready for late-stage or registrational clinical development. Our internal development capabilities combined with our deep insight into China’s regulatory framework and our clinical network enable us to efficiently navigate through the drug development process to registration. To date, we have built an innovative China Portfolio consisting of five investigational drugs with an aim for near-term product launch. All of these investigational drugs have passed Phase 1 or Phase 2 clinical trials with favorable safety and preliminary efficacy data in Europe, the United States or elsewhere and are either in or ready for Phase 2 or Phase 3 clinical trials in China. TJ202 is undergoing two registrational trials, a monotherapy trial and a combination therapy trial in relapsed or refractory multiple myeloma in Greater China, and we will soon initiate a Phase 1b trial in systemic lupus erythematosus (“SLE”). For TJ101, we expect to submit an investigational new drug (“IND”) for a Phase 3 registrational trial in China by early 2020. For enoblituzumab, we expect to initiate either a registrational trial (pending the NMPA’s regulatory approval) or a Phase 2 trial in mid-2020. As a result, the investigational drugs in our China Portfolio are positioned for a series of new drug applications (NDAs) in China with the submission of the first NDA expected in 2021.

Fast-to-PoC Global Approach

Our fast-to-PoC global approach focuses on advancing our own novel or differentiated biologics towards clinical validation in the United States. First, we seek PoC of these drug candidates in the United States, leveraging the FDA’s streamlined regulatory system for innovative drug discovery, including a predictable timeline towards approval. Second, after validating clinical safety and preliminary efficacy, we will use the data generated to advance clinical development in China, which we believe confers several advantages, including access to China’s large patient pool, extensive clinical trial resources through collaborations with leading hospitals in China, and a regulatory pathway for fast-track approval of drugs supported by solid overseas clinical data. Building on this approach, we typically out-license the global rights (excluding Greater China) of these investigational drugs following clinical validation in the United States, while retaining the Greater China rights for further development and commercialization. We believe this approach will allow Chinese patients to benefit from our most advanced treatments concurrently or soon after their market approvals elsewhere. To date, we have created a Global Portfolio that consists of two molecular classes—monoclonal antibodies and bi-specific antibodies, which are internally generated. They are highly innovative molecules compared to global competitor assets in the same or related classes of drug candidates. Three investigational drugs in our Global Portfolio (TJM2, TJC4 and TJD5) are in Phase 1 trials in the United States.

These two approaches and the resulting two portfolios complement each other and enable us to achieve a balance among our ambition to develop the first-in-class and best-in-class drugs, our goal to efficiently advance our pipeline assets towards commercialization and the inherent development risks.

Our Capabilities

Our Innovative Discovery Expertise

Built by an elite group of seasoned immunologists with extensive academic research and drug development experience, our discovery engine has generated a panel of internally developed innovative drug molecules in a short span of four years. Among them, 11 innovative drug molecules have met our standard of first-in-class or best-in-class and have advanced toward further development. This achievement is a testament to our discovery team's acumen and technical prowess in translating target biology into points of innovation or differentiation.

The discovery of TJC4 showcases our innovative research capabilities. Not settling on performing routine or traditional antibody screening, we set a specific goal to identify and select a unique CD47 antibody that is free from binding to red blood cells (RBC) among all CD47 antibody leads that naturally bind to RBCs. As a result, we selected by design, our proprietary CD47 antibody (TJC4), a rare epitope that uniquely spares binding to RBCs as a differentiation point from other CD47 antibodies that typically cause inherent hematologic side effects. TJC4 has been validated in a series of in vitro assays as well as multiple monkey studies for its unique differentiation and is in a Phase 1 clinical trial in the United States.

Another example of our R&D capability relates to our novel bi-specific antibody panel that represents a new wave of oncology drug candidates. We created novel biological properties of these bi-specific antibodies that are capable of enriching immune cells in tumors through dual targeting of PD-L1 and immune cells for a synergistic anti-tumor effect. These bi-specific drug candidates have been shown to exhibit unique properties that render tumors more responsive to treatment. Our discovery expertise, when combined with our "fit-for-purpose" antibody engineering technology platforms, becomes a powerful engine of innovation to create novel molecules of first-in-class and best-in-class potential.

Our Fit-for-Purpose Technology Platforms

Our proprietary antibody engineering platforms enable us to accurately capture the biological properties of bi-specific antibodies and retain good manufacturability and druggability of the molecules. To date, we have created seven novel pre-clinical stage bi-specific drug molecules. In addition to our own Ig-scFv bi-specific antibody platform, we partnered with ABL Bio and WuXi Biologics to access their antibody engineering platforms in order to increase the probability of success, as different molecular configurations require different technologies. Furthermore, our proprietary antibody-cytokine technology has enabled another form of bi-specific antibodies such as TJ-L117 and TJ-C4GM that link a tumor-engaging antibody with an immuno-modulatory cytokine. Superior to monoclonal antibodies or cytokines alone, this class of bi-specific antibodies has demonstrated unique properties capable of concentrating the drug molecules in tumors for a desired target effect with reduced systemic toxicity of cytokines or creating biologic synergy that can potentially translate into better treatment efficacy and clinical safety.

Our Biomarker-Enabled Translational Medicine Capabilities

As we focus on developing innovative drug molecules, the ability to apply relevant biomarkers that link a drug response to treatment efficacy is critical for early-stage clinical trials of our investigational drugs. This translational medicine capability requires cross-functional knowledge and unique skills to link the target biology of an investigational drug to clinical responses. We have been developing tailor-made biomarkers for each of our investigational drugs, which are used to select potential responders, predict and measure target engagement, support dose determination and enable timely informed decisions on advancing our assets to the next phase of clinical development. For example, for the development of TJD5, we intend to use CD73 in tumor tissue in combination with other tumor biomarkers to stratify potential target patient populations in our clinical trial.

that end, we have developed assays to measure CD73 expression and activity in tumor tissues. Furthermore, we have developed specialized assays to measure TJD5 drug concentrations in tumor tissues. By linking drug concentration with its activity in the same tumor location, these data help us determine appropriate dose selection for further efficacy studies.

Our Clinical Development Capabilities

Our clinical development capabilities are highlighted by a global team of clinical scientists, industry physicians, data management specialists, biostatisticians, clinical operation staff and drug safety experts. Our clinical team accounts for approximately 80% of our entire R&D organization's headcount and 80% of our budget allocation. The skillset of our clinical development team is highlighted by a combination of extensive global pharma experience, local drug development and operational experience with clinical networks in China and the United States. The team is driven by high ethical standards, clinical science and passion for improving the lives of patients.

Our clinical development capabilities are also highlighted by our ability to integrate internal core development functions, which encompass regulatory affairs, translational medicine, clinical research and operations, data management, biostatistics, clinical safety and pharmacovigilance, portfolio and project management, and global drug supplies. We also effectively leverage external resources, including clinical contract research organizations, academic clinical centers and/or networks, and global pharmaceutical or biotech partnerships. Furthermore, we have established and implemented a robust internal clinical governance system to safeguard patient safety and data reporting. Our current clinical development capabilities are strategically based in Shanghai, Beijing, and the United States to cover Phase 1 through Phase 3 clinical trials in China and early-stage clinical trials in the United States.

Our clinical development capabilities are best demonstrated by our rapid implementation of seven ongoing clinical trials, including four Phase 1/2 and registrational trials in Greater China and three Phase 1 trials in the United States within the past three years. To ensure regulatory approval and subsequent product launch as currently planned, we strive to reach the following critical clinical milestones by the end of 2020—ten active clinical programs consisting of six registrational and Phase 1/2 trials in China and four active clinical programs in the United States.

Our Global Strategic Collaborations

We have established an excellent track record of in-licensing and out-licensing deals with our global and regional partners. These in-licensing deals enable us to acquire multiple innovative clinical stage assets of first-in-class and best-in-class potential with favorable clinical safety and early efficacy data. We have quickly built our China Portfolio through in-licensing deals with global biotech partners, including MorphoSys, Genexine, MacroGenics and Ferring. In that respect, we are often regarded as an ideal China partner because of our strong development capabilities and proven track record. The out-licensing deals enable us to streamline our pipeline and focus our resources on the most valuable assets. In addition, we seek co-development opportunities to share development costs and risks and territorial commercial rights with our partners. In the past two years, we have out-licensed three de-prioritized assets and initiated four co-development programs with partners such as ABL Bio, Everest Medicines and WuXi Biologics. The revenue from out-licensing and co-development deals is expected to continue to grow as our pipeline progresses.

Our Drug Pipeline

The chart below summarizes the development status of our drug pipeline.

	Drug Candidate (Licensor)	Indication / Therapeutic Area	Commercial rights	Preclinical	Phase 1	Phase 2	Phase 3	Expected NDA / BLA filing
China Portfolio	TJ202 (MorphoSys) Differentiated CD38 antibody	Multiple myeloma / Autoimmune disease	Greater China Myeloma shared	[Progress bar]			★	2021-2024
	Eftansomatropin TJ101 (Genexine) Long-acting growth hormone	Pediatric growth hormone deficiency	Greater China	[Progress bar]			★	
	Olimkicept TJ301 (Ferring) Soluble gp130 IL-6 inhibitor	Ulcerative colitis / Autoimmune disease	Greater China S. Korea	[Progress bar]				
	Enoblituzumab (MacroGenics) B7-H3 antibody	Head and neck cancer / Oncology	Greater China	[Progress bar]			★	
	Eflinaptakin TJ107 (Genexine) Novel long-acting IL-7	Oncology-related lymphopenia	Greater China	[Progress bar]				
Global Portfolio	TJM2 GM-CSF antibody	Autoimmune disease/ Cytokine release syndrome	Global	[Progress bar]				2024-
	TJC4 Differentiated CD47 antibody	Multiple cancer Indications	Global	[Progress bar]				
	TJD5 Differentiated CD73 antibody	Multiple cancer Indications	Global	[Progress bar]				
	TJ210 (MorphoSys) Differentiated C5aR antibody	Oncology / Auto-Immune disease	Greater China Global Shared	[Progress bar]				
	TJX7 Novel CXCL13 antibody	Autoimmune disease	Global	[Progress bar]				
	Bi-specific antibody panel * Including five PD-L1-based bi-specifics, TJ-C4GM and TJ-CLDN4B	Multiple cancer Indications	Global Some shared	[Progress bar]				

Notes:

- é (i) TJ202 has two ongoing registrational trials, a monotherapy trial and a combination therapy trial in relapsed or refractory multiple myeloma in Greater China, and we will soon initiate a Phase 1b trial in systemic lupus erythematosus (“SLE”); (ii) for TJ101, we expect to submit an IND for a Phase 3 registrational trial in China by early 2020; and (iii) for enoblituzumab, we expect to initiate either a registrational trial (pending the NMPA’s regulatory approval) or a Phase 2 trial in mid-2020.
- * Our bi-specific antibody panel consists of (i) five PD-L1-based bi-specific antibodies, including TJ-L1C4 (PD-L1 and CD47), TJ-L1D5 (PD-L1 and CD73), TJ-L1H3 (PD-L1 and B7-H3), TJ-L14B (PD-L1 and 4-1BB) and TJ-L117 (anti-PD-L1 and IL-7 cytokine fusion), (ii) TJ-C4GM (anti-CD47 and GM-CSF cytokine fusion), and (iii) TJ-CLDN4B (Claudin 18.2 and 4-1BB).

Highlights of Our Fast-to-Market China Portfolio

Our fast-to-market China approach is demonstrated by our China Portfolio, which consists of first-in-class and best-in-class investigational drugs with favorable clinical safety and preliminary efficacy data. TJ202, TJ107, enoblituzumab and TJ101 are the four anchor assets in our China Portfolio.

TJ202 is a differentiated CD38 antibody originally developed by MorphoSys with good clinical safety and efficacy data from a clinical trial conducted in the European Union (EU). In-licensed from MorphoSys, TJ202 is being developed to address the current unmet needs and commercial opportunities in China for multiple myeloma and potentially autoimmune diseases, such as SLE. We own an exclusive license to develop TJ202 in Greater China. We believe TJ202 is potentially best-in-class compared with the currently marketed CD38 antibody. First, under a similar pre-medication condition with dexamethasone, anti-pyretics and anti-histamines, TJ202 has demonstrated a significantly shorter infusion time and lower infusion reaction rate. Second, unlike the currently marketed CD38 antibody, TJ202 does not down-regulate CD38 expression on the surface of bone marrow myeloma cells in vitro, maintaining sensitivity of myeloma cells to TJ202 for repeated treatments. We have entered into a collaboration arrangement with Everest, under which we and Everest will share development costs and commercial rights of TJ202 in multiple myeloma in Greater China, while we retain full rights for all

other indications. TJ202 is undergoing a Phase 2 registrational trial as a third-line monotherapy and a Phase 3 trial in combination with lenalidomide as a second-line therapy, both in patients with relapsed/refractory multiple myeloma in Greater China. We aim to submit an NDA for TJ202 as a monotherapy in 2021, followed by another NDA submission for TJ202 as a combination therapy. Moreover, we believe TJ202 has great market potential in the treatment of pathogenic antibody-mediated autoimmune diseases, such as SLE, where there is a significant unmet need for more effective therapies. An IND application for a trial in SLE is expected to be submitted in the fourth quarter of 2019.

TJ107 is a long-acting IL-7 known to boost cancer-fighting T lymphocytes by increasing their number and function and is being developed as a potential first-in-class oncology investigational drug. The clinical safety and effect of TJ107 on T cells have been demonstrated in multiple previous and ongoing clinical trials in South Korea and the United States. TJ107 is being positioned to address a huge unmet medical need in oncology. First, TJ107 can be an oncology-care agent to treat cancer treatment-related lymphopenia (low blood lymphocyte levels), a common condition that occurs in cancer patients who have received chemotherapy or radiation therapy, and there is no approved treatment for this condition. According to the Frost & Sullivan Report, in Greater China, the incidence of lymphopenia reached 1.5 million in 2018 and is estimated to increase to 1.7 million in 2023 and further to 2.0 million in 2030. This condition causes further damage to patients' already compromised immune system and weakens its ability to fight cancers. Second, TJ107 has been shown to synergize with a PD-1 antibody in a tumor animal model potentially through increased T lymphocyte activation and proliferation. We are conducting a Phase 1b trial in China to determine a suitable dose range for a Phase 2 trial in combination with PD-1 antibody. We are coordinating our study globally with Genexine, which is conducting a Phase 2 clinical trial in South Korea and parallel clinical trials in the United States towards clinical PoC.

Enoblituzumab is a humanized antibody directed at B7-H3, a member of the B7 family of T cell checkpoint regulators that is widely expressed across multiple tumor types and plays a key role in the regulation of immune response against cancers. Similar to other inhibitors of the B7 family such as PD-L1, targeting B7-H3 potentially provides a treatment option for a variety of cancers expressing B7-H3. Enoblituzumab was originally developed by MacroGenics, and we own the Greater China rights of this product. In multiple clinical trials conducted by MacroGenics, enoblituzumab has shown a favorable safety profile and preliminary clinical efficacy when combined with pembrolizumab in recurrent or metastatic squamous cell carcinoma of the head and neck ("SCCHN") and non-small cell lung cancer ("NSCLC"). We plan to conduct a registrational trial (if approved by the NMPA) in China in patients with recurrent or metastatic SCCHN. Further clinical development is being planned together with MacroGenics to extend to other cancer indications in China and globally.

TJ101 is a potential best-in-class long-acting human growth hormone that is being developed as a weekly treatment for pediatric growth hormone deficiency as compared to currently available daily regimens of recombinant human growth hormone (rhGH). TJ101 was originally developed by Genexine, and we own the Greater China rights of this product, which has the potential to address an important clinical need and to cover a significant market gap in pediatric growth hormone deficiency. According to the Frost & Sullivan Report, there are approximately 3.4 million pediatric patients with growth hormone deficiency in China, but only 3.7% of them receive growth hormone therapies, which are mostly daily regimens. In a previous Phase 2 trial conducted by Genexine in South Korea and the EU, both weekly and bi-weekly administration of TJ101 demonstrated similar efficacy to daily injection of Genotropin, a short-acting rhGH. We expect to submit an IND for a Phase 3 registrational trial in China by early 2020.

Highlights of Our Fast-to-PoC Global Portfolio

Our fast-to-PoC global approach is demonstrated by our Global Portfolio, which mainly consists of our internally developed novel or differentiated biologics with first-in-class and best-in-class potential. Our Global Portfolio focuses on two molecular classes—monoclonal antibodies and bi-specific antibodies.

Monoclonal antibodies—Among the five monoclonal antibody drug candidates, TJM2, TJC4 and TJD5 are undergoing Phase 1 clinical trials in the United States. TJ210 and TJX7 are at the CMC stage and are expected to be ready for IND submissions and subsequent Phase 1 clinical trials in 2020 in the United States. These monoclonal antibody drug candidates have either first-in-class potential or best-in-class potential, consistent with our strategy.

TJC4 is an internally discovered, fully human monoclonal antibody targeting CD47, which is one of the most promising immuno-oncology targets after PD-1/PD-L1. Blocking CD47 activates tumor-engulfing macrophages, a component of the innate immune system as an important cancer-fighting mechanism. CD47 antibodies are being actively pursued in clinical trials by a few global companies and have shown some preliminary clinical efficacy. However, current development efforts on CD47 antibody drugs are hampered by hematologic side effects (such as anemia) due to their inherent binding to human RBCs. For example, at least two clinical trials conducted by other companies have been suspended. Unlike competitor investigational drugs, TJC4 is a rare antibody originally selected, by design, to purposefully avoid or minimize inherent binding to RBCs while maintaining a high antibody affinity and tumor killing properties. TJC4's unique property of minimal RBC binding and no significant hematologic changes has been extensively validated in a whole series of robust in vitro assays and primate studies. In a GLP toxicology study involving 40 monkeys, no hematologic side-effects were seen even with repeated injections of 100 mg/kg doses. This unique property potentially enables TJC4 to be used safely at an efficacious dose range to explore its treatment efficacy in cancers, differentiating it from other clinical stage CD47 investigational antibody drugs. TJC4 is being evaluated in a Phase 1 clinical trial with cancer patients in the United States, and no anemia has been observed in the first cohort of patients so far. In parallel, leveraging the Phase 1 data generated in the United States, we plan to begin a Phase 1 clinical trial of TJC4 in AML patients by the end of 2019 in China, followed by a separate clinical trial in NHL patients in China.

Bi-specific antibody panel—This novel antibody class represents an emerging and fast-moving area of new drug discovery. Bi-specific antibodies are typically constructed to have a dual specificity of two selected antibodies or combined properties of an antibody linked with a cytokine, previously called an immuno-cytokine. According to the Frost & Sullivan Report, checkpoint inhibitors targeting PD-1/PD-L1 had global sales of more than US\$16.0 billion in 2018 and are predicted to reach more than US\$63.0 billion in global sales by 2030. However, despite the recent success of checkpoint inhibitors, clinical efficacy of these drugs has been unsatisfactory. It is estimated that over 60% of cancer patients, including those with melanoma, renal cell cancer, colorectal cancer, non-small cell lung cancer, urothelial cancer and head and neck squamous cell carcinoma, do not respond to single-agent therapy with checkpoint inhibitors. In addition, some patients develop resistance after initial treatment with these therapies. As a result, the standard of care today leaves many cancer patients underserved. There is consensus among cancer immunologists that tumors that do not respond to PD-1/PD-L1 treatment have poor immunologic features, such as an absence or paucity of tumor-fighting immune cells or the presence of dysfunctional immune cells within the tumors, collectively known as “cold tumors.” We believe that PD-1/PD-L1 non-responders can be better treated with novel bi-specific antibodies. The unique and superior properties of these bi-specific antibodies over PD-L1 inhibitors alone stem from a second targeting component attached to the PD-L1 antibody moiety of the bi-specific molecules, thereby enabling them to elicit a sufficient immune response and converting a “cold tumor” to an immune-active “hot tumor.” Such unique properties of bi-specific antibodies cannot be substituted by a combination of the PD-L1 antibody with a selected second component (either cytokine or antibody) in a free form. The underlying mechanism is such that the second component must be structurally integrated with the tumor-engaging PD-L1 antibody in order to concentrate and function inside the tumor, which cannot be readily achieved by the two free agents used in combination.

We have successfully generated a panel of five bi-specific antibodies in which our proprietary PD-L1 antibody acts as the backbone (the first signal) and is linked with various second components (the second signal) including a 4-1BB agonist antibody (TJ-L14B), a B7-H3 antibody (TJ-L1H3), a CD73 antibody (TJ-L1D5), a

CD47 antibody (TJ-L1C4) and an IL-7 cytokine (TJ-L1I7), which are shown to work synergistically with the PD-L1 backbone in various assays and cancer animal models. This unique panel of bi-specific antibodies is only made possible by our proprietary and partnered antibody engineering technologies and the availability of our proprietary monoclonal antibodies. Furthermore, we have generated two other bi-specific antibodies (TJ-C4GM and TJ-CLDN4B) that are tailor-made to function as novel fortified antibodies by linking TJC4 with an engineered GM-CSF cytokine for the treatment of solid tumors and by linking our Claudin-18.2 antibody with a 4-1BB antibody as a unique gastric cancer treatment agent that only activates T cells conditionally upon tumor engagement. All bi-specific antibodies have been validated in a series of robust *in vitro* and *in vivo* studies for biology proof-of-concept, providing a solid basis for clinical validation in cancer patients.

Our Strategies

We plan to achieve our goal by pursuing the following strategies:

- Rapidly advance our China Portfolio towards commercialization.
- Expand our research and development capabilities and footprint in the United States to advance our Global Portfolio.
- Build our manufacturing capabilities.
- Maximize the value of our pipeline.

Our Challenges

Investing in our ADSs involves risks. If any of these risks actually occurs, our business, financial condition or results of operations would likely be materially adversely affected. In such case, the trading price of our ADSs would likely decline, and you may lose all or part of your investment. The following is a summary of some of the principal risks that we face:

- We have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.
- We recorded net cash outflow from operating activities since our inception. We may need to obtain additional financing to fund our operations, and if we are unable to obtain such financing, we may be unable to complete the development and commercialization of our major drug candidates.
- We depend substantially on the success of our investigational drugs and drug candidates, all of which are in clinical or pre-clinical development, respectively, and our ability to identify additional investigational drugs and drug candidates. If we are unable to successfully identify new investigational drugs or drug candidates, complete clinical development, obtain regulatory approval and commercialize them, or experience significant delays in doing so, our business will be materially harmed.
- We may not be able to identify, discover or in-license new drug candidates, and may allocate our limited resources to pursue a particular drug candidate or indication and fail to capitalize on drug candidates or indications that may later prove to be more profitable, or for which there is a greater likelihood of success.
- Even if we receive regulatory approval for our drug candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expenses and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our drug candidates.

- Our drug candidates may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.
- As we rely on third parties to conduct our pre-clinical studies and clinical trials, if we lose our relationships with these third parties or if they do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed.
- If we are unable to obtain and maintain patent and other intellectual property protection for our drug candidates, 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.
- 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 expansion strategies.

Please see “Risk Factors,” “Special Note Regarding Forward-Looking Statements” and other information included in this prospectus for a discussion of these and other risks and uncertainties that we face.

Corporate History and Structure

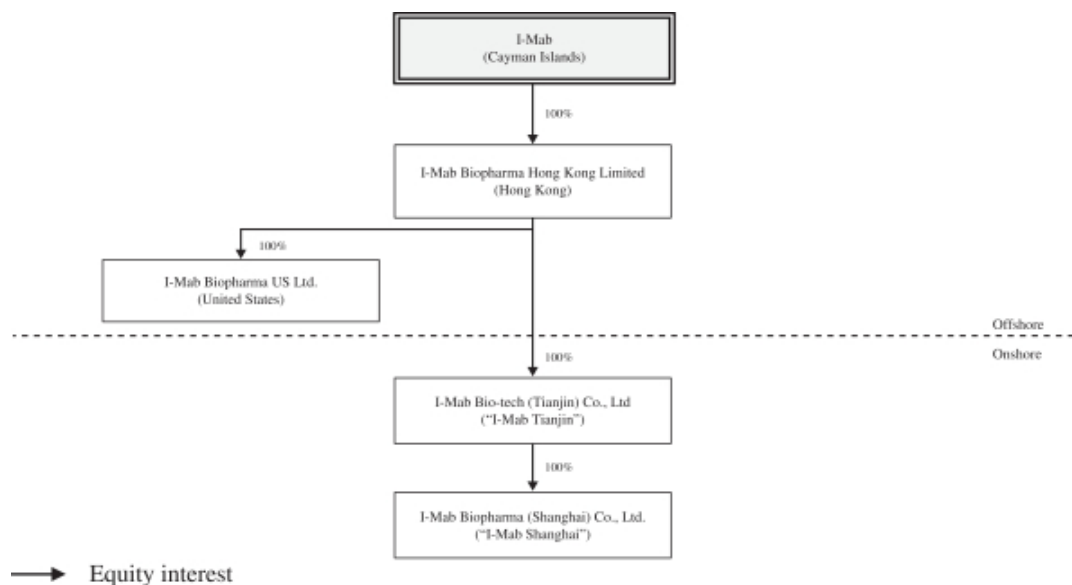
We commenced our operations in November 2014, when our predecessor Third Venture Biopharma (Nanjing) Co., Ltd (“Third Venture”) was established.

I-Mab was established in June 2016 under the laws of the Cayman Islands as our offshore holding company. In July 2016, I-Mab established I-Mab Biopharma Hong Kong Limited (“I-Mab Hong Kong”), as its intermediary holding company. In August 2016, I-Mab Hong Kong established a wholly-owned PRC subsidiary, I-Mab Biopharma (Shanghai) Co., Ltd. (“I-Mab Shanghai”). In September 2016, the assets and operations of Third Venture were consolidated into I-Mab Shanghai.

In July 2017, I-Mab Hong Kong acquired a controlling interest in I-Mab Bio-tech (Tianjin) Co., Ltd. (“I-Mab Tianjin”), formerly known as Tasgen Bio-tech (Tianjin) Co., Ltd., a company focused on CMC management of biologics in China. Through an internal corporate restructuring, I-Mab Tianjin became the 100% owner of I-Mab Shanghai in September 2017 and I-Mab Hong Kong acquired the remaining interest in I-Mab Tianjin in May 2018, becoming the 100% owner of I-Mab Tianjin.

In February 2018, I-Mab Hong Kong established in Maryland, United States, a wholly-owned subsidiary I-Mab Biopharma US Limited (“I-Mab US”), as the hub for the discovery and development of the drug candidates in our Global Portfolio.

The following diagram illustrates our corporate structure, including our principal subsidiaries, as of the date of this prospectus:



Implication of Being an Emerging Growth Company

As a company with less than US\$1.07 billion in revenue for our last fiscal year, we qualify as an “emerging growth company” pursuant to the Jumpstart Our Business Startups Act of 2012, as amended (the “JOBS Act”). An emerging growth company may take advantage of specified reduced reporting and other requirements compared to those that are otherwise applicable generally to public companies. These provisions include an exemption from the auditor attestation requirement under Section 404 of the Sarbanes-Oxley Act of 2002 in the assessment of the emerging growth company’s internal control over financial reporting. The JOBS Act also provides that an emerging growth company does not need to comply with any new or revised financial accounting standards until such date that a private company is otherwise required to comply with such new or revised accounting standards. However, we have elected to “opt out” of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted for public companies. This decision to opt out of the extended transition period under the JOBS Act is irrevocable.

We will remain an emerging growth company until the earliest of (a) the last day of the fiscal year during which we have total annual gross revenues of at least US\$1.07 billion; (b) the last day of our fiscal year following the fifth anniversary of the completion of this offering; (c) the date on which we have, during the preceding three-year period, issued more than US\$1.0 billion in non-convertible debt; or (d) the date on which we are deemed to be a “large accelerated filer” under the United States Securities Exchange Act of 1934, as amended, (the “Exchange Act”), which would occur if the market value of our ADSs that are held by non-affiliates exceeds US\$700 million as of the last business day of our most recently completed second fiscal quarter. Once we cease to be an emerging growth company, we will not be entitled to the exemptions provided in the JOBS Act discussed above.

Corporate Information

Our principal executive offices are located at Suite 802, West Tower, OmniVision, 88 Shangke Road, Pudong District, Shanghai, People's Republic of China. Our telephone number at this address is +86 21-6057-8000. Our registered office in the Cayman Islands is located at Vistra (Cayman) Limited, P.O. Box 31119 Grand Pavilion, Hibiscus Way, 802 West Bay Road, Grand Cayman, KY1-1205, Cayman Islands. Our agent for service of process in the United States is _____, located at _____.

Investors should submit any inquiries to the address or through the telephone number of our principal executive offices. Our main website is <http://www.i-mabbiopharma.com/en/>. The information contained on our website is not a part of this prospectus.

Conventions that Apply to this Prospectus

Unless otherwise indicated or the context otherwise requires, and for purposes of this prospectus only:

- "ADRs" refer to the American depositary receipts that evidence our ADSs;
- "ADSs" refer to our American depositary shares, each of which represents _____ ordinary shares;
- "China" or "the PRC" refers to the People's Republic of China, excluding, for the purposes of this prospectus only, Hong Kong, Macau and Taiwan, and "Greater China" does not exclude Hong Kong, Macau and Taiwan;
- "China Portfolio" refers to our investigational drugs of which we in-license Greater China rights from reputable global biopharmaceutical companies and rely on our own research and development capabilities to advance into pivotal clinical trials and commercialize in Greater China with an aim for near-term product launch;
- "Global Portfolio" refers to our own proprietary novel or differentiated drug candidates that we are advancing towards clinical validation in the United States;
- "I-Mab," "we," "us," "our company" and "our" refer to I-Mab, a Cayman Islands exempted company, and its subsidiaries;
- "RMB" refers to the legal currency of China;
- "shares" or "ordinary shares" refer to our ordinary shares, par value US\$0.0001 per share; and
- "US\$," "U.S. dollars," "\$," and "dollars" refer to the legal currency of the United States.

Unless the context indicates otherwise, all information in this prospectus assumes no exercise by the underwriters of their option to purchase additional ADSs.

Our reporting currency is RMB. This prospectus also contains translations of certain foreign currency amounts into U.S. dollars for the convenience of the reader. Unless otherwise stated, all translations from RMB to U.S. dollars were made at a rate of RMB6.8755 to US\$1.00, the exchange rate in effect as of December 31, 2018 as set forth in the H.10 statistical release of the Board of Governors of the Federal Reserve System on December 31, 2018. We make no representation that any RMB or U.S. dollar amounts referred to in this prospectus could have been or could be converted into U.S. dollars or RMB, as the case may be, at any particular rate, or at all. On July 19, 2019, the noon buying rate for RMB was RMB6.8812 to US\$1.00.

THE OFFERING

Offering price	We currently estimate that the initial public offering price will be between US\$ and US\$ per ADS.
ADSs offered by us	ADSs (or ADSs if the underwriters exercise their option to purchase additional ADSs in full).
ADSs outstanding immediately after this offering	ADSs (or ADSs if the underwriters exercise their option to purchase additional ADSs in full).
Ordinary shares issued and outstanding immediately after this offering	(or ordinary shares if the underwriters exercise their option to purchase additional ADSs in full). This number assumes the conversion, on a one-for-one basis, of all of our outstanding preferred shares into our ordinary shares immediately upon the completion of this offering.
The ADSs	<p>Each ADS represents ordinary shares, par value US\$0.0001 per share.</p> <p>The depositary will hold ordinary shares underlying your ADSs. You will have rights as provided in the deposit agreement among us, the depositary and holders and beneficial owners of ADSs from time to time.</p> <p>We do not expect to pay dividends in the foreseeable future. If, however, we declare dividends on our ordinary shares, the depositary will pay you the cash dividends and other distributions it receives on our ordinary shares after deducting its fees and expenses in accordance with the terms set forth in the deposit agreement.</p> <p>You may surrender your ADSs to the depositary in exchange for ordinary shares. The depositary will charge you fees for any such exchange.</p> <p>We may amend or terminate the deposit agreement without your consent. If you continue to hold your ADSs after an amendment to the deposit agreement, you agree to be bound by the deposit agreement as amended.</p> <p>To better understand the terms of the ADSs, you should carefully read the “Description of American Depositary Shares” section of this prospectus. You should also read the deposit agreement, which is filed as an exhibit to the registration statement that includes this prospectus.</p>
Option to purchase additional shares	We have granted to the underwriters an option, exercisable within 30 days from the date of this prospectus, to purchase up to an additional ADSs.

Use of proceeds	<p>We expect that we will receive net proceeds of approximately US\$ million from this offering, or approximately US\$ million if the underwriters exercise their option to purchase additional ADSs in full, assuming an initial public offering price of US\$ per ADS, which is the midpoint of the estimated range of the initial public offering price, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.</p> <p>We intend to use the net proceeds from this offering to (i) research and development of our existing and future drug candidates, (ii) potential investments in the establishment of our own manufacturing capacities, and (iii) general corporate purposes. See “Use of Proceeds” for more information.</p>
Lock-up	<p>[We, our directors and executive officers, our current shareholders [and certain of our option holders] have agreed with the underwriters not to sell, transfer or otherwise dispose of any ADSs, ordinary shares or similar securities for a period of [180] days after the date of this prospectus, subject to certain exceptions. In addition, we will not authorize or permit , as depository, to accept any deposit of any ordinary shares or issue any ADSs for 180 days after the date of this prospectus unless we expressly consent to such deposit or issuance and we have agreed not to provide such consent without the prior written consent of the representatives on behalf of the underwriters. The foregoing does not affect the right of ADS holders to cancel their ADSs and withdraw the underlying ordinary shares. See “Shares Eligible for Future Sales” and “Underwriting.”]</p>
[Directed ADS Program	<p>At our request, the underwriters have reserved for sale, at the initial public offering price, up to an aggregate of ADSs offered in this offering to some of our directors, officers, employees, business associates and related persons through a directed ADS program.]</p>
Listing	<p>We intend to apply to have the ADSs listed on [the Nasdaq Global Market] under the symbol “IMAB.” Our ADSs and shares will not be listed on any other stock exchange or traded on any automated quotation system.</p>
Payment and settlement	<p>The underwriters expect to deliver the ADSs against payment therefor through the facilities of The Depository Trust Company on , 2019.</p>
Depository	

SUMMARY CONSOLIDATED FINANCIAL DATA

The following summary consolidated statements of comprehensive loss data for the years ended December 31, 2017 and 2018, summary consolidated statements of balance sheet data as of December 31, 2017 and 2018 and summary consolidated statements of cash flow data for the years ended December 31, 2017 and 2018 have been derived from our audited consolidated financial statements included elsewhere in this prospectus. Our consolidated financial statements are prepared and presented in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”). Our historical results are not necessarily indicative of results expected for future periods. You should read this Summary Consolidated Financial Data section together with our consolidated financial statements and the related notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in this prospectus.

	For the Year Ended December 31,		
	2017	2018	
	RMB	RMB	US\$
(in thousands, except for share and per share data)			
Summary Consolidated Statements of Comprehensive Loss Data:			
Revenues			
Licensing and collaboration revenue	11,556	53,781	7,823
Expenses			
Research and development expenses ⁽¹⁾	(267,075)	(426,028)	(61,963)
Administrative expenses ⁽¹⁾	(25,436)	(66,391)	(9,656)
Loss from operations	(280,955)	(438,638)	(63,796)
Interest expenses, net	(4,785)	(7,098)	(1,032)
Other income (expenses), net	1,527	(16,780)	(2,441)
Fair value change of warrants	(14,027)	61,405	8,931
Loss before income tax expense	(298,240)	(401,111)	(58,338)
Income tax expense	—	(1,722)	(250)
Net loss attributable to I-Mab	(298,240)	(402,833)	(58,588)
Other comprehensive income			
Foreign currency translation adjustments, net of nil tax	5,918	53,689	7,809
Total comprehensive loss attributable to I-Mab	(292,322)	(349,144)	(50,779)
Net loss attributable to ordinary shareholders	(298,240)	(402,833)	(58,588)
Weighted-average number of ordinary shares used in calculating net loss per shares			
Basic and diluted	5,742,669	6,529,092	6,529,092
Net loss per share attributable to ordinary shareholders			
Basic	(51.93)	(61.70)	(8.97)
Diluted	(51.93)	(61.70)	(8.97)

Note:
 (1) Share-based compensation expenses were allocated as follows:

	For the Year Ended December 31,		
	2017	2018	
	RMB	RMB	US\$
(in thousands)			
Research and development expenses	2,112	1,056	154
Administrative expenses	4,927	2,464	358
Total	7,039	3,520	512

The following table presents our summary consolidated statements of balance sheet data as of December 31, 2017 and 2018:

	As of December 31,		
	2017	2018	
	RMB	RMB	US\$
	(in thousands)		
Summary Consolidated Statements of Balance Sheet Data:			
Current assets:			
Cash and cash equivalents	307,930	1,588,278	231,005
Restricted cash	104,783	92,653	13,476
Contract assets	—	11,000	1,600
Prepayments and other receivables	12,633	88,972	12,942
Other financial assets	266,245	255,958	37,228
Total current assets	691,591	2,036,861	296,251
Property, equipment and software	22,336	27,659	4,023
Intangible assets	148,844	148,844	21,648
Goodwill	162,574	162,574	23,645
Total assets	1,025,345	2,375,938	345,567
Total liabilities	309,151	415,684	60,460
Total mezzanine equity	1,015,989	2,915,358	424,021
Shareholders' equity (deficit)			
Ordinary shares (US\$0.0001 par value, 500,000,000 shares authorized as of December 31, 2017 and 2018, 8,363,719 shares authorized, issued and outstanding as of December 31, 2017 and 2018, respectively)	6	6	1
Treasury stock	(1)	(1)	—
Additional paid-in capital	52,369	—	—
Accumulated other comprehensive income	5,691	59,380	8,636
Accumulated deficit	(357,860)	(1,014,489)	(147,551)
Total shareholders' equity (deficit)	(299,795)	(955,104)	(138,914)
Total liabilities, mezzanine equity and shareholders' equity (deficit)	1,025,345	2,375,938	345,567

The following table presents our summary consolidated statements of cash flow data for the years ended December 31, 2017 and 2018:

	For the Year Ended December 31,		
	2017	2018	
	RMB	RMB	US\$
	(in thousands)		
Summary Consolidated Statements of Cash Flow Data:			
Net cash used in operating activities	(252,157)	(280,705)	(40,827)
Net cash (used in) generated from investing activities	(157,665)	9,500	1,382
Net cash generated from financing activities	758,585	1,479,669	215,210
Net increase in cash, cash equivalents and restricted cash	348,631	1,268,218	184,454
Cash, cash equivalents and restricted cash, beginning of the year	64,082	412,713	60,027
Cash, cash equivalents and restricted cash, end of the year	<u>412,713</u>	<u>1,680,931</u>	<u>244,481</u>

RISK FACTORS

An investment in our ADSs involves significant risks. You should carefully consider all of the information in this prospectus, including the risks and uncertainties described below, before making an investment in our ADSs. Any of the following risks could have a material adverse effect on our business, financial condition and results of operations. In any such case, the market price of our ADSs could decline, and you may lose all or part of your investment.

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.

We are a clinical stage biopharmaceutical company with a limited operating history. Our operations to date have focused on organizing and staffing our operations, business planning, raising capital, establishing our intellectual property portfolio and conducting pre-clinical and clinical trials of our drug candidates. We have not yet demonstrated an ability to successfully manufacture, obtain marketing approvals for or commercialize our drug candidates. We have no products approved for commercial sale and have not generated 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.

We are focused on the discovery and development of innovative drugs for the treatment of various immuno-oncological and immuno-inflammatory diseases. Our limited operating history, 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, may make it 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 early-stage 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.

We have incurred net losses in each period since our inception and anticipate that we will continue to incur net losses for the foreseeable future.

Investment in the development of biopharmaceutical products is highly speculative as it entails substantial upfront capital expenditures and significant risks that a drug candidate may fail to demonstrate efficacy and/or safety to gain regulatory or marketing approvals or become commercially viable. To date, we have financed our activities primarily through private placements. While we have generated revenue from licensing and collaboration deals, we have not generated any revenue from commercial product sales to date, and we continue to incur significant research and development expenses and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred net losses in each period since our inception. In 2017 and 2018, our net loss was RMB298.2 million and RMB402.8 million (US\$58.6 million), respectively. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We expect to continue to incur net losses in the foreseeable future, and that these net losses will increase as we carry out certain activities relating to our development, including, but not limited to, the following:

- conducting clinical trials of our drug candidates;
- manufacturing clinical trial materials through contract manufacturing organizations, or CMOs, in and out of China;
- seeking regulatory approvals for our drug candidates;
- commercializing our drug candidates for which we have obtained marketing approval;

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- completing the construction of and maintaining our manufacturing facilities;
- hiring additional clinical, operational, financial, quality control and scientific personnel;
- establishing a sales, marketing and commercialization team for any future products that have obtained regulatory approval;
- seeking to identify additional drug candidates;
- obtaining, maintaining, expanding and protecting our intellectual property portfolio;
- enforcing and defending any intellectual property-related claims; and
- acquiring or in-licensing other drug candidates, intellectual property and technologies.

Typically, it takes many years to develop one new drug from the time it is discovered to when it becomes available for treating patients. During the process, we may encounter unforeseen 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 rate of the future growth of our expenses, our ability to generate revenues and the timing and amount of milestone payments and other payments that we receive from or pay to third parties. If any of our drug 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.

We recorded net cash outflow from operating activities since our inception. Even if we consummate this offering, we may need to obtain additional financing to fund our operations. If we are unable to obtain such financing, we may be unable to complete the development and commercialization of our major drug candidates.

Since our inception, our operations have consumed substantial amounts of cash. Through December 31, 2018, we had raised approximately US\$330 million of cash in equity financing from our dedicated group of investors, including leading healthcare-focused funds. We spent RMB252.2 million and RMB280.7 million (US\$40.8 million) in net cash to finance our operations in 2017 and 2018, respectively.

We expect our expenses to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our clinical-stage drug candidates, continue the research and development of our pre-clinical stage drug candidates and initiate additional clinical trials of, and seek regulatory approval for, these and other future drug candidates.

In addition, if we obtain regulatory approvals for any of our drug 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. In particular, costs that may be required for the manufacture of any drug candidate that has received regulatory approval may be substantial as we may need to modify or increase our production capacity in the future at manufacturing facilities. We may also incur expenses as we create additional infrastructure to support our operations as a public company. 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. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, limit, reduce or terminate our research and development programs or any future commercialization efforts.

Raising additional capital may cause dilution to the interests to the holders of our ADSs and our shareholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.

We may seek additional funding through a combination of equity offerings, debt financings, collaborations, licensing arrangements, strategic alliances or partnerships and government grants or subsidies. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our ADSs. The incurrence of additional indebtedness or the issuance of certain equity securities could give rise to increased fixed payment obligations and 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, the issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our ADSs to decline.

In the event 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 our rights to technologies or drug candidates on unfavorable terms, which we would have otherwise sought to develop or commercialize on our own or reserve for future potential arrangements when we are more likely to achieve more favorable terms.

Risks Related to Clinical Development of Our Drug Candidates

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, and its outcome is inherently uncertain. While our exclusive focus is to develop drug candidates with first-in-class or best-in-class potential in China and globally, we cannot guarantee that we are able to achieve this for each of our drug candidates. Failure can occur at any time during the clinical development process. The results of pre-clinical studies and early clinical trials of our drug candidates may not be predictive of the results of later-stage clinical trials. Drug candidates during later stages of clinical trials may fail to show the desired results in safety and efficacy despite having progressed through pre-clinical studies and initial clinical trials and despite 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 between different trials of the same drug candidate due to numerous factors, including, but not limited to, differences in individual patient conditions, including genetic differences, and other compounding factors, such as other medications or pre-existing medical conditions.

In the case of 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. 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 with respect to drug candidates we have identified as having first-in-class or best-in-class potential based on currently available clinical and pre-clinical data.

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

Our business will depend on the successful development, regulatory approval and commercialization of our drug candidates for the treatment of patients with our targeted indications, all of which are still in pre-clinical or clinical development, and other new drug candidates that we may identify and develop. As of the date of this prospectus, we have obtained IND approvals from the NMPA for three of our drug candidates, TJ301, TJ107 and

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TJC4. In addition, we have obtained IND approvals from the FDA for three of our drug candidates, TJC4, TJD5 and TJM2; from the Taiwan Food and Drug Administration (the “TFDA”) for two of our drug candidates, TJ202 and TJ301; and from the Korea Ministry of Food and Drug Safety (the “MFDS”) for TJ301. However, we cannot guarantee that we are able to obtain regulatory approvals for our other existing drug candidates in a timely manner, or at all. In addition, none of our drug candidates has been approved for marketing in China or any other jurisdiction. Each of our drug candidates will require additional pre-clinical and/or clinical development, regulatory approvals in multiple jurisdictions, development of manufacturing supply and capacity, substantial investment and significant marketing efforts before we generate any revenue from product sales.

The success of our drug candidates will depend on several factors, including but not limited to the successful completion of pre-clinical and/or clinical trials or studies, receipt of regulatory approvals from applicable regulatory authorities for planned clinical trials, future clinical trials or drug registrations, establishing adequate manufacturing capabilities and capacities, commercialization of our existing drug candidates, hiring sufficient technical experts to oversee all development and regulatory activities and license renewal and meeting of the 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 drug candidates, which would materially harm our business and we may not be able to generate sufficient revenues and cash flows to continue our operations. As a result, our financial condition, results of operations and prospects will be materially and adversely harmed.

We may not be able to identify, discover or in-license new drug candidates, and may allocate our limited resources to pursue a particular drug candidate or indication and fail to capitalize on drug candidates or indications that may later prove to be more profitable, or for which there is a greater likelihood of success.

Although a substantial amount of our effort will focus on the continued clinical testing, potential approval, and commercialization of our existing drug candidates, the success of our business depends in part upon our ability to identify, license, discover, develop, or commercialize additional drug candidates. Research programs to identify new drug candidates require substantial technical, financial, and human resources. We may focus our efforts and resources on potential programs or drug candidates that ultimately prove to be unsuccessful. Our research programs or licensing efforts may fail to identify, discover or in-license new drug candidates for clinical development and commercialization for a number of reasons, including, without limitation, the following:

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential drug candidates;
- our potential drug candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval; and
- it may take greater human and financial resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs than we possess, thereby limiting our ability to diversify and expand our drug portfolio.

Because we have limited financial and managerial resources, we focus on research programs and drug candidates for specific indications. As a result, we may forgo or delay pursuit of opportunities with other drug candidates or for other indications that later may prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs, which could materially adversely affect our future growth and prospects.

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If we encounter delays or difficulties enrolling patients in our clinical trials, our clinical development progress could be delayed or otherwise adversely affected.

We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the NMPA, the FDA, or similar regulatory authorities, or if there are delays in the enrollment of eligible patients as a result of the competitive clinical enrollment environment. The inability to enroll a sufficient number of patients who meet the applicable criteria for our clinical trials would result in significant delays. As of the date of this prospectus, we have initiated clinical trials for TJ301 in South Korea, Taiwan and China, for TJ107 in China, for TJ202 in Taiwan, and for TJM2, TJC4 and TJD5 in the United States. In addition, we expect to initiate clinical trials for TJC4 by the end of 2019 in China.

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

Patient enrollment for our clinical trials may be affected by other factors, including but not limited to the following:

- severity of the disease under investigation;
- total size and nature of the relevant patient population;
- design and eligibility criteria for the clinical trial in question;
- perceived risks and benefits of the drug 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; and
- proximity and availability of clinical trial sites for prospective patients.

Even if we are able to enroll a sufficient number of patients 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 drug candidates.

If clinical trials of our drug 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 drug candidates.

Before obtaining regulatory approval for the sale of our drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in 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 drug candidates, including, without limitation:

- regulators, institutional review boards, or 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 terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

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- manufacturing issues, including problems with manufacturing, supply quality, compliance with good manufacturing practice, or GMP, or obtaining sufficient quantities of a drug candidate from third parties for use in a clinical trial;
- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide to conduct additional clinical trials or abandon drug development programs, or regulators may require us to do so;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, enrollment may be insufficient or slower than we anticipate or patients may drop out at a higher rate than we anticipate;
- our third-party contractors, including clinical investigators, 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 drug 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;
- regulators, IRBs or ethics committees may require that we or our investigators suspend or terminate clinical research or not rely on the results of clinical research for various reasons, including non-compliance with regulatory requirements;
- the cost of clinical trials of our drug candidates may be greater than we anticipate; and
- the supply or quality of our drug candidates, companion diagnostics or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate.

If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently plan, if we are unable to successfully complete clinical trials of our drug candidates or other testing, 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 drug candidates; (ii) obtain approval for indications that are not as broad as intended; (iii) not obtain regulatory approval at all; (iv) have the drug 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 drug is distributed or used; or (vii) be unable to obtain reimbursement for use of the drug.

Significant clinical trial delays may also increase our development costs and could shorten any periods during which we have the exclusive right to commercialize our drug candidates or allow our competitors to bring drugs to market before we do. This could impair our ability to commercialize our drug candidates and may harm our business and results of operations.

Risks Related to Obtaining Regulatory Approval for Our Drug Candidates

All material aspects of the research, development and commercialization of pharmaceutical products are heavily regulated.

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 activities in the major markets of China and the United States. These jurisdictions 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 that make for a more complex and costly regulatory compliance burden for a company like us that plans to operate in these regions.

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

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requirements at any time during the product development process and approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include: refusal to approve pending applications; withdrawal of an approval; license revocation; clinical hold; voluntary or mandatory product recalls; product seizures; total or partial suspension of production or distribution; injunctions; fines; refusals of government contracts; providing restitution; undergoing disgorgement; or other civil or criminal penalties. Failure to comply with these regulations could have a material adverse effect on our business.

The regulatory approval processes of the NMPA, the FDA and other comparable regulatory authorities are time-consuming and may evolve over time, and if we are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed.

The time required to obtain the approval of the NMPA, the FDA and other comparable regulatory authorities is inherently uncertain and depends on numerous factors, including the substantial discretion of the regulatory authorities. Generally, such approvals take many years to obtain following the commencement of pre-clinical studies and clinical trials, although they are typically provided within 12 to 18 months after clinical trials are completed. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a drug candidate's clinical development and may vary among jurisdictions. As of the date of this prospectus, we have obtained IND approvals from the NMPA for TJ301, TJ107 and TJC4. In addition, we have obtained IND approvals from the FDA for TJC4, TJD5 and TJM2, from the TFDA for TJ202 and TJ301 and from the MFDS for TJ301. However, we cannot guarantee that we are able to obtain regulatory approvals for our other existing drug candidates or any drug candidates we may discover, in-license or acquire and seek to develop in the future.

Our drug candidates could fail to receive the regulatory approval of the NMPA, the FDA or a comparable regulatory authority for many reasons, including, without limitation:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a drug candidate is safe and effective and potent for its proposed indication;
- failure of our clinical trial results to meet the level of statistical significance required for approval;
- failure of our clinical trial process to pass relevant good clinical practice ("GCP") inspections;
- failure to demonstrate that a drug candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from pre-clinical studies or clinical trials;
- insufficient data collected from the clinical trials of our drug candidates to support the submission and filing of a new drug application, or NDA, or other submissions or to obtain regulatory approval;
- failure of our drug candidates to pass current Good Manufacturing Practice ("cGMP"), inspections during the regulatory review process or across the production cycle of our drug;
- failure of our clinical sites to pass audits carried by out by the NMPA, the FDA or comparable regulatory authorities, resulting in a potential invalidation of our research data;
- findings by the NMPA, the FDA or comparable regulatory authorities of deficiencies related to our manufacturing processes or the facilities of third-party manufacturers with whom we contract for clinical and commercial supplies;
- changes in approval policies or regulations that render our pre-clinical and clinical data insufficient for approval; and
- failure of our clinical trial process to keep up with any scientific or technological advancements required by approval policies or regulations.

The NMPA, the FDA 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. Even if we were to obtain approval, regulatory authorities may approve any of our drug candidates for fewer or more limited indications than we request, grant approval contingent on the performance of costly post-marketing clinical trials, or approve a drug candidate with an indication that is not desirable for the successful commercialization of that drug candidate. Any of the foregoing scenarios could materially harm the commercial prospects of our drug candidates.

The absence of patent linkage, patent term extension and data and market exclusivity for NMPA-approved pharmaceutical products could increase the risk of early generic competition with our products in China.

In the United States, the Federal Food, Drug and Cosmetic Act, as amended by the law generally referred to as “Hatch-Waxman,” provides the opportunity for patent-term restoration, meaning a patent term extension of up to five years to reflect patent term 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 during the pendency of litigation between the follow-on applicant and the patent holder or licensee, generally for a period of 30 months. 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 United States to the first applicant to obtain approval of a new chemical entity 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 drug 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.

Depending upon the timing, duration and specifics of any FDA marketing approval process for any drug candidates we may develop, one or more of our U.S. patents, if issued, 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 term 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. Furthermore, the applicable time period or the scope of patent protection afforded could be less than we request.

In China, however, there is no currently effective law or regulation providing for patent term extension, patent linkage, or data exclusivity (referred to as regulatory data protection). Therefore, a lower-cost generic drug can emerge onto the market much more quickly. Chinese regulators have set forth a framework for integrating patent linkage and data exclusivity into the Chinese regulatory regime, as well as for establishing a pilot program for patent term extension. To be implemented, this framework will require adoption of regulations. To date, no regulations have been issued. These factors result in weaker protection for us against generic competition in China than could be available to us in the United States. For instance, the patents we have in China are not yet eligible to be extended for patent term lost during clinical trials and the regulatory review process. 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 drug candidates may cause undesirable adverse events or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval.

Undesirable adverse events caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and may result in a more restrictive label, a delay or denial of regulatory approval by the NMPA, the FDA or other comparable regulatory authorities, or a significant change in our clinical protocol or even our development plan. In particular, as is the case with drugs treating cancers and auto-immune diseases, it is likely that there may be side effects, such as nausea, fatigue and infusion-related reactions, associated with the use of certain of our drug candidates. Results of our trials could reveal a high and unacceptable severity or prevalence of certain adverse events. In such an event, our trials could be suspended or terminated and the NMPA, the FDA or other comparable regulatory authorities could order us to cease further development of, or deny approval of, our drug candidates for any or all targeted indications. Adverse events related to our drug candidates may affect patient recruitment or the ability of enrolled subjects to complete the trial, and could result in potential liability claims. Any of these occurrences may significantly harm our reputation, business, financial condition and prospects.

Additionally, if we or others identify undesirable side effects caused by those of our existing drug candidates that have received regulatory approval, or our other drug candidates after having received regulatory approval, this may lead to potentially significant negative consequences which include, but are not limited to, the following:

- we may suspend marketing of the drug candidate;
- regulatory authorities may withdraw their approvals of or revoke the licenses for the drug candidate;
- regulatory authorities may require additional warnings on the label;
- the FDA may require the establishment of a Risk Evaluation and Mitigation Strategy, or REMS, or the NMPA or a comparable regulatory authority may require the establishment of a similar strategy that may, for instance, restrict distribution of our drugs and impose burdensome implementation requirements on us;
- we may be required to conduct specific post-marketing studies;
- we could be subjected to litigation proceedings and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of any particular drug candidate that is approved and could significantly harm our business, results of operations and prospects.

Further, combination therapy, such as using our wholly-owned drug candidates as well as third-party agents, may involve unique adverse events that could be exacerbated compared with adverse events from monotherapies. Results of our trials could reveal a high and unacceptable severity or prevalence of adverse events. These types of adverse events could be caused by our drug candidates and could cause us or regulatory authorities to interrupt, delay or halt clinical trials and may result in a more restrictive indication or the delay or denial of regulatory approval by the NMPA, the FDA or other comparable regulatory authority.

If we are unable to obtain the NMPA approval for our drug candidates to be eligible for an expedited registration pathway as innovative drug candidates, the time and cost we incur to obtain regulatory approvals may increase.

The NMPA has mechanisms in place for expedited review and approval for drug candidates that are innovative drug applications, provided such drug or drug candidate has a new and clearly defined structure,

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pharmacological property and apparent clinical value and has not been marketed anywhere in the world. However, there is no assurance that an innovative drug designation will be granted by the NMPA for any of our drug candidates. Moreover, an innovative drug designation, which is typically granted only towards the end of a drug's developmental stage, does not increase the likelihood that our drug candidates will receive regulatory approval on a fast-track basis, or at all.

Further, there have been recent regulatory initiatives in China in relation to clinical trial approvals, the evaluation and approval of certain drugs and medical devices and the simplification and acceleration of the clinical trial process.

As a result, the regulatory process in China is evolving and subject to change. Any future policies, or changes to current policies might require us to change our planned clinical study design or otherwise spend additional resources and effort to obtain approval of our drug candidates. In addition, policy changes may contain significant limitations related to use restrictions for certain age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for our drug candidates in the PRC, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of our drug candidates or any other drug candidate that we may in-license, acquire or develop in the future.

Even if we receive regulatory approval for our drug candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expenses and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our drug candidates.

If the NMPA, the FDA or a comparable regulatory authority approves any of our drug candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the drug 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 current cGMPs, and GCPs and potential post-approval studies for the purposes of license renewal.

Any regulatory approvals that we receive for our drug candidates may also be subject to limitations on the approved indicated uses for which the drug 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 NMPA, the FDA 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 drug products, it may result in, among other things:

- restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market, or voluntary or mandatory drug recalls;
- fines, warning letters or holds on our clinical trials;
- refusal by the NMPA, the FDA or comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of drug license approvals;
- refusal by the NMPA, the FDA or comparable regulatory authorities to accept any of our other IND approvals, NDAs or BLAs;

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- drug seizure or detention, or refusal to permit the import or export of drugs; and
- injunctions or the imposition of civil, administrative or criminal penalties.

Any government investigation of alleged violations of law could require us to expend significant time and resources and could 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 drug 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.

Illegal and/or parallel imports and counterfeit pharmaceutical products may reduce demand for our future approved drug candidates and could have a negative impact on our reputation and business.

The illegal importation of competing products from countries where government price controls or other market dynamics result in lower prices may adversely affect the demand for our future approved drug candidates and, in turn, may adversely affect our sales and profitability in China and other countries where we commercialize our products. Unapproved foreign imports of prescription drugs are illegal under the current laws of China. However, illegal imports may continue to occur or even increase as the ability of patients and other customers to obtain these lower priced imports continues to grow. Furthermore, cross-border imports from lower-priced markets (which are known as parallel imports) into higher-priced markets could harm sales of our future drug products and exert commercial pressure on pricing within one or more markets. In addition, competent government authorities may expand consumers' ability to import lower priced versions of our future approved products or competing products from outside China or other countries where we operate. Any future legislation or regulations that increase consumer access to lower priced medicines from outside China or other countries where we operate could have a material adverse effect on our business.

Certain products distributed or sold in the pharmaceutical market may be manufactured without proper licenses or approvals, or be fraudulently mislabeled with respect to their content or manufacturers. These products are generally referred to as counterfeit pharmaceutical products. The counterfeit pharmaceutical product control and enforcement system, particularly in developing markets such as China, may be inadequate to discourage or eliminate the manufacturing and sale of counterfeit pharmaceutical products imitating our products. Since counterfeit pharmaceutical products in many cases have very similar appearances compared with the authentic pharmaceutical products but are generally sold at lower prices, counterfeits of our products could quickly erode the demand for our future approved drug candidates.

In addition, counterfeit pharmaceutical products are not expected to meet our or our collaborators' rigorous manufacturing and testing standards. A patient who receives a counterfeit pharmaceutical product may be at risk for a number of dangerous health consequences. Our reputation and business could suffer harm as a result of counterfeit pharmaceutical products sold under our or our collaborators' brand name(s). In addition, thefts of inventory at warehouses, plants or while in-transit, which are not properly stored and which are sold through unauthorized channels, could adversely impact patient safety, our reputation and our business.

Risks Related to Commercialization of Our Drug Candidates

Our drug candidates may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if our drug candidates receive regulatory approval, they may nonetheless fail to gain sufficient market acceptance by physicians and patients and others in the medical community. Physicians and patients may prefer other drugs or drug candidates to ours. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant revenue from sales of our drugs or drug candidates and may not become profitable.

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The degree of market acceptance of our drug candidates, if and only when they are approved for commercial sale, will depend on a number of factors, including, but not limited to:

- the clinical indications for which our drug candidates are approved;
- physicians, hospitals and patients considering our drug candidates as a safe and effective treatment;
- whether our drug candidates have achieved a first-in-class or best-in-class status and the potential and perceived advantages of our drug candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or package insert requirements of the NMPA, the FDA or other comparable regulatory authorities;
- limitations or warnings contained in the labeling approved by the NMPA, the FDA or other comparable regulatory authorities;
- timing of market introduction of our drug candidates as well as competitive drugs;
- cost of treatment in relation to alternative treatments;
- availability of adequate coverage and reimbursement under the national and provincial reimbursement drug lists in the PRC, or from third-party payors and government authorities in the United States or any other jurisdictions;
- willingness of patients to pay any out-of-pocket expenses in the absence of coverage and reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared with alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If our drug candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals or others in the medical community, we will not be able to generate significant revenue or become profitable. Even if our drugs achieve market acceptance, we may not be able to maintain such market acceptance over time if new products or technologies are introduced which are more favorably received than our drugs, are more cost effective or render our drugs obsolete.

We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced, or more effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our drug candidates.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. While our exclusive focus is to develop drug candidates with global first-in-class or best-in-class potential, we continue to face competition with respect to our current drug candidates, and will face competition with respect to any drug candidates that we may seek to develop or commercialize in the future. Our competitors include major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. We are developing our drug candidate for the treatment of cancer in competition with a number of large biopharmaceutical companies that currently market and sell drugs or are pursuing the development of drugs also for the treatment of cancer. Some of these competitive drugs and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. For details, see “Business—Our Drug Pipeline.” Potential competitors further include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

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Many of our competitors have substantially greater financial, technical, and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval from the NMPA, the FDA or other comparable regulatory authorities more rapidly than we are able to and may be more effective in selling and marketing their products as well. For example, the NMPA has recently accelerated market approval of drugs for diseases with high unmet medical need. In particular, the NMPA may review and approve drugs that have gained regulatory market approval in the United States, the European Union or Japan in the recent ten years without requiring further clinical trials in China. This may lead to potential increased competition from drugs which have already obtained approval in other jurisdictions.

Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring, or licensing on an exclusive basis, products that are more effective or less costly than any drug candidate that we may develop, or achieve earlier patent protection, regulatory approval, product commercialization, and market penetration than we do. Additionally, technologies developed by our competitors may render our potential drug candidates uneconomical or obsolete, and we may not be successful in marketing our drug candidates against competitors.

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

We have limited experience in managing the manufacturing process. The manufacture of biopharmaceutical products is a complex process, in part due to strict regulatory requirements. As of the date of this prospectus, we have no existing manufacturing infrastructure or capabilities. If we are unable to identify an appropriate production site or a suitable partner to develop our manufacturing infrastructure, or fail to do so in a timely manner, this may lead to significant delays in the manufacturing of our drug candidates once regulatory and marketing approvals have been obtained. The investment for building a new biologics manufacturing facility that is compliant with cGMP regulations may also be a significant upfront cost for us. In turn, this could materially harm our commercialization plans.

In addition, problems may arise during the manufacturing process for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials, delays related to the construction of new facilities or expansion of any future manufacturing facilities, including changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements, changes in the types of products produced, increases in the prices of raw materials, physical limitations that could inhibit continuous supply, man-made or natural disasters and environmental factors. If problems arise during the production of a batch of future products, that batch of future products may have to be discarded and we may experience product shortages or incur added expenses. This could, among other things, lead to increased costs, lost revenue, damage to customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before such product is released to the market, recall and product liability costs may also be incurred.

We have no experience in launching and marketing drug candidates. We may not be able to effectively build and manage our sales network, or benefit from third-party collaborators' sales network.

We currently have no sales, marketing or commercial product distribution capabilities and have no experience in marketing drugs. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other biopharmaceutical companies to recruit, hire, train and retain marketing and sales personnel.

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If we are unable or decide not to establish internal sales, marketing and commercial distribution capabilities for any or all of the drugs we develop, we will likely pursue collaborative arrangements regarding the sales and marketing of our drugs. However, there can be no assurance 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 drug candidates ourselves. We will also face competition in our search for third parties to assist us with the sales and marketing efforts of our drug candidates.

There can be no assurance that we will be able to develop in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any product, and as a result, we may not be able to generate product sales revenue.

Even if we are able to commercialize any approved drug candidates, reimbursement may be limited or unavailable in certain market segments for our drug candidates, and we may be subject to 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 drug in a particular country, but then be subject to price regulations that delay our commercial launch of the drug and negatively impact the revenues we are able to generate from the sale of the drug in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if our drug candidates obtain regulatory approval. For example, according to a statement, Opinions on Reforming the Review and Approval Process for Pharmaceutical Products and Medical Devices, 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 new drug on PRC mainland 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 drugs successfully also will depend in part on the extent to which reimbursement for these drugs 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 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 drug 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 drug for which we obtain regulatory approval. Obtaining reimbursement for our drugs may be particularly difficult because of the higher prices often associated with drugs 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 drug candidate that we successfully develop.

There may be significant delays in obtaining reimbursement for approved drug candidates, and coverage may be more limited than the purposes for which the drug candidates are approved by the NMPA, the FDA 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 drugs, 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 drug and the clinical setting in

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which it is used, may be based on payments allowed for lower cost drugs that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for drugs 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 drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any future approved drug candidates and any new drugs that we develop could have a material adverse effect on our business, our operating results, and our overall financial condition.

Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug candidates and affect the prices we may obtain.

In the United States and certain other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our drug candidates, restrict post-approval activities and affect our ability to sell profitably any drug candidates for which we obtain marketing approval.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, became law. The ACA is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the ACA of importance to our drug candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service Act's pharmaceutical pricing program;
- new requirements to report to CMS financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report to the FDA drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals, if any, of our drug candidates may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing conditions and other requirements.

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As we out-license some of our commercialization rights and engage in other forms of collaboration worldwide, including conducting clinical trials abroad, we may be exposed to specific risks of conducting our business and operations in international markets.

Markets outside of China form an important component of our growth strategy, as we out-license some of our commercialization rights to third parties outside the PRC and conduct certain of our clinical trials abroad. If we fail to obtain applicable licenses or fail to enter into strategic collaboration arrangements with third parties in these markets, or if these collaboration arrangements turn out unsuccessful, our revenue-generating growth potential will be adversely affected.

Moreover, international business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- efforts to enter into collaboration or licensing arrangements with third parties in connection with our international sales, marketing and distribution efforts may increase our expenses or divert our management's attention from the acquisition or development of drug candidates;
- changes in a specific country's or region's political and cultural climate or economic condition;
- differing regulatory requirements for drug approvals and marketing internationally;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- potentially reduced protection for intellectual property rights;
- potential third-party patent rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation or political instability;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- the effects of applicable non-PRC tax structures and potentially adverse tax consequences;
- currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incidental to doing business in another country;
- workforce uncertainty and labor unrest;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from an international market with low or lower prices rather than buying them locally;
- failure of our employees and contracted third parties to comply with Office of Foreign Assets Control rules and regulations and the Foreign Corrupt Practices Act of the United States, and other applicable rules and regulations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

These and other risks may materially adversely affect our ability to attain or sustain revenue from international markets.

If safety, efficacy, or other issues arise with any medical product that is used in combination with our drug candidates, we may be unable to market such drug candidate or may experience significant regulatory delays or supply shortages, and our business could be materially harmed.

We plan to develop certain of our drug candidates for use as a combination therapy. If the NMPA, the FDA or another comparable regulatory agency revokes its approval of another therapeutic we use in combination with

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our drug candidates, we will not be able to market our drug candidates in combination with such revoked therapeutic. If safety or efficacy issues arise with these or other therapeutics that we seek to combine with our drug candidates in the future, we may experience significant regulatory delays, and we may be required to redesign or terminate the applicable clinical trials. In addition, if manufacturing or other issues result in a supply shortage of any component of our combination drug candidates or if we cannot secure supply of any component of our drug candidates at commercially reasonable or acceptable prices, we may not be able to complete clinical development of our drug candidates on our current timeline or within our current budget, or at all.

Lack of third-party combination drugs may materially and adversely affect demand for our drugs.

Our drug candidates may be administered in combination with drugs of other pharmaceutical companies as one regimen. In addition, we often use such third-party drugs in our development and clinical trials as controls for our studies. As a result, both the results of our clinical trials and the sales of our drugs may be affected by the availability of these third-party drugs. If other pharmaceutical companies discontinue these combination drugs, regimens that use these combination drugs may no longer be prescribed, and we may not be able to introduce or find an alternative drug to be used in combination with our drugs at all or in a timely manner and on a cost-effective basis. As a result, demand for our drugs may be lowered, which would in turn materially and adversely affect our business and results of operations.

Risks Related to Our Reliance on Third Parties

As we rely on third parties to conduct our pre-clinical studies and clinical trials, if we lose our relationships with these third parties or if they do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed.

We have relied on and plan to continue to rely on third-party contract research organization (“CROs”) to monitor and manage data for some of our ongoing pre-clinical and clinical programs. We rely on these parties for the execution of our pre-clinical and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We also rely on third parties to assist in conducting our pre-clinical studies in accordance with Good Laboratory Practices (“GLP”). We and our CROs are required to comply with GCP, GLP and other regulatory regulations and guidelines enforced by the NMPA, the FDA and comparable foreign regulatory authorities for all of our drug candidates in clinical development. Regulatory authorities enforce these GCP, GLP or other regulatory requirements through periodic inspections of trial sponsors, investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, GLP or other regulatory requirements, the relevant data generated in our clinical trials may be deemed unreliable and the NMPA, the FDA or other comparable regulatory authorities may require us to perform additional clinical studies before approving our marketing applications. There can be no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP requirements. In addition, our clinical trials must be conducted with drug candidates or products produced under cGMP requirements. Failure to comply with these regulations may require us to repeat pre-clinical and clinical trials, which would delay the regulatory approval process.

Our CROs have the right to terminate their agreements with us in the event of an unrectified material breach. 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) meet our desired clinical development timelines. 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.

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Except for remedies available to us under our agreements with our CROs, we cannot control whether or not our CROs devote sufficient time and resources to our ongoing clinical, nonclinical and pre-clinical programs. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, our results of operations and the commercial prospects for our drug candidates would be harmed and our costs could increase. In turn, our ability to generate revenues could be delayed or compromised.

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. In addition, the use of third-party service providers requires us to disclose our proprietary information to these third parties, which could increase the risk that such information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party service providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. 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.

We expect to rely on third parties to manufacture at least a portion of our drug candidate supplies, and we intend to rely on third parties for at least a portion of the manufacturing process of our drug candidates, if approved. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices.

Although we plan to either construct or acquire a facility that will be used as our clinical-scale manufacturing and processing facility, we intend to also partially rely on third-party vendors to manufacture supplies and process our drug candidates. We have not yet manufactured or processed our drug candidates on a commercial scale and may not be able to do so for any of our drug candidates. We have limited experience in managing the manufacturing process, and our process may be more difficult or expensive than the approaches currently in use.

Our anticipated reliance on third-party manufacturers exposes us to certain risks, including, but not limited to, the following:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the NMPA, the FDA or other comparable regulatory authorities must approve any manufacturers as part of their regulatory oversight of our drug candidates. This approval would require new testing and cGMP-compliance inspections by the NMPA, the FDA or other comparable regulatory authorities. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our drugs;
- our contract manufacturers may have little or no experience with manufacturing our drug candidates, and therefore may require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to manufacture our drug candidates;
- our contract manufacturers may have limited capacity or limited manufacturing slots, which may affect the timeline for the production of our drugs;
- our contract manufacturers might be unable to timely manufacture our drug candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- contract manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;

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- our future contract manufacturers may not perform as agreed, may not devote sufficient resources to our drugs, or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our drugs;
- our contract manufacturers are subject to ongoing periodic unannounced inspections by the NMPA and the FDA to ensure strict compliance with cGMP and other government regulations in the PRC and the United States, respectively, and by other comparable regulatory authorities for corresponding regulatory requirements. We do not have control over third-party manufacturers' 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 manufacturers in the manufacturing process for our drugs;
- our contract manufacturers could breach or terminate their agreements with us;
- our contract manufacturers may be unable to sustain their business and become bankrupt as a result;
- 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;
- products and components from our third-party manufacturers may be subject to additional customs and import charges, which may cause us to incur delays or additional costs as a result;
- our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters; and
- our contract manufacturers may have unacceptable or inconsistent product quality success rates and yields.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our drug candidates by the NMPA, the FDA or other comparable regulatory authorities, result in higher costs or adversely impact the commercialization of our drug candidates. In addition, we will rely on third parties to perform certain specification tests on our drug candidates prior to delivery to patients. If these tests are not appropriately done and test data is not reliable, patients could be put at risk of serious harm and the NMPA, the FDA or other comparable regulatory authorities could place significant restrictions on our company until deficiencies are remedied.

The manufacture of biopharmaceutical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Currently, our drug raw materials for our manufacturing activities are supplied by multiple source suppliers. We have agreements for the supply of drug materials with manufacturers or suppliers that we believe have sufficient capacity to meet our demands. In addition, we believe that adequate alternative sources for such supplies exist. However, there is a risk that, if supplies are interrupted, our business would be materially harmed.

Manufacturers of biopharmaceutical products often encounter difficulties in production, particularly in scaling up or out, validating the production process, 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 and availability of qualified personnel, as well as compliance with strictly enforced regulations in the PRC, the United States and other applicable jurisdictions. Further, if contaminants are discovered in the supply of our drug candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time for us to investigate and remedy the contamination. There can be no assurance that any stability failures or other issues relating to the manufacture of our drug candidates will not occur in the future. Additionally, our contract manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environment. If our contract manufacturers were to encounter

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any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our drug candidate to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of our 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.

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

We may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop. Any of these relationships may require us to incur recurring or non-recurring expenses and other charges, increase our near and long-term expenditures, issue securities that dilute the value of our ADSs, or disrupt our management and business. For example, we have entered into a license and collaboration agreement with MorphoSys AG (“MorphoSys”), pursuant to which we in-licensed from MorphoSys the development and commercialization rights of TJ202 in Greater China. Furthermore, we have entered into a product collaboration agreement with Everest Medicines Limited (“Everest”), pursuant to which we and Everest agreed to share the development cost and economic interest in TJ202 with respect to multiple myeloma. In addition, 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 drug 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 drug 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 drug candidate, we can expect to relinquish some or all of the control over the future success of that drug candidate to the third party.

Further, collaborations involving our drug candidates are subject to specific risks, which include, but are not limited to, the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue the development and commercialization of our drug candidates or may elect not to continue or renew the development or commercialization programs based on clinical trial results, change in their strategic focus due to the acquisition of competitive drugs, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, discontinue a clinical trial, repeat or conduct new clinical trials, or require a new formulation of a drug candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, drugs that compete directly or indirectly with our drug candidates or future drugs;
- collaborators with marketing and distribution rights to one or more of our drug candidates or future drugs may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend 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;
- collaborators may not always be cooperative or responsive in providing their services in a clinical trial;

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- disputes may arise between us and a collaborator that cause a delay or termination of the research, development or commercialization of our drug candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable drug candidates; and
- collaborators may own or co-own intellectual property covering our drug candidates or future drugs that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into collaboration agreements and strategic partnerships or license our drugs, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate these agreements or partnerships with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business.

Neither can we be certain that, following a strategic transaction or license, we will be able to 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, on acceptable terms, or at all, we may have to curtail the development of a drug 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 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, we may not be able to further develop our drug candidates or bring them to market and generate product sales revenue, which would harm our business, financial condition, results of operations and prospects.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent and other intellectual property protection for our drug candidates, 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 our proprietary technology and drug candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights, including patent rights. As of July 15, 2019, our owned patent portfolio consist of five patents and 127 patent applications primarily in connection with the drug candidates in our Global Portfolio, including 15 Patent Cooperation Treaty (“PCT”) patent applications, seven U.S. patent applications, ten PRC patent applications and 95 patent applications in other jurisdictions. In addition, as of July 15, 2019, we in-licensed the Greater China rights relating to 19 issued patents and 25 pending patent applications primarily in connection with TJ202, TJ101, TJ301, enoblituzumab and TJ107. We seek to protect the drug candidates and technology that we consider commercially important by filing patent applications in China, the United States and other countries or regions, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. This process is expensive and time-consuming, and we or our licensors may not be able to file and prosecute all necessary or desirable patent applications in all jurisdictions at a reasonable cost or in a timely manner. It is also possible that we or our licensors will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our

pending and future patent applications may not result in patents being issued which protect our technology or drug candidates or which effectively prevent others from commercializing competitive technologies and drug candidates. The patent examination process may require us or our licensors to narrow the scope of the claims of our or our licensors' pending and future patent applications, which may limit the scope of patent protection that may be obtained. We cannot assure that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent application from being issued as a patent.

Even if patents do issue on any of these applications, there can be no assurance that a third party will not challenge their validity, enforceability, or scope, which may result in the patent claims being narrowed or invalidated, or that we will obtain sufficient claim scope in those patents to prevent a third party from competing successfully with our drug candidates. We may become involved in interference, *inter partes* review, post grant review, ex parte reexamination, derivation, opposition or similar other proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drug candidates and compete directly with us, or result in our inability to manufacture or commercialize drug candidates without infringing third-party patent rights. Thus, even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage.

Our competitors may be able to circumvent our patents by developing similar or alternative technologies or drug candidates in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and other countries. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and drug candidates, or limit the duration of the patent protection of our technology and drug candidates. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such assets might expire before or shortly after such assets are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drug candidates similar or identical to ours.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. Under the America Invents Act ("AIA") enacted in 2011, the United States moved to this first-to-file system in early 2013 from the previous system under which the first to make the claimed invention was entitled to the patent. Assuming the other requirements for patentability are met, the first to file a patent application is entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States 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.

We enjoy only limited geographical protection with respect to certain patents and may not be able to protect our intellectual property rights throughout the world, including in the PRC.

Filing and prosecuting patent applications and defending patents covering our drug candidates in all countries throughout the world could be prohibitively expensive. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection to develop their own drug candidates and, further, may export otherwise infringing drug candidates to territories, including the PRC, where we and our licensors have patent protection, but enforcement rights are not as strong as that in the United States or Europe. These drug candidates may compete with our drug candidates, and our and our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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The laws of some jurisdictions, including the PRC, do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and Europe, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing drug candidates in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing as patents, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our drug candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our drug candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired.

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 and annuity fees on any issued patent are due to be paid to the United States Patent and Trademark Office (“USPTO”) and foreign patent agencies over the lifetime of a patent. In addition, the USPTO and other foreign patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. While an inadvertent failure to make payment of such fees or to comply with such provisions 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 such non-compliance will result in the abandonment or lapse of the patent or patent application, and the 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, and non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our licensors fail to maintain the patents and patent applications covering our drug candidates or if we or our licensors otherwise allow our patents or patent applications to be abandoned or lapse, our competitors might be able to enter the market, which would hurt our competitive position and could impair our ability to successfully commercialize our drug candidates in any indication for which they are approved.

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Our owned and in-licensed patents and other intellectual property may be subject to further priority disputes or to inventorship disputes and similar proceedings. If we or our licensors are unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms or at all, or to modify or cease the development, manufacture and commercialization of one or more of the drug candidates we may develop, 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 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 drug 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.

Claims that our drug candidates or the sale or use of our future products infringe, misappropriate or otherwise violate the patents or other intellectual property rights of third parties could result in costly litigation or could require substantial time and money to resolve, even if litigation is avoided.

We cannot guarantee that our drug candidates or the sale or use of our future products do not and will not in the future infringe, misappropriate or otherwise violate third-party patents or other intellectual property rights. Third parties might allege that we are infringing their patent rights or that we have misappropriated their trade secrets, or that we are otherwise violating their intellectual property rights, whether with respect to the manner in which we have conducted our research, or with respect to the use or manufacture of the compounds we have developed or are developing. Litigation relating to patents and other intellectual property rights in the biopharmaceutical and pharmaceutical industries is common, including patent infringement lawsuits. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. Some claimants may have substantially greater resources than we have and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. Third parties might resort to litigation against us or other parties we have agreed to indemnify, which litigation could be based on either existing intellectual property or intellectual property that arises in the future. For example, we are aware of a third-party U.S. patent and its counterpart European patents that relate to the use of antibodies having specificity to PD-L1 to treat cancer.

It is also possible that we failed to identify, or may in the future fail to identify, relevant patents or patent applications held by third parties that cover our drug candidates. Publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent, or the first to file patent applications on, our drug candidates or for their uses, or that our drug candidates will not infringe patents that are currently issued or that are issued in the future. In the event that a third party has also filed a patent application covering one of our drug candidates or a similar invention, our patent application may be regarded as a competing application and may not be approved in the end. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our products or their use.

If a third party were to assert claims of patent infringement against us, even if we believe such third-party claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize the applicable product unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention, or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable. In addition, defending such claims would cause us to incur substantial expenses and could cause us to pay substantial damages, if we are found to be infringing a third party's patent rights. These damages potentially include increased damages and attorneys' fees if we are found to have infringed such rights willfully. In order to avoid or settle potential claims with respect to any patent or other intellectual property rights of third parties, we may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both, which could be substantial. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a drug candidate, or be forced, by court order or otherwise, to modify or cease some or all aspects of our business operations, if, as a result of actual or threatened patent or other intellectual property claims, we are unable to enter into licenses on acceptable terms. Further, we could be found liable for significant monetary damages as a result of claims of intellectual property infringement.

Defending against claims of patent infringement, misappropriation of trade secrets or other violations of intellectual property rights could be costly and time-consuming, regardless of the outcome. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs.

Issued patents covering one or more of our drug 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 drug 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 drug 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, SIPO, 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 drug 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 drug candidates. Any loss of patent protection could have a material adverse impact on one or more of our drug candidates and our business.

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).

Intellectual property litigation may lead to unfavorable publicity which may harm our reputation and cause the market price of our ADSs to decline, and any unfavorable outcome from such litigation could limit our research and development activities and/or our ability to commercialize our drug candidates.

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 drug candidates, future drugs, programs or intellectual property could be diminished. Accordingly, the market price of our ADSs may decline. Such announcements could also harm our reputation or the market for our drug candidates, which could have a material adverse effect on our business.

In the event of intellectual property litigation, there can be no assurance that we would prevail, even if the case against us is weak or flawed. If third parties successfully assert their intellectual property rights against us, prohibitions against using certain technologies, or prohibitions against commercializing our drug candidates, could be imposed by a court or by a settlement agreement between us and a plaintiff. In addition, if we are unsuccessful in defending against allegations that we have infringed, misappropriated or otherwise violated the patent or other intellectual property rights of others, we may be forced to pay substantial damage awards to the plaintiff. Additionally, we may be required to obtain a license from the intellectual property owner in order to continue our research and development programs or to commercialize any resulting product. It is possible that the necessary license will not be available to us on commercially acceptable terms, or at all. This may not be technically or commercially feasible, may render our products less competitive, or may delay or prevent the launch of our products to the market. Any of the foregoing could limit our research and development activities, our ability to commercialize one or more drug candidates, or both.

Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex intellectual property litigation longer than we could. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to conduct our clinical trials, continue our internal research programs, in-license needed technology, or enter into strategic partnerships that would help us bring our drug candidates to market.

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.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patent rights. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and is therefore costly, time-consuming, and inherently uncertain. In addition, the United States has recently enacted and is implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained, if any. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and

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patents that we might obtain in the future. For example, in a recent case, *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain claims to naturally-occurring substances are not patentable. Although we do not believe that our currently issued patents and any patents that may issue from our pending patent applications directed to our drug candidates if issued in their currently pending forms, as well as patent rights licensed by us, will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patent rights. There could be similar changes in the laws of foreign jurisdictions that may impact the value of our patent rights or our other intellectual property rights.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. We also may be subject to claims that our employees, consultants, or advisers 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 issued patents and pending patent applications, we rely on trade secret and confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drug 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, advisers 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 advisers, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants, and advisers, including members 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, but in the future litigation may be necessary to defend against such claims. 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 management. 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, and furthermore, 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, be a distraction to our management and scientific personnel and 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.

Because our programs may involve additional drug candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire and maintain licenses or other rights to use these proprietary rights. 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 or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or drug candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects for growth.

Our rights to develop and commercialize our drug candidates are subject, in part, to the terms and conditions of licenses granted to us by others.

We rely on licenses to certain patent rights and other intellectual property from third parties that are important or necessary to the development of our drug candidates. These and other licenses may not provide exclusive rights to use such intellectual property in all relevant fields of use and in all territories in which we may wish to develop or commercialize our drug products. As a result, we may not be able to prevent competitors from developing and commercializing competitive drug products in territories included in all of our licenses.

We may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the drug candidates that we license from third parties. Moreover, we have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights that we jointly own with certain of our licensors and sub-licensors. 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 licensors fail to prosecute, maintain, enforce and 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 drugs that are subject of such licensed rights could be adversely affected.

Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity or unenforceability of these patents. Even if we are permitted to pursue the enforcement or defense of our licensed patents, we will require the cooperation of our licensors and any applicable patent owners and such cooperation may not be provided to us. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. If we lose any of our licensed intellectual property, our right to develop and commercialize any of our drug candidates that are subject of such licensed rights could be adversely affected.

In addition, our licensors may have relied on third party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-license. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

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In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize drug products covered by these license agreements. If such licenses are terminated, we may be required seek alternative in-license arrangements, which may not be available on commercially reasonable terms or at all, or may be non-exclusive. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, we may need to modify or cease the development, manufacture, and commercialization of one or more of our drug candidates and competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could be required to pay monetary damages or could lose license rights that are important to our business.

Our business relies, in large part, on our ability to develop and commercialize drug candidates we have licensed from third parties, and we have entered into license agreements with third parties providing us with rights to various third-party intellectual property, including rights in patents and patent applications. Our licenses may not encumber all intellectual property rights owned or controlled by the affiliates of our licensors and relevant to our drug candidates, and we may need to obtain additional licenses from our existing licensors and others to advance our research or allow commercialization of drug candidates we may develop. In such case, we may need to obtain additional licenses which may not be available on an exclusive basis, on commercially reasonable terms or at a reasonable cost, if at all. In that event, we may be required to expend significant time and resources to redesign our drug candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected drug candidates, which could harm our business, financial condition, results of operations, and prospects significantly.

In addition, if our licensors breach the license agreements, we may not be able to enforce such agreements against our licensors' parent entity or affiliates. Under each of our license and intellectual property-related agreements, in exchange for licensing or sublicensing us the right to develop and commercialize the applicable drug candidates, our licensors will be eligible to receive from us milestone payments, tiered royalties from commercial sales of such drug candidates, assuming relevant approvals from government authorities are obtained, or other payments. Our license and intellectual property-related agreements also require us to comply with other obligations including development and diligence obligations, providing certain information regarding our activities with respect to such drug candidates and/or maintaining the confidentiality of information we receive from our licensors.

If we fail to comply with our obligations under our current or future license agreements, our counterparties may have the right to terminate these agreements and, upon the effective date of such termination, have the right to re-obtain the licensed and sub-licensed technology and intellectual property. If any of our licensors terminate any of our licenses, we might not be able to develop, manufacture or market any drug or drug candidate that is covered by the licenses provided for under these agreements and other third parties may be able to market drug candidates similar or identical to ours. In such case, we may have to negotiate new or reinstated agreements with less favorable terms, and may be required to provide a grant back license to the licensors under our own intellectual property with respect to the terminated products. We may also face claims for monetary damages or other penalties under these agreements. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under the intellectual property rights licensed and sublicensed to us, we may not be able to do so in a timely manner, at an acceptable

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cost or at all. In particular, some of the milestone payments are payable upon our drug candidates reaching development milestones before we have commercialized, or received any revenue from, sales of such drug candidate, and we cannot guarantee that we will have sufficient resources to make such milestone payments. Any uncured, material breach under the license agreements could result in our loss of exclusive rights and may lead to a complete termination of our rights to the applicable drug candidate. Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. Certain of our license agreements also require us to meet development thresholds to maintain the license, including establishing a set timeline for developing and commercializing products. Disputes may arise regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe, misappropriate or violate intellectual property of the licensor that is not subject to the license agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected drug candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily protect us from all potential threats to our competitive advantage.

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. The following examples are illustrative:

- others may be able to make compounds that are similar to our drug candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or may in the future exclusively license, which could result in the patents applied for not being issued or being invalidated after issuing;
- we might not have been the first to file patent applications covering certain of our inventions, which could result in the patents applied for not being issued or being invalidated after issuing;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;

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- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors or other third parties;
- we may obtain patents for certain compounds many years before we receive regulatory approval for drugs containing such compounds, and because patents have a limited life, which may begin to run prior to the commercial sale of the related drugs, the commercial value of our patents may be limited;
- 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 drugs for commercialization in our major markets;
- we may fail to develop additional proprietary technologies that are patentable;
- we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate;
- third parties may gain unauthorized access to our intellectual property due to potential lapses in our information systems; and
- the patents of others may have an adverse effect on our business, for example by preventing us from commercializing one or more of our drug candidates for one or more indications.

Any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business and future prospects.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our competitive position may be adversely affected.

We own registered trademarks. We may not be able to obtain trademark protection in territories that we consider of significant importance to us. In addition, any of our trademarks or trade names, whether registered or unregistered, may be challenged, opposed, infringed, cancelled, circumvented or declared generic, or determined to be infringing on other marks, as applicable. We may not be able to protect our rights to these trademarks and trade names, which we will need to build name recognition by potential collaborators or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

Terms of our future patents may not be sufficient to effectively protect our drug candidates and business.

In many countries where we file applications for patents, the term of an issued patent is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. Although various extensions may be available, the life of a patent and the protection it affords are limited. Even if we obtain patents covering our drug candidates, we may still be open to competition from other companies, as well as generic medications once the patent life has expired for a drug. While there are patent regulations in the PRC in respect of regulatory data protection of new drugs containing new chemical components, there are currently no other clear mechanisms providing patent term extension or patent linkages for other drugs in the PRC. Therefore, it is possible that a lower-cost generic drug can emerge onto the market much more quickly. PRC regulators have set out a framework for integrating patent linkage and data exclusivity into the PRC regulatory regime, as well as for establishing a pilot program for patent term extension. This framework will require adoption of regulations to be implemented, although no such regulations have been issued to date. These factors may result in weaker protection for us against generic competition in the PRC than could be available to us in other jurisdictions, such as the United States. In addition, patents which we expect to obtain in the PRC may not be eligible to be extended for patent terms lost during clinical trials and the regulatory review process.

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If we are unable to obtain patent term extensions or if such extensions are less than requested for, our competitors may obtain approval of competing products following our patent expirations and our business, financial condition, results of operations and prospects could be materially harmed as a result.

If we do not obtain additional protection under the Hatch-Waxman Amendments and similar legislation in other countries extending the terms of our patents, if issued, relating to our drug candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA regulatory approval for our drug candidates, one or more of our U.S. patents, if issued, may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Amendments”). The Hatch-Waxman Amendments permit a patent term extension of up to five years as compensation for patent term lost during drug development and the FDA regulatory review process. Patent term extensions, however, cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval by the FDA, and only one patent can be extended for a particular drug.

The application for patent term extension is subject to approval by the USPTO, in conjunction with the FDA. We may not be granted an extension because of, for example, 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. If we are unable to obtain a patent term extension for a given patent or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our drug will be shortened and our competitors may obtain earlier approval of competing drugs, and our ability to generate revenues could be materially adversely affected.

Risks Related to Our Industry, Business and Operations

Our future success depends on our ability to attract, retain and motivate senior management and qualified scientific employees.

We are highly dependent on the expertise of the members of our research and development team, as well as the principal members of our management, including Dr. Jingwu Zhang Zang, M.D., Ph.D., our founder. We have entered into employment letter agreements with our executive officers, but each of them may terminate their employment with us at any time with prior written notice. In addition, we currently do not have “key-man” insurance for any of our executive officers or other key personnel.

Recruiting, retaining and motivating qualified management, scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Further, replacing executive officers and key employees 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 drugs. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous biopharmaceutical companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, our management will be required to devote significant time to new compliance initiatives from our status as a public company, which may require us to recruit more management personnel.

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

We expect to experience significant growth in the number of our employees and consultants and the scope of our operations, particularly in the areas of clinical development, regulatory affairs and business development.

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To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. 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. 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.

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, manufacturing technology development programs and clinical programs. We also engage in substantial information gathering following the identification of a promising drug candidate. Because data in the healthcare industry is 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 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 drug 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, our partners 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 does 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 Related to Our Reliance on Third Parties—As we rely on third parties to conduct our pre-clinical studies and clinical trials, if we lose our relationships with these third parties or if they do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed” above.

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

We currently carry liability insurance 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

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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, but not limited to:

- decreased demand for our drug candidates or any resulting products;
- injury 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 drug candidates; and
- a decline in the market price of our ADSs.

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 or key-man 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.

Disruptions in the financial markets and economic conditions could affect our ability to raise capital.

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.

In addition, 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. There have been concerns over unrest and terrorist threats in the Middle East, Europe and Africa and over the conflicts involving Ukraine, Syria and North Korea. There have also been concerns on the relationship among China and other Asian countries, which may result in or intensify potential conflicts in relation to territorial disputes or the trade related disputes between the United States and China. In addition, the U.K. held a referendum on June 23, 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"). The U.K.'s departure from the European Union remains uncertain. 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.

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

For example, our founder, Dr. Jingwu Zhang Zang, was the corresponding author of a research paper prepared by scientists at GSK China's research center and published in Nature Medicine in 2010. The paper was retracted in 2013 as a result of misrepresentation of certain data for which Dr. Zang admitted his management oversight. In addition, Dr. Zang received a warning letter from the FDA in March 1999 relating to the lack of IND approval before the initiation of a clinical research study in human subjects. For details, please see "Management—Certain Past Incidents." We cannot assure you that there will not be any inquiries, investigations or other actions against Dr. Zang by any regulatory or government authorities or any negative publicity against Dr. Zang or us regarding these incidents, any of which could distract Dr. Zang and our management's attention and negatively affect our business and results of operations.

If we obtain approval of any of our drug candidates and begin commercializing those drugs 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.

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.

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If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute the value of your investment in our ADSs, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including, but not limited to:

- 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 merger 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 drugs or drug 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.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

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 advantage. In addition, although currently our primary operating business is in China, we are subject to the Foreign Corrupt Practices Act (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 healthcare programs. Other remedial measures could

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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.

Any failure to comply with applicable regulations and industry standards or obtain various licenses and permits could harm our reputation and our business, results of operations and prospects.

A number of governmental agencies or industry regulatory bodies in the PRC, the United States and other applicable jurisdictions impose strict rules, regulations and industry standards governing biopharmaceutical research and development activities, which apply to us. Our or our CROs' failure to comply with such regulations could result in the termination of ongoing research, administrative penalties imposed by regulatory bodies or the disqualification of data for submission to regulatory authorities. This could harm our business, reputation, prospects for future work and results of operations. For example, if we or our CROs were to treat research animals inhumanely or in violation of international standards set out by the Association for Assessment and Accreditation of Laboratory Animal Care, it could revoke any such accreditation and the accuracy of our animal research data could be questioned.

If we or our CROs or other contractors or consultants 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 and third parties, such as our CROs or other contractors or consultants, 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 involve the use of hazardous and flammable materials, including chemicals and radioactive and biological materials. Our operations also produce hazardous waste products. We generally 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.

Although we maintain workers' compensation 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 do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of biological, hazardous or radioactive 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.

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

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 drugs. 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.

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

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. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we partially rely on our third-party research institution collaborators for research and development of our drug candidates and other third parties for the manufacture of our drug candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business.

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 drug candidates could be delayed.

Failure to comply with existing or future laws and regulations related to privacy or data security could lead to government enforcement actions, which could include civil or criminal fines or penalties, private litigation, other liabilities, and/or adverse publicity. Compliance or the failure to comply with such laws could increase the costs of our products and services, could limit their use or adoption, and could otherwise negatively affect our operating results and business.

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of personal information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Regulatory authorities in virtually every jurisdiction in which we operate have implemented and are considering a number of legislative and regulatory proposals concerning personal data protection.

Regulatory authorities in China have implemented and are considering a number of legislative and regulatory proposals concerning data protection. For example, China's Cyber Security Law, which became effective in June 2017, created China's first national-level data protection for "network operators," which may include all organizations in China that provide services over the internet or another information network. Numerous regulations, guidelines and other measures are expected to be adopted under the umbrella of the Cyber Security Law. Drafts of some of these measures have now been published, including the draft rules on cross-border transfers published by the China Cyberspace Administration in 2017, which may, upon enactment, require security review before transferring human health-related data out of China. In addition, certain industry-specific laws and regulations affect the collection and transfer of personal data in China. For example, the PRC State Council promulgated Regulations on the Administration of Human Genetic Resources in May 2019 and will become effective in July 2019, which require approval from the Science and Technology Administration Department of the State Council where human genetic resources, or HGR, are involved in any international collaborative project and additional approval for any export or cross-border transfer of the HGR samples or associated data. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices, potentially resulting in confiscation of HGR samples and associated data and administrative fines. In addition, the interpretation and application of data protection laws in China and elsewhere are often uncertain and in flux.

In the United States, we are subject to laws and regulations that address privacy, personal information protection and data security at both the federal and state levels. Numerous laws and regulations, including security breach notification laws, health information privacy laws, and consumer protection laws, govern the collection, use, disclosure and protection of health-related and other personal information. Given the variability

and evolving state of these laws, we face uncertainty as to the exact interpretation of the new requirements, and we may be unsuccessful in implementing all measures required by regulators or courts in their interpretation.

Regulatory authorities in Europe have implemented and are considering a number of legislative and regulatory proposals concerning data protection. For example, the General Data Protection Regulation (EU) 2016/679, or GDPR, which became effective in May 2018, imposes a broad range of strict requirements on companies subject to the GDPR, such as us, including, but not limited to, requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the European Economic Area (including to the United States), providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, and recordkeeping. The GDPR substantially increases the penalties to which we could be subject in the event of any non-compliance, including fines of up to 10,000,000 Euros or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to 20,000,000 Euros or up to 4% of our total worldwide annual turnover for more serious offenses. Given the new law, we face uncertainty as to the exact interpretation of the new requirements, and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law. National laws of member states of the European Union are in the process of being adapted to the requirements under the GDPR. Because the GDPR specifically gives member states flexibility with respect to certain matters, national laws may partially deviate from the GDPR and impose different obligations from country to country, leading to additional complexity and uncertainty.

We expect that we will continue to face uncertainty as to whether our efforts to comply with evolving obligations under global data protection, privacy and security laws will be sufficient. Any failure or perceived failure by us to comply with applicable laws and regulations could result in reputational damage or proceedings or actions against us by governmental entities, individuals or others. These proceedings or actions could subject us to significant civil or criminal penalties and negative publicity, result in the delayed or halted transfer or confiscation of certain personal information, require us to change our business practices, increase our costs and materially harm our business, prospects, financial condition and results of operations. In addition, our current and future relationships with customers, vendors, pharmaceutical partners and other third parties could be negatively affected by any proceedings or actions against us or current or future data protection obligations imposed on them under applicable law, including the GDPR. In addition, a data breach affecting personal information, including health information, could result in significant legal and financial exposure and reputational damage that could potentially have an adverse effect on our business.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Natural disasters, acts of war or terrorism 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.

We have identified two material weaknesses in our internal controls as of December 31, 2018, and if we fail to implement and maintain an effective system of internal controls to remediate our material weaknesses over financial reporting, we may be unable to accurately report our results of operations, meet our reporting obligations or prevent fraud.

Prior to this offering, we have been a private company with limited accounting personnel and other resources with which to address our internal controls. In the course of auditing our consolidated financial statements, we and our independent registered public accounting firm identified two material weaknesses and control deficiencies in our internal control over financial reporting. As defined in the standards established by the U.S. Public Company Accounting Oversight Board, a “material weakness” is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company’s annual or interim financial statements will not be prevented or detected on a timely basis.

The material weaknesses that have been identified relate to (i) our lack of sufficient and competent financial reporting and accounting personnel with appropriate knowledge of U.S. GAAP and the reporting and compliance requirements of the United States Securities and Exchange Commission, or the SEC, to formalize key controls over financial reporting and to prepare consolidated financial statements and related disclosures; and (ii) our lack of sufficient documented financial closing policies and procedures, specifically those related to (a) accounting for licensing and collaboration agreements and (b) period end expenses cut-off and accruals. These material weaknesses, if not timely remedied, may lead to significant misstatements in our consolidated financial statements in the future. Following the identification of the material weaknesses and other control deficiencies, we have taken measures and plan to continue to take measures to remediate these deficiencies. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Internal Control over Financial Reporting.” However, the implementation of those measures may not fully remediate the material weaknesses in a timely manner. Our failure to correct these deficiencies or our failure to discover and address any other deficiencies could result in inaccuracies in our financial statements and impair our ability to comply with applicable financial reporting requirements and related regulatory filings on a timely basis. Moreover, ineffective internal control over financial reporting could significantly hinder our ability to prevent fraud.

Upon the completion of this offering, we will become subject to the Sarbanes-Oxley Act of 2002. Section 404 of the Sarbanes-Oxley Act, or Section 404, requires that we include a report from management on the effectiveness of our internal control over financial reporting in our annual report on Form 20-F beginning with our annual report for the fiscal year ending December 31, 2020. In addition, once we cease to be an “emerging growth company” as defined in the JOBS Act, our independent registered public accounting firm must attest to and report on the effectiveness of our internal control over financial reporting. Our management may conclude that our internal control over financial reporting is not effective. Moreover, even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm, after conducting its own independent testing, may issue an adverse report if it is not satisfied with our internal controls or the level at which our controls are documented, designed, operated or reviewed, or if it interprets the relevant requirements differently from us. In addition, once we have become a public company, our reporting obligations may place a significant strain on our management, operational and financial resources and systems for the foreseeable future. We may be unable to timely complete our evaluation testing and any required remediation.

During the course of documenting and testing our internal control procedures, in order to satisfy the requirements of Section 404, we may identify other weaknesses and deficiencies in our internal control over financial reporting. In addition, if we fail to maintain the adequacy of our internal control over financial reporting, as these standards are modified, supplemented or amended from time to time, we may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404. If we fail to establish and maintain adequate internal controls, we could suffer material misstatements in our financial statements and fail to meet our reporting obligations, which would likely cause

investors to lose confidence in our reported financial information. This could limit our access to capital markets, adversely affect our results of operations and lead to a decline in the trading price of the ADSs. Additionally, ineffective internal controls could expose us to an increased risk of fraud or misuse of corporate assets and subject us to potential delisting from the stock exchange on which we list or to other regulatory investigations and civil or criminal sanctions. We could also be required to restate our historical financial statements.

Our auditor, like other independent registered public accounting firms operating in China, is not permitted to be subject to inspection by Public Company Accounting Oversight Board, and consequently investors may be deprived of the benefits of such inspection.

Our auditor, the independent registered public accounting firm that issued the audit report included elsewhere in this registration statement, as an auditor of companies that are traded publicly in the United States and a firm registered with the Public Company Accounting Oversight Board (United States), or PCAOB, is subject to laws in the United States pursuant to which the PCAOB conducts regular inspections to assess its compliance with applicable professional standards. Our auditor is located in, and organized under the laws of, the PRC, which is a jurisdiction where the PCAOB, has been unable to conduct inspections without the approval of the Chinese authorities. In May 2013, PCAOB announced that it had entered into a Memorandum of Understanding on Enforcement Cooperation with the CSRC and the PRC Ministry of Finance, which establishes a cooperative framework between the parties for the production and exchange of audit documents relevant to investigations undertaken by PCAOB, the CSRC or the PRC Ministry of Finance in the United States and the PRC, respectively. PCAOB continues to be in discussions with the China Securities Regulatory Commission, or CSRC, and the PRC Ministry of Finance to permit joint inspections in China of audit firms that are registered with PCAOB and audit Chinese companies that trade on U.S. exchanges.

On December 7, 2018, the SEC and the PCAOB issued a joint statement highlighting continued challenges faced by the U.S. regulators in their oversight of financial statement audits of U.S.-listed companies with significant operations in China. However, it remains unclear what further actions, if any, the SEC and PCAOB will take to address the problem.

This lack of PCAOB inspections in China prevents the PCAOB from fully evaluating audits and quality control procedures of our independent registered public accounting firm. As a result, we and investors in our ordinary shares are deprived of the benefits of such PCAOB inspections. The inability of the PCAOB to conduct inspections of auditors in China makes it more difficult to evaluate the effectiveness of our independent registered public accounting firm's audit procedures or quality control procedures as compared to auditors outside of China that are subject to PCAOB inspections, which could cause investors and potential investors in our stock to lose confidence in our audit procedures and reported financial information and the quality of our financial statements.

Proceedings instituted by the SEC against "big four" PRC-based accounting firms, including our independent registered public accounting firm, could result in financial statements being determined to not be in compliance with the requirements of the Exchange Act.

Starting in 2011 "big four" PRC-based accounting firms, including our independent registered public accounting firm, were affected by a conflict between U.S. and Chinese law. Specifically, for certain U.S.-listed companies operating and audited in mainland China, the SEC and the PCAOB sought to obtain from the Chinese firms access to their audit work papers and related documents. The firms were, however, advised and directed that under Chinese law, they could not respond directly to the U.S. regulators on those requests, and that requests by foreign regulators for access to such papers in China had to be channeled through the CSRC.

In late 2012, this impasse led the SEC to commence administrative proceedings under Rule 102(e) of its Rules of Practice and also under the Sarbanes-Oxley Act of 2002 against the Chinese accounting firms, including our independent registered public accounting firm. A first instance trial of the proceedings in July 2013 in the

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SEC's internal administrative court resulted in an adverse judgment against the firms. The administrative law judge proposed penalties on the firms including a temporary suspension of their right to practice before the SEC, although that proposed penalty did not take effect pending review by the Commissioners of the SEC. On February 6, 2015, before a review by the Commissioner had taken place, the firms reached a settlement with the SEC. Under the settlement, the SEC accepted that future requests by the SEC for the production of documents will normally be made to the CSRC. The firms were to receive matching Section 106 requests, and were required to abide by a detailed set of procedures with respect to such requests, which in substance require them to facilitate production via the CSRC. If they failed to meet specified criteria, the SEC retained authority to impose a variety of additional remedial measures on the firms depending on the nature of the failure.

Under the terms of the settlement, the underlying proceeding against the four China-based accounting firms was deemed dismissed with prejudice four years after entry of the settlement. The four-year mark occurred on February 6, 2019. While we cannot predict if the SEC will further challenge the four China-based accounting firms' compliance with U.S. law in connection with U.S. regulatory requests for audit work papers or if the results of such a challenge would result in the SEC imposing penalties such as suspensions. If additional remedial measures are imposed on the "big four" PRC-based accounting firms, including our independent registered public accounting firm, we could be unable to timely file future financial statements in compliance with the requirements of the Exchange Act.

In the event the "big four" PRC-based accounting firms become subject to additional legal challenges by the SEC or PCAOB, depending upon the final outcome, listed companies in the United States with major PRC operations may find it difficult or impossible to retain auditors in respect of their operations in China, which could result in financial statements being determined to not be in compliance with the requirements of the Exchange Act, including possible delisting. Moreover, any negative news about any such future proceedings against these audit firms may cause investor uncertainty regarding China-based, U.S.-listed companies and the market price of our common stock may be adversely affected.

If our independent registered public accounting firm was denied, even temporarily, the ability to practice before the SEC and we were unable to timely find another registered public accounting firm to audit and issue an opinion on our financial statements, our financial statements could be determined not to be in compliance with the requirements of the Exchange Act. Such a determination could ultimately lead to the delisting of the ADSs from [the Nasdaq Global Market] or deregistration from the SEC, or both, which would substantially reduce or effectively terminate the trading of the ADSs in the United States.

Our reputation is important to our business success. Negative publicity may adversely affect our reputation and business prospects.

Any negative publicity concerning us, our affiliates or any entity that shares the "I-Mab" name, even if untrue, could adversely affect our reputation and business prospects. There can be no assurance that negative publicity about us or any of our affiliates or any entity that shares the "I-Mab" name would not damage our brand image or have a material adverse effect on our business, results of operations and financial condition.

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 and prospect.

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. For example, a number of media reported that our founder, Dr. Jingwu Zhang Zang, was involved in misrepresentation of certain data in a research paper prepared by scientists at GSK China's research center and published in Nature Medicine in 2010, for which Dr. Zang was the corresponding author, and consequently Dr. Zang was dismissed by GSK in

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2013. In addition, Dr. Zang received a warning letter from the FDA in March 1999 relating to the lack of IND approval before the initiation of a clinical research study in human subjects. For details, please see “Management—Certain Past Incidents.” To the best of our knowledge, Dr. Zang was not and is not subject to any legal or regulatory charges, proceedings or disciplinary actions in connection with these incidents. However, we cannot assure you that there will not be any inquiries, investigations or other actions against Dr. Zang by any regulatory or government authorities in the future. Any regulatory inquiries or investigations or other actions against Dr. Zang or our other 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 talents and business partners and grow our business.

Moreover, any negative media publicity about the biopharmaceutical 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 prospect.

Change in business prospects of acquisitions may result in impairment to our goodwill, which could negatively affect our reported results of operations.

We acquired a controlling interest in I-Mab Tianjin in July 2017 and the remaining interest in I-Mab Tianjin in May 2018. In connection with our acquisition of I-Mab Tianjin, we identified RMB148.8 million of intangible assets and RMB162.6 million of goodwill of I-Mab Tianjin attributable to core technology and synergy effects expected from combining the operation of the discovery and development of innovative biologics and the development of clinical stage biologics. We are required to test our goodwill annually, or more frequently if events or changes in circumstances indicate that it might be impaired. Goodwill is allocated to cash-generating units or groups of cash-generating units for the purpose of impairment testing. An impairment loss of goodwill is recognized for the amount by which the relevant cash-generating unit’s or group of cash-generating unit’s carrying amount exceeds its recoverable amount, and we would be required to write down the carrying value of our goodwill during the period in which it is determined to be impaired, which would materially and adversely affect our results of operations.

We are subject to changing law and regulations regarding regulatory matters, corporate governance and public disclosure that have increased both our costs and the risk of non-compliance.

We are or will be subject to rules and regulations by various governing bodies, including, for example, once we have become a public company, the SEC, which is charged with the protection of investors and the oversight of companies whose securities are publicly traded, and the various regulatory authorities in China and the Cayman Islands, and to new and evolving regulatory measures under applicable law. Our efforts to comply with new and changing laws and regulations have resulted in and are likely to continue to result in, increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

Moreover, because these laws, regulations and standards are subject to varying interpretations, their application in practice may evolve over time as new guidance becomes available. This evolution may result in continuing uncertainty regarding compliance matters and additional costs necessitated by ongoing revisions to our disclosure and governance practices. If we fail to address and comply with these regulations and any subsequent changes, we may be subject to penalty and our business may be harmed.

Risks Related 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 drugs.

Our research and development operations and manufacturing facilities are in China, which we believe confers clinical, commercial and regulatory 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 drugs. See “Regulation” 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 drug candidates in China and reduce the current benefits we believe are available to us from developing and manufacturing drugs 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.

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 expansion strategies.

A significant portion of our operations are in China. Our financial condition and results of operations are affected to a large extent by economic, political and legal developments in China.

The PRC economy differs from the economies of most developed countries in many respects, including the extent of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. Although the PRC government has implemented measures emphasizing the utilization of market forces for economic reform, the reduction of state ownership of productive assets, and the establishment of improved corporate governance in business enterprises, a substantial portion of productive assets in China is still owned by the government. In addition, the PRC government continues to play a significant role in regulating industrial development by imposing industrial policies. The PRC government also exercises significant control over China’s economic growth by allocating resources, controlling payment of foreign currency-denominated obligations, setting monetary policy, regulating financial services and institutions and providing preferential treatment to particular industries or companies.

While the PRC economy has experienced significant growth in the past four decades, growth has been uneven, both geographically and among various sectors of the economy. The PRC government has implemented various measures to encourage economic growth and guide the allocation of resources. Some of these measures may benefit the overall PRC economy, but may also have a negative effect on us. Our business, financial condition and results of operations could be materially and adversely affected by government control over capital investments or changes in tax regulations that are 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 operations. 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.

There are uncertainties regarding the interpretation and enforcement of PRC laws, rules and regulations.

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 and, unlike the common law system, prior court decisions can only be cited as reference and 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. 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. Further, the legal protections available to us and our investors under these laws, rules and regulations may be limited.

In addition, any administrative or 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 in more developed legal systems. These uncertainties may impede our ability to enforce various 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, enforcing foreign judgments or bringing actions in China against us or our management named in the prospectus based on foreign laws.

We are a company incorporated under the laws of the Cayman Islands, we conduct substantially all of our operations in China and substantially all of our assets are located in China. In addition, all our senior executive officers reside within China for a significant portion of the time and some of them are PRC nationals. As a result, it may be difficult for you to effect service of process upon us or those persons inside China. It may also be difficult for you to enforce in U.S. courts judgments obtained in U.S. courts based on the civil liability provisions of the U.S. federal securities laws against us and our officers and directors as none of them currently resides in the United States or has substantial assets located in the United States. In addition, there is uncertainty as to whether the courts of the Cayman Islands or the PRC would recognize or enforce judgments of U.S. courts against us or such persons predicated upon the civil liability provisions of the securities laws of the United States or any state.

The recognition and enforcement of foreign judgments are provided for under the PRC Civil Procedures Law. PRC courts may recognize and enforce foreign judgments in accordance with the requirements of the PRC Civil Procedures Law based either on treaties between China and the country where the judgment is made or on principles of reciprocity between jurisdictions. China does not have any treaties or other forms of written arrangement with the United States that provide for the reciprocal recognition and enforcement of foreign judgments. In addition, according to the PRC Civil Procedures Law, the PRC courts will not enforce a foreign judgment against us or our directors and officers if they decide that the judgment violates the basic principles of PRC laws or national sovereignty, security or the public interest. As a result, it is uncertain whether and on what basis a PRC court would enforce a judgment rendered by a court in the United States.

We may be restricted from transferring our scientific data abroad.

On March 17, 2018, the General Office of the PRC State Council promulgated the Measures for the Management of Scientific Data, 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 PRC 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. Currently, as the term “state secret” is not clearly defined, there is no assurance 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, or to our foreign partners in China.

If we are unable to obtain the necessary approvals in a timely manner, or at all, our research and development of drug candidates may be hindered, which may materially and adversely affect our business, results of operations, financial conditions and prospects. If 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 specific administrative penalties imposed by those government authorities.

Changes in U.S. and international trade policies, particularly with regard to China, may adversely impact our business and operating results.

The U.S. government has recently made statements and taken certain actions that may lead to potential changes to U.S. and international trade policies, including imposing several rounds of tariffs affecting certain products manufactured in China. In March 2018, U.S. President Donald J. Trump announced the imposition of tariffs on steel and aluminum entering the United States and in June 2018 announced further tariffs targeting goods imported from China. Recently both China and the U.S. have each imposed tariffs indicating the potential for further trade barriers. It is unknown whether and to what extent new tariffs (or 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 drug candidates, any unfavorable government policies on international trade, such as capital controls or tariffs, may affect the demand for our drug products, the competitive position of our drug products, the hiring of scientists and other research and development personnel, and import or export of raw materials in relation to drug development, or prevent us from selling our drug products in certain countries. If any new tariffs, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if the U.S. government takes retaliatory trade actions due to the recent U.S.-China trade tension, such changes could have an adverse effect on our business, financial condition and results of operations.

If we are classified as a PRC resident enterprise for PRC income tax purposes, such classification could result in unfavorable tax consequences to us and our non-PRC shareholders or ADS holders.

Under the PRC Enterprise Income Tax Law and its implementation rules, an enterprise established outside of the PRC with “de facto management body” within China is considered a “resident enterprise” and will be subject to the enterprise income tax on its global income at the rate of 25%. The implementation rules define the term “de facto management body” as the body that exercises full and substantial control and overall management over the business, productions, personnel, accounts and properties of an enterprise. In 2009, the SAT issued the Circular of the State Administration of Taxation on Issues Relating to Identification of PRC-Controlled Overseas Registered Enterprises as Resident Enterprises in Accordance With the De Facto Standards of Organizational Management, or SAT Circular 82, which provides certain specific criteria for determining whether the “de facto management body” of a PRC-controlled enterprise that is incorporated offshore is located in China. Although this circular only applies to offshore enterprises controlled by PRC enterprises or PRC enterprise groups, not those controlled by PRC individuals or foreigners, the criteria set forth in the circular may reflect the SAT’s general position on how the “de facto management body” text should be applied in determining the tax resident

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status of all offshore enterprises. According to SAT Circular 82, an offshore incorporated enterprise controlled by a PRC enterprise or a PRC enterprise group will be regarded as a PRC tax resident by virtue of having its “de facto management body” in China and will be subject to PRC enterprise income tax on its global income only if all of the following conditions are met: (i) the primary location of the day-to-day operational management is in China; (ii) decisions relating to the enterprise’s financial and human resource matters are made or are subject to approval by organizations or personnel in China; (iii) the enterprise’s primary assets, accounting books and records, company seals, and board and shareholder resolutions, are located or maintained in China; and (iv) at least 50% of voting board members or senior executives habitually reside in China.

We believe that we are not a PRC resident enterprise for PRC tax purposes. However, the tax resident status of an enterprise is subject to determination by the PRC tax authorities and uncertainties remain with respect to the interpretation of the term “de facto management body.” If the PRC tax authorities determine that we are a PRC resident enterprise for enterprise income tax purposes, we could be subject to PRC tax at a rate of 25% on our worldwide income, which could materially reduce our net income, and we may be required to withhold a 10% withholding tax from dividends we pay to our shareholders that are non-resident enterprises (including the holders of our ADSs). In addition, non-resident enterprise shareholders (including our ADS holders) may be subject to PRC tax on gains realized on the sale or other disposition of ADSs or ordinary shares, if such income is treated as sourced from within China. Furthermore, if we are deemed a PRC resident enterprise, dividends payable to our non-PRC individual shareholders (including our ADS holders) and any gain realized on the transfer of ADSs or ordinary shares by such shareholders may be subject to PRC tax at a rate of 10% in the case of non-PRC enterprises or a rate of 20% in the case of non-PRC individuals unless a reduced rate is available under an applicable tax treaty. It is unclear whether non-PRC shareholders of our company would be able to claim the benefits of any tax treaties between their country of tax residence and the PRC in the event that we are treated as a PRC resident enterprise. Any such tax may reduce the returns on your investment in the ADSs or ordinary shares.

Failure to renew our current leases or locate desirable alternatives for our leased properties could materially and adversely affect our business.

We lease properties for our offices and laboratories. We may not be able to successfully extend or renew such leases upon expiration of the current term on commercially reasonable terms or at all, and may therefore be forced to relocate our affected operations. This could disrupt our operations and result in significant relocation expenses, which could adversely affect our business, financial condition and results of operations. In addition, we compete with other businesses for premises at certain locations or of desirable sizes. As a result, even though we could extend or renew our leases, rental payments may significantly increase as a result of the high demand for the leased properties. In addition, we may not be able to locate desirable alternative sites for our current leased properties as our business continues to grow and failure in relocating our affected operations could adversely affect our business and operations.

Certain of 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.

We have not registered certain of 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 timeframe.

We have granted, and may continue to grant, options and other types of awards under our share incentive plans, which may result in increased share-based compensation expenses.

We have adopted an Amended and Restated 2017 Employee Stock Option Plan (the “2017 Plan”) and a 2018 Employee Stock Option Plan (the “2018 Plan”), for the purpose of granting share-based compensation awards to employees, directors and consultants to incentivize their performance and align their interests with ours. We recognize expenses in our consolidated financial statements in accordance with U.S. GAAP. As of the date of this prospectus, options to purchase a total of 9,941,650 ordinary shares and 13,550,805 ordinary shares have been granted and outstanding under the 2017 Plan and 2018 Plan, respectively. See “Management—Share Incentive Plans.”

We believe the granting of share-based compensation is of significant importance to our ability to attract and retain key personnel and employees, and we will continue to grant share-based compensation to employees in the future. As a result, our expenses associated with share-based compensation may increase, which may have an adverse effect on our results of operations. We may re-evaluate the vesting schedules, lock-up period, exercise price or other key terms applicable to the grants under our currently effective share incentive plans from time to time. If we choose to do so, we may experience substantial change in our share-based compensation charges in the reporting periods following this offering.

Fluctuations in exchange rates could have a material and adverse effect on our results of operations and the value of your investment.

The value of RMB against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in political and economic conditions in China and by China’s foreign exchange policies. On July 21, 2005, the PRC government changed its decade-old policy of pegging the value of RMB to the U.S. dollar, and RMB appreciated more than 20% against the U.S. dollar over the following three years. Between July 2008 and June 2010, this appreciation halted and the exchange rate between RMB and the U.S. dollar remained within a narrow band. Since June 2010, RMB has fluctuated against the U.S. dollar, at times significantly and unpredictably. On November 30, 2015, the Executive Board of the International Monetary Fund completed the regular five-year review of the basket of currencies that make up the Special Drawing Right, or the SDR, and decided that with effect from October 1, 2016, RMB is determined to be a freely usable currency and will be included in the SDR basket as a fifth currency, along with the U.S. dollar, the Euro, the Japanese yen and the British pound. In the fourth quarter of 2016, RMB has depreciated significantly in the backdrop of a surging U.S. dollar and persistent capital outflows of China. This depreciation halted in 2017, and RMB appreciated approximately 7% against the U.S. dollar during this one-year period. With the development of the foreign exchange market and progress towards interest rate liberalization and RMB internationalization, the PRC government may in the future announce further changes to the exchange rate system, and we cannot assure you that RMB will not appreciate or depreciate significantly in value against the U.S. dollar in the future. It is difficult to predict how market forces or PRC or U.S. government policy may impact the exchange rate between RMB and the U.S. dollar in the future.

Significant revaluation of RMB may have a material and adverse effect on your investment. For example, to the extent that we need to convert U.S. dollars we receive from this offering into RMB for our operations, appreciation of RMB against the U.S. dollar would have an adverse effect on the RMB amount we would receive from the conversion. Conversely, if we decide to convert our RMB into U.S. dollars for the purpose of making payments for dividends on our ordinary shares or ADSs or for other business purposes, appreciation of the U.S. dollar against RMB would have a negative effect on the U.S. dollar amount available to us.

Very limited hedging options are available in China to reduce our exposure to exchange rate fluctuations. To date, we have not entered into any hedging transactions in an effort to reduce our exposure to foreign currency exchange risk. While we may decide to enter into hedging transactions in the future, the availability and effectiveness of these hedges may be limited and we may not be able to adequately hedge our exposure or at all.

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In addition, our currency exchange losses may be magnified by PRC exchange control regulations that restrict our ability to convert RMB into foreign currency.

In addition, the PRC government imposes controls on the convertibility of RMB into foreign currencies and, in certain cases, the remittance of currency out of China. We receive substantially all of our revenues in RMB. Under our current corporate structure, our Cayman Islands holding company primarily relies on dividend payments from our PRC subsidiary to fund any cash and financing requirements we may have. Under existing PRC foreign exchange regulations, payments of current account items, including profit distributions, interest payments and trade and service-related foreign exchange transactions, can be made in foreign currencies without prior approval of the State Administration of Foreign Exchange, or SAFE, by complying with certain procedural requirements. Specifically, under the existing exchange restrictions, without prior approval of SAFE, cash generated from the operations of our PRC subsidiaries in China may be used to pay dividends to our company. However, approval from or registration with appropriate government authorities is required where RMB is to be converted into foreign currency and remitted out of China to pay capital expenses, such as the repayment of loans denominated in foreign currencies. As a result, we need to obtain SAFE approval to use cash generated from the operations of our PRC subsidiaries to pay off their respective debt in a currency other than RMB owed to entities outside China, or to make other capital expenditure payments outside China in a currency other than RMB. In light of the flood of capital outflows of China, the PRC government may from time to time impose more restrictive foreign exchange policies and step up scrutiny of major outbound capital movement. More restrictions and a substantial vetting process may be required by SAFE or other government authorities to regulate cross-border transactions falling under the capital account. The PRC government may at its discretion restrict access to foreign currencies for current account transactions in the future. If the foreign exchange control system prevents us from obtaining sufficient foreign currencies to satisfy our foreign currency demands, we may not be able to pay dividends in foreign currencies to our shareholders, including holders of our ADSs.

Certain PRC regulations may make it more difficult for us to pursue growth through acquisitions.

The Regulations on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors, or the M&A Rules, adopted by six PRC regulatory agencies in 2006 and amended in 2009, established additional procedures and requirements that could make merger and acquisition activities by foreign investors more time-consuming and complex. Such regulation requires, among other things, that the Ministry of Commerce, or MOFCOM, be notified in advance of any change of control transaction in which a foreign investor acquires control of a PRC domestic enterprise and involves any of the following circumstances: (i) any important industry is concerned; (ii) such transaction involves factors that impact or may impact national economic security; or (iii) such transaction will lead to a change in control of a domestic enterprise which holds a famous trademark or PRC time-honored brand. We do not expect that this offering will trigger MOFCOM pre-notification under each of the above-mentioned circumstances or any review by other PRC government authorities, except as disclosed below in “—The approval of the CSRC may be required in connection with this offering, and, if required, we cannot predict whether we will be able to obtain such approval.” Moreover, the Anti-Monopoly Law promulgated by the Standing Committee of National People’s Congress which became effective in 2008 requires that transactions which are deemed concentrations and involve parties with specified turnover thresholds must be cleared by State Administration for Market Regulation (the “SAMR”), the successive authority of MOFCOM, before they can be completed.

We may rely on dividends and other distributions on equity paid by our PRC subsidiaries to fund any cash and financing requirements we may have, and any limitation on the ability of our PRC subsidiaries to make payments to us could have a material and adverse effect on our ability to conduct our business.

We are a Cayman Islands holding company and we may rely on dividends and other distributions on equity paid by our PRC subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to our shareholders and service any debt we may incur. If any of our PRC subsidiaries incur debt on its own behalf in the future, the instruments governing the debt may restrict their

ability to pay dividends or make other distributions to us. Under PRC laws and regulations, our PRC subsidiaries, each of which is a wholly foreign-owned enterprise may pay dividends only out of its respective accumulated profits as determined in accordance with PRC accounting standards and regulations. In addition, a wholly foreign-owned enterprise is required to set aside at least 10% of its after-tax profits each year, if any, to fund a certain statutory reserve fund, until the aggregate amount of such fund reaches 50% of its registered capital. At its discretion, a wholly foreign-owned enterprise may allocate a portion of its after-tax profits based on PRC accounting standards to a staff welfare and bonus fund. The reserve fund and staff welfare and bonus fund cannot be distributed to us as dividends.

Our PRC subsidiaries generate primarily all of their revenue in RMB, which is not freely convertible into other currencies. As result, any restriction on currency exchange may limit the ability of our PRC subsidiaries to use their RMB revenues to pay dividends to us.

The PRC government may continue to strengthen its capital controls, and more restrictions and a substantial vetting process may be put forward by SAFE for cross-border transactions falling under both the current account and the capital account. Any limitation on the ability of our PRC subsidiaries to pay dividends or make other kinds of payments to us could materially and adversely limit our ability to grow, make investments or acquisitions that could be beneficial to our business, pay dividends, or otherwise fund and conduct our business.

In addition, the PRC Enterprise Income Tax Law and its implementation rules provide that a withholding tax rate of up to 10% will be applicable to dividends payable by PRC companies to non-PRC-resident enterprises unless otherwise exempted or reduced according to treaties or arrangements between the PRC central government and governments of other countries or regions where the non-PRC-resident enterprises are incorporated.

PRC regulations relating to offshore investment activities by PRC residents may limit our PRC subsidiaries' ability to change their registered capital or distribute profits to us or otherwise expose us or our PRC resident beneficial owners to liability and penalties under PRC laws.

In July 2014, SAFE promulgated the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment Through Special Purpose Vehicles, or SAFE Circular 37. SAFE Circular 37 requires PRC residents (including PRC individuals and PRC corporate entities as well as foreign individuals that are deemed as PRC residents for foreign exchange administration purpose) to register with SAFE or its local branches in connection with their direct or indirect offshore investment activities. SAFE Circular 37 further requires amendment to the SAFE registrations in the event of any changes with respect to the basic information of the offshore special purpose vehicle, such as changes of a PRC individual shareholder, name and operation term, or any significant changes with respect to the offshore special purpose vehicle, such as increase or decrease of capital contribution, share transfer or exchange, or mergers or divisions. SAFE Circular 37 is applicable to our shareholders who are PRC residents. If our shareholders who are PRC residents fail to make the required registration or to update the previously filed registration, our PRC subsidiaries may be prohibited from distributing their profits or the proceeds from any capital reduction, share transfer or liquidation to us, and we may also be prohibited from making additional capital contributions into our PRC subsidiaries.

In February 2015, SAFE promulgated a Notice on Further Simplifying and Improving Foreign Exchange Administration Policy on Direct Investment, or SAFE Notice 13, effective June 2015. Under SAFE Notice 13, applications for foreign exchange registration of inbound foreign direct investments and outbound overseas direct investments, including those required under SAFE Circular 37, will be filed with qualified banks instead of SAFE. The qualified banks will directly examine the applications and accept registrations under the supervision of SAFE.

All of our shareholders who we are aware of being subject to the SAFE regulations have completed the initial registrations with the local SAFE branch or qualified banks as required by SAFE Circular 37. However,

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we may not be informed of the identities of all the PRC residents holding direct or indirect interests in our company, and we cannot provide any assurance that these PRC residents will comply with our request to make or obtain any applicable registrations or continuously comply with all requirements under SAFE Circular 37 or other related rules. The failure or inability of the relevant shareholders to comply with the registration procedures set forth in these regulations may subject us to fines and legal sanctions, such as restrictions on our cross-border investment activities, on the ability of our wholly foreign-owned subsidiaries in China to distribute dividends and the proceeds from any reduction in capital, share transfer or liquidation to us. Moreover, failure to comply with the various foreign exchange registration requirements described above could result in liability under PRC law for circumventing applicable foreign exchange restrictions. As a result, our business operations and our ability to distribute profits could be materially and adversely affected.

Any failure to comply with PRC regulations regarding our employee equity incentive plans may subject the PRC plan participants or us to fines and other legal or administrative sanctions.

We and our directors, executive officers and other employees who are PRC citizens or who have resided in China for a continuous period of not less than one year and who will be granted restricted shares or options are subject to the Notice on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plan of Overseas Publicly Listed Company, issued by SAFE in February 2012, according to which, employees, directors, supervisors and other management members participating in any share incentive plan of an overseas publicly listed company who are PRC citizens or who are non-PRC citizens residing in China for a continuous period of not less than one year, subject to limited exceptions, are required to register with SAFE through a domestic qualified agent, which could be a PRC subsidiary of such overseas listed company, and complete certain other procedures. In addition, an overseas entrusted institution must be retained to handle matters in connection with the exercise or sale of stock options and the purchase or sale of shares and interests. Failure to complete the SAFE registrations may subject them to fines and legal sanctions and may also limit our ability to make payments under our equity incentive plans or receive dividends or sales proceeds related thereto, or our ability to contribute additional capital into our wholly foreign-owned enterprises in China and limit our wholly foreign-owned enterprises' ability to distribute dividends to us. We also face regulatory uncertainties that could restrict our ability to adopt additional equity incentive plans for our directors and employees under PRC law.

In addition, the SAT has issued circulars concerning employee share options or restricted shares. Under these circulars, employees working in China who exercise share options, or whose restricted shares vest, will be subject to PRC individual income tax. The PRC subsidiaries of an overseas listed company have obligations to file documents related to employee share options or restricted shares with relevant tax authorities and to withhold individual income taxes of those employees related to their share options or restricted shares. If the employees fail to pay, or the PRC subsidiaries fail to withhold applicable income taxes, the PRC subsidiaries may face sanctions imposed by the tax authorities or other PRC government authorities.

PRC regulation of loans to and direct investment in PRC entities by offshore holding companies and governmental control of currency conversion may delay or prevent us from using the proceeds of this offering to make loans to our PRC subsidiaries in China, which could materially and adversely affect our liquidity and our ability to fund and expand our business.

We are an offshore holding company conducting our operations in China through our PRC subsidiaries. We may make loans to our PRC subsidiaries subject to the approval from governmental authorities and limitation on the available loan amount, or we may make additional capital contributions to our wholly foreign-owned subsidiaries in China.

Any loans to our wholly foreign-owned subsidiaries in China, which are treated as foreign-invested enterprises under PRC law, are subject to PRC regulations and foreign exchange loan registrations. For example, loans by us to our wholly foreign-owned subsidiaries in China to finance their activities cannot exceed statutory

limits and must be registered with the local counterpart of SAFE. In addition, a foreign-invested enterprise shall use its capital pursuant to the principle of authenticity and self-use within its business scope. The capital of a foreign-invested enterprise shall not be used for the following purposes: (i) directly or indirectly used for payment beyond the business scope of the enterprises or the payment prohibited by relevant laws and regulations; (ii) directly or indirectly used for investment in securities or investments other than banks' principal-secured products unless otherwise provided by relevant laws and regulations; (iii) the granting of loans to non-affiliated enterprises, except where it is expressly permitted in the business license; and (iv) paying the expenses related to the purchase of real estate that is not for self-use (except for the foreign-invested real estate enterprises).

SAFE promulgated the Notice of the State Administration of Foreign Exchange on Reforming the Administration of Foreign Exchange Settlement of Capital of Foreign-invested Enterprises, or SAFE Circular 19, effective June 2015, in replacement of 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, the Notice from the State Administration of Foreign Exchange on Relevant Issues Concerning Strengthening the Administration of Foreign Exchange Businesses, and the Circular on Further Clarification and Regulation of the Issues Concerning the Administration of Certain Capital Account Foreign Exchange Businesses. According to SAFE Circular 19, the flow and use of RMB capital converted from foreign currency-denominated registered capital of a foreign-invested company is regulated such that RMB capital may not be used for the issuance of RMB entrusted loans, the repayment of inter-enterprise loans or the repayment of banks loans that have been transferred to a third party. Although SAFE Circular 19 allows RMB capital converted from foreign currency-denominated registered capital of a foreign-invested enterprise to be used for equity investments within China, it also reiterates the principle that RMB converted from the foreign currency-denominated capital of a foreign-invested company may not be directly or indirectly used for purposes beyond its business scope. Thus, it is unclear whether SAFE will permit such capital to be used for equity investments in China in actual practice. SAFE promulgated the Notice of the State Administration of Foreign Exchange on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account, or SAFE Circular 16, effective on June 9, 2016, which reiterates some of the rules set forth in SAFE Circular 19, but changes the prohibition against using RMB capital converted from foreign currency-denominated registered capital of a foreign-invested company to issue RMB entrusted loans to a prohibition against using such capital to issue loans to non-associated enterprises. Violations of SAFE Circular 19 and SAFE Circular 16 could result in administrative penalties. SAFE Circular 19 and SAFE Circular 16 may significantly limit our ability to transfer any foreign currency we hold, including the net proceeds from this offering, to our PRC subsidiaries, which may adversely affect our liquidity and our ability to fund and expand our business in China.

In light of the various requirements imposed by PRC regulations on loans to and direct investment in PRC entities by offshore holding companies, 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 to our PRC subsidiaries or future capital contributions by us to our wholly foreign-owned subsidiaries in China. As a result, uncertainties exist as to our ability to provide prompt financial support to our PRC subsidiaries when needed. If we fail to complete such registrations or obtain such approvals, our ability to use the proceeds we expect to receive from this offering and to capitalize or otherwise fund our PRC operations may be negatively affected, which could materially and adversely affect our liquidity and our ability to fund and expand our business.

We and our shareholders face uncertainties with respect to indirect transfers of equity interests in PRC resident enterprises or other assets attributable to a PRC establishment of a non-PRC company.

On February 3, 2015, the SAT issued the Bulletin on Issues of Enterprise Income Tax and Indirect Transfers of Assets by Non-PRC Resident Enterprises, or Bulletin 7. Pursuant to this Bulletin, an "indirect transfer" of "PRC taxable assets," including equity interests in a PRC resident enterprise, by non-PRC resident enterprises may be recharacterized and treated as a direct transfer of PRC taxable assets, if such arrangement does not have a reasonable commercial purpose and was established for the purpose of avoiding payment of PRC enterprise

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income tax. As a result, gains derived from such indirect transfer may be subject to PRC enterprise income tax. When determining whether there is a “reasonable commercial purpose” of the transaction arrangement, factors to be taken into consideration include: whether the main value of the equity interest of the relevant offshore enterprise derives from PRC taxable assets; whether the assets of the relevant offshore enterprise mainly consist of direct or indirect investment in China or if its income mainly derives from China; whether the offshore enterprise and its subsidiaries directly or indirectly holding PRC taxable assets have real commercial nature which is evidenced by their actual function and risk exposure; the duration of existence of the business model and organizational structure; the replicability of the transaction by direct transfer of PRC taxable assets; and the tax situation of such indirect transfer and applicable tax treaties or similar arrangements. On October 17, 2017, the SAT issued the Announcement of the State Administration of Taxation on Issues Concerning the Withholding of Non-resident Enterprise Income Tax at Source, or Bulletin 37, which came into effect on December 1, 2017. Bulletin 37 further clarifies the practice and procedure of the withholding of non-resident enterprise income tax.

Late payment of applicable tax will subject the transferor to default interest. Gains derived from the sale of shares by investors are not subject to the PRC enterprise income tax pursuant to Bulletin 7 where such shares were acquired in a transaction through a public stock exchange. However, the sale of ADSs or ordinary shares by a non-PRC resident enterprise outside a public stock exchange may be subject to PRC enterprise income tax under Bulletin 7.

There are uncertainties as to the application of Bulletin 7. Bulletin 7 may be determined by the tax authorities to be applicable to the sale of the shares of our offshore subsidiaries or investments where PRC taxable assets are involved. The transferors and transferees may be subject to the tax filing and withholding or tax payment obligation, while our PRC subsidiaries may be requested to assist in the filing. Furthermore, we, our non-resident enterprises and PRC subsidiaries may be required to spend valuable resources to comply with Bulletin 7 or to establish that we and our non-resident enterprises should not be taxed under Bulletin 7, for our previous and future restructuring or disposal of shares of our offshore subsidiaries, which may have a material adverse effect on our financial condition and results of operations.

The PRC tax authorities have the discretion under Bulletin 7 to make adjustments to the taxable capital gains based on the difference between the fair value of the taxable assets transferred and the cost of investment. If the PRC tax authorities make adjustments to the taxable income of the transactions under Bulletin 7 / Bulletin 37, our income tax costs associated with such potential acquisitions or disposals will increase, which may have an adverse effect on our financial condition and results of operations.

The approval of the CSRC may be required in connection with this offering, and, if required, we cannot predict whether we will be able to obtain such approval.

The M&A Rules require overseas special purpose vehicles that are controlled by PRC companies or individuals and formed for the purpose of seeking a public listing on an overseas stock exchange through acquisitions of PRC domestic companies using shares of such special purpose vehicles or held by its shareholders as consideration to obtain the approval of the CSRC, prior to the listing and trading of such special purpose vehicle’s securities on an overseas stock exchange. However, the application of the M&A Rules remains unclear. If CSRC approval is required, it is uncertain whether it would be possible for us to obtain the approval, and any failure to obtain or delay in obtaining CSRC approval for this offering would subject us to sanctions imposed by the CSRC and other PRC regulatory agencies.

Our PRC counsel has advised us based on their understanding of the current PRC laws, rules and regulations that the CSRC’s approval may not be required for the listing and trading of our ADSs on the [Nasdaq Stock Market] in the context of this offering, given that: (i) the CSRC currently has not issued any definitive rule or interpretation concerning whether offerings like ours in this prospectus are subject to this regulation, (ii) I-Mab Tianjin was not acquired by a connected merger or by acquisition of equity interest or assets of a PRC domestic

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company owned by PRC companies or individuals as defined under the M&A Rules and (iii) I-Mab Shanghai was incorporated as a wholly foreign-owned enterprise by means of direct investment.

However, our PRC counsel has further advised us that there remain some uncertainties as to how the M&A Rules will be interpreted or implemented in the context of an overseas offering and its opinions summarized above are subject to any new laws, rules and regulations or detailed implementations and interpretations in any form relating to the M&A Rules. We cannot assure you that relevant PRC government agencies, including the CSRC, would reach the same conclusion as we do. If it is determined that CSRC approval is required for this offering, we may face sanctions by the CSRC or other PRC regulatory agencies for failure to seek CSRC approval for this offering. These sanctions may include fines and penalties on our operations in China, limitations on our operating privileges in China, delays in or restrictions on the repatriation of the proceeds from this offering into the PRC, restrictions on or prohibition of the payments or remittance of dividends by our subsidiaries in China, or other actions that could have a material and adverse effect on our business, financial condition, results of operations, reputation and prospects, as well as the trading price of our ADSs. The CSRC or other PRC regulatory agencies may also take actions requiring us, or making it advisable for us, to halt this offering before the settlement and delivery of the ADSs that we are offering. Consequently, if you engage in market trading or other activities in anticipation of and prior to the settlement and delivery of the ADSs we are offering, you would be doing so at the risk that the settlement and delivery may not occur. In addition, if the CSRC or other regulatory agencies later promulgate new rules or explanations requiring that we obtain their approvals for this offering, we may be unable to obtain a waiver of such approval requirements, if and when procedures are established to obtain such a waiver.

Recent litigation and negative publicity surrounding China-based companies listed in the U.S. may result in increased regulatory scrutiny of us and negatively impact the trading price of the ADSs and could have a material adverse effect upon our business, including our results of operations, financial condition, cash flows and prospects.

We believe that litigation and negative publicity surrounding companies with operations in China that are listed in the U.S. have negatively impacted stock prices for such companies. Various equity-based research organizations have published reports on China-based companies after examining, among other things, their corporate governance practices, related party transactions, sales practices and financial statements that have led to special investigations and stock suspensions on national exchanges. Any similar scrutiny of us, regardless of its lack of merit, could result in a diversion of management resources and energy, potential costs to defend ourselves against rumors, decreases and volatility in the ADS trading price, and increased directors and officers insurance premiums and could have a material adverse effect upon our business, including our results of operations, financial condition, cash flows and prospects.

Risks Related to Our ADSs and This Offering

There has been no public market for our shares or ADSs prior to this offering, and you may not be able to resell our ADSs at or above the price you paid, or at all.

Prior to this initial public offering, there has been no public market for our shares or ADSs. We will apply to list our ADSs on the [Nasdaq Stock Market]. Our shares will not be listed on any exchange or quoted for trading on any over-the-counter trading system. If an active trading market for our ADSs does not develop after this offering, the market price and liquidity of our ADSs will be materially and adversely affected.

Negotiations with the underwriters will determine the initial public offering price for our ADSs which may bear no relationship to their market price after the initial public offering. We cannot assure you that an active trading market for our ADSs will develop or that the market price of our ADSs will not decline below the initial public offering price.

The trading price of our ADSs may be volatile, which could result in substantial losses to you.

The trading price of our ADSs can be volatile and fluctuate widely in response to a variety of factors, many of which are beyond our control. In addition, the performance and fluctuation of the market prices of other companies with business operations located mainly in the PRC that have listed their securities in the United States may affect the volatility in the price of and trading volumes for our ADSs. Some of these companies have experienced significant volatility. The trading performances of these PRC companies' securities may affect the overall investor sentiment towards other PRC companies listed in the United States and consequently may impact the trading performance of our ADSs.

In addition to market and industry factors, the price and trading volume for our ADSs may be highly volatile for specific business reasons, including:

- announcements of regulatory approval or a complete response letter, or specific label indications or patient populations for a drug's use, or changes or delays in the regulatory review process;
- announcements of therapeutic innovations, new products, acquisitions, strategic relationships, joint ventures or capital commitments by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- any adverse changes to our relationship with manufacturers or suppliers;
- the results of our testing and clinical trials;
- the results of our efforts to acquire or license additional drug candidates;
- variations in the level of expenses related to our existing drugs and drug candidates or pre-clinical, clinical development and commercialization programs;
- any intellectual property infringement actions in which we may become involved;
- announcements concerning our competitors or the pharmaceutical industry in general;
- fluctuations in product revenue, sales and marketing expenses and profitability; manufacture, supply or distribution shortages;
- variations in our results of operations;
- announcements about our results of operations that are not in line with analyst expectations, the risk of which is enhanced because it is our policy not to give guidance on results of operations;
- publication of operating or industry metrics by third parties, including government statistical agencies, that differ from expectations of industry or financial analysts;
- changes in financial estimates by securities research analysts;
- media reports, whether or not true, about our business, our competitors or our industry;
- additions to or departures of our management;
- fluctuations of exchange rates between the RMB and the U.S. dollar;
- release or expiry of lock-up or other transfer restrictions on our outstanding ordinary shares or ADSs;
- sales or perceived potential sales of additional ordinary shares or ADSs by us, our executive officers and directors or our shareholders;
- general economic and market conditions and overall fluctuations in the U.S. equity markets;
- changes in accounting principles; and
- changes or developments in the PRC or global regulatory environment.

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In addition, the stock market, in general, and pharmaceutical and biotechnology companies have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our ADSs, regardless of our actual operating performance. Further, the current volatility in the financial markets and related factors beyond our control may cause the market price of our ADSs to decline rapidly and unexpectedly.

After the completion of this offering, we may face an increased risk of securities class action litigation.

Historically, securities class action litigation has often been brought against a company following a significant decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant share price volatilities in recent years. If we were to face lawsuits, it could lead to substantial costs and a distraction of management's attention and resources, which could harm our business.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, or if they adversely change their recommendations regarding our ADSs, the market price for our ADSs and trading volume could decline.

The trading market for our ADSs will depend in part on the research and reports that securities or industry analysts publish about us or our business. If research analysts do not establish and maintain adequate research coverage or if one or more of the analysts who covers us downgrades our ADSs or publishes inaccurate or unfavorable research about our business, the market price for our ADSs would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which, in turn, could cause the market price or trading volume for our ADSs to decline.

Because our initial public offering price is substantially higher than our net tangible book value per share, you will experience immediate and substantial dilution.

If you purchase ADSs in this offering, you will pay more for your ADSs than the amount paid by our existing shareholders for their ordinary shares on a per ADS basis. As a result, you will experience immediate and substantial dilution of US\$ _____ per ADS, representing the difference between the initial public offering price of US\$ _____ per ADS and our adjusted net tangible book value per ADS as of December 31, 2018, after giving effect to our sale of the ADSs offered in this offering. In addition, you may experience further dilution to the extent that our ordinary shares are issued upon the exercise of share options. See "Dilution" for a more complete description of how the value of your investment in the ADSs will be diluted upon completion of this offering.

Because we do not expect to pay dividends in the foreseeable future after this offering, you must rely on price appreciation of our ADSs for return on your investment.

We currently intend to retain most, if not all, of our available funds and any future earnings after this offering to fund the development and growth of our business. 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 ADSs as a source for any future dividend income.

Our board of directors has complete discretion as to whether to distribute dividends, subject to certain requirements of Cayman Islands law. In addition, our shareholders may by ordinary resolution declare a dividend, but no dividend may exceed the amount recommended by our directors. Under Cayman Islands law, a Cayman Islands company may pay a dividend out of either profit or share premium account of the company, provided that in no circumstances may a dividend be paid out of share premium if this would result in the company being unable to pay its debts as they fall due in the ordinary course of business. Even if our board of

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directors 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 of directors. Accordingly, the return on your investment in our ADSs will likely depend entirely upon any future price appreciation of our ADSs. There is no guarantee that our ADSs will appreciate in value after this offering or even maintain the price at which you purchased the ADSs. You may not realize a return on your investment in our ADSs and you may even lose your entire investment in our ADSs.

Substantial future sales or perceived potential sales of our ADSs in the public market could cause the price of our ADSs to decline.

Sales of our ADSs in the public market after this offering, or the perception that these sales could occur, could cause the market price of our ADSs to decline. Upon completion of this offering, we will have _____ ordinary shares issued and outstanding, including _____ ordinary shares represented by ADSs, assuming the underwriters do not exercise their over-allotment option. All ADSs sold in this offering will be freely transferable without restriction or additional registration under the United States Securities Act of 1933, as amended, or the Securities Act. The remaining ordinary shares issued and outstanding after this offering will be available for sale, upon the expiration of the [180]-day lock-up period beginning from the date of this prospectus, subject to volume and other restrictions as applicable under Rules 144 and 701 under the Securities Act. Any or all of these shares may be released prior to the expiration of the lock-up period at the discretion of the representatives of the underwriters of this offering. To the extent shares are released before the expiration of the lock-up period and sold into the market, the market price of our ADSs could decline.

After completion of this offering, certain holders of our ordinary shares may cause us to register under the Securities Act the sale of their shares, subject to the [180]-day lock-up period in connection with this offering. Registration of these shares under the Securities Act would result in ADSs representing these shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. Sales of these registered shares in the form of ADSs in the public market could cause the price of our ADSs to decline.

The voting rights of holders of ADSs are limited by the terms of the deposit agreement, and you may not be able to exercise the same rights as our shareholders.

Holders of ADSs do not have the same rights as our shareholders. As a holder of our ADSs, you will not have any direct right to attend general meetings of our shareholders or to cast any votes at such meetings. As an ADS holder, you will only be able to exercise the voting rights carried by the underlying ordinary shares indirectly by giving voting instructions to the depositary in accordance with the provisions of the deposit agreement. Under the deposit agreement, you may vote only by giving voting instructions to the depositary. Upon receipt of your voting instructions, the depositary will try, as far as is practicable, to vote the ordinary shares underlying your ADSs in accordance with your instructions. If we ask for your instructions, then upon receipt of your voting instructions, the depositary will try to vote the underlying ordinary shares in accordance with these instructions. If we do not instruct the depositary to ask for your instructions, the depositary may still vote in accordance with instructions you give, but it is not required to do so. You will not be able to directly exercise your right to vote with respect to the underlying ordinary shares unless you withdraw the shares, and become the registered holder of such shares prior to the record date for the general meeting. When a general meeting is convened, you may not receive sufficient advance notice of the meeting to withdraw the shares underlying your ADSs and become the registered holder of such shares to allow you to attend the general meeting and to vote directly with respect to any specific matter or resolution to be considered and voted upon at the general meeting. In addition, under our post-offering memorandum and articles of association that will become effective prior to completion of this offering, for the purposes of determining those shareholders who are entitled to attend and vote at any general meeting, our directors may close our register of members and/or fix in advance a record date for such meeting, and such closure of our register of members or the setting of such a

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record date may prevent you from withdrawing the ordinary shares underlying your ADSs and becoming the registered holder of such shares prior to the record date, so that you would not be able to attend the general meeting or to vote directly. If we ask for your instructions, the depositary will notify you of the upcoming vote and will arrange to deliver our voting materials to you. We have agreed to give the depositary notice of shareholder meetings sufficiently in advance of such meetings. Nevertheless, we cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote the underlying ordinary shares represented by your ADSs. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for their manner of carrying out your voting instructions. This means that you may not be able to exercise your right to direct how the shares underlying your ADSs are voted and you may have no legal remedy if the shares underlying your ADSs are not voted as you requested. In addition, in your capacity as an ADS holder, you will not be able to call a shareholders' meeting. Except in limited circumstances, the depositary for our ADSs will give us a discretionary proxy to vote the ordinary shares underlying your ADSs if you do not vote at shareholders' meetings, which could adversely affect your interests.

[Under the deposit agreement for the ADSs, if you do not vote, the depositary will give us a discretionary proxy to vote the ordinary shares underlying your ADSs at shareholders' meetings unless:

- we have instructed the depositary that we do not wish a discretionary proxy to be given;
- we have informed the depositary that there is substantial opposition as to a matter to be voted on at the meeting;
- a matter to be voted on at the meeting would have a material adverse impact on shareholders; or
- the voting at the meeting is to be made on a show of hands.]

The effect of this discretionary proxy is that you cannot prevent our ordinary shares underlying your ADSs from being voted, except under the circumstances described above. This may make it more difficult for shareholders to influence the management of our company. Holders of our ordinary shares are not subject to this discretionary proxy.

Your right to participate in any future rights offerings may be limited, which may cause dilution to your holdings.

We may from time to time distribute rights to our shareholders, including rights to acquire our securities. However, we cannot make rights available to you in the United States unless we register both the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. Under the deposit agreement, the depositary will not make rights available to you unless both the rights and the underlying securities to be distributed to ADS holders are either registered under the Securities Act or exempt from registration under the Securities Act. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective and we may not be able to establish a necessary exemption from registration under the Securities Act. Accordingly, you may be unable to participate in our rights offerings and may experience dilution in your holdings.

You may not receive cash dividends if the depositary decides it is impractical to make them available to you.

The depositary will pay cash dividends on the ADSs only to the extent that we decide to distribute dividends on our ordinary shares or other deposited securities, and we do not have any present plan to pay any cash dividends on our ordinary shares in the foreseeable future. To the extent that there is a distribution, the depositary of our ADSs has agreed to pay to you the cash dividends or other distributions it or the custodian receives on our ordinary shares or other deposited securities after deducting its fees and expenses. You will receive these distributions in proportion to the number of ordinary shares your ADSs represent. However, the depositary may, at its discretion, decide that it is inequitable or impractical to make a distribution available to any holders of

ADSs. For example, the depositary may determine that it is not practicable to distribute certain property through the mail, or that the value of certain distributions may be less than the cost of mailing them. In these cases, the depositary may decide not to distribute such property to you.

You may be subject to limitations on transfer of your ADSs.

Your ADSs are transferable on the books of the depositary. However, the depositary may close its transfer books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may close its books from time to time for a number of reasons, including in connection with corporate events such as a rights offering, during which time the depositary needs to maintain an exact number of ADS holders on its books for a specified period. The depositary may also close its books in emergencies, and on weekends and public holidays. In addition, the depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary deems it advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason.

Certain judgments obtained against us by our shareholders may not be enforceable.

We are an exempted company incorporated under the laws of the Cayman Islands. We conduct our operations in China and substantially all of our assets are located in China. In addition, our directors and executive officers, and some of the experts named in this prospectus, reside within China, and most of the assets of these persons are located within China. As a result, it may be difficult or impossible for you to bring an action against us or against these individuals in the United States in the event that you believe that your rights have been infringed under the U.S. federal securities laws or otherwise. Even if you are successful in bringing an action of this kind, the laws of the Cayman Islands and of the PRC may render you unable to enforce a judgment against our assets or the assets of our directors and officers. For more information regarding the relevant laws of the Cayman Islands and China, see “Enforceability of Civil Liabilities.”

ADSs holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could result in less favorable outcomes to the plaintiff(s) in any such action.

The deposit agreement governing the ADSs representing our ordinary shares provides that, subject to the depositary’s right to require a claim to be submitted to arbitration, the federal or state courts in the City of New York have exclusive jurisdiction to hear and determine claims arising under the deposit agreement and in that regard, to the fullest extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our shares, the ADSs or the deposit agreement, including any claim under the U.S. federal securities laws. Also, we may amend or terminate the deposit agreement without your consent. If you continue to hold your ADSs after an amendment to the deposit agreement, you agree to be bound by the deposit agreement as amended.

If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable based on the facts and circumstances of that case in accordance with the applicable U.S. state and federal law. To our knowledge, the enforceability of a contractual pre-dispute jury trial waiver in connection with claims arising under the U.S. federal securities laws has not been finally adjudicated by the United States Supreme Court. However, we believe that a contractual pre-dispute jury trial waiver provision is generally enforceable, including under the laws of the State of New York, which govern the deposit agreement. In determining whether to enforce a contractual pre-dispute jury trial waiver provision, courts will generally consider whether a party knowingly, intelligently and voluntarily waived the right to a jury trial. We believe that this is the case with respect to the deposit agreement and the ADSs. It is advisable that you consult legal counsel regarding the jury waiver provision before investing in the ADSs.

If you or any other holders or beneficial owners of ADSs bring a claim against us or the depositary in connection with matters arising under the deposit agreement or the ADSs, including claims under U.S. federal

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securities laws, you or such other holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us and/or the depository. If a lawsuit is brought against us and/or the depository under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, in which the trial would be conducted according to different civil procedures and may result in different outcomes than a trial by jury would have had, including results that could be less favorable to the plaintiff(s) in any such action.

Nevertheless, if this jury trial waiver provision is not enforced, to the extent a court action proceeds, it would proceed under the terms of the deposit agreement with a jury trial. No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depository of compliance with any substantive provision of the U.S. federal securities laws and the rules and regulations promulgated thereunder.

You may face difficulties in protecting your interests, and your ability to protect your rights through U.S. courts may be limited, because we are incorporated under Cayman Islands law.

We are an exempted company incorporated under the laws of the Cayman Islands with limited liability. Our corporate affairs are governed by our memorandum and articles of association, the Companies Law (2018 Revision) of the Cayman Islands, which we refer to as the Companies Law, and the common law of the Cayman Islands. The rights of shareholders to take action against our directors, actions by our minority shareholders and the fiduciary duties 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 the common law of England, the decisions of whose courts are of persuasive authority, but are not binding, on a court in the Cayman Islands. The rights of our shareholders and the fiduciary duties of our directors under Cayman Islands law are not as clearly established as they would be under statutes or judicial precedent in some jurisdictions in the United States. In particular, the Cayman Islands has a less developed body of securities laws than the United States. Some U.S. states, such as Delaware, have more fully developed and judicially interpreted bodies of corporate law than the Cayman Islands. In addition, Cayman Islands companies may not have standing to initiate a shareholder derivative action in a federal court of the United States.

Shareholders of Cayman Islands exempted companies like us have no general rights under Cayman Islands law to inspect corporate records or to obtain copies of lists of shareholders of these companies. Our directors have discretion under our post-offering articles of association that will become effective immediately prior to completion of this offering to determine whether or not, and under what conditions, our corporate records may be inspected by our shareholders, but are not obliged to make them available to our shareholders. This may make it more difficult for you to obtain the information needed to establish any facts necessary for a shareholder motion or to solicit proxies from other shareholders in connection with a proxy contest.

As a result of all of the above, our public shareholders may have more difficulty in protecting their interests in the face of actions taken by management, members of the board of directors or controlling shareholders than they would as public shareholders of a company incorporated in the United States. For a discussion of significant differences between the provisions of the Companies Law and the laws applicable to companies incorporated in the United States and their shareholders, see “Description of Share Capital—Differences in Corporate Law.”

We have not determined a specific use for a portion of the net proceeds from this offering and we may use these proceeds in ways with which you may not agree.

We have not determined a specific use for a portion of the net proceeds of this offering, and our management will have considerable discretion in deciding how to apply these proceeds. You will not have the opportunity to assess whether the proceeds are being used appropriately before you make your investment decision. You must rely on the judgment of our management regarding the application of the net proceeds of this

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offering. We cannot assure you that the net proceeds will be used in a manner that would improve our results of operations or increase our ADS price, nor that these net proceeds will be placed only in investments that generate income or appreciate in value.

The post-offering memorandum and articles of association that we plan to adopt and that will become effective immediately prior to the completion of this offering will contain anti-takeover provisions that could discourage a third party from acquiring us and adversely affect the rights of holders of our ordinary shares and the ADSs.

We plan to conditionally adopt amended and restated memorandum and articles of association that will become effective immediately prior to the completion of this offering. Our new memorandum and articles of association will contain provisions to limit the ability of others to acquire control of our company or cause us to engage in change of control transactions. These provisions could have the effect of depriving our shareholders of an opportunity to sell their shares at a premium over prevailing market prices by discouraging third parties from seeking to obtain control of our company in a tender offer or similar transaction. Our board of directors has the authority, without further action by our shareholders, to issue preferred shares in one or more series and to fix their designations, powers, preferences, privileges, and relative participating, optional or special rights and the qualifications, limitations or restrictions, including dividend rights, conversion rights, voting rights, terms of redemption and liquidation preferences, any or all of which may be greater than the rights associated with our ordinary shares, in the form of ADS or otherwise. Preferred shares could be issued quickly with terms calculated to delay or prevent a change in control of our company or make removal of management more difficult. If our board of directors decides to issue preferred shares, the price of our ADSs may fall and the voting and other rights of the holders of our ordinary shares and ADSs may be materially and adversely affected.

We are an emerging growth company within the meaning of the Securities Act and may take advantage of certain reduced reporting requirements.

We are an “emerging growth company,” as defined in the U.S. Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we may take advantage of certain exemptions from various requirements applicable to other public companies that are not emerging growth companies including, most significantly, not being required to comply with the auditor attestation requirements of Section 404 of Sarbanes-Oxley Act of 2002 for so long as we are an emerging growth company. As a result, if we elect not to comply with such auditor attestation requirements, our investors may not have access to certain information they may deem important.

The JOBS Act also provides that an emerging growth company does not need to comply with any new or revised financial accounting standards until such date that a private company is otherwise required to comply with such new or revised accounting standards. However, we have elected to “opt out” of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted for public companies. This decision to opt out of the extended transition period under the JOBS Act is irrevocable.

We are a foreign private issuer within the meaning of the rules under the Exchange Act, and as such we are exempt from certain provisions applicable to U.S. domestic public companies.

Because we qualify as a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the securities rules and regulations in the United States that are applicable to U.S. domestic issuers, including:

- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q or current reports on Form 8-K;
- the sections of the Exchange Act regulating the solicitation of proxies, consents, or authorizations in respect of a security registered under the Exchange Act;

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- the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and
- the selective disclosure rules by issuers of material nonpublic information under Regulation FD promulgated by SEC.

We will be required to file an annual report on Form 20-F within four months of the end of each fiscal year. In addition, we intend to publish our results on a quarterly basis as press releases, distributed pursuant to the rules and regulations of the [Nasdaq Stock Market]. Press releases relating to financial results and material events will also be furnished to the SEC on Form 6-K. However, the information we are required to file with or furnish to the SEC will be less extensive and less timely compared to that required to be filed with the SEC by U.S. domestic issuers. As a result, you may not be afforded the same protections or information that would be made available to you were you investing in a U.S. domestic issuer.

As an exempted company incorporated in the Cayman Islands, we are permitted to adopt certain home country practices in relation to corporate governance matters that differ significantly from the [Nasdaq Stock Market]’s corporate governance requirements; these practices may afford less protection to shareholders than they would enjoy if we complied fully with the [Nasdaq Stock Market]’s corporate governance requirements.

As a Cayman Islands company listed on the [Nasdaq Stock Market], we are subject to the [Nasdaq Stock Market]’s corporate governance requirements. However, the [Nasdaq Stock Market] rules permit a foreign private issuer like us to follow the corporate governance practices of its home country. Certain corporate governance practices in the Cayman Islands, which is our home country, may differ significantly from the [Nasdaq Stock Market]’s corporate governance requirements. For example, neither the Companies Law nor our post-offering memorandum and articles of association that will become effective immediately prior to the completion of this offering requires a majority of our directors to be independent and we could include non-independent directors as members of our compensation committee and nominating committee, and our independent directors would not necessarily hold regularly scheduled meetings at which only independent directors are present. Currently, we do not plan to rely on home country practice with respect to our corporate governance after we complete this offering. However, if we choose to follow home country practice in the future, our shareholders may be afforded less protection than they otherwise would under the [Nasdaq Stock Market]’s corporate governance requirements applicable to U.S. domestic issuers.

There can be no assurance that we will not be classified as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes for any taxable year, which could subject U.S. investors in our ADSs or ordinary shares to significant adverse U.S. income tax consequences.

We will be a passive foreign investment company, or PFIC, for any taxable year if either (i) 75% or more of our gross income for such year consists of certain types of “passive” income or (ii) 50% or more of the average quarterly value of our assets (as determined on the basis of fair market value) during such year produce or are held for the production of passive income (the “asset test”). No assurance can be given with respect to our PFIC status for the current taxable year or any future taxable year. The determination of whether we are or will become a PFIC is uncertain because it is a fact-intensive inquiry made on an annual basis that will depend, in part, on the composition of our income and assets. Fluctuations in the market price of our ADSs may cause us to be a PFIC for the current or subsequent taxable years because the value of our assets for purposes of the asset test may be determined by reference to the market price of our ADSs from time to time (which may be volatile for biopharmaceutical companies, such as ours, that have not yet achieved commercialization with respect to any of their products). The composition of our income and assets may also be affected by how, and how quickly, we use our liquid assets and the cash raised in this offering. Under circumstances where our revenue from activities that produce passive income increases relative to our revenue from activities that produce non-passive income, or where we determine not to deploy cash for active purposes, our risk of being a PFIC will substantially increase. Because there are uncertainties in the application of the relevant rules, it is possible that the IRS may challenge

our classification or valuation of certain income and assets, each of which may result in our being or becoming a PFIC for the current or subsequent taxable years.

If we are a PFIC in any taxable year, a U.S. Holder (as defined in “Taxation—United States Federal Income Tax Considerations”) may incur significantly increased U.S. income tax on gain recognized on the sale or other disposition of the ADSs or ordinary shares and on the receipt of distributions on the ADSs or ordinary shares to the extent such gain or distribution is treated as an “excess distribution” under the U.S. federal income tax rules and such holder may be subject to burdensome reporting requirements. Further, if we are a PFIC for any year during which a U.S. holder holds our ADSs or ordinary shares, we generally will continue to be treated as a PFIC for all succeeding years during which such U.S. holder holds our ADSs or ordinary shares. For more information see “Taxation—United States Federal Income Tax Considerations—Passive Foreign Investment Company Considerations.”

We will incur increased costs and become subject to additional rules and regulations as a result of being a public company, particularly after we cease to qualify as an “emerging growth company.”

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC and [the Nasdaq Global Market], impose various requirements on the corporate governance practices of public companies. As a company with less than US\$1.07 billion in net revenues for our last fiscal year, we qualify as an “emerging growth company” pursuant to the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other requirements that are otherwise applicable generally to public companies. These provisions include exemption from the auditor attestation requirement under Section 404 of the Sarbanes-Oxley Act of 2002 in the assessment of the emerging growth company’s internal control over financial reporting and permission to delay adopting new or revised accounting standards until such time as those standards apply to private companies. However, we have elected to “opt out” of the provision that allows us to delay adopting new or revised accounting standards and, as a result, we will comply with new or revised accounting standards as required when they are adopted for public companies. This decision to opt out of the extended transition period under the JOBS Act is irrevocable.

We expect these rules and regulations to increase our legal and financial compliance costs and to make some corporate activities more time-consuming and costly. After we are no longer an “emerging growth company,” we expect to incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and the other rules and regulations of the SEC. We also expect that operating as a public company will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. In addition, we will incur additional costs associated with our public company reporting requirements. It may also be more difficult for us to find qualified persons to serve on our board of directors or as executive officers. We are currently evaluating and monitoring developments with respect to these rules and regulations, and we cannot predict or estimate with any degree of certainty the amount of additional costs we may incur or the timing of such costs.

In the past, shareholders of a public company often brought securities class action suits against the company following periods of instability in the market price of that company’s securities. If we were involved in a class action suit, it could divert a significant amount of our management’s attention and other resources from our business and operations, which could harm our results of operations and require us to incur significant expenses to defend the suit. Any such class action suit, whether or not successful, could harm our reputation and restrict our ability to raise capital in the future. In addition, if a claim is successfully made against us, we may be required to pay significant damages, which could have a material adverse effect on our financial condition and results of operations.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that reflect our current expectations and views of future events. The forward-looking statements are contained principally in the sections entitled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business.” Known and unknown risks, uncertainties and other factors, including those listed under “Risk Factors,” may cause our actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements.

You can identify some of these forward-looking statements by words or phrases such as “may,” “will,” “expect,” “anticipate,” “aim,” “estimate,” “intend,” “plan,” “believe,” “is/are likely to,” “potential,” “continue” or other similar expressions. We have based these forward-looking statements largely on our current expectations and projections about future events that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements include statements relating to:

- the timing of initiation and completion, and the progress of our drug discovery and research programs;
- the timing and likelihood of regulatory filings and approvals;
- our ability to advance our drug candidates into drugs, and the successful completion of clinical trials;
- the approval, pricing and reimbursement of our drug candidates;
- the commercialization of our drug candidates;
- the market opportunities and competitive landscape of our drug candidates;
- the payment, receipt and timing of any milestone payments in relation to the licensing agreements;
- 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 future business development, financial condition and results of operations;
- 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 continue to maintain our market position in China’s biopharmaceutical and biotechnology industries;
- our ability to identify and integrate suitable acquisition targets; and
- changes to regulatory and operating conditions in our industry and markets.

These forward-looking statements involve various risks and uncertainties. Although we believe that our expectations expressed in these forward-looking statements are reasonable, our expectations may later be found to be incorrect. Our actual results could be materially different from our expectations. Important risks and factors that could cause our actual results to be materially different from our expectations are generally set forth in “Prospectus Summary—Our Challenges,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Business,” “Regulation” and other sections in this prospectus. You should read thoroughly this prospectus and the documents that we refer to with the understanding that our actual future results may be materially different from and worse than what we expect. We qualify all of our forward-looking statements by these cautionary statements.

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This prospectus contains certain data and information that we obtained from various government and private publications. Statistical data in these publications also include projections based on a number of assumptions. The biopharmaceutical industry may not grow at the rate projected by market data, or at all. Failure of this market to grow at the projected rate may have a material and adverse effect on our business and the market price of our ADSs. In addition, the rapidly evolving nature of the biopharmaceutical industry results in significant uncertainties for any projections or estimates relating to the growth prospects or future condition of our market. Furthermore, if any one or more of the assumptions underlying the market data are later found to be incorrect, actual results may differ from the projections based on these assumptions. You should not place undue reliance on these forward-looking statements.

The forward-looking statements made in this prospectus relate only to events or information as of the date on which the statements are made in this prospectus. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, after the date on which the statements are made or to reflect the occurrence of unanticipated events. You should read this prospectus and the documents that we refer to in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect.

USE OF PROCEEDS

We estimate that we will receive net proceeds from this offering of approximately US\$ million, or approximately US\$ million if the underwriters exercise their option to purchase additional ADSs in full, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. These estimates are based upon an assumed initial public offering price of US\$ per ADS, which is the mid-point of the price range shown on the cover page of this prospectus. A US\$1.00 increase (decrease) in the assumed initial public offering price of US\$ per ADS would increase (decrease) the net proceeds to us from this offering by US\$, assuming the number of ADSs offered by us as set forth on the cover page of this prospectus remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The primary purposes of this offering are to create a public market for our shares for the benefit of all shareholders, retain talented employees by providing them with equity incentives, and obtain additional capital. We plan to use the net proceeds of this offering as follows:

- approximately US\$ million for research and development of our existing and future drug candidates, including:
 - (i) approximately US\$ million for the ongoing registrational trials and other planned studies for TJ202 and the milestone payments in connection with development of TJ202;
 - (ii) approximately US\$ million for the planned registrational trial and other planned studies for enoblituzumab and the milestone payments in connection with development of enoblituzumab; and
 - (iii) approximately US\$ million for research and development of our other pipeline assets, mainly for TJ101, TJ301, TJ107, TJC4, TJD5 and TJM2;
- approximately US\$ million for potential investments in the establishment of our own manufacturing capacities, including the construction of our manufacturing facility in Hangzhou, China; and
- approximately US\$ million for general corporate purposes (including working capital needs), potential strategic alliances, investments or acquisitions, although we have not identified any specific alliances, investment or acquisition opportunities as of the date of this prospectus.

The foregoing represents our current intentions based upon our present plans and business conditions to use and allocate the net proceeds of this offering. Our management, however, will have significant flexibility and discretion to apply the net proceeds of this offering. If an unforeseen event occurs or business conditions change, we may use the proceeds of this offering differently than as described in this prospectus. See “Risk Factors—Risks Related to Our ADSs and This Offering—We have not determined a specific use for a portion of the net proceeds from this offering and we may use these proceeds in ways with which you may not agree.”

Pending any use described above, we plan to invest the net proceeds from this offering in short-term, interest-bearing, debt instruments or demand deposits.

DIVIDEND POLICY

Our board of directors has complete discretion on whether to pay dividends, subject to certain requirements of Cayman Islands law. Even if our board of directors decides to pay dividends on our ordinary shares, the form, frequency and amount will depend upon our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that our board of directors may deem relevant.

We do not have any present plan to pay any cash dividends on our ordinary shares in the foreseeable future after this offering. We currently intend to retain most, if not all, of our available funds and any future earnings to operate and expand our business.

We are a holding company incorporated in the Cayman Islands. We may rely on dividends from our subsidiaries in China for our cash requirements, including any payment of dividends to our shareholders. PRC regulations may restrict the ability of our PRC subsidiaries to pay dividends to us. See “Regulation—PRC Regulation—Regulations Relating to Foreign Exchange and the Dividend Distribution.”

If we pay any dividends on our ordinary shares, we will pay those dividends which are payable in respect of the ordinary shares underlying our ADSs to the depositary, as the registered holder of such ordinary shares, and the depositary then will pay such amounts to our ADS holders in proportion to the ordinary shares underlying the ADSs held by such ADS holders, subject to the terms of the deposit agreement, including the fees and expenses payable thereunder. See “Description of American Depositary Shares.” Cash dividends on our ordinary shares, if any, will be paid in U.S. dollars.

CAPITALIZATION

The following table sets forth our capitalization as of December 31, 2018:

- on an actual basis;
- on a pro forma basis to reflect the automatic conversion of all of our issued and outstanding preferred shares into ordinary shares on a one-for-one basis immediately upon the completion of this offering; and
- on a pro forma as adjusted basis to reflect (i) the automatic conversion of all of our issued and outstanding preferred shares into ordinary shares on a one-for-one basis immediately upon the completion of this offering and (ii) the sale of ordinary shares represented by ADSs by us in this offering at an assumed initial public offering price of US\$ per ADS, which is the mid-point of the estimated range of the initial public offering price shown on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, assuming the underwriters do not exercise their option to purchase additional ADSs.

You should read this table together with our consolidated financial statements and the related notes included elsewhere in this prospectus and the information under “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	As of December 31, 2018			
	Actual		Pro Forma	
	RMB	US\$ (in thousands) ⁽¹⁾	RMB	US\$
Mezzanine equity				
Series A convertible preferred shares (US\$0.0001 par value, 21,865,233 and 30,227,056 shares authorized, issued and outstanding as of December 31, 2017 and 2018, respectively)	687,482	99,990	—	—
Series B convertible preferred shares (US\$0.0001 par value, 15,894,594 and 30,305,212 shares authorized, issued and outstanding as of December 31, 2017 and 2018, respectively)	921,243	133,989	—	—
Series C convertible preferred shares (US\$0.0001 par value, 31,046,360 shares authorized, issued and outstanding as of December 31, 2018)	1,306,633	190,042	—	—
Redeemable non-controlling interests	—	—	—	—
Total mezzanine equity	2,915,358	424,021	—	—
Shareholders’ equity (deficit)				
Ordinary shares (US\$0.0001 par value, 500,000,000 shares authorized as of December 31, 2017 and 2018, 8,363,719 shares authorized, issued and outstanding as of December 31, 2017 and 2018, respectively)	6	1	69	10
Treasury stock	(1)	—	(1)	—
Additional paid-in capital	—	—	2,926,531	425,646
Accumulated other comprehensive income	59,380	8,636	59,380	8,636
Accumulated deficit	(1,014,489)	(147,551)	(1,020,107)	(148,368)
Total shareholders’ equity (deficit)	(955,104)	(138,914)	1,965,872	285,924
Total mezzanine equity and shareholders’ equity (deficit)	1,960,254	285,107	1,965,872	285,924

Note:

(1) The pro forma and pro forma as adjusted equity securities are reflected using a rate of RMB6.8755 to US\$1.00, the exchange rate in effect as of the end of December 2018.

DILUTION

If you invest in our ADSs, your interest will be diluted to the extent of the difference between the initial public offering price per ADS and our net tangible book value per ADS after this offering. Dilution results from the fact that the initial public offering price per ordinary share is substantially in excess of the book value per ordinary share attributable to the existing shareholders for our presently outstanding ordinary shares.

Our net tangible book value as of December 31, 2018 was approximately US\$, or US\$ per ordinary share as of that date and US\$ per ADS. Net tangible book value represents the amount of our total consolidated tangible assets, less the amount of our total consolidated liabilities. Dilution is determined by subtracting net tangible book value per ordinary share, after giving effect to the additional proceeds we will receive from this offering, from the assumed initial public offering price of US\$ per ordinary share, which is the midpoint of the estimated initial public offering price range set forth on the cover page of this prospectus adjusted to reflect the ADS-to-ordinary share ratio, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Without taking into account any other changes in net tangible book value after December 31, 2018, other than to give effect to our sale of the ADSs offered in this offering at the assumed initial public offering price of US\$ per ADS, which is the midpoint of the estimated range of the initial public offering price, after deduction of the underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2018 would have been US\$, or US\$ per ordinary share and US\$ per ADS. This represents an immediate increase in net tangible book value of US\$ per ordinary share and US\$ per ADS to the existing shareholders and an immediate dilution in net tangible book value of US\$ per ordinary share and US\$ per ADS to investors purchasing ADSs in this offering. The following table illustrates such dilution:

	<u>Per Ordinary Share</u>	<u>Per ADS</u>
Assumed initial public offering price	US\$	US\$
Net tangible book value as of December 31, 2018	US\$	US\$
Pro forma net tangible book value after giving effect to the conversion of our preferred shares	US\$	US\$
Pro forma as adjusted net tangible book value after giving effect to the conversion of our preferred shares and this offering	US\$	US\$
Amount of dilution in net tangible book value to new investors in this offering	US\$	US\$

A US\$1.00 increase (decrease) in the assumed initial public offering price of US\$ per ADS would increase (decrease) our pro forma as adjusted net tangible book value after giving effect to this offering by US\$, the pro forma as adjusted net tangible book value per ordinary share and per ADS after giving effect to this offering by US\$ per ordinary share and US\$ per ADS and the dilution in pro forma as adjusted net tangible book value per ordinary share and per ADS to new investors in this offering by US\$ per ordinary share and US\$ per ADS, assuming no change to the number of ADSs offered by us as set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and other offering expenses.

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The following table summarizes, on a pro forma as adjusted basis as of December 31, 2018, the differences between existing shareholders and the new investors with respect to the number of ordinary shares (represented by ADSs or shares) purchased from us, the total consideration paid and the average price per ordinary share and per ADS paid before deducting the underwriting discounts and commissions and estimated offering expenses. The total number of ordinary shares does not include ordinary shares underlying the ADSs issuable upon the exercise of the over-allotment option granted to the underwriters.

	<u>Ordinary Shares Purchased</u>		<u>Total Consideration</u>		<u>Average Price Per Ordinary Share</u>	<u>Average Price Per ADS</u>
	<u>Number</u>	<u>Percent</u>	<u>Amount</u>	<u>Percent</u>		
Existing shareholders			US\$	%	US\$	US\$
New investors			US\$	%	US\$	US\$
Total			US\$	100.0%		

The pro forma as adjusted information discussed above is illustrative only. Our net tangible book value following the completion of this offering is subject to adjustment based on the actual initial public offering price of our ADSs and other terms of this offering determined at pricing.

The discussion and tables above assume no exercise of any outstanding share options outstanding as of the date of this prospectus. As of the date of this prospectus, there are ordinary shares issuable upon exercise of outstanding share options at a weighted average exercise price of US\$ per share, and there are ordinary shares available for future issuance upon the exercise of future grants under our share incentive plans. To the extent that any of these options are exercised, there will be further dilution to new investors.

ENFORCEABILITY OF CIVIL LIABILITIES

We are incorporated under the laws of the Cayman Islands as an exempted company with limited liability. We are incorporated in the Cayman Islands because of certain benefits associated with being a Cayman Islands exempted company, such as political and economic stability, an effective judicial system, a favorable tax system, the absence of foreign exchange control or currency restrictions and the availability of professional and support services. However, the Cayman Islands has a less developed body of securities laws than the United States and provides less protection for investors. In addition, Cayman Islands companies do not have standing to sue before the federal courts of the United States.

Most of our assets are located outside the United States. In addition, most of our directors and officers are nationals or residents of jurisdictions other than the United States and all or a substantial portion of their assets are located outside the United States. As a result, it may be difficult for investors to effect service of process within the United States upon us or these persons, or to enforce judgments obtained in U.S. courts against us or them, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any state in the United States. It may also be difficult for you to enforce judgments obtained in U.S. courts based on the civil liability provisions of the U.S. federal securities laws against us and our officers and directors.

We have appointed _____ as our agent to receive service of process with respect to any action brought against us in the U.S. District Court for the Southern District of New York in connection with this offering under the federal securities laws of the United States or the securities laws of any state in the United States or any action brought against us in the Supreme Court of the State of New York in the County of New York in connection with this offering under the securities laws of the State of New York.

Conyers Dill & Pearman, our counsel as to Cayman Islands law, has advised us that there is uncertainty as to whether the courts of the Cayman Islands would (1) recognize or enforce judgments of U.S. courts obtained against us or our directors or officers that are predicated upon the civil liability provisions of the federal securities laws of the United States or the securities laws of any state in the United States, or (2) entertain original actions brought in the Cayman Islands against us or our directors or officers that are predicated upon the federal securities laws of the United States or the securities laws of any state in the United States.

Conyers Dill & Pearman has informed us that the uncertainty with regard to Cayman Islands law relates to whether a judgment obtained from the U.S. courts under civil liability provisions of the securities law will be determined by the courts of the Cayman Islands as penal or punitive in nature. The courts of the Cayman Islands may not recognize or enforce such judgments against a Cayman company, and because such a determination has not yet been made by a court of the Cayman Islands, it is uncertain whether such civil liability judgments from U.S. courts would be enforceable in the Cayman Islands. Conyers Dill & Pearman has further advised us that the courts of the Cayman Islands would recognize as a valid judgment, a final and conclusive judgment in personam obtained in the federal or state courts of the United States under which a sum of money is payable (other than a sum of money payable in respect of multiple damages, taxes or other charges of a like nature or in respect of a fine or other penalty) or, in certain circumstances, an in personam judgment for non-monetary relief, and would give a judgment based thereon provided that (a) such courts had proper jurisdiction over the parties subject to such judgment; (b) such courts did not contravene the rules of natural justice of the Cayman Islands; (c) such judgment was not obtained by fraud; (d) the enforcement of the judgment would not be contrary to the public policy of the Cayman Islands; (e) no new admissible evidence relevant to the action is submitted prior to the rendering of the judgment by the courts of the Cayman Islands; and (f) there is due compliance with the correct procedures under the laws of the Cayman Islands.

JunHe LLP, our counsel as to PRC law, has advised us that there is uncertainty as to whether the courts of China would (1) recognize or enforce judgments of United States courts obtained against us or our directors or officers predicated upon the civil liability provisions of the securities laws of the United States or any state in the United States, or (2) entertain original actions brought in each respective jurisdiction against us or our directors or officers predicated upon the securities laws of the United States or any state in the United States.

JunHe LLP has further advised us that the recognition and enforcement of foreign judgments are provided for under the PRC Civil Procedures Law. The PRC courts may recognize and enforce foreign judgments in accordance with the requirements of the PRC Civil Procedures Law based either on treaties between China and the country where the judgment is made or on principles of reciprocity between jurisdictions. China does not have any treaties or other form of reciprocal arrangements with the United States or the Cayman Islands that provide for the reciprocal recognition and enforcement of foreign judgments. In addition, according to the PRC Civil Procedures Law, courts in China will not enforce a foreign judgment against us or our directors and officers if they decide that the judgment violates the basic principles of PRC law or national sovereignty, security or public interest. As a result, it is uncertain whether and on what basis a PRC court would enforce a judgment rendered by a court in the United States or in the Cayman Islands. Under the PRC Civil Procedures Law, foreign shareholders may initiate actions based on PRC law before a PRC court against a company for disputes, if the plaintiff can establish a sufficient contact with China for a PRC court to exercise jurisdiction and has a direct interest, cause of action and a concrete claim. The action may be initiated by a shareholder through filing a complaint with the PRC court. The PRC court will determine whether to accept the complaint in accordance with the PRC Civil Procedures Law. The shareholder may participate in the action by itself or entrust any other person or PRC legal counsel to participate on behalf of such shareholder. In addition, it will be difficult for U.S. shareholders to originate actions against us in China in accordance with PRC laws because we are incorporated under the laws of the Cayman Islands and it will be difficult for U.S. shareholders, by virtue only of holding our ADSs or ordinary shares, to establish a connection to China for a PRC court to have jurisdiction as required under the PRC Civil Procedures Law.

CORPORATE HISTORY AND STRUCTURE

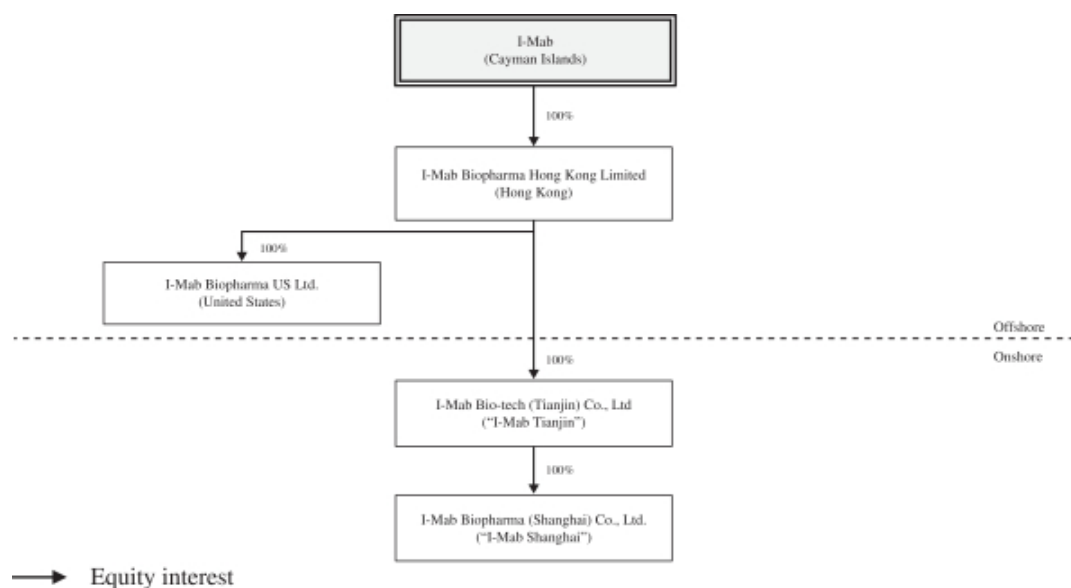
We commenced our operations in November 2014, when our predecessor Third Venture Biopharma (Nanjing) Co., Ltd (“Third Venture”) was established.

I-Mab was established in June 2016 under the laws of the Cayman Islands as our offshore holding company. In July 2016, I-Mab established I-Mab Biopharma Hong Kong Limited (“I-Mab Hong Kong”), as its intermediary holding company. In August 2016, I-Mab Hong Kong established a wholly-owned PRC subsidiary, I-Mab Biopharma (Shanghai) Co., Ltd. (“I-Mab Shanghai”). In September 2016, the assets and operations of Third Venture were consolidated into I-Mab Shanghai.

In July 2017, I-Mab Hong Kong acquired a controlling interest in I-Mab Bio-tech (Tianjin) Co., Ltd. (“I-Mab Tianjin”), formerly known as Tasgen Bio-tech (Tianjin) Co., Ltd., a company focused on CMC management of biologics in China. Through an internal corporate restructuring, I-Mab Tianjin became the 100% owner of I-Mab Shanghai in September 2017 and I-Mab Hong Kong acquired the remaining interest in I-Mab Tianjin in May 2018, becoming the 100% owner of I-Mab Tianjin.

In February 2018, I-Mab Hong Kong established in Maryland, United States, a wholly-owned subsidiary I-Mab Biopharma US Limited (“I-Mab US”), as the hub for the discovery and development of the drug candidates in our Global Portfolio.

The following diagram illustrates our corporate structure, including our principal subsidiaries, as of the date of this prospectus:



SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated statements of comprehensive loss data for the years ended December 31, 2017 and 2018, selected consolidated statements of balance sheet data as of December 31, 2017 and 2018 and selected consolidated statements of cash flow data for the years ended December 31, 2017 and 2018 have been derived from our audited consolidated financial statements included elsewhere in this prospectus. Our consolidated financial statements are prepared and presented in accordance with accounting principles generally accepted in the U.S. GAAP. Our historical results are not necessarily indicative of results expected for future periods. You should read this Selected Consolidated Financial Data section together with our consolidated financial statements and the related notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in this prospectus.

	For the Year Ended December 31,		
	2017	2018	
	RMB	RMB	US\$
(in thousands, except for share and per share data)			
Selected Consolidated Statements of Comprehensive Loss Data:			
Revenues			
Licensing and collaboration revenue	11,556	53,781	7,823
Expenses			
Research and development expenses ⁽¹⁾	(267,075)	(426,028)	(61,963)
Administrative expenses ⁽¹⁾	(25,436)	(66,391)	(9,656)
Loss from operations	(280,955)	(438,638)	(63,796)
Interest expenses, net	(4,785)	(7,098)	(1,032)
Other income (expenses), net	1,527	(16,780)	(2,441)
Fair value change of warrants	(14,027)	61,405	8,931
Loss before income tax expense	(298,240)	(401,111)	(58,338)
Income tax expense	—	(1,722)	(250)
Net loss attributable to I-Mab	(298,240)	(402,833)	(58,588)
Other comprehensive income			
Foreign currency translation adjustments, net of nil tax	5,918	53,689	7,809
Total comprehensive loss attributable to I-Mab	(292,322)	(349,144)	(50,779)
Net loss attributable to ordinary shareholders	(298,240)	(402,833)	(58,588)
Weighted-average number of ordinary shares used in calculating net loss per shares			
Basic and diluted	5,742,669	6,529,092	6,529,092
Net loss per share attributable to ordinary shareholders			
Basic	(51.93)	(61.70)	(8.97)
Diluted	(51.93)	(61.70)	(8.97)

Note:

(1) Share-based compensation expenses were allocated as follows:

	For the Year Ended December 31,		
	2017	2018	
	RMB	RMB	US\$
	(in thousands)		
Research and development expenses	2,112	1,056	154
Administrative expenses	4,927	2,464	358
Total	7,039	3,520	512

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The following table presents our selected consolidated statements of balance sheet data as of December 31, 2017 and 2018:

	As of December 31,		
	2017	2018	
	RMB	RMB	US\$
(in thousands)			
Selected Consolidated Statements of Balance Sheet Data:			
Current assets:			
Cash and cash equivalents	307,930	1,588,278	231,005
Restricted cash	104,783	92,653	13,476
Contract assets	—	11,000	1,600
Prepayments and other receivables	12,633	88,972	12,942
Other financial assets	266,245	255,958	37,228
Total current assets	691,591	2,036,861	296,251
Property, equipment and software	22,336	27,659	4,023
Intangible assets	148,844	148,844	21,648
Goodwill	162,574	162,574	23,645
Total assets	1,025,345	2,375,938	345,567
Total liabilities	309,151	415,684	60,460
Total mezzanine equity	1,015,989	2,915,358	424,021
Shareholders' equity (deficit)			
Ordinary shares (US\$0.0001 par value, 500,000,000 shares authorized as of December 31, 2017 and 2018, 8,363,719 shares authorized, issued and outstanding as of December 31, 2017 and 2018, respectively)	6	6	1
Treasury stock	(1)	(1)	—
Additional paid-in capital	52,369	—	—
Accumulated other comprehensive income	5,691	59,380	8,636
Accumulated deficit	(357,860)	(1,014,489)	(147,551)
Total shareholders' equity (deficit)	(299,795)	(955,104)	(138,914)
Total liabilities, mezzanine equity and shareholders' equity (deficit)	1,025,345	2,375,938	345,567

The following table presents our selected consolidated statements of cash flow data for the years ended December 31, 2017 and 2018:

	For the Year Ended December 31,		
	2017	2018	
	RMB	RMB	US\$
(in thousands)			
Selected Consolidated Statements of Cash Flow Data:			
Net cash used in operating activities	(252,157)	(280,705)	(40,827)
Net cash (used in) generated from investing activities	(157,665)	9,500	1,382
Net cash generated from financing activities	758,585	1,479,669	215,210
Net increase in cash, cash equivalents and restricted cash	348,631	1,268,218	184,454
Cash, cash equivalents and restricted cash, beginning of the year	64,082	412,713	60,027
Cash, cash equivalents and restricted cash, end of the year	<u>412,713</u>	<u>1,680,931</u>	<u>244,481</u>

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the section entitled "Selected Consolidated Financial Data" and our consolidated financial statements and the consolidated financial statements of I-Mab Bio-tech (Tianjin) Co., Ltd. ("I-Mab Tianjin") and the related notes included elsewhere in this prospectus. This discussion contains forward-looking statements that reflect our current expectations and views of future events, which may involve risks and uncertainties. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" and elsewhere in this prospectus.

We acquired a controlling interest in I-Mab Tianjin on July 15, 2017 and have consolidated the results of operations of I-Mab Tianjin and its subsidiaries since July 15, 2017. In this section, when discussing historical facts and operating results for the period before July 15, 2017, "we," "us," "our company" and "our" refer to I-Mab and its then subsidiaries, and do not include I-Mab Tianjin or its subsidiaries.

Overview

We are a clinical stage biopharmaceutical company committed to the discovery, development and commercialization of first-in-class and best-in-class biologics to treat diseases with significant unmet medical needs, particularly cancers and autoimmune disorders. Our mission is to bring transformational medicines to patients through innovation.

We were founded to capture the opportunities presented by the confluence of two major developments—the emergence of an attractive and growing biologics market in China, and the revolutionary scientific breakthroughs in cancer and autoimmune disease medicines. We believe we are well-positioned to become a biotech leader in China because of our innovative discovery expertise, fit-for-purpose technology platforms, biomarker-enabled translational medicine capabilities, and clinical development capabilities. These integrated capabilities are further enhanced by our deep understanding of China's biologics regulatory framework and our direct access to extensive pre-clinical and clinical trial resources in China. To date, we have developed an innovative pipeline of more than 10 clinical and pre-clinical stage assets through our internal research and development efforts and in-licensing arrangements with global pharmaceutical and biotech companies.

We see vast commercial opportunities for immuno-oncology and autoimmune biologics therapies in China. First, both the incidence and mortality of cancers in China have been increasing in recent years and are outpacing those in the United States and the rest of the world. Second, many innovative biologics approved to treat cancer and autoimmune diseases in the United States and Europe are not yet available in China. Third, the Chinese government has implemented new policies and regulations to simplify the review and approval cycle of clinical trials and new drug applications to encourage biologics innovation. Fourth, there has been a continuous and rapid increase in personal disposable income in China coupled with ongoing improvement in basic national health insurance coverage, making innovative biologics more accessible to more Chinese patients. According to the Frost & Sullivan Report, China's biologics market is growing faster than the global biologics market and is expected to reach approximately RMB1.3 trillion (US\$189.1 billion) by 2030 in terms of sales revenue.

We believe we are uniquely positioned as a China-based global player to tap into these vast commercial opportunities. This is best demonstrated by our short journey in becoming one of the top clinical stage innovative biotech companies in China. To date, our research and development capabilities encompass discovery, biologics CMC development, pre-clinical development and clinical development with footprints in Shanghai, Beijing and the United States. We are now at a critical juncture to transition from a clinical stage biotech company into a fully integrated end-to-end global biopharmaceutical company in the next few years.

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Since the commencement of our operation in 2014, we have devoted most of our efforts and financial resources to organize and staff our operations, business planning, raise capital, establish our intellectual property portfolio and conduct pre-clinical and clinical trials of our drug candidates.

Through December 31, 2018, we had raised approximately US\$330 million of cash in equity financing from our dedicated group of investors, including leading healthcare-focused funds. We have not generated any revenue from product sales, and as a result, we have never been profitable and have incurred net losses since the commencement of our operations. In 2017 and 2018, our net loss was RMB298.2 million and RMB402.8 million (US\$58.6 million), respectively. We do not expect to generate product revenue unless and until we obtain marketing approval for and commercialize a drug candidate, and we cannot assure you that we will ever generate significant revenue or profits.

Key Factors Affecting Our Results of Operations

Our results of operations, financial condition, and the year-to-year comparability of our financial results have been, and are expected to continue to be, principally affected by the below factors:

Cost and Expenses Structure

Our results of operations are significantly affected by our cost structure, which primarily consists of research and development expenses and administrative expenses.

Research and development activities are central to our business model. We believe our ability to successfully develop drug candidates will be the primary factor affecting our long-term competitiveness, as well as our future growth and development. Developing high-quality drug candidates requires a significant investment of resources over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. Since our inception, we have focused our resources on our research and development activities, including conducting pre-clinical studies and clinical trials, and activities related to regulatory filings for our drug candidates. Our research and development expenses primarily include the following:

- costs related to development of our pipeline assets under all stages including discovery, pre-clinical testing or clinical trials;
- patent license fees and other fees under the licensing, collaboration and development agreements with respect to our in-licensed drug candidates; and
- employee salaries and related benefit costs, including share-based compensation expenses, for research and development personnel.

At this time, we are unable to predict when, if ever, we will be able to achieve profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods thereafter. This is due to the numerous risks and uncertainties associated with developing such drug candidates, including the uncertainty of:

- successful enrollment in and completion of clinical trials;
- establishing an appropriate safety profile;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- receipt of marketing approvals from applicable regulatory authorities;
- commercializing the drug candidates, if and when approved, whether alone or in collaboration with others;

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- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our drug candidates;
- continued acceptable safety profiles of the products following approval; and
- retention of key research and development personnel.

Any change in the outcome of any of these variables with respect to the development of any of our drug candidates would significantly change the costs, timing and viability associated with the development of that drug candidate. We expect research and development costs to continue to increase for the foreseeable future as we expand our operations and our development programs progress, including as we continue to support and advance the clinical trials of our drug candidates.

Our administrative expenses consist primarily of employee salaries and related benefit costs. Other administrative expenses include professional fees for consulting and auditing as well as other direct and allocated expenses for rental expenses for our facilities, travel costs and other supplies used in administrative activities. We expect our administrative expenses to increase in the future to support our pipeline assets and research and development efforts, and the commercialization of our drug candidates once approval is obtained. We also anticipate that our administrative expenses will increase as we operate as a public company following the completion of this offering.

Revenue from Out-Licensing Agreements

We continue to seek out-licensing opportunities for our de-prioritized assets to streamline our pipeline. During fiscal years 2017 and 2018, our revenue consisted primarily of payments from granting licenses to use and otherwise exploit certain of our intellectual properties linked to our de-prioritized assets. See “Business—Licensing and Collaboration Arrangements” for more information on the existing out-licensing arrangements. In addition, after validating clinical safety and preliminary efficacy of a drug candidate in our Global Portfolio in clinical trials in the United States, we may elect to out-license the global rights (excluding Greater China) of such drug candidate, while retaining the Greater China rights for further development and commercialization. But we may also choose to retain these rights for the United States or other countries or regions as we may deem fit. Before the commercialization of one or more of our drug candidates, we expect that the majority of our revenue will continue to be generated from out-licensing our intellectual properties.

Funding for Our Operations

During the periods presented, we funded our operations primarily from financing through the issuance and sale of preferred shares and convertible promissory notes in private placement transactions. Going forward, in the event of successful commercialization of one or more of our drug candidates, we expect to fund our operations in part with revenue generated from sales of our commercialized drug products. However, with the continuing expansion of our business and our product pipeline, we may require further funding through public or private offerings, debt financing, collaboration, and licensing arrangements or other sources. Any fluctuation in our ability to fund our operations will impact our cash flow plan and our results of operations.

Our Ability to Commercialize Our Drug Candidates

Our business and results of operations depend on our ability to commercialize our drug candidates, once and if those candidates are approved for marketing by the respective health authority. Currently, our pipeline consists of more than ten drug candidates ranging in development status from pre-clinical to late-stage clinical programs. Although we currently do not have any product approved for commercial sale and have not generated any revenue from product sales, we expect to generate revenue from sales of a drug candidate after we complete the clinical development, obtain regulatory approval, and successfully commercialize such drug candidate. Our late-stage investigational drugs at or potentially near pivotal trials are TJ202, TJ101, TJ301 and enoblituzumab. See “Business—Our Drug Pipeline” for more information on the development status of our various drug candidates.

The Effect of Our Acquisition of I-Mab Tianjin

We acquired a controlling interest in I-Mab Tianjin on July 15, 2017 and the remaining interest in I-Mab Tianjin in May 2018. Since our acquisition of the controlling interest in I-Mab Tianjin on July 15, 2017, I-Mab Tianjin has been consolidated into our results of operations. Shortly after we acquired the controlling interest in I-Mab Tianjin, we integrated the operations of I-Mab Tianjin into our operations.

I-Mab Tianjin did not generate any revenue from July 15, 2017 to December 31, 2018. In connection with our acquisition of I-Mab Tianjin, we identified RMB148.8 million of intangible assets and RMB162.6 million of goodwill of I-Mab Tianjin. Goodwill is not amortized, but impairment of goodwill assessment is performed on at least an annual basis on December 31 or whenever events or changes in circumstances indicate that the carrying value of the assets may not be recoverable. No impairment was identified as of December 31, 2017 and 2018. Impairment charges could substantially affect our results of operations in the periods of such charges. In addition, impairment charges would negatively impact our financial ratios and could limit our ability to obtain financing in the future. See “Risk Factors—Risks Related to Our Industry, Business and Operations—Change in business prospects of acquisitions may result in impairment to our goodwill, which could negatively affect our reported results of operations.”

Key Components of Results of Operations

Revenues

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from product sales for the foreseeable future before the successful commercialization of one or more of our drug candidates.

We generated substantially all of our revenues for the years ended December 31, 2017 and 2018 from granting licenses to use and otherwise exploit certain of our intellectual properties in connection with our de-prioritized assets.

Research and Development Expenses

Research and development expenses primarily consist of: (i) payroll and other related expenses of research and development personnel, (ii) fees associated with the exclusive development rights of our in-licensed drug candidates, (iii) fees for services provided by contract research organizations, investigators and clinical trial sites that conduct our clinical studies, and (iv) expenses relating to the development of our drug candidates, including raw materials and supplies, product testing, depreciation, and facility related expenses.

Our current research and development activities primarily relate to the clinical development of the following investigational drugs:

- TJ202, a potential best-in-class CD38 antibody for multiple myeloma and autoimmune diseases;
- TJ107, a potential first-in-class long-acting IL-7 for cancer treatment-related lymphopenia and cancer immunotherapy;
- TJ101, a potential best-in-class long-acting growth hormone for growth hormone deficiency;
- TJ301, a potential best-in-class IL-6 blocker for ulcerative colitis and other autoimmune diseases;
- Enoblituzumab, a potential first-in-class B7-H3 antibody as an immuno-oncology treatment;
- TJC4, a potential best-in-class CD47 monoclonal antibody with unique RBC-sparing differentiation;
- TJD5, a potential best-in-class CD73 antibody for immuno-oncology; and
- TJM2, a GM-CSF monoclonal antibody for rheumatoid arthritis and CAR-T-related therapies.

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We incurred research and development expenses of RMB267.1 million and RMB426.0 million (US\$62.0 million) for the years ended December 31, 2017 and 2018, respectively, representing 91.3% and 86.5% of our total research and development and administrative expenses for the corresponding periods. We expect our research and development expenses to continue to increase for the foreseeable future, as we continue to expand our operations and to advance our pipeline and our drug candidates toward later stages.

Administrative Expenses

Administrative expenses primarily consist of salaries and related benefit costs, including share-based compensation, for employees engaged in managerial and administrative positions or involved in general corporate functions, professional fees for consulting and auditing as well as other direct and allocated expenses for rental expenses for our facilities, travel costs and other supplies used in administrative activities. For the years ended December 31, 2017 and 2018, our administrative expenses amounted to RMB25.4 million and RMB66.4 million (US\$9.7 million), respectively.

Interest Expenses, Net

Interest expenses consist primarily of interest expenses on our (i) short-term bank borrowings and (ii) convertible promissory notes issued to certain investors.

Interest income consists primarily of interest income derived from our restricted cash pledged as collateral for a working capital loan.

Other Income (Expenses), Net

Other income consists primarily of income from other financial assets.

Other expenses consist primarily of the net loss resulting from the conversion of a portion of our convertible promissory notes.

Fair Value Change of Warrants

Fair value change of warrants consists primarily of the non-cash items incurred in connection with changes in the fair value of our warrant liabilities that we issued to certain investors.

Taxation

Cayman Islands

I-Mab, our holding entity, is incorporated in the Cayman Islands. Under the current laws of the Cayman Islands, I-Mab is not subject to tax on income or capital gain. Additionally, the Cayman Islands does not impose a withholding tax on payments of dividends to shareholders.

Hong Kong

I-Mab Biopharma Hong Kong Limited is incorporated in Hong Kong. Companies registered in Hong Kong are subject to Hong Kong profits tax on the taxable income as reported in their respective statutory financial statements adjusted in accordance with the relevant Hong Kong tax laws. The applicable tax rate is 16.5% in Hong Kong. For the years ended December 31, 2017 and 2018, I-Mab Biopharma Hong Kong Limited did not make any provisions for Hong Kong profit tax as there were no assessable profits derived from or earnings in Hong Kong for any of the periods presented. Under the Hong Kong tax law, I-Mab Biopharma Hong Kong Limited is exempted from income tax on its foreign-derived income and there are no withholding taxes in Hong Kong on remittance of dividends.

United States

I-Mab Biopharma US Ltd. is incorporated in Maryland and is subject to U.S. federal corporate income tax at a rate of 21%. It is also subject to state income tax in Maryland at a rate of 8.25%. I-Mab Biopharma US Ltd. has no taxable income for all periods presented and therefore no provision for income taxes is required.

China

On March 16, 2007, the National People's Congress of PRC enacted a new Corporate Income Tax Law ("new CIT law"), under which Foreign Investment Enterprises ("FIEs") and domestic companies would be subject to corporate income tax at a uniform rate of 25%. The new CIT law became effective on January 1, 2008. Under the new CIT law, preferential tax treatments will continue to be granted to entities which conduct businesses in certain encouraged sectors and to entities otherwise classified as "High and New Technology Enterprises."

I-Mab Shanghai has been qualified as a "High and New Technology Enterprise" and enjoys a preferential income tax rate of 15% from 2018 to 2020. No provision for income taxes has been accrued because all of our PRC subsidiaries are in cumulative loss positions for all the periods presented. I-Mab Tianjin is subject to the statutory income tax at a rate of 25%.

A valuation allowance is provided to reduce the amount of deferred tax assets if it is considered more likely than not that some portion or all of the deferred tax assets will not be realized in the foreseeable future. In making such determination, we evaluate a variety of positive and negative factors including our operating history, accumulated deficit, the existence of taxable temporary differences and reversal periods.

We have incurred net accumulated operating losses for income tax purposes since our inception. We believe that it is more likely than not that these net accumulated operating losses will not be utilized in the future. Therefore, we have provided full valuation allowances for the deferred tax assets as of December 31, 2017 and 2018.

We evaluate each uncertain tax position (including the potential application of interest and penalties) based on the technical merits, and measure the unrecognized benefits associated with the tax positions. As of December 31, 2017 and 2018, we did not have any significant unrecognized uncertain tax positions.

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Results of Operations

The following table sets forth a summary of our consolidated results of operations for the periods indicated. This information should be read together with our consolidated financial statements and related notes included elsewhere in this prospectus. The operating results in any period are not necessarily indicative of the results that may be expected for any future period.

	For the Year Ended December 31,		
	2017	2018	
	RMB	RMB	US\$
	(in thousands, except for share and per share data)		
Revenues			
Licensing and collaboration revenue	11,556	53,781	7,823
Expenses			
Research and development expenses ⁽¹⁾	(267,075)	(426,028)	(61,963)
Administrative expenses ⁽¹⁾	(25,436)	(66,391)	(9,656)
Loss from operations	(280,955)	(438,638)	(63,796)
Interest expenses, net	(4,785)	(7,098)	(1,032)
Other income (expenses), net	1,527	(16,780)	(2,441)
Fair value change of warrants	(14,027)	61,405	8,931
Loss before income tax expense	(298,240)	(401,111)	(58,338)
Income tax expense	—	(1,722)	(250)
Net loss attributable to ordinary shareholders	(298,240)	(402,833)	(58,588)

Note:

(1) Share-based compensation expenses were allocated as follows:

	For the Year Ended December 31,		
	2017	2018	
	RMB	RMB	US\$
	(in thousands)		
Research and development expenses	2,112	1,056	154
Administrative expenses	4,927	2,464	358
Total	7,039	3,520	512

Comparison of Twelve Months Ended December 31, 2018 and 2017

Revenues

Our revenues generated from licensing and collaboration increased by 365.4% from RMB11.6 million for the year ended December 31, 2017 to RMB53.8 million (US\$7.8 million) for the year ended December 31, 2018, primarily attributable to (i) our fulfillment of the related upfront payment obligations under the out-licensing arrangement with ABL, and (ii) our fulfillment of the related milestone obligations under the out-licensing agreement with HDYM.

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Research and Development Expenses

The following table sets forth a breakdown of the major components of our research and development expenses in absolute amounts and as a percentage of our total research and development expenses for the periods indicated:

	For the Year Ended December 31,				
	2017		2018		
	RMB	%	RMB	US\$	%
	(in thousands, except percentages)				
CRO service fees	83,047	31.1	212,278	30,875	49.8
In-licensed patent right fees	134,846	50.5	108,794	15,823	25.5
Employment benefit expenses	26,799	10.0	56,630	8,236	13.3
Material costs for drug candidates	10,393	3.9	19,652	2,858	4.6
Other expenses	11,990	4.5	28,674	4,171	6.8
Total	<u>267,075</u>	<u>100.0</u>	<u>426,028</u>	<u>61,963</u>	<u>100.0</u>

Our research and development expenses increased by 59.5% from RMB267.1 million for the year ended December 31, 2017 to RMB426.0 million (US\$62.0 million) for the year ended December 31, 2018, primarily attributable to (i) an increase in the CRO service fees from RMB83.0 million in 2017 to RMB212.3 million (US\$30.9 million) in 2018, as we initiated a few more research and development programs and advanced some of our existing investigational drugs into more advanced clinical development stages; and (ii) an increase in employee benefit expenses of employees involved in research and development from RMB26.8 million in 2017 to RMB56.6 million (US\$8.2 million) in 2018, due to an increase in the headcount.

Administrative Expenses

Our administrative expenses increased from RMB25.4 million for the year ended December 31, 2017 to RMB66.4 million (US\$9.7 million) for the year ended December 31, 2018, primarily attributable to (i) the increase in employee benefit expenses due to headcount increase, and (ii) the increase in third-party professional expenses.

Interest Expenses, Net

Our net interest expenses increased by 48.3% from RMB4.8 million for the year ended December 31, 2017 to RMB7.1 million (US\$1.0 million) for the year ended December 31, 2018, primarily attributable to (i) the interest on the convertible promissory notes we issued in September 2017 and February 2018; and (ii) the interest on the one-year bank borrowing facilities we entered into in the third quarter of 2017 and July 2018, respectively.

Other Income (Expenses), Net

We recorded RMB1.5 million of other income for the year ended December 31, 2017 and RMB16.8 million (US\$2.4 million) of other expenses for the year ended December 31, 2018. The change was primarily attributable to the net loss resulting from the conversion of a portion of our convertible promissory notes, partially offset by an increase in the income from the other financial assets.

Fair Value Change of Warrants

We recorded a loss from change in the fair value of warrant liability of RMB14.0 million for the year ended December 31, 2017, and a gain from change in the fair value of warrant liability of RMB61.4 million (US\$8.9 million) for the year ended December 31, 2018. The change was primarily attributable to (i) the change in fair value of warrants, and (ii) the modification in 2018 that added certain forfeiture conditions to the warrants, which increased the possibility of forfeiture of the warrants and therefore resulted in a reduction in our warrant liabilities.

Liquidity and Capital Resources

Since inception, we have incurred net losses and negative cash flows from our operations. Substantially all of our losses have resulted from funding our research and development programs and administrative costs associated with our operations. We incurred net losses of RMB298.2 million and RMB402.8 million (US\$58.6 million) for the years ended December 31, 2017 and 2018, respectively. Our primary use of cash is to fund our research and development activities. We used RMB252.2 million and RMB280.7 million (US\$40.8 million) in cash for our operating activities for the years ended December 31, 2017 and 2018, respectively. Historically, we have financed our operations principally through proceeds from the issuance and sale of preferred shares and convertible promissory notes in private placement transactions. For more information of our equity financing, see “Description of Share Capital—History of Securities Issuances.” As of December 31, 2018, we had cash, cash equivalents and restricted cash of RMB1,680.9 million (US\$244.5 million). Our cash, cash equivalents and restricted cash consist primarily of cash in bank and on hand.

The following table sets forth a summary of our cash flows for the periods presented:

	For the Year Ended December 31,		
	2017	2018	
	RMB	RMB	US\$
	(in thousands)		
Net cash used in operating activities	(252,157)	(280,705)	(40,827)
Net cash (used in) generated from investing activities	(157,665)	9,500	1,382
Net cash generated from financing activities	758,585	1,479,669	215,210
Net increase in cash, cash equivalents and restricted cash	348,631	1,268,218	184,454
Cash, cash equivalents and restricted cash, beginning of the year	64,082	412,713	60,027
Cash, cash equivalents and restricted cash, end of the year	412,713	1,680,931	244,481

We do not expect to generate any revenue from product sales unless and until we obtain regulatory approval of and commercialize one of our current or future drug candidates. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our drug candidates and begin to commercialize any approved products. Upon the completion of this offering, we expect to incur additional costs associated with operating as a public company. In addition, subject to obtaining regulatory approval of any of our drug candidates, we expect to incur significant commercialization expenses for product sales, marketing and manufacturing. Accordingly, we anticipate that we will need substantial additional funding in connection with our continuing operations.

Based on our current operating plan, we believe that our current cash and cash equivalents, proceeds from this offering and our anticipated cash flows from operations will be sufficient to meet our current and anticipated working capital requirements and capital expenditures for at least the next 12 months. In that time, we expect that our expenses will increase substantially as we fund new and ongoing research and development activities and working capital needs. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our drug candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development and commercialization of our drug candidates.

After this offering, we may decide to enhance our liquidity position or increase our cash reserve for future operations and investments through additional financing. The issuance and sale of additional equity would result in further dilution to our shareholders and ADS holders, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as an ADS holder. The incurrence of indebtedness would result in increased fixed obligations and could result in operating covenants that would restrict our operations, which could potentially dilute your interest. If we raise additional funds through collaborations, strategic

alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or research programs or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or drug candidates that we would otherwise prefer to develop and market ourselves.

As of December 31, 2018, 5% of our cash and cash equivalents were denominated in RMB and held in China. In utilizing the proceeds we expect to receive from this offering, we may make additional capital contributions to our PRC subsidiaries, establish new PRC subsidiaries and make capital contributions to these new PRC subsidiaries, make loans to our PRC subsidiaries, or acquire offshore entities with business operations in China in offshore transactions. However, most of these uses are subject to PRC regulations and approvals. See “Risk Factors—Risks Related to Doing Business in China—PRC regulation of loans to and direct investment in PRC entities by offshore holding companies and governmental control of currency conversion may delay or prevent us from using the proceeds of this offering to make loans to our PRC subsidiaries in China, which could materially and adversely affect our liquidity and our ability to fund and expand our business” and “Use of Proceeds” for more information on the related PRC rules and regulations on the use of proceeds.

We expect that the majority of our future revenues will be denominated in RMB. Under existing PRC foreign exchange regulations, payments of current account items, including profit distributions, interest payments and trade and service-related foreign exchange transactions, can be made in foreign currencies without prior SAFE approval as long as certain routine procedural requirements are fulfilled. Therefore, our PRC subsidiaries are allowed to pay dividends in foreign currencies to us without prior SAFE approval by following certain routine procedural requirements. However, approval from or registration with competent government authorities is required where RMB is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of loans denominated in foreign currencies. The PRC government may at its discretion restrict access to foreign currencies for current account transactions in the future.

Operating Activities

Net cash used in operating activities for the year ended December 31, 2018 was RMB280.7 million (US\$40.8 million). Our net loss was RMB402.8 million (US\$58.6 million) for the same period. The difference between our net loss and our net cash used in operating activities was primarily attributable to certain non-cash expenses or gains, including fair value gains of warrants of RMB61.4 million (US\$8.9 million), and changes in certain working capital items, including (i) an increase in the research and development funding of RMB178.7 million (US\$26.0 million) and (ii) an increase in accruals and other payables of RMB55.6 million (US\$8.1 million), partially offset by an increase in prepayments and other receivables of RMB76.3 million (US\$11.1 million). The accruals and other payables principally consist of accrued external research and development activities related expenses and staff salaries and welfare payables. The change in fair value of warrant liabilities was attributable to the exercise of part of the warrants issued in 2017 and the modification in 2018 that added certain forfeiture conditions to the warrants. Prepayments and other receivables primarily consist of our prepayment to CRO partners and value-added tax recoverable.

Net cash used in operating activities for the year ended December 31, 2017 was RMB252.2 million. Our net loss was RMB298.2 million. The difference between our net loss and our net cash used in operating activities was primarily attributable to certain non-cash expenses or gains, including the fair value loss of warrant liabilities of RMB14.0 million, and changes in certain working capital items, including (i) an increase in contract liabilities of RMB15.8 million and (ii) a decrease in prepayments and other receivables of RMB8.8 million.

Investing Activities

Net cash generated from investing activities for the year ended December 31, 2018 was RMB9.5 million (US\$1.4 million). The net cash increase was primarily attributable to RMB40.0 million (US\$5.8 million) of the

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cash received from disposal of other financial assets, partially offset by RMB30.0 million (US\$4.4 million) of the cash used in other financial assets.

Net cash used in investing activities for the year ended December 31, 2017 was RMB157.7 million. The net cash decrease was primarily attributable to RMB369.0 million of investments in other financial assets, partially offset by RMB133.0 million of proceeds from disposal of other financial assets and RMB93.3 million of cash acquired from acquisition of I-Mab Tianjin.

Financing Activities

Net cash generated from financing activities in the year ended December 31, 2018 was RMB1,479.7 million (US\$215.2 million), primarily attributable to (i) proceeds from issuance of RMB1,306.6 million (US\$190.0 million) convertible preferred shares and (ii) receipt of RMB132.3 million (US\$19.2 million) resulting from the exercise of warrants by investors.

Net cash generated from financing activities in the year ended December 31, 2017 was RMB758.6 million, primarily attributable to proceeds of our issuance of RMB346.5 million convertible preferred shares, RMB161.2 million redeemable non-controlling interest and RMB99.0 million proceeds from bank borrowings.

Capital Expenditures

Our capital expenditures were incurred for purposes of purchasing property, equipment and software. Our capital expenditures were RMB20.3 million and RMB14.4 million (US\$2.1 million) in the years ended December 31, 2017 and 2018, respectively.

We expect that our capital expenditures in 2019 will primarily consist of purchase of intangible assets. We intend to fund our future capital expenditures with our existing cash and proceeds from this offering. We will continue to make capital expenditures to meet the expected growth of our business.

Contractual Obligations

The following table sets forth our contractual obligations as of December 31, 2018:

	<u>Total</u>		<u>Less than 1 year</u>		<u>1-3 years</u>		<u>3-5 years</u>		<u>More than 5 years</u>	
	<u>RMB</u>	<u>US\$</u>	<u>RMB</u>	<u>US\$</u>	<u>RMB</u>	<u>US\$</u>	<u>RMB</u>	<u>US\$</u>	<u>RMB</u>	<u>US\$</u>
Operating lease commitments	14,935	2,172	5,754	837	8,785	1,278	120	17	276	40

Our operating lease commitments relate to leases for our office premises pursuant to non-cancellable operating lease agreements. Other than as shown above, we did not have any significant capital and other commitments, long-term obligations or guarantees as of December 31, 2018.

Off-Balance Sheet Commitments and Arrangements

We have not entered into any financial guarantees or other commitments to guarantee the payment obligations of any third parties. In addition, we have not entered into any derivative contracts that are indexed to our shares and classified as shareholder's equity or that are not reflected in our consolidated financial statements. Furthermore, we do not have any retained or contingent interest in assets transferred to an unconsolidated entity that serves as credit, liquidity or market risk support to such entity. We do not have any variable interest in any unconsolidated entity that provides financing, liquidity, market risk or credit support to us or engages in leasing, hedging or product development services with us.

Internal Control Over Financial Reporting

Prior to this offering, we have been a private company with limited accounting personnel and other resources with which to address our internal control over financial reporting. In connection with the audits of our consolidated financial statements included in this prospectus, we and our independent registered public accounting firm identified the following material weaknesses and other control deficiencies in our internal control over financial reporting. As defined in the standards established by the U.S. Public Company Accounting Oversight Board, a “material weakness” is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company’s annual or interim financial statements will not be prevented or detected on a timely basis.

The material weaknesses that have been identified relate to (i) our lack of sufficient and competent financial reporting and accounting personnel with appropriate knowledge of U.S. GAAP and SEC reporting and compliance requirements, to formalize key controls over financial reporting and to prepare consolidated financial statements and related disclosures; and (ii) our lack of sufficient documented financial closing policies and procedures, specifically those related to (a) accounting for licensing and collaboration agreements and (b) period end expenses cut-off and accruals. These material weaknesses, if not timely remedied, may lead to significant misstatements in our consolidated financial statements in the future.

We have implemented and plan to implement a number of measures to address the material weaknesses that have been identified in connection with the audits of our consolidated financial statements as of and for the years ended December 31, 2017 and 2018. We have hired additional qualified financial and accounting staff with working experience of U.S. GAAP and SEC reporting requirements, and plan to continue such hiring efforts. We intend to conduct regular and continuous U.S. GAAP accounting and financial reporting training programs for our financial reporting and accounting personnel. We further intend to establish sufficient and formal financial closing policies and procedures, specifically those related to accounting for licensing and collaboration arrangements and period end cut-off and accruals. We plan to, as work-in-progress, engage an external consulting firm to assist us to assess Sarbanes-Oxley Act compliance requirements and improve our overall internal controls. Furthermore, we plan to prepare more detailed guidance on accounting policies, manuals and closing procedures to improve the quality and accuracy of our period end financing closing process. We will continue to implement these and other measures to remediate our internal control deficiencies. We may incur significant costs in the implementation of such measures. However, the implementation of these measures may not fully address the deficiencies in our internal control over financial reporting, and we cannot assure you that all of these measures will be sufficient to remediate our material weakness in time, or at all.

As a company with less than US\$1.07 billion in revenue for our last fiscal year, we qualify as an “emerging growth company” pursuant to the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other requirements that are otherwise applicable generally to public companies. These provisions include exemption from the auditor attestation requirement under Section 404 of the Sarbanes-Oxley Act of 2002 in the assessment of the emerging growth company’s internal control over financial reporting.

Inflation

To date, inflation in China has not materially affected our results of operations. According to the National Bureau of Statistics of China, the year-over-year percent changes in the consumer price index for January 2017, 2018 and 2019 were increases of 2.5%, 1.5% and 1.7%, respectively. Although we have not been materially affected by inflation in the past, we may be affected if China experiences higher rates of inflation in the future.

Holding Company Structure

We are a holding company with no material operations of its own. We currently conduct our operations primarily through our PRC subsidiaries. As a result, our ability to pay dividends depends upon dividends paid by

our PRC subsidiaries. If our existing PRC subsidiaries or any newly formed ones incur debt on their own behalf in the future, the instruments governing their debt may restrict their ability to pay dividends to us. In addition, our wholly foreign-owned subsidiaries in China are permitted to pay dividends to us only out of its retained earnings, if any, as determined in accordance with PRC accounting standards and regulations. Under PRC law, each of our subsidiaries and their subsidiaries in China is required to set aside at least 10% of its after-tax profits each year, if any, to fund certain statutory reserve funds until such reserve funds reach 50% of their registered capital. In addition, our wholly foreign-owned subsidiaries in China may allocate a portion of their after-tax profits based on PRC accounting standards to enterprise expansion funds and staff bonus and welfare funds at their discretion, and their subsidiaries may allocate a portion of their after-tax profits based on PRC accounting standards to a surplus fund at their discretion. The statutory reserve funds and the discretionary funds are not distributable as cash dividends. Remittance of dividends by a wholly foreign-owned company out of China is subject to examination by the banks designated by SAFE. Our PRC subsidiaries have not paid dividends and will not be able to pay dividends until they generate accumulated profits and meet the requirements for statutory reserve funds.

Quantitative and Qualitative Disclosures about Market Risk

Interest and Credit Risk

We had cash, cash equivalents and restricted cash of RMB412.7 million and RMB1,680.9 million (US\$244.5 million) as of December 31, 2017 and 2018, respectively. Our exposure to interest rate risk primarily relates to the interest income generated by excess cash, which is mostly held in interest-bearing bank deposits. Interest-earning instruments carry a degree of interest rate risk. We have not been exposed to material risks due to changes in interest rates, and we have not used any derivative financial instruments to manage our interest risk exposure.

Our credit risk is primarily attributable to the carrying amounts of cash and cash equivalents. The carrying amounts of cash and cash equivalents represent the maximum amount of loss due to credit risk. We mainly place or invest cash and cash equivalents with state-owned or reputable financial institutions in the PRC, and reputable financial institutions outside of the PRC. We do not believe that our cash and cash equivalents have significant risk of default or illiquidity, and we will continually monitor the credit worthiness of these financial institutions. While we believe our cash and cash equivalents do not contain excessive risk, future investments may be subject to adverse changes in market value.

Foreign Exchange Risk

Most of our revenues and expenses are denominated in RMB. Our management considers that the business is not exposed to any significant foreign exchange risk and we have not used any derivative financial instruments to hedge exposure to such risk. Although our exposure to foreign exchange risks should be limited in general, the value of your investment in our ADSs will be affected by the exchange rate between U.S. dollar and RMB because the value of our business is effectively denominated in RMB, while our ADSs will be traded in U.S. dollars.

RMB is not freely convertible into foreign currencies for capital account transactions. The value of RMB against the U.S. dollar and other currencies is affected by, among other things, changes in China's political and economic conditions and China's foreign exchange prices. On July 21, 2005, the PRC government changed its policy of pegging the value of the RMB to the U.S. dollar. Following the removal of the U.S. dollar peg, the RMB appreciated more than 20% against the U.S. dollar over the following three years. Between July 2008 and June 2010, this appreciation halted and the exchange rate between the RMB and the U.S. dollar remained within a narrow band. Since June 2010, the PRC government has allowed the RMB to appreciate slowly against the U.S. dollar again, and it has appreciated more than 10% since June 2010. On August 11, 2015, the People's Bank of China announced plans to improve the central parity rate of the RMB against the U.S. dollar by authorizing

market-makers to provide parity to the China Foreign Exchange Trading Center operated by the People's Bank of China with reference to the interbank foreign exchange market closing rate of the previous day, the supply and demand for foreign currencies as well as changes in exchange rates of major international currencies. Effective from October 1, 2016, the International Monetary Fund added RMB to its Special Drawing Rights currency basket. Such change and additional future changes may increase volatility in the trading value of the RMB against foreign currencies. The PRC government may adopt further reforms of its exchange rate system, including making the RMB freely convertible in the future. Accordingly, it is difficult to predict how market forces or PRC or U.S. government policy may impact the exchange rate between RMB and the U.S. dollar in the future.

To the extent that we need to convert U.S. dollars into RMB for our operations, appreciation of RMB against the U.S. dollar would reduce the RMB amount we receive from the conversion. Conversely, if we decide to convert RMB into U.S. dollars for the purpose of making payments for dividends on our ordinary shares or ADSs, servicing our outstanding debt, or for other business purposes, appreciation of the U.S. dollar against the RMB would reduce the U.S. dollar amounts available to us.

As of December 31, 2018, we had RMB-denominated cash, cash equivalents and restricted cash of RMB77.0 million (US\$11.2 million). A 10% depreciation of RMB against U.S. dollar based on the foreign exchange rate on December 31, 2018 would result in a decrease of US\$1.1 million in cash and cash equivalents. A 10% appreciation of RMB against U.S. dollar based on the foreign exchange rate on December 31, 2018 would result in an increase of US\$1.1 million in cash and cash equivalents.

Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Estimates are used when accounting for amounts recorded in connection with acquisitions, including initial fair value determinations of assets and liabilities and other intangible assets as well as subsequent fair value measurements. Additionally, estimates are used in determining items such as useful lives of property, plant and equipment, write-down of inventories, allowance for doubtful accounts, share-based compensation, impairment of long-lived assets, impairment of other intangible asset and goodwill, taxes on income, tax valuation allowances and revenues from research and development projects. Actual results could differ from those estimates.

Revenue Recognition

We adopted Accounting Standard Codification ("ASC") 606, Revenue from Contracts with Customers (Topic 606) ("ASC 606") for all periods presented. Consistent with the criteria of Topic 606, we recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to receive in exchange for those goods or services.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that the entity will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

Once a contract is determined to be within the scope of ASC 606 at contract inception, we review the contract to determine which performance obligations it must deliver and which of these performance obligations are distinct. We recognize as revenue the amount of the transaction price that is allocated to each performance obligation when that performance obligation is satisfied or as it is satisfied.

Collaboration Revenue

At contract inception, we analyze its collaboration arrangements to assess whether they are within the scope of ASC 808, Collaborative Arrangements (“ASC 808”) to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, we first determine if the collaboration is deemed to be within the scope of ASC 808 and those that are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606. For the collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently.

Our collaborative arrangements may contain more than one unit of account, or performance obligation, including grants of licenses to intellectual property rights, agreement to provide research and development services and other deliverables. The collaborative arrangements do not include a right of return for any deliverable. As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. In developing the stand-alone selling price for a performance obligation, we consider competitor pricing for a similar or identical product, market awareness of and perception of the product, expected product life and current market trends. In general, the consideration allocated to each performance obligation is recognized when the respective obligation is satisfied either by delivering a good or providing a service, limited to the consideration that is not constrained.

When the timing of the delivery of product is different from the timing of payments made by the customers, we recognizes either a contract asset (performance precedes the contractual due date) or a contract liability (customer payment precedes performance). Our contractual payment terms are typically due in no more than 30 days from invoicing. In limited situations, certain customer contractual payment terms require us to bill in arrears; thus, we satisfy some or all of our performance obligations before we are contractually entitled to bill the customer. In these situations, billing occurs subsequent to revenue recognition, which results in a contract asset. For example, certain of the contractual arrangements do not permit us to bill until the completion of the production of the samples. In other limited situations, certain customer contractual payment terms allow us to bill in advance; thus, we receive customer cash payment before satisfying some or all of its performance obligations. In these situations, billing occurs in advance of revenue recognition, which results in contract liabilities.

Licenses of Intellectual Property

Upfront non-refundable payments for licensing our intellectual property are evaluated to determine if the license is distinct from the other performance obligations identified in the arrangement. For licenses determined to be distinct, we recognize revenues from non-refundable, up-front fees allocated to the license at a point in time, when the license is transferred to the licensee and the licensee is able to use and benefit from the license.

Research and Development Services

The portion of the transaction price allocated to research and development services performance obligations is deferred and recognized as collaboration revenue over time as delivery or performance of such services occurs.

Milestone Payments

At the inception of each arrangement that includes development, commercialization, and regulatory milestone payments, we evaluate whether the milestones are considered probable of being reached and to the

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extent that a significant reversal of cumulative revenue would not occur in future periods, estimates the amount to be included in the transaction price using the most likely amount method. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achieving such development milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Royalties

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Research and Development Expenses

Elements of research and development expenses primarily include: (1) payroll and other related expenses of personnel engaged in research and development activities, (2) in-licensed patent rights fee of exclusive development rights of drugs granted to us, (3) expenses related to pre-clinical testing of our technologies under development and clinical trials such as payments to contract research organizations (“CRO”), investigators and clinical trial sites that conduct our clinical studies, (4) costs to develop the drug candidates, including raw materials and supplies, product testing, depreciation, and facility related expenses, and (5) other research and development expenses. Research and development expenses are charged to expense as incurred when these expenditures relate to our research and development services and have no alternative future uses.

We have acquired rights to develop and commercialize drug candidates. Upfront payments that relate to the acquisition of a new drug compound, as well as pre-commercial milestone payments, are immediately expensed as acquired in-process research and development in the period in which they are incurred, provided that the new drug compound did not also include processes or activities that would constitute a “business” as defined under U.S. GAAP, the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no established alternative future use. Milestone payments made to third parties subsequent to regulatory approval would be capitalized as intangible assets and amortized over the estimated remaining useful life of the related product. The conditions enabling capitalization of development expenses as an asset have not yet been met and, therefore, all development expenditures are recognized in profit or loss when incurred.

Share-Based Compensation

We grant restricted shares and stock options to eligible employees and account for share-based compensation in accordance with ASC 718, *Compensation—Stock Compensation*.

Employees’ share-based compensation awards are measured at the grant date fair value of the awards and recognized as expenses (i) immediately at the grant date if no vesting conditions are required; (ii) for share-based awards granted with only service conditions, using the graded vesting method net of estimated forfeitures over the vesting period; or (iii) for share-based awards granted with service conditions and the occurrence of an initial public offering as performance condition cumulative share-based compensation expenses for the options that have satisfied the service condition should be recorded upon the completion of the initial public offering using the graded vesting method.

A change in any of the terms or conditions of share-based awards is accounted for as a modification of the awards. We calculate incremental compensation expense of a modification as the excess of the fair value of the

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modified awards over the fair value of the original awards immediately before its terms are modified at the modification date. For vested awards, we recognize incremental compensation cost in the period when the modification occurs. For awards not being fully vested, we recognize the sum of the incremental compensation expense and the remaining unrecognized compensation expense for the original awards over the remaining requisite service period after modification.

Share-based compensation in relation to the restricted shares is measured based on the fair market value of our ordinary shares at the grant date of the award. Prior to the listing, estimation of the fair value of our ordinary shares involves significant assumptions that might not be observable in the market, and a number of complex and subjective variables, including discount rate, and subjective judgments regarding our projected financial and operating results, its unique business risks, the liquidity of its ordinary shares and its operating history and prospects at the time the grants are made. Share-based compensation in relation to the share options is estimated using the Binominal Option Pricing Model. The determination of the fair value of share options is affected by the share price of our ordinary shares as well as the assumptions regarding a number of complex and subjective variables, including the expected share price volatility, risk-free interest rate, exercise multiple and expected dividend yield. The fair value of these awards was determined with the assistance from an independent valuation firm.

Restricted ordinary shares

During the year ended December 31, 2016, we issued 4,019,554 ordinary shares to Mr. Zang Jingwu Zhang, Ms. Qian Lili, Mr. Wang Zhengyi and Mr. Fang Lei (collectively the “Founders”), and we recorded share-based compensation expense of RMB18.7 million for issuance and grant of 3,650,253 ordinary shares to the Founders in June 2016.

In October 2016, the Founders entered into an arrangement with our other investors, and the 87,441 ordinary shares issued to the Founders in June 2016 were cancelled, and out of the remaining 3,932,113 ordinary shares held by the Founders, 70% became restricted and subject to service vesting conditions, that shall vest 20%, 20% and 30% over the next three years, respectively, and these unvested restricted shares will be vested immediately upon the listing.

Deferred share-based compensation was measured for the restricted shares using the estimated fair value of our ordinary shares of US\$0.77 at the date of imposition of the restriction in October 2016, and was amortized to the consolidated statements of comprehensive loss by using graded vesting method over the vesting term of 3 years. The following table summarizes our Founders’ restricted shares activities for the years ended December 31, 2017 and 2018:

	<u>Numbers of shares</u>	<u>Weighted- average grant date fair value</u>
Outstanding at December 31, 2016	2,752,479	0.77
Vested	<u>(786,423)</u>	
Outstanding at December 31, 2017	1,966,056	0.77
Vested	<u>(786,423)</u>	
Outstanding at December 31, 2018	<u>1,179,633</u>	0.77

The shared-based compensation expense in relation to the restricted ordinary shares recognized in the years ended December 31, 2017 and 2018 was RMB7,039 thousand and RMB3,520 thousand, respectively.

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Shared-based compensation expenses relating to restricted shares were included in:

	Year Ended December 31,		
	2017	2018	
	RMB	RMB	US\$
Research and development expenses	2,112	1,056	154
Administrative expenses	4,927	2,464	358
	<u>7,039</u>	<u>3,520</u>	<u>512</u>

2017 Employee Stock Option Plan (“2017 Plan”).

In October 2017, we adopted the 2017 Plan. Under the 2017 Plan, a maximum aggregate number of 13,376,865 shares that may be issued pursuant to all awards granted were approved. Stock options granted to an employee under the 2017 Plan will be exercisable upon the completion of a listing and the employee renders service to us in accordance with a stipulated service schedule starting from the employee’s date of employment. Employees are generally subject to a three-year service schedule, under which an employee earns an entitlement to vest in 50% of the option grants on the second anniversary of the grant date, a vesting of the remaining fifty percent 50% on the third anniversary of the applicable grant date. The stock options under the 2017 Plan, to the extent then vested, shall become exercisable only upon the earlier of (i) a listing, and (ii) occurrence of a change in control.

Prior to the completion of a listing, all stock options granted to an employee shall be forfeited at the time the employee terminates his employment with us. After we complete a listing, vested options not exercised by an employee shall be exercised until later of: (i) 90 days after the date when the options become exercisable, or (ii) 30 days after the date of cessation of employment or directorship, or such longer period as the board of directors may otherwise determine.

We granted 10,646,783 and 1,470,000 stock options to employees, all with an exercise price of US\$1, for the years ended December 31, 2017 and 2018, respectively. No options are exercisable as of December 31, 2017 and 2018 and prior to the completion of a listing.

The following table sets forth the stock options activities for the years ended December 31, 2017 and 2018:

	Number of shares	Weighted average exercise price US\$	Weighted average remaining contractual term	Aggregate intrinsic value US\$
Outstanding as of December 31, 2016	—	—	—	—
Granted	11,051,230	—	—	—
Other addition (note)	710,366	—	—	—
Outstanding as of December 31, 2017	11,761,596	1.00	8.50	4,890
Granted	1,470,000	—	—	—
Forfeited	(226,000)	—	—	—
Outstanding as of December 31, 2018	<u>13,005,596</u>	<u>1.00</u>	<u>8.61</u>	<u>10,129</u>
Exercisable as of December 31, 2018	—	—	—	—

Note: Other addition represented the modified share options that originally granted to two senior management employees in October 2016 (see “—other share-based compensation”).

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Stock options granted to the employees were measured at fair value on the dates of grant using the Binomial Option Pricing Model with the following assumptions:

	Year ended December 31,	
	2017	2018
Expected volatility	62.34%	61.32%-62.13%
Risk-free interest rate (per annum)	2.32%	2.81%-3.06%
Exercise multiple	2.8	2.8
Expected dividend yield	—	—
Contractual term (in years)	10	10

The expected volatility was estimated based on the historical volatility of comparable peer public companies with a time horizon close to the expected term of our options. The risk-free interest rate was estimated based on the yield to maturity of U.S. treasury bonds denominated in US\$ for a term consistent with the expected term of our options in effect at the option valuation date. The expected exercise multiple was estimated as the average ratio of the stock price to the exercise price when employees would decide to voluntarily exercise their vested options. As we did not have sufficient information of past employee exercise history, it was estimated by referencing to a widely-accepted academic research publication. Expected dividend yield is zero as we have never declared or paid any cash dividends on its shares, and we do not anticipate any dividend payments in the foreseeable future. Expected term is the contract life of the option.

The fair value of stock options granted to employees for the years ended December 31, 2017 and 2018 amounted to RMB99.0 million and RMB45.2 million, respectively. Since the exercisability is dependent upon the listing, and it is not probable that this performance condition can be achieved until a listing is effective, no share-based compensation expense relating to the 2017 Plan was recorded for the years ended December 31, 2017 and 2018. We will recognize compensation expenses relating to options vested cumulatively upon the completion of our listing.

Other share-based compensation

For the year ended December 31, 2016, we recorded share-based compensation expense of RMB3.3 million for issuance and grant of 710,366 stock options to two senior management employees in October 2016, as rewards for their services they had performed in the past and in exchange for their full-time devotion and professional expertise. Stock options granted to the two employees were exercisable once granted, with an exercise price of US\$0.06.

In October 2017, in connection with the adoption of the 2017 Plan, we amended the stock option agreement with the two aforementioned employees, under which the stock options would become exercisable only upon the earlier of (i) a listing, and (ii) occurrence of a change in control that defined in the stock option agreements. As the modification of terms and conditions of share-based compensation were not beneficial to its employees, no further accounting impact was resulting from it.

Fair Value of Ordinary Shares

We are required to estimate the fair value of the ordinary shares on grant dates of share-based compensation awards/share option to our employees and the issuance of financial instruments to investors. Therefore, our board of directors has estimated the fair value of our ordinary shares on various dates, with inputs from management, considering the third-party valuations. The valuations of our ordinary shares were performed using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants Audit and Accounting Practice Aid Series: Valuation of Privately-Held-Company Equity Securities Issued as Compensation, or the AICPA Practice Guide.

In addition, our board of directors considered various objective and subjective factors, along with inputs from management and the independent third-party valuation firm, to determine the fair value of our ordinary shares, including: external market conditions affecting the biopharmaceutical industry, trends within the biopharmaceutical industry, the prices at which we sold convertible preferred shares, the superior rights and preference of the convertible preferred shares or other senior securities relative to our ordinary shares at the time

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of each grant and the likelihood of achieving a liquidity event such as an initial public offering. The option-pricing method was used to allocate the enterprise's value to preferred shares or other senior securities and ordinary shares, taking into account the guidance prescribed by the AICPA Practice Guide. This method treats ordinary shares and convertible preferred shares or other senior securities as call options on the enterprise's value, with exercise prices based on their respective payoffs upon a liquidity event.

In determining the enterprise's value, we applied the market approach/backsolve method based on pricing from recent transactions in our own securities. The basis for application of this method is our transactions in equity securities with unrelated parties or among unrelated parties themselves. No evidence is observed to indicate these transactions are not arm's-length transactions.

Our board of directors determined the fair value of our share options and the restricted shares as of the dates of grant, taking into consideration the various objective and subjective factors described above, including the conclusion of valuation of our ordinary shares as of dates close to the grant dates of our share options and the restricted shares. We computed the per share estimated fair value for share options based on the binomial option pricing model and the per share estimated fair value for restricted shares based on per share estimated fair value of ordinary shares as of the date of grant.

Once public trading market of the ADSs has been established in connection with the completion of this offering, it will no longer be necessary for our board of directors to estimate the fair value of our ordinary shares in connection with our accounting for granted share options and restricted shares.

Fair Value Measurements

Our financial assets and liabilities primarily comprise of cash and cash equivalents, restricted cash, other financial assets, contract assets, other receivables, short-term borrowings, accruals and other payables and warrant liabilities. As of December 31, 2017 and 2018, except for other financial assets and warrants liabilities, the carrying values of these financial assets and liabilities approximated their fair values because of their generally short maturities. We report other financial assets and warrant liabilities at fair value at each balance sheet date and changes in fair value are reflected in the consolidated statements of comprehensive loss.

We measure our financial assets and liabilities using inputs from the following three levels of the fair value hierarchy. The three levels are as follows:

Level 1 inputs are unadjusted quoted prices in active markets for identical assets that the management has the ability to access at the measurement date.

Level 2 inputs include quoted prices for similar assets in active markets, quoted prices for identical or similar assets in markets that are not active, inputs other than quoted prices that are observable for the asset (i.e., interest rates, yield curves, etc.), and inputs that are derived principally from or corroborated by observable market data by correlation or other means (market corroborated inputs).

Level 3 includes unobservable inputs that reflect the management's assumptions about the assumptions that market participants would use in pricing the asset. The management develops these inputs based on the best information available, including the own data.

We measured our short-term investments at fair value on a recurring basis. As our other financial assets and derivative liabilities are not traded in an active market with readily observable prices, we use significant unobservable inputs to measure the fair value of other financial assets, and derivatives liabilities. These instruments are categorized in the Level 3 valuation hierarchy based on the significance of unobservable factors in the overall fair value measurement.

Recent Accounting Pronouncements

A list of recently issued accounting pronouncements that are relevant to us is included in note 2 "Principal Accounting Policies – 2.24 Recent Accounting Pronouncements" of our consolidated financial statements included elsewhere in this prospectus.

INDUSTRY

We see vast commercial opportunities for immuno-oncology and autoimmune biologics therapies. In 2018, approximately 60.8% of the antibody-based biologics in terms of global sales revenue targeted conditions in these areas, according to the Frost & Sullivan Report. In China, the need for efficacious drugs to treat cancer and autoimmune diseases is rising due to limited availability of such medicines and delayed access to global innovative medicines.

Despite the recent success of checkpoint inhibitors, such as PD-1 and PD-L1, clinical efficacy of these drugs has not lived up to expectations. The Frost & Sullivan Report estimates that more than 60% of cancer patients, including those with melanoma, renal cell cancer, colorectal cancer, non-small cell lung cancer, urothelial cancer and head and neck squamous cell carcinoma, do not respond to single-agent therapy with checkpoint inhibitors. Even for the tumor type with a high tumor mutational burden (i.e., the total number of mutations with coding region of a tumor cell genome) the ORR rarely exceeds 30% for PD-1/PD-L1 therapies. Similar findings are observed using PD-L1 as a biomarker in the treatment of NSCLC with pembrolizumab: the average ORR is 41% for PD-L1 positive tumor and 13% for PD-L1 negative tumor. The immuno-oncology field has been diligently seeking a more efficacious therapy with treatment agent(s) that works synergistically with PD-1/PD-L1 therapies. Such a novel combination therapy may provide an effective treatment option for those who do not respond to current PD-1/PD-L1 therapies. For example, our investigational drugs, including TJ107, enoblituzumab, TJC4, and TJD5, are intended to work as combination therapies with PD-1/PD-L1 regimens to address unmet medical needs in oncology. Currently, our target indications in the area of immuno-oncology cover a variety of hematologic malignancies, such as multiple myeloma, lymphoma and solid tumors, such as head and neck cancer, and cancer treatment-related lymphopenia. For autoimmune diseases, our target indications include systemic lupus erythematosus, ulcerative colitis, rheumatoid arthritis and other IL-6-implicated autoimmune diseases. The discussion below provides (i) an overview of the market trends and growth drivers in China's biologics market and (ii) an overview of the competitive landscape and key segments with respect to our most advanced clinical stage product candidates.

Trends and Growth Drivers of Biologics Market in China

According to the Frost & Sullivan Report, the growth of China's biologics market is attributable, in particular, to:

- *Large and Growing Oncology and Autoimmune Disease Patient Populations*—China's oncology patient population, especially treatment-naïve patients, has been increasing over the years. New cases of cancers in China reached 4.3 million in 2018 and are projected to reach 4.9 million in 2023. China also has a large autoimmune disease population. In 2018, systemic lupus erythematosus, ulcerative colitis and rheumatoid arthritis affected approximately 1.0 million, 0.4 million and 5.9 million patients in China, respectively.
- *Unmet Demands for Innovative Biologics Therapies Targeting Oncology*—Many biologics, especially monoclonal antibodies, have proved to have superior efficacy and less side effects for treating cancer. However, many antibody drugs approved to treat cancer in the United States are not available in China. From 1997 to 2018, 37 therapeutic antibodies were launched globally, but only seven of them are marketed in China.
- *Unmet Demands for Effective Therapies Targeting Autoimmune Diseases*—To date, there are no curative therapies for many autoimmune diseases. Targeted biologics that aim to improve physical functioning and prevent irreversible tissue or organ damage offer a promising trajectory. This class of biologics is expected to stimulate the biologics market that targets autoimmune diseases in China. The sales revenue of this market was RMB2.5 billion in 2018 and is projected to increase to RMB87.8 billion in 2030, representing a compound annual growth rate ("CAGR") of 34.6%.

- *Increasing Cost Burden of Autoimmune Diseases*—Autoimmune diseases have been reported to be on the rise in China, making this poorly understood category of diseases a public health issue at levels comparable to heart disease and cancer. Because of a lack of effective treatment and awareness amongst the general public and medical practitioners, the associated cost of autoimmune diseases accounts for a significant portion of the rising cost of healthcare burden in China. Innovative biologic treatments, as a means of reducing healthcare spending while ensuring improved public health, can help address the mounting pressure surrounding autoimmune diseases.
- *Increasing Investment in Biologics*—Research and development in innovative biologics therapies is the key to industry growth. Discovery and development of new biologics is a long, difficult and expensive process. Research and development investment for biologics in China is expected to continue rising in the future, leading to more new products entering the market. The continuous launch of new products will further drive the growth of China’s biologics industry.
- *Favorable Environment for Clinical Trials*—With nearly a one-fourth of the world’s cancer patient population, China provides an excellent opportunity to access a large patient pool and clinical resources for oncology drug development and market demands. The Chinese government has taken initiatives to address regulatory challenges that previously caused a lag in clinical trial applications of therapeutic biologics. Notably, in October 2017, the General Office of the CPC Central Committee and the General Office of the State Council issued the Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices, which aims to improve the regulatory approval process and encourage technological innovation for new drugs. In addition, in July 2018, the NMPA implemented Technical Guidelines for Accepting Data from Overseas Clinical Trials of Drugs, which significantly shortens the registration process and provides potential clinical trial exemptions for drugs that have robust clinical data from trials conducted overseas.
- *Increasing Affordability*—The average disposable income of the Chinese population is expected to continue growing rapidly, increasing the willingness and ability of patients to pay for medications. In 2018, households with an annual disposable income of over US\$20,000 accounted for 50.3% of the total households in China and are expected to increase to 84.3% of the total households in China by 2023. As more Chinese households increase their spending power, they can afford more expensive medical treatments, particularly for life-threatening diseases. In addition, inclusion of a drug in the National Reimbursement Drug List (“NRDL”) typically results in a much higher sales volume and significant sales growth despite a reduction in price. Such inclusion is expected to be implemented for innovative biologics on a regular basis, suggesting that more biologics are expected to be covered by the NRDL in the future, further increasing the affordability of biologics in China. As biologics become increasingly affordable to the general public, they will be used more commonly as a treatment for oncology and autoimmune diseases. As a result, the market size of the biologics industry in China is expected to continue to grow.

Multiple Myeloma

Overview

Multiple myeloma (“MM”) is a type of blood cancer that starts in the bone marrow and is characterized by excessive proliferation of malignant plasma cells that accumulate in the bone marrow, where they displace and suppress healthy blood progenitor cell populations, cause destructive lytic bone lesions (rounded, punched-out areas of the bone), diffuse osteoporosis, bone pain, and produce abnormal proteins that accumulate in the urine, and anemia.

In Greater China, new cases of MM reached approximately 20,500 in 2018 and is expected to increase to approximately 23,700 in 2023, representing a CAGR of 2.9%, according to the Frost & Sullivan Report. MM is primarily a disease of the elderly, and this population of patients 65 years and older continues to grow at a fast clip in China. In fact, the new incidence of MM in China is projected to reach approximately 28,300 in 2030, representing a CAGR of 2.6% from 2023 to 2030.

Treatment of MM

MM treatment is individualized but generally includes small molecules drugs and biologics. The primary treatment regimens are cytoreductive chemotherapies, in combination with stem cell transplants, aimed at achieving a cure, if possible. In addition, MM patients require substantial supportive therapy aimed at managing complications of the disease (such as bone damage) and ameliorating the side effects of treatment. There are a number of drug classes for MM treatment, including monoclonal antibodies, immunomodulatory drugs, proteasome inhibitors, chemotherapy, histone deacetylase inhibitors, and steroids. A patient’s individual treatment plan is based on factors such as age and general health, results of laboratory and cytogenetic (genomic) tests, symptoms and disease complications, prior myeloma treatment as well as the patient’s lifestyle, goals, views on quality of life, and personal preferences. In addition, many cancer centers have developed their own guidelines for treating MM. In China, drugs approved for treating relapsed or refractory MM (“RRMM”) include daratumumab (Darzalex from Janssen), lenalidomide (Revlimid from Celgene), thalidomide (Thalomid from Celgene) bortezomib (Velcade from Takeda), and ixazomib (Ninlaro from Takeda).

Unmet Medical Need

Currently, there is no curative treatment for RRMM. Although the currently marketed CD38 antibody product is efficacious, it takes a long time to be administered by IV infusion (up to six hours) and causes a high infusion reaction rate (“IRR”). In clinical trials, approximately half of all patients experience an infusion reaction, which may include fever, chills, nausea, bronchospasm, hypoxia, dyspnea, hypertension, laryngeal edema and pulmonary edema. Thus, there is a need for an efficacious and convenient-to-use drug with a better safety profile. Such a drug may be combined with other therapeutic agents for better treatment efficacy in RRMM.

Competitive Landscape

There are various monotherapy agents and combination treatments currently under clinical development targeting different lines of MM therapies. Our TJ202 is a potentially best-in-class CD38 monoclonal antibody and could be the second antibody therapy for MM to launch in China. The following tables illustrate the competitive landscape of biologic MM therapies targeting CD38 antibody in China and the rest of the world. (Source: Frost & Sullivan Report)

Marketed CD38 Antibody Drug for Treating MM

Product	Company	FDA Approval Time	NMPA Approval Time	Patent Expiry in the U.S.	Global Sales Revenue in 2018 (in Bn, US\$)
Daratumumab IV	Johnson & Johnson	2015	2019	2026	2.0

Investigational CD38 Antibody Drugs for Treating MM

Investigational Drugs (1)	Company	Global Status	China Status
Daratumumab SC	Johnson & Johnson	Phase 3	N/A
Isatuximab	ImmunoGen and Sanofi	BLA	Phase 3
TJ202(2)	I-Mab	N/A	Phase 3
TAK-079	Takeda	Phase 1/2	N/A

Notes:
 (1) Investigational drugs prior to Phase 2 clinical trials are not included in this table.

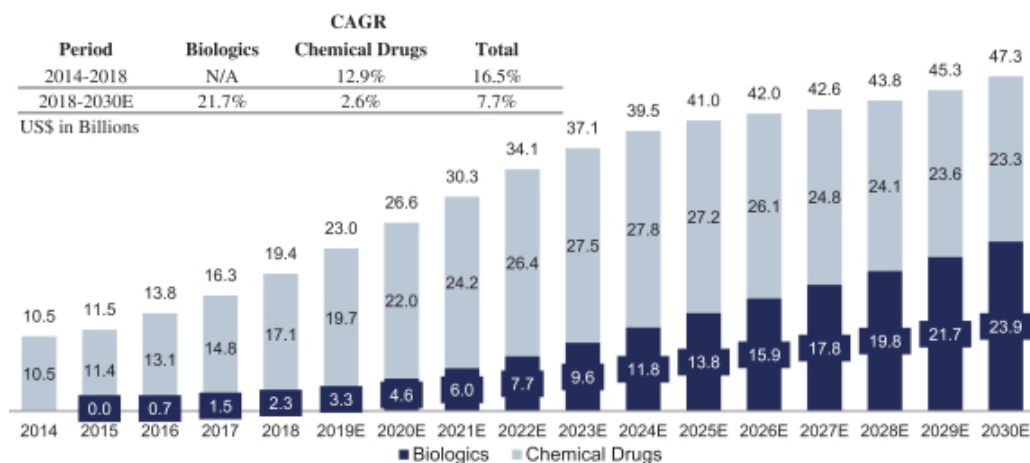
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- (2) In November 2017, we and MorphoSys entered into an exclusive regional licensing agreement to develop and commercialize MOR202, which we refer to as TJ202 in this prospectus, in Greater China (including Taiwan, Hong Kong and Macao). TJ202 is currently undergoing two registrational clinical trials in relapsed/refractory multiple myeloma in Greater China. We aim to submit a new drug application (“NDA”) to the NMPA for TJ202 as a monotherapy in 2021.

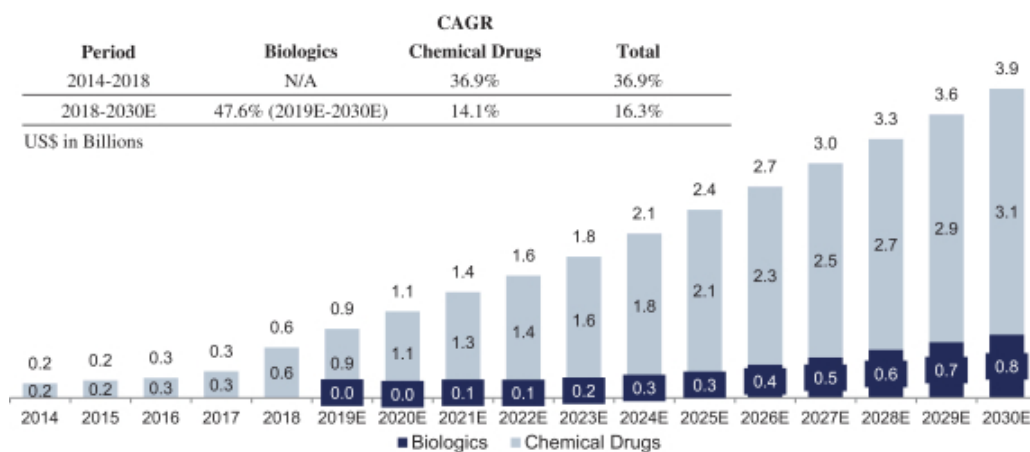
Historical and Forecast Market Size of MM Therapeutics Globally and in China

The following diagrams illustrate the market size of all MM therapeutics in terms of sales revenue globally and in China. (Source: Frost & Sullivan Report)

Global MM Therapeutics Market Size (2014-2030E)



China MM Therapeutics Market Size (2014-2030E)



Head and Neck Cancer

Overview

Head and neck cancers occur in various parts of the head and neck, including the mouth, nose, throat, larynx, sinuses, and salivary glands. More than 90% of head and neck cancers are classified as squamous cell

carcinomas (“SCCHN”), which begins in the squamous cells that line the moist, mucosal surfaces inside the head and neck. Symptoms of head and neck cancers may include a lump or sore that does not heal, a sore throat that does not go away, difficulty swallowing or breathing, a change or hoarseness in the voice, unusual bleeding, and facial swelling. According to the Frost & Sullivan Report, in Greater China, new cases of head and neck cancer reached approximately 140,200 in 2018 and are predicted to increase to approximately 155,300 in 2023, representing a CAGR of 2.1%, and new cases of head and neck cancers in China are projected to grow, reaching approximately 173,400 in 2030 with a CAGR of 1.6% from 2023 to 2030.

Treatment of Head and Neck Cancer

The treatment principles and regimens for head and neck cancer in China are similar to those in the rest of the world. Treatment strategies often depend on the location and stage of the cancer, the patient’s physical status, and response to prior treatments. Early-stage disease is primarily treated with surgical resection, while patients with locally advanced, recurrent or metastatic disease are typically treated with drug therapy. The combination of surgery and drug therapy, with or without radiation therapy, is the current standard of care for Stage 3 SCCHN patients with locally advanced disease. Platinum-based chemotherapy regimens are widely used as first-line therapies for Stage 4 and distant relapse patients. Erbitux (cetuximab from Eli Lilly and Merck KGaA) was approved in 2006 as a first-line treatment of locally advanced SCCHN in combination with radiation therapy. Regimens containing Erbitux, platinum-based chemotherapy, and 5-fluorouracil, known as EXTREME, are often considered as the standard of care for first-line treatment of distant relapse SCCHN. Second-line therapy is highly varied, including single-agent docetaxel or paclitaxel, Erbitux monotherapy, or Erbitux/paclitaxel combination therapy.

In 2016, PD-1 inhibitors were approved globally as a second-line therapy and more recently, Keytruda (pembrolizumab from Merck & Co), as a single agent or in combination with chemotherapy, was approved by the FDA as a first-line therapy for metastatic or unresectable recurrent SCCHN, but no PD-1 inhibitors have been approved for this indication in China.

Unmet Medical Need

According to Datamonitor Healthcare’s epidemiology forecast (2016-2036), 76% of all actively treated patients with SCCHN have Stage 3, Stage 4, local relapse or distant relapse disease, but efficacious treatment options are limited for these patients. For example, only about 35% of all patients with distant relapse SCCHN respond to EXTREME, and the resulting overall median survival is only 10.1 months. In addition, about half of the patients on first-line therapies need later line therapies. In addition, the average ORR for second-line PD-1 therapies has been less than 15%. As such, SCCHN patients, especially those with late stage or relapsed disease, need more efficacious treatments with fewer side effects, which represents a significant unmet medical need.

Competitive Landscape

Our enoblituzumab is the only conventional B7-H3 antibody in clinical development globally. The following table illustrates the competitive landscape of investigational B7-H3 antibody drugs in China and the rest of the world. (Source: Frost & Sullivan Report)

Investigational B7-H3 Antibody Drugs

Investigational Drugs	Drug Form	Company	Indications	Global Status	China Status
¹³¹ I-Omburtamab	Radio-labeled antibody	Y-mAbs Therapeutics	CNS/leptomeningeal metastases of neuroblastoma	Pivotal Phase 2	N/A
Enoblituzumab(1)	Monoclonal antibody	MacroGenics I-Mab(1)	Solid tumors	Phase 2	N/A
MGC-018	Antibody-Drug Conjugate	MacroGenics	Solid tumors	Phase 1/2	N/A
¹²⁴ I-Omburtamab	Radio-labeled antibody	Y-mAbs Therapeutics	Glioma	Phase 2	N/A

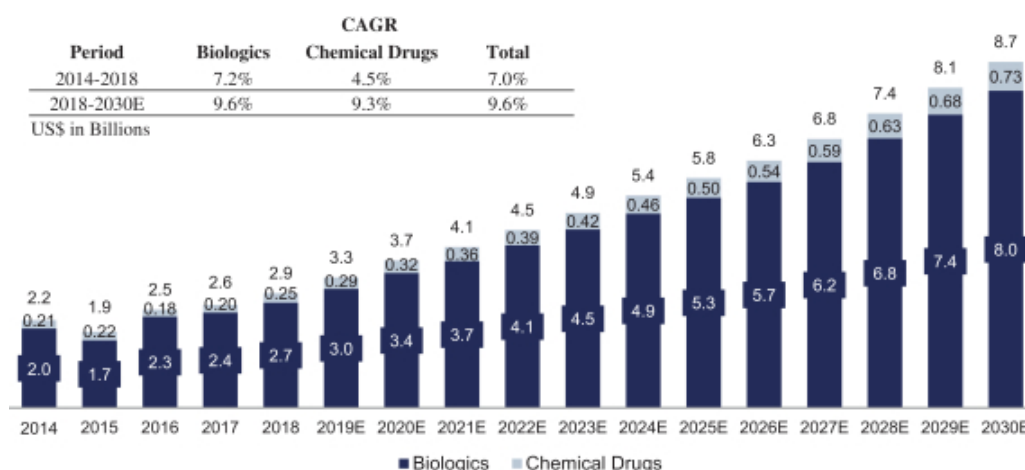
Note:

(1) We have the development and commercialization rights for enoblituzumab in Greater China pursuant to a partnership agreement with MacroGenics.

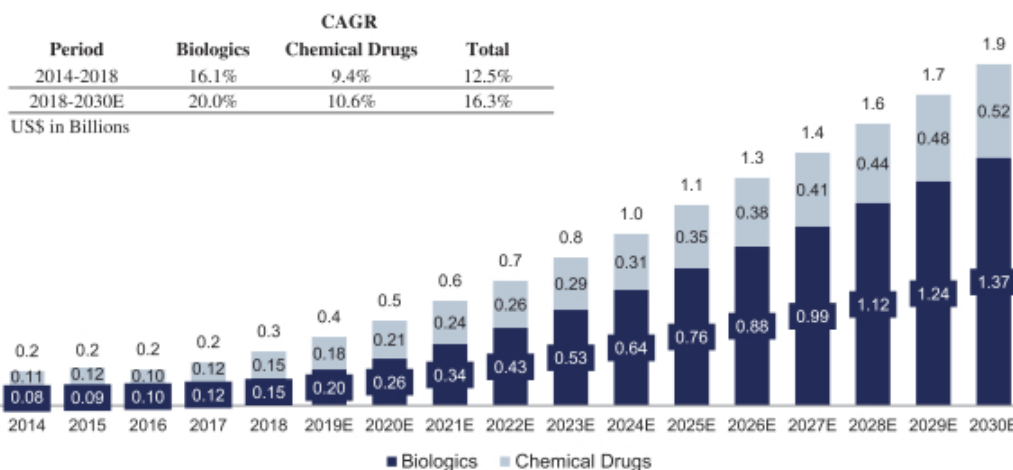
Historical and Forecast Market Size of Head and Neck Cancer Therapeutics Globally and in China

The following diagrams illustrate the size of the head and neck cancer drug market in terms of sales revenue in global and China markets. (Source: Frost & Sullivan Report)

Global Head and Neck Cancer Therapeutics Market Size (2014-2030E)



China Head and Neck Cancer Therapeutics Market Size (2014-2030E)



Cancer Treatment-Related Lymphopenia

Overview

Lymphopenia is a decrease in lymphocyte cell count that is lower than the age-appropriate reference level. Cancer patients who undergo chemotherapy and/or radiation therapy often develop severe lymphopenia (<500 cells/mm³), which further damages their already compromised immune systems and their ability to fight against cancers. According to the Frost & Sullivan Report, more than 85% of cancer patients receive chemotherapy or radiation therapy, and approximately 43% of them develop lymphopenia. Furthermore, there is a two-fold increase in the risk of early cancer death associated with severe lymphopenia. Currently no drug is available for cancer treatment-related lymphopenia.

In Greater China, according to the Frost & Sullivan Report, the incidence of lymphopenia reached 1.5 million in 2018 and is estimated to increase to 1.7 million in 2023 and further to 2.0 million in 2030.

Treatment of Cancer Treatment-Related Lymphopenia

There is currently no guideline and no specific or effective treatment for cancer treatment-related lymphopenia. Most patients with cancer treatment-related lymphopenia are clinically monitored without specific treatment both globally and in China. Proleukin is a recombinant human IL-2 that has shown some therapeutic effect in promoting overall T cell populations in cancers, which also include tumor-protecting T regulatory (Treg) cells.

Unmet Medical Need

There is currently no FDA-approved drug for cancer treatment-related lymphopenia. There remains a substantial need for an effective treatment for lymphopenia as prolonged lymphopenia often correlates with shortened survival time as reported in the medical literature (Grossman et al., J Natl Compr Canc Netw. 2015 October ; 13(10): 1225–1231). Proleukin has a limited effect on lymphopenia with serious side effects. There are global research and development efforts to find effective T cell cytokines capable of selectively promoting proliferation of tumor-fighting T cells but not tumor-protecting Treg cells. These efforts include IL-7, IL-12 and IL-15, all of which are in early stages of development.

Competitive Landscape

There are only two IL-7-based investigational drugs, TJ107 (efineptakin) and CYT-107. (Source: Frost & Sullivan Report)

Investigational Drugs of Recombinant Human IL-7

Investigational Drugs	Drug Form	Company	Indications	Global Status	China Status
Efineptakin(1)	Long-acting rhIL-7	I-Mab	Lymphopenia and cancer	N/A	Phase 1b/2a
Efineptakin(1)	Long-acting rhIL-7	Genexine Inc. (KOSDAQ: 095700)	Solid tumors	Phase 2	N/A
CYT-107	Glycosylated rhIL-7	Revimmune	Sepsis and septic shock	Phase 2	N/A

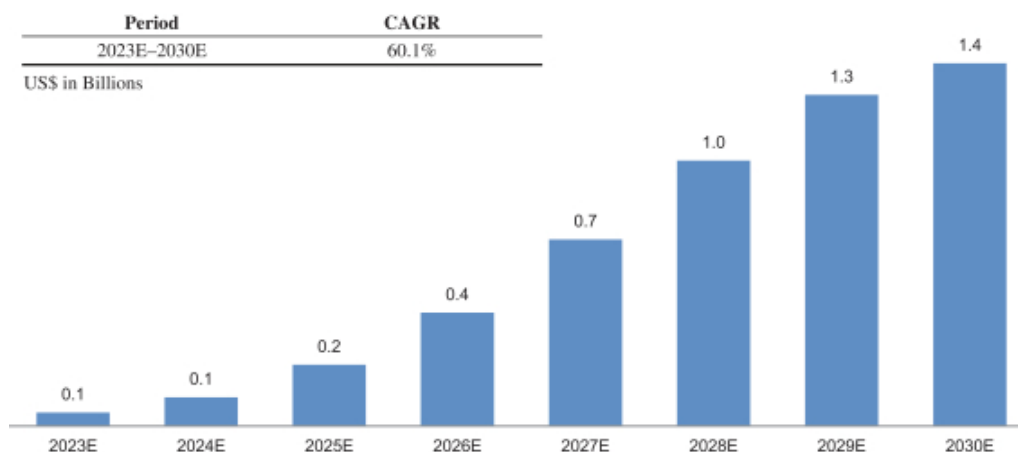
Note:

(1) We have the development and commercialization rights for efineptakin in Greater China pursuant to a partnership agreement with Genexine. We are conducting clinical trials in China as part of the coordinated global clinical development plan.

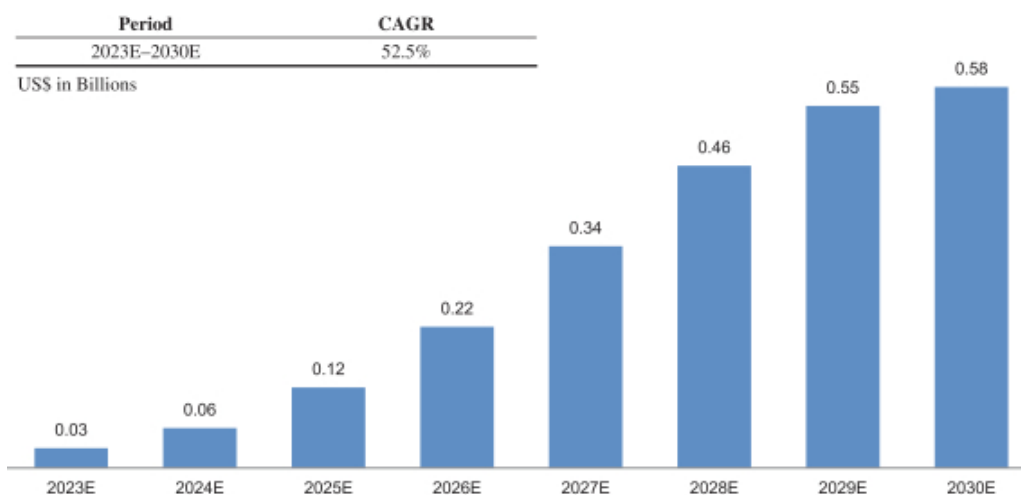
Forecast Market Size of Potential Cancer Treatment-Related Lymphopenia Globally and in China

According to the Frost & Sullivan Report, since most patients with cancer treatment-related lymphopenia are not actively treated, there is currently no such drug market globally or in China. However, there is a huge market potential as the following diagrams illustrate the forecast size of the market when an effective drug for treatment-related lymphopenia becomes available. (Source: Frost & Sullivan Report)

Global Cancer Treatment-Related Lymphopenia Market Size (2023E-2030E)



China Cancer Treatment-Related Lymphopenia Market Size (2023E-2030E)



Systemic Lupus Erythematosus

Overview

Systemic lupus erythematosus (“SLE”) is a chronic, multi-system and incurable autoimmune disease that can potentially lead to serious organ damage, systemic complications and even death. Patients with SLE have aberrant production of auto-antibodies (antibodies against self-antigens) by CD38-positive plasma cells, and dysregulated CD38-positive pathogenic B cells. As part of the disease mechanism, immune complexes induced by auto-antibodies are formed and deposit in the kidneys and cause tissue damage. Common symptoms of SLE include painful and swollen joints, unexplained fever, chest pain, hair loss, mouth ulcers, swollen lymph nodes, extreme fatigue, and red rashes that most commonly appear on the face, and these symptoms vary widely among patients and fluctuate unpredictably over time as the disease progresses. More importantly, at the advanced stage of the disease, patients can develop renal damage and renal failure.

According to the Frost & Sullivan Report, SLE had an estimated prevalence of approximately 1.04 million in 2018 in Greater China, which is projected to increase to 1.08 million in 2023, representing a CAGR of 0.8%. Cases of SLE in China are projected to increase to 1.11 million in 2030.

Treatment of Systemic Lupus Erythematosus

Currently, there is a significant unmet medical need for more effective therapies for SLE. Since SLE is a chronic disease, current treatments aim to manage symptoms and reduce the frequency of disease flares. Patients with mild SLE are often managed by non-steroidal anti-inflammatory drugs, while more severe patients may need corticosteroids or immunosuppressants. Combination treatments can also be used as disease-modifying treatment regimens, aiming to control the disease and prevent chronic tissue damage. Approved by the FDA in 2011 and by the NMPA in July 2019, Belimumab (belimumab), a B-lymphocyte stimulator (BLyS)-specific inhibitor developed by GSK, is currently the world’s only biologic approved to treat SLE.

Unmet Medical Need

The effect of symptomatic treatments for SLE, including non-steroidal anti-inflammatory drugs, is short-lived and often very limited. The therapeutic role of corticosteroids or immunosuppressants in the long-term

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management of SLE is hampered by severe drug-related side effects and lack of a disease-modifying effect. As auto-antibodies and resulting immune complexes produced by CD38-positive B cells and plasma cells act at the core of the pathogenesis of SLE, direct inhibition and selective depletion of pathogenic B cells and plasma cells are believed to offer superior treatment efficacy and better safety. TJ202 has the potential to offer such a disease-modifying treatment option. In addition, the advantages of TJ202 include convenience of use and a lower IRR, making it a more favorable treatment agent in the long-term clinical management of SLE if proven efficacious.

Competitive Landscape

The following tables illustrate the competitive landscape of the biologics treating SLE in China and the rest of the world. (Source: Frost & Sullivan Report)

Marketed Biological Products for SLE

Product	Target	Company	FDA Approval Time	NMPA Approval Time	Patent Expiry in the U.S.	Global Sales Revenue in 2018 (in Bn, US\$)
Belimumab	BLyS	GSK	2011	2019	2025	0.63

Investigational Drugs for SLE in China

Investigational Drugs (1)	Target	Drug Form	Company	Global Status	China Status
RCT-18	BLyS and APRIL	Antibody fusion protein	Rong Chang	N/A	Phase 3
Ustekinumab	IL-12/23	Monoclonal antibody	Johnson & Johnson	Phase 3	Phase 3
TJ202	CD38	Monoclonal antibody	I-Mab	N/A	IND 2019

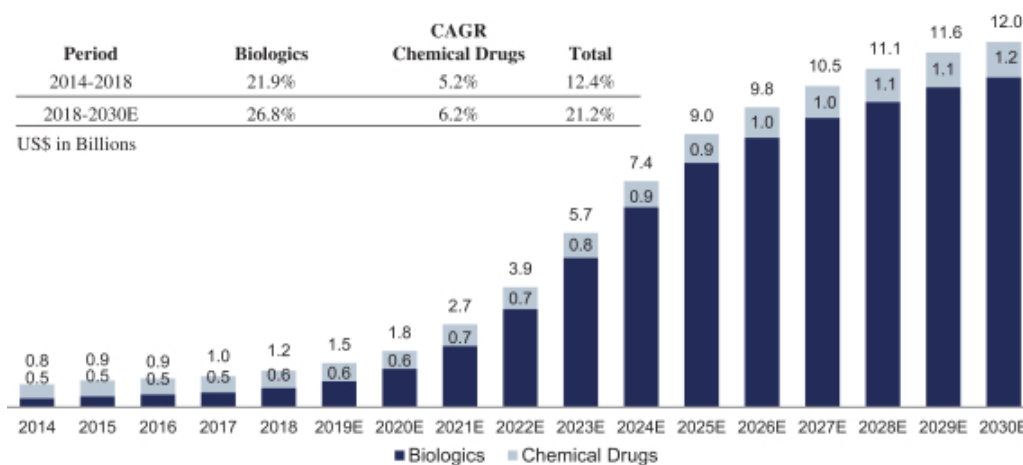
Note:

(1) Competing investigational biologics that are prior to Phase 3 clinical trials are not included in this table.

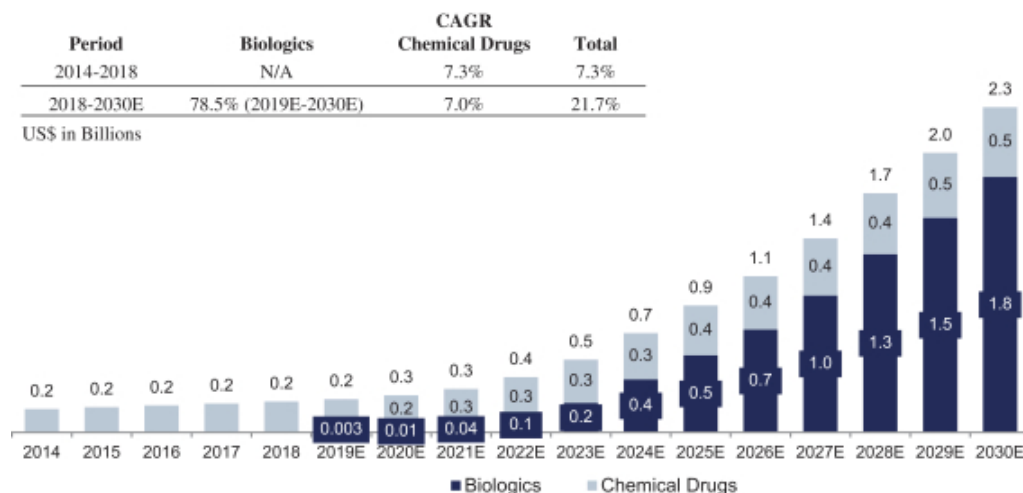
Historical and Forecast Market Size of SLE Therapeutics Globally and in China

The following diagrams illustrate the size of the SLE drug market in terms of sales revenue in the global and China markets. (Source: Frost & Sullivan Report)

Global SLE Therapeutics Market Size (2014-2030E)



China SLE Therapeutics Market Size (2014-2030E)



Ulcerative Colitis

Overview

Ulcerative colitis (“UC”) is an inflammatory bowel disease (“IBD”) that causes chronic and often relapsing inflammation and ulceration of the colon and rectum, in which the lining of the colon and rectum become inflamed and develop tiny open sores, or ulcers, which produce pus and mucous. This combination of inflammation and ulceration can cause abdominal discomfort and frequent emptying of the colon. UC patients

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experience recurrent flares of abdominal pain and bloody diarrhea. Other UC symptoms include fatigue, weight loss, and fever. Disease complications may include megacolon, inflammation of the eye, joints, or liver, and colon cancer. According to the Frost & Sullivan Report, in Greater China, UC affected approximately 370,132 patients in 2018, which is predicted to increase to approximately 543,723 cases in 2023, representing a CAGR of 8.0%. Greater China has a relatively lower UC incidence and prevalence compared to those in Western countries, but the absolute number of patients is predicted to increase to approximately 918,296 in 2030 with a CAGR of 7.8% from 2023 to 2030, as a result of the increasingly westernized lifestyle in Greater China.

Treatment of UC

Currently, there is no curative treatment for UC. Most of the approved biologics for UC are TNF- α inhibitors. Vedolizumab (Entyvio), an integrin $\alpha 4\beta 7$ antibody that blocks lymphocytes from accumulating in the intestinal wall, is currently the only non-anti-TNF- α biologic approved for UC. Vedolizumab is also in a Phase 3 trial in China. In May 2018, tofacitinib (Xeljanz), which is a small molecule Jak1/3 kinase inhibitor, became the first oral medication approved for chronic use in moderate to severe UC in the United States. In China, non-steroidal anti-inflammatory drugs, such as 5-aminosalicylic acids (“5-ASAs”), and corticosteroids or other immunosuppressants, including azathioprine, mercaptopurine and cyclosporine, are often used as an initial treatment and throughout the course of clinical management with limited treatment efficacy. Approved by the NMPA in 2019, infliximab (Remicade), which is a TNF- α inhibitor, is currently the only biologic approved to treat UC in China.

Unmet Medical Need

The incidence of UC is increasing rapidly, but UC patients, especially those with a moderate-to-severe disease, have few treatment options, which have limited treatment efficacy and considerable side-effects. For example, Jak1/3 kinase inhibitors can carry the risk of serious infections and malignancies. TNF- α inhibitors also have inherent side effects and do not work in all patients. According to the Frost & Sullivan Report, approximately 45% patients are considered treatment non-responders to TNF- α drugs among all autoimmune diseases. Thus, there is a substantial unmet medical need in UC for a treatment agent(s) that is efficacious and safe through pathways beyond the traditional drug targets. TJ301 is believed to potentially fulfill such a product profile as it works through the IL-6 trans-signaling pathway for treatment efficacy with a better safety profile.

Competitive Landscape

Our TJ301 is the only clinical stage selective interleukin-6 (“IL-6”) inhibitor that works through the trans-signaling mechanism. It is a potential best-in-class IL-6 blocker for UC. The following table illustrates the competitive landscape of investigational biologics for treating UC that are in late-stage development in China and the rest of the world. (Source: Frost & Sullivan Report)

Product(1)	Target	Company	Global Status	China Status
Vedolizumab	$\alpha 4\beta 7$ integrin	Takeda	Approved	Phase 3
Ustekinumab	IL-12/IL-23	Johnson & Johnson	NDA filed	N/A
Risankizumab	IL-23	AbbVie	Phase 3	Phase 3
Mirikizumab	IL-23	Eli Lilly	Phase 3	N/A
Etrolizumab	$\beta 7$ integrin	Roche	Phase 3	N/A
Ontamalimab	MAdCAM	Takeda/Shire	Phase 3	N/A
Spesolimab	IL-36	Boehringer Ingelheim	Phase 2/3	N/A
Olamkicept TJ301(2)	IL-6	I-Mab	Phase 2	Phase 2

Notes:

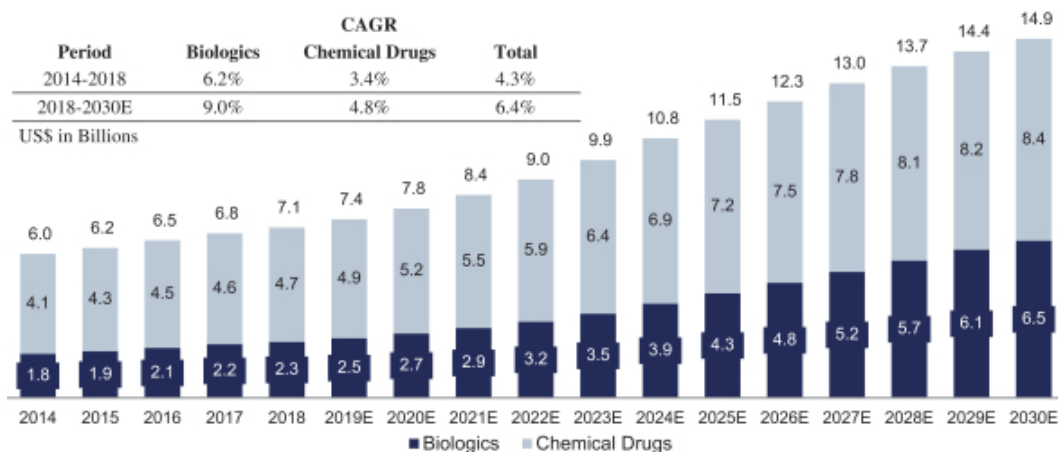
(1) Competing investigational biologics that are prior to Phase 3 clinical trials are not included in this table.

- (2) We have the development and commercialization rights for olamkicept in Greater China pursuant to a partnership agreement with Ferring Pharmaceuticals. A regional multi-center Phase 2 trial in China, Taiwan and South Korea sponsored by I-Mab is ongoing.

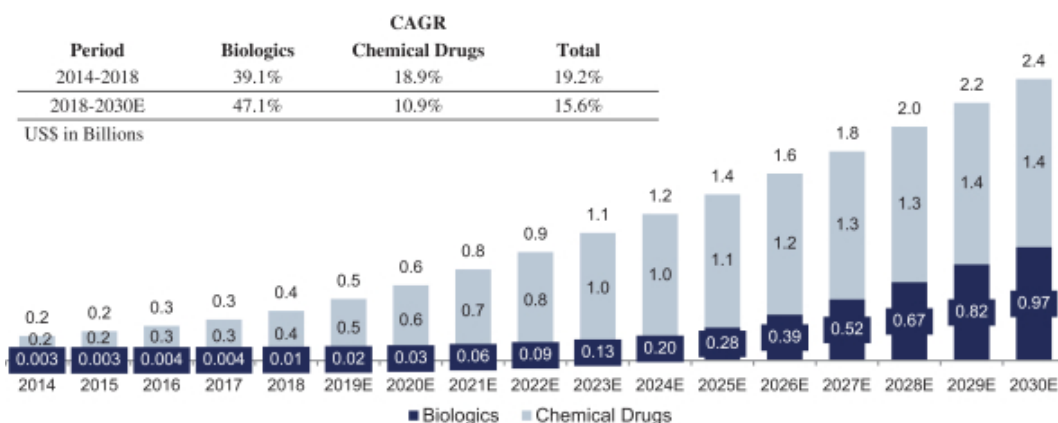
Historical and Forecast Market Size of UC Therapeutics Globally and in China

The following diagrams illustrate the size of the UC drug market in terms of sales revenue in the global and China markets. (Source: Frost & Sullivan Report)

Global Ulcerative Colitis Therapeutics Market Size (2014-2030E)



China Ulcerative Colitis Therapeutics Market Size (2014-2030E)



Growth Hormone Deficiency

Overview

Growth hormone deficiency (“GHD”) is an endocrine disorder that occurs when the production of growth hormone, normally secreted by the pituitary gland, is disrupted. Since growth hormone plays a critical role in stimulating body growth and development and is involved in the production of muscle protein and the breakdown of fats, deficiency in growth hormone affects numerous physiological processes, resulting in short stature in children and other physical ailments in both children (“PGHD”) and adults (“AGHD”). According to the Frost & Sullivan Report, PGHD affected approximately 3.4 million patients in 2018 in Greater China.

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Treatment of PGHD

The widely adopted treatment for PGHD is patient-specific growth hormone replacement therapy, which is given in a calculated weight-based dosing regimen. Currently, short-acting recombinant human growth hormone (“rhGH”) is commonly used for the long-term treatment of children and adults with inadequate endogenous growth hormone secretion. There are certain safety concerns related to long-term use of pegylated drugs, such as potential renal toxicity, cellular vacuolation and formation of anti-polyethylene glycol antibodies.

Approved by the NMPA in 2014, Jintrolong (developed by GeneScience) is currently the only long-acting pegylated rhGH in China. Other companies in China currently developing long-acting rhGH include Anhui Anke Biotechnology and Generon Pharmaceutical Technology.

Unmet Medical Need

According to the Frost & Sullivan Report, only 3.7% of all PGHD patients in China were receiving growth hormone replacement therapy in 2018, which consists of daily injections of rhGH before sleep. This dosing regimen puts a substantial burden on pediatric patients and their families because it requires drug preparation and needle injection every day, which is painful and extremely inconvenient, often resulting in poor patient compliance. More importantly, studies have shown that skipping just one or two doses in a week can significantly reduce the efficacy of the treatment. Therefore, there is a substantial medical need for long-acting growth hormone therapies that are similarly efficacious but with reduced injection frequency, and the market potential for such a long-acting rhGH in China is largely untapped. In addition, recombinant human growth hormone therapy has been included in the National Reimbursement Drug List (NRDL) in China. Inclusion of a drug in the NRDL typically results in a much higher sales volume and significant sales growth despite a reduction in price.

Competitive Landscape

Our TJ101 is the only Fc-based long-acting rhGH ready for a Phase 3 clinical trial in China. The following tables illustrate the competitive landscape of long-acting growth hormone products and product candidates in China and the rest of the world. (Source: Frost & Sullivan Report)

Marketed Products of Long-acting GH

Product	Drug Form	Company	FDA Approval	NMPA Approval	Patent Expiry in China	Global Sales Revenue in 2018 (in Bn, RMB)
Jintrolong	PEGylated GH	GeneScience	N/A	2014	2028	0.47

Investigational Drugs of Long-acting rhGH

Investigational Drug ⁽¹⁾	Drug Form	Company	Global Status	China Status
Somapacitan	PEGylated hGH	Novo Nordisk	Phase 3	N/A
ACP—001	TransCon hGH	Ascendis	Phase 3	N/A
eftansomatropin TJ101 ⁽²⁾	Hy-Fc (Fc fusion protein)	I-Mab	N/A	Phase 3 ready
eftansomatropin GX-H9 ⁽²⁾		Genexine	Phase 3 ready	N/A
PEG-rhGH	PEGylated GH	Anhui Anke	N/A	Phase 2/3

Notes:

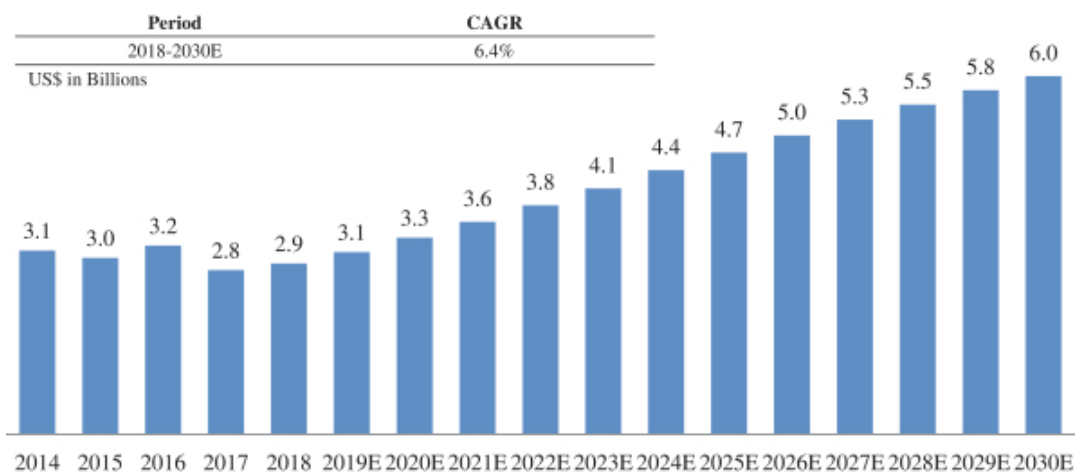
(1) Competing investigational biologics that are prior to Phase 2 clinical trials are not included in this table.

(2) TJ101 and GX-H9 are the same investigational drug. We have the development and commercialization rights for TJ101 in Greater China pursuant to a partnership agreement with Genexine. We plan to submit an IND for a Phase 3 clinical trial (pending the NMPA's approval) in China in mid-2020.

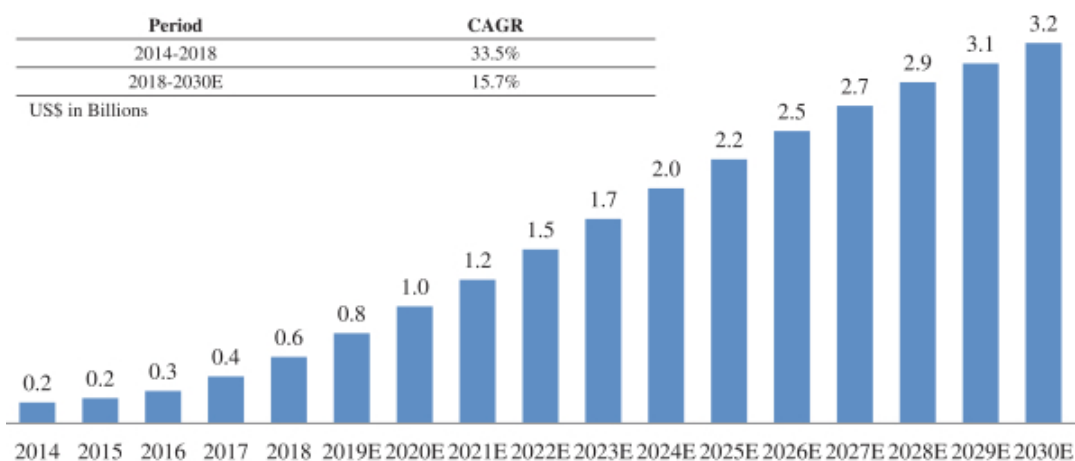
Historical and Forecast Market Size of PGHD Therapeutics Globally and in China

The following diagram illustrates the size of the PGHD drug market in terms of sales revenue in the global and China markets. (Source: Frost & Sullivan Report)

Global PGHD Therapeutics Market Size (2014-2030E)



China PGHD Therapeutics Market Size (2014-2030E)



BUSINESS

Overview

We are a clinical stage biopharmaceutical company committed to the discovery, development and commercialization of first-in-class and best-in-class biologics to treat diseases with significant unmet medical needs, particularly cancers and autoimmune disorders. Our mission is to bring transformational medicines to patients through innovation.

We were founded to capture the opportunities presented by the confluence of two major developments—the emergence of an attractive and growing biologics market in China, and the revolutionary scientific breakthroughs in cancer and autoimmune disease medicines. We believe we are well-positioned to become a biotech leader in China because of our innovative discovery expertise, fit-for-purpose technology platforms, biomarker-enabled translational medicine capabilities, and clinical development capabilities. These integrated capabilities are further enhanced by our deep understanding of China’s biologics regulatory framework and our direct access to extensive pre-clinical and clinical trial resources in China. To date, we have developed an innovative pipeline of more than 10 clinical and pre-clinical stage assets through our internal research and development efforts and in-licensing arrangements with global pharmaceutical and biotech companies.

Commercial Opportunities in China and Our Unique Position

We see vast commercial opportunities for immuno-oncology and autoimmune biologics therapies in China. First, both the incidence and mortality of cancers in China have been increasing in recent years and are outpacing those in the United States and the rest of the world. Second, many innovative biologics approved to treat cancer and autoimmune diseases in the United States and Europe are not yet available in China. Third, the Chinese government has implemented new policies and regulations to simplify the review and approval cycle of clinical trials and new drug applications to encourage biologics innovation. Fourth, there has been a continuous and rapid increase in personal disposable income in China coupled with ongoing improvement in basic national health insurance coverage, making innovative biologics more accessible to more Chinese patients. According to the Frost & Sullivan Report, China’s biologics market is growing faster than the global biologics market and is expected to reach approximately RMB1.3 trillion (US\$189.1 billion) by 2030 in terms of sales revenue.

We believe we are uniquely positioned as a China-based global player to tap into these vast commercial opportunities. This is best demonstrated by our short journey in becoming one of the top clinical stage innovative biotech companies in China. Through December 31, 2018, we had raised approximately US\$330 million of cash in equity financing from our dedicated group of investors, including leading healthcare-focused funds. To date, our research and development capabilities encompass discovery, biologics CMC development, pre-clinical development and clinical development with footprints in Shanghai, Beijing and the United States. We are now at a critical juncture to transition from a clinical stage biotech company into a fully integrated end-to-end global biopharmaceutical company in the next few years.

Our Unique Business Model

To achieve our mission and capitalize on these commercial opportunities, we have developed a business model built on two pillars: a fast-to-market China approach and a fast-to-PoC (proof of concept) global approach.

Fast-to-Market China Approach

Our fast-to-market China approach focuses on seeking opportunities to in-license the development and commercialization rights of investigational drugs from global biopharmaceutical companies for Greater China. We only select investigational drugs with favorable clinical safety and preliminary efficacy data that have the potential to become first-in-class and best-in-class medicines. Through our substantial in-house research and

development efforts, we build additional data packages to meet the requirements of the National Medical Products Administration (the “NMPA”) to ensure programs are ready for late-stage or registrational clinical development. Our internal development capabilities combined with our deep insight into China’s regulatory framework and our clinical network enable us to efficiently navigate through the drug development process to registration. To date, we have built an innovative China Portfolio consisting of five investigational drugs with an aim for near-term product launch. All of these investigational drugs have passed Phase 1 or Phase 2 clinical trials with favorable safety and preliminary efficacy data in Europe, the United States or elsewhere and are either in or ready for Phase 2 or Phase 3 clinical trials in China. TJ202 is undergoing two registrational trials, a monotherapy trial and a combination therapy trial in relapsed or refractory multiple myeloma in Greater China, and we will soon initiate a Phase 1b trial in systemic lupus erythematosus (“SLE”). For TJ101, we expect to submit an IND for a Phase 3 registrational trial in China by early 2020. For enoblituzumab, we expect to initiate either a registrational trial (pending the NMPA’s regulatory approval) or a Phase 2 trial in mid-2020. As a result, the investigational drugs in our China Portfolio are positioned for a series of new drug applications (NDAs) in China with the submission of the first NDA expected in 2021.

Fast-to-PoC Global Approach

Our fast-to-PoC global approach focuses on advancing our own novel or differentiated biologics towards clinical validation in the United States. First, we seek PoC of these drug candidates in the United States, leveraging the FDA’s streamlined regulatory system for innovative drug discovery, including a predictable timeline towards approval. Second, after validating clinical safety and preliminary efficacy, we will use the data generated to advance clinical development in China, which we believe confers several advantages, including access to China’s large patient pool, extensive clinical trial resources through collaborations with leading hospitals in China, and a regulatory pathway for fast-track approval of drugs supported by solid overseas clinical data. Building on this approach, we typically out-license the global rights (excluding Greater China) of these investigational drugs following clinical validation in the United States, while retaining the Greater China rights for further development and commercialization. We believe this approach will allow Chinese patients to benefit from our most advanced treatments concurrently or soon after their market approvals elsewhere. To date, we have created a Global Portfolio that consists of two molecular classes—monoclonal antibodies and bi-specific antibodies, which are internally generated. They are highly innovative molecules compared to global competitor assets in the same or related classes of drug candidates. Three investigational drugs in our Global Portfolio (TJM2, TJC4 and TJD5) are in Phase 1 trials in the United States.

These two approaches and the resulting two portfolios complement each other and enable us to achieve a balance among our ambition to develop the first-in-class and best-in-class drugs, our goal to efficiently advance our pipeline assets towards commercialization and the inherent development risks.

Our Capabilities

Our Innovative Discovery Expertise

Built by an elite group of seasoned immunologists with extensive academic research and drug development experience, our discovery engine has generated a panel of internally developed innovative drug molecules in a short span of four years. Among them, 11 innovative drug molecules have met our standard of first-in-class or best-in-class and have advanced toward further development. This achievement is a testament to our discovery team’s acumen and technical prowess in translating target biology into points of innovation or differentiation.

The discovery of TJC4 showcases our innovative research capabilities. Not settling on performing routine or traditional antibody screening, we set a specific goal to identify and select a unique CD47 antibody that is free from binding to red blood cells (RBC) among all CD47 antibody leads that naturally bind to RBCs. As a result, we selected by design, our proprietary CD47 antibody (TJC4), a rare epitope that uniquely spares binding to RBCs as a differentiation point from other CD47 antibodies that typically cause inherent hematologic side

effects. TJC4 has been validated in a series of in vitro assays as well as multiple monkey studies for its unique differentiation and is in a Phase 1 clinical trial in the United States.

Another example of our R&D capability relates to our novel bi-specific antibody panel that represents a new wave of oncology drug candidates. We created novel biological properties of these bi-specific antibodies that are capable of enriching immune cells in tumors through dual targeting of PD-L1 and immune cells for a synergistic anti-tumor effect. These bi-specific drug candidates have been shown to exhibit unique properties that render tumors more responsive to treatment. Our discovery expertise, when combined with our “fit-for-purpose” antibody engineering technology platforms, becomes a powerful engine of innovation to create novel molecules of first-in-class and best-in-class potential.

Our Fit-for-Purpose Technology Platforms

Our proprietary antibody engineering platforms enable us to accurately capture the biological properties of bi-specific antibodies and retain good manufacturability and druggability of the molecules. To date, we have created seven novel pre-clinical stage bi-specific drug molecules. In addition to our own Ig-scFv bi-specific antibody platform, we partnered with ABL Bio and WuXi Biologics to access their antibody engineering platforms in order to increase the probability of success, as different molecular configurations require different technologies. Furthermore, our proprietary antibody-cytokine technology has enabled another form of bi-specific antibodies such as TJ-L1I7 and TJ-C4GM that link a tumor-engaging antibody with an immuno-modulatory cytokine. Superior to monoclonal antibodies or cytokines alone, this class of bi-specific antibodies has demonstrated unique properties capable of concentrating the drug molecules in tumors for a desired target effect with reduced systemic toxicity of cytokines or creating biologic synergy that can potentially translate into better treatment efficacy and clinical safety.

Our Biomarker-Enabled Translational Medicine Capabilities

As we focus on developing innovative drug molecules, the ability to apply relevant biomarkers that link a drug response to treatment efficacy is critical for early-stage clinical trials of our investigational drugs. This translational medicine capability requires cross-functional knowledge and unique skills to link the target biology of an investigational drug to clinical responses. We have been developing tailor-made biomarkers for each of our investigational drugs, which are used to select potential responders, predict and measure target engagement, support dose determination and enable timely informed decisions on advancing our assets to the next phase of clinical development. For example, for the development of TJD5, we intend to use CD73 in tumor tissue in combination with other tumor biomarkers to stratify potential target patient populations in our clinical trial. To that end, we have developed assays to measure CD73 expression and activity in tumor tissues. Furthermore, we have developed specialized assays to measure TJD5 drug concentrations in tumor tissues. By linking drug concentration with its activity in the same tumor location, these data help us determine appropriate dose selection for further efficacy studies.

Our Clinical Development Capabilities

Our clinical development capabilities are highlighted by a global team of clinical scientists, industry physicians, data management specialists, biostatisticians, clinical operation staff and drug safety experts. Our clinical team accounts for approximately 80% of our entire R&D organization’s headcount and 80% of our budget allocation. The skillset of our clinical development team is highlighted by a combination of extensive global pharma experience, local drug development and operational experience with clinical networks in China and the United States. The team is driven by high ethical standards, clinical science and passion for improving the lives of patients.

Our clinical development capabilities are also highlighted by our ability to integrate internal core development functions, which encompass regulatory affairs, translational medicine, clinical research and

operations, data management, biostatistics, clinical safety and pharmacovigilance, portfolio and project management, and global drug supplies. We also effectively leverage external resources, including clinical contract research organizations, academic clinical centers and/or networks, and global pharmaceutical or biotech partnerships. Furthermore, we have established and implemented a robust internal clinical governance system to safeguard patient safety and data reporting. Our current clinical development capabilities are strategically based in Shanghai, Beijing, and the United States to cover Phase 1 through Phase 3 clinical trials in China and early-stage clinical trials in the United States.

Our clinical development capabilities are best demonstrated by our rapid implementation of seven ongoing clinical trials, including four Phase 1/2 and registrational trials in Greater China and three Phase 1 trials in the United States within the past three years. To ensure regulatory approval and subsequent product launch as currently planned, we strive to reach the following critical clinical milestones by the end of 2020—ten active clinical programs consisting of six registrational and Phase 1/2 trials in China and four active clinical programs in the United States.

Our Global Strategic Collaborations

We have established an excellent track record of in-licensing and out-licensing deals with our global and regional partners. These in-licensing deals enable us to acquire multiple innovative clinical stage assets of first-in-class and best-in-class potential with favorable clinical safety and early efficacy data. We have quickly built our China Portfolio through in-licensing deals with global biotech partners, including MorphoSys, Genexine, MacroGenics and Ferring. In that respect, we are often regarded as an ideal China partner because of our strong development capabilities and proven track record. The out-licensing deals enable us to streamline our pipeline and focus our resources on the most valuable assets. In addition, we seek co-development opportunities to share development costs and risks and territorial commercial rights with our partners. In the past two years, we have out-licensed three de-prioritized assets and initiated four co-development programs with partners such as ABL Bio, Everest Medicines and WuXi Biologics. The revenue from out-licensing and co-development deals is expected to continue to grow as our pipeline progresses.

Our Drug Pipeline

The chart below summarizes the development status of our drug pipeline.

	Drug Candidate (Licensor)	Indication / Therapeutic Area	Commercial rights	Preclinical	Phase 1	Phase 2	Phase 3	Expected NDA / BLA filing
China Portfolio	TJ202 (MorphoSys) Differentiated CD38 antibody	Multiple myeloma / Autoimmune disease	Greater China Myeloma shared	[Progress bar]			★	2021-2024
	Eftansomatropin TJ101 (Genexine) Long-acting growth hormone	Pediatric growth hormone deficiency	Greater China	[Progress bar]			★	
	Olimkicept TJ301 (Ferring) Soluble gp130 IL-6 inhibitor	Ulcerative colitis / Autoimmune disease	Greater China S. Korea	[Progress bar]				
	Enoblituzumab (MacroGenica) B7-H3 antibody	Head and neck cancer / Oncology	Greater China	[Progress bar]			★	
	Elnetaktin TJ107 (Genexine) Novel long-acting IL-7	Oncology-related lymphopenia	Greater China	[Progress bar]				
Global Portfolio	TJM2 GM-CSF antibody	Autoimmune disease/ Cytokine release syndrome	Global	[Progress bar]				2024-
	TJC4 Differentiated CD47 antibody	Multiple cancer Indications	Global	[Progress bar]				
	TJD5 Differentiated CD73 antibody	Multiple cancer Indications	Global	[Progress bar]				
	TJ210 (MorphoSys) Differentiated CSaR antibody	Oncology / Auto- Immune disease	Greater China Global Shared	[Progress bar]				
	TJX7 Novel CXCL13 antibody	Autoimmune disease	Global	[Progress bar]				
	Bi-specific antibody panel * Including five PD-L1-based bi-specifics, TJ-C4GM and TJ-CLDN4B	Multiple cancer Indications	Global Some shared	[Progress bar]				

Notes:

é (i) TJ202 has two ongoing registrational trials, a monotherapy trial and a combination therapy trial in relapsed or refractory multiple myeloma in Greater China, and we will soon initiate a Phase 1b trial in systemic lupus erythematosus (“SLE”); (ii) for TJ101, we expect to submit an IND for a Phase 3 registrational trial in China by early 2020; and (iii) for enoblituzumab, we expect to initiate either a registrational trial (pending the NMPA’s regulatory approval) or a Phase 2 trial in mid-2020.

* Our bi-specific antibody panel consists of (i) five PD-L1-based bi-specific antibodies, including TJ-L1C4 (PD-L1 and CD47), TJ-L1D5 (PD-L1 and CD73), TJ-L1H3 (PD-L1 and B7-H3), TJ-L14B (PD-L1 and 4-1BB) and TJ-L1I7 (anti-PD-L1 and IL-7 cytokine fusion), (ii) TJ-C4GM (anti-CD47 and GM-CSF cytokine fusion), and (iii) TJ-CLDN4B (Claudin 18.2 and 4-1BB).

Highlights of Our Fast-to-Market China Portfolio

Our fast-to-market China approach is demonstrated by our China Portfolio, which consists of first-in-class and best-in-class investigational drugs with favorable clinical safety and preliminary efficacy data. TJ202, TJ107, enoblituzumab and TJ101 are the four anchor assets in our China Portfolio.

TJ202 is a differentiated CD38 antibody originally developed by MorphoSys with good clinical safety and efficacy data from a clinical trial conducted in the European Union (EU). In-licensed from MorphoSys, TJ202 is being developed to address the current unmet needs and commercial opportunities in China for multiple myeloma and potentially autoimmune diseases, such as SLE. We own an exclusive license to develop TJ202 in Greater China. We believe TJ202 is potentially best-in-class compared with the currently marketed CD38 antibody. First, under a similar pre-medication condition with dexamethasone, anti-pyretics and anti-histamines, TJ202 has demonstrated a significantly shorter infusion time and lower infusion reaction rate. Second, unlike the currently marketed CD38 antibody, TJ202 does not down-regulate CD38 expression on the surface of bone marrow myeloma cells in vitro, maintaining sensitivity of myeloma cells to TJ202 for repeated treatments. We have entered into a collaboration arrangement with Everest, under which we and Everest will share development costs and commercial rights of TJ202 in multiple myeloma in Greater China, while we retain full rights for all other indications. TJ202 is undergoing a Phase 2 registrational trial as a third-line monotherapy and a Phase 3 trial in combination with lenalidomide as a second-line therapy, both in patients with relapsed/refractory multiple

myeloma in Greater China. We aim to submit an NDA for TJ202 as a monotherapy in 2021, followed by another NDA submission for TJ202 as a combination therapy. Moreover, we believe TJ202 has great market potential in the treatment of pathogenic antibody-mediated autoimmune diseases, such as SLE, where there is a significant unmet need for more effective therapies. An IND application for a trial in SLE is expected to be submitted in the fourth quarter of 2019.

TJ107 is a long-acting IL-7 known to boost cancer-fighting T lymphocytes by increasing their number and function and is being developed as a potential first-in-class oncology investigational drug. The clinical safety and effect of TJ107 on T cells have been demonstrated in multiple previous and ongoing clinical trials in South Korea and the United States. TJ107 is being positioned to address a huge unmet medical need in oncology. First, TJ107 can be an oncology-care agent to treat cancer treatment-related lymphopenia (low blood lymphocyte levels), a common condition that occurs in cancer patients who have received chemotherapy or radiation therapy, and there is no approved treatment for this condition. According to the Frost & Sullivan Report, in Greater China, the incidence of lymphopenia reached 1.5 million in 2018 and is estimated to increase to 1.7 million in 2023 and further to 2.0 million in 2030. This condition causes further damage to patients' already compromised immune system and weakens its ability to fight cancers. Second, TJ107 has been shown to synergize with a PD-1 antibody in a tumor animal model potentially through increased T lymphocyte activation and proliferation. We are conducting a Phase 1b trial in China to determine a suitable dose range for a Phase 2 trial in combination with PD-1 antibody. We are coordinating our study globally with Genexine, which is conducting a Phase 2 clinical trial in South Korea and parallel clinical trials in the United States towards clinical PoC.

Enoblituzumab is a humanized antibody directed at B7-H3, a member of the B7 family of T cell checkpoint regulators that is widely expressed across multiple tumor types and plays a key role in the regulation of immune response against cancers. Similar to other inhibitors of the B7 family such as PD-L1, targeting B7-H3 potentially provides a treatment option for a variety of cancers expressing B7-H3. Enoblituzumab was originally developed by MacroGenics, and we own the Greater China rights of this product. In multiple clinical trials conducted by MacroGenics, enoblituzumab has shown a favorable safety profile and preliminary clinical efficacy when combined with pembrolizumab in recurrent or metastatic squamous cell carcinoma of the head and neck ("SCCHN") and non-small cell lung cancer ("NSCLC"). We plan to conduct a registrational trial (if approved by the NMPA) in China in patients with recurrent or metastatic SCCHN. Further clinical development is being planned together with MacroGenics to extend to other cancer indications in China and globally.

TJ101 is a potential best-in-class long-acting human growth hormone that is being developed as a weekly treatment for pediatric growth hormone deficiency as compared to currently available daily regimens of recombinant human growth hormone (rhGH). TJ101 was originally developed by Genexine, and we own the Greater China rights of this product, which has the potential to address an important clinical need and to cover a significant market gap in pediatric growth hormone deficiency. According to the Frost & Sullivan Report, there are approximately 3.4 million pediatric patients with growth hormone deficiency in China, but only 3.7% of them receive growth hormone therapies, which are mostly daily regimens. In a previous Phase 2 trial conducted by Genexine in South Korea and the EU, both weekly and bi-weekly administration of TJ101 demonstrated similar efficacy to daily injection of Genotropin, a short-acting rhGH. We expect to submit an IND for a Phase 3 registrational trial in China by early 2020.

Highlights of Our Fast-to-PoC Global Portfolio

Our fast-to-PoC global approach is demonstrated by our Global Portfolio, which mainly consists of our internally developed novel or differentiated biologics with first-in-class and best-in-class potential. Our Global Portfolio focuses on two molecular classes—monoclonal antibodies and bi-specific antibodies.

Monoclonal antibodies—Among the five monoclonal antibody drug candidates, TJM2, TJC4 and TJD5 are undergoing Phase 1 clinical trials in the United States. TJ210 and TJX7 are at the CMC stage and are expected to be ready for investigational new drug ("IND") submissions and subsequent Phase 1 clinical trials in 2020 in the

United States. These monoclonal antibody drug candidates have either first-in-class potential or best-in-class potential, consistent with our strategy.

TJC4 is an internally discovered, fully human monoclonal antibody targeting CD47, which is one of the most promising immuno-oncology targets after PD-1/PD-L1. Blocking CD47 activates tumor-engulfing macrophages, a component of the innate immune system as an important cancer-fighting mechanism. CD47 antibodies are being actively pursued in clinical trials by a few global companies and have shown some preliminary clinical efficacy. However, current development efforts on CD47 antibody drugs are hampered by hematologic side effects (such as anemia) due to their inherent binding to human RBCs. For example, at least two clinical trials conducted by other companies have been suspended. Unlike competitor investigational drugs, TJC4 is a rare antibody originally selected, by design, to purposefully avoid or minimize inherent binding to RBCs while maintaining a high antibody affinity and tumor killing properties. TJC4's unique property of minimal RBC binding and no significant hematologic changes has been extensively validated in a whole series of robust in vitro assays and primate studies. In a GLP toxicology study involving 40 monkeys, no hematologic side-effects were seen even with repeated injections of 100 mg/kg doses. This unique property potentially enables TJC4 to be used safely at an efficacious dose range to explore its treatment efficacy in cancers, differentiating it from other clinical stage CD47 investigational antibody drugs. TJC4 is being evaluated in a Phase 1 clinical trial with cancer patients in the United States, and no anemia has been observed in the first cohort of patients so far. In parallel, leveraging the Phase 1 data generated in the United States, we plan to begin a Phase 1 clinical trial of TJC4 in AML patients by the end of 2019 in China, followed by a separate clinical trial in NHL patients in China.

Bi-specific antibody panel—This novel antibody class represents an emerging and fast-moving area of new drug discovery. Bi-specific antibodies are typically constructed to have a dual specificity of two selected antibodies or combined properties of an antibody linked with a cytokine, previously called an immuno-cytokine. According to the Frost & Sullivan Report, checkpoint inhibitors targeting PD-1/PD-L1 had global sales of more than US\$16.0 billion in 2018 and are predicted to reach more than US\$63.0 billion in global sales by 2030. However, despite the recent success of checkpoint inhibitors, clinical efficacy of these drugs has been unsatisfactory. It is estimated that over 60% of cancer patients, including those with melanoma, renal cell cancer, colorectal cancer, non-small cell lung cancer, urothelial cancer and head and neck squamous cell carcinoma, do not respond to single-agent therapy with checkpoint inhibitors. In addition, some patients develop resistance after initial treatment with these therapies. As a result, the standard of care today leaves many cancer patients underserved. There is consensus among cancer immunologists that tumors that do not respond to PD-1/PD-L1 treatment have poor immunologic features, such as an absence or paucity of tumor-fighting immune cells or the presence of dysfunctional immune cells within the tumors, collectively known as “cold tumors.” We believe that PD-1/PD-L1 non-responders can be better treated with novel bi-specific antibodies. The unique and superior properties of these bi-specific antibodies over PD-L1 inhibitors alone stem from a second targeting component attached to the PD-L1 antibody moiety of the bi-specific molecules, thereby enabling them to elicit a sufficient immune response and converting a “cold tumor” to an immune-active “hot tumor.” Such unique properties of bi-specific antibodies cannot be substituted by a combination of the PD-L1 antibody with a selected second component (either cytokine or antibody) in a free form. The underlying mechanism is such that the second component must be structurally integrated with the tumor-engaging PD-L1 antibody in order to concentrate and function inside the tumor, which cannot be readily achieved by the two free agents used in combination.

We have successfully generated a panel of five bi-specific antibodies in which our proprietary PD-L1 antibody acts as the backbone (the first signal) and is linked with various second components (the second signal) including a 4-1BB agonist antibody (TJ-L14B), a B7-H3 antibody (TJ-L1H3), a CD73 antibody (TJ-L1D5), a CD47 antibody (TJ-L1C4) and an IL-7 cytokine (TJ-L1I7), which are shown to work synergistically with the PD-L1 backbone in various assays and cancer animal models. This unique panel of bi-specific antibodies is only made possible by our proprietary and partnered antibody engineering technologies and the availability of our proprietary monoclonal antibodies. Furthermore, we have generated two other bi-specific antibodies (TJ-C4GM and TJ-CLDN4B) that are tailor-made to function as novel fortified antibodies by linking TJC4 with an

engineered GM-CSF cytokine for the treatment of solid tumors and by linking our Claudin-18.2 antibody with a 4-1BB antibody as a unique gastric cancer treatment agent that only activates T cells conditionally upon tumor engagement. All bi-specific antibodies have been validated in a series of robust *in vitro* and *in vivo* studies for biology proof-of-concept, providing a solid basis for clinical validation in cancer patients.

Our Strategies

Moving forward, we strive to become a fully integrated end-to-end global biopharmaceutical company whose capabilities encompass drug discovery, GMP manufacturing, pre-clinical and clinical development and commercialization. To achieve this goal, we intend to pursue the following strategies.

Rapidly advance our China Portfolio towards commercialization

We intend to pursue the most efficient pathway to NDA approval for the investigational drugs in our China Portfolio. In the next 12 months, we expect to make significant advances with our China Portfolio. All of the clinical assets of our China Portfolio are expected to undergo Phase 2, Phase 3 or registrational clinical trials in 2020. We plan to submit NDAs to the NMPA for these products in sequence from 2021 to 2024. With respect to commercialization capabilities, we plan to initially partner with a specialty pharmaceutical company that has existing commercial capabilities and infrastructure in China to jointly market our leading products. Once we have acquired commercial experience and developed a distribution network, we plan to build a robust internal sales and marketing platform.

Expand our research and development capabilities and footprint in the United States to advance our Global Portfolio

As part of our global strategy, we plan to expand our research and development capabilities in the United States to include regulatory affairs, translational medicine, drug formulation and clinical operations. These specific research and development functions in the United States are complementary to and an integral part of our overall research and development capabilities to support clinical development of our Global Portfolio. Currently, three of our investigational antibody drugs (TJM2, TJC4 and TJD5) are in clinical trials in the United States. We aim to continue advancing the ongoing clinical trials to Phase 2 for clinical validation and to initiate multiple new clinical programs by the end of 2020 or early 2021 in the United States. In addition, we intend to expand our operational footprint in the United States to create an independent multi-functional business entity covering global business development, investor relations and corporate communications and other operational capabilities. We are in the process of assembling an integrated management team with global experience and extensive track record dedicated to overseeing our operations in the United States.

Build our manufacturing capabilities

We believe it is advantageous that we own and control our GMP manufacturing process in order to ensure quality and secure production slots for clinical trial materials and commercial supplies. We plan to commence the construction of our own comprehensive biologics manufacturing facility by the end of 2019 in Hangzhou, China. At this planned manufacturing facility, we intend to produce drug substance and drug product for clinical use as well as future commercial use. We envisage this facility to include a pilot GMP manufacturing plant with two 500-liter and two 2,000-liter single-use bioreactors, and upon completion of the construction, a commercial scale manufacturing plant with eight more 2,000-liter single-use bioreactors with filling and finishing lines.

Maximize the value of our pipeline

In addition to our successful in-licensing efforts, we have established a good track record of out-licensing collaborations and co-development partnerships. For the years ended December 31, 2017 and 2018, we recorded

revenues of RMB11.6 million and RMB53.8 million from upfront and milestone payments through two out-licensing deals, respectively. We have reached cost-sharing co-development deals for some of our drug candidates with multiple global and regional partners. These achievements have not only demonstrated our ability to optimize our pipeline but also provided a sustainable revenue stream. Going forward, we plan to enhance our out-licensing efforts. We expect that the revenue generated from out-licensing opportunities will continue to increase and will account for the majority of our net revenue before the commercialization of our marketed products.

Our Drug Pipeline

China Portfolio

TJ202: A Potential Best-in-Class CD38 Antibody for Multiple Myeloma and Autoimmune Diseases

Summary

TJ202 (MOR202) is a fully human, highly differentiated monoclonal antibody directed against CD38. TJ202 is positioned as a potential best-in-class anti-CD38 therapy for multiple myeloma (“MM”), either as a monotherapy or as a combination therapy with other anti-cancer agents. We aim to demonstrate the advantages of TJ202, including its shorter infusion time, lower infusion reaction rate (“IRR”) and potentially sustained efficacy compared to other CD38 antibodies, in our ongoing clinical trials in China. Additionally, as pathogenic CD38-positive B cells and plasma cells are strongly implicated in the disease progression of pathogenic antibody-mediated autoimmune diseases, we believe the therapeutic value of TJ202 can be extended to these diseases that have significant unmet medical needs. We have begun to explore its therapeutic application in systemic lupus erythematosus (“SLE”) and later in other autoimmune diseases. In November 2017, we obtained an exclusive license from MorphoSys to develop TJ202 in Greater China. The development of TJ202 is driven by a fast-to-market strategy. We have started a Phase 2 registrational trial for a third-line monotherapy and a Phase 3 trial in combination with lenalidomide as a second-line therapy, both in patients with relapsed or refractory MM (“RRMM”) in Greater China. We aim to submit an NDA for TJ202 as a monotherapy in 2021, followed by another NDA submission for TJ202 as a combination therapy. An IND application for a trial in SLE is expected to be submitted in the fourth quarter of 2019.

Therapeutic Options and Current Development

Multiple Myeloma (MM)

The treatment options and investigational drugs under development in China include: (i) for small molecule drugs, two or three approved drugs known as doublets or triplets are used. VRD triplet (Velcade (bortezomib), Revlimid (lenalidomide) and dexamethasone) has recently been approved for overseas frontline treatment and is recommended in China in the 2017 version of treatment guideline. VCD triplet (Velcade, cyclophosphamide and dexamethasone) is the most widely adopted first-line treatment in China due to its lower cost. In 2017, lenalidomide and bortezomib were included in the National Reimbursement Drug List in China; (ii) with respect to CD38 antibody therapy, daratumumab (from Johnson & Johnson) received conditional NDA approval from the NMPA in July 2019, and isatuximab (from Sanofi) is in a Phase 3 trial in China; and (iii) for CAR-T therapy, several Phase 1 or 2 clinical trials are ongoing in China.

However, there is no curative treatment for MM. Although the currently marketed CD38 antibody in China is efficacious, it takes a long time to be administered by IV infusion (up to six hours) and causes a high infusion reaction rate (“IRR”). In clinical trials, approximately half of all patients experience an infusion reaction, symptoms of which may include fever, chills, nausea, bronchospasm, hypoxia, dyspnea, hypertension, laryngeal edema and pulmonary edema. Thus, there is a need for an efficacious and convenient-to-use drug with a better safety profile. Such a drug may be combined with other therapeutic agents for better treatment efficacy in MM.

Systemic Lupus Erythematosus (SLE)

Patients with mild SLE are often given non-steroidal anti-inflammatory drugs, while more severe patients may need corticosteroids or immunosuppressants. Approved by the FDA in 2011 and by the NMPA in July 2019, Benlysta (belimumab), a B-lymphocyte stimulator (BLyS)-specific inhibitor developed by GSK, is currently the world's only biologic approved to treat SLE. However, there remains a significant unmet medical need beyond belimumab for SLE in China and the rest of the world. As dysregulated CD38-positive B cells and auto-antibodies produced by CD38-positive plasma cells and resulting immune complexes are at the core of the pathogenesis of SLE, direct inhibition and selective depletion of pathogenic B cells and plasma cells are believed to offer superior treatment efficacy and better safety. Our TJ202 has the potential to offer such a disease-modifying treatment option. In addition, as described below, the advantages of our TJ202 include convenience of use and a lower IRR, making it a more favorable treatment agent in the long-term clinical management of SLE if proven efficacious.

Advantages of TJ202

TJ202 is a potentially best-in-class CD38 monoclonal antibody and could be the second antibody therapy for MM to launch in China. A Phase 2a trial of TJ202 in MM showed a level of efficacy comparable to that observed in trials of the currently marketed CD38 antibody. However, available trial data from MorphoSys and Johnson & Johnson indicate that with similar pre-medications of dexamethasone, anti-pyretics and anti-histamines, TJ202 required only a short infusion time of 0.5 to 2 hours, compared to 3.5 to 6.5 hours for the currently marketed CD38 antibody. Moreover, the IRR was as low as 7% for TJ202, compared to 48% for the currently marketed CD38 antibody. The advantages of TJ202 associated with infusion may be attributed to its lack of antibody CDC activity and are likely to translate into clinical benefits in terms of tolerability and convenience of use as well as economic benefits due to the cost and length of hospital stay. In addition, unlike the currently marketed CD38 antibody, TJ202 treatment does not down-regulate CD38 expression on the surface of bone marrow myeloma cells in vitro, maintaining sensitivity of malignant myeloma cells to repeated TJ202 treatments. As TJ202 is being considered for long-term treatment management of autoimmune diseases, we believe such clinical differentiation is critical.

For autoimmune diseases, TJ202 has advantages over other B cell-targeting therapies such as CD20 antibodies, as it specifically targets malfunctioned CD38^{high} B cells and pathogenic plasma cells involved in autoimmune diseases while CD20 antibodies target most B cells, including those involved in normal immune functions and regulatory functions, but not plasma cells producing pathogenic antibodies. Thus, TJ202 is expected to deliver greater efficacy with fewer side-effects.

Mechanism of Action

TJ202 binds to CD38 overexpressed on the surface of target cells and kills them by inducing antibody-dependent cellular cytotoxicity (“ADCC”) and antibody-dependent cellular phagocytosis (“ADCP”). The target cells are the malignant plasma cells in MM and a group of dysregulated CD38^{high} B cells and plasma cells that produce pathogenic antibodies in autoimmune conditions such as SLE.

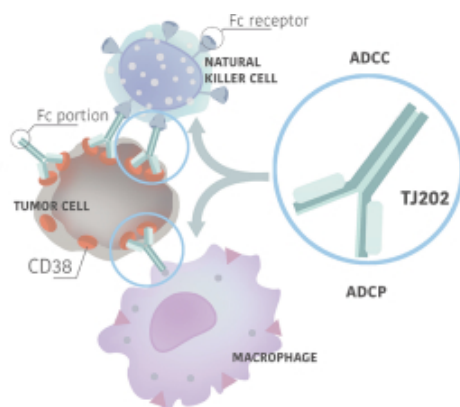


Figure: TJ202 kills CD38-bearing tumor cells by inducing ADCC and ADCP.

Summary of Clinical Results

MorphoSys has conducted a Phase 1/2a study in adult patients with relapsed or refractory MM in Austria and Germany.

Study Design. The open-label, multicenter, dose-escalation study was designed to characterize the safety profile and preliminary efficacy of TJ202 in adults with RRMM. A 3+3 dose escalation design was used to establish the maximum tolerated dose (“MTD”), recommended dose and dosing regimen of TJ202 as monotherapy, weekly or bi-weekly, with or without dexamethasone (“DEX”), and in combination with pomalidomide (“POM”) and DEX or lenalidomide (“LEN”) and DEX standard regimens. The MTD and recommended dose and dosing regimens were to be confirmed in three confirmation cohorts of at least six evaluable subjects each. TJ202 dose levels in this study ranged from 0.01 mg/kg to 16.0 mg/kg, administered by intravenous (“IV”) infusion.

The clinical study results as of the data cutoff date, December 31, 2017, are summarized as follows.

Safety. TJ202 was safe and well tolerated in patients with RRMM, as a single agent and in combination with DEX, or with POM/DEX, or with LEN/DEX. The MTD of TJ202 was not reached. In the 56 patients from three groups receiving combination regimens, grade 3 adverse events (“AEs”) were mainly in the hematological system reflected by a decrease of various blood cells. This was as expected, because of decreased bone marrow function due to the presence of myeloma as well as the expression of CD38 on various cell lineages of the myeloid and lymphoid compartments. Most of the hematological adverse events were transient and generally manageable. These data suggest that TJ202 has a good safety profile.

TJ202 was administered as a two-hour IV infusion at first dose and infusion time could be reduced to as short as 30 minutes at subsequent doses without obvious safety concerns. Among all cohorts, infusion-related reactions, including tachycardia, pyrexia and hypersensitivity, occurred in 18 of 91 patients (19.8%) and were mostly mild to moderate. In the combination cohorts containing DEX, a very low IRR (4 out of 56 patients (7%)) was observed. These results compared favorably with the historical data of the currently marketed CD38 antibody.

Clinical Efficacy. Preliminary efficacy results were based on 56 patients from three groups treated with TJ202 combination therapies. No responses were observed for the monotherapy groups which were primarily serving for dose escalation. TJ202 in combination with low dose DEX, POM/DEX or LEN/DEX demonstrated an overall response rate (“ORR”) of 28%, 48% and 65%, respectively. Durable responses were observed as median progression-free survival (“PFS”) was of 8.4 months and 17.5 months for the DEX and the POM/DEX combination groups, respectively, and PFS levels were not reached for the LEN/DEX combination group, as there were not sufficient events of progression recorded.

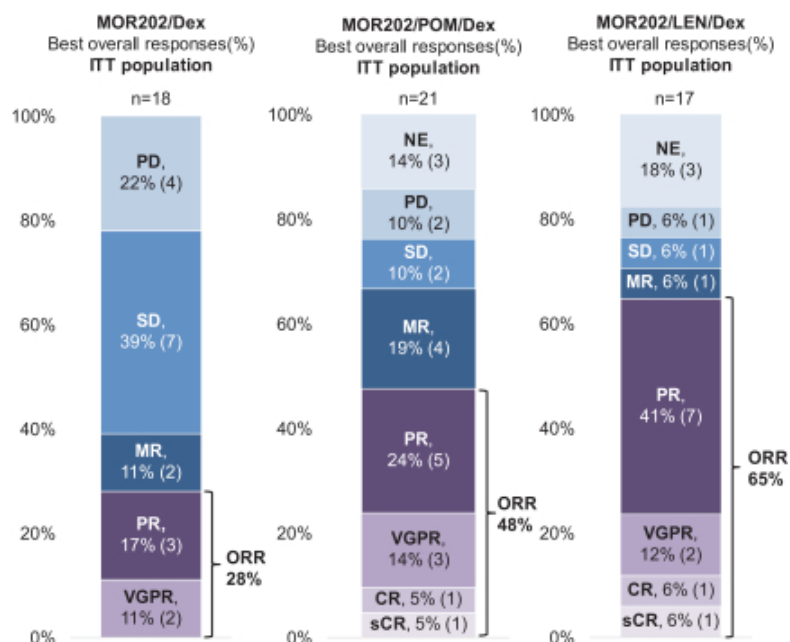


Figure: Best overall response and ORR. Patients were treated with TJ202 (MOR202) in combination with low dose of DEX (40 mg for 75 years old and younger, or 20 mg for older than 75 years old), POM (4 mg) /Dex or LEN (25 mg)/Dex. Dex: dexamethasone; POM: pomalidomide; LEN: lenalidomide; ITT: intent to treat; NE: not evaluable; PD: progressive disease; SD: stable disease; MR: minimal response; PR: partial response; VGPR: very good partial response; CR: complete response; sCR: stringent complete response; ORR: overall response rate. (Source: MorphoSys)

Pharmacodynamics. As a pharmacodynamic marker, serum myeloma (M) protein levels were used to evaluate severity and clinical response. The median relative change in M protein levels from baseline to post-baseline nadir for TJ202 in combination with low doses of DEX, POM/DEX or LEN/DEX was -13%, -58% and -81%, respectively. The data below show strong effects of TJ202 in reducing M protein levels.

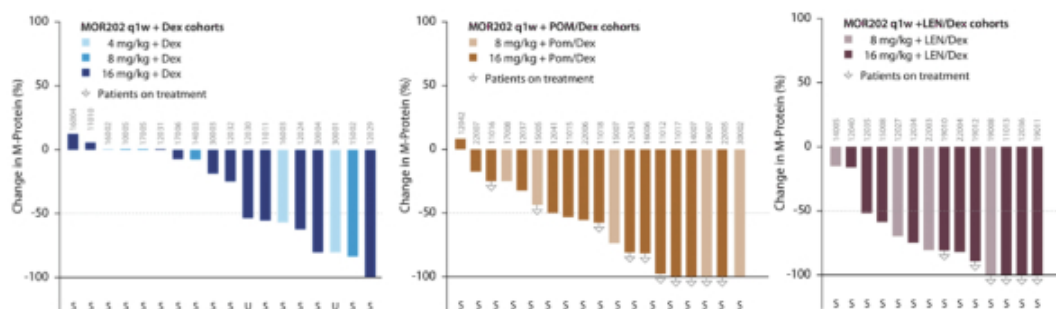


Figure: The relative change in M protein levels from baseline to post-baseline nadir. Patients were treated with TJ202 (MOR202) in combination with low doses of DEX, POM/DEX or LEN/DEX. S: serum sample; U: urine sample. (Source: MorphoSys)

Pharmacokinetics (“PK”). The PK of TJ202 in humans was well characterized by a two-compartment model at dose levels greater than 4 mg/kg. At these doses, stable or even increasing trough levels could be observed over time suggesting the potential for full target occupancy, especially at the highest dose level (16 mg/kg). For most subjects, steady state at 16 mg/kg was observed after the fourth infusion. Terminal half-life at high-dose levels (3 4 mg/kg) was at approximately two weeks. Pharmacokinetics of TJ202 were generally consistent across different individuals and dosing days and not affected by the co-medications.

Immunogenicity. No anti-drug antibody (“ADA”) against TJ202 was observed as of the cut-off date. Thus, risk of ADA induction for TJ202 in humans is considered low.

Clinical Development Plan

Immediately after in-licensing TJ202, we formulated a robust clinical development strategy with an aim for an NDA submission by 2021. With an approved IND, we have started a single-arm registrational trial with TJ202 and DEX as a third-line therapy for RRMM patients in Greater China using ORR as the primary endpoint (NCT03860038). Dosing of the first patient took place in March 2019. Data from this 82-patient study are expected to be the major package supporting registrational filing for conditional approval in 2021. In parallel, we started a Phase 3 registrational trial combining TJ202 with LEN and DEX as a second-line combination therapy in RRMM patients (NCT03952091). Dosing of the first patient took place in Taiwan in April 2019.

Our clinical development plan for SLE starts with a Phase 1b clinical trial to explore dose range, clinical safety and tolerability as well as TJ202’s profiles of PK and pharmacodynamics (“PD”) in SLE patients. We expect to file an IND application in the fourth quarter of 2019.

TJ107 (Efineptakin): A Potential First-in-Class Long-Acting IL-7 for Cancer Treatment-Related Lymphopenia and Cancer Immunotherapy

Summary

TJ107 (international nonproprietary name (“INN”): efineptakin) is the world’s first and only long-acting recombinant human interleukin-7 (“rhIL-7”), which is being developed as a T lymphocyte-booster for cancer-related immunotherapy. Due to its advantages in terms of selective immune functions, improved stability,

developability, and extended half-life, TJ107 is differentiated from an earlier generation of short-acting rhIL-7 and T cell growth factor (interleukin-2). In December 2017, we acquired exclusive rights from Genexine to develop and commercialize TJ107 in Greater China. We plan to position TJ107 first as a monotherapy or an oncology care product for cancer patients with cancer treatment-related lymphopenia (low blood lymphocyte levels) induced by chemotherapy or radiation therapy. This target indication covers a large population of cancer patients who develop cancer treatment-related lymphopenia, a condition that weakens the ability to receive continued chemotherapy or radiation therapy and leads to worsened disease prognosis and clinical outcome. Currently, there is no treatment available for this condition. Second, TJ107 is expected to show a therapeutic effect as a combination therapy with immune checkpoint inhibitors, i.e., PD-1/PD-L1 therapies, due to its inherent selective T cell-boosting properties. Pre-clinical studies have indicated that TJ107 provides additional treatment efficacy when combined with PD-1/PD-L1 therapies through a synergistic effect. If proven efficacious, we believe such a combination therapy, can potentially treat a large population of cancer patients who do not respond or respond poorly to PD-1/PD-L1 therapies. We are conducting a Phase 1b study in China to determine a suitable dose range for a Phase 2 trial in combination with a PD-1 antibody.

Therapeutic Options and Current Development

One of the target therapeutic indications of TJ107 is cancer treatment-related lymphopenia. Cancer patients who undergo chemotherapy and/or radiation therapy often develop cancer treatment-related lymphopenia, which further damages their already compromised immune systems and their ability to fight against cancers. According to the Frost & Sullivan Report, more than 85% of all cancer patients receive chemotherapy or radiation therapy, and 43% of these patients develop lymphopenia, which represents a significant unmet medical need, as currently no drug is available for the treatment of lymphopenia. Advanced solid tumor is another indication of TJ107 as a combination therapy with PD-1/PD-L1 treatments. As more than 60% cancer patients either do not respond or respond poorly to current PD-1/PD-L1 therapies, there are intense attempts to identify an effective agent that can work synergistically with PD-1/PD-L1 therapies to increase the probability of treatment success. TJ107 is believed to provide such a treatment option, which is supported by pre-clinical reports that IL-7 exhibits a synergistic effect with PD-1/PD-L1 antibodies in the treatment of cancers.

Advantages of TJ107

TJ107 has an advantage over other T lymphocyte cytokines with therapeutic potential in oncology. Pre-clinical and clinical results generated so far indicate that TJ107 has a favorable immune function profile over recombinant human interleukin-2 (“rhIL-2”) in that TJ107 activates and expands tumor-fighting CD4, CD8 and natural killer T cells but spares tumor-protecting Treg cells. By contrast, rhIL-2 is a well-known inducer of Tregs, which suppresses tumor-fighting effector T cells. Furthermore, rhIL-2 has a narrow therapeutic window and causes serious side effects such as capillary leak syndrome, breathing problems, serious infections, and seizures. A polyethylene glycol (PEG)-conjugated IL-2 variant recently developed by Nektar Therapeutics has yielded mixed results, indicating the complexity associated with using IL-2 as a cancer treatment. Owing to its preferred immune function and molecular profiles demonstrated in pre-clinical and Phase 1/2 clinical trials, we believe that TJ107 is a superior T cell cytokine investigational drug for cancer treatment-related lymphopenia and cancer immunotherapy.

TJ107, as an engineered rhIL-7, has the advantages of improved stability and half-life extension through Genexine’s proprietary hybrid fragment crystallizable region (“hyFc”). Introducing a few hydrophilic amino acid residues to the N-terminus of IL-7 overcomes stability issues that hampered the development of previous rhIL-7 drug candidates. Furthermore, application of the hyFc technology enhances IL-7’s function, increases its half-life (from 48 to 112 hours after a single subcutaneous (“SC”) dose in clinical studies), and allows for a robust purification process. By contrast, the half-life of first-generation rhIL-7 was reported to be about 12 hours after SC dosing in human subjects. The hyFc in TJ107 is also non-cytolytic, so it will not damage the T cells to which it binds. Unlike TJ107, the previous rhIL-7 drug candidates adopt non-glycosylated (CYT 99-007) or glycosylated (CYT-107) forms of short-acting rhIL-7 and were developed by Revimmune Inc (formerly known

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as Cytheris SA). These molecules had low stability, low production yield, and a short half-life because IL-7 protein is intrinsically unstable and prone to aggregation. However, the preliminary clinical results from Phase 1 and Phase 2 trials in patients with AIDS did show an increase of T lymphocytes following treatment with CYT-107 (Thiebaut R et al., PLoS Comput Biol., 2014).

Mechanism of Action

IL-7 is a cytokine essential for the survival and homeostatic proliferation of naive and memory T cells (see figure below). IL-7 is critically involved in restoring T cells to normal levels in the event of lymphopenia by stimulating T cell proliferation. IL-7 exerts its functions by binding to and activating the IL-7 receptor, which is expressed primarily on lymphocytes, including the lymphoid precursors, developing T and B cells, naive T cells, and memory T cells, but not on tumor-protecting Tregs. TJ107 as a monotherapy may enhance anti-tumor immunity by augmenting the number and functionality of T cells, whereas TJ107 in combination with an immune checkpoint inhibitor, cancer vaccine or CAR-T may improve the anti-tumor response by restoring T cell numbers, reconstituting T cell pools and reinvigorating exhausted T cells.

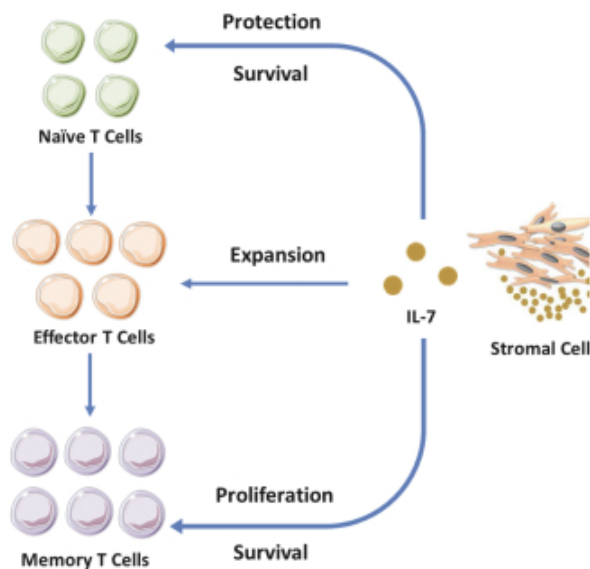


Figure: Role of IL-7 in T cell maintenance and proliferation.

Summary of Clinical Results

A first-in-human Phase 1 trial has been conducted by Genexine in South Korea. This was a randomized, double-blind, placebo-controlled, single ascending dose study, to evaluate the safety, tolerability, pharmacokinetic and pharmacodynamic properties of 20 or 60 $\mu\text{g}/\text{kg}$ TJ107 via SC or intramuscular (“IM”) administration in healthy volunteers. Each dose group consisted of 10 subjects, eight of whom were administered TJ107 and two were given placebo via the same route of administration.

Safety. TJ107 was well-tolerated in all 30 subjects without serious adverse events. The most common adverse events were transient Grade 1 or 2 injection site skin reactions.

Pharmacodynamics (“PD”). Because IL-7 promotes the survival and proliferation of T cells, absolute lymphocyte count (“ALC”) in the peripheral blood was used as a reliable and convenient PD marker for TJ107

(see figure below). ALC initially decreased transiently in all TJ107 groups. This effect is often termed margination, which is a physiological phenomenon common to many cytokines as a result of increased adherence of cytokine-stimulated white blood cells to the blood vessels and subsequent trafficking to tissues and lymphoid organs. ALC recovered in approximately seven days, reaching a maximum value at close to 21 days, before gradually declining. This result indicated that a single dose of TJ107 had a long-lasting effect of increasing lymphocyte levels. Overall, a greater increase in ALC was observed in Cohort 2 compared with Cohort 1, demonstrating a dose-dependent response. Additionally, a higher increase in ALC was observed in Cohort 3 compared with Cohort 2, which was consistent with the results of an animal study, where IM injection induced a more effective increase in lymphocytes than SC injection.

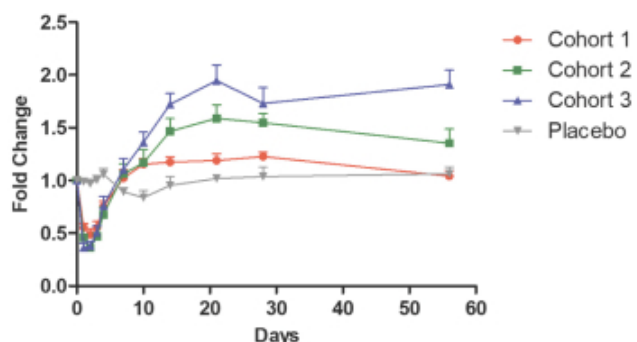


Figure: Median fold changes of ALC following a single dose of TJ107 in humans. Cohort 1: 20 $\mu\text{g}/\text{kg}$, SC; Cohort 2: 60 $\mu\text{g}/\text{kg}$, SC; and Cohort 3: 60 $\mu\text{g}/\text{kg}$, IM. (Source: Genexine)

TJ107 treatment resulted in a substantial increase in the number of CD4 and CD8 T cells, natural killer T cells, naive T cells, central memory, effector memory, and terminally differentiated effector memory T cells, without affecting the number of B cells, natural killer cells, monocytes or Tregs.

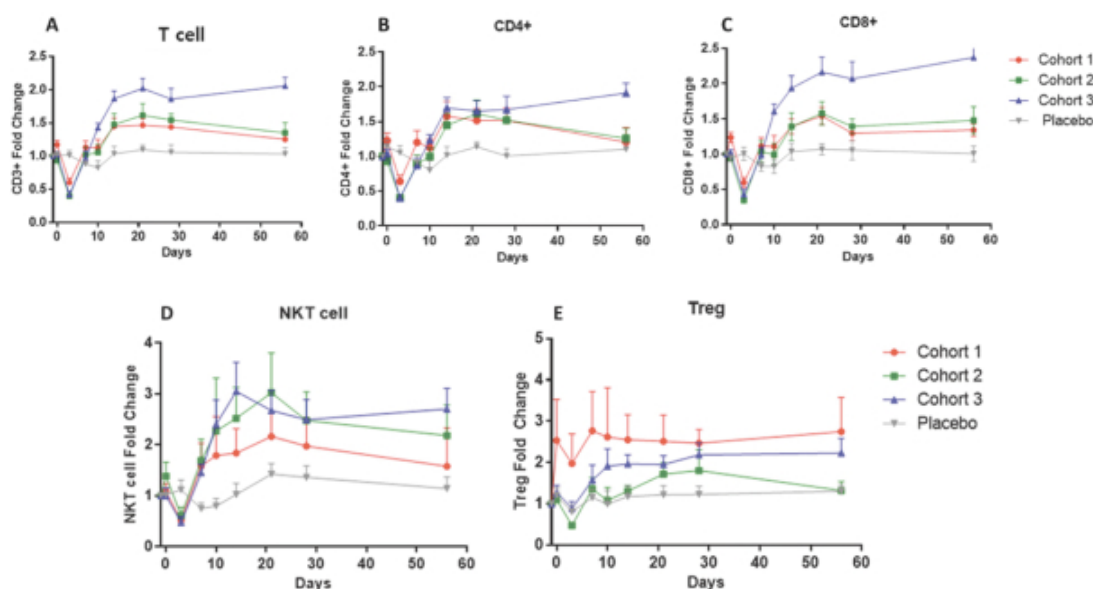


Figure: Median fold changes of T cells and subsets following a single dose of TJ107 in human subjects. Cohort 1: 20 $\mu\text{g}/\text{kg}$, SC; Cohort 2: 60 $\mu\text{g}/\text{kg}$, SC; Cohort 3: 60 $\mu\text{g}/\text{kg}$, IM. (A) CD3+T cells, (B) CD4+T cells, (C)CD8 + T cells, (D) Natural Killer T cells, and (E) regulatory T cells (Treg). (Source: Genexine)

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Pharmacokinetics. TJ107 was slowly absorbed, particularly after SC administration, and was slowly removed, resulting in a half-life of 48 to 112 hours, longer than that reported for the first generation rhIL-7 (about 12 hours). Intramuscular TJ107 showed approximately two-fold greater exposure than SC administration at the same dose level of 60 µg/kg. The higher plasma exposure of TJ107 after IM administration was well-correlated with a more robust PD effect on ALC in Cohort 3.

Immunogenicity. ADAs were detected in 22 of 24 subjects treated with TJ107. One subject in Cohort 3 was positive for ADAs before treatment. Neutralizing antibodies were observed in 42% and 46% of the subjects within one to two months following administration, respectively, but only one person still harbored neutralizing ADAs five months after administration.

The clinical relevance of ADA was evaluated during long-term follow-up monitoring. ALC levels were maintained above the baseline values, endogenous IL-7 was maintained at normal levels, and no specific adverse events associated with ADAs were observed. These results are consistent with well-documented reports that a normal individual can harbor pre-existing auto-antibodies for cytokines such as IL-2, IL-3, IL-4, and IL-7, and that these anti-cytokine antibodies tend to serve as a reservoir and carrier of the cytokines in the blood, extending the half-life of these cytokines and preserving their functions.

Clinical Development Plan

By leveraging the results of Genexine's ongoing clinical trials in South Korea and the United States, we aim to rapidly advance the clinical development of TJ107 for approval in Greater China. Currently, a Phase 1b trial in China is ongoing to investigate the safety, tolerability and PK/PD response of TJ107 in patients with advanced solid cancers. The clinical trial (NCT04001075) is designed to include: (i) dose escalation of TJ107 using a conventional "3 + 3" study design to identify a safe and effective dose range and (ii) dose expansion to confirm the safety and obtain preliminary evidence of efficacy. We have finished the dose escalation for the first patient cohort, and the safety and tolerability profile as well as the PK/PD response are consistent with other ongoing studies of TJ107.

After determining the recommended Phase 2 dose ("RP2D") in the Phase 1b trial, we expect to start a Phase 2 trial in combination with a PD-1 therapy. Based on results from the subgroup of patients with lymphopenia in the Phase 1b trial, we plan to further develop TJ107 monotherapy in cancer treatment-related lymphopenia.

Genexine has initiated a dose-finding trial in combination with checkpoint inhibitors in patients with solid tumors. Meanwhile, Genexine is also sponsoring additional early-stage clinical trials in advanced solid tumors, including glioblastoma and high-risk skin cancer, in the United States and South Korea. The safety, pharmacology and preliminary efficacy data from these ongoing studies are expected to significantly facilitate our clinical development of TJ107 in Greater China.

TJ101: A Potential Best-in-Class Long-Acting Growth Hormone for Growth Hormone Deficiency

Summary

TJ101 is a potential best-in-class long-acting recombinant human growth hormone ("rhGH") (INN: eftansomatropin) being developed as a more convenient and effective therapy for growth hormone deficiency ("GHD"), for which there is substantial unmet medical need in China. TJ101 demonstrated a good safety profile in three multi-regional clinical trials conducted in Europe and Asia and has shown preliminary efficacy in pre-pubertal growth hormone naive pediatric growth hormone deficient ("PGHD") patients. In contrast to marketed short-acting rhGH such as Genotropin, TJ101 showed similar efficacy in a weekly (vs. daily) regimen. Furthermore, TJ101 does not have the safety concerns typically associated with approved pegylated drugs. We in-licensed the China rights to TJ101 from Genexine and are positioning TJ101 as a best-in-class growth

hormone replacement therapy because of its advantages over a daily regimen in terms of injection frequency (weekly vs. daily) and a favorable safety profile (natural protein-based vs. pegylated long-acting rhGH), especially in pediatric patients. We are preparing for a registrational Phase 3 trial in China to validate the efficacy, safety, pharmacodynamics, and pharmacokinetics of TJ101 in PGHD, with a plan for IND submission in early 2020.

Therapeutic Options and Current Development

Our current therapeutic indication is PGHD. The widely adopted treatment for PGHD is patient-specific growth hormone replacement therapy, which is given in a calculated weight-based dosing regimen. Currently, short-acting recombinant human growth hormone (“rhGH”) is commonly used for the long-term treatment of children and adults with inadequate endogenous growth hormone secretion. There are certain safety concerns related to long-term use of pegylated drugs, such as potential renal toxicity, cellular vacuolation and formation of anti-polyethylene glycol antibodies. Approved by the NMPA in 2014, Jintrolong (developed by GeneScience) is currently the only long-acting pegylated rhGH in China, according to the Frost & Sullivan Report. Other companies in China currently developing long-acting rhGH include Anhui Anke Biotechnology and Generon Pharmaceutical Technology. Our TJ101 is the only Fc-based long-acting rhGH ready for a Phase 3 clinical trial in China.

According to the Frost & Sullivan Report, only 3.7% of all PGHD patients in China were receiving growth hormone replacement therapy in 2018, which primarily consists of daily injections of rhGH before sleep. This dosing regimen puts a substantial burden on pediatric patients and their families because it requires drug preparation and needle injection every day, which is painful and extremely inconvenient, often resulting in poor patient compliance. More importantly, studies have shown that skipping just one or two doses in a week can markedly reduce the efficacy of the treatment. Therefore, there is a substantial unmet medical need for long-acting growth hormone therapies that are similarly efficacious but with reduced injection frequency, and the market potential for such a long-acting rhGH in China is largely untapped. In addition, recombinant human growth hormone therapy has been included in the National Reimbursement Drug List (NRDL) in China. Inclusion of a drug in the NRDL typically results in a much higher sales volume and significant sales growth despite a reduction in price.

Advantages of TJ101

We believe that TJ101 has the following advantages: (i) when compared to the daily regimen of rhGH, TJ101 is expected to be a more convenient therapy with better patient compliance due to a reduced dosing frequency to either weekly or twice-monthly administration, while maintaining similar efficacy; and (ii) TJ101 does not have safety concerns typically associated with pegylated drugs, such as potential renal toxicity, pre-existing or treatment-induced anti-PEG antibodies, and cellular vacuolation in macrophages, renal tubule cells and the choroid plexus epithelial cells.

Mechanism of Action

Like endogenous growth hormone, TJ101 stimulates the production of insulin-like growth factor 1 (“IGF-1”) in the liver, which has growth-stimulating effects on a variety of tissues, including osteoblast and chondrocyte activities that stimulate bone growth. Thus, IGF-1 is a reliable pharmacodynamic marker and more importantly, the key mediator of TJ101’s growth-promoting activity. TJ101 is based on Genexine’s patented hyFc technology. The hyFc part consists of a portion of human immunoglobulin D (“IgD”) and G₄ (“IgG₄”). The former contains a flexible hinge, and the latter is responsible for half-life extension through neonatal Fc receptor (“FcRn”)-mediated recycling. Additionally, TJ101’s increased molecular weight (103 kilodalton) is expected to reduce renal clearance.



Figure: Schematic presentation of the structure of TJ101. CH2 & CH3: Constant regions 2 & 3 of antibody heavy chains, respectively; hGH: human growth hormone. (Source: Genexine)

Summary of Clinical Results

Genexine has completed three clinical trials with TJ101, including one Phase 1 trial in healthy adult volunteers, one Phase 1b/2 multi-regional trial in adults with GHD, and one Phase 2 multi-regional trial in PGHD in Europe, altogether involving 32 healthy subjects and 99 patients with GHD and PGHD. Overall, TJ101 was shown to be safe and well-tolerated, and clinical efficacy of weekly or twice-monthly TJ101 administration was comparable to that of daily administration of Genotropin.

Phase 1 Clinical Trial

The first-in-human trial of TJ101 was a randomized, double-blind, placebo-controlled single dose-ascending study in four groups of healthy subjects. A total of 32 subjects were enrolled, and 31 completed the study. TJ101 was shown to be safe and well-tolerated at all dose levels studied (0.2–1.6 mg/kg). TJ101 was detectable in the blood until Day 7 for the 0.2 mg/kg dose group, Day 14 for the 0.4 and 0.8 mg/kg dose groups, and Day 21 for the 1.6 mg/kg dose group. A single subcutaneous (“SC”) injection of TJ101 at dose levels of 0.4 mg/kg and higher increased IGF-1 and IGF-binding protein-3 (“IGFBP-3”) levels for at least one week. No safety concerns were identified. TJ101 showed a half-life ranging from 69.2 to 138 hours.

Phase 2 Clinical Trial in PGHD

Study Design. The Phase 2 trial in PGHD was a randomized, open-label, active-controlled study to assess the safety, tolerability, efficacy, pharmacokinetics, and pharmacodynamics of weekly and twice-monthly doses of TJ101, as compared to a daily injection of Genotropin, which is currently the standard of care for PGHD. Subjects were randomly assigned to receive one of three doses of TJ101 (0.8 mg/kg/weekly, 1.2 mg/kg/weekly or 2.4 mg/kg/twice monthly) or 0.03 mg/kg/daily of Genotropin for up to 24 months. The primary clinical endpoint was annualized height velocity (aHV) in centimeters (cm) per year (equivalent to annual growth rate), measured at six months. A total of 56 subjects were randomized at 27 centers in nine European countries and South Korea. Fifty two subjects completed the six-month treatment (through Visit 7), meeting the primary endpoint. Two subjects withdrew from the study before first drug administration, and two subjects discontinued due to treatment-related adverse events (“AEs”). Genexine and its co-developer Handok presented the latest interim results of the Phase 2 clinical trial for PGHD in March 2018 at the Endocrine Society’s annual meeting.

Safety. TJ101 demonstrated a good safety profile with no study drug-related serious adverse events (“SAEs”) or death. The tolerability of TJ101 was consistent with known properties of marketed products. The AE incidence rate was generally similar across the TJ101 cohorts treated with three different dose levels (ranging between 69.2% and 84.6%) and the Genotropin cohort (57.1%). A total of two (14.3%), three (23.1%), two (15.4%), and zero subjects experienced treatment-related AEs in the 0.8 mg/kg/week, 1.2 mg/kg/week, and 2.4 mg/kg/twice monthly TJ101 groups, and the 0.03 mg/kg/daily Genotropin group, respectively.

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Two subjects withdrew from the study due to treatment-related AEs. One subject from Cohort 2 (1.2 mg/kg/week of TJ101) discontinued due to retinal vascular disorder. The Data and Safety Monitoring Board (“DSMB”) reviewed this case independently, concluding that the retinal finding was more likely to be of completely different etiology than treatment-induced intracranial hypertension. One subject from Cohort 3 (2.4 mg/kg/twice monthly of TJ101) discontinued due to pseudopapilloedema (optic disc drusen), which was assessed by the principal investigator to be mild with continuous frequency and possibly related to the study drug.

Injection site reactions (“ISRs”) were reported by 13 out of 40 subjects (32.5%) in the TJ101 cohorts. Pain was the most prominent and common symptom observed in 10 subjects. Also, six subjects reported redness, four reported itching, and one reported bruising, swelling and warmth. With respect to the Genotropin cohort, pain was the only ISR reported in 683 cases by 11 out of 14 subjects (78.5%). None of the ISRs led to discontinuation of treatment, and most of the reported ISRs posed no issue for the subjects and were resolved quickly. No safety signal was detected in laboratory parameters or vital signs for either TJ101 or Genotropin.

Pharmacokinetics. Half-life of TJ101 was 77.75–141.95 hours after a single dose and 43.92–55.66 hours (compared to 5.27 hours for Genotropin) after three months of multiple-dose administration.

Immunogenicity. Formation of treatment-emergent ADA with neutralizing property was reported in two subjects (one from Cohort 2 and one from Cohort 3) out of a total of 40 subjects randomized and dosed with TJ101. With respect to the Genotropin cohort, the presence of treatment-emergent ADA with neutralizing property was not observed in any subject.

Clinical Efficacy. Subcutaneous administration of TJ101 over the dose range of 0.8 mg/kg/week–2.4 mg/kg/twice monthly resulted in an increase in aHV over the six-month study period. Subjects who received TJ101 at 0.8 mg/kg weekly, 1.2 mg/kg weekly, and 2.4 mg/kg twice monthly showed growth rates of 11.50, 11.54, and 11.86 cm/year, respectively, while the growth rate in the control group treated with Genotropin was approximately 11.24 cm/year. These results indicated that weekly or twice monthly treatment with TJ101 produced clinical efficacy comparable to daily Genotropin administration.

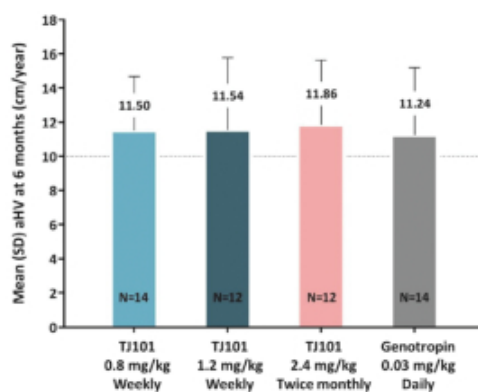


Figure: The aHV at six months indicated comparable growth rates between all doses of TJ101 (both weekly and twice-monthly treatment) and the active comparator, Genotropin. (Source: Genexine)

Pharmacodynamics. The growth-promoting effect of TJ101 was accompanied by elevated serum IGF-1 levels. This hormone is an important biomarker, which mediates growth hormone’s biological effects. The Standard Deviation Score (“SDS”), which is a calculated score with reference to the normal age- and sex-matched IGF-1 levels, is a standardized parameter to compare IGF-1 levels across laboratories and populations. Mean IGF-1 SDS at the beginning of the study was below the lower limit of the normal range in all treatment arms. Following initiation of treatment, the IGF-1 SDS values quickly normalized by five days

(Visit 2) and three weeks (Visit 3) after the initial treatment, respectively, for the TJ101 treatment arms and the Genotropin treatment arm. IGF-1 responses were maintained throughout the intended dosing interval, supporting both the weekly and twice monthly treatment regimens. IGF-1 mean peak levels were mostly within the upper limit of the physiologic range, which is considered safe in clinical practice.

Clinical Development Plan

Based on Genexine's Phase 2 study in PGHD, we are preparing to conduct a registrational Phase 3, randomized, active-controlled, and multi-center study in China to assess the efficacy, safety, and pharmacokinetics of TJ101 in PGHD. The primary objective is to demonstrate non-inferiority of 1.2 mg/kg/week of TJ101 administered SC, based on aHV after 26 weeks of treatment, compared to the active control Jintropin, a daily rhGH marketed in China. We have finalized the study design with key opinion leaders, and our development plan and study design have been discussed with the NMPA through a face-to-face pre-IND meeting. We expect to submit an IND application in early 2020.

TJ301: A Potential Best-in-Class IL-6 Blocker for Ulcerative Colitis and other Autoimmune Diseases

Summary

TJ301 (INN: olamkicept) is the only clinical stage selective interleukin-6 ("IL-6") inhibitor that works through the trans-signaling mechanism. IL-6 is an important cytokine driver in the propagation and maintenance of chronic inflammation in autoimmune diseases. Compared to the approved antibody drugs that directly block IL-6 or IL-6 receptor ("IL-6R"), TJ301 is expected to provide a better safety profile for the treatment of IL-6 mediated inflammation without affecting some of the normal physiological functions of IL-6, e.g., acute immune response against infection and metabolic regulation. TJ301 demonstrated efficacy in pre-clinical studies in animal models of autoimmune diseases, including inflammatory colitis. Moreover, TJ301 has demonstrated a well-tolerated safety profile in three clinical trials in Germany involving 128 subjects. We believe that TJ301 has the potential to become a best-in-class therapy to target autoimmune diseases. We acquired an exclusive license from Ferring Pharmaceuticals to develop and commercialize TJ301 in Greater China and South Korea with an option of licensing worldwide rights. As part of our fast-to-market strategy for TJ301, we are conducting a Phase 2 clinical trial in ulcerative colitis ("UC") for the following reasons: (i) TJ301 was shown to be effective in animal models of colitis; (ii) an exploratory Phase 2a biomarker trial showed promising interim efficacy of TJ301 in UC patients; and (iii) even though UC incidence is increasing rapidly, innovative biologic treatments for this disease are lacking in China. After clinical efficacy and differentiation are validated for UC, we plan to develop TJ301 in other inflammation indications, in which the pathogenic role of IL-6 is clinically proven by approved anti-IL-6 biologics.

Therapeutic Options and Current Development

Our current therapeutic indication for development is UC. UC and Crohn's disease ("CD") are the main types of inflammatory bowel disease ("IBD"), which cause chronic and often relapsing inflammation of the large and small intestines, respectively. Anti-inflammatory drugs, such as 5-aminosalicylic acids ("5-ASAs") and corticosteroids, are often used as initial treatment for UC. Immune system suppressors are also used to control inflammation in patients with UC, including azathioprine, mercaptopurine, and cyclosporine. Biologics that inhibit tumor necrosis factor alpha (TNF- α), including infliximab (Remicade), adalimumab (Humira), and golimumab (Simponi), are efficacious in some UC patients who fail to respond to conventional therapies. Entyvio, an integrin $\alpha_4\beta_7$ antibody that blocks lymphocytes from accumulating in the intestinal wall, is the first and, to date, the only non-anti-TNF- α biologics approved for UC. In China, Remicade is currently the only biologic approved for treatment of UC.

There is a substantial unmet medical need in UC for a treatment agent(s) that is efficacious and safe through pathways beyond the traditional drug targets. The incidence of UC is increasing rapidly, but UC patients,

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especially those with a moderate-to-severe disease, have few treatment options, which have limited efficacy and considerable side-effects. For example, Jak1/3 kinase inhibitors can carry the risk of serious infections and malignancies. TNF- α inhibitors also have inherent side effects and do not work in all patients. According to the Frost & Sullivan Report, approximately 45% patients with autoimmune diseases are considered treatment non-responders to TNF- α drugs and less than one third the UC patients taking TNF- α drugs achieve drug free remission. Thus, as the only clinical stage selective interleukin-6 (“IL-6”) inhibitor that works through the trans-signaling mechanism, we believe TJ301 has a better profile and has the potential to become the best-in-class IL-6 blocker for UC.

Advantages of TJ301

The existing IL-6 or IL-6R blockers cause total inhibition of IL-6 signaling and are associated with significant adverse events in the clinic, such as infection, gastrointestinal perforation, metabolic disturbances, and insulin resistance. TJ301 is expected to provide a better safety profile as it works through a different mechanism, the trans-signaling pathway. This key advantage has been demonstrated in pre-clinical studies and three clinical trials conducted in Germany. The results indicated that TJ301 has no side effects on lipid, glucose or bone metabolism, and it has no agonistic activities that could activate receptors or trigger detrimental immune cascades. We expect that selective inhibition of IL-6 trans-signaling is an effective and safer approach to the treatment of chronic inflammation.

Mechanism of Action

TJ301 is a homodimer of a fusion protein consisting of the extracellular domains of human glycoprotein130 (“gp130”) and the fragment crystallizable (Fc) domain of human IgG₁. Mimicking the function of endogenous soluble gp130, TJ301 works as a decoy by binding to a complex consisting of IL-6 and soluble IL-6 receptor (“sIL-6R”), thereby preventing TJ301 from stimulating the trans-signaling pathway in cells that do not express IL-6R. The gp130 part selectively binds the IL-6/sIL-6R complex with high affinity (K_d=130 pM), whereas the Fc part initiates dimerization and offers longer half-life for the molecule. TJ301 is not expected to affect the beneficial effects of IL-6, such as the acute immune response against infection mediated by the classical pathway.

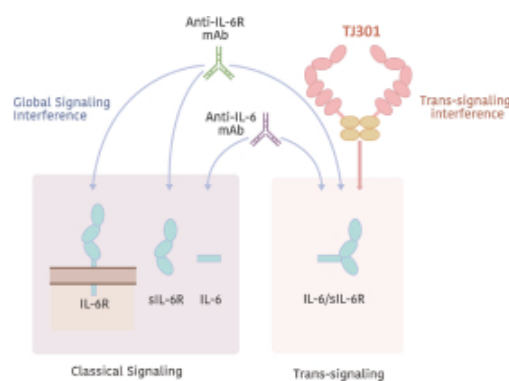


Figure: Classical signaling and trans-signaling pathways of IL-6. Anti-IL-6R and anti-IL-6 block both pathways, whereas TJ301 blocks only trans-signaling. IL-6R: IL-6 receptor; sIL-6R: Soluble IL-6 receptor.

Summary of Clinical Results

Ferring Pharmaceuticals has completed two Phase 1 trials to evaluate TJ301’s safety and clinical pharmacology. TJ301 was shown to be safe and well-tolerated based on the clinical results collected from a total

of 112 subjects exposed to the drug. In addition, a Phase 2a biomarker study in active IBD (known as the FUTURE study) has been completed in Germany with promising pharmacodynamic and efficacy results.

Phase 1 Clinical Trial: Single Dose Ascending Trial

Study Design. The first-in-human trial of TJ301 was a single dose, placebo-controlled, single-blind, randomized within dose, and parallel group dose-escalating trial. The trial recruited both healthy subjects and patients with Crohn's Disease ("CD") in clinical remission. The primary objective was to examine the safety, tolerability and pharmacokinetics after a single dose of TJ301. Several dose levels were tested, ranging from 0.75 mg to 750 mg, with each dose level including six subjects receiving TJ301 and two receiving placebo.

Pharmacokinetics. In healthy subjects and CD patients, TJ301 showed similar terminal half-life of 4.3 to 5.1 days. The maximum concentration (C_{max}) in plasma and the area under curve ("AUC") of the plasma drug concentration-time curve were dose proportional. For SC administration of TJ301 (60 mg), the C_{max} was approximately 1.0 $\mu\text{g/mL}$ at 2.3 days, and the bioavailability was approximately 48%.

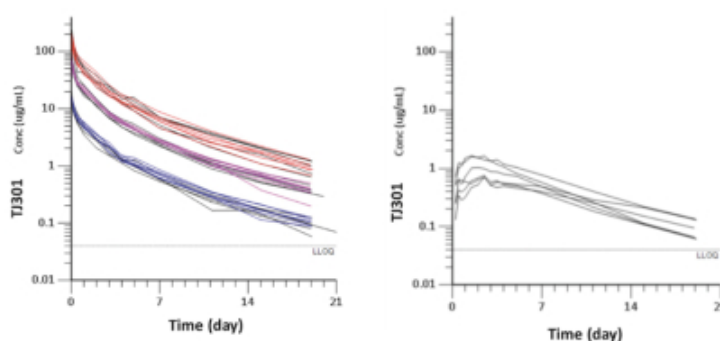


Figure: Single dose pharmacokinetic profile of TJ301. Left, healthy subjects (colored lines) and IBD patients in remission (gray lines) received a single IV infusion at 75 mg (blue lines), 300 mg (magenta lines) or 600 mg (red lines) fixed doses. Right, healthy subjects received a single SC injection at 60 mg. LLOQ: lower limit of quantitation. (Source: Ferring Pharmaceuticals)

Safety. TJ301 was safe and well-tolerated when administered as a single IV dose at up to 750 mg and as a single SC dose at 60 mg. No apparent dose-related AE was observed. Infusion was discontinued in two subjects due to mild to moderate infusion-related reactions, with skin symptoms such as urticaria and swelling, which were rapidly resolved. Only one healthy subject in the 300 mg group showed non-neutralizing treatment-emergent ADAs at the follow-up visit five to six weeks after administration.

Phase 1 Clinical Trial: Multiple Dose Ascending Trial

Study Design. This trial was a placebo-controlled, double-blind, and randomized dose-escalating trial in healthy subjects. A total of 24 healthy subjects were randomized into three dose groups and received four weekly infusions of TJ301 at 75 mg, 300 mg or 600 mg.

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Pharmacokinetics. PK characteristics were similar on the first and last treatment days of the multiple dose-ascending trial and were similar to results in the single dose-ascending study.

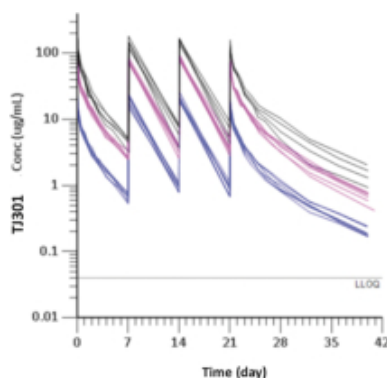


Figure: Multiple dose pharmacokinetic profile of TJ301. Healthy subjects received weekly IV infusions at 75 mg (blue lines), 300 mg (magenta lines) or 600 mg (gray lines) fixed doses. LLOQ, lower limit of quantitation. (Source: Ferring Pharmaceuticals)

Safety. The safety profile of TJ301 was favorable with only a few mild or moderate AEs reported across all treatment groups. One subject from the 600 mg group withdrew due to mild infusion-related reactions with urticaria and pruritus 30 minutes after administering the first dose. No apparent dose-related trends or treatment-related change in vital signs, electrocardiogram or clinical chemistry parameters were observed. No ADAs were reported by any subject. Overall, TJ301 was safe and well-tolerated when administered by IV at up to 600 mg once weekly for four weeks.

Overall Summary of Treatment-Emergent Adverse Events

	75 mg (N = 6)	300 mg (N = 6)	600 mg (N = 6)	Placebo (N = 6)	Total Active (N = 18)
	n (%) E	n (%) E	n (%) E	n (%) E	n (%) E
Any TEAE ⁽¹⁾	6 (100) 13	2 (33) 5	4 (67) 6	6 (100) 14	12 (67) 24
Serious TEAEs	0	0	0	0	0
Adverse Drug Reactions ⁽¹⁾	6 (100) 11	2 (33) 2	3 (50) 5	4 (67) 6	11 (61) 18
TEAEs Leading to Withdrawal	0	0	1 (17) 1	0	1 (6) 1
Deaths	0	0	0	0	0

Source: Ferring Pharmaceuticals

Note:

(1) Reasonably possibly related to treatment; N: number of subjects exposed; n: number of subjects with AE; %: n/N*100; E: number of AEs

Phase 2a Biomarker Study in Active IBD (FUTURE Study)

Study Design. This was an open-label exploratory study to assess the mechanisms of molecular activity (effects on biomarkers), safety and tolerability of TJ301 in adult patients with active IBD. Nine UC patients and seven CD patients were dosed with TJ301 (600 mg, IV, q2w) for up to 12 weeks followed by 42 days of safety follow-up. Patients enrolled had moderately to severe active UC or ileocolonic CD with median disease duration of 5.3 (UC) and 6.9 (CD) years and with immunologically active inflammation (C-reactive protein >5 mg/l), who had failed conventional therapies and had no prior biologics treatment.

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The primary endpoint was the proportion of patients with reduced mucosal expression of a predefined set of inflammation-relevant genes (TNFA, IL1A, REG1A, IL8, IL1B and LILRA) as a composite score. Objective assessments included centrally read endoscopies, histology readings, and various explorative molecular parameters and inflammatory biomarkers. The trial was sponsored and conducted by the University Hospital Schleswig Holstein and Paul-Ehrlich Institute (EUDRA-CT 2016-000205-36), with financial and material support from Ferring Pharmaceuticals. The study has been completed, and the abstract of the results is expected to be presented at the United European Gastroenterology Week meeting in late 2019.

Safety. TJ301 was well-tolerated. Reported AEs were unspecific in nature and showed no signs of immune suppression. Five SAEs were observed, none of which were life-threatening or deemed to be related to TJ301.

Pharmacokinetics. After single and repeated IV administration of TJ301 (600 mg, Q2W) to patients with UC and CD, similar serum exposure was observed after the first and last dosing events, with respect to C_{max} and total exposure over 14 days. Maximal serum drug concentration after each dosing was reached at the end of infusion. The mean terminal half-life of TJ301 after the last administration was approximately 5.1 days. Circulating biological activity of TJ301 was confirmed by whole-blood STAT3 phosphorylation assays in all patients. A minimal and transient ADA production was observed in three patients. ADAs were only detected at week 12 and week 15, but no longer detectable at week 18.

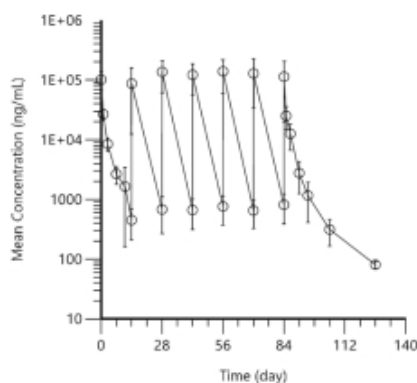


Figure: Time course of the mean serum concentration of TJ301.

Pharmacodynamics. In the assessment of the primary endpoint, it was observed that clinical remission was associated with a significant reduction of IL-1B, IL-8 and REG1A gene expression in the intestinal mucosa. Pathway analysis of blood transcriptome signatures showed an early molecular anti-inflammatory signature as early as four hours after treatment in all patients, irrespective of treatment outcome, which indicated a thorough inhibitory effect of IL-6 trans-signaling blockade on inflammatory pathways.

Clinical Efficacy. A preliminary efficacy signal was observed in both UC and CD patients, which appeared to be stronger in patients with UC than those with CD. Overall, 55% of UC patients (5/9) responded to TJ301, with 22% (2/9) reaching clinical remission, whereas 29% of CD patients (2/7) responded to TJ301, with 14% (1/7) reaching clinical remission. All three patients in clinical remission showed a fast and thorough induction of clinical, endoscopic, and immunologic remission within the first four weeks.

Clinical Development Plan

We are positioning TJ301 as a differentiated IL-6 blocker for a number of autoimmune diseases. The first target indication is active stage UC that is not well-controlled by conventional therapies such as mesalazine. With a goal of developing TJ301 as a second-line therapy for mild UC and first-line therapy for moderate-to-severe

UC, we have initiated a multi-regional Phase 2 clinical trial in Taiwan, South Korea, and China to assess the pharmacokinetics, safety, and efficacy of TJ301 in patients with active UC (NCT03235752). This is a randomized, double-blind, and placebo-controlled clinical trial with three treatment arms. A total of 30 patients have been dosed. Besides UC, we are evaluating the possibility of extending TJ301 to other autoimmune conditions where there is significant unmet medical need in China. We expect to initiate a second clinical trial for chronic inflammatory disorders, such as neuromyelitis optica, systemic sclerosis, Castleman's disease, and system vasculitis, in which IL-6 is implicated as a key pathogenic cytokine.

Enoblituzumab: A Potential First-in-Class B7-H3 Antibody as an Immuno-oncology Treatment

Summary

Enoblituzumab is a humanized antibody directed at B7-H3, a member of the B7 family of T cell checkpoint regulators. B7-H3 is a promising immuno-oncology drug target as it is widely expressed across multiple tumor types and plays a key role in regulating immune response against cancers. Increasing pre-clinical and clinical evidence suggests that antibodies targeting the two T cell checkpoint molecules—B7-H3 and PD-1—work synergistically in treating cancer. Given B7-H3's critical role, enoblituzumab has a wide range of cancer applications as either a monotherapy or in combination with PD-1 therapies. At the molecular level, enoblituzumab is engineered to possess an enhanced anti-tumor ADCC function and is at the forefront in global clinical development. Originally developed by MacroGenics, enoblituzumab has been evaluated in multiple clinical trials as a monotherapy or in combination with CTLA-4 or PD-1 therapies in patients with B7-H3-expressing cancers. Enoblituzumab is also being evaluated in a neoadjuvant Phase 2 study as a single agent in patients with intermediate and high-risk localized prostate cancer. The clinical studies so far have shown that enoblituzumab is well-tolerated, and it increased CD8 T cell infiltration in tumors with more focused T cell repertoires in patients treated with enoblituzumab as a monotherapy. Recent clinical studies conducted by MacroGenics indicate that combination therapy with enoblituzumab and pembrolizumab correlates with preliminary efficacy signals in recurrent or metastatic squamous cell carcinoma of the head and neck ("SCCHN") and non-small cell lung cancer ("NSCLC"). We recently acquired the development and commercial rights of enoblituzumab from MacroGenics for Greater China. Our initial clinical development plan includes a registrational trial (if approved by the NMPA) in patients with recurrent or metastatic SCCHN in China. As more clinical and pre-clinical data become available, further clinical trials will be planned together with MacroGenics to extend enoblituzumab to other cancer indications in China and globally.

Therapeutic Options and Current Development

Our initial therapeutic indication is head and neck cancer. Head and neck cancers occur in various parts of the head and neck, including the mouth, nose, throat and salivary glands. More than 90% of head and neck cancers are classified as SCCHN, which begin in the squamous cells that line the moist, mucosal surfaces inside the head and neck. The treatment principles and regimens for head and neck cancer in China are similar to those in the rest of the world. Treatment strategies often depend on the location and stage of the cancer, the patient's physical status, and response to prior treatments. Early-stage disease is primarily treated with surgical resection, while patients with locally advanced, recurrent or metastatic disease are typically treated with drug therapy. The combination of surgery and drug therapy, with or without radiation therapy, is the current standard of care for Stage 3 SCCHN patients with locally advanced disease. Platinum-based chemotherapy regimens are widely used as first-line therapies for Stage 4 and distant relapse patients. Erbitux (cetuximab from Eli Lilly and Merck KGaA) was approved in 2006 as a first-line treatment of locally advanced SCCHN in combination with radiation therapy. Regimens containing Erbitux, platinum-based chemotherapy, and 5-fluorouracil, known as EXTREME, are often considered as the standard of care for first-line treatment of distant relapse SCCHN. However, only about 35% of patients respond to EXTREME, and the resulting overall median survival is only 10.1 months. Furthermore, about half of the patients on first-line therapies need later-line therapies.

In addition, even second-line therapy is highly varied, including single-agent docetaxel or paclitaxel, Erbitux monotherapy, and Erbitux and paclitaxel combination therapy. In 2016, PD-1 inhibitors were approved

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globally as second-line therapies. Recently, Keytruda (pembrolizumab from Merck & Co), used as a single agent or in combination with chemotherapy, was approved by the FDA as first-line therapy for patients with metastatic or unresectable recurrent SCCHN. The average ORR for second-line therapies has been less than 15%.

As such, we believe that SCCHN patients, especially those with late stage or relapsed disease, need more efficacious treatments with fewer side effects, which represents a significant unmet medical need for immunotherapy and targeted therapy.

Advantages of Enoblituzumab

Enoblituzumab is a potentially first-in-class investigational drug. The foregoing statement applies only to conventional therapeutic B7-H3 antibodies and does not include radio-labeled B7-H3 antibodies in development by Y-mabs Therapeutics. Targeting B7-H3 offers several advantages over other target options within the class of T cell checkpoint molecules. First, B7-H3 is a tumor-associated antigen that is over-expressed in a variety of solid tumors while its expression in normal tissues is rather limited, enabling the tumor killing mechanism of enoblituzumab. Second, B7-H3 is a unique checkpoint whose expression in tumors is associated with disease prognosis. For example, biomarker analysis of more than 400 NSCLC patients revealed that among all the elevated immune checkpoint inhibitors, including PD-1/PD-L1, PD-L2, B7-H3, TIM-3, BTLA and CTLA4, only B7-H3 is negatively correlated with clinical efficacies of neoadjuvant treatments (Lou et al., *Clinical Cancer Research*, 2016). Furthermore, recent studies have shown that when combined with a PD-1 antibody, a blockade of B7-H3 results in superior treatment efficacy in relevant cancer animal models while another study indicates that B7-H3 expression correlates with a lack of anti-PD-1 response (Yonesaka et al., *Clinical Cancer Research*, 2018). The advantages summarized above make B7-H3 a favorable tumor target for immuno-therapeutic intervention.

Mechanism of Action

Enoblituzumab (MGA271) is an investigational humanized immunoglobulin (IgG1/kappa monoclonal antibody) that binds to B7 homolog 3 (B7-H3). This antibody consists of an engineered human IgG1 fragment crystallizable (Fc) domain that imparts increased affinity for the human activating Fc gamma receptor (FcγR) IIIA (CD16A) and decreased affinity for the human inhibitory FcγRIIB (CD32B). The engineered Fc domain confers enoblituzumab with enhanced target-specific antibody-dependent cellular cytotoxicity (“ADCC”) in vitro and anti-tumor activity in preclinical studies. Therefore, enhanced cytolysis of B7-H3-expressing tumor cells is a mechanism that supports the development of this molecule as an antineoplastic agent.

In addition, data suggest that enoblituzumab impacts T-cell homeostasis in vivo. Cancer patients display a more narrowly focused T-cell repertoire following enoblituzumab treatment compared to their baseline repertoire distribution. Moreover, enhanced local T-cell infiltration has been observed in prostate cancer patients treated with enoblituzumab.

These data are consistent with the notion that enoblituzumab is capable of engaging both innate and adaptive immunity as mediators of its anti-tumor activity.

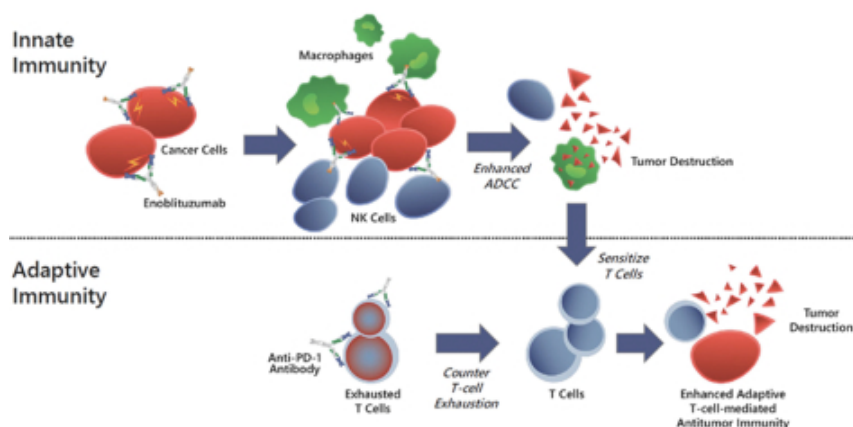


Figure: Enoblituzumab contributes to the coordination and engagement of innate and adaptive immunity to mediate tumor regression. Enoblituzumab binds to tumor cells, activates innate immune cells such as natural killer cells (NK cells) to kill cancer cells through ADCC. The released tumor antigens may then be presented by antigen-presenting cells, such as macrophages, which, in concert with PD-1 blockade, can promote tumor-specific T-cell immunity. (Source: MacroGenics)

Summary of Clinical Results

Phase 1 Study of Enoblituzumab Monotherapy

Study Design. This was an open-label, multi-dose, single-arm, multi-center, and dose-escalation study to define safety, tolerability, maximum tolerated dose (“MTD”), PK, immunogenicity, and potential anti-tumor activity of enoblituzumab in patients with refractory cancers that express B7-H3 conducted by MacroGenics. In the dose escalation segment of the study, six doses (0.15–15 mg/kg QW) were evaluated in a conventional “3+3” design.

No MTD or dose-limiting toxicity (“DLT”) was observed in the dose escalation phase, so the highest administered dose, 15 mg/kg, was used in the cohort expansion, in which patients received weekly infusions of enoblituzumab in eight-week cycles for up to 12 cycles. Tumor evaluation was carried out by both Response Evaluation Criteria in Solid Tumors (“RECIST”) and immune-related response criteria (“irRC”) with an initial response assessment after eight weeks. This entailed seven tumor-specific cohorts, including melanoma (post-checkpoint inhibitor failure, n=31), head and neck cancer (n=19), prostate cancer (n=34), triple-negative breast cancer (n=17), renal cell carcinoma (n=16), NSCLC (n=8), and bladder cancer (n=12).

Safety. Interim data analysis as of the data cut-off date of April 13, 2017, indicates that enoblituzumab is well-tolerated. Treatment-related AEs (per investigator assessment) were experienced by 134 out of 170 (78.8%) patients, most of which were infusion-related reactions (n=62, 36.5%), fatigue (n=54, 31.8%), nausea (n=32, 18.8%), and chills (n=24, 14.1%). Only three out of 179 patients (1.7%) had a treatment-related discontinuation, and 7.3% of the patients experienced treatment-related Grade 3 or higher AEs (fatigue, infusion-related reactions, and nausea). Mild to moderate infusion-related reactions were managed with low dose steroids or a decrease of the infusion rate. No severe immune-mediated toxicity was observed.

Pharmacokinetics. Preliminary analysis and population PK modeling based on 18 patients dosed at 15 mg/kg indicate that PK of enoblituzumab was characterized primarily by target-mediated drug disposition and was consistent with a typical human IgG1 with near-linear PK.

Efficacy. Evidence of decreased size of target and non-target lesions as well as extended time to progression were observed across a broad range of tumors, including heavily pretreated cancers. Three patients achieved PR (partial responses) by RECIST out of a total of approximately 71 patients being evaluated.

Phase 1 Study of Enoblituzumab in Combination with Pembrolizumab

Study Design. This is an open-label, dose escalation, cohort expansion, and efficacy follow-up study of enoblituzumab in combination with pembrolizumab conducted by MacroGenics. The dose escalation phase is designed to characterize the safety and tolerability of the combination and to define the maximum tolerated or maximum administered dose. Three dose levels of enoblituzumab (3, 10, 15 mg/kg, IV, QW) have been evaluated in combination with pembrolizumab (2 mg/kg, IV, Q3W). No MTD has been identified, and so the maximum administered dose of enoblituzumab (15 mg/kg) in combination with pembrolizumab was given to additional cohorts of patients enrolled during the cohort expansion phase. The efficacy follow-up period consists of the two-year period after administering the final dose of the study drug. All tumor evaluations are carried out by both RECIST and irRC.

A total of 133 patients with B7-H3-expressing melanoma, squamous cell carcinoma of the head and neck (SCCHN), non-small cell lung cancer (“NSCLC”), and urothelial cancer have been treated in the study. The interim results as of the data cut-off date, October 12, 2018, were presented at the 2018 Annual Meeting of the Society for Immunotherapy of Cancer (SITC), which showed an acceptable safety profile and ORR (overall response rate) that compared favorably with historical experience with anti-PD-1 monotherapy in anti-PD-1/PD-L1 naive patients.

Safety. The combination of enoblituzumab and pembrolizumab demonstrated acceptable safety and tolerability in patients treated to date. Grade 3 or higher AEs occurred in 27.1% of all patients. Drug-related AEs of all grades included infusion-related reactions (n=73, 54.9%), fatigue (n=37, 27.8%), rash (n=14, 10.5%), and nausea (n=12, 9.0%). The incidence of immune-related AEs in the study was comparable to that observed in patients who received anti PD-1 monotherapy. Nine patients experienced drug-related AEs leading to treatment discontinuation. Drug-related AEs and immune-related AEs of special interest are summarized in the table below.

**Drug-Related and Immune-Related Adverse Events
During Combination Treatment with Enoblituzumab and Pembrolizumab**

Drug-Related AEs (35% of Patients)	No. (%) of Patients	
	All Grades Total (N=133)	³ Grade 3 (N=133)
Any adverse event	115 (86.5)	36 (27.1)
Infusion-related reaction	73 (54.9)	9 (6.8)
Fatigue	37 (27.8)	2 (1.5)
Rash	14 (10.5)	1 (0.8)
Nausea	12 (9.0)	0
Pyrexia	12 (9.0)	0
Lipase increased	11 (8.3)	8 (6.0)
Arthralgia	10 (7.5)	0
Decreased appetite	9 (6.8)	2 (1.5)
Diarrhea	9 (6.8)	1 (0.8)
Hypothyroidism	8 (6.0)	0
Anemia	7 (5.3)	1 (0.8)
Pneumonitis	7 (5.3)	2 (1.5)
Chills	7 (5.3)	0

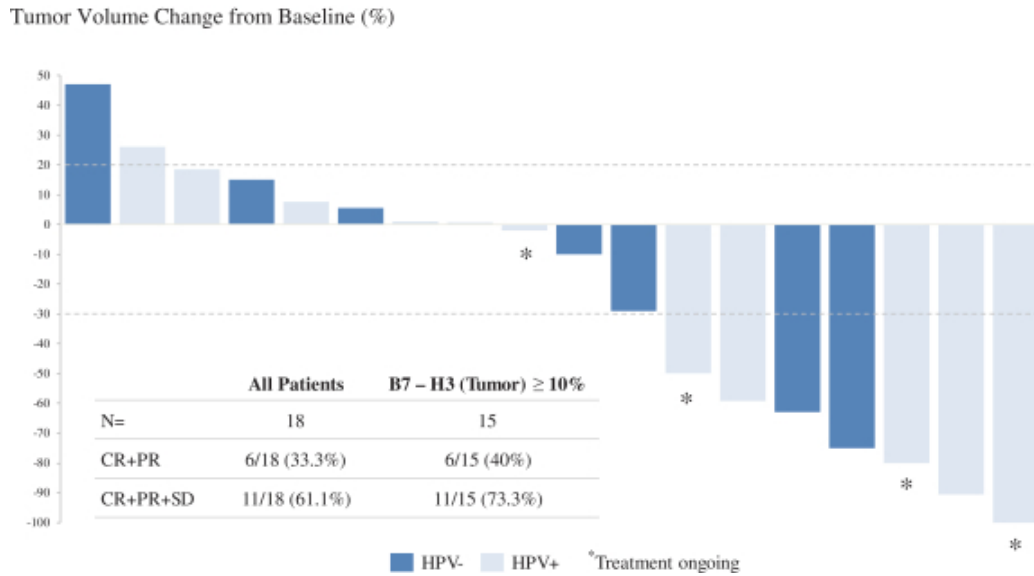
Immune-Related Adverse Events of Special Interest (AESI)	No. (%) of Patients	
	All Grades Total (N=133)	³ Grade 3 (N=133)
Pneumonitis	5 (3.8)	2 (1.5)
Myocarditis	2 (1.5)	1 (0.8)
Diarrhea	1 (0.8)	1 (0.8)
Adrenal insufficiency	1 (0.8)	1 (0.8)
Colitis	1 (0.8)	0

- Drug-related AEs:
 - Leading to treatment discontinuation: 6.8%
 - Leading to death: 0.8% (1 patient with pneumonitis)
- Nature of events consistent with enoblituzumab or pembrolizumab alone

Source: MacroGenics.

Clinical Efficacy. As of October 12, 2018, the cut-off date of the most recent data analysis, preliminary results indicated that among the 18 response-evaluable SCCHN patients who had not previously received PD-1/PD-L1 therapies, six patients (33.3%) had confirmed partial responses (“PRs”). Among the subset of patients with 10% or higher B7-H3 tumor expression, six out of 15 (40.0%) had confirmed PRs (see figure below) compared to previously reported SCCHN patients treated with PD-1 monotherapy, which achieved ORRs ranging from 13% to 16%.

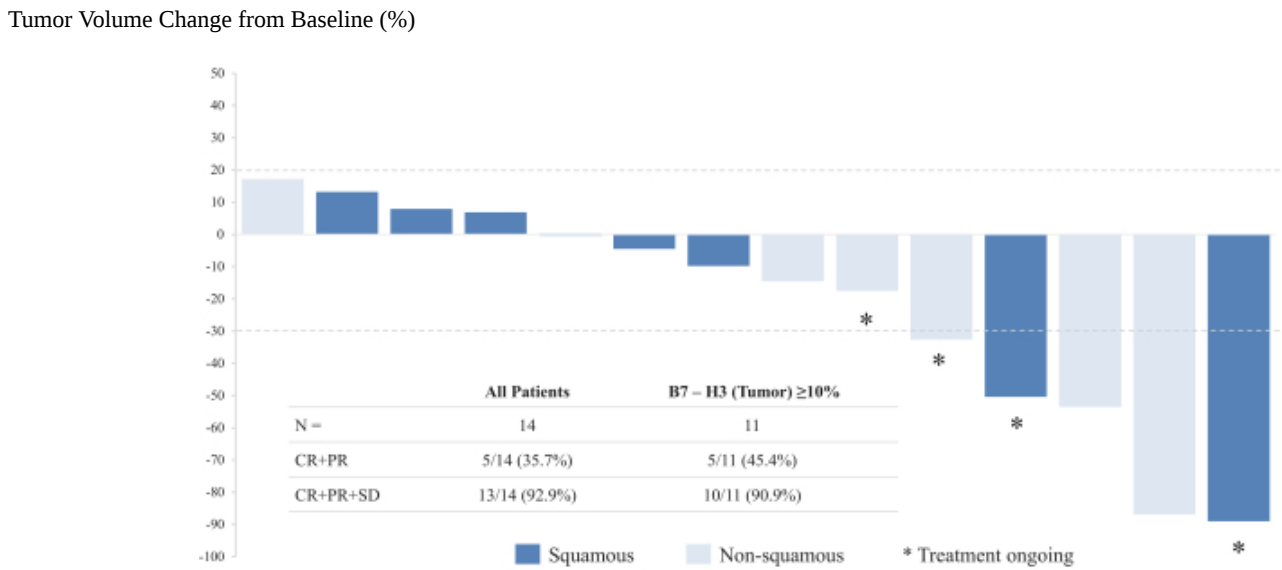
Antitumor Activity in Anti-PD-1/PD-L1-Naive SCCHN Patients



Source: MacroGenics

Among 14 response-evaluable NSCLC patients who had not previously received PD-1/PD-L1 therapies and were PD-L1 negative, i.e., PD-L1 less or equal to 1%, five patients (35.7%) had confirmed PRs (see figure below). Objective response rates ranging from 8% to 17% were reported in PD-L1 negative NSCLC patients treated with PD-1 monotherapy.

Efficacy in PD-1-Naive NSCLC Patients Who are PD-L1 Negative (PD-L1 < 1%)



Source: MacroGenics

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Clinical Development Plan

We plan to develop enoblituzumab as a combination therapy with a PD-1 antibody in a registrational clinical trial (pending regulatory approval by the NMPA) in patients with recurrent or metastatic SCCHN. The primary efficacy endpoint of this study will be objective response rate (ORR) performed by central review. In addition, we are planning to explore enoblituzumab development in a variety of B7-H3 expressing solid tumors. MacroGenics plans to combine enoblituzumab and a PD-1 antibody with and without chemotherapy in a two-part Phase 2 study for first-line treatment of patients with recurrent or metastatic SCCHN not curable by localized therapy.

Global Portfolio

TJM2: A GM-CSF Monoclonal Antibody for Rheumatoid Arthritis and CAR-T-related Therapies

Summary

TJM2 is an internally discovered neutralizing antibody against human granulocyte-macrophage colony-stimulating factor (“GM-CSF”), an important cytokine that plays a critical role in chronic inflammation and destruction in autoimmune diseases such as rheumatoid arthritis (“RA”). TJM2 is a humanized IgG1 that displays high affinity binding to GM-CSF and blocks its signaling and downstream effects. TJM2 is being developed for the treatment of autoimmune and inflammatory diseases, including RA, cytokine release syndrome (“CRS”) and neuroinflammation from CAR-T therapy. We will file an IND application with the NMPA for multiple-dose Phase 1 studies in Chinese patients with RA before expanding to other autoimmune and inflammatory indications with high unmet medical need, where GM-CSF is known as a pathogenic cytokine in disease activity and progression. TJM2 is expected to be the first compound of its class to enter the clinic in China in early 2020. If approved, it is expected to provide an effective treatment option as a disease-modifying anti-rheumatic drug (“DMARD”) therapy.

Therapeutic Options and Current Development

Our current therapeutic indication is RA, a systemic chronic inflammatory disease considered to be one of the most prevalent immune-mediated inflammatory diseases. RA is nearly always polyarticular and causes joint destruction, deformity, and loss of function. Extra-articular manifestations include cardiopulmonary diseases, eye diseases, Sjogren’s syndrome, rheumatoid vasculitis and neurological diseases. Current therapies for RA in China include traditional Chinese medicine, corticosteroids, and DMARDs, including immunosuppressants and targeted therapies such as TNF inhibitors. Although the market for RA has become more competitive in China, new medicines targeting different pathways with greater clinical efficacy and safety remain a significant unmet need. Our GM-CSF antibody targets an entirely different disease pathway and has these desired characteristics to treat RA.

Clinical evidence supporting the role of a GM-CSF antibody in RA is highlighted in a few recent global studies. For example, both otilimab (MOR103), a GM-CSF antibody from MorphoSys and GSK, and mavrilimumab, a GM-CSF receptor antibody from Medimmune, have shown an early onset of clinical responses and evidence of clinical efficacy in Phase 2 proof-of-concept trials with RA patients. In addition to RA, attempts to develop a GM-CSF antibody for treating other autoimmune diseases, such as ankylosing spondylitis, are being studied by Amgen and Takeda. These autoimmune conditions involve the same autoimmune cell types, including macrophages, and neutrophils and the same connective tissues such as bones, joints, and tendons. Given the large patient population affected and the burden of these diseases, we are keen to explore the therapeutic role of TJM2 in treating these diseases, if initial studies in RA patients meet primary end-points.

The therapeutic role of TJM2 goes beyond autoimmune diseases. A recent study indicates that GM-CSF plays a critical role in serious side effects associated with chimeric antigen receptor (CAR)-T therapy, such as cytokine release syndrome (“CRS”) and neurotoxicity. As CAR-T therapy has become an effective treatment

option for certain cancer types, finding a treatment solution for CAR-T-related toxicities that occur frequently and can turn into a serious and potentially fatal condition becomes an urgent need. These severe toxicities add to the morbidity and mortality of CAR-T therapy. CRS is caused by a massive release of circulating cytokines by expanding CAR-T cells, and GM-CSF is one of the key cytokines of CRS. Currently, there are no effective therapies to prevent CRS or neurotoxicity. Tocilizumab, an IL-6 receptor antagonist, is approved for severe CRS with limited therapeutic coverage. Recent studies indicate that neutralizing GM-CSF *in vivo* may ameliorate and potentially prevent CRS and neuroinflammation without affecting CAR-T cell activity. Humanigen recently teamed up with Kite to evaluate lenzilumab, a GM-CSF antibody, as a preventive or treatment agent in association with Yescarta, an approved CD19-directed CAR-T therapy. In parallel with an RA clinical trial, we are seeking opportunities to co-develop TJM2 as a treatment option for CRS associated with CAR-T therapy.

Advantages of TJM2

Based on reported clinical findings with front-runner GM-CSF antibodies compared to other RA biologics that are clinically used, we have the following expectations:

- *Fast onset of therapeutic effect.* Because GM-CSF acts at a relatively early stage in the inflammatory cascade, GM-CSF blockade is expected to take effect after just a few initial doses and provide quick symptomatic relief to patients. This early onset of therapeutic effect in RA has been shown in Phase 2 clinical trials on otilimab and mavrilimumab (NCT01023256 and NCT01050998);
- *Convenience and increased patient compliance.* Given the favorable development profile (high affinity, excellent PK, clean immunogenicity and concentrated formulation) exhibited by TJM2 thus far, the clinically efficacious dose for TJM2 is expected to be low, which is advantageous for chronic maintenance of the disease by subcutaneous administration. This provides convenience to the patients and will likely increase patient compliance; and
- *Analgesic effect on inflammatory pain.* Because the GM-CSF receptor is also expressed on sensory neurons and is involved in RA-associated inflammatory pain, GM-CSF blockade is expected to provide relief for inflammatory pain, which provides additional clinical benefits to patients. This analgesic effect has been demonstrated in a Phase 2 clinical trial on mavrilimumab (NCT01706926).

Mechanism of Action

GM-CSF is a central driver cytokine in orchestrating an innate immune response during inflammation. It is responsible for myeloid cell proliferation and functions, such as chemotaxis, adhesion, phagocytosis, and microbial killing. Importantly, GM-CSF can polarize macrophages into a pro-inflammatory M1 phenotype and is known to induce an inflammatory cascade involving other pro-inflammatory cytokines such as TNF, IL-1, IL-6, IL-12, and IL-23. It is evident that GM-CSF plays a crucial role in the pathogenesis and disease progression of multiple autoimmune conditions. The action of GM-CSF is mediated by binding of its cognate receptor on target cells and subsequent phosphorylation of signal transducer and activator of transcription 5 (“STAT5”).

TJM2 specifically binds to human GM-CSF with high affinity and can block GM-CSF from binding to its receptor, thereby preventing downstream signaling and target cell activation. As a result, it can effectively inhibit inflammatory responses mediated by macrophages, neutrophils, and dendritic cells, leading to reduced tissue inflammation and damage.

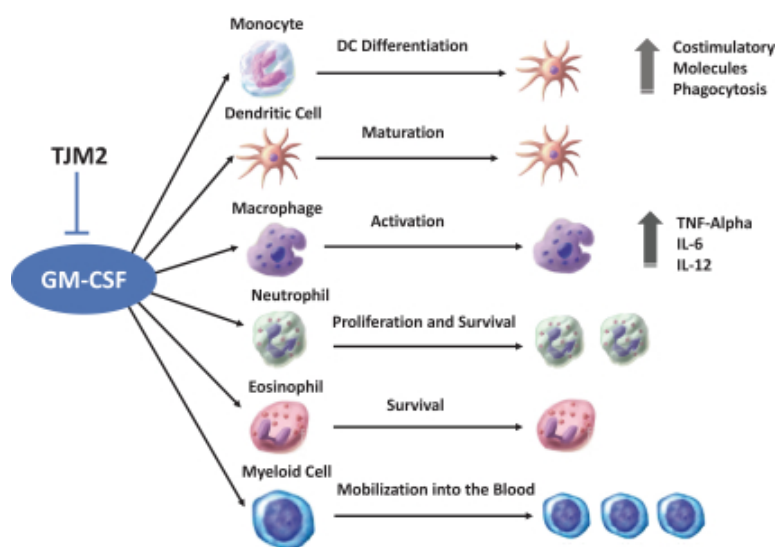


Figure: Role of GM-CSF in orchestrating coordinated immune response.

Summary of Pre-clinical Results

A series of nonclinical studies have been conducted to evaluate the pharmacology, PK, and toxicology profiles of TJM2. The completed pharmacology studies included evaluation of the binding affinity and specificity to GM-CSF, species cross-reactivity, blockade of GM-CSF/GM-CSFR interaction, inhibition on phosphorylation of STAT5 in peripheral blood mononuclear cells (“PBMCs”) from human or cynomolgus monkeys, and *in vivo* efficacy in monkey RA models. The PK profile of TJM2 in cynomolgus monkeys was characterized following a single IV injection and a single SC injection. Toxicokinetics (“TK”) was studied in conjunction with a GLP-compliant multilevel (0, 20, 60, 200 mg/kg) and four-week repeat-dose general toxicology study in cynomolgus monkeys. The no observed adverse effect level (“NOAEL”), which is the highest dosage level at which chronic exposure to the substance shows no adverse effects, was considered to be 60 mg/kg. The nonclinical studies performed to date have demonstrated an acceptable efficacy and safety profile to allow TJM2 to progress to clinical studies in healthy volunteers.

In Vitro Pharmacodynamics

TJM2 specifically binds to GM-CSF at sub-nanomolar affinity. TJM2 cross-reacts with monkey GM-CSF but not rat or murine GM-CSF. TJM2 inhibited GM-CSF-dependent proliferation of a human erythroleukemic cell line and GM-CSF-induced STAT5 phosphorylation in human PBMCs in a concentration-dependent manner. TJM2 demonstrated no hemolytic potential at a concentration of 105.5 mg/mL when incubated with rabbit blood cells.

Pharmacokinetics in Cynomolgus Monkeys

The systemic exposure in monkeys after a single IV injection of TJM2 appeared to increase proportionally with doses from 5, 25 to 50 mg/kg. The mean half-life was 217–241 hours, the mean maximum observed

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concentration (C_{max}) were 112–1220 $\mu\text{g}/\text{mL}$, and the mean exposure ($\text{AUC}_{0\text{-last}}$) were 14800–124000 $\mu\text{g}\cdot\text{h}/\text{mL}$ in the dose range of 5–50 mg/kg. TJM2 also exhibited linear PK behavior in terms of C_{max} (50.2–504 $\mu\text{g}/\text{mL}$) and AUC following a single subcutaneous (“SC”) injection at 5, 25 to 50 mg/kg, with the mean $T_{1/2}$ being 215–242 hours and the mean bioavailability ranging from 73 to 79%. No apparent sex difference was observed in main PK parameters. The elimination rate of TJM2 was independent of the dose route. ADAs were of low titers and detected only in one animal on two occasions, namely, before dosing and on Day 42 post-IV dose, which did not affect the PK profile. ADA was clean for the SC administration. These results indicate that TJM2 is not a strong immunogen to cynomolgus monkeys.

In Vivo Pharmacodynamics in Cynomolgus Monkeys

Type II collagen-induced arthritis (“CIA”) is a recognized animal model for RA, and drugs approved for RA have shown efficacy in this model. TJM2 was tested in a monkey CIA model. The animals were immunized with type II collagen to induce the disease. Once the animals exhibited signs of disease (joint swelling), weekly injections of vehicle control or 40 mg/kg TJM2 for four weeks were initiated. TJM2 significantly decreased the severity of CIA as measured by the arthritis score over the entire treatment period (see figure below) and inhibited STAT5 phosphorylation in monkey PBMCs 24 hours after treatment. In the second dose response experiment, TJM2 was found to reduce STAT5 phosphorylation in PBMCs from CIA monkeys obtained 24 hours after treatment across different dosing levels.

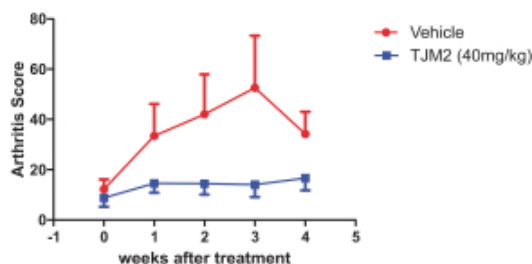


Figure: Weekly treatment with 40 mg/kg of TJM2 reduced disease severity (arthritis score) in a monkey CIA model.

Repeat-Dose Toxicology Study in Cynomolgus Monkeys

A GLP-compliant four-week repeat-dose toxicology study with a 30-day recovery was conducted in cynomolgus monkeys to evaluate the potential toxicity of TJM2. Forty cynomolgus monkeys were randomly assigned into four groups (5/sex/group) and were given five weekly doses of TJM2 at 20, 60 or 200 mg/kg via IV injection. Following the fourth dose, TK parameters, including time of maximum concentration (T_{max}), C_{max} , $\text{AUC}_{0\text{-t}}$, and clearance (CL), were similar to those following the first dose. No apparent sex difference was observed. All samples were detected as ADA-negative throughout the study period.

No TJM2-related death or moribund sacrifices occurred in this study. Pulmonary granulomas were observed in one male animal given 200 mg/kg dose, in which TJM2-relation could not be completely excluded. Minimal congestion and alveolar protein were observed in one male animal given 20 mg/kg dose during the recovery period, which had uncertain relation to TJM2 effect and was not considered adverse due to the lack of impact on respiratory functions and their absence in animals given higher doses of TJM2 or terminal sacrificed animals. Other than the above observations, TJM2 did not exhibit apparent impact on other study endpoints, including safety pharmacology parameters, immunotoxicity, especially cytokine production, or local effect on the injection sites.

Based on the study results, the NOAEL was considered to be 60 mg/kg. The corresponding mean C_{max} and $\text{AUC}_{0\text{-t}}$ following the fourth dose were 2010 $\mu\text{g}/\text{mL}$ and 117000 $\mu\text{g}\cdot\text{h}/\text{mL}$ for males, respectively, and 1930 $\mu\text{g}/\text{mL}$ and 119000 $\mu\text{g}\cdot\text{h}/\text{mL}$ for females, respectively.

Clinical Development Plan

Based on these pre-clinical results, we have initiated a first-in-human study in healthy volunteers in the United States. This randomized, double-blind, placebo-controlled, and single dose-ascending study (NCT03794180) is designed to assess the safety, tolerability, PK/PD, and immunogenicity of TJM2 (referred to as TJ003234) IV infusion. We have completed dosing of four planned cohorts. Data from this clinical trial will facilitate IND filing with the NMPA in China later this year for a multiple-dose Phase 1b/2a study in patients with RA, before expanding to other autoimmune and inflammatory conditions with a high unmet medical need. We also intend to investigate the efficacy of TJM2 in reducing or preventing CRS and neurotoxicity associated with CAR-T therapy through collaborations.

TJC4: A Potential Best-in-Class CD47 Antibody for Immuno-Oncology

Summary

TJC4 is a fully human CD47 monoclonal antibody that we have discovered and developed internally for cancer immunotherapy. CD47 has emerged as one of the most promising immuno-oncology targets. Unlike other immuno-oncology targets being explored, the CD47-SIRP α pathway is involved in tumor progression by delivering a “don’t eat me” signal to tumor-engulfing macrophages, thereby protecting tumors from natural attacks by macrophages. Blockade of this pathway by CD47 antibody represents one of the most effective tumor killing mechanisms. However, due to the inherent epitope sharing between tumor cells and normal red blood cells (“RBCs”), the first-wave of clinical stage CD47 antibodies were found in clinical trials to bind to RBCs and cause significant hematologic adverse effects, such as severe anemia, which has hampered the development of these CD47 antibodies as a potential cancer therapy.

We developed TJC4 by design to possess a unique property or differentiation, to minimize binding to RBCs while retaining anti-tumor activities in line with other antibodies of the same class. This key differentiation is achieved through additional RBC counter-screening to select rare antibody clones that bind to CD47 with high affinity but do not bind to or bind minimally to RBCs. TJC4 has been validated in a series of *in vitro* and *in vivo* pre-clinical studies, which have consistently shown a unique RBC-sparing profile comprised of minimal RBC binding, lack of hemagglutination and no significant adverse hematologic changes in cynomolgus monkeys even when used at a high dose (100 mg/kg). Our pre-clinical data thus far indicate that TJC4 is a potentially best-in-class anti-tumor CD47 antibody with the advantage of minimizing hematologic side effects. We have obtained the IND approval from the FDA and the NMPA, respectively. We have initiated a Phase 1 clinical trial in the United States to validate the safety profile, especially the hematologic profile, of TJC4 and to assess its pharmacokinetics, pharmacodynamics and early efficacy signals in cancer patients, and no anemia has been observed in the first cohort of patients so far. In parallel, leveraging the Phase 1 data generated in the United States, we plan to begin a Phase 1 clinical trial of TJC4 in acute myeloid leukemia (“AML”) patients in China by the end of 2019, followed by a separate clinical trial in non-Hodgkin’s lymphoma (“NHL”) patients in China.

Therapeutic Options and Current Development

We plan to evaluate the therapeutic role of TJC4 in a variety of solid tumors, such as cancers of the ovary, lung, liver, pancreas, breast and colon, and hematological malignancies such as AML, lymphoblastic leukemia, and NHL. Although PD-1/PD-L1 therapies represent a new paradigm in cancer treatment, less than 40% of cancer patients have a clinically meaningful response to PD-1/PD-L1 treatment. As a result, targeting other immune components or cells involved in the immune system’s anti-tumor mechanism has become an area of hot pursuit in the field of immuno-oncology. TJC4 is one such innovative and promising therapeutic antibody, which is capable of mobilizing macrophage functions for effective and direct tumor-killing. Currently, a number of CD47 antibodies are in clinical development by Forty-Seven, Inc., Celgene, Surface Oncology and Arch Oncology. The most advanced asset, 5F9 from Forty-Seven, Inc., is in Phase 2 clinical studies for multiple cancer indications. However, almost all clinical trials with CD47 antibodies so far have shown significant hematologic adverse effects, presumably due to inherent RBC-binding properties of generic CD47 antibodies, and as a result, some clinical studies had to be terminated.

Advantages of TJC4

TJC4 has similar nanomolar binding affinity as other CD47 antibodies and exhibits comparable anti-tumor activity. The key advantage of TJC4 is its minimal binding to RBCs, thus potentially avoiding or minimizing inherent hematologic adverse effects typically seen in other CD47 antibodies in clinical trials. This differentiated property of TJC4 is due to its unique epitope interaction as revealed by crystallography, which appears different from those recognized by other CD47 antibodies currently in clinical development. The differentiation of TJC4 is highlighted in a series of pre-clinical studies summarized as the following: (i) TJC4 displays only minimal RBC-binding even at high antibody concentrations by flow cytometry; (ii) TJC4 does not induce RBC agglutination even in a high dose range; and (iii) most importantly, TJC4 does not cause significant hematologic changes or systemic toxicologic effects even at high doses in multiple cynomolgus monkey studies, including a pivotal 4-week GLP toxicity study. Taken together, TJC4 has a potentially better clinical safety profile and can be used at higher doses to explore its true efficacy compared to other clinical stage competitor molecules.

Mechanism of Action

TJC4 blocks the interaction between CD47 expressed on cancer cells and SIRP α expressed on macrophages, leading to increased phagocytosis of cancer cells by macrophages. In addition to stimulating the phagocytosis of cancer cells, CD47 blockade was shown to support other anti-tumor mechanisms, such as the enhancement of ADCC, direct induction of apoptosis (programmed cell death) of cancer cells by CD47 cross-linking, induction of differentiation of cancer stem cells, and inhibition of metastasis. Blockade of CD47 by TJC4 may also promote the development of anti-tumor T cell responses, resulting from increased tumor antigen presentation by professional antigen-presenting cells such as macrophages and dendritic cells.

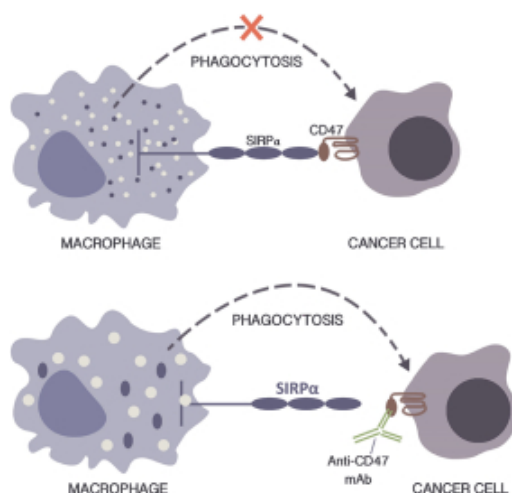


Figure: Targeting the CD47/SIRP α myeloid-specific immune checkpoint. CD47 is highly expressed on many different types of cancers. SIRP α is an inhibitory receptor expressed on macrophages and other myeloid immune cells. When CD47 binds to SIRP α , it causes the inhibition of phagocytosis. CD47 antibodies disrupt the CD47/SIRP α axis and enable the phagocytosis of cancer cells.

Summary of Pre-clinical Results

CD47-related In Vitro and In Vivo Anti-tumor Activities

TJC4 exhibits high-affinity binding to human CD47 protein and CD47-expressing tumor cells at the nanomolar level and effectively blocks interaction of CD47 with its receptor SIRP α . As compared with other

CD47 antibodies currently under clinical development, TJC4 demonstrated comparable potency in the enhanced macrophage-mediated phagocytosis of Raji tumor cells (see Figure A below) and comparable anti-tumor efficacy in the HL-60 leukemia and Raji xenograft models (see Figure B below). Moreover, when combined with rituximab, TJC4 exhibited a markedly enhanced inhibition on tumor growth in a diffuse large B cell lymphoma (DLBCL) animal model, through the synergistic effect of both agents (see Figure C below).

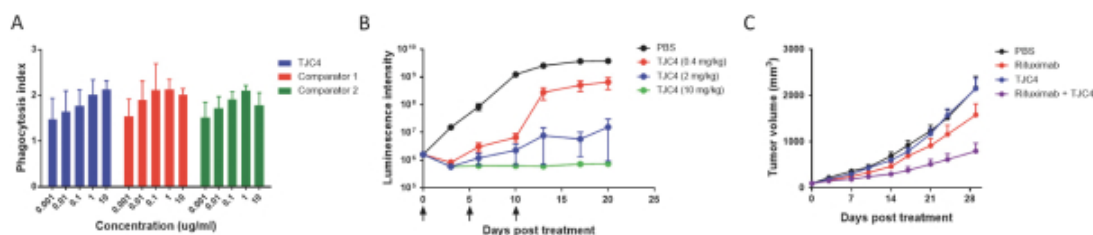


Figure: *In vitro and in vivo anti-tumor efficacy of TJC4. (A) In vitro phagocytosis of Raji cells by primary human macrophages in the presence of different doses of TJC4 or comparator CD47 antibodies. (B) In vivo efficacy of TJC4 mono-treatment in Raji xenograft model. (C) In vivo efficacy of TJC4 (5 mg/kg, BIW) in combination with Rituximab (5 mg/kg, BIW) in the DLBCL model.*

Assessment of Potential CD47-related In Vitro and In Vivo Hematologic Effects

First, in a representative flow cytometric analysis (see Figure A below), TJC4 showed minimal binding to human RBCs compared to comparator CD47 antibodies used at the same concentration (1 µg/ml). The minimal binding of TJC4 to RBCs was confirmed when compared with other CD47 antibodies across multiple concentrations in another flow cytometric experiment (see Figure B below).

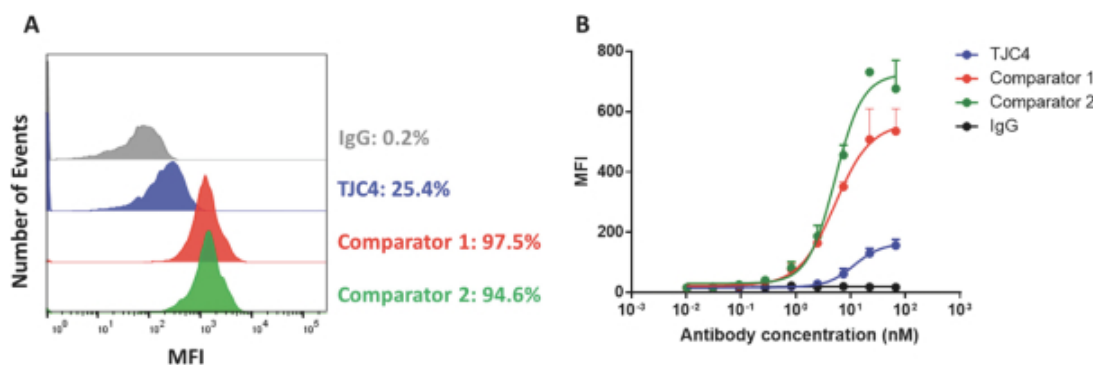


Figure: *Binding of CD47 monoclonal antibodies to RBCs. (A) Representative graph of the staining of human RBCs with CD47 monoclonal antibodies or control IgG (1 µg/ml); (B) Dose dependent binding of CD47 monoclonal antibodies with human RBCs from different healthy donors (n = 3). MFI: mean fluorescence intensity.*

Second, as CD47 is expressed on normal RBCs, binding of CD47 antibodies to the surface of RBCs could cross-link the RBCs into lattices and prevent them from precipitating into compact pellets, which is a phenomenon termed hemagglutination. Our results showed that TJC4 did not induce RBC agglutination across a wide range of antibody concentrations, while a comparator antibody caused significant hemagglutination starting at a concentration of 0.3 µg/ml. Results from a representative experiment are shown below.

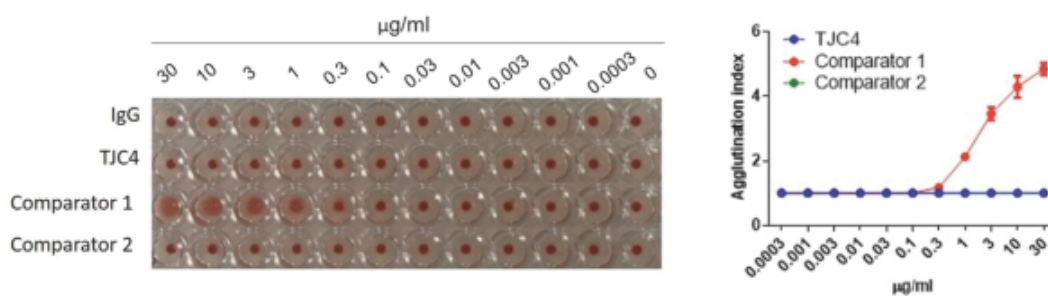


Figure: Hemagglutination by CD47 monoclonal antibodies. Left: representative graph of hemagglutination (haze appearance) or lack thereof (precipitate) by different concentrations of control IgG, TJC4, and comparator antibodies. Right: quantification through an index determined by the area of RBC occupation in the presence of the test antibodies, normalized to that of IgG control.

Thirdly, *in vivo* safety studies were performed in cynomolgus monkeys to assess the effects of TJC4 on the hematology parameters. Whereas a single bolus IV injection of the comparator antibody caused a significant drop in the number of RBCs and hemoglobin (“HGB”) levels, treatment with TJC4 at a dose of 10 mg/kg did not significantly affect the number of RBCs, HGB levels or reticulocyte or platelet counts (see figure below).

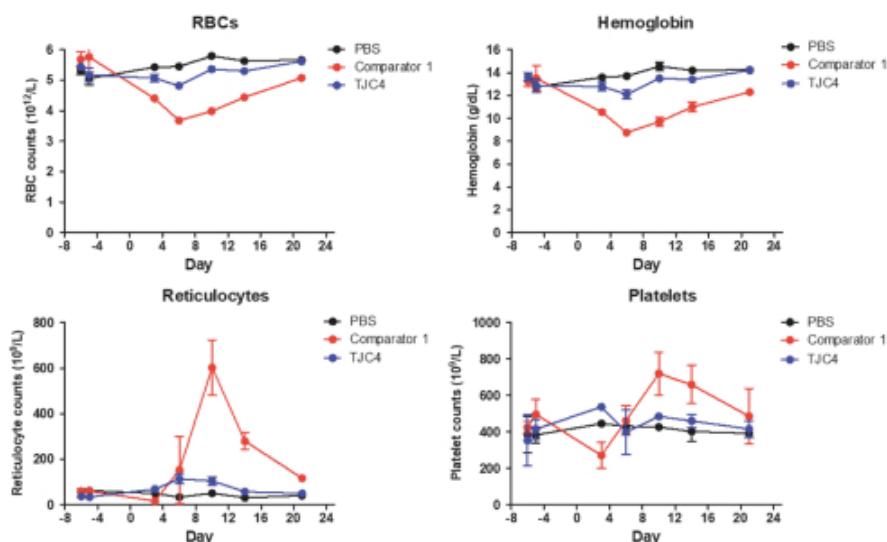


Figure: Hematological parameters in non-human primates treated with a single dose of CD47 antibodies. On Day 0, naive cynomolgus monkeys were IV injected with PBS control (n=2), TJC4 (n=2, 10 mg/kg) or a comparator antibody (n=2, 10 mg/kg). Blood cells were counted, twice before drug injection (baseline) and at 3, 6, 10, 14 and 21 days post-injection.

Moreover, in a four-week GLP toxicology study, TJC4 treatment did not induce significant overall toxicologic changes. Only mild decreases in the number of RBCs, HGB and hematocrit were found, which reached nadir at Day 4 post-first administration and then gradually recovered to the normal range following administration. The changes were not dose-dependent. Compared with the placebo control, the average decrease of RBCs in the treated animals was approximately 6% to 9% with only one animal showing an 18% drop at a dose of 30 mg/kg. No RBC-associated changes were noted in histopathologic examinations or in bone marrow smears (including erythrocytic series). Therefore, NOAEL was defined at 100 mg/kg.

Clinical Development Plan

We have recently initiated a Phase 1 clinical trial in patients with advanced cancer in the United States. The clinical trial (NCT03934814) is designed to assess the safety of TJC4 and, in particular, to validate the hematologic safety profile, including anemia and other potential changes of the hematologic parameters. The clinical trial includes typical dose escalation schemes up to 30 mg/kg and cohort expansions in cancer patients. In the same clinical trial, we also intend to evaluate the pharmacokinetics, pharmacodynamics and efficacy signals of TJC4 as a single agent and in combination with a PD-1 inhibitor or rituximab in patients with advanced solid tumors and relapsed or refractory lymphoma. The first cohort of patients have been dosed at 1 mg/kg and no anemia has been observed so far. In parallel, leveraging the Phase 1 data generated in the United States, we plan to begin a Phase 1 clinical trial of TJC4 in AML patients in China, followed by a separate clinical trial in NHL patients. The goals of our global and China clinical development plans are to (i) advance clinical development of TJC4 in NHL and AML towards registration, and (ii) explore TJC4's treatment efficacy in various solid tumors in combination with PD-1 therapies, including ovarian cancer, gastric cancer, hepatocellular carcinoma, renal cell carcinoma, NSCLC and urothelial carcinoma, in which CD47 is highly expressed.

TJD5: A Potential Best-in-Class CD73 Antibody for Cancer Treatment

Summary

TJD5 is an internally developed, humanized inhibitory antibody against human CD73. CD73 is a homodimeric enzyme expressed in tumors and plays a critical role in suppressing immune cells in tumor micro-environment. TJD5 displays sub-nanomolar binding affinity to CD73 and inhibits its nucleotidase activity. *In vitro*, TJD5 completely reversed the AMP- or tumor cell-mediated suppression of T cells. *In vivo*, when combined with a PD-L1 antibody, TJD5 exhibited a superior or synergistic inhibitory effect on tumor growth. The key differentiation of TJD5 when compared to some of the other clinical stage antibodies of the same class, is related to its novel epitope, which works through a unique intra-dimer binding mode, resulting in a complete inhibition of the enzymatic activity and avoiding the aberrant pharmacological property known as the "hook effect." With this particular mode of action, TJD5 has the potential to become a best-in-class CD73 antibody. We have initiated a Phase 1 clinical trial in cancer patients in partnership with TRACON Pharmaceuticals in the United States.

Therapeutic Options and Current Development

Despite recent breakthroughs with PD-1/PD-L1 therapies, clinical non-response rates to such treatments remains high in cancer patients (exceeding 60%). This non-responsiveness to these standard treatments is partly due to the fact that T cells within an inhibitory tumor environment are suppressed and fail to respond to stimulation induced by PD-1/PD-L1 therapies. CD73, which converts extracellular adenosine monophosphate ("AMP") to adenosine, is implicated in one of the protective mechanisms of tumors that evade immune attack by creating an adenosine-rich microenvironment inhibitory to immune cells. Pre-clinical studies have indicated that the inhibition of CD73 renders T cells more responsive to PD-1/PD-L1 therapies by altering the tumor micro-environment, resulting in a superior anti-tumor effect. As CD73 is widely expressed in various cancers, a combination therapy of TJD5 with a PD-1/PD-L1 antibody may increase the likelihood of treatment success in cancer patients who do not respond to standard PD-1/PD-L1 therapies. The potential cancer indications of TJD5 include thyroid cancer, lung cancer, colorectal cancer, stomach cancer, urothelial cancer, endometrial cancer, head and neck cancer, breast cancer, ovarian cancer, and melanoma, in which CD73 is widely expressed.

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A number of global companies are running active clinical development programs with CD73 antibodies. MEDI-9447 from Medimmune and BMS-986179 from Bristol-Myers Squibb are the two most advanced CD73 antibodies, which are in Phase 1/2 clinical trials. BMS-986179 is being studied as a single agent and in combination with nivolumab (a PD-1 antibody) for the treatment of advanced colorectal, esophageal, gastric, ovarian, and pancreatic cancers. MedImmune is testing MEDI-9447 for the treatment of solid tumors as a single agent or in combination with durvalumab (a PD-L1 antibody) or chemotherapy. NZV-930 (from Novartis) and CPI-006 (from Corvus) have entered Phase 1 clinical trials for the treatment of solid tumors.

Advantages of TJD5

Extracellular AMP can be generated from ATP, cyclic AMP and nicotinamide adenine dinucleotide (“NAD”) through separate biochemical pathways, all of which converge to CD73 to generate adenosine. Thus, CD73 antibody is expected to block adenosine generation more completely than other related pathways. Further, CD73 antibody works through a substrate non-competitive fashion and has advantages over small molecule inhibitors targeting the adenosine pathway through a substrate competing fashion. More importantly, TJD5 is potentially best-in-class among the clinical stage CD73 antibodies as it binds to a novel epitope in the C-terminal domain of CD73 without causing a “hook effect.”

TJD5 has the following key advantages: (i) TJD5 exhibits a typical dose-response curve without the “hook effect” and with a complete inhibition of both soluble and surface-bound CD73 and (ii) TJD5 has a non-competitive inhibitory effect that is not blunted by high levels of CD73 enzyme substrates, which would be expected for small-molecule competitive blockers. These pharmacological properties may translate into efficient target inhibition in tumors and superior anti-tumor activity, especially in an adenosine-rich micro-environment.

Mechanism of Action

Adenosine is a potent immunosuppressive signaling molecule abundant in the tumor microenvironment. CD73 is the rate-limiting enzyme that generates adenosine from extracellular AMP. TJD5 allosterically inhibits the CD73 enzyme by preventing the inactive CD73 dimer from changing into the active conformation in a substrate non-competitive manner. This results in a decrease in adenosine production in the tumor micro-environment, increasing T cell anti-tumor activity.

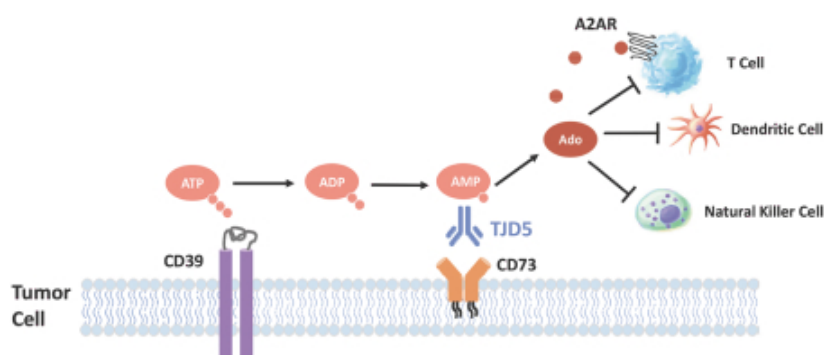


Figure: Schematic diagram of CD73-catalyzed adenosine (Ado) generation and immunosuppression by Ado in the tumor microenvironment.

Summary of Pre-clinical Results

Inhibition of CD73 by TJD5. As shown in the figure below, TJD5 displayed complete inhibition of soluble CD73 enzymatic activity (IC_{50} = 0.22 nM) without the “hook effect” in contrast to the comparator molecule,

which at higher concentrations caused a paradoxical rebound of enzymatic activity presumably due to its inter-dimer binding mode.

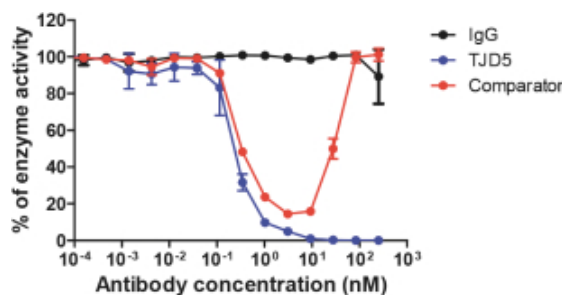


Figure: Inhibition of soluble CD73 enzymatic activity by CD73 antibodies.

Restoration of T Cell Activity by TJD5 In Vitro. We observed that AMP inhibited interferon gamma (IFN-g) production by CD4 or CD8 T cells through adenosine generation, mimicking the suppressive tumor microenvironment where AMP is abundantly produced. However, this suppression could be reversed by TJD5 in a concentration-dependent manner. Moreover, in an experimental system where CD73^{high} human ovarian cell line SK-OV-3 and human T cells were co-cultured, addition of TJD5 restored T cell activity as measured by IFN-g production in a concentration-dependent manner.

In Vivo Anti-tumor Efficacy of TJD5. TJD5 monotherapy showed a moderate anti-tumor effect in a mouse xenograft model bearing A375 melanoma cells. To examine whether TJD5 can enhance the anti-tumor activity of the PD-L1 antibody, we evaluated the therapeutic effects of TJD5 used as a single agent and in combination with a PD-L1 antibody in the same A375 melanoma model. The combination treatment group resulted in 68% inhibition of tumor growth which is significantly better than the vehicle and TJD5 monotherapy.

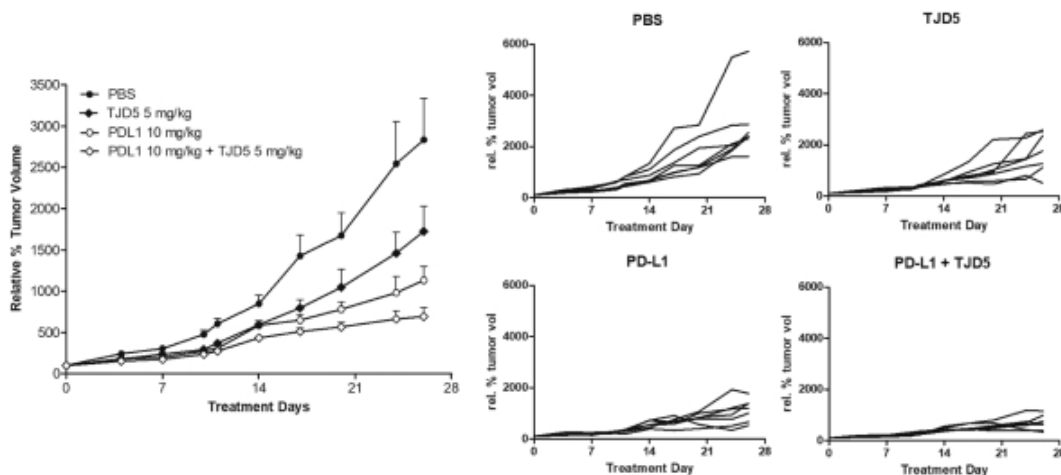


Figure: In vivo efficacy of TJD5 and anti-PD-L1 in A375 melanoma xenograft model. Mice were treated with PBS control, anti-PD-L1 (10 mg/kg), TJD5 (5 mg/kg) or a combination of anti-PD-L1 and TJD5 twice a week for three weeks. Tumor volumes as percentages relative to baseline (day 0) for each treated group (n=7 per group) (left) and for each individual mouse (right) were plotted.

Pharmacokinetics of TJD5 in Cynomolgus Monkeys. Following a single IV injection of TJD5 at 5, 25 and 50 mg/kg, the mean C_{max} ranged dose-proportionally from 136 to 1430 µg/mL, and the systemic exposure

indicated by the AUC_{0-last} increased in a non-linear manner, ranging from 4020 to 135000 hr*µg/mL. Mean half-life was 44.9 hours, 61.5 hours and 104 hours, respectively, reflecting decreased clearance of TJD5 with increasing dose. No apparent sex difference was observed in the main PK parameters. Positive ADAs against TJD5 were detected in the majority of the animals, without an apparent impact on systemic exposure.

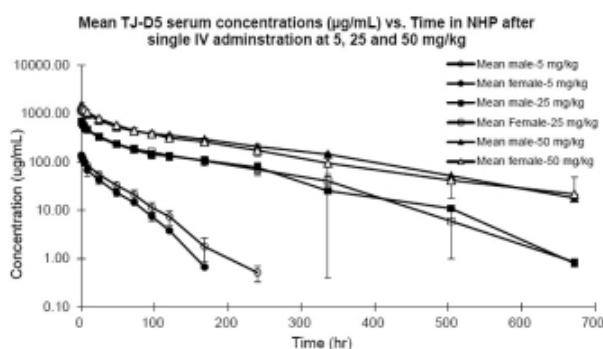


Figure: Concentration-profile of TJD5 in cynomolgus monkeys. time

Repeat-dose Toxicology Study of TJD5 in Cynomolgus Monkeys. A four-week GLP toxicity study was conducted in cynomolgus monkeys followed by a six-week recovery period to evaluate the potential toxicity of TJD5. Forty cynomolgus monkeys were randomly assigned into four groups (5/sex/group) and given five weekly doses of TJD5 at 20, 60 or 200 mg/kg via IV injection. Systemic exposures (C_{max} and AUC_{0-t}) generally increased dose-proportionately, and the Day 22 values were generally higher than those on Day 1, with mean accumulation ratios (AR) ranging between 1.65 and 2.19. No apparent sex difference was observed. Positive TJD5 antibodies were detected in the majority of animals following repeat administration at all doses, while no significant impact was observed on the TK profiles.

The only TJD5-related effect was decreased monocyte chemoattractant protein 1 (MCP-1) on Day 1 (24 or 48 hours post-dosing) in treated animals. Due to a lack of corresponding findings or impact on the well-being of the animals, this effect was not considered adverse. No abnormality was observed in other study endpoints, including safety pharmacology parameters and immunotoxicity. The no observed adverse effect level (NOAEL) was defined at 200 mg/kg. This dose level corresponded to the mean C_{max} and AUC values of 6890 µg/mL and 594000 µg*hr/mL in males, respectively, and 6450 µg/mL and 501000 µg*hr/mL in females, respectively, on Day 22 of the dosing phase.

Clinical Development Plan

The current clinical development plan is to develop TJD5 in the United States and China in parallel. In the United States, we have initiated a Phase 1 clinical trial in patients with advanced solid tumors in partnership with TRACON Pharmaceuticals, Inc., which will be responsible for conducting the clinical trial in the United States (TJD5 is referred to as TJ004309, NCT03835949). After determining the RP2D, the trial will enroll additional patients with advanced solid tumors to confirm tolerability and to explore preliminary efficacy of the combination therapy with atezolizumab. In China, we plan to begin a clinical trial to evaluate the safety, tolerability, PK/PD, and potential efficacy primarily in patients with lung cancer. An IND application was submitted to the NMPA in June 2019.

Pre-clinical Assets (Monoclonal antibodies)

TJ210 and TJX7 are monoclonal antibodies currently at the CMC stage, moving towards IND submission and clinical trials in the United States by 2020. Like the other assets in our Global Portfolio, both TJ210 and TJX7 have either first-in-class or best-in-class potential.

TJ210: A Potential Best-in-Class Antibody Targeting Myeloid Derived Suppressor Cells in Cancers and Autoimmune Diseases

TJ210 is a fully human, high affinity antibody against human C5aR1 for the treatment of cancers and potentially autoimmune diseases. Tumors produce large amounts of complement factor C5a to attract C5aR1-expressing myeloid derived suppressor cells (“MDSCs”), M2 macrophages and neutrophils. These myeloid cells critically contribute to an immunosuppressive microenvironment as part of the evading mechanism of tumors and are associated with poor prognosis and resistance to PD-1/PD-L1 therapies in many cancers. Inhibition of C5a or its receptor C5aR in mice leads to markedly reduced MDSCs and has an inhibitory effect on tumor growth in various tumor-bearing animal models. The C5aR-blocking antibody has been shown to have significant therapeutic efficacy when combined with PD-1 therapies in PD-1-resistant tumor models. TJ210 exerts strong anti-tumor activity by blocking the activation and migration of C5aR1-expressing myeloid cells and has best-in-class potential as it binds to a novel epitope and possesses superior functional properties. Compared to the only competitor antibody from Innate Pharma, TJ210 shows a more potent anti-tumor effect, especially when C5a concentrations are high, and binds to C5a receptors in both humans and monkeys, making pre-clinical safety assessment possible. In addition, TJ210 has therapeutic potential in multiple inflammatory and autoimmune indications, in which the role of the C5a/C5aR axis has been validated. We partnered with the original developer of TJ210, MorphoSys, for Greater China rights and shared global rights. TJ210 is progressing towards IND submission by 2020 in the United States, and we plan to work jointly with MorphoSys to develop this asset.

TJX7: A Potential First-in-Class CXCL13 Antibody for Autoimmune Diseases

TJX7 is an internally discovered, potentially first-in-class humanized neutralizing antibody targeting the CXCL13 chemokine. CXCL13, through its receptor CXCR5, plays a key role in forming germinal centers, which are critical for immune response. The role of CXCL13 in forming germinal centers is to guide the migration of germinal center B cells and follicular T cells within the lymphoid organs and facilitate their interaction, maturation and function. One of the key pathogenic features in autoimmune diseases is related to the aberrant formation of ectopic germinal centers formed in affected organs, contributing to chronic inflammation and tissue destruction. Elevated serum CXCL13 levels, CXCR5-expressing T cells and pathogenic germinal center B cells and even ectopic germinal center formation are found in multiple autoimmune diseases, including Sjögren’s syndrome, RA, multiple sclerosis, and SLE. TJX7 is being developed for the treatment of autoimmune disorders and has been shown to bind to CXCL13 with sub-nanomolar affinity, effectively blocking the interaction between CXCL13 and CXCR5 and the downstream signaling. TJX7 has been shown to completely inhibit the migration of primary human tonsil B cells. Pharmacodynamic studies in mice and cynomolgus monkeys have confirmed TJX7’s inhibitory effects on germinal center formation and antibody production. Results generated so far indicate that TJX7 may provide a new therapeutic angle in the treatment of autoimmune diseases as it acts uniquely at the core of tissue pathologies. TJX7 is currently under CMC and pre-clinical development.

Pre-clinical Assets (Bi-Specific Antibody Panel)

PD-L1-based Bi-specific Antibodies. As previously discussed, this panel of PD-L1-based bi-specific antibodies is designed according to the scientific rationale that a PD-L1 antibody, when engineered with a selected second immune component such as a cytokine or another antibody, is able to convert “cold tumors,” which typically do not respond to PD-1/PD-L1 inhibitors, to “hot tumors,” which are more sensitive to PD-1/PD-L1 therapies. Such PD-L1-based bi-specific antibodies are expected to increase the probability of treatment success in patients who do not respond to PD-1/PD-L1 treatment. Based on this concept, we have generated a panel of bi-specific antibodies using our proprietary PD-L1 antibody sequence as the backbone (the first signal), linked to a second component (the second signal) of selected immune properties. The second signals for this panel of bi-specific antibodies include IL-7 cytokine (expanding T effector cells), 4-1BB and B7-H3 antibodies (activating T cells synergistically with PD-L1), CD47 antibody (adding the macrophage killing mechanism) and CD73 antibody (altering tumor microenvironment). We strive to validate all bi-specific antibodies through a series of robust *in vitro* and *in vivo* studies for proof-of-concept, thus providing a solid basis

for further development. Collectively, we have demonstrated that the second paired component must be structurally integrated with the tumor-engaging anti-PD-L1 backbone to concentrate and function effectively inside tumors, which cannot be achieved by simply combining two free agents.

“Fortified” Bi-specific Antibodies for Specific Cancer Therapeutic Purposes. TJ-C4GM is a “fortified” version of the CD47 antibody, which is specifically designed for the treatment of solid tumors through the CD47-mediated macrophage killing mechanism. As the majority of tumor-associated macrophages adopt an anti-inflammatory and tumor-promoting M2 phenotype rather than a pro-inflammatory M1 phenotype, they are less efficient in phagocytosis in response to CD47 blockade. Thus, treatment of solid tumors with the CD47 antibody may exhibit limited efficacy. TJ-C4GM is a novel molecule composed of TJC4 with an engineered GM-CSF moiety fused at the C-terminus of the antibody heavy chain. GM-CSF is a potent cytokine known to convert tumor-resident M2 macrophages into tumor-engulfing M1 macrophages, which enables TJ-C4GM to exert a better phagocytic effect in solid tumors. These unique functional properties of TJ-C4GM are confirmed in a series of *in vitro* and *in vivo* tumor animal models, in which TJ-C4GM exerts superior anti-tumor activity against solid tumors, which cannot be achieved by TJC4 or GM-CSF used either alone or in combination. TJ-C4GM is currently at the CMC and pre-clinical development stage.

TJ-CLDN4B is a bi-specific antibody targeting both Claudin18.2 (CLDN18.2), a tumor antigen preferentially expressed in gastric and pancreatic cancers, and 4-1BB, a co-stimulatory molecule on T cells. CLDN18.2 is a tight junction molecule normally expressed only on epithelial cells of the gastric mucosa, which is inaccessible by antibodies under normal conditions, making it a highly attractive tumor target. Although a CLDN18.2 monoclonal antibody (claudiximab) showed good efficacy in a Phase 2 trial, only the CLDN18.2 high-expressing tumors seemed to be susceptible. In collaboration with ABL Bio, we developed a bi-specific antibody, TJ-CLDN4B, which provides two key advantages over current CLDN18.2 antibodies and 4-1BB agonistic antibodies. First, TJ-CLDN4B is capable of binding to tumor cells even with low levels of CLDN18.2 expression, making it more suitable for a broader patient population. Second, only upon tumor cell engagement by TJ-CLDN4B are T cells activated. In contrast, other pan-activating 4-1BB antibodies that activate T cells regardless of tumor engagement are prone to liver toxicity as seen in clinical studies. In a humanized mouse model, TJ-CLDN4B suppressed tumor growth to a greater extent than anti-CLDN18.2 or anti-4-1BB alone or in combination. TJ-CLDN4B is currently at the CMC and pre-clinical development stage.

Licensing and Collaboration Arrangements

A. In-Licensing Arrangements

Licensing Agreement with MorphoSys (MOR202/TJ202)

In November 2017, we entered into a license and collaboration agreement with MorphoSys AG (“MorphoSys”) with respect to the development and commercialization of MOR202/TJ202, MorphoSys’s proprietary investigational antibody against CD38 (the “CD38 product”).

Under this agreement, MorphoSys granted to us an exclusive, royalty-bearing, sublicensable license to exploit MOR202/TJ202 for any human therapeutic or diagnostic purpose in the licensed territory, namely Greater China.

Pursuant to this agreement, we granted to MorphoSys an exclusive license to our rights in any inventions that we make while exploiting MOR202/TJ202 under this agreement, solely to exploit MOR202/TJ202 outside of Greater China.

We also received the right to sublicense to affiliates and third parties acting as contract manufacturers, contract research organizations, distributors or wholesalers without prior written consent, as well as the right to sublicense to other third parties with the prior written consent of MorphoSys, not to be unreasonably withheld, delayed or conditioned.

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We are solely responsible for the development and commercialization of MOR202/TJ202 in Greater China, and must use commercially reasonable efforts as we develop and commercialize MOR202/TJ202.

Pursuant to this agreement, we paid to MorphoSys an upfront license fee of US\$20.0 million. We also agreed to make milestone payments to MorphoSys, conditioned upon the achievement of certain development, regulatory and commercial milestones, in the aggregate amount of US\$98.5 million. Such milestones include first patient dosed in human clinical trials, marketing approval, and first annual net sales of CD38 products covered by the agreement in excess of a certain amount.

In addition, we are required to pay tiered -double-digit royalties to MorphoSys on a country-by-country and product-by-product basis during the term, commencing with the first commercial sale of a relevant licensed product in Greater China. The end of the royalty term is linked to (i) the expiration, invalidation or abandonment of relevant patent claims, (ii) a defined number of years from the date of first commercial sale of such CD38 product, and (iii) marketing exclusivity for such relevant licensed product. Unless terminated earlier in accordance with the terms thereof, this agreement will remain in effect until the expiration of our last payment obligation under the agreement.

Assignment and License Agreement with Genexine (TJ101)

In October 2015, I-Mab Bio-tech Tianjin Co., Ltd., known as Tasgen Bio-tech (Tianjin) Co., Ltd. at the time (which subsequently became our subsidiary following the Acquisition) (“I-Mab Tianjin”), entered into an intellectual property assignment and license agreement with Genexine, Inc. (“Genexine”), further amended in December 2017, with respect to four licensed products, namely GX-H9 (TJ101), GX-G3 (TJ102), GX-G8 and GX-P2 and one assigned product, GX-G6 (TJ103). Under this agreement, Genexine (i) granted to I-Mab Tianjin an exclusive, non-transferable, sublicensable license to use and otherwise exploit certain intellectual property to engage in pre-clinical and clinical development, manufacturing, sale and distribution of the above-mentioned licensed products for (A) the treatment of any disease with respect to GX-H9 and GX-G3 in China (which, for clarity excludes, Hong Kong, Macau and Taiwan), (B) the treatment of chemically induced diarrhea, with respect to GX-G8 anywhere in the world and (C) the treatment of rheumatoid arthritis and lupus (not including psoriasis) with respect to GX-P2 anywhere in the world and further (ii) assigned to I-Mab Tianjin a certain Chinese patent and related know-how related to the assigned product (TJ103) and granted I-Mab Tianjin an exclusive license to exploit the assigned intellectual property to engage in pre-clinical and clinical development, manufacturing, sale and distribution of the assigned product (TJ103) for the treatment of any disease in China (which, for clarity, excludes Hong Kong, Macau and Taiwan). I-Mab Tianjin will also receive an exclusive license to any improvements that Genexine develops or acquires related to any of the aforementioned products.

Under this agreement, I-Mab Tianjin paid an aggregate upfront license fee of US\$13.0 million in relation to the patents, patent applications, know-how, data and information in connection with the four licensed products and a purchase fee of US\$7.0 million in connection with the assigned product (TJ103). I-Mab Tianjin also agreed to make certain milestone payments, including milestone payments in the aggregate amount of US\$40.0 million for GX-H9, US\$25.0 million for TJ103 and US\$15.0 million for GX-G3, conditioned upon the achievement of certain net sales targets.

The term of this agreement is 30 years unless terminated earlier in accordance with the terms thereof. During the term of this agreement, if I-Mab Tianjin develops or acquires any improvement, modification or alteration to the licensed products, I-Mab Tianjin will become the sole legal owner of such improvements, modifications and alterations and has full power, right and authority to grant licenses or transfer ownership of the same. I-Mab Tianjin is required to promptly notify Genexine in writing giving details of any such improvements, modifications or alterations and provide Genexine with such explanations or trainings to enable Genexine to legally and effectively use the same. Additionally, I-Mab Tianjin shall grant to Genexine a fully paid up, royalty-free, exclusive license to use any such improvements, modifications and alterations anywhere outside of the territory for which I-Mab Tianjin is licensed under this agreement.

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Licensing Agreement with Genexine (GX-I7/TJ107)

In December 2017, we entered into an intellectual property license agreement with Genexine with respect to GX-I7, a long-acting IL-7 cytokine. Under this agreement, Genexine granted to us an exclusive, sublicensable and transferable license to use and otherwise exploit certain intellectual property (including improvements subsequently developed or acquired by Genexine) in connection with the pre-clinical and clinical development, manufacturing, sale and distribution of GX-I7 to treat cancers in the field of oncology in China, Hong Kong, Macau and Taiwan.

Under this agreement, we paid an upfront license fee of US\$12.0 million to Genexine. We also agreed to make milestone payments in the aggregate amount of US\$23.0 million, conditioned upon the achievement of certain development milestones, including completion of Phase 2 and Phase 3 clinical studies and NDA or BLA approval in any of China, Hong Kong, Macau or Taiwan.

Further, we agreed to make milestone payments in the aggregate amount of US\$525.0 million, conditioned upon the achievement of certain cumulative net sales of GX-I7 up to US\$2,000 million. We also are required to pay Genexine a low-single-digit percentage royalty in respect of the total annual net sales of GX-I7. The aforesaid milestones and royalties (other than the upfront payment) will be reduced by 50% following the entry of a generic version of GX-I7 in China, Hong Kong, Macau and Taiwan without the consent or authorization of us or any of our sublicensees.

Unless terminated earlier in accordance with the terms thereof, this agreement will remain in effect until the later of (i) the expiry of the last to expire patent of the licensed intellectual property that includes a valid claim for China, Hong Kong, Macau or Taiwan, and that covers the composition of GX-I7; and (ii) 15 years from the date of the first commercial sale of GX-I7.

During the term of this agreement, if we develop or acquire any improvement, modification or alteration to the licensed product, we will own such improvements, modifications or alterations and provide Genexine details thereof, whether patentable or not. Additionally, we shall grant to Genexine a fully paid up, royalty-free, exclusive license (with a right to sublicense) to use any such improvements, modifications or alterations anywhere outside of China, Hong Kong, Macau and Taiwan.

Licensing Agreement with Ferring (TJ301)

In November 2016, we entered into a license and sublicense agreement with Ferring International Center SA (“Ferring”) with respect to (i) FE301, an interleukin-6 inhibitor, and (ii) all pharmaceutical formulations in finished packaged form containing FE301 covered by certain patents or patent applications. Under this agreement, Ferring granted to us an exclusive, sublicensable license (excluding any non-exclusive license that Ferring granted to Conaris Research Institute AG under a licensing agreement entered into in November 2008) under certain Ferring intellectual property to research, develop, make, have made, import, use, sell and offer to sell FE301 (and the licensed products containing FE301) in China, Hong Kong, Macau, Taiwan and South Korea. We also have an option to receive an exclusive, sublicensable license under certain Ferring intellectual property to research, develop, make, have made, import, use, sell and offer to sell FE301 (and the licensed products containing FE301) in the countries in North America, the European Union and Japan that are mutually agreed upon by the parties.

We are required to use commercially reasonable efforts to obtain approval of FE301 and to promote, market, distribute and sell it in China, Hong Kong, Macau, Taiwan, and South Korea. Such activities are to be at our own cost and expense.

Under this agreement, we paid to Ferring an upfront license fee of US\$2.0 million. We also agreed to make milestone payments to Ferring, in the aggregate amount of US\$14.5 million, conditioned on the achievement of

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certain development milestones in the licensed territory, including completion of Phase 1b and Phase 2a clinical studies and the submission and approval of the new drug application. Further, if we exercise our option to receive a license in any of the mutually agreed upon countries in North America, the European Union and Japan, we are required to pay to Ferring an additional US\$3.0 million as an upfront license fee (upon the exercise of the option), and milestone fees up to the aggregate amount of US\$30.0 million, conditioned upon the licensed product achieving certain development milestones in certain countries in the option territory.

In addition, we agreed to pay Ferring tiered royalties ranging from the mid-single-digit to high-single-digit percentages of annual net sales for countries in China, Hong Kong, Macau, Taiwan, and South Korea, and from the high-single-digits to 10% of annual net sales for the mutually agreed upon countries in North America, the European Union and Japan.

The royalty term commences with the first commercial sale of the licensed product in the relevant country and ends upon the later of (i) 15 years from the date of launch, and (ii) the expiry of the last to expire patent of Ferring that includes a valid claim covering the development, making, using or selling of the licensed compound or licensed product in the licensed territory and/or option territory. Unless terminated earlier in accordance with the terms thereof, this agreement will remain in effect until the later of the expiry of the royalty term, and the first date on which we are not conducting any necessary and outstanding clinical study with respect to the licensed product or seeking to obtain any necessary and pending regulatory approval for the licensed product, if applicable.

During the term of the licensing agreement, if we develop or acquire any improvement, modification, enhancement or addition to the licensed product, we will own and retain all rights, title and interest therein, and grant to Ferring a non-exclusive, fully paid, royalty-free, worldwide license thereto.

Collaboration Agreement with MacroGenics (enoblituzumab)

In July 2019, we entered into a license and collaboration agreement with MacroGenics, Inc. for development and commercialization of an Fc-optimized antibody known as enoblituzumab that targets B7-H3, including in combination with other agents, such as the anti-PD-1 antibody known as MGA012, in the People's Republic of China, Hong Kong, Macau and Taiwan.

Under this agreement, MacroGenics granted to us an exclusive, sublicenseable, royalty-bearing license to MacroGenics' patents and know-how to develop and commercialize the enoblituzumab product, and a combination regimen of enoblituzumab and MGA012, in Greater China during the term of the agreement.

In exchange for these rights, in addition to certain financial consideration, we granted to MacroGenics a royalty-free, sublicenseable, license outside of Greater China, to our patents and know-how that are related to the enoblituzumab product or useful or necessary for MacroGenics to develop or commercialize the enoblituzumab product or a product containing MGA012, and combinations thereof. The license is (i) non-exclusive with respect to the enoblituzumab product, and (ii) exclusive with regard to MGA012.

Where co-ownership is possible, we will co-own all clinical data generated pursuant to this agreement in any clinical trial conducted solely in Greater China, and marketing approval in Greater China to the extent not required for MacroGenics to maintain marketing approvals in China as part of its globally developed enoblituzumab portfolio. MacroGenics will solely and exclusively own all other clinical data generated pursuant to this agreement.

Additionally, we will pay MacroGenics an up-front payment of US\$15.0 million. We also agreed to pay MacroGenics development and regulatory milestone fees of up to US\$135.0 million and tiered double-digit royalties (ranging from mid-teens to twenty percent) based on annual net sales in the territories.

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We are responsible for, and must use commercially reasonable efforts, to develop and commercialize the enoblituzumab product (which includes the enoblituzumab product in combination with MGA012) in Greater China. This includes conducting all clinical studies required for approval, participating in a planned, global Phase 3 trial (or another mutually agreeable global clinical trial) of the enoblituzumab combination product, the conduct of at least two Phase 2 or Phase 3 trials each targeting B7-H3 expressing patient populations, and submissions to regulatory authorities in Greater China. MacroGenics is responsible for, and must use commercially reasonable efforts to, develop and commercialize the enoblituzumab product (which includes the enoblituzumab product in combination with MGA012) in the rest of the world.

We are responsible for all development costs in Greater China. MacroGenics is responsible for all development costs in the rest of the world, except that we are responsible for 20% of the costs incurred in (i) activities supporting global clinical trials in which we participate, (ii) certain CMC activities for material intended to be used in clinical trials in Greater China, and (iii) companion diagnostic development and validation for indications being studied in Greater China.

Unless terminated earlier in accordance with the terms thereof, this agreement will remain in effect, on a country-by-country and region-by-region basis, until the later of (i) the twelfth (12th) anniversary of the first commercial sale of an enoblituzumab product in such country or region, (ii) the expiration the last-to-expire MacroGenics patent licensed under this agreement, and (iii) the expiration of the latest data exclusivity period for the enoblituzumab product in such country or region.

Other In-Licensing Arrangements

In November 2018, we entered into a license and collaboration agreement with MorphoSys for MorphoSys's proprietary antibody (MOR210/TJ210) directed against C5aR (the "C5aR Agreement"). Under this agreement, MorphoSys granted to us an exclusive, royalty-bearing license to explore, develop and commercialize MOR210/TJ210 in Greater China and South Korea. I-Mab will perform and fund all global development activities related to the development of MOR210/TJ210 in Greater China and South Korea, including all relevant clinical trials (including in the U.S. and China) and all development activities required for IND filing in the US as well as CMC development of manufacturing processes. MorphoSys retains rights in respect of development and commercialization of MOR210/TJ210 in the rest of the world. Additionally, MorphoSys maintains the right to conduct activities in Greater China and South Korea that enable MorphoSys to exploit MOR210/TJ210 outside of those countries. Pursuant to the C5aR Agreement, we are required to use commercially reasonable efforts as we develop and commercialize MOR210/TJ210 in Greater China and South Korea.

B. Out-Licensing Arrangements

Licensing Agreement with ABL Bio

In July 2018, we entered into a license and collaboration agreement with ABL Bio (the "ABL Bio License"). Under the ABL Bio License, we granted to ABL Bio exclusive, worldwide (excluding Greater China, royalty-bearing rights to develop and commercialize a bispecific antibody (the "BsAb") using certain of our monoclonal antibody sequences. ABL Bio has developed expertise in the area of bispecific antibodies for cancer treatment and has developed proprietary intellectual property around the BsAb technology, and the license allows ABL Bio to further develop and commercialize the BsAb based on monoclonal antibodies licensed from us under the ABL Bio License. ABL Bio granted to us an exclusive, royalty-free, sublicensable license under its interest in the BsAb and related know-how (including improvements thereto) to exploit the licensed BsAb in Greater China.

Under the ABL Bio License, we and ABL Bio each are responsible for using commercially reasonable efforts to develop the licensed products through the completion of in vivo studies, and ABL Bio is responsible for using commercially reasonable efforts thereafter. We agreed to split costs fifty-fifty (50:50) with ABL Bio through the completion of in vivo studies, with ABL Bio responsible for all costs and activities following that

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time. ABL Bio is responsible for all development and commercialization activities, subject to our input through a joint committee comprised of an equal number of our and ABL Bio's representatives (though ABL Bio has final decision-making authority).

In consideration of the license, ABL Bio paid us an upfront fee of US\$2.5 million and agrees to make milestone payments in the aggregate amount of US\$97.5 million conditioned upon achieving certain research, clinical development and sales milestones. Further, ABL Bio agreed to pay us royalties at mid-single-digit percentages in respect of the total annual net sales of the licensed BsAb product.

In addition, ABL Bio granted to us an exclusive, royalty-free, sublicensable license to use its BsAb technology solely to exploit the licensed BsAb product for all indications in Greater China.

We also agreed that, during the term of the ABL Bio License, neither we nor ABL Bio would develop independently from the other a bispecific antibody that uses the same pair of antibodies as the bispecific antibody molecules created under the ABL Bio License.

The ABL Bio License will continue to be in effect until expiration of the last payment obligation thereunder, unless earlier terminated according to its terms. At any time, ABL Bio may terminate the ABL Bio License upon a notice period that varies based upon the stage of development.

Upon expiration (but not termination) of the ABL Bio License, we and ABL Bio will each retain our respective licenses granted under the ABL Bio License. If the ABL Bio License is terminated other than pursuant to ABL Bio's right to terminate at will, we and ABL Bio will negotiate in good faith regarding ABL Bio's assignment of assets related to the licensed BsAb product and the continuation of the licenses granted to us. If the ABL Bio License is terminated pursuant to ABL Bio's termination at will, all rights and obligations (including all licenses granted) shall terminate and the parties will negotiate regarding our takeover of the exploitation of the BsAb product outside of Greater China, which takeover shall be in exchange for reasonable compensation.

Licensing Agreement with CSPC Entity

In December 2018, we entered into a product development agreement (the "CSPC Agreement") with an entity controlled by CSPC Pharmaceutical Group Limited (01093.HK) ("CSPC entity"). Under the CSPC Agreement, we granted to CSPC entity exclusive, non-transferable, non-irrevocable and sublicensable rights under our patent rights in China to develop and commercialize TJ103 for treating type 2 diabetes mellitus and any other potential therapeutic applications. CSPC entity's right to sublicense is conditioned on our prior written consent, which we cannot unreasonably withhold, other than sublicense to CSPC entity's affiliates. CSPC entity is a comprehensive pharmaceutical and drug manufacturing company, with an increasing focus on its research and development of new products focusing the therapeutic area of oncology, among others.

Under the CSPC Agreement, CSPC entity is responsible for using commercially reasonable efforts to develop, obtain market approval and commercialize the licensed products, while we are responsible for using commercially reasonable efforts to transfer the manufacturing technology of the licensed products to CSPC entity and assist or guide CSPC entity in the continued optimization of such manufacturing technology thereafter. CSPC entity has final decision-making authority with respect to product development (though the research plan shall be jointly developed by both parties and any changes to the plan shall be discussed and approved by the joint development committee) and commercialization.

We also agreed that, during the term of the CSPC Agreement, we shall not develop, either for ourselves or for third parties, any other hyFc platform technology-based long-acting recombinant GLP-1 Fc fusion proteins that may be in a competitive position with TJ103.

In consideration of the license, CSPC entity paid us an upfront fee of RMB15.0 million and agreed to make milestone payments in an aggregate amount of RMB135.0 million conditioned upon achieving certain clinical

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development and regulatory approval milestones, including completion of Phase 2 and Phase 3 clinical studies and obtaining NDA approval or market approval. Further, we will also be entitled to royalties at up to low-double-digit percentages in respect of the total annual net sales of the products after their commercialization in China. The royalty term shall terminate at the later of: (i) the expiry date of the underlying patents of the licensed products with application numbers 201410851771.1 and 201580071643.8 (final grant of rights requested relating to GLP-1) in China, whichever is later; and (ii) the ten-year anniversary of the initial commercialization of the product developed under the CSPC Agreement.

Unless terminated earlier in accordance with the terms thereof, the CSPC Agreement will remain in effect until the termination of the royalty term.

During the term of the CSPC Agreement, CSPC entity shall have exclusive, royalty-free rights in China to any work product generated by us, and be responsible for any patent application and maintenance costs of such work product. CSPC entity shall have all rights to any work product generated by itself under the CSPC Agreement.

Other Out-Licensing Arrangements

In April 2017, our subsidiary I-Mab Shanghai entered into a technology transfer agreement (the “HDYM License”) with Ningbo Hou De Yi Min Information Technology Co., Ltd. (“HDYM”) and Hangzhou HealSun Biopharm Co., Ltd. (“HealSun”) with respect to PD-L1 humanized monoclonal antibodies. HealSun is a portfolio company of Lepu Biotech (乐普生物). Under the HDYM License, I-Mab Shanghai agreed to grant to HDYM exclusive (even to I-Mab Shanghai itself), worldwide and sublicensable rights to develop, manufacture, have manufactured, use, sell, have sold, import, or otherwise exploit certain PD-L1 related patents, patent applications, know-hows, data and information of I-Mab Shanghai, relevant cell lines as well as any PD-L1 monoclonal antibody arising from such cell lines for the treatment of diseases. Further, I-Mab Shanghai and its cooperative party HealSun agreed to provide subsequent research and development services on such intellectual property to HDYM, including the selection and examination of innovative PD-L1 humanized monoclonal antibodies, cultivation and selection of stable cell lines, establishment of cell bank, research and development of manufacturing processes and preparation of samples, toxicological and pharmacological testing, pre-clinical pharmaceutical experiment report drafting, and application for and registration of clinical trials.

C. Collaboration Arrangements

Collaboration Agreement with Everest

In January 2018, we entered into a collaboration agreement with Everest Medicines Limited (“Everest”) whereby both parties agreed to collaborate to co-develop MorphoSys’ proprietary CD38 antibody (TJ202 or the CD38 product) and commercialize the CD38 product in Greater China for all indications in hematologic oncology.

Under the agreement, we and Everest established a joint steering committee with equal representation from each party to, among other things, coordinate and oversee the development and commercialization regarding the CD38 product. All decisions of the joint steering committee shall be made by unanimous vote. We have final decision-making authority on matters related to the development of the CD38 product, provided that Everest has the right to opt out of sharing of development cost increases for new work or clinical trials added to the initial development plan and budget. Everest has final decision-making authority on matters related to the commercialization of the CD38 product.

Under the agreement, we are primarily responsible for using commercially reasonable efforts to carry out the development, manufacture and supply of the CD38 product, and we are also responsible for seeking regulatory approval of the CD38 product. Everest is primarily responsible for sharing with us, by the proportion

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of 75% for Everest and 25% for us, the development costs of the CD38 product, including payments due to MorphoSys under the License and Collaboration Agreement, dated November 30, 2017, between us and MorphoSys.

The joint steering committee will decide whether we or Everest shall be responsible for conducting the commercialization of the CD38 product pursuant to the commercialization plan approved by the committee. If Everest is selected to be responsible for commercialization, we shall grant an exclusive royalty-free license to Everest to commercialize the CD38 product for all indications in hematologic oncology in Greater China.

We and Everest will share the CD38 product's profit and loss in proportion to the costs that each of us incur in developing the product. The parties will also split out-license revenue according to the proportion of development costs incurred, with us getting an additional five percent (5%) share and Everest receiving five percent (5%) less. Everest cannot share in any profit from the commercialization of CD38 product until it has fulfilled its payment obligations under this agreement.

If we want to develop the CD38 product for indications other than hematologic oncology in Greater China, we must first provide notice of such intent to Everest and, at their election, negotiate with them in good faith regarding such rights.

The agreement shall continue as effective so long as we and Everest continue to develop the CD38 product for any indications in hematologic oncology in Greater China. In addition to other termination rights of the parties, if we fail to initiate or conduct any material development activities in relation to any therapeutic, prophylactic or palliative CD38 product for a period of three months (other than as a result of a regulatory requirement), Everest will have the right to terminate this agreement.

Upon any termination of the agreement, the terminating party has the right to continue the development and commercialization of CD38 product. If Everest is the rightful terminating party, we shall reasonably cooperate with Everest to, among other things, (i) assign the MorphoSys license to Everest (subject to the terms and conditions of such license); (ii) grant to Everest an exclusive license to all intellectual property rights we own or control to further develop, manufacture, and commercialize the CD38 product; and (iii) transfer the development, manufacture and commercialization of the CD38 product to Everest, including providing reasonable technical assistance and assigning to Everest any agreement with third party vendors pertaining to the development, manufacture and commercialization of the CD38 product. In addition, the terminating party that elects to continue the development and commercialization of the CD38 product shall be solely responsible for the cost and expense of such development and commercialization after termination. In the event that such continuing party successfully develops and commercializes the CD38 product, it shall pay to the other party a percentage of the product profit and out-license income generated therefrom in accordance with the terms of this agreement.

Other Collaboration Arrangements

In July 2018, we entered into a collaboration agreement with ABL Bio whereby both parties agreed to collaborate to develop three PD-L1-based bispecific antibodies by using ABL Bio's proprietary BsAb technology and commercialize them in their respective territories, which, collectively, include the PRC, Hong Kong, Macau, Taiwan and South Korea, and other territories throughout the rest of the world if both parties agree to do so in such other territories during the performance of the agreement.

In September 2018, we entered into a collaboration and platform technology license agreement with WuXi Biologics Ireland Limited ("WuXi Biologics"), whereby both parties agreed to collaborate in the research and development of at least three bispecific antibodies for our company to commercialize them worldwide. Such bispecific antibodies shall be created using our proprietary monoclonal antibodies and WuXi Biologics' proprietary WuXiBody platform technology for generating bispecific antibodies, shall be developed and manufactured through the exclusive service of WuXi Biologics. In April 2019, we extended our existing

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partnership with WuXi Biologics (Shanghai) Co., Ltd. (“WuXi Biologics Shanghai”). We entered into a long-term, strategic collaboration agreement with WuXi Biologics Shanghai to facilitate the CMC development and GMP manufacturing of both clinical and commercial supplies of certain of our monoclonal and bispecific antibodies and fusion products, leveraging WuXi Biologics’ and its affiliates’ expertise in this area and supporting our pre-existing collaboration and platform technology license agreement with WuXi Biologics.

In November 2018, we entered into collaboration agreements with TRACON Pharmaceuticals, Inc. (“TRACON”), whereby we and TRACON agreed to (1) collaborate to co-develop our proprietary CD73 antibody, TJD5 and (2) collaborate to co-develop up to five BsAbs. Additionally, in March 2019, we agreed with TRACON and F. Hoffmann-La Roche Ltd (“Roche”) on a clinical supply agreement for Roche to supply Atezolizumab for use in clinical studies under the collaboration agreement with TRACON.

Intellectual Property

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for our drug candidates and other commercially important products, technologies, inventions and know-how, as well as on our ability to defend and enforce our patents including any patent that we have or may issue from our patent applications, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of other parties.

As of July 15, 2019, our owned patent portfolio consist of (i) five issued patents, including two issued in the U.S., one issued in the PRC and two issued in Korea; and (ii) 127 pending patent applications, including 15 PCT patent applications, seven U.S. patent applications, ten PRC patent applications and 95 patent applications in other jurisdictions. Our owned patents and patent applications primarily relate to the drug candidates in our Global Portfolio. Furthermore, as of July 15, 2019, we in-licensed the Greater China rights relating to (i) 19 issued patents, including 12 issued in the PRC, five issued in Hong Kong and two issued in Taiwan; and (ii) 25 pending patent applications, including three PCT patent applications, 11 PRC patent applications, seven Hong Kong patent applications, three Taiwan patent applications and one Korean patent application. The in-licensed patents and patent applications primarily relate to TJ202, TJ101, TJ301, enoblituzumab and TJ107.

<u>TJ202</u>	As of July 15, 2019, we exclusively licensed from MorphoSys eight issued patents (including five issued in the PRC, two issued in Hong Kong and one issued in Taiwan) and six pending patent applications (including three in the PRC and three in Hong Kong) relating to TJ202. The licensed patents include composition of matter patents in China, Hong Kong and Taiwan. The patents (including patent applications if issued) in this portfolio are expected to expire between 2025 and 2037, before taking into account any extension that may be obtained through patent term extension or adjustment, or term reduction due to filing of terminal disclaimers.
<u>TJ101</u>	As of July 15, 2019, we (i) exclusively licensed from Genexine two pending PRC patent applications directly relating to TJ101 and (ii) exclusively licensed from Genexine three issued patents in the PRC and one pending PRC patent application relating to a hyFc platform that develops TJ101. The licensed patents include composition of matter patents in China. The patents (including patent applications if issued) in this portfolio are expected to expire between 2028 and 2037, before taking into account any extension that may be obtained through patent term extension or adjustment, or term reduction due to filing of terminal disclaimers.
<u>TJ301</u>	As of July 15, 2019, we exclusively licensed from Ferring one issued patent in the PRC relating to TJ301. The licensed patent relates to composition of matter. This patent is expected to expire in 2027, before taking into account any extension that may be obtained through patent term extension or adjustment, or term reduction due to filing of terminal disclaimers.
<u>Enoblituzumab</u>	As of July 15, 2019, we exclusively licensed from MacroGenics six issued patents (including two issued in the PRC, three issued in Hong Kong and one issued in Taiwan) and eight pending patent applications (including two in the PRC, four in Hong Kong and

two in Taiwan) relating to enoblituzumab. The patents (including patent applications if issued) in this portfolio are expected to expire between 2023 and 2036, before taking into account any extension that may be obtained through patent term extension or adjustment, or term reduction due to filing of terminal disclaimers.

<u>TJ107</u>	As of July 15, 2019, we (i) exclusively licensed from Genexine one pending PRC patent application directly relating to TJ107 and (ii) exclusively license from Genexine three issued patents in the PRC and one pending PRC patent application relating to a hyFc platform that develops TJ107. The patents (including patent applications if issued) in this portfolio are expected to expire between 2028 and 2036, before taking into account any extension that may be obtained through patent term extension or adjustment, or term reduction due to filing of terminal disclaimers.
<u>TJM2</u>	As of July 15, 2019, we owned one pending PCT patent application that relates to TJM2 and it has entered national phases in China, the United States and 22 other jurisdictions. We expect that any patent that may issue under this application will expire in 2037, before taking into account any extension that may be obtained through patent term extension or adjustment, or term reduction due to filing of terminal disclaimers.
<u>TJC4</u>	As of July 15, 2019, we owned two pending PCT patent applications and one of them has entered national phases in the PRC, the United States and 21 other jurisdictions. We expect that any patents that may issue under these applications will expire between 2037 and 2038, before taking into account any extension that may be obtained through patent term extension or adjustment, or term reduction due to filing of terminal disclaimers.
<u>TJD5</u>	We owned one pending PCT patent application and it has entered national phases in the PRC, the United States, and 18 other jurisdictions. We expect that any patent that may issue under this application will expire in 2038, before taking into account any extension that may be obtained through patent term extension or adjustment, or term reduction due to filing of terminal disclaimers.

The term of a patent depends upon the laws of the country in which it is issued. In most jurisdictions, a patent term is 20 years from the earliest filing date of a non-provisional patent application. Under the PRC Patent Law, the term of patent protection starts from the date of application. Patents relating to inventions are effective for twenty years, and utility models and designs are effective for ten years from the date of application. There are no patent term adjustments or patent term extensions available in the PRC for issued patents.

In addition to patents, we rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and know-how can be difficult to protect. We seek to protect our proprietary information, in part, by executing confidentiality agreements with our partners, collaborators, scientific advisors, employees, consultants and other third parties, and invention assignment agreements with our consultants and employees. We have also executed agreements requiring assignment of inventions with selected scientific advisors and collaborators. The confidentiality agreements we enter into are designed to protect our proprietary information and the agreements or clauses requiring assignment of inventions to us are designed to grant us ownership of technologies that are developed through our relationship with the respective counterparty. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes or that these agreements will afford us adequate protection of our intellectual property and proprietary information rights. If any of the partners, collaborators, scientific advisors, employees and consultants who are parties to these agreements breaches or violates the terms of any of these agreements or otherwise discloses our proprietary information, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result.

Additionally, as of July 15, 2019, we had (i) three registered trademarks in Hong Kong and 13 trademark applications in the PRC and two trademark applications in the United States; (ii) nine domain names in the PRC,

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including *www.i-mabbiopharma.com*, four domain names in Hong Kong and two domain names in the United States and (iii) 12 software copyrights in the PRC.

For more information on these and other risks related to intellectual property, see “Risk Factors—Risks Related to Our Intellectual Property.”

Manufacturing and Supply

Our manufacturing strategy for our drug candidates consists of two progressive steps, involving (i) using contract development and manufacturing organizations (“CDMOs”) and (ii) establishing our own capabilities and infrastructure, including a manufacturing facility. We believe that development of our own manufacturing facility will provide us with enhanced control of material supply for both clinical trials and the commercial market, enable the more rapid implementation of process changes and help us achieve better long-term margins.

We currently outsource the manufacturing of clinical trial material for our internally developed, IND enabling projects to leading CDMOs in China such as WuXi Biologics, and the manufacturing of clinical trial material for clinical stage projects which were in-licensed from our global partners to reputable global CDMOs, which have established track records for both clinical trial material supply and commercial material supply. We have assembled a seasoned internal team with deep experience in this area to drive and monitor this process. For contingency planning purposes, we have also established relationships with other CDMOs. We expect to continue our outsourcing relationships with contract manufacturers to meet the ongoing needs for the development of our drug candidates. We have framework agreements with these external service providers, under which they provide services to us on a project-by-project basis. We also monitor the manufacturing activities of clinical trial material at CDMO to ensure the compliance with local and international cGMP and applicable regulations. Currently, our contract manufacturers obtain raw materials and supplies for the manufacturing activities from multiple suppliers who we believe have sufficient capacity to meet our demands. We typically order materials and services on a purchase order basis. We also enter into long-term capacity or minimum supply arrangements with them.

We believe it is advantageous that we own and control our GMP manufacturing process in order to ensure quality and secure production slots for clinical trial materials and commercial supplies. We plan to commence the construction of our own state-of-the-art biologics manufacturing facility in Hangzhou, China by the end of 2019. At this manufacturing facility, we plan to produce drug substance and drug product for clinical or, in the future, commercial use. We expect this facility to include a pilot GMP manufacturing plant with two 500-liter and two 2,000-liter single use bioreactors, and upon completion of the construction, a commercial scale manufacturing plant with eight more 2,000-liter single use bioreactors with filling and finishing lines.

Manufacturing is subject to extensive regulations governing quality management systems, manufacturing processes and controls, personnel training, and operating procedures. The CDMOs will be required to operate under cGMP conditions. These cGMP conditions are regulatory requirements for the production of pharmaceuticals for human use.

R&D Governance

We have established robust governance regime for all stages of our research and development activities, through our internal discovery, CMC, pre-clinical and clinical development programs, and through product acquisition and in-licensing strategies. The research and development governance regime has enabled our senior management to continuously oversee and monitor our company’s research and development activities for complying with applicable laws, regulations, rules, guidelines and internal policies. The research and development governance regime has been put in practice and has operated independently of the Chief Executive Officer’s responsibilities.

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We have established various governance and decision-making committees, composed of senior representatives from the respective functional units to review, discuss and determine, for instance, whether a drug candidate molecule is qualified to move forward into the next stage or not, what data package is considered appropriate and compliant to be submitted to regulatory agencies and how clinical safety of our investigational drugs will be monitored and reported. These committees make decisions over the critical “checkpoints” of our research and development activities and include our (i) Science Committee, (ii) IND Scientific Advisory Committee, (iii) R&D Project/Program/Portfolio Governance, (iv) Medical Safety Council, and (v) Safety Management Team.

Science Committee for Early Stage Research of Drug Candidates

Our Science Committee is composed of selected functional heads and members of the leadership, chaired by Dr. Taylor B. Guo. The Science Committee will collaborate with the management team to enhance our company’s research practices and assist management in evaluating scientific aspects of potential in-licensing opportunities, collaborations and new technologies that may bolster our pipeline and research and development capabilities. The Science Committee’s responsibilities include:

- approving the target review package submitted by our discovery group;
- providing governance on the quality and integrity of drug candidates, before entering into CMC process development;
- examining the experimental data and scientific evidence supporting the drug candidate;
- reviewing and making recommendations on our company’s resource allocation in further development; and
- setting the direction for scientific and technical review of potential in-licensing opportunities.

Furthermore, our Corporate Compliance Function led by Mr. Thomas Song has taken a number of steps to review the integrity and reliability of the experimental data submitted with the selected drug candidate. The design, operation and monitoring of this data integrity program is integral to our quality control and assurance system, and is independent with respect to our research and development unit and Science Committee, to ensure the compliance with the principles of scientific data integrity, including controls over changes to, and deletions of source of data.

IND Scientific Advisory Committee for Drug Candidates Entering into Clinical Development Stage

Our IND Scientific Advisory Committee is composed of Dr. Joan Huaqiong Shen, Dr. Zheru Zhang, Dr. Jane Meng and Rebecca Zhang. The IND Scientific Advisory Committee is accountable for our IND application strategy and the data quality of our IND registration dossier before submission to the FDA, the NMPA and other comparable authorities. Our IND Scientific Advisory Committee advises the project team on policy matters and provides overall direction of new drug studies, and to that extent serves as a standing modality committee.

R&D Project/Program/Portfolio Governance (“IP3 Governance”)

Our IP3 Governance is composed of Dr. Jingwu Zhang Zang, Dr. Joan Huaqiong Shen, Dr. Zheru Zhang, Dr. Chao Zhang, with Dr. Jingwu Zhang Zang serving as the chair. Our IP3 Governance is a decision-making body that assesses and approves research and development portfolio strategy and execution proposals from a multi-discipline perspective, with an integrated approach incorporating scientific, clinical and commercial considerations. Our IP3 Governance aims to ensure that the project, program and/or portfolio-related decisions are logical, robust and repeatable and that our investments in research and development activities is aligned with our vision and strategy. The IP3 Governance responsibilities include:

- reviewing and determining the in-licensing and out-licensing strategic plan;

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- performing reviews on critical research and development stage gates, including clinical asset selection, GLP pharmacology and toxicology studies, FIH studies, clinical development and regulatory submission; and
- reviewing product development strategy and monitoring project timeline and costs.

Medical Safety Council (“MSC”)

Our MSC is composed of selected research and development functional heads and Subject Matter Experts, chaired by Yuan Meng. Our MSC is the highest medical safety governance body engaged in setting standards for protecting the medical safety of patients and users of our products, and providing strategic direction in product vigilance and patient or user safety. The MSC’s responsibilities include:

- establishing standards and policies, and identifying best practices related to medical safety;
- providing oversight of all medical safety relevant activities, and overseeing the implementation of our company’s medical safety standard, as well as the outcomes of the periodic audits;
- addressing safety information that could result in a significant change in the benefit-risk profile of our products; and
- reviewing and approving FIH studies and any other issues with respect to the safety of human exposure during early development stage.

Safety Management Teams (“SMT”) for Product-Related Safety System

Our SMT is composed of representatives from each research and development function, chaired by Yuan Meng. The SMT is a product-based, cross-functional collaborative team responsible for the review, assessment, and evaluation of medical safety data arising from any source throughout the product lifecycle. Our SMT performs assessments to identify changes in safety profiles or potential safety signals. Based on these safety evaluations, the SMT will determine the appropriate safety-related actions to be taken with respect to the product based on its benefit-risk profile for subjects in clinical trials and for patients treated with the marketed product.

Our SMT works closely with and escalates safety issues, as appropriate, to the MSC to fulfill our medical safety obligations. Our SMT is responsible for reviewing available safety information from multiple sources on a regular basis and make final decisions on safety in a timely manner with appropriate cross-functional input.

Code of Conduct

We have adopted a Code of Conduct that is applicable to many aspects of our business operation, such as business ethics, responsible research and development activities, IP and data protection, workplace ethics and other corporate governance topics, as well as implementing high ethical standards that are mandatory for our employees. In addition, we have adopted an employee handbook which describes the compliance management system implemented at I-Mab to ensure compliance with applicable legal and regulatory requirements.

Quality Control and Assurance

In addition to the research and development governance regime described above, we have established an independent quality control and assurance system and devote significant attention to quality control for the designing, manufacturing and testing of our drug candidates. Our Assurance Board is composed of Dr. Joan Huaqiong Shen, Dr. Zheru Zhang and Thomas Song. Our senior management is firmly committed to delivering our quality performance, actively involved in allocating sufficient resources to quality management system and setting quality governance mechanism.

For pre-clinical and clinical trials, the overall quality management outlines the implementation of our business policies and procedures in order to consistently comply with the regulatory requirements, including

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Good Laboratory Practices, or GLP; Good Clinical Practices, or GCP; Good Pharmacovigilance Practice, or GVP and other applicable regulatory requirements in the performance of the trials. This includes:

- predefined policies and procedures to manage pre-clinical and clinical studies;
- dedicated resources and personnel with well delineated roles and responsibilities;
- quality risk management across the product lifecycle;
- continuous quality management system improvement;
- non-conformance management via quality issue management process;
- development and execution of quality audit program; and
- regulatory inspection readiness.

For CMC, we have established a quality management system to oversee the process development and API and drug production at the CDMOs. This system takes a holistic approach bringing senior management, quality assurance team and company policies together to create an efficient and agile quality culture. Our CMC quality commitment includes, but not limited to:

- ensure that the product manufacturing, releasing, packaging, storage, and shipment meets all specifications and the requirements of the FDA and/or NMPA's quality system regulations, cGMP or other applicable laws and regulations;
- review of process deviations and changes, root cause analysis, impact assessment, corrective and preventative actions, and validation;
- ensure the consistency of key quality practices with our CDMOs;
- proactive quality system review based on audits, process data analysis, equipment condition, and periodic review of internal and external sources of data; and
- assessment of regulatory guidance and ensure readiness for regulatory inspections.

Employees

We had 59 and 134 employees as of December 31, 2017 and 2018, respectively. As of December 31, 2018, 125 employees were located in China and nine were located outside China. The table below sets forth our employees by function as of December 31, 2018:

	<u>Number</u>
Management	7
Research and development	73
Chemistry, manufacturing and controls	28
Operations	15
Finance	5
Business and corporate development	6
Total	<u><u>134</u></u>

We recruit our employees primarily through recruitment websites, recruiters, internal referrals and job fairs. We recruit our employees based on their qualification and potential. We promote culture diversity, and our employees come from the United States, Taiwan and South Korea, in addition to China. The remuneration package of our employees includes salary, benefits and bonus. Our compensation programs are designed to remunerate our employees based on their performance, measured against specified objective criteria. We are required to make contributions to social insurance and housing provident funds in accordance with PRC laws and regulations from time to time.

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We provide new hire training to our employees and periodic on-the-job training to enhance the skills and knowledge of our employees. We have not established a labor union. We have not experienced any material labor disputes or strikes that may have a material and adverse effect on our business, financial condition or results of operations.

We enter into 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 innovations 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, see “Management.”

Facilities

Our headquarter is located in Shanghai, China, where we lease and occupy approximately 2,479 square meters as office space and laboratories. We currently lease approximately 235 square meters of office space in Beijing, approximately 54 square meters of office space in Tianjin, approximately 49 square meters of office space in Chengdu, approximately 105 square meters of office space and laboratories in Hong Kong, and approximately 441 square meters of office space and laboratories in Maryland. The terms of these leases range from one year to five years.

Legal Proceedings

From time to time we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, results of operations, financial condition or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Internal Control and Risk Management

We have implemented various risk management policies and measures to identify, assess and manage risks arising from our operations. In addition, we have codified risk categories identified by our management, internal and external reporting mechanisms, remedial measures and contingency management as part of our policies. For details on major risks identified by our management, see “Risk Factors” in this prospectus.

To monitor the ongoing implementation of our risk management policies and corporate governance measures following this offering, we have adopted or will adopt, among other things, the following risk management and internal control measures:

- the establishment of an audit committee responsible for overseeing our financial records, internal control procedures and risk management systems. See “Management—Committees of the Board of Directors” in this prospectus for information of our audit committee members and detailed description of the responsibility of our audit committee; and
- the engagement of external legal advisors to advise us on compliance with relevant regulatory requirements and applicable laws to which we will be subject to as a public company, where necessary.

Further, we have adopted or will adopt before this offering, various internal regulations against corrupt and fraudulent activities, including measures against bribery and the misuse of company assets. Key measures and procedures to implement such regulations include:

- authorizing our compliance department to assume responsibility for our anti-corruption and anti-fraud measures, including handling complaints, conducting internal investigations and ensuring protection for whistleblowers;

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- providing anti-corruption compliance training to our senior management and employees on a periodic basis to enhance their knowledge and compliance with applicable laws and regulations, including relevant policies and prohibitions against non-compliance set out in our employee handbook; and
- evaluating and undertaking rectification measures with respect to any identified corrupt or fraudulent activity, including proposing and establishing preventative measures to avoid future non-compliance.

We will continue to implement and enforce these measures and procedures to ensure ongoing compliance with all applicable laws and regulations, including the prevention of our employees from engaging in corruption, bribery or other improper conduct. During the periods presented, we were not subject to any government investigation or litigation with respect to claims or allegations relating to monetary and non-monetary bribery activities.

We have also designated responsible personnel to monitor our ongoing compliance with relevant laws and regulations that govern our business operations, and to oversee the implementation of any necessary measures. Meanwhile, we plan to provide our directors, senior management and relevant employees with continuing training programs and updates regarding relevant laws and regulations on a regular basis, with a view to proactively identifying concerns or issues relating to any potential non-compliance.

REGULATION

PRC Regulation

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.

Regulations on Company Establishment and Foreign Investment

Company Law

The establishment, operation and management of companies in China is governed by the PRC Company Law, which was passed by the Standing Committee of the National People's Congress (the "NPC"), on December 29, 1993 and came into effect on July 1, 1994 and was latest revised or amended on October 26, 2018, respectively. In light of the PRC Company Law, companies established in the PRC are either in the form of a limited liability company or a joint stock company. The PRC Company Law applies to both PRC domestic companies and foreign-invested companies, unless otherwise provided in the relevant foreign investment laws and regulations.

Foreign Investment Law

On March 15, 2019, the NPC approved the PRC Foreign Investment Law, which will become effective on January 1, 2020 and replace the three existing laws on foreign investment in China, namely, the PRC Equity Joint Venture Law, the PRC Cooperation Joint Venture Law and the Wholly Foreign-Owned Enterprise Law, together with their implementation rules and ancillary regulations. The Foreign Investment Law embodies an expected PRC regulatory trend to rationalize its foreign investment regulatory regime in line with prevailing international practice and the legislative efforts to unify the corporate legal requirements for both foreign and domestic invested enterprises in China. The Foreign Investment Law establishes the basic framework for the access to, and the promotion, protection and administration of foreign investments in view of investment protection and fair competition. According to the Foreign Investment Law, "foreign investment" refer to investment activities directly or indirectly conducted by one or more natural persons, business entities, or other organizations of a foreign country (collectively referred to as "foreign investor") within China, and "investment activities" include the following activities: (i) a foreign investor, individually or together with other investors, establishes a foreign-invested enterprise within China; (ii) a foreign investor acquires stock shares, equity shares, shares in assets, or other similar rights and interests of an enterprise within China; (iii) a foreign investor, individually or together with other investors, invests in a new construction project within China; and (iv) investments in other means as provided by the laws, administrative regulations or the State Council.

Regulations Relating to Foreign Investment

During the interim period before the Foreign Investment Law becomes effective, investments in the PRC by foreign investors, particularly the establishment procedures, examination and approval procedures, registered capital, foreign exchange, taxation and labor matters of a wholly foreign-owned enterprise, are subject to the Wholly Foreign-Owned Enterprise Law of the PRC promulgated on April 12, 1986 and amended on October 31, 2000 and September 3, 2016, respectively, the Detailed Implementing Rules for the Wholly Foreign-Owned Enterprise Law of the People's Republic China promulgated on December 12, 1990 and amended on April 12, 2001 and February 19, 2014, respectively.

Furthermore, PRC-based investments by foreign investors shall also be regulated by the Catalogue for the Guidance of Foreign Investment Industries (2017 Revision) issued on June 28, 2017 and effective from July 28, 2017, and the Special Management Measures (Negative List) for the Access of Foreign Investment (2018) issued on June 28, 2018 and effective from July 28, 2018. According to the aforesaid catalogue and management

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measures, foreign-invested industries fall into four categories, namely, “encouraged,” “permitted,” “restricted” and “prohibited,” and certain ownership requirements, requirements for senior executives and other special management measures shall apply to foreign investors with regard to the access of foreign investments in certain categories. The Special Management Measures (Negative List) for the Access of Foreign Investment (2019) and the Catalogue of Industries for Encouraging Foreign Investment (2019 Version), which will become effective on July 30, 2019, further reduce restrictions on the foreign investment and will replace the Special Management Measures (Negative List) for the Access of Foreign Investment (2018).

Pursuant to the Interim Administrative Measures for the Record-filing of the Incorporation and Change of Foreign-invested Enterprises, foreign-invested enterprises investing in categories not subject to the special management measures are only required to complete an online registration of their incorporation and any changes with the Ministry of Commerce (the “MOFCOM”), or its local counterparts.

M&A Rules

According to the Provisions on the Merger or Acquisition of Domestic Enterprises by Foreign Investors jointly issued by the MOFCOM, the State Assets Supervision and Administration Commission of the State Council, the State Administration of Taxation (the “SAT”), the State Administration for Industry and Commerce (now known as the State Administration for Market Regulation), the China Securities Regulatory Commission and the State Administration of Foreign Exchange (the “SAFE”), on August 8, 2006 and amended by the MOFCOM on June 22, 2009, among other things, (i) the purchase of an equity interest or subscription to the increase in the registered capital of non-foreign-invested enterprises, (ii) the establishment of foreign-invested enterprises to purchase and operate the assets of non-foreign-invested enterprises, or (iii) the purchase of the assets of non-foreign-invested enterprises and the use of such assets to establish foreign-invested enterprises to operate such assets, in each case, by foreign investors shall be subject to the Provisions on the Merger or Acquisition of Domestic Enterprises by Foreign Investors. Particularly, application shall be made for examination and approval of the acquisition of any company in China affiliating to a domestic company, enterprise or natural person, which is made in the name of an overseas company established or controlled by such domestic company, enterprise or natural person.

PRC Drug Regulation

The Drug Administration Law of the PRC promulgated by the Standing Committee of the NPC on September 20, 1984 and effective from July 1, 1985 and amended on February 28, 2001, December 28, 2013 and April 24, 2015, respectively, and the Implementing Measures of the Drug Administration Law promulgated by the State Council on August 4, 2002 and effective from September 15, 2002 and amended on February 6, 2016 and March 2, 2019, respectively, have jointly established the legal framework for the administration of pharmaceutical products in China, including the research, development and manufacturing of new drugs. The Drug Administration Law applies to entities and individuals engaged in the development, production, trade, application, supervision and administration of pharmaceutical products, which regulates and provides for a framework for the administration of pharmaceutical manufacturers, pharmaceutical trading companies and medicinal preparations of medical institutions, and the development, research, manufacturing, distribution, packaging, pricing and advertisements of pharmaceutical products. The Implementing Measures of the Drug Administration Law, on the other hand, provides detailed implementation regulations for the Drug Administration Law.

We are required to follow the above-mentioned regulations in respect of our non-clinical research, clinical trials and production of new drugs.

Regulatory Authorities and Recent Government Reorganization

Pharmaceutical products and medical devices and equipment in China are monitored and supervised on a national scale by the NMPA (formerly known as the China Food and Drug Administration, or the “CFDA”),

while the local provincial medical products administrative authorities are responsible for the supervision and administration of drugs within their respective administrative regions. Pursuant to the Decision of the First Session of the Thirteenth National People's Congress on the State Council Institutional Reform Proposal made by the NPC on March 17, 2018, the NMPA is no longer an independent agency and its duties shall be performed by the newly established State Administration for Market Regulation, into which the various agencies responsible for, among other areas, consumer protection, advertising, anticorruption, pricing, fair competition and intellectual property, have been merged.

The NMPA is still the chief drug regulatory agency and implements the same laws, regulations, rules, and guidelines as the CFDA, and the NMPA 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 (the "CDE"), which remains under the NMPA, conducts the technical evaluation of each drug and biologic application for safety and effectiveness.

Formed on March 2018, the National Health Commission (the "NHC") (formerly known as the Ministry of Health ("MOH") and the National Health and Family Planning Commission ("NHFPC")) is China's chief healthcare regulator. It is primarily responsible for overseeing the operation of medical institutions, which also serve as clinical trial sites, and regulating the licensure of hospitals and medical personnel. The NHC plays a significant role in drug reimbursement. Furthermore, the NHC and its local counterparts at or below provincial-level local governments also oversee and organize public medical institutions' centralized bidding and procurement process for pharmaceutical products, which is the chief means through which public hospitals and their internal pharmacies acquire drugs.

Also, as part of its 2018 reorganization, the PRC government formed a new State Medical Insurance Bureau (the "SMIB"), which focuses on regulating reimbursement under the state-sponsored insurance plans.

Non-Clinical Research

On August 4, 2003, the NMPA promulgated the Administrative Measures for Good Laboratories Practice of Non-clinical Laboratory, which was revised on July 27, 2017, to improve the quality of non-clinical research, and began to conduct the Good Laboratories Practice. Pursuant to the Circular on Administrative Measures for Certification of Good Laboratory Practice for Non-clinical Laboratory issued by the NMPA on April 16, 2007, the NMPA is responsible for the certification of non-clinical research institutions nationwide and local provincial medical products administrative authorities is in charge of the daily supervision of non-clinical 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. A Good Laboratory Practice Certification will be issued by the NMPA if all the relevant requirements are satisfied, which will also be published on the NMPA's website.

Pursuant to the Regulations for the Administration of Affairs Concerning Experimental Animals promulgated by the State Science and Technology Commission on November 14, 1988 and amended on January 8, 2011, July 18, 2013 and March 1, 2017, respectively, by the State Council, the Administrative Measures on Good Practice of Experimental Animals jointly promulgated by the State Science and Technology Commission and the State Bureau of Quality and Technical Supervision on December 11, 1997, and the Administrative Measures on the Certificate for Experimental Animals (Trial) promulgated by the State Science and Technology Commission and other regulatory authorities on December 5, 2001, a Certificate for Use of Laboratory Animals is required for performing experimentation on animals. Applicants must satisfy the following conditions:

- Laboratory animals must be qualified and sourced from institutions that have Certificates for Production of Laboratory Animals;

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- The environment and facilities for the animals' living and propagating must meet national requirements;
- The animals' feed and water must meet national requirements;
- The animals' feeding and experimentation must be conducted by professionals, specialized and skilled workers, or other trained personnel;
- The management systems must be effective and efficient; and
- The applicable entity must follow other requirements as stipulated by Chinese laws and regulations.

Pre-clinical and Clinical Development

The NMPA requires supporting pre-clinical data for the registration applications for imported and domestic drugs. Pre-clinical work, including pharmacology and toxicology studies, must satisfy the requirements of the Administrative Measures for Good Laboratories Practice of Non-clinical Laboratory. No approval is required from the NMPA to conduct pre-clinical studies.

Clinical Trials and Registration of New Drugs

Categories

Pursuant to the Administrative Measures for Drug Registration promulgated by the NMPA on July 10, 2007 and effective from October 1, 2007, which provides the standards and requirements for clinical trials and drug registration applications, drug registration applications are divided into three different types, namely, New Drug Application, Generic Drug Application, and Imported Drug Application. Drugs are categorized based on their working mechanism, including chemical medicine, biological product or traditional Chinese or natural medicine. As provided in the Administrative Measures for Drug Registration, the Drug Administration Law and Implementing Measures of the Drug Administration Law, upon completion of non-clinical research, clinical trials shall be conducted for the application of new drug registration, upon approval from NMPA or authorized institutions.

Prior to engaging with the NMPA on research and development approval, an applicant shall determine the registration category for its drug candidate (subject to ultimate confirmation by the NMPA), which will determine the requirements for its clinical trial and marketing application. There are five categories for small molecule drugs: Category 1 ("innovative drugs") refers to drugs with a new chemical entity that have not been marketed anywhere in the world; Category 2 ("improved new drugs") refers to drugs with a new indication, dosage form, route of administration, combination, or certain formulation changes not previously approved anywhere in the world; Categories 3 and 4 refer to generic drugs that reference an innovator drug (or certain well-known generic drugs) marketed either abroad or in China, respectively; and Category 5 refers to innovative or generic drugs that have already been marketed abroad but are not yet approved in China (i.e., various imported drugs).

Approval

All clinical trials conducted in China must be approved and conducted at hospitals accredited by the NMPA. For imported drugs, proof of foreign approval is required prior to the trial, unless the drug has never been approved anywhere in the world. In addition to a standalone trial in China, imported drug applicants may establish a site in China as part of an international multi-center trial (the "IMCT") at the outset of the global trial. Domestically manufactured drugs are not subject to foreign approval requirements, and by contrast to prior practice, the NMPA has recently decided to also permit such drugs to be tested and developed through an IMCT.

In addition, the NMPA has adopted a notification system for clinical trials of new drugs. Pursuant to the Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on

Drugs and Medical Devices (the “Innovation Opinion”) and the Announcement on Adjusting the Evaluation and Approval Procedure of Drug Clinical Trial, clinical trials may be commenced as long as the applicant has not received any objections from the CDE within 60 business days of application filing, as opposed to the lengthier prior clinical trial pre-approval process, in which an affirmative approval from the NMPA must be obtained to commence clinical trials. The number of trial sites in China may increase due to the shortening of the accreditation timeline resulting from the replacement of the pre-approval procedure with the notification procedure.

Drug Clinical Trial Registration

Pursuant to the Administrative Measures for Drug Registration, upon obtaining the clinical trial approval and before commencing a clinical trial, the applicant shall file a registration with the NMPA containing various details of the clinical trial, including the clinical study protocol, the name of the principal researcher of the leading institution, names of participating institutions and researchers, an approval letter from the ethics committee, and a sample of the Informed Consent Form, with a copy sent to the competent provincial administration departments where the trial institutions will be located. On September 6, 2013, the NMPA released the Announcement on Drug Clinical Trial Information Platform, providing that for all clinical trials approved by the NMPA and conducted in China, instead of the aforementioned registration filed with the NMPA, clinical trial registration shall be completed and trial information shall be published through the Drug Clinical Trial 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 registration of certain follow-up information before the first subject’s enrollment in the trial. If approval of the foregoing pre-registration and registration is not obtained 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 expire.

Human Genetic Resources Approval

On June 10, 1998, the Ministry of Science and Technology and the MOH jointly established the rules for protecting and utilizing human genetic resources in China. On July 2, 2015, the Ministry of Science and Technology issued the Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading, Exporting Human Genetic Resources, or Taking Such Resources out of the PRC, which provides that foreign-invested sponsors that sample and collect human genetic resources in clinical trials shall be required to file with the China Human Genetic Resources Management Office through its online system. On October 26, 2017, the Ministry of Science and Technology issued the Circular on Optimizing the Administrative Examination and Approval of Human Genetic Resources, which simplified the approval for sampling and collecting human genetic resources for the purpose of commercializing a drug in the PRC.

On June 10, 2019, the State Council of PRC issued the National Regulations on the Management of Human Genetic Resources, which formalized the approval requirements pertinent to research collaborations between Chinese and foreign-owned entities. Pursuant to this new rule, a new notification system (as opposed to the advance approval approach originally in place) is put in place for clinical trials using China’s human genetic resources at clinical institutions without involving the export of human genetic resources outside of China.

Trial Exemptions and Acceptance of Foreign Data

The NMPA may reduce its requirements for clinical trials and data, depending on the drug and the existing data. The NMPA has granted waivers for all or part of trials and has stated that it will accept data generated abroad (even if not as part of a global study), including early phase data, that meets its requirements. On July 6, 2018, the NMPA issued the Technical Guidance Principles on Accepting Foreign Drug Clinical Trial Data (the “Guidance Principles”) as one of the implementing rules for the Innovation Opinion. According to the Guidance Principles, the data of foreign clinical trials must meet the authenticity, completeness, accuracy and traceability

requirements, and such data must be obtained in consistency with the relevant requirements under the Good Clinical Trial Practice (GCP) of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (the “ICH”). Clinical trial sponsors must be attentive to potentially meaningful ethnic differences in the subject population.

The NMPA now officially permits, and its predecessor agencies have permitted on a case-by-case basis in the past, drugs approved outside of China to be approved in China on a conditional basis without pre-approval clinical trials being conducted in China. Specifically, in 2018, the NMPA issued the Procedures for Reviewing and Approval of Clinical Urgently Needed Overseas New Drugs, permitting drugs that have been approved within the last ten years in the United States, the European Union or Japan and that prevent or treat orphan diseases or prevent or treat serious life-threatening illnesses for which there is either no effective therapy in China or for which the foreign-approved drug would have clear clinical advantages. Applicants will be required to establish a risk mitigation plan and may be required to complete trials in China after the drug has been marketed. The CDE has developed a list of qualifying drugs that meet the foregoing criteria.

Clinical Trial Process and Good Clinical Practices

Typically, drug clinical trials in China have four phases. Phase 1 refers to the initial clinical pharmacology and human safety evaluation studies. Phase 2 refers to the preliminary evaluation of a drug candidate’s therapeutic efficacy and safety for target indication(s) in patients. Phase 3 (often the pivotal study) refers to clinical trials that further verify the drug candidate’s therapeutic efficacy and safety on patients with target indication(s) and ultimately provide sufficient evidence for the review of a drug registration application. Phase 4 refers to a new drug’s post-marketing study to assess therapeutic effectiveness and adverse reactions when the drug is widely used, to evaluate overall benefit-risk relationships of the drug when used among the general population or specific groups and to adjust the administration dose, etc.

On August 6, 2003, the NMPA promulgated the Administration of Quality of Drug Clinical Practice (the “GCP”) to improve the quality of clinical trials. On February 19, 2004, the NMPA issued the Circular on Measures for Certification of Drug Clinical Institutions (Trial), providing that the NMPA is responsible for the certification of clinical trial institutions nationwide and that the NHFPC is responsible for the certification of clinical trial institutions within its duties. The NMPA requires that the different phases of clinical trials in China receive ethics committee approval prior to the approval of the clinical trials and that the clinical trials shall comply with GCP. Under the Circular on Measures for Certification of Drug Clinical Institutions (Trial), the NMPA and the NHFPC shall decide whether an institution is qualified for undertaking pharmaceutical clinical trials upon evaluating the institution’s organizational administration, research personnel, equipment and facilities, management system and standard operational rules. Pursuant to the Circular on Measures for Certification of Good Laboratory Practice for Non-clinical Laboratory, a Good Laboratory Practice Certification will be issued by the NMPA if all the relevant requirements are satisfied, which will also be published on the NMPA’s website. Pursuant to the Opinions on Deepening the Reform of the Evaluation and Approval System and Inspiring Innovation of Drugs and Medical Devices and Equipment, 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 Good Laboratory Practice, and the protocols must be approved by the ethics committees of each study site.

Reform of Evaluation and Approval System for Drugs

On August 9, 2015, the State Council promulgated the Opinions on the Reform of Evaluation and Approval System for Drugs and Medical Devices and Equipment, which establishes the reform framework of the evaluation and approval system for drugs, medical devices and equipment, indicating the enhancement of the standard of approval for drug registration and accelerating the evaluation and approval process for innovative drugs.

On November 11, 2015, the NMPA issued the Circular Concerning Several Policies on Drug Registration Review and Approval, which further clarifies the measures and policies with regard to the simplification and acceleration of the approval process for drugs.

According to the Decision of the NMPA on Adjusting the Approval Procedures under the Administrative Approval Items for Certain Drugs made on March 17, 2017 and effective from May 1, 2017, the approval for a clinical trial application can be directly issued by the CDE under the NMPA on behalf of the NMPA.

On October 8, 2017, the General Office of the State Council promulgated the Innovation Opinions, which further promotes the structural adjustment to and technical innovations of drugs, medical devices and equipment.

On December 21, 2017, the NMPA promulgated the Opinions on Encouraging the Prioritized Evaluation and Approval for Drug Innovations, replacing the Opinions on Priority Review and Approval for Resolving Drug Registration Applications Backlog promulgated on February 24, 2016, which provides for fast track clinical trial approval or drug registration pathway to innovative drugs.

On May 23, 2018, the NMPA and the NHC jointly issued the Circular on Issues Concerning Optimizing Drug Registration Review and Approval, which further simplifies and accelerates the clinical trial approval process.

Special Examination and Fast Track Approval for Innovative Drugs under Current Reform Frame

Pursuant to the Provisions on the Administration of Special Examination and Approval of Registration of New Drugs promulgated by the NMPA on January 7, 2009, the NMPA conducts special examination and approval for new drug registration applications when, among others, (1) the effective constituent of a drug extracted from plants, animals, minerals, etc., as well as the preparations thereof, have never been marketed in China, or the material medicines and the preparations thereof are newly discovered; (2) the chemical raw material medicines as well as the preparations thereof and the biological product have not been approved for marketing anywhere in the world; (3) the new drugs are for treating AIDS, malignant tumors and rare diseases, etc., and have obvious advantages in clinical treatment; or (4) the new drugs are for treating diseases with no effective methods of treatment. The Provisions on the Administration of Special Examination and Approval of Registration of New Drugs provides that the applicant may file for special examination and approval at the clinical trial application stage if the drug candidate falls within items (1) or (2). The provisions provide that for drug candidates that fall within items (3) or (4), the application for special examination and approval cannot be made until filing for production.

The Circular Concerning Several Policies on Drug Registration Review and Approval issued on November 11, 2015 further clarifies the above-mentioned policy, potentially simplifying and accelerating the approval process of clinical trials: (x) a one-time umbrella approval procedure allowing the overall approval of all phases of a new drug's clinical trials, replacing the current phase-by-phase application and approval procedure, will be adopted for new drugs' clinical trial applications; and (y) a fast track drug registration or clinical trial approval pathway for the following applications: (i) registration of innovative new drugs treating AIDS, malignant tumors, serious infectious diseases and rare diseases; (ii) registration of pediatric drugs; (iii) registration of drugs treating specific or prevalent diseases in elders; (iv) registration of drugs listed in national major science and technology projects or national key research and development plan; (v) registration of innovative drugs using advanced technology, using innovative treatment methods, or having distinctive clinical benefits; (vi) registration of foreign innovative drugs to be manufactured locally in China; (vii) concurrent applications for new drug clinical trials which are already approved in the United States or the European Union or concurrent drug registration applications for drugs which have applied to the competent drug approval authorities for marketing authorization and passed such authorities' onsite inspections in the United States or European Union and are manufactured using the same production line in China; and (viii) clinical trial approval for drugs with urgent clinical need and patent expiry within three years, and manufacturing authorization applications for drugs with urgent clinical need and patent expiry within one year.

The Opinions on Encouraging the Prioritized Evaluation and Approval for Drug Innovations promulgated on December 21, 2017 provides that a fast track clinical trial approval or drug registration pathway will be available to both innovative drugs with distinctive clinical benefits, which have not been sold within or outside China, and drugs using advanced technology, innovative treatment methods or having distinctive treatment advantages.

The Opinions on the Reform of Evaluation and Approval System for Drugs and Medical Devices and Equipment promulgated on August 9, 2015 provides that the composition of the examiner team of the CDE shall be strengthened by, among other actions, (1) recruiting professional evaluation talent from the public, (2) engaging relevant experts to participate in technological examination and evaluation, and (3) establishing a system of chief professional positions. Additionally, the Opinions on Encouraging the Prioritized Evaluation and Approval for Drug Innovations emphasizes the improvement of the examination and evaluation system, which requires the establishment of a new drug examination and evaluation team comprising professionals specialized in clinical medicine, pharmaceutical sciences, pharmacology, toxicology and statistics. As a result, since 2015, the NMPA and the CDE have started a large-scale expansion of examiners, which could greatly accelerate the new drug approval process in China.

Manufacturing and Distribution

According to the Drug Administration Law, all facilities that manufacture drugs in China must receive a drug manufacturing license from the local drug regulatory authority. Each drug manufacturing license issued to a pharmaceutical manufacturing enterprise is effective for a period of five years. Any enterprise holding a drug manufacturing license is subject to review by the relevant regulatory authorities on an annual basis. A separate certification of compliance with Good Manufacturing Practice (the “GMP”) is also required.

Similarly, to conduct sales, importation, shipping and storage (collectively, the “distribution activities”), a company must obtain a Drug Distribution License from the local drug regulatory authority, subject to renewal every five years. A separate certification of compliance with the NMPA’s drug good supply practice (the “GSP”), is also required.

China has implemented a “Two-Invoice System” to control the distribution of prescription drugs. The “Two-Invoice System” generally requires that no more than two invoices be issued throughout the distribution chain: one from the manufacturer to a distributor and another from the distributor to the end-user hospital. This excludes the sale of products invoiced from the manufacturer to its wholly-owned or controlled distributors, or for imported drugs, to its exclusive distributor, or from a distributor to its wholly-owned or controlled subsidiary (or between its wholly-owned or controlled subsidiaries). However, the system still significantly limits the options for companies to use multiple distributors to reach a larger geographic area in China. Compliance with the Two-Invoice System is a prerequisite for pharmaceutical companies to participate in the procurement processes of public hospitals, which currently provide most of China’s healthcare services. Manufacturers and distributors that fail to implement the Two-Invoice System may lose their qualifications to participate in the bidding process. Non-compliant manufacturers may also be blacklisted from engaging in drug sales to public hospitals in a locality.

The Two-Invoice System was first implemented in 11 provinces involved in pilot comprehensive medical reforms, and the program has been expanded to nearly all provinces, each with its own individual rules for the program.

New Drug Application

Pursuant to the Administrative Measures for Drug Registration, when Phases 1, 2 and 3 clinical trials have been completed, the applicant may apply to the NMPA for approval of a new drug application. The NMPA shall then determine whether to approve the application according to the comprehensive evaluation opinion provided by the CDE of the NMPA.

International Multi-center Clinical Trials Regulations

On January 30, 2015, the NMPA promulgated the Notice on Issuing the International Multi-Center Clinical Trial Guidelines (Trial), effective as of March 1, 2015, to provide guidance on the regulation of the application, implementation and administration of international multi-center clinical trials in China. Pursuant to the Notice on Issuing the International Multi-Center Clinical Trial Guidelines (Trial), international multi-center clinical trial applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol. Where the applicant plans to make use of the data derived from the international multi-center clinical trials for its application to the NMPA for approval of a new drug application, such international multi-center clinical trials shall satisfy, in addition to the requirements set forth in the Drug Administration Law and its implementation measures, the Administrative Measures for Drug Registration and other relevant laws and regulations, the following requirements:

- The applicant shall first conduct an overall evaluation on the global clinical trial data and further make trend analysis of the Asian and Chinese clinical trial data. In the analysis of Chinese clinical trial data, the applicant shall consider the representativeness of the research subjects, i.e., the participating patients;
- The applicant shall analyze whether the amount of Chinese research subjects is sufficient to assess and adjudicate the safety and effectiveness of the drug under clinical trial, and satisfy the statistical and relevant legal requirements; and
- The onshore and offshore international multi-center clinical trial research centers shall be subject to on-site inspections by competent PRC governmental agencies.

International multi-center clinical trials shall follow international prevailing GCP principles and ethics requirements. Applications shall ensure the truthfulness, reliability and trustworthiness of clinical trials results; the researchers shall have the qualification and capability to perform relevant clinical trials; and an ethics committee shall continuously review the trials and protect the subjects' interests, benefits and safety. Before the performance of the international multi-center clinical trial, applicants shall obtain clinical trial approvals or complete filings pursuant to requirements under the local regulations where clinical trials are conducted, and register and disclose the information of all major researchers and clinical trial organizations on the NMPA drug clinical trial information platform.

Pursuant to the Opinions on Deepening the Reform of the Evaluation and Approval System and Inspiring Innovation of Drugs and Medical Devices and Equipment, clinical trial data obtained from foreign centers may be used to apply for registration in China as long as such data meet the relevant requirements for the registration of drugs and medical devices in China. When using international multi-center clinical trial data to support new drug applications in China, applicants shall submit the completed global clinical trial report, statistical analysis report and database, along with relevant supporting data in accordance with ICH-CTD (International Conference on Harmonization-Common Technical Document) content and format requirements; subgroup research results summary and comparative analysis shall also be conducted concurrently.

Pilot Plan for the Marketing Authorization Holder System

Pursuant to the Opinions on the Reform of Evaluation and Approval System for Drugs and Medical Devices and Equipment promulgated on August 9, 2015, the State Council published the policy for carrying out a pilot plan for the drug marketing authorization holder mechanism. Under the authorization of the Standing Committee of the NPC, the State Council issued the Pilot Plan for the Drug Marketing Authorization Holder Mechanism on May 26, 2016, providing a detailed pilot plan for the drug marketing authorization holder mechanism in ten provinces in China. Under the drug marketing authorization holder mechanism, domestic drug research and development institutions and individuals in the pilot regions are eligible to be holders of drug registrations without having to become drug manufacturers. The marketing authorization holders may engage contract manufacturers for manufacturing, provided that the contract manufacturers are licensed and GMP-certified and

are also located within the pilot regions. Drugs that qualify for the drug marketing authorization holder mechanism include: (1) new drugs (including biological products for curative uses of Class I, Class VII and biosimilars under the Administration of Drug Registration) approved after the implementation of the drug marketing authorization holder mechanism; (2) generic drugs approved as Category 3 or 4 drugs under the Reform Plan for Registration Category of Chemical Medicine issued by the NMPA on March 4, 2016; (3) previously approved generics that have passed equivalence assessments against their original drugs; and (4) previously approved drugs whose licenses were held by drug manufacturers originally located within the pilot regions but have moved out of the pilot regions due to corporate mergers or other reasons.

On August 15, 2017, the NMPA issued the Circular on the Matters Relating to Promotion of the Pilot Program for the Drug Marketing Authorization Holder System, clarifying that the marketing authorization holder shall be responsible for managing the whole manufacturing and marketing chain and the whole life cycle of drugs and shall assume full legal liabilities for the non-clinical drug study, clinical trials, manufacturing, marketing and distribution and adverse drug reaction monitoring. The marketing authorization holder is permitted to entrust several drug manufacturers under the drug quality management system established by the marketing authorization holder. The marketing authorization holder shall submit a report of drug manufacturing, marketing, prescription, techniques, pharmacovigilance, quality control measures and certain other matters to the NMPA within 20 working days after the end of each year.

Administrative Observation Periods for New Drugs

According to the Implementing Measures of the Drug Administration Law, the NMPA may, for the purposes of protecting public health, set an administrative observation period of not more than five years for a new drug produced by a drug manufacturer. During the administrative observation period, no approval shall be given to any other manufacturer to produce or import the said drug.

Non-Inferiority Standard

In China, a drug may receive regulatory approval without showing superiority in its primary endpoint. Rather, a drug may be approved for use if it shows non-inferiority in its primary endpoint and superiority in one of its secondary endpoints.

Packaging of Pharmaceutical Products

Pursuant to the Administration of Quality of Drug Clinical Practice, the applicant shall be responsible for proper packaging and labeling of drugs for clinical trials, and in double-blinded clinical trials, the test drug shall be consistent with the control drug or placebo in appearance, odor, packaging, labeling, and certain other features. According to the Measures for the Administration of Pharmaceutical Packaging promulgated on February 12, 1988 and effective from September 1, 1988, pharmaceutical packaging must comply with national and professional standards. If there is no national or professional standard available, an applicant may formulate and implement its own standards after obtaining the approval of the provincial administration or bureau of standards. The applicant must reapply if it needs to change its own packaging standards. Drugs that have not been developed and approved for packaging standards must not be sold or marketed in the PRC (except for drugs for the military).

National List of Essential Drugs

On August 18, 2009, the MOH and eight other ministries and commissions in the PRC issued the Provisional Measures on the Administration of the National List of Essential Drugs which was revised on February 13, 2015 aim to promote essential medicines sold to consumers at fair prices in the PRC and ensure that the general public in the PRC has equal access to the drugs contained in the National List of Essential Drugs. The MOH promulgated the National List of Essential Drugs on March 13, 2013 and on September 30, 2018.

According to these regulations, basic healthcare institutions funded by the government shall store up and use drugs listed in the National List of Essential Drugs. The drugs listed in the National List of Essential Drugs shall be purchased by centralized tender process and shall be subject to the price control by the National Development and Reform Commission (the “NDRC”). Remedial drugs in the National List of Essential Drugs are all listed in the NRDL and the purchase price of such drugs is entitled to reimbursement.

Government Price Controls

The Chinese government has abolished the 15-year-old government-led pricing system for drugs. On May 4, 2015, the NDRC and six other ministries and commissions in the PRC issued the Opinion on Promoting Drug Pricing Reform, which lifted the government-prescribed maximum retail price for most drugs, except for narcotic drugs and Class I psychotropic drugs. The government regulates drug prices mainly by establishing a consolidated procurement mechanism, restructuring medical insurance reimbursement standards and strengthening the regulation of medical and pricing practices as discussed below.

Centralized Procurement and Tenders

Under the current regulations, public medical institutions owned by the government or owned by State-owned or controlled enterprises are required to purchase pharmaceutical products through centralized online procurement processes. There are exceptions for drugs on the National List of Essential Drugs, which have their own procurement rules, and for certain drugs subject to the central government’s special control, such as toxic, radioactive and narcotic drugs and traditional Chinese medicines.

The centralized procurement process takes the form of public tenders operated by provincial or municipal-level government agencies. The centralized tender process is typically conducted once every year. The bids are assessed by a committee randomly selected from a database of experts. The committee members assess the bids based on a number of factors, including, but not limited to, bid price, product quality, clinical effectiveness, product safety, level of technology, qualifications and reputation of the manufacturer, after-sale services and innovation.

The State Council approved state-run centralized medicine procurement and 11 pilot cities for the program in a circular issued on January 17, 2019. It is an effort to deepen reform of the medical and health sector and optimize the pricing system of drugs. According to the circular, in the 11 pilot cities drugs will be selected from generic brands for centralized medicine procurement. The selected drugs must pass the consistency evaluation on quality and effectiveness. The policy is aimed at lowering drug costs for patients, reducing transaction costs for enterprises, regulating drug use of institutions, and improving the centralized medicine procurement and pricing system. The centralized procurement is open to all approved enterprises that can produce drugs on the procurement list in China. Clinical effects, adverse reactions, and batch stability of the drugs will be considered, and their consistency will be the main criteria for evaluation, while production capacity and stability of the supplier will also be considered.

Commercial Insurance

On October 25, 2016, the State Council issued the Plan for Healthy China 2030. According to the Plan, the country will establish a multi-level medical security system built around basic medical insurance, with other forms of insurance supplementing the basic medical insurance, including serious illness insurance for urban and rural residents, commercial health insurance and medical assistance. Furthermore, the Plan encourages enterprises and individuals to participate in commercial health insurance and various forms of supplementary insurance. The evolving medical insurance system makes innovative drugs more affordable and universally available to the Chinese population, which renders greater opportunities to drug manufacturers that focus on the research and development of innovative drugs, such as high-cost cancer therapeutics.

Healthcare System Reform

The PRC government recently promulgated several healthcare reform policies and regulations to reform the healthcare system. On March 17, 2009, the State Council issued the Guidelines on Strengthening the Reform of Healthcare System. On December 27, 2016, the State Council issued the Notice on the Issuance of the 13th Five-year Plan on Strengthening the Reform of Healthcare System. On April 25, 2017, the General Office of the State Council issued the Notice on the Main Tasks of Strengthening the Reform of Healthcare System in 2017.

Highlights of the aforementioned healthcare reform policies and regulations include the following:

- One of the main objectives of the reform is to establish a basic healthcare system that covers both urban and rural residents and provides Chinese citizens with safe, effective, convenient and affordable healthcare services. By 2020, a basic healthcare system covering both urban and rural residents shall be established.
- Another main objective of the reform is to improve the healthcare system through the development of a graded hierarchical healthcare system, modern hospital management, basic medical insurance, drug supply support and comprehensive supervision.
- The reforms aimed to promote orderly market competition and improve the efficiency and quality of the healthcare system to meet the various medical need of the Chinese population. From 2009, basic public healthcare services such as preventive healthcare, maternal and child healthcare and health education have been provided to urban and rural residents. In the meantime, the reforms also encourage innovations by pharmaceutical companies to eliminate pharmaceutical products that fail to demonstrate reliable efficacy and positive risk-benefit ratio.
- The key tasks of the reform were as follows: (1) to deepen the reform of public hospitals; (2) to accelerate the development of a graded diagnosis and treatment system; (3) to consolidate and improve the universal medical insurance system; (4) to guarantee drug supply; (5) to establish and improve a comprehensive supervision system; (6) to cultivate talented health-care practitioners; (7) to stabilize and perfect the basic public health service equalization system; (8) to advance the construction of health information technology; (9) to accelerate the development of the health services industry generally and (10) to strengthen organization and implementation.

Chronic Diseases Prevention and Treatment

Pursuant to the Guiding Opinion of the General Office of the State Council on Promoting the Construction of the Hierarchical Healthcare System issued by the General Office of the State Council on September 8, 2015 and the Notice on Promoting Pilot Work for Hierarchical Healthcare System jointly promulgated by the NHFPC and the State Administration of Traditional Chinese Medicine on August 19, 2016, the hierarchical healthcare system is expected to be gradually improved, and the framework for division and coordination among medical and health institutions shall be substantially established by 2017, and a diagnosis and treatment model featuring objectives, such as initial diagnosis of common diseases and frequent diseases at primary hospitals and separate treatment of acute and chronic diseases, are expected to be gradually established. According to the Guiding Opinion of the General Office of the State Council on Promoting the Construction of the Hierarchical Healthcare System, several chronic diseases, including hypertension, diabetes, cancer and cardiovascular and cerebrovascular diseases, are pilot diseases under the hierarchical healthcare system. Primary healthcare institutions, rehabilitation hospitals and nursing institutions may provide treatment, rehabilitation and nursing services for patients with chronic diseases, patients in stable conditions, elderly patients, and advanced cancer patients who have clear diagnosis and stable disease conditions.

On January 22, 2017, the General Office of the State Council issued the Notice on the Medium and Long-Term Plan for Chronic Disease Prevention and Treatment in China (2017-2025), which sets up the objectives of the management of diabetes patients, targeting the involvement of 35 million diabetic patients by 2020 and

40 million by 2025 in chronic disease management. The Notice on the Medium and Long-Term Plan for Chronic Disease Prevention and Treatment in China (2017-2025) reaffirms that the hierarchical healthcare system of chronic diseases such as diabetes shall be promoted and encourages the initial diagnosis of common diseases and frequent diseases at primary hospitals. In addition, social participation in regional medical services, health management and chronic disease prevention services, as well as investments in the field of chronic disease prevention by social capital, are encouraged.

Intellectual Property Rights

China became a member of the World Trade Organization and a party to the Agreement on Trade-Related Aspects of Intellectual Property Rights on December 11, 2001. China has also entered into several international conventions on intellectual property rights, including, but not limited to, the Paris Convention for the Protection of Industrial Property, the Madrid Agreement Concerning the International Registration of Marks, and the Patent Cooperation Treaty.

Patents

Pursuant to the PRC Patent Law promulgated by the Standing Committee of the NPC on March 12, 1984 and amended on September 4, 1992, August 25, 2000 and December 27, 2008, respectively, and effective from October 1, 2009, and the Implementation Rules of the Patent Law of the PRC promulgated by the State Council on June 15, 2001 and amended on December 28, 2002 and January 9, 2010, respectively, patents in China fall into three categories: invention, utility model and design. An invention patent is granted to a new technical solution proposed in respect of a product or method or an improvement of a product or method. A utility model is granted to a new technical solution that is practicable for application and proposed in respect of the shape, structure or a combination of both of a product. A design patent is granted to the new design of a certain product in shape, pattern or a combination of both and in color, shape and pattern combinations aesthetically suitable for industrial application. Under the PRC Patent Law, the term of patent protection starts from the date of application. Patents relating to invention are effective for twenty years, and utility models and designs are effective for ten years from the date of application. The PRC Patent Law adopts the principle of “first-to-file” system, which provides that where more than one person files a patent application for the same invention, a patent will be granted to the person who files the application first.

Existing patents can become narrowed, invalid or unenforceable due to a variety of grounds, including lack of novelty, creativity, and deficiencies in patent application. In China, a patent must have novelty, creativity and practical applicability. Under the PRC Patent Law, novelty means that before a patent application is filed, no identical invention or utility model has been publicly disclosed in any publication in China or overseas or has been publicly used or made known to the public by any other means, whether in or outside of China, nor has any other person filed with the patent authority an application that describes an identical invention or utility model and is recorded in patent application documents or patent documents published after the filing date. Creativity means that, compared with existing technology, an invention has prominent substantial features and represents notable progress, and a utility model has substantial features and represents any progress. Practical applicability means an invention or utility model can be manufactured or used and may produce positive results. Patents in China are filed with the State Intellectual Property Office (the “SIPO”). Normally, the SIPO publishes an application for an invention patent within 18 months after the filing date, which may be shortened at the request of applicant. The applicant must apply to the SIPO for a substantive examination within three years from the date of application.

Article 20 of the PRC Patent Law provides that, for an invention or utility model completed in China, any applicant (not just Chinese companies and individuals), before filing a patent application outside of China, must first submit it to the SIPO for a confidential examination. Failure to comply with this requirement will result in the denial of any Chinese patent for the relevant invention. This added requirement of confidential examination by the SIPO has raised concerns by foreign companies who conduct research and development activities in China or outsource research and development activities to service providers in China.

Patent Enforcement

Unauthorized use of patents without consent from owners of patents, forgery of the patents belonging to other persons, or engagement in other patent infringement acts, will subject the infringers to infringement liability. Serious offenses such as forgery of patents may be subject to criminal penalties.

When a dispute arises out of infringement of the patent owner's patent right, Chinese law requires that the parties first attempt to settle the dispute through mutual consultation. However, if the dispute cannot be settled through mutual consultation, the patent owner, or an interested party who believes the patent is being infringed, may either file a civil legal suit or file an administrative complaint with the relevant patent administration authority. A Chinese court may issue a preliminary injunction upon the patent owner's or an interested party's request before instituting any legal proceedings or during the proceedings. Damages for infringement are calculated as the loss suffered by the patent holder arising from the infringement, and if the loss suffered by the patent holder arising from the infringement cannot be determined, the damages for infringement shall be calculated as the benefit gained by the infringer from the infringement. If it is difficult to ascertain damages in this manner, damages may be determined by using a reasonable multiple of the license fee under a contractual license. Statutory damages may be awarded in the circumstances where the damages cannot be determined by the above-mentioned calculation standards. The damage calculation methods shall be applied in the aforementioned order. Generally, the patent owner has the burden of proving that the patent is being infringed. However, if the owner of an invention patent for manufacturing process of a new product alleges infringement of its patent, the alleged infringer has the burden of proof.

Medical Patent Compulsory License

According to the PRC Patent Law, for the purpose of public health, the SIPO may grant a compulsory license for manufacturing patented drugs and exporting them to countries or regions covered under relevant international treaties to which the PRC has acceded.

Trade Secrets

Pursuant to the PRC Anti-Unfair Competition Law promulgated by the Standing Committee of the NPC on September 2, 1993 and amended on November 4, 2017 and April 23, 2019, respectively, the term "trade secrets" refers to technical and business information that is unknown to the public, has utility, may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders. Under the PRC Anti-Unfair Competition Law, business persons are prohibited from infringing others' trade secrets by (1) obtaining the trade secrets from the legal owners or holders by any unfair methods, such as theft, bribery, fraud, coercion, electronic intrusion, or any other illicit means; (2) disclosing, using or permitting others to use the trade secrets obtained illegally under item (1) above; (3) disclosing, using or permitting others to use the trade secrets, in violation of any contractual agreements or any requirements of the legal owners or holders to keep such trade secrets in confidence; or (4) instigating, inducing or assisting others to disclose, use or permit others to use the trade secrets, in violation of any contractual agreements or any requirement of the legal owners or holders to keep such trade secret in confidence. If a third party knows or should have known of the above-mentioned illegal conduct but nevertheless obtains, uses or discloses trade secrets of others, the third party may be deemed to have committed a misappropriation of the others' trade secrets. The parties whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may terminate any illegal activities and impose fines on the infringing parties.

Trademarks

Pursuant to the Trademark Law of the PRC promulgated by the Standing Committee of the NPC on August 23, 1982 and amended on February 22, 1993, October 27, 2001 and August 30, 2013, respectively, and effective from May 1, 2014, which has been amended on April 23, 2019 and will become effective from

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November 1, 2019, the period of validity for a registered trademark is ten years, commencing from the date of registration. The registrant shall go through the formalities for renewal within twelve months prior to the expiry date of the trademark if continued use is intended. Where the registrant fails to do so, a grace period of six months may be granted. The validity period for each renewal of registration is ten years, commencing from the day immediately after the expiry of the preceding period of validity for the trademark. In the absence of a renewal upon expiry, the registered trademark shall be cancelled. Industrial and commercial administrative authorities have the authority to investigate any behavior in infringement of the exclusive right under a registered trademark in accordance with the law. In case of a suspected criminal offense, the case shall be timely referred to a judicial authority and decided according to the law.

Domain Names

Domain names are protected under the Measures on Administration of Domain Names for the Chinese Internet promulgated by the Ministry of Industry and Information Technology, on November 5, 2004 and effective from December 20, 2004, which was replaced by the Administrative Measures on the Internet Domain Names issued by the Ministry of Industry and Information Technology on August 24, 2017 and effective from November 1, 2017, and the Implementing Rules on Registration of Domain Names issued by China Internet Network Information Center on May 28, 2012, which became effective on May 29, 2012. The Ministry of Industry and Information Technology is the main regulatory body responsible for the administration of PRC internet domain names. Domain name registrations are handled through domain name service agencies established under the relevant regulations, and the applicants become domain name holders upon successful registration.

Product Liability

The Product Quality Law of the PRC promulgated by the Standing Committee of the NPC on February 22, 1993 and amended on July 8, 2000, August 27, 2009 and December 29, 2018, respectively, is the principal governing law relating to the supervision and administration of product quality. According to the Product Quality Law, manufacturers shall be liable for the quality of products produced by them, and sellers shall take measures to ensure the quality of the products sold by them. A manufacturer shall be liable for compensating for any bodily injuries or property damages, other than the defective product itself, resulting from the defects in the product, unless the manufacturer is able to prove that: (1) the product has never been distributed; (2) the defects causing injuries or damages did not exist at the time when the product was distributed; or (3) the science and technology at the time when the product was distributed was at a level incapable of detecting the defects. A seller shall be liable for compensating for any bodily injuries or property damages of others caused by the defects in the product if such defects are attributable to the seller. A seller shall pay compensation if it fails to indicate either the manufacturer or the supplier of the defective product. A person who is injured or whose property is damaged by the defects in the product may claim for compensation from the manufacturer or the seller.

Pursuant to the General Principles of the Civil Law of the PRC promulgated by the NPC on April 12, 1986 and amended on August 27, 2009, both manufacturers and sellers shall be held liable where the defective products result in property damages or bodily injuries to others. Pursuant to the Tort Liability Law of the PRC promulgated by the Standing Committee of the NPC on December 26, 2009 and effective from July 1, 2010, manufacturers shall assume tort liabilities where the defects in products cause damages to others. Sellers shall assume tort liabilities where the defects in products that have caused damages to others are attributable to the sellers. The aggrieved party may claim for compensation from the manufacturer or the seller of the defected product that has caused damage.

Regulation of Commercial Bribery

Pharmaceutical companies involved in a criminal investigation or administrative proceedings related to bribery are listed in the Adverse Records of Commercial Briberies by their respective provincial health and

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family planning administrative department. Pursuant to the Provisions on the Establishment of Adverse Records of Commercial Briberies in the Medicine Purchase and Sales Industry which became effective on March 1, 2014, provincial health and family planning administrative departments formulate the implementing measures for establishment of Adverse Records of Commercial Briberies. Where a pharmaceutical company or its agent is listed in the Adverse Records of Commercial Briberies on one occasion, it will be prohibited from participating in the procurement bidding process or selling its products to public medical institutions located in the local provincial-level region for two years from the publication of the adverse records. The evaluation points of such pharmaceutical company or agent in respect of the procurement bidding process and procurement by public medical institutions must be credited by public medical institutions in the other provincial-level regions for two years from the publication of the adverse records. Where a pharmaceutical company or its agent is listed in the Adverse Records of Commercial Briberies on two or more occasions within five years, it will be prohibited from participating in the procurement bidding process or selling its products to all public medical institutions in the PRC for two years from the publication of these adverse records.

Regulations Relating to Employee Stock Incentive Plan

In February 2012, the SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies (the “Stock Option Rules”), which replaced the Application Procedures of Foreign Exchange Administration for Domestic Individuals Participating in Employee Stock Ownership Plans or Stock Option Plans of Overseas Publicly Listed Companies issued by the SAFE on March 28, 2007. In accordance with the Stock Option Rules and relevant rules and regulations, PRC citizens or non-PRC citizens residing in China for a continuous period of not less than one year, who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with the SAFE through a domestic qualified agent, which could be a PRC subsidiary of such overseas listed company, and complete certain procedures. We and our employees who are PRC citizens or who reside in China for a continuous period of not less than one year and who participate in our stock incentive plan will be subject to such regulation. In addition, the SAT has issued circulars concerning employee share options or restricted shares. Under these circulars, employees working in the PRC who exercise share options, or whose restricted shares vest, will be subject to PRC individual income tax (the “IIT”). The PRC subsidiaries of an overseas listed company have obligations to file documents related to employee share options or restricted shares with relevant tax authorities and to withhold IIT of those employees related to their share options or restricted shares. If the employees fail to pay, or the PRC subsidiaries fail to withhold, their IIT according to relevant laws, rules and regulations, the PRC subsidiaries may face sanctions imposed by the tax authorities or other PRC government authorities.

Regulations Relating to Foreign Exchange and the Dividend Distribution

Foreign Exchange Control

The State Council promulgated the PRC Regulation for the Foreign Exchange on January 29, 1996, which was amended on January 14, 1997 and August 5, 2008, respectively. On June 20, 1996, the People’s Bank of China promulgated the Regulation on the Administration of the Foreign Exchange Settlement, Sales and Payment, which came into effect on July 1, 1996. Pursuant to the above-mentioned regulations, foreign exchanges required for distribution of profits and payment of dividends may be purchased from designated foreign exchange banks in the PRC upon presentation of a board resolution authorizing the distribution of profits or payment of dividends. The Regulation on the Administration of the Foreign Exchange Settlement, Sales and Payment removed the previous restrictions on convertibility of foreign exchange in respect of current account items, including the distribution of dividends, interest and royalty payments, trade and service-related foreign exchange transactions, while foreign exchange transactions in respect of capital account items, such as direct investment, loan, securities investment and repatriation of investment, remain subject to the approval of the SAFE.

On November 19, 2012, the SAFE issued the Operating Rules for Foreign Exchange Issues with Regard to Direct Investment under Capital Account as an appendix to the Circular of the SAFE on Further Improving and Adjusting the Foreign Exchange Policies on Direct Investment, which was issued on November 19, 2012 and amended on May 4, 2015. According to the Circular of the SAFE on Further Improving and Adjusting the Foreign Exchange Policies on Direct Investment, (i) the opening of and payment into foreign exchange accounts under direct investment accounts are no longer subject to approval by the SAFE; (ii) reinvestment with the legal income of foreign investors in China is no longer subject to approval by the SAFE; (iii) the procedures for capital verification and confirmation that foreign-funded enterprises need to go through are simplified; (iv) the purchase and external payment of foreign exchange under direct investment accounts are no longer subject to approval by the SAFE; (v) domestic transfer of foreign exchange under direct investment accounts is no longer subject to approval by the SAFE; and (vi) the administration over the conversion of foreign exchange capital of foreign-funded enterprises is improved. On February 13, 2015, the SAFE issued the Circular on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of Direct Investment, which came into effect on June 1, 2015, providing that the banks, instead of the SAFE, can directly handle the foreign exchange registration and approval under foreign direct investment, while the SAFE and its branches indirectly supervise the foreign exchange registration and approval under foreign direct investment through the banks.

On May 11, 2013, the SAFE promulgated the Provisions on the Administration of Foreign Exchange in Foreign Direct Investments by Foreign Investors, which became effective on May 13, 2013, and relevant supporting documents that regulate and clarify the administration over foreign exchange administration in foreign direct investments.

On March 30, 2015, the SAFE released the Circular on the Reform of the Management Method for the Settlement of Foreign Exchange Capital of Foreign-invested Enterprises, which came into effect on June 1, 2015 and superseded the Notice on the Relevant Operating Issues Concerning the Improvement of the Administration of Payment and Settlement of Foreign Currency Capital of Foreign-funded Enterprises issued by the SAFE on August 29, 2008. The Circular on the Reform of the Management Method for the Settlement of Foreign Exchange Capital of Foreign-invested Enterprises has made certain adjustments to some regulatory requirements on the settlement of foreign exchange capital of foreign-invested enterprises, and some foreign exchange restrictions provided in the Notice on the Relevant Operating Issues Concerning the Improvement of the Administration of Payment and Settlement of Foreign Currency Capital of Foreign-funded Enterprises. On June 9, 2016, the SAFE issued the Circular on the Reform and Standardization of the Management Policy of the Settlement of Capital Projects. Under the Circular on the Reform and Standardization of the Management Policy of the Settlement of Capital Projects and the Circular on the Reform of the Management Method for the Settlement of Foreign Exchange Capital of Foreign-invested Enterprises, the settlement of foreign exchange by foreign-invested enterprises shall be governed by the policy of foreign exchange settlement on a discretionary basis. However, the aforementioned circulars also reiterate 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 these circulars are relatively new, it is unclear how they will be implemented, and there exist great uncertainties with respect to their interpretation and implementation by the authorities.

The SAFE promulgated the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment through Special Purpose Vehicles on July 4, 2014, which requires PRC residents to register with local branches of the SAFE in connection with their direct establishment or indirect control of an offshore entity for the purpose of overseas investment and financing, with such PRC residents' legally owned assets or equity interests in domestic enterprises or offshore assets or interests as a "special purpose vehicle" as defined therein. The aforesaid circular further requires amendment to the registration in the event of any significant changes with respect to the special purpose vehicle. Failure to comply with the SAFE registration requirements under the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment through Special Purpose Vehicles could result in liabilities under PRC law for evasion of foreign

exchange controls. The Circular on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of Direct Investment, provides that local banks, instead of the SAFE, can directly handle the initial foreign exchange registration and amendment registration under the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment through Special Purpose Vehicles.

Dividend Distribution

Pursuant to the PRC Company Law, the Wholly Foreign-Owned Enterprise Law of the PRC and the Detailed Implementing Rules for the Wholly Foreign-Owned Enterprise Law of the People's Republic of China, foreign-invested enterprises in the PRC may pay dividends only out of their accumulated profits as determined in accordance with PRC accounting standards and regulations. In addition, a foreign-invested enterprise is required to set aside at least 10% of its accumulated profits each year to fund certain reserve funds, until the accumulative amount of such fund reaches 50% of its registered capital. These wholly foreign-owned companies may also allocate a portion of their after-tax profits based on PRC accounting standards to employee welfare and bonus funds. Amounts allocated to these reserve funds and employee welfare and bonus funds reduce the amount distributable as cash dividends. Upon approval of the competent governmental authorities, foreign investors may utilize RMB dividends to invest or re-invest in enterprises established in China.

On January 26, 2017, the SAFE issued the Notice on Improving the Check of Authenticity and Compliance to Further Promote Foreign Exchange Control, which stipulates several capital control measures with respect to outbound remittance of profits from domestic entities to offshore entities, including the following: (i) under the principle of genuine transaction, banks shall check board resolutions regarding profit distribution, the original version of tax filing records and audited financial statements; and (ii) domestic entities shall hold income to account for previous years' losses before remitting the profits. Moreover, domestic entities shall provide detailed explanations of the sources of capital and the utilization arrangements and board resolutions, contracts and other proof when completing the registration procedures in connection with an outbound investment.

Regulations Relating to Labor

Labor Law and Labor Contract Law

Pursuant to the PRC Labor Law promulgated by the Standing Committee of the NPC on July 5, 1994 and effective from January 1, 1995 and amended on August 27, 2009 and December 29, 2018, respectively, the PRC Labor Contract Law promulgated by the Standing Committee of the NPC on June 29, 2007 and effective from January 1, 2008 and amended on December 28, 2012 and effective from July 1, 2013, and the Implementing Regulations of the Employment Contracts Law of the PRC promulgated by the State Council on September 18, 2008, labor contracts in written form shall be executed to establish labor relationships between employers and employees. Wages cannot be lower than the local minimum wage. The employer must establish a system for labor safety and sanitation, strictly abide by the state rules and standards, provide education regarding labor safety and sanitation to its employees, provide employees with labor safety and sanitary conditions and necessary protection materials in compliance with the state rules and standards, and carry out regular health examinations for employees engaged in work involving occupational hazards.

Social Insurance and Housing Provident Funds

Under applicable PRC laws, including the Social Insurance Law of the PRC which became effective on July 1, 2011 and was amended on December 19, 2018, the Interim Regulations on the Collection and Payment of Social Security Funds promulgated by the State Council on January 22, 1999 and amended on March 24, 2019, and the Regulations on the Administration of Housing Provident Funds promulgated by the State Council on April 3, 1999 and amended on March 24, 2002 and March 24, 2019, respectively, employers are required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension

insurance, unemployment insurance, basic medical insurance, occupational injury insurance, maternity insurance and housing provident funds. These payments are made to local administrative authorities, and any employer who fails to contribute may be fined and ordered to pay the deficit amount within a stipulated time limit.

Regulations Relating to Enterprise Income Tax

Pursuant to the Enterprise Income Tax Law of the PRC effective as of January 1, 2008 and as amended on February 24, 2017 and December 29, 2018, respectively, the income tax rate for both domestic and foreign-invested enterprises is 25% with certain exceptions. To clarify certain provisions in the Enterprise Income Tax Law, the State Council promulgated the Implementation Rules of the Enterprise Income Tax Law on December 6, 2007, which became effective on January 1, 2008. Under the Enterprise Income Tax Law and the Implementation Rules of the Enterprise Income Tax Law, enterprises are classified as either “resident enterprises” or “non-resident enterprises.” Besides enterprises established within the PRC, enterprises established outside of China whose “de facto management bodies” are located in China are considered “resident enterprises” and subject to the uniform 25% enterprise income tax rate for their global income. In addition, the Enterprise Income Tax Law provides that a non-resident enterprise refers to an entity established under foreign law whose “de facto management bodies” are not within the PRC, but has an establishment or place of business in the PRC, or does not have an establishment or place of business in the PRC but has income sourced within the PRC.

The Implementation Rules of the Enterprise Income Tax Law provide that since January 1, 2008, an income tax rate of 10% shall normally be applicable to dividends declared to non-PRC resident enterprise investors that do not have an establishment or place of business in the PRC, or have such establishment or place of business but the relevant income is not effectively connected with the establishment or place of business, to the extent such dividends are derived from sources within the PRC. The income tax on the dividends may be reduced pursuant to a tax treaty between China and the jurisdictions in which the non-PRC shareholders reside.

Other PRC National- and Provincial-Level Laws and Regulations

We are subject to changing regulations under many other laws and regulations administered by governmental authorities at the national, provincial and municipal levels, some of which are or may become applicable to our business. For example, regulations control the confidentiality of patients’ medical information and the circumstances under which patient medical information may be released for inclusion in our databases, or released by us to third parties. These laws and regulations governing both the disclosure and the use of confidential patient medical information may become more restrictive in the future.

We also comply with numerous additional national and provincial laws relating to matters such as safe working conditions, manufacturing practices, environmental protection and fire hazard control. We believe that we are currently in compliance with these laws and regulations; however, we may be required to incur significant costs to comply with these laws and regulations in the future. Unanticipated changes in existing regulatory requirements or adoption of new requirements could therefore have a material adverse effect on our business, results of operations and financial condition.

U.S. Regulation

Government Regulation and Product Approval in the United States

The FDA and other regulatory authorities in the United States at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, recordkeeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biological products. Along with third-party contractors, we will be required to navigate the various pre-clinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to

conduct studies or seek approval or licensure of our drug candidates. The processes for obtaining regulatory approvals in the United States and in foreign jurisdictions, along with subsequent compliance with applicable laws and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Government policies may change and additional government regulations may be enacted that could prevent or delay further development or regulatory approval of any of our drug candidates, or anticipated manufacturing processes, disease indications, or labeling. We cannot predict the likelihood, nature or extent of government regulation that might arise from future legislative or administrative action.

Review and Approval for Licensing Biologics in the United States

In the United States, the FDA regulates our current drug candidates as biological products, or biologics, under the Federal Food, Drug, and Cosmetic Act (the “FDCA”), the Public Health Service Act and associated implementing regulations. Biologics, like other drugs, are used for the treatment, prevention or cure of disease in humans. In contrast to chemically synthesized small molecular weight drugs, which have a well-defined structure and can be thoroughly characterized, biologics are generally derived from living material (human, animal, or microorganism) and are complex in structure, and thus are usually not fully characterized. Biologics include immunomedicines for cancer and other diseases.

Biologics are also subject to other federal, state and local statutes and regulations. The failure to comply with applicable statutory and regulatory requirements at any time during the product development process, approval process or after approval may subject a sponsor or applicant to administrative or judicial enforcement actions. These actions could include the suspension or termination of clinical trials by the FDA, the FDA’s refusal to approve pending applications or supplemental applications, withdrawal of an approval, “Warning Letters” (official messages from the FDA to a manufacturer or other organization that it has violated some rule in a federally regulated activity) or “Untitled Letters” (initial correspondences from the FDA with a regulated industry that cite violations that do not meet the threshold of regulatory significance for a Warning Letter and request correction of the violation), product recalls, product seizures, total or partial suspension of production or distribution, import detention, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA, the Department of Justice (the “DOJ”), or other governmental entities.

An applicant seeking approval to market and distribute a biologic in the United States typically must undertake the following:

- completion of non-clinical laboratory tests and animal studies performed in accordance with the FDA’s good laboratory practice (the “GLP”), regulations;
- submission to the FDA of an application for an Investigational New Drug (“IND”), which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- manufacture, labeling and distribution of an investigational drug in compliance with current good manufacturing practice (the “cGMP”);
- approval by an independent institutional review board (the “IRB”), or ethics committee at each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with the FDA’s current Good Clinical Practices requirements (the “cGCP”), to establish the safety, purity and potency of the proposed biological drug candidate for its intended purpose;
- preparation of and submission to the FDA of a biologics license application (“BLA”), after completion of all pivotal clinical trials requesting marketing approval for one or more proposed indications;

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- satisfactory completion of an FDA Advisory Committee review, where appropriate or if applicable, as may be requested by the FDA to assist with its review;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the proposed product, or components thereof, are produced to assess compliance with cGMP and data integrity requirements to assure that the facilities, methods and controls are adequate to preserve the biologic's identity, safety, quality, purity and potency;
- satisfactory completion of FDA audits of selected clinical investigation sites to assure compliance with cGCP requirements and the integrity of the clinical data;
- payment of user fees under the Prescription Drug User Fee Act (the "PDUFA"), for the relevant year;
- obtaining FDA review and approval of the BLA to permit commercial marketing of the licensed biologic for particular indications for use in the United States; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy (the "REMS"), and the potential requirement to conduct post-approval studies.

The testing and approval process requires substantial time, effort and financial resources and we cannot be certain that any approvals for our drug candidates will be granted on a timely basis, if at all.

From time to time, legislation is drafted, introduced and passed in the Congress of the United States that could significantly change the statutory provisions governing the testing, approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations and policies are often revised or interpreted by the agency in ways that may significantly affect our business and our drug candidates. It is impossible to predict whether further legislative changes will be enacted or whether FDA regulations, guidance, policies or interpretations will be changed or what the effect of such changes, if any, may be.

Pre-clinical and Clinical Development in the United States

Before a BLA applicant can begin testing the potential asset in human subjects, the applicant must first conduct pre-clinical studies. Pre-clinical studies include laboratory evaluations of product chemistry, toxicity and formulation, as well as in vitro and animal studies to assess the potential safety and activity of the biologic for initial testing in humans and to establish a rationale for therapeutic use. Pre-clinical studies are subject to federal regulations and requirements, including GLP regulations. The results of an applicant's pre-clinical studies are submitted to the FDA as part of an IND.

An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. An IND is an exemption from the FDCA that allows an unapproved drug to be shipped in interstate commerce for use in an investigational clinical trial. Such authorization must be secured prior to interstate shipment. In support of a request for an IND, applicants must submit a range of information, including pre-clinical data, manufacturing information and a detailed protocol for each clinical trial. Any subsequent protocol amendments must be submitted to the FDA as part of the IND.

Human clinical trials may not begin until an IND is effective. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises safety concerns or questions about the proposed clinical trial within the 30-day time period. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

The FDA may also place a clinical hold or partial clinical hold on such trial following commencement of a clinical trial under an IND. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed

clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, a specific protocol or part of a protocol is not allowed to proceed, while other protocols may do so. No more than 30 days after the imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor with a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an investigation may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with cGCP regulations, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all FDA IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with cGCP regulations in order to use the study as support for an IND or application for marketing approval, including review and approval by an independent ethics committee and informed consent from subjects.

Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives.

Some trials also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board (the “DSMB”). DSMBs provide authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial and may halt the clinical trial if a DSMB determines that there is an unacceptable safety risk for subjects or based on other grounds, such as no demonstration of efficacy. Other grounds for suspension or termination may be made based on evolving business objectives and/or competitive climate. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

Clinical Trials

For purposes of BLA approval, clinical trials are typically conducted in the following sequential phases that may overlap or be combined:

- Phase 1: The investigational product is initially introduced into a small number of healthy human subjects or patients with the target disease or condition. These trials are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans and the side effects associated with increasing doses. These trials may also yield early evidence of effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product is suspected or known to be unavoidably toxic, the initial human testing may be conducted in patients.
- Phase 2: The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to

identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3: The investigational product is administered to an expanded patient population generally at multiple geographically dispersed clinical trial sites to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety. These clinical trials are intended to generate sufficient data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval by the FDA.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product, referred to as Phase 4 trials. Such post-approval trials, when applicable, are conducted following initial approval, typically to develop additional data and information relating to the biological characteristics of the product and treatment of patients in the intended therapeutic indication.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. In addition, IND safety reports must be submitted to the FDA for any of the following: suspected serious and unexpected adverse reactions; findings from epidemiological studies, pooled analysis of multiple studies, animal or in vitro testing, or other clinical studies, whether or not conducted under an IND, and whether or not conducted by the sponsor, that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the rate of a serious suspected adverse reaction over such rate listed in the protocol or investigator brochure, which is a comprehensive document summarizing the body of information about an investigational product obtained during clinical and non-clinical trials.

Each of Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites to assure compliance with cGCP and the integrity of the clinical data submitted.

During clinical development, the sponsor often refines the indication and endpoints on which the BLA will be based. For endpoints based on patient-reported outcomes (the "PROs"), and observer-reported outcomes (the "OROs"), the process typically is an iterative one. The FDA has issued guidance on the framework it uses to evaluate PRO instruments. Although the agency may offer advice on optimizing PRO and ORO instruments during the clinical development process, the FDA usually reserves final judgment until it reviews the BLA.

Concurrent with clinical trials, companies often complete additional animal studies, and develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, must develop methods for testing the identity, strength, quality, purity and potency of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission and Review

Assuming successful completion of all required clinical testing in accordance with all applicable regulatory requirements, an applicant may submit a BLA requesting licensing to market the biologic for one or more indications in the United States. The BLA must include the results of product development, non-clinical studies

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and clinical trials; detailed information on the product's chemistry, manufacture and controls; and proposed labeling. Under the Prescription Drug User Fee Amendments, a BLA submission is subject to an application user fee, unless a waiver or exemption applies.

The FDA will initially review the BLA for completeness before accepting it for filing. Under the FDA's procedures, the agency has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing and substantive review. If the agency determines that the application does not meet this initial threshold standard, the FDA may refuse to file the application and request additional information, in which case the application must be resubmitted with the requested information and review of the application delayed.

With certain exceptions, BLAs must include a pediatric assessment, generally based on clinical trial data, of the safety and effectiveness of the biologic in relevant pediatric populations. Under certain circumstances, the FDA may waive or defer the requirement for a pediatric assessment, either at the sponsor's request or by the agency's initiative.

After the BLA is accepted for filing, the FDA reviews the BLA to determine, among other things, whether a product is safe, pure and potent and if the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued identity, strength, quality, safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities comply with cGMP and are adequate to assure consistent production of the product within required specifications. In addition, the FDA expects that all data be reliable and accurate, and requires sponsors to implement meaningful and effective strategies to manage data integrity risks. Data integrity is an important component of the sponsor's responsibility to ensure the safety, efficacy and quality of its product or products.

The FDA will typically inspect one or more clinical sites to assure compliance with cGCP regulations before approving a BLA. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

FDA performance goals generally provide for action on a BLA within ten months of filing, which (as discussed above) typically occurs within 60 days of submission, but that deadline is extended in certain circumstances. Furthermore, the review process is often significantly extended by FDA requests for additional information or clarification.

The FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee. Typically, an advisory committee consists of a panel that includes clinicians and other experts who will review, evaluate and provide a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions and usually has followed such recommendations.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its components will be produced, the FDA may issue an approval letter or a Complete Response Letter (the "CRL"). An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. A CRL will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. If and when the deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. In

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issuing the CRL, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional data, information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, and may require additional testing or information and/or require post-marketing studies and clinical trials. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

During the approval process, the FDA will determine whether a REMS is necessary to assure the safe use of the biologic. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. If the FDA concludes that a REMS is needed, the BLA sponsor must submit a proposed REMS and the FDA will not approve the BLA without a REMS that the agency has determined is acceptable.

In addition, under the Pediatric Research Equity Act of 2003 (the “PREA”), as amended and reauthorized, certain applications or supplements must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

If the FDA approves a product, it may limit the approved indications for use for the product, or require that contraindications, warnings or precautions be included in the product labeling. The FDA may also require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug’s safety after approval. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs.

The FDA may also require testing and surveillance programs to monitor the product after commercialization. For biologics, such testing may include official lot release, which requires the manufacturer to perform certain tests on each lot of the product before it is released for distribution. The manufacturer then typically must submit samples of each lot of product to the FDA, together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer’s tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products itself, before releasing the lots for distribution by the manufacturer.

After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are often subject to further testing requirements and FDA review and approval, depending on the nature of the post-approval change. The FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace.

Post-Approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, reporting of certain deviations and adverse experiences, product sampling and distribution and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to FDA review and approval. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their third-party contractors are required to register their establishments with the FDA and certain state agencies. These establishments are subject to routine and periodic

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unannounced inspections by the FDA and certain state agencies for compliance with cGMP and data integrity requirements, which impose certain procedural and documentation requirements to assure quality of manufacturing and product. The FDA has increasingly observed cGMP violations involving data integrity during site inspections and investigating compliance with data integrity requirements is a significant focus of its oversight. Requirements with respect to data integrity include, among other things, controls to ensure data are complete and secure; activities documented at the time of performance; audit trail functionality; authorized access and limitations; validated computer systems; and review of records for accuracy, completeness and compliance with established standards.

Post-approval changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP, data integrity, pharmacovigilance (i.e., post-marketing safety reporting obligations) and other aspects of regulatory compliance.

The FDA may withdraw a product approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-approval studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS. Other potential consequences include:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, Warning Letters, Untitled Letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products that it believes present safety problems by issuing an Import Alert;
- permanent injunctions and consent decrees, including the imposition of civil or criminal penalties; or
- voluntary product recall.

The FDA strictly regulates the marketing, labeling, advertising and promotion of prescription drug products placed on the market. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA's regulation includes, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities and promotional activities involving the Internet and social media. Promotional claims relating to a product's safety or effectiveness are prohibited before the drug is approved. After approval, a product generally may not be promoted for uses that are not approved by the FDA, as reflected in the product's prescribing information. In the United States, healthcare professionals are generally permitted to prescribe drugs for such uses not described in the drug's labeling, known as off-label uses, because the FDA does not regulate the practice of medicine. However, FDA regulations impose rigorous restrictions on manufacturers' communications, prohibiting the promotion of off-label uses. It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in non-promotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information.

If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the DOJ or the Office of the Inspector General of the

Department of Health and Human Services, as well as other federal and state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion, and has also requested that companies enter into consent decrees and permanent injunctions under which specified promotional conduct is changed or curtailed.

The distribution of prescription drugs and biologics are subject to the Drug Supply Chain Security Act (the “DSCSA”), which requires manufacturers and other stakeholders to comply with product identification, tracing, verification, detection and response, notification and licensing requirements. In addition, the Prescription Drug Marketing Act (the “PDMA”), and its implementing regulations, and state laws limit the distribution of prescription pharmaceutical product samples, and the DSCSA imposes requirements to ensure accountability in distribution and to identify and remove prescription drug and biological products that may be counterfeit, stolen, contaminated, or otherwise harmful from the market.

Patent Term Restoration and Marketing Exclusivity

After approval, owners of relevant drug or biological product patents may apply for up to a five-year patent extension to restore a portion of patent term lost during product development and FDA review of a BLA if approval of the application is the first permitted commercial marketing or use of a biologic containing the active ingredient under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The allowable patent term extension is calculated as one-half of the product’s testing phase, which is the time between IND and BLA submission, and all of the review phase, which is the time between BLA submission and approval, up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval. The United States Patent and Trademark Office (the “USPTO”), in consultation with the FDA, reviews and approves the application for patent term restoration.

For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug candidate covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug candidate for which a BLA has not been submitted.

Expedited Development and Review Programs

The FDA is required to facilitate the development and expedite the review of pharmaceutical products that are intended for the treatment of a serious or life-threatening condition for which there is no effective treatment and which demonstrate the potential to address unmet medical need for the condition. Under the fast track program, the sponsor of a new drug candidate may request the FDA to designate the product for a specific indication as a fast track product concurrent with or after the filing of the IND for the drug candidate. The FDA must determine if the drug candidate qualifies for fast track designation within 60 days after receipt of the sponsor’s request.

In addition to other benefits, such as the ability to have more frequent interactions with the FDA, the agency may initiate review of sections of a fast track product’s BLA before the application is complete. This rolling review is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA’s PDUFA review period for a fast track application does not begin until the last section of the BLA is submitted. In addition, the fast track

designation may be withdrawn by the FDA if the agency believes that the designation is no longer supported by data emerging in the clinical trial process.

Healthcare Regulation

Pharmaceutical Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the United States, sales of any products for which we may receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement from third-party payors. Third-party payors include government authorities, managed care providers, private health insurers and other organizations. Third-party payors establish the coverage and reimbursement policies for pharmaceutical products, and the marketability of any products for which we may receive regulatory approval for commercial sale depends on those payors' coverage policies and reimbursement rates. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include one or more of our drug candidates, if approved. Third-party payors, together with regulators and others, are increasingly challenging the prices charged for pharmaceutical products and health services, in addition to their cost-effectiveness, safety and efficacy.

In addition, no uniform policy for coverage and reimbursement exists in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement rates can vary significantly from payor to payor.

Moreover, obtaining coverage and adequate reimbursement is a time-consuming and costly process. We may be required to provide scientific and clinical support for the use of any product to each third-party payor separately with no assurance that approval will be obtained, and we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. We cannot be certain that our drug candidates will be considered cost-effective by third-party payors. This process could delay the market acceptance of any drug candidates for which we may receive approval and could have a negative effect on our future revenues and operating results.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our business may be subject to healthcare fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business, particularly once third-party reimbursement becomes available for one or more of our products. The healthcare fraud and abuse laws and regulations that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under the Medicare and Medicaid programs, or other federal healthcare programs;
- The federal civil and criminal false claims laws and civil monetary penalty laws, including the civil False Claims Act, or FCA, which prohibits, among other things, knowingly presenting, or causing to be presented, claims for payment of government funds that are false or fraudulent, or knowingly making, or using or causing to be made or used, a false record or statement material to a false or fraudulent claim to avoid, decrease, or conceal an obligation to pay money to the federal government;
- The federal Health Insurance Portability and Accountability Act of 1996 (the "HIPAA"), which, among other things, prohibits executing a scheme to defraud any healthcare benefit program, including private

third-party payors, and prohibits (i) knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation and (ii) making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (the “HITECH”), and their respective implementing regulations, which impose requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities, including health plans, healthcare clearinghouses and certain healthcare providers, and their business associates, individuals or entities that perform certain services on behalf of a covered entity that involve the use or disclosure of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys’ fees and costs associated with pursuing federal civil actions;
- The federal Physician Payments Sunshine Act, being implemented as the Open Payments Program, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare and Medicaid Services (the “CMS”), information related to direct or indirect payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held in a company by physicians and their immediate family members. Beginning in 2022, applicable manufacturers will also be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives; and
- U.S. state and local laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs; state laws that require drug manufacturers to report information related to clinical trials, or information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require drug manufacturers to report information on the pricing of certain drugs; state laws and local ordinances that require identification or licensing of sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

We will be required to spend substantial time and money to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations. Even then, governmental authorities may conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If governmental authorities find that our operations violate any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and we may be required to curtail or restructure our operations. Moreover, we expect that there will continue to be federal and state laws and regulations, proposed and implemented, that could impact our operations and business. In addition, the approval

and commercialization of any drug candidate we develop outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. The extent to which future legislation or regulations, if any, relating to health care fraud and abuse laws or enforcement, may be enacted or what effect such legislation or regulation would have on our business remains uncertain.

Healthcare Reform

In the United States there have been, and continue to be, several legislative and regulatory changes and proposed reforms of the healthcare system to contain costs, improve quality and expand access to care. In the United States, there have been and continue to be a number of healthcare-related legislative initiatives that have significantly affected the pharmaceutical industry. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the “ACA”), was passed in March 2010, substantially changing the way healthcare is financed by both governmental and private insurers and significantly impacting the U.S. pharmaceutical industry. Among other things, the ACA subjects biologics to potential competition by lower-cost biosimilars; addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations; establishes annual fees and taxes on manufacturers of certain branded prescription drugs; and creates a new Medicare Part D coverage gap discount program in which, as a condition of coverage of its products under Medicare Part D, manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. In addition, there have been efforts by the Trump Administration to repeal or replace certain aspects of the ACA and to alter the implementation of the ACA and related laws. For example, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 (the “Tax Act”), includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year commonly referred to as the “individual mandate.” On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018 (the “BBA”), among other things, amends the ACA, effective January 1, 2019, to reduce the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole.” In addition, in July 2018, the CMS issued a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. Additional legislative changes or regulatory changes related to the ACA remain possible. In December 2018, a United States District Court Judge for the Northern District of Texas ruled that the entire ACA is unconstitutional because the tax penalty associated with the “individual mandate” was repealed by Congress as part of the Tax Act. This ruling is under appeal and stayed pending appeal. While the United States District Court Judge for the Northern District of Texas, as well as the Trump Administration and the CMS, have stated that the ruling will have no effect while this appeal is pending, it is unclear how this decision, subsequent appeals and other efforts to invalidate the ACA, regulations promulgated under the ACA or portions thereof, will impact the ACA and its implementation.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and

proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing; reduce the cost of prescription drugs under Medicare; review the relationship between pricing and manufacturer patient programs; and reform government program reimbursement methodologies for drugs. For example, the Trump Administration released a “Blueprint” to lower drug prices and reduce out-of-pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. On January 31, 2019, Office of the Inspector General of the Department of Health and Human Services proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will remove safe harbor protection from rebates paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. Although a number of these, and other proposed measures may require additional authorization to become effective, Congress and the Trump Administration have each indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement limitations, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs.

Moreover, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

MANAGEMENT

Directors and Executive Officers

The following table sets forth information regarding our directors and executive officers as of the date of this prospectus.

Directors and Executive Officers	Age	Position/Title
Jingwu Zhang Zang, M.D., Ph.D.	63	Founder and Director
Zheru Zhang, Ph.D.	56	Director and President
Huaqiong Shen (Joan), M.D., Ph.D.	57	Director and Head of Discovery and Clinical Development
Jielun Zhu	43	Director and Chief Financial Officer
Wei Fu	37	Director
Mengjiao Jiang	38	Director
Jie Yu	44	Director
Lin Li, Ph.D.	40	Director
Lili Qian, Ph.D.	37	Vice President of Operations
Weimin Tang, Ph.D.	53	Executive Vice President of Global Business Development
Yunhan Lin (Raven), Ph.D.	41	Vice President of Corporate Development

Jingwu Zhang Zang, M.D., Ph.D., is our founder and director. Prior to joining our company, Dr. Zang served as the chief scientific officer and president of Sincere Pharmaceutical Group from July 2013 to April 2016. Dr. Zang held senior management positions at GlaxoSmithKline (GSK), as the global senior vice president and head of GSK's Research and Development in China from April 2007 to June 2013. The academic career of Dr. Zang started in Dr. Willems Institute and University of Limburg in Belgium. Dr. Zang became a professor at Baylor College of Medicine in Houston and later joined the Chinese Academy of Sciences as the founding director of the Institute of Health Sciences and as a co-director of Institute Pasteur Shanghai, an independent non-profit life science institute to address public health problems in China, where he served as its director from October 2004 to September 2008. Dr. Zang also served as a director of Institute of Health, Chinese Academy of Sciences, Shanghai Institute of Immunology from June 2002 to April 2007. Dr. Zang received his M.D. from Shanghai Second Medical University (now part of Shanghai Jiaotong University) in 1984, and his Ph.D. in neuroimmunology from the University of Brussels in 1990. Dr. Zang conducted his post-doctoral work at Harvard Medical School in 1992, and obtained his U.S. medical license from the Texas Medical Board through a clinical residency at Baylor College of Medicine in Houston.

Zheru Zhang, Ph.D., has served as our director and president since September 2017. Prior to joining our company, Dr. Zhang served as the president at Tasgen Bio-tech (Tianjin) Co., Ltd. from November 2015 to April 2017, as the chief executive officer at Shanghai JMT-Bio Co., Ltd. from October 2012 to October 2015, as a vice president, research and development at Celltrion Inc. from March 2008 to October 2012, as a group leader for the development of analytics and drug products at Johnson & Johnson (NYSE: JNJ) from January 2006 to March 2008, and as a research investigator at Bristol-Myers Squibb Company from May 2000 to January 2006, focusing on bioanalytical development and protein therapeutics development, respectively. Dr. Zhang received his master's degree in chemistry from Suzhou University in 1991, and his Ph.D. in chemistry from University of Alberta in Canada in 2000.

Huaqiong Shen (Joan), M.D., Ph.D., has served as our head of discovery and clinical development since September 2017 and as our director since July 2019. Prior to joining our company, Dr. Shen served as the vice president and development head of Janssen Pharmaceutical Companies of Johnson & Johnson from September 2015 to September 2017. Dr. Shen was the chief medical officer and vice president in Jiangsu Hengrui Medicine, Co., Ltd. (SHA: 600276) from May 2013 to August 2015. Dr. Shen served as the head of the China clinical department and a senior director at Pfizer (China) Research and Development Co., Ltd. from August 2011 to May 2013. Prior to that, Dr. Shen worked as a senior medical director at Pfizer Inc. (NYSE: PFE) from November 2009 to August 2011. From August 2005 to November 2009, Dr. Shen was the medical director at

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Wyeth Research, a leading pharmaceutical company. Dr. Shen worked as a clinical research physician at Eli Lilly and Company (NYSE: LLY) from September 2003 to August 2005. Dr. Shen received her M.D. from Southeast University Medical College in 1983, master's degree in anatomy from West China University of Medical Sciences, currently Sichuan University School of Medicine in 1989, and her Ph.D. in anatomy/neuroscience from the Indiana University School of Medicine in 1996.

Jielun Zhu has served as our chief financial officer since August 2018 and as our director since July 2019. Prior to joining our company, Mr. Zhu held positions as a managing director and the head of healthcare investment banking, Asia, at Jefferies Hong Kong Limited from December 2015 to July 2018, advising biotechnology and healthcare clients globally on initial public offerings, mergers and acquisitions and other strategic transactions. From August 2008 to December 2015, Mr. Zhu worked at the Deutsche Bank Group in its Hong Kong branch, with his last position being a director in the corporate finance division. He worked as an investment banker at UBS Investment Bank in Hong Kong from July 2007 to July 2008. Mr. Zhu received his bachelor's degree of arts with honors in mathematics-economics from Wesleyan University in May 2000 and master's degree in business administration from the Harvard Business School with Distinction in June 2007. Mr. Zhu was awarded the Chartered Financial Analyst (CFA) charter by the CFA Institute in January 2012.

Wei Fu has served as our director since June 2018. Mr. Fu was appointed by the C-Bridge entities pursuant to our shareholders agreement dated July 6, 2018. Mr. Fu has served as the chief executive officer and a managing partner of C-Bridge Capital Investment Management, Ltd. since April 2014. Mr. Fu currently also serves on the board of several private companies. From August 2011 to December 2013, Mr. Fu served as the general manager of the investment department at Far East Horizon International, a financial services organization. Mr. Fu served as a partner and the head of the Beijing office of Themes Investment Management Ltd, a private equity firm specializing in healthcare and environmental businesses, from July 2010 to July 2011. From March 2008 to April 2010, Mr. Fu worked as an associate director of the private equity department at Standard Chartered Business Consulting (Beijing) Co., Ltd, where he was mainly responsible for private equity investment in relation to infrastructure projects. Mr. Fu received his bachelor's degree in electrical engineering and business administration from Nanyang Technological University in Singapore in February 2005.

Mengjiao Jiang has served as our director since September 2017. Ms. Jiang was appointed by the C-Bridge entities pursuant to our shareholders agreement dated July 6, 2018. Ms. Jiang is a managing director of C-Bridge Capital Investment Management, Ltd., a healthcare-dedicated private equity firm, and has served as a partner and a managing director since January, 2014. Ms. Jiang currently also serves on the board of several private companies. Ms. Jiang served as a director at International Far East Horizon International, a financial services organization, from March 2012 to December 2013. Prior to that, Ms. Jiang served at ARC China Inc. as a managing director from May 2008 to June 2011. Ms. Jiang received her bachelor's degree in economics with a political science double major from Wellesley College in Massachusetts in May 2003.

Jie Yu has served as our director since July 2019. Mr. Yu was appointed by the Tasly entities pursuant to our shareholders agreement dated July 6, 2018. Mr. Yu has served as the secretary of the board at Tasly Pharmaceutical Group Co., Ltd. since November 2016. Prior to that, Mr. Yu was a director of brand management office at China Minsheng Investment Co., Ltd., an international private capital investment group, from March 2015 to October 2016. Mr. Yu worked as the head of the brand management department and the head of Chinese media affairs department at Huawei Technologies Co., Ltd. from April 2001 to March 2015. Mr. Yu received his bachelor's degree in management from Harbin Normal University in 1998 and master's degree in management from Northeast Forestry University in 2001.

Lin Li, Ph.D. has served as our director since July 2018. Dr. Li was appointed by the Hony entity pursuant to our shareholders agreement dated July 6, 2018. Dr. Li has served as an investment director at Hony Capital since December 2016. Dr. Li worked as an associate at Snow Lake Capital (HK) Limited from November 2014 to November 2016. Dr. Li served as a senior investment manager in the cross-border investment group at Hony Capital from April 2012 to October 2014. Prior to that, he worked as an associate in the corporate finance

department of Goldman Sachs Gao Hua Securities Company Limited in Beijing from July 2010 to April 2012. Dr. Li received his bachelor's degree in biology from Peking University in July 2000, Ph.D. in biology from Boston University in 2006, and master's degree in business administration from the Harvard Business School in 2010.

Lili Qian, Ph.D., has served as the vice president of operations since June 2016 and our director from September 2017 to July 2019. Dr. Qian worked at Bioscikin Biopharma Technology Co., Ltd. from January 2016 to May 2016, serving as the secretary to the board of directors and president office manager. Prior to that, Dr. Qian held various positions at Simcere Pharmaceutical Group as the president assistant and a project management manager from October 2013 to December 2015, and as a business development manager from July 2013 to October 2013. She was the project leader of the national key laboratory of protein and plant genetic engineering at Peking University from September 2007 to June 2013. Dr. Qian received her bachelor's degree in biochemistry from University of British Columbia in 2005 and her Ph.D. in biochemistry and molecular biology from Peking University in 2013.

Weiming Tang, Ph.D., has served as our executive vice president of global business development since April 2018. Prior to joining our company, Dr. Tang served as an executive director and a business director at Hengrui Therapeutics, Inc. from July 2015 to April 2018. Dr. Tang served as the vice president and a business director at Crown Bioscience Inc., a pre-clinical contract research organization, from July 2011 to July 2015. Prior to that, Dr. Tang served as the vice president and a business director at ShanghaiBio Corporation Shanghai Biotechnology Cooperation, a biotech company based in Shanghai, from October 2010 to July 2011. Dr. Tang received his bachelor's degree in plant pathology from Zhejiang University in 1986, master's degree in microbiology from Chinese Academy of Sciences in 1989, and Ph.D. in biochemistry from Rutgers University, New Jersey in 1997.

Yunhan Lin (Raven), Ph.D., has served as our vice president of corporate development since September 2017. Prior to joining our Company, Dr. Lin served as the head of business development at Mycenax Biotech Inc., a Taiwan-based public pharmaceutical company, from January 2016 to September 2017. Prior to that, Dr. Lin served as the head of business development at SynCore Biotechnology Co., Ltd, a Taiwan-based public biopharmaceutical company, from February 2012 to December 2015. Dr. Lin worked as a science project deputy manager at Sinphar Pharmaceutical Co., Ltd., a Taiwan-based pharmaceutical company, from September 2001 to January 2012. Dr. Lin received his bachelor's degree in applied chemistry from Providence University, Taiwan in 2000, master's degree in chemistry from Fu Jen Catholic University, Taiwan in 2003, and Ph.D. in chemistry from Tamkang University, Taiwan in 2008.

Our Scientific Advisory Board

The members of our scientific advisory board provide scientific, portfolio and project strategy advice to us, including the evaluation of research and development strategies. The members of our scientific advisory board receive cash compensation for their services.

Eric K. Rowinsky, M.D., has served on our scientific advisory board since June 2019. Dr. Rowinsky is an independent consultant and/or board member of various public and private companies and not-for-profit efforts. Since 2017, Dr. Rowinsky has served as an advisor to C-Bridge Capital and the U.S. Chief Medical Officer for Everest Medicines, Inc. Since 2015, Dr. Rowinsky has served as an Executive Director and President at Rgenix Inc. and as the Chief Scientific Officer of Clearpath Development Co. From 2005 to 2015, Dr. Rowinsky held various positions with various biotechnology companies. At ImClone Systems (now a wholly-owned subsidiary of Eli Lilly), Dr. Rowinsky and his team developed and registered cetuximab (Erbix) and ramucirumab in five indications and two other monoclonal antibodies in North America and elsewhere. Dr. Rowinsky has been an Adjuvant Professor of Medicine at New York University School of Medicine since 2005. From 1987 to 2005, Dr. Rowinsky held various academic and research positions with various universities and research institutions

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including the Institute for Drug Development of the Cancer Therapy and Research Center in San Antonio, where he held the SBC Endowed Chair for Early Drug Development, and the Johns Hopkins University School of Medicine. Dr. Rowinsky received his B.A. degree from New York University and his M.D. from the Vanderbilt University School of Medicine and completed fellowship training at the Johns Hopkins University School of Medicine. Dr. Rowinsky received the career development award of the American Cancer Society and the 6th Annual Emil J. Freireich Award. He has also served on the Board of Scientific Counselors of the NCI. Dr. Rowinsky is the Editor-in-Chief of Investigational New Drugs, an Editorial Board Member of Cancer Research and several other oncology journals.

Patricia LoRusso, D.O., M.A., PhD, has served on our scientific advisory board since July 2019. Dr. LoRusso is currently a professor of medicine and a clinical scholar in medical oncology and Associate Director of Innovative Medicine at Yale Cancer Center in New Haven, Connecticut, USA, where she is also Director of Early Therapeutics Disease-Aligned Team. Dr LoRusso's expertise is in testing new treatments on patient volunteers with advanced-stage cancer. She heads the early clinical trials program at Yale Cancer Center. She has served as the co-leader of the Stand Up To Cancer/Melanoma Research Alliance-funded Melanoma Dream Team, a Komen Promise grant co-Principal Investigator, and has been a Principal Investigator of the National Cancer Institute Phase 1/early phase clinical trials program grant in excess of 20 years. She is currently primary investigator or co-investigator of numerous clinical trials. Prior to joining Yale in August 2014, Dr. LoRusso served in numerous leadership roles at Wayne State University's Barbara Karmanos Cancer Institute for more than 25 years, most recently as director of the Phase 1 Clinical Trials Program and of the Eisenberg Center for Experimental Therapeutics. Dr. LoRusso also worked as a director in Karmanos Cancer Institute, a cancer research and provider network, from 1997 to 2014. Dr. LoRusso received her B.A. degree of science in religion/religious studies and biology, her master's degree at Yale University, her D.O. and Ph.D. from Michigan State University, and completed fellowship training at Wayne State University. Dr. LoRusso served as co-chair of the National Cancer Institute Cancer Therapy Evaluation Program (NCI CTEP) Investigational Drug Steering Committee, a prior parent member of the NCI's Quick Trials Clinical Subcommittee, and has served as either an ad hoc or an appointed member on multiple study sections and has reviewed for Komen Promise grants, numerous SPORE and P01 study sections, and translational research grants. She has served on the education and scientific committees of the American Society of Clinical Oncology, the Scientific Committee of the American Association for Cancer Research as well as a Vice-Chair for the 2019 AACR annual meeting. She is a member of the NCI Board of Scientific Council and has served on the Board of Directors for the American Association for Cancer Research.

Certain Past Incidents

From June 2007 to June 2013, our founder, Dr. Jingwu Zhang Zang worked and held senior management positions at GlaxoSmithKline ("GSK"), as a global senior vice president, and head of GSK's Research and Development in China. Dr. Zang was dismissed by GSK in June 2013 after GSK became aware of misrepresentation of certain data in a research paper entitled "Crucial role of interleukin-7 in T helper type 17 survival and expansion in autoimmune disease," which was prepared by scientists at GSK China's research center and published in Nature Medicine in 2010. Dr. Zang was the corresponding author of the paper, primarily handling manuscript editing and communications with editors and reviewers of the paper. According to Dr. Zang and the first author of the paper, Dr. Zang, as the head of GSK China's research center and a member of GSK's global senior management, was neither involved in nor aware of the mislabeled samples relating to the misrepresented data referenced in the paper at the time when the paper was prepared and published. Nonetheless, Dr. Zang admitted his management oversight as the corresponding author and agreed to retract the paper. The paper was retracted by GSK in September 2013.

From 1996 to 2002, Dr. Zang was employed by Baylor College of Medicine in Houston, Texas initially as an associate professor and was later promoted to full professor. At that time, Dr. Zang's team was conducting a clinical study on T-cell vaccination for the treatment of multiple sclerosis after approval by Baylor's Institutional Review Board ("IRB"). Dr. Zang was led to believe that such clinical research would not require FDA approval.

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In March 1999, the Food and Drug Administration, or the FDA, issued a warning letter to Dr. Zang stating that the clinical study did require IND approval from the FDA in addition to the approval from the IRB and requested the study to be suspended. The study was suspended and later re-initiated and successfully completed after the IND approval was obtained.

To the best of our knowledge, Dr. Zang was not and is not subject to any legal or regulatory charges, proceedings or disciplinary actions in connection with the above incidents.

For risks related to the above incidents, please see “Risk Factors—Risks Related to Our Industry, Business and Operations—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 and prospect.”

For the measures and systems we have in place to ensure the integrity and legal compliance of our R&D process and business operations, please see “Business—R&D Governance” and “Business—Quality Control and Assurance.”

Board of Directors

Our board of directors will consist of _____ directors upon the SEC’s declaration of effectiveness of our registration statement on Form F-1, of which this prospectus forms a part. A director is not required to hold any shares in our company by way of qualification. A director may vote with respect to any contract, proposed contract or arrangement in which he is materially interested, provided that (a) such director, if his or her interest in such contract or arrangement is material, has declared the nature of his or her interest at the earliest meeting of the board at which it is practicable for him or her to do so, either specifically or by way of a general notice and (b) if such contract or arrangement is a transaction with a related party, such transaction has been approved by the audit committee. The directors may exercise all the powers of our company to borrow money, mortgage its undertaking, property and uncalled capital, and issue debentures or other securities whenever money is borrowed or as security for any obligation of our company or of any third party. None of our directors who are not our executive officers has a service contract with us that provides for benefits upon termination of service.

Committees of the Board of Directors

We will establish three committees under the board of directors immediately upon the effectiveness of our registration statement on Form F-1, of which this prospectus forms a part: an audit committee, a compensation committee and a nominating and corporate governance committee. We will adopt a charter for each of the three committees. Each committee’s members and functions are described below.

Audit Committee. Our audit committee will consist of _____, _____ and _____. _____ will be the chairman of our audit committee. We have determined that each of _____, _____ and _____ satisfies the “independence” requirements of [Rule 5605(c)(2) of the Nasdaq Stock Market Rules] and meets the independence standards under Rule 10A-3 under the Exchange Act. We have determined that _____ qualifies as an “audit committee financial expert.” The audit committee will oversee our accounting and financial reporting processes and the audits of the financial statements of our company. The audit committee will be responsible for, among other things:

- appointing the independent auditors and pre-approving all auditing and non-auditing services permitted to be performed by the independent auditors;
- reviewing with the independent auditors any audit problems or difficulties and management’s response;
- discussing the annual audited financial statements with management and the independent auditors;
- reviewing the adequacy and effectiveness of our accounting and internal control policies and procedures and any steps taken to monitor and control major financial risk exposures;

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- reviewing and approving all proposed related party transactions;
- meeting separately and periodically with management and the independent auditors; and
- monitoring compliance with our code of business conduct and ethics, including reviewing the adequacy and effectiveness of our procedures to ensure proper compliance.

Compensation Committee. Our compensation committee will consist of _____, _____ and _____. _____ will be the chairman of our compensation committee. We have determined that each of _____, _____ and _____ satisfies the “independence” requirements of [Rule 5605(a)(2) of the Nasdaq Stock Market Rules]. The compensation committee will assist the board in reviewing and approving the compensation structure, including all forms of compensation, relating to our directors and executive officers. Our chief executive officer may not be present at any committee meeting during which his compensation is deliberated. The compensation committee will be responsible for, among other things:

- reviewing and approving, or recommending to the board for its approval, the compensation for our chief executive officer and other executive officers;
- reviewing and recommending to the board for determination with respect to the compensation of our directors who are not our employees;
- reviewing periodically and approving any incentive compensation or equity plans, programs or similar arrangements; and
- selecting compensation consultant, legal counsel or other adviser only after taking into consideration all factors relevant to that person’s independence from management.

Nominating and Corporate Governance Committee. Our nominating and corporate governance committee will consist of _____, _____ and _____. _____ will be the chairman of our nominating and corporate governance committee. We have determined that each of _____, _____ and _____ satisfies the “independence” requirements of [Rule 5605(a)(2) of the Nasdaq Stock Market Rules]. The nominating and corporate governance committee will assist the board of directors in selecting individuals qualified to become our directors and in determining the composition of the board and its committees. The nominating and corporate governance committee will be responsible for, among other things:

- selecting and recommending to the board nominees for election by the shareholders or appointment by the board;
- reviewing annually with the board the current composition of the board with regards to characteristics such as independence, knowledge, skills, experience and diversity;
- making recommendations on the frequency and structure of board meetings and monitoring the functioning of the committees of the board; and
- advising the board periodically with regards to significant developments in the law and practice of corporate governance as well as our compliance with applicable laws and regulations, and making recommendations to the board on all matters of corporate governance and on any remedial action to be taken.

Duties of Directors

Under Cayman Islands law, our directors owe fiduciary duties to our company, including a duty of loyalty, a duty to act honestly, and a duty to act in what they consider in good faith to be in our best interests. Our directors must also exercise their powers only for a proper purpose. Our directors also have a duty to exercise skills they actually possess and with such care and diligence that a reasonably prudent person would exercise in comparable circumstances. It was previously considered that a director need not exhibit in the performance of his or her duties a greater degree of skill than what may reasonably be expected from a person of his or her knowledge and

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experience. However, English and Commonwealth courts have moved towards an objective standard with regard to the required skill and care, and these authorities are likely to be followed in the Cayman Islands. In fulfilling their duty of care to us, our directors must ensure compliance with our memorandum and articles of association, as amended from time to time, and the class rights vested thereunder in the holders of the shares. Our company has the right to seek damages if a duty owed by our directors is breached. A shareholder may in certain limited circumstances have the right to seek damages in our name if a duty owed by the directors is breached.

Our board of directors has all the powers necessary for managing, and for directing and supervising, our business affairs. The functions and powers of our board of directors include:

- convening shareholders' annual general meetings and reporting its work to shareholders at such meetings;
- declaring dividends and other distributions;
- appointing officers and determining the term of office of the officers;
- exercising the borrowing powers of our company and mortgaging the property of our company; and
- approving the transfer of shares in our company, including the registration of such shares in our share register.

Terms of Directors and Officers

Our directors may be elected by an ordinary resolution of our shareholders. Alternatively, our board of directors may, by the affirmative vote of a simple majority of the directors present and voting at a board meeting appoint any person as a director to fill a casual vacancy on our board or as an addition to the existing board. Our directors are not automatically subject to a term of office and hold office until such time as they are removed from office by an ordinary resolution of our shareholders. In addition, a director will cease to be a director if he or she (i) becomes bankrupt or makes any arrangement or composition with his or her creditors; (ii) dies or is found to be or becomes of unsound mind; (iii) resigns his or her office by notice in writing; (iv) without special leave of absence from our board, is absent from meetings of our board for three consecutive meetings and our board resolves that his or her office be vacated; or (v) is removed from office pursuant to any other provision of our articles of association.

Our officers are appointed by and serve at the discretion of the board of directors, and may be removed by our board of directors.

[Employment Agreements and Indemnification Agreements

We have entered into employment agreements with each of our executive officers. Under these agreements, each of our executive officers is employed for a specified time period. We may terminate employment for cause, at any time, without advance notice or remuneration, for certain acts of the executive officer, such as conviction or plea of guilty to a felony or any crime involving moral turpitude, negligent or dishonest acts to our detriment, or misconduct or a failure to perform agreed duties. We may also terminate an executive officer's employment without cause upon a three month prior written notice. In such case of termination by us, we will provide severance payments to the executive officer as expressly required by applicable law of the jurisdiction where the executive officer is based. The executive officer may resign at any time with a three month prior written notice.

Each executive officer has agreed to hold, both during and after the termination or expiry of his or her employment agreement, in strict confidence and not to use, except as required in the performance of his or her duties in connection with the employment or pursuant to applicable law, any of our confidential information or trade secrets, any confidential information or trade secrets of our clients or prospective clients, or the confidential or proprietary information of any third party received by us and for which we have confidential obligations. The

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executive officers have also agreed to disclose in confidence to us all inventions, designs and trade secrets which they conceive, develop or reduce to practice during the executive officer's employment with us and to assign all right, title and interest in them to us, and assist us in obtaining and enforcing patents, copyrights and other legal rights for these inventions, designs and trade secrets.

In addition, each executive officer has agreed to be bound by non-competition and non-solicitation restrictions during the term of his or her employment and typically for one year following the last date of employment. Specifically, each executive officer has agreed not to (i) approach our suppliers, clients, customers or contacts or other persons or entities introduced to the executive officer in his or her capacity as a representative of us for the purpose of doing business with such persons or entities that will harm our business relationships with these persons or entities; (ii) assume employment with or provide services to any of our competitors, or engage, whether as principal, partner, licensor or otherwise, any of our competitors, without our express consent; or (iii) seek directly or indirectly, to solicit the services of any of our employees who is employed by us on or after the date of the executive officer's termination, or in the year preceding such termination, without our express consent.

We have also entered into indemnification agreements with each of our directors and executive officers. Under these agreements, we agree to indemnify our directors and executive officers against certain liabilities and expenses incurred by such persons in connection with claims made by reason of their being a director or officer of our company.]

Compensation of Directors and Executive Officers

For the fiscal year ended December 31, 2018, we paid an aggregate of approximately RMB22.1 million (US\$3.2 million) in cash to our executive officers, and we did not pay any compensation to our directors who are not our executive officers. We have not set aside or accrued any amount to provide pension, retirement or other similar benefits to our executive officers and directors. Our PRC subsidiaries are required by law to make contributions equal to certain percentages of each employee's salary for his or her pension insurance, medical insurance, unemployment insurance and other statutory benefits and a housing provident fund.

Share Incentive Plans

Amended and Restated 2017 Employee Stock Option Plan

In 2017, we adopted an equity incentive plan, as amended and restated in 2019, which we refer to as the 2017 Plan, to secure and retain the services of valuable employees, directors or consultants, and provide incentives for such persons to exert their best efforts for the success of our business. Pursuant to the 2017 Plan, the maximum aggregate number of ordinary shares which may be issued pursuant to all awards under the 2017 Plan is 13,376,865, subject to further amendment. As of the date of this prospectus, awards to purchase 9,941,650 ordinary shares under the 2017 Plan have been granted and outstanding, excluding awards that were forfeited or cancelled after the relevant grant dates.

The following paragraphs describe the principal terms of the 2017 Plan.

Types of awards. The 2017 Plan permits the awards of options.

Plan administration. Our board of directors will administer the 2017 Plan. The board of directors will determine, among other things, the participants to receive options, the number and subscription price of options to be granted to each participant, and the terms and conditions of each option granted.

Offer letter. Options granted under the 2017 Plan are evidenced by an offer letter that sets forth terms, conditions and limitations for each option, which may include the term of the option, and the provisions applicable in the event that the grantee's employment or service terminates.

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Eligible participants. We may grant awards to employees, officers, directors, contractors, advisors and consultants of our company.

Vesting schedule. Unless otherwise approved by the board of directors and set forth in an offer letter, the vesting schedule shall be a three-year vesting schedule consisting of a cliff vesting 50% on the second anniversary of the applicable vesting commencement date, and a vesting of the remaining 50% on the third anniversary of the applicable vesting commencement date. Except as otherwise approved by the board of directors, vested portion of option shall become exercisable upon the earlier of a listing or the occurrence of a change in control.

Exercise of options. The board of directors determines the subscription price for each option, which is stated in the offer letter. The vested portion of each option will expire if not exercised prior to the time as the board of directors determines at the time of its grant. However, the maximum exercisable term is ten years from the applicable vesting commencement date or such shorter period specified in the award agreement. Further, an option will lapse upon the earliest of, among other circumstances, two years after the date when the option becomes exercisable upon the listing or the occurrence of a change in control, and a violation in transfer restrictions.

Transfer restrictions. Options may not be transferred in any manner by the participant other than in accordance with the exceptions provided in the 2017 Plan or the relevant offer letter or otherwise determined by the board of directors, such as transfers by will or the laws of descent and distribution.

Termination and amendment of the 2017 Plan. Unless terminated earlier, the 2017 Plan has a term of ten years. The board of directors has the authority to amend, suspend or terminate the plan, subject to the limitations of applicable laws. No amendment, suspension or termination may adversely affect in any material way any awards previously granted pursuant to the 2017 Plan unless agreed to by the participant.

The following table summarizes, as of the date of this prospectus, the number of ordinary shares under our outstanding options that we granted under the 2017 Plan to several of our directors and executive officers, excluding awards that were forfeited or cancelled after the relevant grant dates.

<u>Name</u>	<u>Ordinary Shares Underlying Outstanding Options Granted</u>	<u>Exercise Price (US\$/Share)</u>	<u>Date of Grant</u>	<u>Date of Expiration</u>
Zheru Zhang	1,505,128	1.00	October 1, 2017	October 1, 2027
Huaqiong Shen	1,505,128	1.00	October 1, 2017	October 1, 2027
Jielun Zhu	1,125,000	1.00	August 1, 2018	October 1, 2027
Weimin Tang	*	1.00	April 2, 2018	October 1, 2027
Yunhan Lin	*	1.00	October 1, 2017	October 1, 2027
Lili Qian	*	1.00	October 1, 2017	October 1, 2027
Other grantees	4,995,646	1.00	October 1, 2017 to February 21, 2019	October 1, 2027
Total	9,941,650			

Note:

* Less than 1% of our total outstanding shares.

2018 Employee Stock Option Plan

In 2019, we adopted an equity incentive plan, which we refer to as the 2018 Plan, to secure and retain the services of valuable employees, directors or consultants, and provide incentives for such persons to exert their best efforts for the success of our business. Pursuant to the 2018 Plan, the maximum aggregate number of

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ordinary shares which may be issued pursuant to all awards under the 2018 Plan is 14,005,745, subject to further amendment. If we successfully list on an internationally recognized securities exchange for a qualified public offering by December 31, 2019, the maximum aggregate number of ordinary shares which may be issued pursuant to all awards under the 2018 Plan shall be 15,452,620. As of the date of this prospectus, awards to purchase 13,550,805 ordinary shares under the 2018 Plan have been granted and outstanding, excluding awards that were forfeited or cancelled after the relevant grant dates.

The following paragraphs describe the principal terms of the 2018 Plan.

Types of awards. The 2018 Plan permits the awards of options.

Plan administration. Our board of directors will administer the 2018 Plan. The board of directors will determine, among other things, the participants to receive options, the number and subscription price of options to be granted to each participant, and the terms and conditions of each option granted.

Offer letter. Options granted under the 2018 Plan are evidenced by an offer letter that sets forth terms, conditions and limitations for each option, which may include the term of the option, and the provisions applicable in the event that the grantee's employment or service terminates.

Eligible participants. We may grant awards to employees or if approved by the board, designee of any employee.

Vesting schedule. Unless otherwise approved by the board of directors and set forth in an offer letter, the vesting schedule shall be a two-year vesting schedule consisting of a cliff vesting 50% on the first anniversary of the applicable vesting commencement date, and a vesting of the remaining 50% on the second anniversary of the applicable vesting commencement date. Notwithstanding the foregoing, if a listing occurs at anytime prior to any option granted under the 2018 Plan becoming full vested, and to the extent such option has been granted and outstanding, any such option shall vest in full with immediate effect upon the listing. Except as otherwise approved by the board of directors, vested portion of option shall become exercisable upon the earlier of six months after a listing or the occurrence of a change in control; provided, however that in each case, no option of an employee shall become exercisable until the third anniversary of such employee's employment commencement date.

Exercise of options. The board of directors determines the subscription price for each option, which is stated in the offer letter. The vested portion of each option will expire if not exercised prior to the time as the board of directors determines at the time of its grant. However, the maximum exercisable term is ten years from the applicable vesting commencement date or such shorter period specified in the award agreement. Further, an option will lapse upon the earliest of, among other circumstances, two years after the date when the option becomes exercisable upon the listing or the occurrence of a change in control, and a violation in transfer restrictions.

Transfer restrictions. Options may not be transferred in any manner by the participant other than in accordance with the exceptions provided in the 2018 Plan or the relevant offer letter or otherwise determined by the board of directors, such as transfers by will or the laws of descent and distribution.

Termination and amendment of the 2018 Plan. Unless terminated earlier, the 2018 Plan has a term of ten years. The board of directors has the authority to amend, suspend or terminate the plan, subject to the limitations of applicable laws. No amendment, suspension or termination may adversely affect in any material way any awards previously granted pursuant to the 2018 Plan unless agreed to by the participant.

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The following table summarizes, as of the date of this prospectus, the number of ordinary shares under our outstanding options that we granted under the 2018 Plan to several of our directors and executive officers, excluding awards that were forfeited or cancelled after the relevant grant dates.

<u>Name</u>	<u>Ordinary Shares Underlying Outstanding Options Granted</u>	<u>Exercise Price (US\$/Share)</u>	<u>Date of Grant</u>	<u>Date of Expiration</u>
Jingwu Zhang Zang	10,438,088	1.00	February 22, 2019	February 22, 2029
Zheru Zhang	*	1.00	July 25, 2019	February 22, 2029
Huaqiong Shen	*	1.00	July 25, 2019	February 22, 2029
Jielun Zhu	*	1.00	July 25, 2019	February 22, 2029
Weimin Tang	*	1.00	July 25, 2019	February 22, 2029
Yunhan Lin	*	1.00	July 25, 2019	February 22, 2029
Lili Qian	*	1.00	July 25, 2019	February 22, 2029
Other grantees	1,124,426	1.00	July 25, 2019	February 22, 2029
Total	13,550,805			

Note:

* Less than 1% of our total outstanding shares.

PRINCIPAL SHAREHOLDERS

Except as specifically noted, the following table sets forth information with respect to the beneficial ownership of our ordinary shares on an as-converted basis as of the date of this prospectus by:

- each of our directors and executive officers; and
- each person known to us to own beneficially 5% or more of our ordinary shares.

The calculations in the table below are based on 99,942,347 ordinary shares on an as-converted basis outstanding as of the date of this prospectus, and ordinary shares outstanding immediately after the completion of this offering, assuming the underwriters do not exercise their over-allotment option.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, we have included shares that the person has the right to acquire within 60 days, including through the exercise of any option, warrant or other right or the conversion of any other security. These shares, however, are not included in the computation of the percentage ownership of any other person.

	Ordinary Shares Beneficially Owned Prior to This Offering		Ordinary Shares Beneficially Owned Immediately After This Offering	
	Number	%	Number	%
Directors and Executive Officers:				
Jingwu Zhang Zang ⁽¹⁾	14,370,201	13.0		
Zheru Zhang	*	*		
Huaqiong Shen (Joan)	—	—		
Wei Fu ⁽²⁾	40,395,989	40.4		
Mengjiao Jiang	—	—		
Jie Yu	—	—		
Lin Li	—	—		
Lili Qian	*	*		
Jielun Zhu	—	—		
Weimin Tang	—	—		
Yunhan Lin (Raven)	—	—		
All Directors and Executive Officers as a Group	55,311,556	49.9		
Principal Shareholders:				
C-Bridge entities ⁽²⁾	40,395,989	40.4		
Tasly entities ⁽³⁾	15,852,781	15.9		
Hony entity ⁽⁴⁾	8,537,749	8.5		
Genexine ⁽⁵⁾	9,261,823	9.2		

Notes:

- * Less than 1% of our total ordinary shares on an as-converted basis outstanding as of the date of this prospectus.
- ** Except as otherwise indicated below, the business address of our directors and executive officers is Suite 802, West Tower, OmniVision, 88 Shangke Road, Pudong District, Shanghai, China. The business address of Wei Fu and Mengjiao Jiang is Suite 3306-3307, Two Exchange Square, 8 Connaught Place, Central, Hong Kong. The business address of Jie Yu is Tianshili Great Health City, No. 2, East Puji River Road, Beichen District, Tianjin, China. The business address of Lin Li is 6F, South Tower C, Raycom Info Tech Park, No.2, Kexueyuan South Road, Haidian District, Beijing, China.
- (1) Represents (i) 3,932,113 ordinary shares directly held by Mabcore Limited, a British Virgin Islands company. Dr. Zang, through himself and The Jingwu Zhang Zang 2018 Retained Annuity Trust, owns a

55.6% equity interest in Mabcore Limited. Lili Qian and two other individuals own the remaining equity interest in Mabcore Limited, and (ii) 10,438,088 ordinary shares issuable upon exercise of options exercisable within 60 days after the date of this prospectus held by Dr. Zang. Dr. Zang is the sole director of Mabcore Limited. The Jingwu Zhang Zang 2018 Retained Annuity Trust was established under the laws of New York and is managed by Dr. Zang, as the trustee, the settlor and the sole beneficiary. Pursuant to the currently effective memorandum and articles of association of Mabcore Limited, Dr. Zang, as the sole director, has the power to direct the actions of Mabcore Limited, including the voting and disposal of Mabcore Limited's shares in I-Mab. Accordingly, Dr. Zang is deemed to indirectly own all of the 3,932,113 ordinary shares held by Mabcore Limited, while Dr. Qian and the other two individuals are only entitled to their respective pro-rata economic interest in Mabcore Limited.

- (2) Represents 40,395,989 ordinary shares issuable upon the conversion of (i) 4,629,231 Series A-1 preferred shares and 512,356 Series A-2 preferred shares held by IBC Investment Seven Limited, a Hong Kong limited liability company, (ii) 8,361,823 Series A-3 preferred shares held by CBC SPVII LIMITED, a Hong Kong limited liability company, (iii) 14,089,714 Series B preferred shares, 2,247,321 Series B-1 preferred shares, and 1,997,618 Series B-2 preferred shares held by CBC Investment I-Mab Limited, a British Virgin Islands limited liability company, and (iv) 1,804,880 Series B preferred shares, 287,880 Series B-1 preferred shares, and 255,894 Series B-2 preferred shares held by C-Bridge II Investment Ten Limited, a British Virgin Islands limited liability company, and (v) 6,209,272 Series C preferred shares directly held by C-Bridge II Investment Seven Limited, a British Virgin Islands limited liability company. IBC Investment Seven Limited, CBC SPVII LIMITED, CBC Investment I-Mab Limited, C-Bridge II Investment Ten Limited and C-Bridge II Investment Seven Limited are collectively referred to as the C-Bridge entities. CBC Investment I-Mab Limited, C-Bridge II Investment Ten Limited and C-Bridge II Investment Seven Limited are controlled by C-Bridge Healthcare Fund II, L.P., whose general partner is C-Bridge Healthcare Fund GP II, L.P., and its general partner is C-Bridge Capital GP, Ltd. CBC SPVII Limited and IBC Investment Seven Limited are controlled by I-Bridge Healthcare Fund, L.P., whose general partner is I-Bridge Healthcare GP, L.P., and its general partner is I-Bridge Capital GP, Ltd., which is indirectly controlled by C-Bridge Capital GP, Ltd. Wei Fu is the sole director of C-Bridge Capital GP, Ltd. The business address of C-Bridge entities is Suite 3306-3307, Two Exchange Square, 8 Connaught Place, Central, Hong Kong.
- (3) Represents 15,852,781 ordinary shares issuable upon the conversion of (i) 8,361,823 Series A-3 preferred shares and 5,938,640 Series B preferred shares held by Tasly Biopharm Limited, a British Virgin Islands limited liability company, and (ii) 1,552,318 Series C preferred shares directly held by Tasly International Capital Limited. Tasly International Capital Limited is wholly-owned by Tasly Holding Group Co., Ltd. Tasly Biopharm Limited's sole shareholder is Tasly Biopharmaceuticals Co., Ltd., which is controlled by Tasly Pharmaceutical Group Co., Ltd., which is in turn controlled by Tasly Holding Group Co., Ltd. Tasly Holding Group Co., Ltd. is controlled by Tianjin Tasly Health Industry Investment Group Co., Ltd., which is in turn controlled by Tianjin Fuhuade Science & Technology Development Co., Ltd. Kaijing Yan is the controlling shareholder of Tianjin Fuhuade Science & Technology Development Co., Ltd. and the ultimate beneficial owner of Tasly Biopharm Limited. The registered address of Tasly Biopharm Limited is P.O. Box 957, Offshore Incorporation Centre, Road Town, Tortola, British Virgin Islands. We refer to the entities in the preceding sentence collectively as the Tasly entities. The registered address of Tasly International BioInv One Limited is 4th Floor, Harbour Place, 103 South Church Street, P.O. Box 10240, Grand Cayman KY1-1002, Cayman Islands.
- (4) Represents 8,537,749 ordinary shares issuable upon the conversion of 8,537,749 Series C preferred shares held by Fortune Eight Jogging Limited, a British Virgin Islands limited liability company. Fortune Eight Jogging Limited is wholly-owned by Hony Hongling (Shanghai) Investment Center, a PRC limited partnership, whose general partner is Hony Capital (Shanghai) Ltd. The sole shareholder of Hony Capital (Shanghai) Ltd is Beijing Hony Hezhong Management Ltd. Each of Yonggang Cao, Minsheng Xu and Lijie Wang holds 33.3% equity interests in Beijing Hony Hezhong Management Ltd. The registered address of Fortune Eight Jogging Limited is Kingston Chambers, PO Box 173, Road Town, Tortola, British Virgin Islands.

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- (5) Represents 9,261,823 ordinary shares issuable upon the conversion of 8,361,823 Series A-3 preferred shares directly held by Genexine, Inc. (Genexine) and 900,000 preferred shares issuable to Genexine upon the full conversion of the US\$9.0 million interest-free convertible promissory note based on a conversion price of US\$10 per share. Genexine is a Korean public company. The registered address of Genexine is 700 Daewangpangyo-ro, Korea Bio Park, Bldg. B4F, Bundang-gu, Seongnam-si, Gyeonggi-do, Korea.

As of the date of this prospectus, none of our ordinary shares outstanding is held by any record holders in the United States.

The ADSs that we issue in this offering will represent ordinary shares.

We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company. See “Description of Share Capital—History of Securities Issuances” for historical changes in our shareholding structure.

RELATED PARTY TRANSACTIONS

Private Placements

See “Description of Share Capital—History of Securities Issuances.”

Shareholders Agreement

See “Description of Share Capital—History of Securities Issuances—Shareholders Agreement.”

Employment Agreements and Indemnification Agreements

See “Management—Employment Agreements and Indemnification Agreements.”

Share Incentive Plans

See “Management—Share Incentive Plans.”

Other Related Party Transactions with Our Shareholders and Affiliates

On September 25, 2017, I-Mab Tianjin and I-Mab Shanghai entered into a loan agreement with each of Qianhai Equity Investment Fund (Limited Partnership) (“Qianhai Fund”), Shanghai Tasly Pharmaceutical Co., Ltd. (“Shanghai Tasly”), and Tianjin Kangshijing Biopharmaceutical Technology Partnership (Limited Partnership) (“CBC RMB Fund”), pursuant to which each of Qianhai Fund, Shanghai Tasly and CBC RMB Fund made a loan to I-Mab Tianjin to fund its business operations in an aggregate principal amount in RMB equivalent to US\$1.3 million, US\$5.1 million and US\$1.6 million, respectively. Each of these loans bears an annual compound interest rate of 8%. Pursuant to these loan agreements, each of Qianhai Fund, Shanghai Tasly and CBC RMB Fund has the right to contribute its interest in the respective loan to I-Mab Tianjin in exchange for I-Mab Tianjin’s equity interests. We fully repaid the loans made by Qianhai Fund and Shanghai Tasly in 2018, and neither of these lenders exercised such right. The loan agreement with CBC RMB Fund was not performed by CBC RMB Fund and was mutually terminated on September 25, 2017.

In January 2018, we entered into a collaboration agreement with Everest, an affiliate of C-Bridge Capital Investment Management, Ltd., whereby both parties agreed to collaborate on programs to co-develop MorphoSys’ proprietary CD38 antibody for all indications in hematologic oncology and commercialize the CD38 product in China, Hong Kong, Macau and Taiwan. For a detailed description of this collaboration agreement, see “Business—Licensing and Collaboration Arrangements—C. Collaboration Arrangements.” As of December 31, 2018, we recorded RMB178.7 million (US\$26.0 million) research and development funding received from Everest.

In June 2018, we entered into a biologics master services agreement with CMAB Biopharma (Suzhou) Inc. (“CMAB”), an affiliate of Bridge Capital Partners LLC. In July 2018, we entered into Service Proposal: CMC Development of A Monoclonal Antibody with this entity. Pursuant to these two agreements, CMAB will provide us with CMC services in connection with the preparation of the IND filings to the FDA and the NMPA in a period of 18 to 22 months for US\$3.6 million. We had paid CMAB RMB2.8 million (US\$0.4 million) for the year ended December 31, 2018.

In September 2016, I-Mab Tianjin entered into a CRO agreement with Tasly Pharmaceutical Group Co., Ltd. (“Tasly”) and three ancillary agreements to this CRO agreement in November 2016, May 2017 and June 2017, respectively. Pursuant to these agreements, Tasly Pharmaceutical Group Co., Ltd. will provide I-Mab Tianjin with CRO services in connection with pre-clinical studies for G-CSF-HyFc fusion protein. All of these agreements were terminated on December 10, 2018. We had paid Tasly RMB0.8 million and nil for the year ended December 31, 2017 and 2018, respectively.

DESCRIPTION OF SHARE CAPITAL

We are a Cayman Islands exempted company with limited liability and our affairs are governed by our memorandum and articles of association, the Companies Law, Cap. 22 (Law 3 of 1961, as consolidated and revised), as amended, of the Cayman Islands, which is referred to as the Companies Law below, and the common law of the Cayman Islands.

As of the date of this prospectus, our authorized share capital is US\$50,000 divided into: (i) 402,796,550 voting ordinary shares of a nominal or par value of US\$0.0001 each, (ii) 4,629,231 voting redeemable Series A-1 preferred shares of a nominal or par value of US\$0.0001 each, (iii) 512,356 voting redeemable Series A-2 preferred shares of a nominal or par value of US\$0.0001 each, (iv) 25,085,469 voting redeemable Series A-3 preferred shares of a nominal or par value of US\$0.0001 each, (v) 23,288,783 voting redeemable Series B preferred shares of a nominal or par value of US\$0.0001 each, (vi) 3,714,580 voting redeemable Series B-1 preferred shares of a nominal or par value of US\$0.0001 each, (vii) 8,254,622 voting redeemable Series B-2 preferred shares of a nominal or par value of US\$0.0001 each, and (viii) 31,718,409 voting redeemable Series C preferred shares of a nominal or par value of US\$0.0001 each. As of the date of this prospectus, 8,363,719 ordinary shares, 4,629,231 Series A-1 preferred shares, 512,356 Series A-2 preferred shares, 25,085,469 Series A-3 preferred shares, 23,288,783 Series B preferred shares, 3,714,580 Series B-1 preferred shares, 3,301,849 Series B-2 preferred shares, and 31,046,360 Series C preferred shares are issued and outstanding. All of our issued and outstanding ordinary and preferred shares are fully paid.

Immediately upon the completion of this offering, _____ preferred shares that are issued and outstanding will be converted into ordinary shares by way of re-designation on a one-for-one basis, and our authorized share capital will be US\$50,000 divided into _____ ordinary shares with a par value of US\$0.0001 each.

[Our Post-Offering Memorandum and Articles

We will adopt an amended and restated memorandum and articles of association, which will become effective and replace our current amended and restated memorandum and articles of association in its entirety immediately prior to the completion of this offering. We refer to this adopted amended and restated memorandum and articles of association as our post-offering memorandum and articles of association. The following is a summary of the material provisions of the post-offering memorandum and articles of association and of the Companies Law, insofar as they relate to the material terms of our ordinary shares.

Objects of Our Company. Under our post-offering memorandum and articles of association, the objects of our company are unrestricted and we have the full power and authority to carry out any object not prohibited by the laws of the Cayman Islands.

Ordinary Shares. Our ordinary shares are issued in registered form and are issued when registered in our register of members. We may not issue shares to bearers. Our shareholders who are non-residents of the Cayman Islands may freely hold and vote their shares.

Dividends. Our directors may from time to time declare dividends (including interim dividends) and other distributions on our shares in issue and authorize payment of the same out of the funds of our company lawfully available therefor. In addition, our shareholders may declare dividends by ordinary resolution, but no dividend shall exceed the amount recommended by our directors. Our post-offering memorandum and articles of association provide that dividends may be declared and paid out of the funds of our company lawfully available therefor. Under the laws of the Cayman Islands, our company may pay a dividend out of either profit or a share premium account; provided that in no circumstances may a dividend be paid out of the same premium account if this would result in our company being unable to pay its debts as they fall due in the ordinary course of business.

Voting Rights. Voting at any meeting of shareholders is by show of hands unless a poll is demanded. A poll may be demanded by the chairman of such meeting or any one shareholder holding not less than [10]% of the votes attaching to the shares present in person or by proxy.

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An ordinary resolution to be passed at a meeting by the shareholders requires the affirmative vote of a simple majority of the votes attaching to the ordinary shares cast at a meeting, while a special resolution requires the affirmative vote of not less than two-thirds of the votes cast attaching to the issued and outstanding ordinary shares at a meeting. A special resolution will be required for important matters such as a change of name or making changes to our post-offering memorandum and articles of association. Our shareholders may, among other things, divide or combine their shares by ordinary resolution.

General Meetings of Shareholders. As a Cayman Islands exempted company, we are not obliged by the Companies Law to call shareholders' annual general meetings. Our post-offering memorandum and articles of association provide that we may (but are not obliged to) in each year hold a general meeting as our annual general meeting in which case we shall specify the meeting as such in the notices calling it, and the annual general meeting shall be held at such time and place as may be determined by our directors.

Shareholders' general meetings may be convened by the chairman of our board of directors or by our directors (acting by a resolution of our board). Advance notice of at least seven days is required for the convening of our annual general shareholders' meeting (if any) and any other general meeting of our shareholders. [A quorum required for any general meeting of shareholders consists of, at the time when the meeting proceeds to business, one or more of our shareholders holding shares which carry in aggregate (or representing by proxy) not less than one-third of all votes attaching to all of our shares in issue and entitled to vote at such general meeting.]

The Companies Law does not provide shareholders with any right to requisition a general meeting, nor any right to put any proposal before a general meeting. However, these rights may be provided in a company's articles of association. Our post-offering memorandum and articles of association provide that upon the requisition of any one or more of our shareholders holding shares which carry in aggregate not less than one-third of all votes attaching to all issued and outstanding shares of our company entitled to vote at general meetings, our board will convene an extraordinary general meeting and put the resolutions so requisitioned to a vote at such meeting. However, our post-offering memorandum and articles of association do not provide our shareholders with any right to put any proposals before annual general meetings or extraordinary general meetings not called by such shareholders.

Transfer of Ordinary Shares. Subject to the restrictions set out below, any of our shareholders may transfer all or any of his or her ordinary shares by an instrument of transfer in the usual or common form or any other form approved by our board of directors.

Our board of directors may, in its absolute discretion, decline to register any transfer of any ordinary share which is not fully paid up or on which we have a lien. Our board of directors may also decline to register any transfer of any ordinary share unless:

- the instrument of transfer is lodged with us, accompanied by the certificate for the ordinary shares to which it relates and such other evidence as our board of directors may reasonably require to show the right of the transferor to make the transfer;
- the instrument of transfer is in respect of only one class of ordinary shares;
- the instrument of transfer is properly stamped, if required;
- in the case of a transfer to joint holders, the number of joint holders to whom the ordinary share is to be transferred does not exceed four; and
- a fee of such maximum sum as [the Nasdaq Global Market] may determine to be payable or such lesser sum as our directors may from time to time require is paid to us in respect thereof.

If our directors refuse to register a transfer, they shall, within [three months] after the date on which the instrument of transfer was lodged, send to each of the transferor and the transferee notice of such refusal.

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The registration of transfers may, on ten calendar days' notice being given by advertisement in such one or more newspapers, by electronic means or by any other means in accordance with the rules of [the Nasdaq Global Market] be suspended and the register closed at such times and for such periods as our board of directors may from time to time determine; provided, however, that the registration of transfers shall not be suspended nor the register closed for more than 30 days in any year.

Liquidation. On the winding up of our company, if the assets available for distribution amongst our shareholders shall be more than sufficient to repay the whole of the share capital at the commencement of the winding up, the surplus shall be distributed amongst our shareholders in proportion to the par value of the shares held by them at the commencement of the winding up, subject to a deduction from those shares in respect of which there are monies due, of all monies payable to our company for unpaid calls or otherwise. If our assets available for distribution are insufficient to repay all of the paid-up capital, such assets will be distributed so that, as nearly as may be, the losses are borne by our shareholders in proportion to the par value of the shares held by them.

Calls on Shares and Forfeiture of Shares. Our board of directors may from time to time make calls upon shareholders for any amounts unpaid on their shares in a notice served to such shareholders [at least 14 days] prior to the specified time and place of payment. The shares that have been called upon and remain unpaid are subject to forfeiture.

Redemption, Repurchase and Surrender of Shares. We may issue shares on terms that such shares are subject to redemption, at our option or at the option of the holders of these shares, on such terms and in such manner as may be determined, before the issue of such shares, by our board of directors or by our shareholders by special resolution. Our company may also repurchase any of our shares on such terms and in such manner as have been approved by our board of directors or by an ordinary resolution of our shareholders. Under the Cayman Islands law, any redemption or repurchase of shares by our company may be made out of profits of our company, out of our company's share premium account or out of the proceeds of a fresh issue of shares made for the purpose of the repurchase or, if so authorized by the articles of association and subject to provisions of the Companies Law, out of capital. Any premium payable on a redemption or repurchase over the par value of the shares to be repurchased must be provided for 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 of association and subject to the provisions of the Companies Law, out of capital. At no time may a company redeem or repurchase its shares unless they are fully paid. A company may not redeem or repurchase any of its shares if, as a result of the redemption or repurchase, there would no longer be any issued shares of the company other than shares held as treasury shares. In addition, our company may accept the surrender of any fully paid share for no consideration.

Variations of Rights of Shares. Whenever the capital of our company is divided into different classes the rights attached to any such class may, subject to any rights or restrictions for the time being attached to any class, only be varied with the consent in writing of the holders of all of the issued shares of that class or with the sanction of an ordinary resolution passed at a separate meeting of the holders of the shares of that class. The rights conferred upon the holders of the shares of any class issued with preferred or other rights shall not, subject to any rights or restrictions for the time being attached to the shares of that class, be deemed to be varied by the creation, allotment or issue of further shares ranking *pari passu* with such existing class of shares.

Issuance of Additional Shares. Our post-offering memorandum and articles of association authorize our board of directors to issue additional ordinary shares from time to time as our board of directors shall determine.

Our post-offering memorandum and articles of association also authorize our board of directors to issue from time to time one or more series of preference shares and to determine, with respect to any series of preference shares, the terms and rights of that series, including:

- the designation of the series;

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- the number of shares of the series;
- the dividend rights, dividend rates, conversion rights, voting rights; and
- the rights and terms of redemption and liquidation preferences.

Our board of directors may issue preference shares without action by our shareholders. Issuance of these shares may dilute the voting power of holders of ordinary shares.

Inspection of Books and Records. Shareholders have no general right under Cayman Islands law to inspect or obtain copies of our list of shareholders or our corporate records. However, we intend to provide our shareholders with annual audited financial statements. See “Where You Can Find Additional Information.”

Anti-Takeover Provisions. Some provisions of our post-offering memorandum and articles of association may discourage, delay or prevent a change of control of our company or management that shareholders may consider favorable, including provisions that:

- authorize our board of directors to issue preference shares in one or more series and to designate the price, rights, preferences, privileges and restrictions of such preference shares without any further vote or action by our shareholders; and
- limit the ability of shareholders to requisition and convene general meetings of shareholders.

However, under Cayman Islands law, our directors may only exercise the rights and powers granted to them under our post-offering memorandum and articles of association for a proper purpose and for what they believe in good faith to be in the best interests of our company.

Exempted Company. We are an exempted company with limited liability under the Companies Law. The Companies Law distinguishes between ordinary resident companies and exempted companies. Any company that is registered in the Cayman Islands but conducts business mainly outside of the Cayman Islands may apply to be registered as an exempted company. The requirements for an exempted company are essentially the same as for an ordinary company except that an exempted company:

- does not have to file an annual return of its shareholders with the Registrar of Companies;
- is not required to open its register of members for inspection;
- does not have to hold an annual general meeting;
- may issue negotiable or bearer shares or shares with no par value;
- may obtain an undertaking against the imposition of any future taxation (such undertakings are usually given for 20 years in the first instance);
- may register by way of continuation in another jurisdiction and be deregistered in the Cayman Islands;
- may register as a limited duration company; and
- may register as a segregated portfolio company.

“Limited liability” means that the liability of each shareholder is limited to the amount unpaid by the shareholder on the shares of the company.]

Differences in Corporate Law

The Companies Law is modeled after that of England but does not follow recent English statutory enactments and differs from laws applicable to U.S. corporations and their shareholders. Set forth below is a summary of the significant differences between the provisions of the Companies Law applicable to us and the laws applicable to companies incorporated in the United States and their shareholders.

Mergers and Similar Arrangements. The Companies Law 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) a “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 authorized by (a) a special resolution of the shareholders of each constituent company, and (b) such other authorization, if any, as may be specified in such constituent company’s articles of association. The 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 statement 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. Court approval is not required for a merger or consolidation which is effected in compliance with these statutory procedures.

A merger between a Cayman parent company and its Cayman subsidiary or subsidiaries does not require authorization by a resolution of shareholders if a copy of the plan of merger is given to every member of that Cayman subsidiary to be merged unless that member agrees otherwise. For this purpose a company is a “parent” of a subsidiary if it holds issued shares that together represent at least ninety percent (90%) of the votes at a general meeting of the subsidiary.

The consent of each holder of a fixed or floating security interest over a constituent company is required unless this requirement is waived by a court in the Cayman Islands.

Save in certain limited circumstances, a shareholder of a Cayman constituent company who dissents from the merger or consolidation is entitled to payment of the fair value of his or her shares (which, if not agreed between the parties, will be determined by the Cayman Islands court) upon dissenting to the merger or consolidation, provided that the dissenting shareholder complies strictly with the procedures set out in the Companies Law. The exercise of dissenter rights will preclude the exercise by the dissenting shareholder of any other rights to which he or she might otherwise be entitled by virtue of holding shares, save for the right to seek relief on the grounds that the merger or consolidation is void or unlawful.

Separate from the statutory provisions relating to mergers and consolidations, the Companies Law also contains statutory provisions that facilitate the reconstruction and amalgamation of companies by way of schemes of arrangement, provided that the arrangement is approved by a majority in number of each class of shareholders and creditors with whom the arrangement is to be made, and who must in addition represent three-fourths in value of each such class of shareholders or creditors, as the case may be, that are present and voting either in person or by proxy at a meeting, or meetings, convened for that purpose. The convening of the meetings and subsequently the arrangement must be sanctioned by the Grand Court of the Cayman Islands. While a dissenting shareholder has the right to express to the court the view that the transaction ought not to be approved, the court can be expected to approve the arrangement if it determines that:

- the statutory provisions as to the required majority vote have been met;
- the shareholders have been fairly represented at the meeting in question and the statutory majority are acting bona fide without coercion of the minority to promote interests adverse to those of the class;
- the arrangement is such that may be reasonably approved by an intelligent and honest man or woman of that class acting in respect of his interest; and
- the arrangement is not one that would more properly be sanctioned under some other provision of the Companies Law.

When a takeover offer is made and accepted by holders of 90% of the shares within four months, the offeror may, within a two-month period commencing on the expiration of such four-month period, require the holders of the remaining shares to transfer such shares to the offeror on the terms of the offer. An objection can be made to the Grand Court of the Cayman Islands but this is unlikely to succeed in the case of an offer which has been so approved unless there is evidence of fraud, bad faith or collusion.

If an arrangement and reconstruction is thus approved, or if a takeover offer is made and accepted, a dissenting shareholder would have no rights comparable to appraisal rights, which would otherwise ordinarily be available to dissenting shareholders of Delaware corporations, providing rights to receive payment in cash for the judicially determined value of the shares.

Shareholders' Suits. In principle, we will normally be the proper plaintiff and as a general rule a derivative action may not be brought by a minority shareholder. However, based on English authorities, which would in all likelihood be of persuasive authority in the Cayman Islands, the Cayman Islands courts can be expected to follow and apply the common law principles (namely the rule in *Foss v. Harbottle* and the exceptions thereto) which may permit a minority shareholder to commence a class action against, or derivative actions in the name of, our company to challenge:

- an act which is ultra vires or illegal and is therefore incapable of ratification by the shareholders;
- an act which constitutes a fraud against the minority where the wrongdoers are themselves in control of the company; and
- an act which requires a resolution with a qualified (or special) majority (i.e., more than a simple majority) which has not been obtained.

Indemnification of Directors and Executive Officers and Limitation of Liability. Cayman Islands law does not limit the extent to which a company's memorandum and 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, such as to provide indemnification against civil fraud or the consequences of committing a crime. [Our post-offering memorandum and articles of association permit indemnification of officers and directors for losses, damages, costs and expenses incurred in their capacities as such unless such losses or damages arise from dishonesty or fraud of such directors or officers.] This standard of conduct is generally the same as permitted under the Delaware General Corporation Law for a Delaware corporation.

[In addition, we have entered into indemnification agreements with our directors and executive officers that provide such persons with additional indemnification beyond that provided in our post-offering memorandum and articles of association.]

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers or persons controlling us under the foregoing provisions, we have been informed that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Directors' Fiduciary Duties. Under Delaware corporate law, a director of a Delaware corporation has a fiduciary duty to the corporation and its shareholders. This duty has two components: the duty of care and the duty of loyalty. The duty of care requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform himself of, and disclose to shareholders, all material information reasonably available regarding a significant transaction. The duty of loyalty requires that a director acts in a manner he or she reasonably believes to be in the best interests of the corporation. He or she must not use his or her corporate position for personal gain or advantage. This duty prohibits self-dealing by a director and mandates that the best interests of the corporation and its shareholders

take precedence over any interest possessed by a director, officer or controlling shareholder and not shared by the shareholders generally. In general, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties. Should such evidence be presented concerning a transaction by a director, the director must prove the procedural fairness of the transaction, and that the transaction was of fair value to the corporation.

As a matter of Cayman Islands law, a director of a Cayman Islands company is in the position of a fiduciary with respect to the company and therefore it is considered that he or she owes the following duties to the company—a duty to act in good faith in the best interests of the company, a duty not to make a personal profit based on his or her position as director (unless the company permits him or her to do so), a duty not to put himself or herself in a position where the interests of the company conflict with his or her personal interest or his or her duty to a third party and a duty to exercise powers for the purpose for which such powers were intended. A director of a Cayman Islands company owes to the company a duty to act with skill and care. It was previously considered that a director need not exhibit in the performance of his or her duties a greater degree of skill than may reasonably be expected from a person of his or her knowledge and experience. However, English and Commonwealth courts have moved towards an objective standard with regard to the required skill and care and these authorities are likely to be followed in the Cayman Islands.

Shareholder Action by Written Consent. Under the Delaware General Corporation Law, a corporation may eliminate the right of shareholders to act by written consent by amendment to its certificate of incorporation. Cayman Islands law and our post-offering articles of association provide that shareholders may approve corporate matters by way of a unanimous written resolution signed by or on behalf of each shareholder who would have been entitled to vote on such matter at a general meeting without a meeting being held.

Shareholder Proposals. Under the Delaware General Corporation Law, a shareholder has the right to put any proposal before the annual meeting of shareholders, provided it complies with the notice provisions in the governing documents. A special meeting may be called by the board of directors or any other person authorized to do so in the governing documents, but shareholders may be precluded from calling special meetings.

The Companies Law does not provide shareholders with any right to requisition a general meeting, nor any right to put any proposal before a general meeting. However, these rights may be provided in a company's articles of association. Our post-offering articles of association allow our shareholders holding in aggregate not less than [one-third] of all votes attaching to the outstanding shares of our company entitled to vote at general meetings to requisition an extraordinary general meeting of our shareholders, in which case our board is obliged to convene an extraordinary general meeting and to put the resolutions so requisitioned to a vote at such meeting. Other than this right to requisition a shareholders' meeting, our post-offering articles of association do not provide our shareholders with any other right to put proposals before annual general meetings or extraordinary general meetings. As an exempted Cayman Islands company, we are not obliged by law to call shareholders' annual general meetings.

Cumulative Voting. Under the Delaware General Corporation Law, cumulative voting for elections of directors is not permitted unless the corporation's certificate of incorporation specifically provides for it. Cumulative voting potentially facilitates the representation of minority shareholders on a board of directors since it permits the minority shareholder to cast all the votes to which the shareholder is entitled on a single director, which increases the shareholder's voting power with respect to electing such director. There are no prohibitions in relation to cumulative voting under the laws of the Cayman Islands but our post-offering articles of association do not provide for cumulative voting. As a result, our shareholders are not afforded any less protections or rights on this issue than shareholders of a Delaware corporation.

Removal of Directors. Under the Delaware General Corporation Law, a director of a corporation with a classified board may be removed only for cause with the approval of a majority of the outstanding shares entitled

to vote, unless the certificate of incorporation provides otherwise. Under our post-offering articles of association, subject to certain restrictions as contained therein, directors may be removed with or without cause, by an ordinary resolution of our shareholders. A director shall hold office until the expiration of his or her term or his or her successor shall have been elected and qualified, or until his or her office is otherwise vacated. In addition, a director's office shall be vacated if the director (i) becomes bankrupt or makes any arrangement or composition with his or her creditors; (ii) is found to be or becomes of unsound mind or dies; (iii) resigns his or her office by notice in writing to the company; (iv) without special leave of absence from our board of directors, is absent from three consecutive meetings of the board and the board resolves that his or her office be vacated; (v) is prohibited by law from being a director; or (vi) is removed from office pursuant to any other provisions of our post-offering memorandum and articles of association.

Transactions with Interested Shareholders. The Delaware General Corporation Law contains a business combination statute applicable to Delaware corporations whereby, unless the corporation has specifically elected not to be governed by such statute by amendment to its certificate of incorporation, it is prohibited from engaging in certain business combinations with an "interested shareholder" for three years following the date that such person becomes an interested shareholder. An interested shareholder generally is a person or a group who or which owns or owned 15% or more of the target's outstanding voting share within the past three years. This has the effect of limiting the ability of a potential acquirer to make a two-tiered bid for the target in which all shareholders would not be treated equally. The statute does not apply if, among other things, prior to the date on which such shareholder becomes an interested shareholder, the board of directors approves either the business combination or the transaction which resulted in the person becoming an interested shareholder. This encourages any potential acquirer of a Delaware corporation to negotiate the terms of any acquisition transaction with the target's board of directors.

Cayman Islands law has no comparable statute. As a result, we cannot avail ourselves of the types of protections afforded by the Delaware business combination statute. However, although Cayman Islands law does not regulate transactions between a company and its significant shareholders, it does provide that such transactions must be entered into bona fide in the best interests of the company and not with the effect of constituting a fraud on the minority shareholders.

Dissolution; Winding up. Under the Delaware General Corporation Law, unless the board of directors approves the proposal to dissolve, dissolution must be approved by shareholders holding 100% of the total voting power of the corporation. Only if the dissolution is initiated by the board of directors may it be approved by a simple majority of the corporation's outstanding shares. Delaware law allows a Delaware corporation to include in its certificate of incorporation a supermajority voting requirement in connection with dissolutions initiated by the board.

Under Cayman Islands law, a company may be wound up by either an order of the courts of the Cayman Islands or by a special resolution of its members or, if the company is unable to pay its debts as they fall due, by an ordinary resolution of its members. The court has authority to order winding up in a number of specified circumstances including where it is, in the opinion of the court, just and equitable to do so. Under the Companies Law and our post-offering articles of association, our company may be dissolved, liquidated or wound up by a special resolution of our shareholders.

Variation of Rights of Shares. Under the Delaware General Corporation Law, a corporation may vary the rights of a class of shares with the approval of a majority of the outstanding shares of such class, unless the certificate of incorporation provides otherwise. Under Cayman Islands law and our post-offering articles of association, if our share capital is divided into more than one class of shares, we may vary the rights attached to any class with the written consent of the holders of a [majority] of the issued shares of that class or with the sanction of a [special resolution] passed at a general meeting of the holders of the shares of that class.

Amendment of Governing Documents. Under the Delaware General Corporation Law, a corporation's governing documents may be amended with the approval of a majority of the outstanding shares entitled to vote,

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unless the certificate of incorporation provides otherwise. As permitted by Cayman Islands law, our post-offering memorandum and articles of association may only be amended with a special resolution of our shareholders.

History of Securities Issuances

The following is a summary of our securities issuances in the past three years.

Ordinary Shares

On June 30, 2016, we issued (i) 1 ordinary share to Offshore Incorporations (Cayman) Limited which was immediately transferred to Mabcore Limited for a purchase price of US\$0.0001 and (ii) 4,019,553 ordinary shares to Mabcore Limited for a purchase price of US\$401.9553. Dr. Zang, through himself and The Jingwu Zhang Zang 2018 Retained Annuity Trust, owns a 55.6% equity interest in Mabcore Limited. Lili Qian and two other individuals own the remaining equity interest in Mabcore Limited.

On October 18, 2016, we repurchased and cancelled 87,441 ordinary shares from Mabcore Limited. The remaining 3,932,113 ordinary shares held by Mabcore Limited have been designated as restricted ordinary shares pursuant to the restricted share agreement, dated as of October 18, 2016, by and among I-Mab, Mabcore Limited and certain other parties thereto. None of these restricted shares may be sold, transferred, pledged, hypothecated, or otherwise disposed of, directly or indirectly, by any shareholder of Mabcore Limited or Mabcore Limited prior to the termination of our repurchase right unless consented to by IBC Investment Seven Limited, an affiliate of C-Bridge Capital Investment Management, Ltd. As of the date of this prospectus, our repurchase right with respect to 70% of these restricted shares has already lapsed, and our repurchase right with respect to the remaining 30% of the restricted shares shall lapse on October 18, 2019. However, such repurchase right may be terminated earlier upon the completion of: (i) a change of control of our company; (ii) the consummation of a firm underwritten public offering of the ordinary shares of our company on the Shenzhen or Shanghai Stock Exchange, the NEEQ (which is the National Equities Exchange and Quotations Co., Ltd., a Chinese over-the-counter system for trading the shares of a public limited company that is not listed on either the Shenzhen or Shanghai Stock Exchange) or other recognized regional or national securities exchange, with an offering price that reflects a market capitalization of not less than US\$200 million (exclusive of underwriting commissions and expenses) and gross proceeds to our company of at least US\$40 million (prior to any underwriters' commissions and expenses), or (iii) the termination of employment or consultancy of any of these shareholders of Mabcore Limited with us without cause. Prior to the termination of our repurchase right, we have the right to repurchase, from Mabcore Limited, all of the restricted shares ultimately held by any of these shareholders of Mabcore Limited, at a repurchase price equal to the equivalent amount of US\$ of RMB0.5385 per share, plus a 12% interest compounded annual interest accruing from October 18, 2016, upon (x) the voluntary termination by a shareholder of Mabcore Limited of his/her employment or consultancy with us, or (y) the termination by us of such person's employment or consultancy with us for cause. To exercise our repurchase right, we shall deliver a written notice to Mabcore Limited and the applicable shareholder of Mabcore Limited within 60 days after the termination of the employment or consultancy of such shareholder. We have no obligation to repurchase any restricted shares. We may not assign any repurchase right to any party without the prior written consent of IBC Investment Seven Limited.

On October 18, 2016, we issued an aggregate of 4,431,606 ordinary shares to BioScikin Co., Ltd. and Hangzhou Tigermed Consulting Co., Ltd for an aggregate purchase price of approximately RMB16.0 million.

Preferred Shares

On October 18, 2016, we issued 4,629,231 Series A-1 preferred shares and 512,356 Series A-2 preferred shares to IBC Investment Seven Limited for an aggregate purchase price of approximately US\$4.6 million and US\$8.4 million, respectively.

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On September 6, 2017, we issued an aggregate of 16,723,646 Series A-3 preferred shares to CBC SPVII LIMITED and Genexine for an aggregate purchase price of US\$30.0 million.

On September 22, 2017, we issued 14,089,714 Series B preferred shares to CBC Investment I-Mab Limited for an aggregate purchase price of US\$48.4 million.

On February 9, 2018, we issued 1,804,880 Series B preferred shares to C-Bridge II Investment Ten Limited for an aggregate purchase price of US\$6.2 million.

On June 29, 2018, we issued an aggregate of 2,535,201 Series B-1 preferred shares to CBC Investment I-MAB Limited and C-Bridge II Investment Ten Limited for an aggregate purchase price of approximately US\$13.7 million as a result of the conversion by these two entities of the convertible promissory notes issued to them on September 25, 2017 and February 9, 2018, respectively. On the same date, we issued an aggregate of 2,253,512 Series B-2 preferred shares to CBC Investment I-MAB Limited and C-Bridge II Investment Ten Limited for an aggregate purchase price of approximately US\$13.7 million as a result of the exercise of the warrants granted to them on September 25, 2017.

On June 29, 2018, we issued 8,361,823 Series A-3 preferred shares, 5,938,640 Series B preferred shares, and 947,218 Series B-1 preferred shares to Tasly Biopharma Limited in exchange for Tasly Biopharma Limited's equity interests in I-Mab Hong Kong.

On July 6, 2018, Tasly Biopharma Limited transferred to Rainbow Horizon Limited 947,218 Series B-1 preferred shares and the warrant in part to purchase 841,971 Series B-2 preferred shares for a total purchase price of US\$6.0 million. On the same date, we issued 841,971 Series B-2 preferred shares to Rainbow Horizon Limited as a result of the exercise of the warrant by Rainbow Horizon for an aggregate purchase price of US\$5.1 million.

On July 6, 2018, we issued to Qianhai Ark (Cayman) Investment Co. Limited ("Qianhai Ark Cayman"), (i) 1,455,549 Series B preferred shares for a purchase price of approximately US\$2.0 million, (ii) 232,161 Series B-1 preferred shares for an aggregate purchase price of US\$1.25 million as a result of the conversion of a convertible promissory note issued to Qianhai Ark Cayman on July 6, 2018, and (iii) 206,366 Series B-2 preferred shares for an aggregate purchase price of US\$1.25 million as a result of the exercise of warrant granted to Qianhai Ark Cayman on September 25, 2017.

On July 6, 2018, we issued an aggregate of 31,046,360 Series C preferred shares to Fortune Eight Jogging Limited, C-Bridge II Investment Seven Limited, HH IMB Holdings Limited, Ally Bridge LB Precision Limited, Marvey Investment Company Limited, Mab Health Limited, Casiority H Limited, Southern Creation Limited (formerly known as Ally Bridge LB-Sunshine Limited), Tasly International Capital Limited, and Parkway Limited for an aggregate purchase price of US\$200.0 million.

On July 25, 2019, we entered into a share purchase agreement with Caesar Pro Holdings Limited, WuXi Biologics HealthCare Venture, and Hongkong Tigermed Co., Limited. Pursuant to the share purchase agreement, these investors will subscribe for an aggregate of 3,857,143 Series C-1 preferred shares of I-Mab for an aggregate purchase price of US\$27.0 million. We expect to close this transaction in October, 2019.

Convertible Promissory Notes

On September 25, 2017, we issued a US\$12.1 million convertible promissory note due September 2020 to CBC Investment I-Mab Limited. On June 29, 2018, CBC Investment I-Mab Limited converted this note to 2,247,321 Series B-1 preferred shares.

On February 5, 2018, we issued a US\$9.0 million convertible promissory note due February 2021 to Genexine. Genexine can at any time prior to February 5, 2021 convert this note into preferred shares of I-Mab at

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US\$10 per share, subject to certain price adjustments. As of the date of this prospectus, Genexine has not converted this note.

On February 9, 2018, we issued a US\$1.6 million convertible promissory note due September 2020 to C-Bridge II Investment Ten Limited. On June 29, 2018, C-Bridge II Investment Ten Limited converted this note into 287,880 Series B-1 preferred shares.

On July 6, 2018, we issued a US\$1.3 million convertible promissory note due July 2021 to Qianhai Ark Cayman. On July 6, 2018, Qianhai Ark Cayman converted this note into 232,161 Series B-1 preferred shares.

Options and Warrants

On October 18, 2016, we granted IBC Investment Seven Limited a warrant to purchase up to 2,246,744 Series A-3 preferred shares. The warrant was cancelled on September 6, 2017 pursuant to a termination agreement between us and IBC Investment Seven Limited, who had not exercised the warrant prior to the termination.

On September 6, 2017, we granted Shanghai Tasly an option to purchase up to 8,361,823 Series A-3 preferred shares. On September 25, 2017, we granted Shanghai Tasly an additional option to purchase up to 5,938,640 Series B preferred shares and 947,218 Series B-1 preferred shares. On June 29, 2018, Tasly Biopharma Limited, as Shanghai Tasly's permitted assign, exercised these options in full.

On September 25, 2017, we granted (i) Qianhai Fund an option to purchase up to 1,455,549 Series B preferred shares and up to 232,161 Series B-1 preferred shares, and (ii) CBC RMB Fund an option to purchase up to 1,804,880 Series B preferred shares and up to 287,880 additional Series B-1 preferred Shares. The option granted to Qianhai Fund was exercised in full on July 6, 2018. The option granted to CMC RMB Fund was terminated on February 9, 2018.

On September 25, 2017, we granted a warrant to each of CBC Investment I-Mab Limited, Shanghai Tasly, Qianhai Fund and C-Bridge II Investment Ten Limited to purchase up to 4,994,046 Series B-2 preferred shares, up to 2,104,928 Series B-2 preferred shares, up to 515,914 Series B-2 preferred shares and up to 639,734 Series B-2 preferred shares, respectively. On July 6, 2018, these investors exercised their warrants in part and purchased 1,997,618 Series B-2 preferred shares, 841,971 Series B-2 preferred shares, 206,366 Series B-2 preferred shares and 255,894 Series B-2 preferred shares, for an aggregate purchase price of US\$20.0 million. These investors have waived and cancelled their rights under the rest of the warrants. On September 25, 2017, we also granted a warrant to CBC RMB Fund to purchase up to 639,734 Series B-2 preferred shares, which was terminated on the same date.

On July 6, 2018, Tasly Biopharm Limited, as Shanghai Tasly's permitted assign, transferred to Rainbow Horizon Limited the warrant in part to purchase 841,971 Series B-2 preferred shares. On the same date, Rainbow Horizon Limited exercised this warrant.

We have granted options to purchase our ordinary shares to certain of our directors, executive officers and employees. See "Management—Share Incentive Plans."

Shareholders Agreement

We entered into our shareholders agreement on July 6, 2018 with our shareholders.

The shareholders agreement provides for certain special rights, including right of first refusal, co-sale rights, preemptive rights and contains provisions governing the board of directors and other corporate governance matters. Unless specifically noted, those special rights, as well as the corporate governance provisions, will automatically terminate upon the completion of a qualified initial public offering.

[Registration Rights

Pursuant to our shareholders agreement dated July 6, 2018, we have granted certain registration rights to our shareholders. Set forth below is a description of the registration rights granted under the agreement.

Demand Registration Rights. At any time after the earlier of (i) December 31, 2020, or (ii) six months following the effectiveness of a registration statement for a firm underwritten public offering of our ordinary shares on The Stock Exchange of Hong Kong Limited, or other internationally recognized securities exchange, with an offering price (exclusive of underwriting commissions and expenses) that reflects a market capitalization (immediately prior to the public offering) of not less than US\$1.0 billion, the holders of a majority of the registrable securities then issued and outstanding may request in writing that we file a registration statement covering the registration of at least 20% of the registrable securities (or any lesser percentage if the anticipated gross receipts from the offering are to exceed US\$5.0 million). Upon such a request, we shall, within ten business days of the receipt of such written request, give written notice of such request to all holders, and use our best efforts to effect, as soon as practicable, the registration of all registrable securities that the holders request to be registered and included in such registration by written notice given by such holders to us within 20 days after receipt of the request notice. We have the right to defer filing of a registration statement for a period of not more than 90 days after receipt of the request of the initiating holders if our board of directors determines in good faith that filing of such registration statement at such time will be materially detrimental to us or our shareholders, but we cannot exercise the deferral right more than once during any twelve-month period and cannot register any other securities during such twelve-month period. We are not obligated to effect any such registration if we have, within the six-month period preceding the date of such request, already effected a registration. We are not obligated to effect more than three demand registrations. This demand registration right is subject to the customary exclusion right of the underwriters.

Registration on Form F-3. If we qualify for registration on Form F-3, any holder or holders of a majority of all registrable securities then issued and outstanding may request in writing that we effect a registration on Form F-3 (or an equivalent registration in a jurisdiction outside of the U.S.). We shall promptly give written notice of the proposed registration and as soon as practicable, effect such registration within 20 days after we provide the aforesaid written notice. The holders are entitled to an unlimited number of registrations on Form F-3 so long as such registration offerings are in excess of US\$500,000. We are not obligated to effect any such registration if we have, within the six-month period preceding the date of such request, already effected a registration other than a registration from which registrable securities of the holders have been excluded, or if we would be required to qualify to do business or to execute a general consent to service of process in effecting such registration in any particular jurisdiction.

Piggyback Registration Rights. If we propose to register for a public offering of our securities (other than registration statements relating to demand registration, Form F-3 registration, any employee benefit plan or a corporate reorganization), we shall give written notice of such registration to all holders of registrable securities at least 30 days prior to filing any registration statement and afford each such holder an opportunity to be included in such registration. If a holder decides not to include all of its registrable securities in any registration statement thereafter filed by us, such holder shall nevertheless continue to have the right to include any registrable securities in any subsequent registration statement or registration statements as may be filed by us, subject to certain limitations. This piggyback registration right is subject to the customary exclusion right of the underwriters.

Expenses of Registration. We will bear all registration expenses. Each holder, however, should bear its proportionate share of all of the underwriting discounts and selling commissions applicable to the sale of registrable securities or other amounts payable to underwriter(s) or brokers in connection with such offering by the holders.

Termination of Obligations. Our obligations to effect any demand, Form F-3 or piggyback registration shall terminate upon the tenth anniversary of our initial public offering.]

DESCRIPTION OF AMERICAN DEPOSITARY SHARES

American Depositary Shares

, as depositary will issue the ADSs which you will be entitled to receive in this offering. Each ADS will represent an ownership interest in ordinary shares which we will deposit with the custodian, as agent of the depositary, under the deposit agreement among us, the depositary and you as an ADR holder. In the future, each ADS will also represent any securities, cash or other property deposited with the depositary but which they have not distributed directly to you. Unless specifically requested by you, all ADSs will be issued on the books of our depositary in book-entry form and periodic statements will be mailed to you which reflect your ownership interest in such ADSs. In our description, references to American depositary receipts or ADRs shall include the statements you will receive which reflect your ownership of ADSs.

The depositary's office is located at .

You may hold ADSs either directly or indirectly through your broker or other financial institution. If you hold ADSs directly, by having an ADS registered in your name on the books of the depositary, you are an ADR holder. This description assumes you hold your ADSs directly. If you hold the ADSs through your broker or financial institution nominee, you must rely on the procedures of such broker or financial institution to assert the rights of an ADR holder described in this section. You should consult with your broker or financial institution to find out what those procedures are.

As an ADR holder, we will not treat you as a shareholder of ours and you will not have any shareholder rights. Cayman Islands law governs shareholder rights. Because the depositary or its nominee will be the shareholder of record for the shares represented by all outstanding ADSs, shareholder rights rest with such record holder. Your rights are those of an ADR holder. Such rights derive from the terms of the deposit agreement to be entered into among us, the depositary and all registered holders from time to time of ADSs issued under the deposit agreement. The obligations of the depositary and its agents are also set out in the deposit agreement. Because the depositary or its nominee will actually be the registered owner of the shares, you must rely on it to exercise the rights of a shareholder on your behalf. The deposit agreement and the ADSs are governed by New York law.

The following is a summary of what we believe to be the material terms of the deposit agreement. Notwithstanding this, because it is a summary, it may not contain all the information that you may otherwise deem important. For more complete information, you should read the entire deposit agreement and the form of ADR which contains the terms of your ADSs. You can read a copy of the deposit agreement which is filed as an exhibit to the registration statement of which this prospectus forms apart. You may also obtain a copy of the deposit agreement at the SEC's Public Reference Room which is located at 100 F Street, NE, Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-732-0330. You may also find the registration statement and the attached deposit agreement on the SEC's website at <http://www.sec.gov>.

Share Dividends and Other Distributions

How will I receive dividends and other distributions on the shares underlying my ADSs?

We may make various types of distributions with respect to our securities. The depositary has agreed that, to the extent practicable, it will pay to you the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, after converting any cash received into U.S. dollars and, in all cases, making any necessary deductions provided for in the deposit agreement. You will receive these distributions in proportion to the number of underlying securities that your ADSs represent.

Except as stated below, the depositary will deliver such distributions to ADR holders in proportion to their interests in the following manner:

- *Cash.* The depositary will distribute any U.S. dollars available to it resulting from a cash dividend or other cash distribution or the net proceeds of sales of any other distribution or portion thereof (to the extent applicable), on an averaged or other practicable basis, subject to (i) appropriate adjustments for taxes withheld, (ii) such distribution being impermissible or impracticable with respect to certain registered ADR holders, and (iii) deduction of the depositary's expenses in (1) converting any foreign currency to U.S. dollars to the extent that it determines that such conversion may be made on a reasonable basis, (2) transferring foreign currency or U.S. dollars to the United States by such means as the depositary may determine to the extent that it determines that such transfer may be made on a reasonable basis, (3) obtaining any approval or license of any governmental authority required for such conversion or transfer, which is obtainable at a reasonable cost and within a reasonable time and (4) making any sale by public or private means in any commercially reasonable manner. The depositary will hold any cash amounts it is unable to distribute in a non-interest-bearing account for the benefit of the applicable holders and beneficial owners of ADSs until the distribution can be effected or the funds that the depositary holds must be escheated as unclaimed property in accordance with the laws of the relevant states of the United States. *If exchange rates fluctuate during a time when the depositary cannot convert a foreign currency, you may lose some or all of the value of the distribution.*
- *Shares.* In the case of a distribution in shares, the depositary will issue additional ADRs to evidence the number of ADSs representing such shares. Only whole ADSs will be issued. Any shares which would result in fractional ADSs will be sold and the net proceeds will be distributed in the same manner as cash to the ADR holders entitled thereto.
- *Rights to Receive Additional Shares.* In the case of a distribution of rights to subscribe for additional shares or other rights, if we provide evidence satisfactory to the depositary that it may lawfully distribute such rights, the depositary will distribute warrants or other instruments in the discretion of the depositary representing such rights. However, if we do not furnish such evidence, the depositary may:
 - sell such rights if practicable and distribute the net proceeds in the same manner as cash to the ADR holders entitled thereto; or
 - if it is not practicable to sell such rights, do nothing and allow such rights to lapse, in which case ADR holders will receive nothing.

We have no obligation to file a registration statement under the Securities Act in order to make any rights available to ADR holders.

- *Other Distributions.* In the case of a distribution of securities or property other than those described above, the depositary may either (i) distribute such securities or property in any manner it deems equitable and practicable or (ii) to the extent the depositary deems distribution of such securities or property not to be equitable and practicable, sell such securities or property and distribute any net proceeds in the same way it distributes cash.

If the depositary determines that any distribution described above is not practicable with respect to any specific registered ADR holder, the depositary may choose any method of distribution that it deems practicable for such ADR holder, including the distribution of foreign currency, securities or property, or it may retain such items, without paying interest on or investing them, on behalf of the ADR holder as deposited securities, in which case the ADSs will also represent the retained items.

Any U.S. dollars will be distributed by checks drawn on a bank in the United States for whole dollars and cents. Fractional cents will be withheld without liability and dealt with by the depositary in accordance with its then current practices.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADR holders.

There can be no assurance that the depositary will be able to convert any currency at a specified exchange rate or sell any property, rights, shares or other securities at a specified price, nor that any of such transactions can be completed within a specified time period.

Deposit, Withdrawal and Cancellation

How does the depositary issue ADSs?

The depositary will issue ADSs if you or your broker deposits shares or evidence of rights to receive shares with the custodian and pays the fees and expenses owing to the depositary in connection with such issuance. In the case of the ADSs to be issued under this prospectus, we will arrange with the underwriters named herein to deposit such shares.

Shares deposited in the future with the custodian must be accompanied by certain delivery documentation and shall, at the time of such deposit, be registered in the name of _____, as depositary for the benefit of holders of ADRs or in such other name as the depositary shall direct.

The custodian will hold all deposited shares (including those being deposited by or on our behalf in connection with the offering to which this prospectus relates) for the account of the depositary. ADR holders thus have no direct ownership interest in the shares and only have such rights as are contained in the deposit agreement. The custodian will also hold any additional securities, property and cash received on or in substitution for the deposited shares. The deposited shares and any such additional items are referred to as “deposited securities.”

Upon each deposit of shares, receipt of related delivery documentation and compliance with the other provisions of the deposit agreement, including the payment of the fees and charges of the depositary and any taxes or other fees or charges owing, the depositary will issue an ADR or ADRs in the name or upon the order of the person entitled thereto evidencing the number of ADSs to which such person is entitled. All of the ADSs issued will, unless specifically requested to the contrary, be part of the depositary’s direct registration system, and a registered holder will receive periodic statements from the depositary which will show the number of ADSs registered in such holder’s name. An ADR holder can request that the ADSs not be held through the depositary’s direct registration system and that a certificated ADR be issued.

How do ADR holders cancel an ADS and obtain deposited securities?

When you turn in your ADR certificate at the depositary’s office, or when you provide proper instructions and documentation in the case of direct registration ADSs, the depositary will, upon payment of certain applicable fees, charges and taxes, deliver the underlying shares to you or upon your written order. At your risk, expense and request, the depositary may deliver deposited securities at such other place as you may request.

The depositary may only restrict the withdrawal of deposited securities in connection with:

- temporary delays caused by closing our transfer books or those of the depositary or the deposit of shares in connection with voting at a shareholders’ meeting, or the payment of dividends;
- the payment of fees, taxes and similar charges; or
- compliance with any U.S. or foreign laws or governmental regulations relating to the ADRs or to the withdrawal of deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

Record Dates

The depositary may, after consultation with us if practicable, fix record dates for the determination of the registered ADR holders who will be entitled (or obligated, as the case may be):

- to receive any distribution on or in respect of shares;
- to give instructions for the exercise of voting rights at a meeting of holders of shares;
- to pay the fee assessed by the depositary for administration of the ADR program and for any expenses as provided for in the ADR; or
- to receive any notice or to act in respect of other matters all subject to the provisions of the deposit agreement.

Voting Rights

How do I vote?

If you are an ADR holder and the depositary asks you to provide it with voting instructions, you may instruct the depositary how to exercise the voting rights for the shares which underlie your ADSs. As soon as practicable after receiving notice of any meeting or solicitation of consents or proxies from us, the depositary will distribute to the registered ADR holders a notice stating such information as is contained in the voting materials received by the depositary and describing how you may instruct the depositary to exercise the voting rights for the shares which underlie your ADSs. For instructions to be valid, the depositary must receive them in the manner and on or before the date specified. No voting instructions may be deemed given to the depositary to give a discretionary proxy to a person designated by us if no instructions are received by the depositary from you on or before the response date established by the depositary. The depositary will try, as far as is practical, subject to the provisions of and governing the underlying shares or other deposited securities, to vote or to have its agents vote the shares or other deposited securities as you instruct. The depositary will only vote or attempt to vote as you instruct. The depositary will not itself exercise any voting discretion. Furthermore, neither the depositary nor its agents are responsible for any failure to carry out any voting instructions, for the manner in which any vote is cast or for the effect of any vote. Notwithstanding anything contained in the deposit agreement or any ADR, the depositary may, to the extent not prohibited by law or regulations, or by the requirements of the stock exchange on which the ADSs are listed, in lieu of distribution of the materials provided to the depositary in connection with any meeting of, or solicitation of consents or proxies from, holders of deposited securities, distribute to the registered holders of ADRs a notice that provides such holders with, or otherwise publicizes to such holders, instructions on how to retrieve such materials or receive such materials upon request (i.e., by reference to a website containing the materials for retrieval or a contact for requesting copies of the materials).

[Under our constituent documents the depositary would be able to provide us with voting instructions without having to personally attend meetings in person or by proxy. Such voting instructions may be provided to us via facsimile, email, mail, courier or other recognized form of delivery and we agree to accept any such delivery so long as it is timely received prior to the meeting. We will endeavor to provide the depositary with written notice of each meeting of shareholders promptly after determining the date of such meeting so as to enable it to solicit and receive voting instructions. In general, the depositary will require that voting instructions be received by the depositary no less than five business days prior to the date of each meeting of shareholders. Under the post-offering memorandum and articles of association that we expect to adopt, the minimum notice period required to convene a general meeting is seven days. The depositary may not have sufficient time to solicit voting instructions, and it is possible that you, or persons who hold their ADSs through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote.]

Notwithstanding the above, we have advised the depositary that under the Cayman Islands law and our constituent documents, each as in effect as of the date of the deposit agreement, voting at any meeting of shareholders is by show of hands unless a poll is (before or on the declaration of the results of the show of hands)

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demand. In the event that voting on any resolution or matter is conducted on a show of hands basis in accordance with our constituent documents, the depositary will refrain from voting and the voting instructions (or the deemed voting instructions, as set out above) received by the depositary from holders shall lapse. The depositary will not demand a poll or join in demanding a poll, whether or not requested to do so by holders of ADSs.

There is no guarantee that you will receive voting materials in time to instruct the depositary to vote and it is possible that you, or persons who hold their ADSs through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote.

Reports and Other Communications

Will ADR holders be able to view our reports?

The depositary will make available for inspection by ADR holders at the offices of the depositary and the custodian the deposit agreement, the provisions of or governing deposited securities, and any written communications from us which are both received by the custodian or its nominee as a holder of deposited securities and made generally available to the holders of deposited securities.

Additionally, if we make any written communications generally available to holders of our shares, and we furnish copies thereof (or English translations or summaries) to the depositary, it will distribute the same to registered ADR holders.

Fees and Expenses

What fees and expenses will I be responsible for paying?

The depositary may charge each person to whom ADSs are issued, including, without limitation, issuances against deposits of shares, issuances in respect of share distributions, rights and other distributions, issuances pursuant to a stock dividend or stock split declared by us or issuances pursuant to a merger, exchange of securities or any other transaction or event affecting the ADSs or deposited securities, and each person surrendering ADSs for withdrawal of deposited securities or whose ADRs are cancelled or reduced for any other reason, US\$5.00 for each 100 ADSs (or any portion thereof) issued, delivered, reduced, cancelled or surrendered, as the case may be. The depositary may sell (by public or private sale) sufficient securities and property received in respect of a share distribution, rights and/or other distribution prior to such deposit to pay such charge.

The following additional charges shall be incurred by the ADR holders, by any party depositing or withdrawing shares or by any party surrendering ADSs or to whom ADSs are issued (including, without limitation, issuance pursuant to a stock dividend or stock split declared by us or an exchange of stock regarding the ADRs or the deposited securities or a distribution of ADSs), whichever is applicable:

- a fee of US\$ per ADR or ADRs for transfers of certificated or direct registration ADRs;
- a fee of up to US\$ per ADS for any cash distribution made pursuant to the deposit agreement;
- a fee of up to US\$ per ADS per calendar year (or portion thereof) for services performed by the depositary in administering the ADRs (which fee may be charged on a periodic basis during each calendar year and shall be assessed against holders of ADRs as of the record date or record dates set by the depositary during each calendar year and shall be payable in the manner described in the next succeeding provision);
- reimbursement of such fees, charges and expenses as are incurred by the depositary and/or any of the depositary's agents (including, without limitation, the custodian and expenses incurred on behalf of holders in connection with compliance with foreign exchange control regulations or any law or regulation relating to foreign investment) in connection with the servicing of the shares or other

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deposited securities, the delivery of deposited securities or otherwise in connection with the depositary's or its custodian's compliance with applicable law, rule or regulation (which charge shall be assessed on a proportionate basis against holders as of the record date or dates set by the depositary and shall be payable at the sole discretion of the depositary by billing such holders or by deducting such charge from one or more cash dividends or other cash distributions);

- a fee for the distribution of securities (or the sale of securities in connection with a distribution), such fee being in an amount equal to the fee for the execution and delivery of ADSs which would have been charged as a result of the deposit of such securities (treating all such securities as if they were shares and there would be a fee of five cents per ADS outstanding);
- stock transfer or other taxes and other governmental charges;
- cable, telex and facsimile transmission and delivery charges incurred at your request in connection with the deposit or delivery of shares;
- transfer or registration fees for the registration of transfer of deposited securities on any applicable register in connection with the deposit or withdrawal of deposited securities; and
- expenses of the depositary in connection with the conversion of foreign currency into U.S. dollars.

We will pay all other charges and expenses of the depositary and any agent of the depositary (except the custodian) pursuant to agreements from time to time between us and the depositary. The charges described above may be amended from time to time by agreement between us and the depositary.

Our depositary has agreed to reimburse us for certain expenses we incur that are related to establishment and maintenance of the ADR program, including investor relations expenses and exchange application and listing fees. Neither the depositary nor we can determine the exact amount to be made available to us because (i) the number of ADSs that will be issued and outstanding, (ii) the level of fees to be charged to holders of ADSs and (iii) our reimbursable expenses related to the ADR program are not known at this time. The depositary collects its fees for issuance and cancellation of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions, or by directly billing investors, or by charging the book-entry system accounts of participants acting for them. The depositary will generally set off the amounts owing from distributions made to holders of ADSs. If, however, no distribution exists and payment owing is not timely received by the depositary, the depositary may refuse to provide any further services to holders that have not paid those fees and expenses owing until such fees and expenses have been paid. At the discretion of the depositary, all fees and charges owing under the deposit agreement are due in advance and/or when declared owing by the depositary.

Payment of Taxes

ADR holders must pay any tax or other governmental charge payable by the custodian or the depositary on any ADS or ADR, deposited security or distribution. If an ADR holder owes any tax or other governmental charge, the depositary may (i) deduct the amount thereof from any cash distributions, or (ii) sell deposited securities (by public or private sale) and deduct the amount owing from the net proceeds of such sale. In either case the ADR holder remains liable for any shortfall. Additionally, if any taxes or other governmental charges (including any penalties and/or interest) shall become payable by or on behalf of the custodian or the depositary with respect to any ADR, any deposited securities represented by the ADSs evidenced thereby or any distribution thereon, including, without limitation, any PRC Enterprise Income Tax owing if the Circular Guoshuifa [2009] No. 82 issued by the SAT or any other circular, edict, order or ruling, as issued and as from time to time amended, is applied or otherwise, such tax or other governmental charge shall be paid by the holder thereof to the depositary. and by holding or having held an ADR the holder and all prior holders thereof, jointly and severally,

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agree to indemnify, defend and save harmless each of the depository and its agents in respect thereof. If any tax or governmental charge is unpaid, the depository may also refuse to effect any registration, registration of transfer, split-up or combination of deposited securities or withdrawal of deposited securities until such payment is made. If any tax or governmental charge is required to be withheld on any cash distribution, the depository may deduct the amount required to be withheld from any cash distribution or, in the case of a non-cash distribution, sell the distributed property or securities (by public or private sale) to pay such taxes and distribute any remaining net proceeds to the ADR holders entitled thereto.

By holding an ADR or an interest therein, you will be agreeing to indemnify us, the depository, its custodian and any of our or their respective directors, employees, agents and affiliates against, and hold each of them harmless from, any claims by any governmental authority with respect to taxes, additions to tax, penalties or interest arising out of any refund of taxes, reduced rate of withholding at source or other tax benefit obtained.

Reclassifications, Recapitalizations and Mergers

If we take certain actions that affect the deposited securities, including (i) any change in par value, split-up, consolidation, cancellation or other reclassification of deposited securities or (ii) any distributions not made to holders of ADRs or (iii) any recapitalization, reorganization, merger, consolidation, liquidation, receivership, bankruptcy or sale of all or substantially all of our assets, then the depository may choose to:

- amend the form of ADR;
- distribute additional or amended ADRs;
- distribute cash, securities or other property it has received in connection with such actions;
- sell any securities or property received and distribute the proceeds as cash; or
- none of the above.

If the depository does not choose any of the above options, any of the cash, securities or other property it receives will constitute part of the deposited securities and each ADS will then represent a proportionate interest in such property.

Amendment and Termination

How may the deposit agreement be amended?

We may agree with the depository to amend the deposit agreement and the ADSs without your consent for any reason. ADR holders must be given at least [30] days' notice of any amendment that imposes or increases any fees or charges (other than stock transfer or other taxes and other governmental charges, transfer or registration fees, cable, telex or facsimile transmission costs, delivery costs or other such expenses), or otherwise prejudices any substantial existing right of ADR holders. Such notice need not describe in detail the specific amendments effectuated thereby, but must give ADR holders a means to access the text of such amendment. If an ADR holder continues to hold an ADR or ADRs after being so notified, such ADR holder is deemed to agree to such amendment and to be bound by the deposit agreement as so amended. Notwithstanding the foregoing, if any governmental body or regulatory body should adopt new laws, rules or regulations which would require amendment or supplement of the deposit agreement or the form of ADR to ensure compliance therewith, we and the depository may amend or supplement the deposit agreement and the ADR at any time in accordance with such changed laws, rules or regulations, which amendment or supplement may take effect before a notice is given or within any other period of time as required for compliance. No amendment, however, will impair your right to surrender your ADSs and receive the underlying securities, except in order to comply with mandatory provisions of applicable law.

How may the deposit agreement be terminated?

The depositary may, and shall at our written direction, terminate the deposit agreement and the ADRs by mailing notice of such termination to the registered holders of ADRs at least [30] days prior to the date fixed in such notice for such termination; provided, however, if the depositary shall have (i) resigned as depositary under the deposit agreement, notice of such termination by the depositary shall not be provided to registered holders unless a successor depositary shall not be operating under the deposit agreement within [45] days of the date of such resignation, and (ii) been removed as depositary under the deposit agreement, notice of such termination by the depositary shall not be provided to registered holders of ADRs unless a successor depositary shall not be operating under the deposit agreement on the [90]th day after our notice of removal was first provided to the depositary. After termination, the depositary's only responsibility will be (i) to deliver deposited securities to ADR holders who surrender their ADRs, and (ii) to hold or sell distributions received on deposited securities. As soon as practicable after the expiration of six months from the termination date, the depositary will sell the deposited securities which remain and hold the net proceeds of such sales (as long as it may lawfully do so), without liability for interest, in trust for the ADR holders who have not yet surrendered their ADRs. After making such sale, the depositary shall have no obligations except to account for such proceeds and other cash.

Limitations on Obligations and Liability to ADS Holders

Limits on our obligations and the obligations of the depositary; limits on liability to ADR holders and holders of ADSs

Prior to the issue, registration, registration of transfer, split-up, combination, or cancellation of any ADRs, or the delivery of any distribution in respect thereof, and from time to time, we or the depositary or its custodian may require:

- payment with respect thereto of (i) any stock transfer or other tax or other governmental charge, (ii) any stock transfer or registration fees in effect for the registration of transfers of shares or other deposited securities upon any applicable register and (iii) any applicable fees and expenses described in the deposit agreement;
- the production of proof satisfactory to it of (i) the identity of any signatory and genuineness of any signature and (ii) such other information, including, without limitation, information as to citizenship, residence, exchange control approval, beneficial ownership of any securities, compliance with applicable law, regulations, provisions of or governing deposited securities and terms of the deposit agreement and the ADRs, as it may deem necessary or proper; and
- compliance with such regulations as the depositary may establish consistent with the deposit agreement.

The issuance of ADRs, the acceptance of deposits of shares, the registration, registration of transfer, split-up or combination of ADRs or the withdrawal of shares, may be suspended, generally or in particular instances, when the ADR register or any register for deposited securities is closed or when any such action is deemed advisable by the depositary; provided that the ability to withdraw shares may only be limited under the following circumstances: (i) temporary delays caused by closing transfer books of the depositary or our transfer books or the deposit of shares in connection with voting at a shareholders' meeting, or the payment of dividends, (ii) the payment of fees, taxes, and similar charges, and (iii) compliance with any laws or governmental regulations relating to ADRs or to the withdrawal of deposited securities.

The deposit agreement expressly limits the obligations and liability of the depositary, us and our and the depositary's respective agents. Neither we nor the depositary nor any such agent will be liable if:

- any present or future law, rule, regulation, fiat, order or decree of the United States, the Cayman Islands, China or any other country, or of any governmental or regulatory authority or securities exchange or market or automated quotation system, the provisions of or governing any deposited

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securities, any present or future provision of our charter, any act of God, war, terrorism or other circumstance beyond our, the depositary's or our respective agents' control shall prevent or delay, or shall cause any of them to be subject to any civil or criminal penalty in connection with, any act which the deposit agreement or the ADRs provide shall be done or performed by us, the depositary or our respective agents (including, without limitation, voting);

- it exercises or fails to exercise discretion under the deposit agreement or the ADRs;
- it performs its obligations under the deposit agreement and ADRs without gross negligence or bad faith;
- it takes any action or refrains from taking any action in reliance upon the advice of or information from legal counsel, accountants, any person presenting shares for deposit, any registered holder of ADRs, or any other person believed by it to be competent to give such advice or information; or
- it relies upon any written notice, request, direction or other document believed by it to be genuine and to have been signed or presented by the proper party or parties.

Neither the depositary nor its agents have any obligation to appear in, prosecute or defend any action, suit or other proceeding in respect of any deposited securities or the ADRs. We and our agents shall only be obligated to appear in, prosecute or defend any action, suit or other proceeding in respect of any deposited securities or the ADRs, which in our opinion may involve us in expense or liability, if indemnity satisfactory to us against all expense (including fees and disbursements of counsel) and liability is furnished as often as may be required. The depositary and its agents may fully respond to any and all demands or requests for information maintained by or on its behalf in connection with the deposit agreement, any registered holder or holders of ADRs, any ADRs or otherwise related to the deposit agreement or ADRs to the extent such information is requested or required by or pursuant to any lawful authority, including, without limitation, laws, rules, regulations, administrative or judicial process, banking, securities or other regulators. The depositary shall not be liable for the acts or omissions made by any securities depository, clearing agency or settlement system in connection with or arising out of book-entry settlement of deposited securities or otherwise. Furthermore, the depositary shall not be responsible for, and shall incur no liability in connection with or arising from, the insolvency of any custodian that is not a branch or affiliate of . The depositary and the custodian(s) may use third-party delivery services and providers of information regarding matters such as pricing, proxy voting, corporate actions, class action litigation and other services in connection with the ADRs and the deposit agreement, and use local agents to provide extraordinary services such as attendance at annual meetings of issuers of securities. Although the depositary and the custodian will use reasonable care (and cause their agents to use reasonable care) in the selection and retention of such third-party providers and local agents, they will not be responsible for any errors or omissions made by them in providing the relevant information or services.

Additionally, none of us, the depositary or the custodian shall be liable for the failure by any registered holder of ADRs or beneficial owner therein to obtain the benefits of credits on the basis of non-U.S. tax paid against such holder's or beneficial owner's income tax liability. Neither we nor the depositary shall incur any liability for any tax consequences that may be incurred by holders or beneficial owners on account of their ownership of ADRs or ADSs.

Neither the depositary nor its agents will be responsible for any failure to carry out any instructions to vote any of the deposited securities, for the manner in which any such vote is cast or for the effect of any such vote. Neither the depositary nor any of its agents shall be liable to registered holders of ADRs or beneficial owners of interests in ADSs for any indirect, special, punitive or consequential damages (including, without limitation, lost profits) of any form incurred by any person or entity, whether or not foreseeable and regardless of the type of action in which such a claim may be brought.

In the deposit agreement each party thereto (including, for avoidance of doubt, each holder and beneficial owner and/or holder of interests in ADRs) irrevocably waives, to the fullest extent permitted by applicable law,

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any right it may have to a trial by jury in any suit, action or proceeding against the depositary and/or the company directly or indirectly arising out of or relating to the shares or other deposited securities, the ADSs or the ADRs, the deposit agreement or any transaction contemplated therein, or the breach thereof (whether based on contract, tort, common law or any other theory).

The depositary may own and deal in any class of our securities and in ADSs.

Disclosure of Interest in ADSs

To the extent that the provisions of or governing any deposited securities may require disclosure of or impose limits on beneficial or other ownership of deposited securities, other shares and other securities and may provide for blocking transfer, voting or other rights to enforce such disclosure or limits, you agree to comply with all such disclosure requirements and ownership limitations and to comply with any reasonable instructions we may provide in respect thereof. We reserve the right to instruct you to deliver your ADSs for cancellation and withdrawal of the deposited securities so as to permit us to deal with you directly as a holder of shares and, by holding an ADS or an interest therein, you will be agreeing to comply with such instructions.

Books of Depositary

The depositary or its agent will maintain a register for the registration, registration of transfer, combination and split-up of ADRs, which register shall include the depositary's direct registration system. Registered holders of ADRs may inspect such records at the depositary's office at all reasonable times, but solely for the purpose of communicating with other holders in the interest of the business of our company or a matter relating to the deposit agreement. Such register may be closed from time to time, when deemed expedient by the depositary.

The depositary will maintain facilities for the delivery and receipt of ADRs.

Pre-release of ADSs

In its capacity as depositary, the depositary shall not lend shares or ADSs; provided, however, that the depositary may issue ADSs prior to the receipt of shares (each such transaction, a "pre-release"). The depositary may receive ADSs in lieu of shares (which ADSs will promptly be cancelled by the depositary upon receipt by the depositary). Each such pre-release will be subject to a written agreement whereby the person or entity (the "applicant") to whom ADSs are to be delivered (a) represents that at the time of the pre-release the applicant or its customer owns the shares that are to be delivered by the applicant under such pre-release, (b) agrees to indicate the depositary as owner of such shares in its records and to hold such shares in trust for the depositary until such shares are delivered to the depositary or the custodian, (c) unconditionally guarantees to deliver to the depositary or the custodian, as applicable, such shares, and (d) agrees to any additional restrictions or requirements that the depositary deems appropriate. Each such pre-release will be at all times fully collateralized with cash, U.S. government securities or such other collateral as the depositary deems appropriate, terminable by the depositary on not more than five (5) business days' notice and subject to such further indemnities and credit regulations as the depositary deems appropriate. The depositary will normally limit the number of ADSs involved in such pre-release at any one time to thirty percent (30%) of the ADSs outstanding (without giving effect to pre-released ADSs outstanding), provided, however, that the depositary reserves the right to change or disregard such limit from time to time as it deems appropriate. The depositary may also set limits with respect to the number of ADSs involved in pre-release with any one person on a case-by-case basis as it deems appropriate. The depositary may retain for its own account any compensation received by it in conjunction with the foregoing. Collateral provided in connection with pre-release transactions, but not the earnings thereon, shall be held for the benefit of the registered holders of ADRs (other than the applicant).

Appointment

In the deposit agreement, each registered holder of ADRs and each person holding an interest in ADSs, upon acceptance of any ADSs (or any interest therein) issued in accordance with the terms and conditions of the deposit agreement will be deemed for all purposes to:

- be a party to and bound by the terms of the deposit agreement and the applicable ADR or ADRs, and
- appoint the depository its attorney-in-fact, with full power to delegate, to act on its behalf and to take any and all actions contemplated in the deposit agreement and the applicable ADR or ADRs, to adopt any and all procedures necessary to comply with applicable laws and to take such action as the depository in its sole discretion may deem necessary or appropriate to carry out the purposes of the deposit agreement and the applicable ADR and ADRs, the taking of such actions to be the conclusive determinant of the necessity and appropriateness thereof.

Governing Law

The deposit agreement and the ADRs shall be governed by and construed in accordance with the laws of the State of New York. In the deposit agreement, we have submitted to the jurisdiction of the courts of the State of New York and appointed an agent for service of process on our behalf. Notwithstanding the foregoing, any action based on the deposit agreement or the transactions contemplated thereby may be instituted by the depository and holders in any competent court in the Cayman Islands, Hong Kong, China and/or the United States or through the commencement of an English language arbitration either in New York, New York in accordance with the Commercial Arbitration Rules of the American Arbitration Association or in Hong Kong following the arbitration rules of the United Nations Commission on International Trade Law (UNCITRAL).

SHARES ELIGIBLE FOR FUTURE SALES

Upon completion of this offering, we will have _____ ADSs outstanding, representing approximately _____ % of our outstanding ordinary shares, assuming the underwriters do not exercise their over-allotment option. All of the ADSs sold in this offering will be freely transferable by persons other than by our “affiliates” without restriction or further registration under the Securities Act. Sales of substantial amounts of our ADSs in the public market could adversely affect prevailing market prices of our ADSs. Prior to this offering, there has been no public market for our ordinary shares or the ADSs. We intend to apply to list the ADSs on [the Nasdaq Global Market], but we cannot assure you that a regular trading market will develop in the ADSs. We do not expect that a trading market will develop for our ordinary shares not represented by the ADSs.

[Lock-up Agreements

We have agreed, for a period of [180] days after the date of this prospectus, [not to offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale, lend or otherwise dispose of, except in this offering, any of our ordinary shares or ADSs or securities that are substantially similar to our ordinary shares or ADSs, including, but not limited to, any options or warrants to purchase our ordinary shares, ADSs or any securities that are convertible into or exchangeable for, or that represent the right to receive, our ordinary shares, ADSs or any such substantially similar securities (other than pursuant to employee stock option plans existing on, or upon the conversion or exchange of convertible or exchangeable securities outstanding as of, the date such lock-up agreement was executed), without the prior written consent of the representatives of the underwriters.]

Furthermore, each of our directors and executive officers, our current shareholders [and certain option holders] has also entered into a similar lock-up agreement for a period of [180] days after the date of this prospectus, subject to certain exceptions, with respect to our ordinary shares, ADSs and securities that are substantially similar to our ordinary shares or ADSs. [These restrictions also apply to any ADSs acquired by our directors and executive officers in the offering pursuant to the directed share program, if any.] These parties collectively own [all of] our outstanding ordinary shares, without giving effect to this offering.

The restrictions described in the preceding paragraphs will be automatically extended under certain circumstances. See “Underwriting.”

Other than this offering, we are not aware of any plans by any significant shareholders to dispose of significant numbers of our ADSs or ordinary shares. However, one or more existing shareholders or owners of securities convertible or exchangeable into or exercisable for our ADSs or ordinary shares may dispose of significant numbers of our ADSs or ordinary shares in the future. We cannot predict what effect, if any, future sales of our ADSs or ordinary shares, or the availability of ADSs or ordinary shares for future sale, will have on the trading price of our ADSs from time to time. Sales of substantial amounts of our ADSs or ordinary shares in the public market, or the perception that these sales could occur, could adversely affect the trading price of our ADSs.]

Rule 144

All of our ordinary shares that will be outstanding upon the completion of this offering, other than those ordinary shares underlying the ADSs sold in this offering, are “restricted securities” as that term is defined in Rule 144 under the Securities Act and may be sold publicly in the United States only if they are subject to an effective registration statement under the Securities Act or pursuant to an exemption from the registration requirement such as those provided by Rule 144 and Rule 701 promulgated under the Securities Act. In general, beginning 90 days after the date of this prospectus, a person (or persons whose shares are aggregated) who at the time of a sale is not, and has not been during the three months preceding the sale, an affiliate of ours and has beneficially owned our restricted securities for at least six months will be entitled to sell the restricted securities without registration under the Securities Act, subject only to the availability of current public information about

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us, and will be entitled to sell restricted securities beneficially owned for at least one year without restriction. Persons who are our affiliates and have beneficially owned our restricted securities for at least six months may sell a number of restricted securities within any three-month period that does not exceed the greater of the following:

- 1% of the then outstanding ordinary shares of the same class, represented by ADSs or otherwise, which immediately after this offering will equal ordinary shares, assuming the underwriters do not exercise their option to purchase additional ADSs; or
- the average weekly trading volume of our ordinary shares of the same class, represented by ADSs or otherwise, during the four calendar weeks preceding the date on which notice of the sale is filed with the SEC.

Sales by our affiliates under Rule 144 are also subject to certain requirements relating to manner of sale, notice and the availability of current public information about us.

Rule 701

In general, under Rule 701 of the Securities Act as currently in effect, each of our employees, consultants or advisors who purchases our ordinary shares from us in connection with a compensatory stock plan or other written agreement executed prior to the completion of this offering is eligible to resell those ordinary shares in reliance on Rule 144, but without compliance with some of the restrictions, including the holding period, contained in Rule 144. However, the Rule 701 shares would remain subject to lock-up arrangements and would only become eligible for sale when the lock-up period expires.

TAXATION

The following summary of the material Cayman Islands, PRC and U.S. federal income tax consequences of an investment in our ADSs or ordinary shares is based upon laws and relevant interpretations thereof in effect as of the date of this prospectus, all of which are subject to change. This summary does not deal with all possible tax consequences relating to an investment in our ADSs or ordinary shares, such as the tax consequences under U.S. state and local tax laws or under the tax laws of jurisdictions other than the Cayman Islands, China and the United States.

Cayman Islands Taxation

The Cayman Islands currently levies no taxes on individuals or corporations based upon profits, income, gains or appreciation and there is no taxation in the nature of inheritance tax or estate duty. There are no other taxes likely to be material to us levied by the government of the Cayman Islands except for stamp duties which may be applicable on instruments executed in, or brought within the jurisdiction of the Cayman Islands. The Cayman Islands are a party to a double tax treaty entered into with the United Kingdom in 2010 but otherwise is not party to any double tax treaties. There are no exchange control regulations or currency restrictions in the Cayman Islands.

Payments of dividends and capital in respect of our shares will not be subject to taxation in the Cayman Islands and no withholding will be required on the payment of a dividend or capital to any holder of the shares, nor will gains derived from the disposal of our shares be subject to Cayman Islands income or corporation tax.

No stamp duty is payable in respect of the issue of the shares or on an instrument of transfer in respect of a share.

PRC Taxation

Under the PRC Enterprise Income Tax Law and its implementation rules, an enterprise established outside China with “de facto management body” within China considered a Tax Resident Enterprise (“TRE”). The implementation rules define the term “de facto management body” as the body that exercises full and substantial control and overall management over the business, productions, personnel, accounts and properties of an enterprise. In April 2009, the State Administration of Taxation issued Circular 82, which provides certain specific criteria for determining whether the “de facto management body” of a PRC-controlled enterprise that is incorporated offshore is located in China. Although this circular only applies to offshore enterprises controlled by PRC enterprises or PRC enterprise groups, not those controlled by PRC individuals or foreigners, the criteria set forth in the circular may reflect the State Administration of Taxation’s general position on how the “de facto management body” text should be applied in determining the tax resident status of all offshore enterprises. According to Circular 82, an offshore incorporated enterprise controlled by a PRC enterprise or a PRC enterprise group will be regarded as a PRC tax resident by virtue of having its “de facto management body” in China only if all of the following conditions are met: (i) the primary location of the day-to-day operational management is in China; (ii) decisions relating to the enterprise’s financial and human resource matters are made or are subject to approval by organizations or personnel located in China; (iii) the enterprise’s primary assets, accounting books and records, company seals, and board and shareholder resolutions, are located or maintained in China; and (iv) at least 50% of voting board members or senior executives habitually reside in China.

We believe that I-Mab is not a PRC resident enterprise for PRC tax purposes, although some members of our management are located in China. I-Mab is not controlled by a PRC enterprise or PRC enterprise group. We have structured a clear management guideline in place to segregate the policy set up and business operating execution responsibilities in order to differentiate the effective control from our headquarter office and subsidiaries including record keeping and offshore work location plan. We do not believe that I-Mab meets all of the conditions above. I-Mab is a company incorporated outside the PRC. As a holding company, its key assets

are its ownership interests in its subsidiaries, and its key assets are located, and its records (including the resolutions of its board of directors and the resolutions of its shareholders) are maintained, outside China. However, the tax resident status of an enterprise is subject to determination by the PRC tax authorities and uncertainties remain with respect to the interpretation of the term “de facto management body.”

If the PRC tax authorities determine that I-Mab is a PRC resident enterprise for enterprise income tax purposes, we may be required to withhold a 10% withholding tax from dividends we pay to our shareholders that are non-resident enterprises, including the holders of our ADSs. In addition, non-resident enterprise shareholders (including our ADS holders) may be subject to a 10% PRC tax on gains realized on the sale or other disposition of ADSs or ordinary shares, if such income is treated as sourced from within China. It is unclear whether our non-PRC individual shareholders (including our ADS holders) would be subject to any PRC tax on dividends or gains obtained by such non-PRC individual shareholders in the event we are determined to be a PRC resident enterprise. If any PRC tax were to apply to such dividends or gains, it would generally apply at a rate of 20% unless a reduced rate is available under an applicable tax treaty. However, it is also unclear whether non-PRC shareholders of I-Mab would be able to claim the benefits of any tax treaties between their country of tax residence and China in the event that I-Mab is treated as a TRE. See “Risk Factors—Risks Related to Doing Business in China—If we are classified as a PRC resident enterprise for PRC income tax purposes, such classification could result in unfavorable tax consequences to us and our non-PRC shareholders or ADS holders.”

United States Federal Income Tax Considerations

The following discussion is a summary of U.S. federal income tax considerations relating to the ownership and disposition of our ADSs or ordinary shares by a U.S. Holder (as defined below) that acquires our ADSs in this offering and holds our ADSs as “capital assets” (generally, property held for investment) under the U.S. Internal Revenue Code of 1986, as amended, or the Code. This discussion is based upon existing U.S. federal tax law, which is subject to differing interpretations or change, possibly with retroactive effect. No ruling has been sought from the U.S. Internal Revenue Service, or the IRS, with respect to any U.S. federal income tax consequences described below, and there can be no assurance that the IRS or a court will not take a contrary position. This discussion does not address the U.S. federal estate, gift, Medicare, and alternative minimum tax considerations, certain information reporting requirements pursuant to section 1471 through 1474 of the Code, or any state, local, and non-U.S. tax considerations, relating to the ownership or disposition of our ADSs or ordinary shares. This discussion, moreover, does not discuss all aspects of U.S. federal income taxation that may be important to particular investors in light of their individual investment circumstances or to investors subject to special tax situations such as:

- banks and other financial institutions;
- insurance companies;
- pension plans;
- cooperatives;
- regulated investment companies;
- real estate investment trusts;
- broker-dealers;
- traders in securities that elect to use a mark-to-market method of accounting;
- certain former U.S. citizens or long-term residents;
- tax-exempt entities (including private foundations);
- investors who are not U.S. Holders;
- investors who own (directly, indirectly or constructively) 10% or more of our stock (by vote or value);

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- investors who acquire their ADSs or ordinary shares pursuant to any employee share option or otherwise as compensation;
- investors that will hold their ADSs or ordinary shares as part of a straddle, hedge, conversion, constructive sale or other integrated transaction for U.S. federal income tax purposes;
- investors required to accelerate the recognition of any item of gross income with respect to our ADSs or ordinary shares as a result of such income being recognized on an applicable financial statement; or
- investors that have a functional currency other than the U.S. dollar;

all of whom may be subject to tax rules that differ significantly from those discussed below. Each U.S. Holder is urged to consult its tax advisor regarding the U.S. federal, state, local and non-U.S. income and other tax considerations of an investment in our ADSs or ordinary shares.

General

For purposes of this discussion, a “U.S. Holder” is a beneficial owner of our ADSs or ordinary shares that is, for U.S. federal income tax purposes, (i) an individual who is a citizen or resident of the United States, (ii) a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created in, or organized under the law of, the United States or any state thereof or the District of Columbia, (iii) an estate the income of which is includible in gross income for U.S. federal income tax purposes regardless of its source, or (iv) a trust (A) the administration of which is subject to the primary supervision of a U.S. court and which has one or more U.S. persons who have the authority to control all substantial decisions of the trust or (B) that has otherwise validly elected to be treated as a U.S. person under the Code.

If a partnership (or other entity treated as a partnership for U.S. federal income tax purposes) is a beneficial owner of our ADSs or ordinary shares, the tax treatment of a partner in the partnership will generally depend upon the status of the partner and the activities of the partner and the partnership. Partnerships holding our ADSs or ordinary shares and their partners are urged to consult their tax advisors regarding an investment in our ADSs or ordinary shares.

For U.S. federal income tax purposes, it is generally expected that a U.S. Holder of ADSs will be treated as the beneficial owner of the underlying shares represented by the ADSs. The remainder of this discussion assumes that a U.S. Holder of our ADSs will be treated as the beneficial owner of the underlying shares represented by the ADSs. Accordingly, deposits or withdrawals of ordinary shares for ADSs will generally not be subject to U.S. federal income tax.

Passive Foreign Investment Company Considerations

A non-U.S. corporation, such as our company, will be classified as a passive foreign investment company, or, or PFIC, for U.S. federal income tax purposes for any taxable year if either (i) 75% or more of its gross income for such year consists of certain types of “passive” income or (ii) 50% or more of the value of its assets (determined on the basis of a quarterly average) during such year is attributable to assets that produce or are held for the production of passive income. For this purpose, cash and assets readily convertible into cash are each categorized as a passive asset and the company’s goodwill and other unbooked intangibles are taken into account. Passive income generally includes, among other things, dividends, interest, rents, royalties, and gains from the disposition of passive assets. We will be treated as owning a proportionate share of the assets and earning a proportionate share of the income of any other corporation in which we own, directly or indirectly, 25% or more (by value) of the stock.

No assurance can be given with respect to our PFIC status for the current taxable year or any future taxable year. The determination of whether we are or will become a PFIC is uncertain, because it is a

fact-intensive inquiry made on an annual basis that depends, in part, on the composition of our income and assets. Fluctuations in the market price of our ADSs may cause us to become a PFIC for the current or subsequent taxable years because the value of our assets for the purpose of the asset test may be determined by reference to the market price of our ADSs from time to time (which may be volatile for biopharmaceutical companies, such as ours, that have not yet achieved commercialization with respect to any of their products). The composition of our income and assets may also be affected by how, and how quickly, we use our liquid assets and the cash raised in this offering. Under circumstances where our revenue from activities that produce passive income increases relative to our revenue from activities that produce non-passive income, or where we determine not to deploy cash for active purposes, our risk of becoming classified as a PFIC will substantially increase. In addition, because there are uncertainties in the application of the relevant rules, it is possible that the IRS may challenge our classification of certain income and assets as non-passive or our valuation of our tangible and intangible assets, each of which may result in our being or becoming a PFIC for the current or subsequent taxable years.

The discussion below under “—Dividends” and “—Sale or Other Disposition of ADSs or Ordinary Shares” is written on the basis that we will not be classified as a PFIC for U.S. federal income tax purposes. The U.S. federal income tax rules that apply if we are treated as a PFIC are generally discussed below under “—Passive Foreign Investment Company Rules.”

Dividends

Subject to the discussion below under “—Passive Foreign Investment Company Rules,” any cash distributions (including the amount of any tax withheld) paid on our ADSs or ordinary shares out of our current or accumulated earnings and profits, as determined under U.S. federal income tax principles, will generally be includible in the gross income of a U.S. Holder as dividend income on the day actually or constructively received by the U.S. Holder. Because we do not intend to determine our earnings and profits on the basis of U.S. federal income tax principles, any distribution we pay will generally be reported as a “dividend” for U.S. federal income tax purposes. Dividends received on our ADSs or ordinary shares will not be eligible for the dividends received deduction allowed to corporations in respect of dividends received from U.S. corporations.

A non-corporate U.S. Holder will generally be subject to tax on dividend income from a “qualified foreign corporation” at a lower applicable capital gains rate rather than the marginal tax rates generally applicable to ordinary income provided that certain conditions are satisfied, including that (1) our ADSs or ordinary shares on which the dividends are paid are readily tradable on an established securities market in the United States, or in the event that we are deemed to be a PRC resident enterprise under the PRC tax law, we are eligible for the benefits of the United States-PRC income tax treaty (the “Treaty”); (2) we are neither a PFIC nor treated as such with respect to a U.S. Holder for the taxable year in which the dividend is paid and the preceding taxable year, and (3) certain holding period requirements are met. We intend to list our ADSs on [the Nasdaq Global Market]. Provided the listing is approved, we believe that the ADSs will be readily tradable on an established securities market in the United States, and that we will be a qualified foreign corporation with respect to dividends paid on the ADSs. Since we do not expect that our ordinary shares will be listed on an established securities market, we do not believe that dividends that we pay on our ordinary shares that are not represented by ADSs will meet the conditions required for the reduced tax rate. There can be no assurance, however, that our ADSs will continue to be considered readily tradable on an established securities market in later years.

In the event that we are deemed to be a PRC resident enterprise under the PRC Enterprise Income Tax Law, we may be eligible for the benefits of Treaty and in that case we would be treated as a qualified foreign corporation with respect to dividends paid on our ordinary shares or ADSs. Each non-corporate U.S. Holder is advised to consult its tax advisors regarding the availability of the reduced tax rate applicable to qualified dividend income for any dividends we pay with respect to our ADSs or ordinary shares.

Dividends will generally be treated as income from foreign sources for U.S. foreign tax credit purposes and will generally constitute passive category income. In the event that we are deemed to be a PRC resident enterprise under the PRC Enterprise Income Tax Law, a U.S. Holder may be subject to PRC withholding taxes on dividends paid on our ADSs or ordinary shares. See “—PRC Taxation” above. In that case, depending on the U.S. Holder’s individual facts and circumstances, a U.S. Holder may be eligible, subject to a number of complex limitations, to claim a foreign tax credit not in excess of any applicable treaty rate in respect of any foreign withholding taxes imposed on dividends received on our ADSs or ordinary shares. A U.S. Holder who does not elect to claim a foreign tax credit for foreign tax withheld may instead claim a deduction, for U.S. federal income tax purposes, in respect of such withholding, but only for a year in which such holder elects to do so for all creditable foreign income taxes. The rules governing the foreign tax credit are complex and their outcome depends in large part on the U.S. Holder’s individual facts and circumstances. Accordingly, U.S. Holders are urged to consult their tax advisors regarding the availability of the foreign tax credit under their particular circumstances.

Sale or Other Disposition of ADSs or Ordinary Shares

Subject to the discussion below under “—Passive Foreign Investment Company Rules,” a U.S. Holder will generally recognize capital gain or loss upon the sale or other disposition of ADSs or ordinary shares in an amount equal to the difference between the amount realized upon the disposition and the holder’s adjusted tax basis in such ADSs or ordinary shares. Any capital gain or loss will be long-term if the ADSs or ordinary shares have been held for more than one year and will generally be U.S. source gain or loss for U.S. foreign tax credit purposes. Long-term capital gain of non-corporate U.S. Holders is generally eligible for a reduced rate of taxation. The deductibility of a capital loss may be subject to limitations. In the event that we are treated as a PRC resident enterprise under the Enterprise Income Tax Law and gain from the disposition of the ADSs or ordinary shares is subject to tax in China, a U.S. Holder that is eligible for the benefits of the Treaty may elect to treat the gain as PRC source income. If a U.S. Holder is not eligible for the benefits of the Treaty or fails to make the election to treat any gain as foreign source, then such U.S. Holder may not be able to use the foreign tax credit arising from any PRC tax imposed on the disposition of the ADSs or ordinary shares unless such credit can be applied (subject to applicable limitations) against U.S. federal income tax due on other income derived from foreign sources in the same income category (generally, the passive category). U.S. Holders are urged to consult their tax advisors regarding the tax consequences if a foreign tax is imposed on a disposition of our ADSs or ordinary shares, including the availability of the foreign tax credit under their particular circumstances and the election to treat any gain as PRC source income.

Passive Foreign Investment Company Rules

If we are classified as a PFIC for any taxable year during which a U.S. Holder holds our ADSs or ordinary shares, and unless the U.S. Holder makes a mark-to-market election (as described below), the U.S. Holder will generally be subject to special tax rules that have a penalizing effect, regardless of whether we remain a PFIC, on (i) any excess distribution that we make to the U.S. Holder (which generally means any distribution paid during a taxable year to a U.S. Holder that is greater than 125 percent of the average annual distributions paid in the three preceding taxable years or, if shorter, the U.S. Holder’s holding period for the ADSs or ordinary shares), and (ii) any gain realized on the sale or other disposition (including, under certain circumstances, a pledge) of ADSs or ordinary shares. Under the PFIC rules:

- the excess distribution or gain will be allocated ratably over the U.S. Holder’s holding period for the ADSs or ordinary shares;
- the amount allocated to the current taxable year and any taxable years in the U.S. Holder’s holding period prior to the first taxable year in which we are classified as a PFIC (each, a “pre-PFIC year”), will be taxable as ordinary income; and
- the amount allocated to each prior taxable year, other than a pre-PFIC year, will be subject to tax at the highest tax rate in effect for individuals or corporations, as appropriate, for that year, increased by an

additional tax equal to the interest on the resulting tax deemed deferred with respect to each such taxable year.

If we are a PFIC for any taxable year during which a U.S. Holder holds our ADSs or ordinary shares and any of our subsidiaries is also a PFIC, such U.S. Holder would be treated as owning a proportionate amount (by value) of the shares of the lower-tier PFIC for purposes of the application of these rules. U.S. Holders are urged to consult their tax advisors regarding the application of the PFIC rules to any of our subsidiaries.

As an alternative to the foregoing rules, a U.S. Holder of “marketable stock” (as defined below) in a PFIC may make a mark-to-market election with respect to such stock. If a U.S. Holder makes this election, the holder will generally (i) include as ordinary income for each taxable year that we are a PFIC the excess, if any, of the fair market value of ADSs held at the end of the taxable year over the adjusted tax basis of such ADSs and (ii) deduct as an ordinary loss the excess, if any, of the adjusted tax basis of the ADSs over the fair market value of such ADSs held at the end of the taxable year, but such deduction will only be allowed to the extent of the amount previously included in income as a result of the mark-to-market election. The U.S. Holder’s adjusted tax basis in the ADSs would be adjusted to reflect any income or loss resulting from the mark-to-market election. If a U.S. Holder makes a mark-to-market election in respect of a corporation classified as a PFIC and such corporation ceases to be classified as a PFIC, the holder will not be required to take into account the gain or loss described above during any period that such corporation is not classified as a PFIC. If a U.S. Holder makes a mark-to-market election, any gain such U.S. Holder recognizes upon the sale or other disposition of our ADSs in a year when we are a PFIC will be treated as ordinary income and any loss will be treated as ordinary loss, but such loss will only be treated as ordinary loss to the extent of the net amount previously included in income as a result of the mark-to-market election. If a U.S. Holder makes a mark-to-market election it will be effective for the taxable year for which the election is made and all subsequent taxable years unless the ADSs are no longer treated as marketable stock or the IRS consents to the revocation of the election.

The mark-to-market election is available only for “marketable stock,” which stock that is regularly traded on a qualified exchange or other market, as defined in applicable United States Treasury Regulations. We expect that our ADSs, but not our ordinary shares, will be treated as marketable stock upon their listing on [the Nasdaq Global Market.] However, we cannot guarantee that our listing will be approved and we cannot guarantee that, once listed, our ADSs will continue to be listed and traded on [the Nasdaq Global Market]. Furthermore, while we anticipate that our ADSs should qualify as being regularly traded, but no assurances may be given in this regard.

Because a mark-to-market election cannot be made for any lower-tier PFICs that we may own, a U.S. Holder may continue to be subject to the PFIC rules with respect to such U.S. Holder’s indirect interest in any investments held by us that are treated as an equity interest in a PFIC for U.S. federal income tax purposes.

We do not intend to provide information necessary for U.S. Holders to make qualified electing fund elections which, if available, would result in tax treatment different from the general tax treatment for PFICs described above.

If a U.S. Holder owns our ADSs or ordinary shares during any taxable year that we are a PFIC, the holder must generally file an annual IRS Form 8621. Each U.S. Holder is urged to consult its tax advisor concerning the U.S. federal income tax consequences of purchasing, holding and disposing ADSs or ordinary shares if we are or become a PFIC, including the possibility of making a mark-to-market election.

UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement with respect to the ADSs being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of ADSs indicated in the following table. China International Capital Corporation Hong Kong Securities Limited is acting as the book-running manager of this offering and as the representative of the underwriters. The address of China International Capital Corporation Hong Kong Securities Limited is 29th Floor, One International Finance Centre, 1 Harbour View Street Central, Hong Kong.

<u>Underwriters</u>	<u>Number of ADSs</u>
[China International Capital Corporation Hong Kong Securities Limited]	[]
Total	[]

The underwriters are offering the ADSs subject to their acceptance of the ADSs from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the ADSs offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated, severally and not jointly, to take and pay for all of the ADSs offered by this prospectus if any such ADSs are taken, other than the ADSs covered by the underwriters' option to purchase additional ADSs described below.

The underwriters initially propose to offer part of the ADSs directly to the public at the public offering price listed on the cover of this prospectus and part of the ADSs to certain dealers at a price that represents a concession not in excess of US\$[] per ADS under the public offering price. After the initial offering of the ADSs, the offering price and other selling terms may from time to time be varied by the underwriters.

[Certain of the underwriters are not broker-dealers registered with the SEC. Therefore, to the extent they intend to make any offers or sales of ADSs in the United States, they will do so only through one or more registered broker-dealers in compliance with applicable securities law and regulations, and FINRA rules. China International Capital Corporation Hong Kong Securities Limited is not a broker-dealer registered with the SEC and, to the extent that its conduct may be deemed to involve participation in offers or sales of ADSs in the United States, those offers or sales will be made through one or more SEC-registered broker-dealers in compliance with applicable laws and regulations.]

Option to Purchase Additional ADSs

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to an aggregate of [] additional ADSs from us at the offering price listed on the cover of this prospectus, less underwriting discounts and commissions. To the extent the option is exercised, each underwriter will become severally obligated, subject to certain conditions, to purchase additional ADSs approximately proportionate to each underwriter's initial amount reflected in the table above.

Commissions and Expenses

Total underwriting discounts and commissions to be paid to the underwriters represent []% of the total amount of the offering. The following table shows the per ADS and total underwriting discounts and commissions to be paid to the underwriters by us. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional ADSs.

	<u>Per ADS</u>	<u>Total</u>	
	<u>US\$[]</u>	<u>No Exercise</u>	<u>Full Exercise</u>
Discounts and commissions paid by us	US\$[]	US\$[]	US\$[]

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We have agreed to pay all fees and expenses that we occur in connection with the offering. We have agreed to reimburse the underwriters for certain expenses in an amount not to exceed US\$[].

Lock-Up Agreements

[We have agreed that, without the prior written consent of the representatives of the underwriters, we will not, during the period ending 180 days after the date of this prospectus, (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of directly or indirectly, any ordinary shares or ADSs or any securities convertible into or exercisable or exchangeable for such ordinary shares or ADSs; (ii) enter into any swap, hedge or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the ordinary shares or ADSs; (iii) establish or increase a put equivalent position or liquidate or decrease a call equivalent position in the ordinary shares or ADSs within the meaning of Section 16 of the Exchange Act; (iv) file any registration statement with the SEC relating to the offering of any ordinary shares, ADSs or any securities convertible into or exercisable or exchangeable for ordinary shares or ADSs; or (v) publicly disclose the intention to make any offer, sale, pledge, disposition or filing, in each case regardless of whether any such transaction described above is to be settled by delivery of ordinary shares, ADSs, or such other securities, in cash or otherwise.

Each of our directors, executive officers, existing shareholders [and certain of our option holders] have agreed that, without the prior written consent of the representatives on behalf of the underwriters, it will not, subject to certain exceptions, during the period ending 180 days after the date of this prospectus, (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any ADSs or ordinary shares or any other securities convertible into or exercisable or exchangeable for ADSs or ordinary shares or (2) enter into any swap, hedge or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of ADSs or ordinary shares, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of ADSs, ordinary shares or such other securities, in cash or otherwise, or publicly disclose the intention to make any such offer, sale, pledge or disposition, or to enter into any such transaction, swap, hedge or other arrangement. The foregoing sentence shall not apply to transactions relating to ADSs, ordinary shares or other securities acquired in this offering or in open market transactions after the completion of this offering and certain other exceptions.

In addition, through a letter agreement, we will instruct [], as depository, not to accept any deposit of any ordinary shares or deliver any ADSs until after 180 days following the date of this prospectus unless we consent to such deposit or issuance. We will not provide such consent without the prior written consent of the representatives of the underwriters. The foregoing does not affect the right of ADS holders to cancel their ADSs and withdraw the underlying ordinary shares.

The representatives of the underwriters, in their sole discretion, on behalf of the underwriters may release the ADSs and other securities subject to the lock-up agreements described above in whole or in part at any time with or without notice.]

Nasdaq Listing

The ADSs [have been] approved for listing on the Nasdaq Global Market under the symbol “IMAB.”

Stabilization, Short Positions and Penalty Bids

In connection with the offering, the underwriters may purchase and sell ADSs in the open market.

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These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of ADSs than they are required to purchase in the offering. “Covered” short sales are sales made in an amount not greater than the underwriters’ option to purchase additional ADSs in the offering. The underwriter may close out any covered short position by either exercising their option to purchase additional ADSs or purchasing ADSs in the open market. In determining the source of ADSs to close out the covered short position, the underwriters will consider, among other things, the price of ADSs available for purchase in the open market as compared to the price at which they may purchase additional ADSs pursuant to the option granted to them. “Naked” short sales are any sales in excess of such option.

The underwriters must close out any naked short position by purchasing ADSs in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the ADSs in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for, or purchases of, ADSs made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discounts received by it because the representatives have repurchased ADSs sold by, or for the account of, such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of the ADSs, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of the ADSs. As a result, the price of the ADSs may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities, and if these activities are commenced, they are required to be conducted in accordance with applicable laws and regulations, and any of these activities may be discontinued at any time. These transactions may be effected on the Nasdaq, the over-the-counter market or otherwise.

Electronic Distribution

A prospectus in electronic format will be made available on the websites maintained by one or more of the underwriters or one or more securities dealers. One or more of the underwriters may distribute prospectuses electronically. The underwriters may agree to allocate a number of ADSs for sale to their online brokerage account holders. ADSs to be sold pursuant to an internet distribution will be allocated on the same basis as other allocations. In addition, ADSs may be sold by the underwriters to securities dealers who resell ADSs to online brokerage account holders.

[Directed ADS Program

At our request, the underwriters have reserved up to []% of the ADSs being offered by this prospectus (assuming no exercise by the underwriters of their option to purchase additional ADSs) for sale at the initial public offering price to certain of our directors, executive officers, employees, business associates and members of their families. The directed ADS program will be administered by []. We do not know if these individuals will choose to purchase all or any portion of these reserved ADSs, but any purchases they do make will reduce the number of ADSs that are available to the general public. Any reserved ADSs that are not so purchased will be offered by the underwriters to the general public on the same terms as the other ADSs offered by this prospectus.]

Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act.

Relationships

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, principal investment, hedging, financing, investment research, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates may have, from time to time, performed, and may in the future perform, various financial advisory, commercial and investment banking services and other services for us and to persons and entities with relationships with us, for which they received or will receive customary fees and commissions.

In addition, in the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve securities and instruments of us and/or persons and entities with relationships with us. The underwriters and their respective affiliates may also make or communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

Pricing of the Offering

Prior to this offering, there has been no public market for our ordinary shares or the ADSs. The initial public offering price was determined by negotiations between us and the representatives of the underwriters. Among the factors to be considered in determining the initial public offering price of the ADSs, in addition to prevailing market conditions, will be our historical performance, estimates of our business potential and earnings prospects, an assessment of our management and the consideration of the above factors in relation to market valuation of companies in related businesses. An active trading market for the ADSs may not develop. It is also possible that after the offering the ADSs will not trade in the public market at or above the initial public offering price.

Selling Restrictions

No action has been taken in any jurisdiction (except in the United States) that would permit a public offering of the ADSs, or the possession, circulation or distribution of this prospectus or any other material relating to us or the ADSs in any jurisdiction where action for that purpose is required.

Accordingly, the ADSs may not be offered or sold, directly or indirectly, and neither this prospectus nor any other material or advertisements in connection with the ADSs may be distributed or published, in or from any country or jurisdiction except in compliance with any applicable laws, rules and regulations of any such country or jurisdiction.

Australia

This prospectus:

- does not constitute a product disclosure document or a prospectus under Chapter 6D.2 of the Corporations Act 2001 (Cth) (the “Corporations Act”);
- has not been, and will not be, lodged with the Australian Securities and Investments Commission (“ASIC”), as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document under Chapter 6D.2 of the Corporations Act;
- does not constitute or involve a recommendation to acquire, an offer or invitation for issue or sale, an offer or invitation to arrange the issue or sale, or an issue or sale, of interests to a “retail client” (as defined in section 761G of the Corporations Act and applicable regulations) in Australia; and

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- may only be provided in Australia to select investors who are able to demonstrate that they fall within one or more of the categories of investors, or Exempt Investors, available under section 708 of the Corporations Act.

The ADSs may not be directly or indirectly offered for subscription or purchased or sold, and no invitations to subscribe for or buy the ADSs may be issued, and no draft or definitive offering memorandum, advertisement or other offering material relating to any ADSs may be distributed in Australia, except where disclosure to investors is not required under Chapter 6D of the Corporations Act or is otherwise in compliance with all applicable Australian laws and regulations. By submitting an application for the ADSs, you represent and warrant to us that you are an Exempt Investor.

As any offer of ADSs under this prospectus will be made without disclosure in Australia under Chapter 6D.2 of the Corporations Act, the offer of those securities for resale in Australia within 12 months may, under section 707 of the Corporations Act, require disclosure to investors under Chapter 6D.2 if none of the exemptions in section 708 applies to that resale. By applying for the ADSs you undertake to us that you will not, for a period of 12 months from the date of issue of the ADSs, offer, transfer, assign or otherwise alienate those securities to investors in Australia except in circumstances where disclosure to investors is not required under Chapter 6D.2 of the Corporations Act or where a compliant disclosure document is prepared and lodged with ASIC.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Canada

The ADSs may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the ADSs must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts, or NI 33-105, the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Cayman Islands

This prospectus does not constitute a public offer of the ADSs or ordinary shares, whether by way of sale or subscription, in the Cayman Islands. ADSs or ordinary shares have not been offered or sold, and will not be offered or sold, directly or indirectly, in the Cayman Islands.

Dubai International Finance Center

This prospectus relates to an Exempt Offer in accordance with the Markets Rules 2012 of the Dubai Financial Services Authority (the “DFSA”). This prospectus is intended for distribution only to persons of a type specified in the Markets Rules 2012 of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus supplement nor taken steps to verify the information set forth herein and has no responsibility for this prospectus. The securities to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

In relation to its use in the DIFC, this prospectus is strictly private and confidential and is being distributed to a limited number of investors and must not be provided to any person other than the original recipient, and may not be reproduced or used for any other purpose. The interests in the securities may not be offered or sold directly or indirectly to the public in the DIFC.

European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a Relevant Member State), with effect from and including the date on which the Prospectus Directive was implemented in that Relevant Member State (the Relevant Implementation Date), an offer of the ADSs to the public may not be made in that Relevant Member State prior to the publication of a prospectus in relation to the ADSs which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that, with effect from and including the Relevant Implementation Date, an offer of ADSs may be made to the public in that Relevant Member State at any time:

- to any legal entity which is a qualified investor as defined under the Prospectus Directive;
- to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive); or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of securities described in this prospectus shall result in a requirement for the publication by us of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of the above paragraph, the expression “an offer of the ADSs to the public” in relation to any ADS in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the ADSs to be offered so as to enable an investor to decide to purchase or subscribe the ADSs, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State. The expression Prospectus Directive means Directive 2003/71/EC (and any amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State) and includes any relevant implementing measure in each Relevant Member State, and the expression “2010 PD Amending Directive” means Directive 2010/73/EU.

Hong Kong

The ADSs may not be offered or sold by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies (Winding Up and Miscellaneous

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Provisions) Ordinance (Cap. 32, Laws of Hong Kong), or (ii) to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a “prospectus” within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong), and no advertisement, invitation or document relating to the ADSs may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to ADSs which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

Indonesia

This prospectus does not, and is not intended to, constitute a public offering in Indonesia under Law Number 8 of 1995 regarding Capital Market. This prospectus may not be distributed in the Republic of Indonesia and the ADSs may not be offered or sold in the Republic of Indonesia or to Indonesian citizens wherever they are domiciled, or to Indonesia residents, in a manner which constitutes a public offering under the laws of the Republic of Indonesia.

Israel

In the State of Israel, the ADSs offered hereby may not be offered to any person or entity other than the following:

- a fund for joint investments in trust (i.e., mutual fund), as such term is defined in the Law for Joint Investments in Trust, 5754-1994, or a management company of such a fund;
- a provident fund as defined in Section 47(a)(2) of the Income Tax Ordinance of the State of Israel, or a management company of such a fund;
- an insurer, as defined in the Law for Oversight of Insurance Transactions, 5741-1981, a banking entity or satellite entity, as such terms are defined in the Banking Law (Licensing), 5741-1981, other than a joint services company, acting for their own account or for the account of investors of the type listed in Section 15A(b) of the Securities Law 1968;
- a company that is licensed as a portfolio manager, as such term is defined in Section 8(b) of the Law for the Regulation of Investment Advisors and Portfolio Managers, 5755-1995, acting on its own account or for the account of investors of the type listed in Section 15A(b) of the Securities Law 1968;
- a company that is licensed as an investment advisor, as such term is defined in Section 7(c) of the Law for the Regulation of Investment Advisors and Portfolio Managers, 5755-1995, acting on its own account;
- a company that is a member of the Tel Aviv Stock Exchange, acting on its own account or for the account of investors of the type listed in Section 15A(b) of the Securities Law 1968;
- an underwriter fulfilling the conditions of Section 56(c) of the Securities Law, 5728-1968;
- a venture capital fund (defined as an entity primarily involved in investments in companies which, at the time of investment, (i) are primarily engaged in research and development or manufacture of new technological products or processes and (ii) involve above-average risk);
- an entity primarily engaged in capital markets activities in which all of the equity owners meet one or more of the above criteria; and
- an entity, other than an entity formed for the purpose of purchasing the ADSs in this offering, in which the shareholders equity (including pursuant to foreign accounting rules, international accounting

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regulations and U.S. generally accepted accounting rules, as defined in the Securities Law Regulations (Preparation of Annual Financial Statements), 1993) is in excess of NIS 250 million.

Any offeree of the ADSs offered hereby in the State of Israel shall be required to submit written confirmation that it falls within the scope of one of the above criteria. This prospectus will not be distributed or directed to investors in the State of Israel who do not fall within one of the above criteria.

Japan

ADSs have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold directly or indirectly in Japan or to, or for the benefit of any Japanese person or to others, for reoffering or re-sale directly or indirectly in Japan or to any Japanese person, except in each case pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Securities and Exchange Law of Japan and any other applicable laws, rules and regulations of Japan. For purposes of this paragraph, “Japanese person” means any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

Korea

The ADSs may not be offered, sold and delivered directly or indirectly, or offered or sold to any person for reoffering or resale, directly or indirectly, in Korea or to any resident of Korea except pursuant to the applicable laws and regulations of Korea, including the Korea Securities and Exchange Act and the Foreign Exchange Transaction Law and the decrees and regulations thereunder. The ADSs have not been registered with the Financial Services Commission of Korea for public offering in Korea. Furthermore, the ADSs may not be resold to Korean residents unless the purchaser of the ADSs complies with all applicable regulatory requirements (including but not limited to government approval requirements under the Foreign Exchange Transaction Law and its subordinate decrees and regulations) in connection with the purchase of the ADSs.

Kuwait

Unless all necessary approvals from the Kuwait Ministry of Commerce and Industry required by Law No. 31/1990 “Regulating the Negotiation of Securities and Establishment of Investment Funds,” its Executive Regulations and the various Ministerial Orders issued pursuant thereto or in connection therewith, have been given in relation to the marketing and sale of the ADSs, these may not be marketed, offered for sale, nor sold in the State of Kuwait. Neither this prospectus (including any related document), nor any of the information contained therein is intended to lead to the conclusion of any contract of whatsoever nature within Kuwait.

Malaysia

No prospectus or other offering material or document in connection with the offer and sale of the ADSs has been or will be registered with the Securities Commission of Malaysia (the “Commission”) for the Commission’s approval pursuant to the Capital Markets and Services Act 2007. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the ADSs may not be circulated or distributed, nor may the ADSs be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Malaysia other than (i) a closed end fund approved by the Commission; (ii) a holder of a Capital Markets Services License; (iii) a person who acquires the ADSs, as principal, if the offer is on terms that the ADSs may only be acquired at a consideration of not less than RM250,000 (or its equivalent in foreign currencies) for each transaction; (iv) an individual whose total net personal assets or total net joint assets with his or her spouse exceeds RM3 million (or its equivalent in foreign currencies), excluding the value of the primary residence of the individual; (v) an individual who has a gross annual income exceeding RM300,000 (or its equivalent in foreign currencies) per annum in the preceding

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twelve months; (vi) an individual who, jointly with his or her spouse, has a gross annual income of RM400,000 (or its equivalent in foreign currencies), per annum in the preceding twelve months; (vii) a corporation with total net assets exceeding RM10 million (or its equivalent in a foreign currencies) based on the last audited accounts; (viii) a partnership with total net assets exceeding RM10 million (or its equivalent in foreign currencies); (ix) a bank licensee or insurance licensee as defined in the Labuan Financial Services and Securities Act 2010; (x) an Islamic bank licensee or takaful licensee as defined in the Labuan Financial Services and Securities Act 2010; and (xi) any other person as may be specified by the Commission; provided that, in the each of the preceding categories (i) to (xi), the distribution of the ADSs is made by a holder of a Capital Markets Services Licence who carries on the business of dealing in securities. The distribution in Malaysia of this prospectus is subject to Malaysian laws. This prospectus does not constitute and may not be used for the purpose of public offering or an issue, offer for subscription or purchase, invitation to subscribe for or purchase any securities requiring the registration of a prospectus with the Commission under the Capital Markets and Services Act 2007.

People's Republic of China

This prospectus may not be circulated or distributed in the PRC and the ADSs may not be offered or sold, and will not offer or sell to any person for re-offering or resale directly or indirectly to any resident of the PRC except pursuant to applicable laws, rules and regulations of the PRC. For the purpose of this paragraph only, the PRC does not include Taiwan and the special administrative regions of Hong Kong and Macau.

Philippines

THE ADSS BEING OFFERED OR SOLD HAVE NOT BEEN AND WILL NOT BE REGISTERED WITH THE PHILIPPINE SECURITIES AND EXCHANGE COMMISSION UNDER THE SECURITIES REGULATION CODE OF THE PHILIPPINES, OR THE SRC. ANY FUTURE OFFER OR SALE OF THE ADSS WITHIN THE PHILIPPINES IS SUBJECT TO THE REGISTRATION REQUIREMENTS UNDER THE SRC UNLESS SUCH OFFER OR SALE QUALIFIES AS A TRANSACTION EXEMPT FROM THE REGISTRATION UNDER THE SRC.

Accordingly, this prospectus, and any other document or material in connection with the offer or sale, or invitation for subscription or purchase of the ADSs, may not be circulated or distributed in the Philippines, and the ADSs may not be offered or sold, or be made the subject of an invitation for subscription or purchase, to persons in the Philippines, other than (i) to qualified investors in transactions that are exempt from the registration requirements of the SRC; and (ii) by persons licensed to make such offers or sales in the Philippines.

Qatar

In the State of Qatar, the offer contained herein is made on an exclusive basis to the specifically intended recipient thereof, upon that person's request and initiative, for personal use only and shall in no way be construed as a general offer for the sale of securities to the public or an attempt to do business as a bank, an investment company or otherwise in the State of Qatar. This prospectus and the underlying securities have not been approved or licensed by the Qatar Central Bank or the Qatar Financial Centre Regulatory Authority or any other regulator in the State of Qatar. The information contained in this prospectus shall only be shared with any third parties in Qatar on a need to know basis for the purpose of evaluating the contained offer. Any distribution of this prospectus by the recipient to third parties in Qatar beyond the terms hereof is not permitted and shall be at the liability of such recipient.

Saudi Arabia

This prospectus may not be distributed in the Kingdom of Saudi Arabia except to such persons as are permitted under the Offers of Securities Regulations issued by the Capital Market Authority. The Capital Market

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Authority does not make any representation as to the accuracy or completeness of this prospectus, and expressly disclaims any liability whatsoever for any loss arising from, or incurred in reliance upon, any part of this prospectus. Prospective purchasers of the securities offered hereby should conduct their own due diligence on the accuracy of the information relating to the securities. If you do not understand the contents of this prospectus you should consult an authorized financial adviser.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the ADSs may not be circulated or distributed, nor may the ADSs be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to compliance with conditions set forth in the SFA.

Where the ADSs are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the ADSs pursuant to an offer made under Section 275 of the SFA except:

- to an institutional investor (for corporations, under Section 274 of the SFA) or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer that is made on terms that such shares, debentures and units of shares and debentures of that corporation or such rights and interest in that trust are acquired at a consideration of not less than US\$200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets, and further for corporations, in accordance with the conditions specified in Section 275 of the SFA;
- where no consideration is or will be given for the transfer; or
- where the transfer is by operation of law.

Switzerland

The ADSs will not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to our company or the ADSs have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of the ADSs will not be supervised by, the Swiss Financial Market Supervisory Authority, and the offer of the ADSs has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (the "CISA"). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of the ADSs.

Taiwan

The ADSs have not been and will not be registered with the Financial Supervisory Commission of Taiwan pursuant to relevant securities laws and regulations and may not be sold, issued or offered within Taiwan through a public offering or in circumstances which constitutes an offer within the meaning of the Securities and Exchange Act of Taiwan that requires a registration or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorized to offer, sell, give advice regarding or otherwise intermediate the offering and sale of the ADSs in Taiwan.

Thailand

This prospectus does not, and is not intended to, constitute a public offering in Thailand. The ADSs may not be offered or sold to persons in Thailand, unless such offering is made under the exemptions from approval and filing requirements under applicable laws, or under circumstances which do not constitute an offer for sale of the shares to the public for the purposes of the Securities and Exchange Act of 1992 of Thailand, nor require approval from the Office of the Securities and Exchange Commission of Thailand.

United Arab Emirates

The ADSs have not been offered or sold, and will not be offered or sold, directly or indirectly, in the United Arab Emirates, except: (i) in compliance with all applicable laws and regulations of the United Arab Emirates; and (ii) through persons or corporate entities authorized and licensed to provide investment advice and/or engage in brokerage activity and/or trade in respect of foreign securities in the United Arab Emirates. The information contained in this prospectus does not constitute a public offer of securities in the United Arab Emirates in accordance with the Commercial Companies Law (Federal Law No. 8 of 1984 (as amended)) or otherwise and is not intended to be a public offer and is addressed only to persons who are sophisticated investors.

United Kingdom

This prospectus is only being distributed to and is only directed at, and any offer subsequently made may only be directed at: (i) persons who are outside the United Kingdom; (ii) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the "Order"); or (iii) high net worth companies, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order (all such persons falling within (1)-(3) together being referred to as "relevant persons"). The ADSs are only available to, and any invitation, offer or agreement to subscribe, purchase or otherwise acquire the ADSs will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this prospectus or any of its contents.

Vietnam

The ADSs have not been and will not be registered with the State Securities Commission of Vietnam under the Law on Securities of Vietnam and its guiding decrees and circulars. The ADSs will not be offered or sold in Vietnam through a public offering and will not be offered or sold to Vietnamese persons other than those who are licensed to invest in offshore securities under the Law on Investment of Vietnam.

EXPENSES RELATED TO THIS OFFERING

Set forth below is an itemization of the total expenses, excluding underwriting discounts and commissions, that we expect to incur in connection with this offering. With the exception of the SEC registration fee, the Financial Industry Regulatory Authority, Inc. (“FINRA”), filing fee, and the [stock exchange application and listing fee], all amounts are estimates.

SEC Registration Fee	US\$
FINRA Fee	
[Stock exchange application and listing fee]	
Printing and Engraving Expenses	
Legal Fees and Expenses	
Accounting Fees and Expenses	
Miscellaneous	
Total	<u>US\$</u>

LEGAL MATTERS

We are being represented by Skadden, Arps, Slate, Meagher & Flom LLP with respect to certain legal matters as to United States federal securities and New York State law. The underwriters are being represented by Davis Polk & Wardwell LLP with respect to certain legal matters as to United States federal securities and New York State law. The validity of the ordinary shares represented by the ADSs to be sold in this offering will be passed upon for us by Conyers Dill & Pearman. Certain legal matters as to PRC law will be passed upon for us by JunHe LLP and for the underwriters by King & Wood Mallesons. Skadden, Arps, Slate, Meagher & Flom LLP may rely upon Conyers Dill & Pearman with respect to matters governed by Cayman Islands law and JunHe LLP with respect to matters governed by PRC law. Davis Polk & Wardwell LLP may rely upon King & Wood Mallesons with respect to matters governed by PRC law.

EXPERTS

The financial statements as of December 31, 2017 and 2018 and for each of the two years in the period ended December 31, 2018 included in this prospectus have been so included in reliance on the report of PricewaterhouseCoopers Zhong Tian LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

The office of PricewaterhouseCoopers Zhong Tian LLP is located at 11th Floor, PricewaterhouseCoopers Center, Link Square 2, 202 Hu Bin Road, Shanghai, the People's Republic of China.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed a registration statement, including relevant exhibits, with the SEC on Form F-1 under the Securities Act with respect to the underlying ordinary shares represented by the ADSs to be sold in this offering. We have also filed a related registration statement on Form F-6 with the SEC to register the ADSs. This prospectus, which constitutes a part of the registration statement on Form F-1, does not contain all of the information contained in the registration statement. You should read our registration statements and their exhibits and schedules for further information with respect to us and our ADSs.

Immediately upon the effectiveness of the registration statement on Form F-1 of which this prospectus forms a part, we will become subject to periodic reporting and other informational requirements of the Exchange Act as applicable to foreign private issuers. Accordingly, we will be required to file reports, including annual reports on Form 20-F, and other information with the SEC. The SEC maintains an internet site at <http://www.sec.gov> that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. We maintain our website at <http://www.i-mabbiopharma.com/en/>.

As a foreign private issuer, we are exempt under the Exchange Act from, among other things, the rules prescribing the furnishing and content of proxy statements, and our executive officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. However, we intend to furnish the depositary with our annual reports, which will include a review of operations and annual audited consolidated financial statements prepared in conformity with U.S. GAAP, and all notices of shareholders' meetings and other reports and communications that are made generally available to our shareholders. The depositary will make such notices, reports and communications available to holders of ADSs and, if we so request, will mail to all record holders of ADSs the information contained in any notice of a shareholders' meeting received by the depositary from us.

I-Mab

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I-Mab

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Note:

Effective July 15, 2017, the registrant acquired 66.67% equity interest of I-Mab Bio-tech (Tianjin) Co., Ltd. (referred to as "Tasgen Group") for approximately US\$63,802,000 by issuance of convertible preferred shares (the "Acquisition"). Under Rule 3-05 of Regulation S-X, when comparing Tasgen Group's total assets with registrant's total assets, the Acquisition was determined to be greater than 50% to the registrant on the basis of the most recent pre-Acquisition annual financial statements (being the year ended December 31, 2016), and the net revenue reported by Tasgen Group in its most recent fiscal year (being the year ended December 31, 2018) was less than US\$100.0 million, hence requiring 2 years of audited financial statements for Tasgen Group to be provided in connection with any public offering of securities by the registrant. To meet the two-year audited financial statements requirement, the registrant is filing the pre-Acquisition financial statements for Tasgen Group from January 1, 2017 (the first day of Tasgen Group's fiscal year) through July 15, 2017 (the Acquisition's effective date), so as to provide potential investors with 2 years of financial statements for Tasgen Group.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of I-Mab

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of I-Mab and its subsidiaries (the “Company”) as of December 31, 2018 and 2017, and the related consolidated statements of comprehensive loss, of changes in shareholders’ equity (deficit) and of cash flows for the years then ended, including the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers Zhong Tian LLP
Shanghai, the People’s Republic of China
July 29, 2019

We have served as the Company’s auditor since 2018.

I-MAB
Consolidated Balance Sheets
As of December 31, 2017 and 2018
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Notes	As of December 31,				
		2017 RMB	2018 RMB	2018 US\$ (Note 2.5)	2018 RMB (Pro forma) (Note 26)	2018 US\$ (Note 2.5) (Pro forma)
Assets						
Current assets						
Cash and cash equivalents		307,930	1,588,278	231,005	1,588,278	231,005
Restricted cash		104,783	92,653	13,476	92,653	13,476
Contract assets	18	—	11,000	1,600	11,000	1,600
Prepayments and other receivables	4	12,633	88,972	12,942	88,972	12,942
Other financial assets	2.4, 5	266,245	255,958	37,228	255,958	37,228
Total current assets		691,591	2,036,861	296,251	2,036,861	296,251
Property, equipment and software	6	22,336	27,659	4,023	27,659	4,023
Intangible assets	7	148,844	148,844	21,648	148,844	21,648
Goodwill	8	162,574	162,574	23,645	162,574	23,645
Total assets		1,025,345	2,375,938	345,567	2,375,938	345,567
Liabilities, mezzanine equity and shareholders' equity (deficit)						
Current liabilities						
Short-term borrowings	9	99,000	80,000	11,636	80,000	11,636
Accruals and other payables	10	14,509	67,674	9,843	67,674	9,843
Contract liabilities	18	15,803	—	—	—	—
Advance from customers	18	—	14,151	2,058	14,151	2,058
Research and development funding received	23	—	178,715	25,993	178,715	25,993
Warrant liabilities	2.4, 15	65,832	5,618	817	—	—
Total current liabilities		195,144	346,158	50,347	340,540	49,530
Convertible promissory notes	14	77,810	67,026	9,749	67,026	9,749
Onshore convertible loans	14	36,197	—	—	—	—
Deferred subsidy income	2.12	—	2,500	364	2,500	364
Total liabilities		309,151	415,684	60,460	410,066	59,643
Commitments and contingencies	22					
Mezzanine equity						
Series A convertible preferred shares (US\$0.0001 par value, 21,865,233 and 30,227,056 shares authorized, issued and outstanding as of December 31, 2017 and 2018, respectively)	13	363,766	687,482	99,990	—	—
Series B convertible preferred shares (US\$0.0001 par value, 15,894,594 and 30,305,212 shares authorized, issued and outstanding as of December 31, 2017 and 2018, respectively)	13	346,515	921,243	133,989	—	—
Series C convertible preferred shares (US\$0.0001 par value, 31,046,360 shares authorized, issued and outstanding as of December 31, 2018)	13	—	1,306,633	190,042	—	—
Redeemable non-controlling interests	16	305,708	—	—	—	—
Total mezzanine equity		1,015,989	2,915,358	424,021	—	—

I-MAB
Consolidated Balance Sheets (Continued)
As of December 31, 2017 and 2018
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Notes	As of December 31,				
		2017 RMB	2018 RMB	2018 US\$ (Note 2.5)	2018 RMB (Pro forma) (Note 26)	2018 US\$ (Note 2.5) (Pro forma)
Shareholders' equity (deficit)						
Ordinary shares (US\$0.0001 par value, 500,000,000 shares authorized as of December 31, 2017 and 2018, 8,363,719 shares authorized, issued and outstanding as of December 31, 2017 and 2018, respectively)	12	6	6	1	69	10
Treasury stock	17	(1)	(1)	—	(1)	—
Additional paid-in capital		52,369	—	—	2,926,531	425,646
Accumulated other comprehensive income		5,691	59,380	8,636	59,380	8,636
Accumulated deficit		(357,860)	(1,014,489)	(147,551)	(1,020,107)	(148,368)
Total shareholders' equity (deficit)		(299,795)	(955,104)	(138,914)	1,965,872	285,924
Total liabilities, mezzanine equity and shareholders' equity (deficit)		1,025,345	2,375,938	345,567	2,375,938	345,567

The accompanying notes are an integral part of these consolidated financial statements.

I-MAB
Consolidated Statements of Comprehensive Loss
For the Years Ended December 31, 2017 and 2018
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Notes	Year Ended December 31,		
		2017	2018	
		RMB	RMB	US\$ (Note 2.5)
Revenues				
Licensing and collaboration revenue	18	11,556	53,781	7,823
Expenses				
Research and development expenses	18	(267,075)	(426,028)	(61,963)
Administrative expenses		(25,436)	(66,391)	(9,656)
Loss from operations		(280,955)	(438,638)	(63,796)
Interest expenses, net		(4,785)	(7,098)	(1,032)
Other income (expenses), net	19	1,527	(16,780)	(2,441)
Fair value change of warrants	2.4	(14,027)	61,405	8,931
Loss before income tax expense		(298,240)	(401,111)	(58,338)
Income tax expense	11	—	(1,722)	(250)
Net loss attributable to I-MAB		(298,240)	(402,833)	(58,588)
Other comprehensive income				
Foreign currency translation adjustments, net of nil tax		5,918	53,689	7,809
Total comprehensive loss attributable to I-MAB		<u>(292,322)</u>	<u>(349,144)</u>	<u>(50,779)</u>
Net loss attributable to ordinary shareholders		(298,240)	(402,833)	(58,588)
Weighted-average number of ordinary shares used in calculating net loss per share—basic and diluted	20	5,742,669	6,529,092	6,529,092
Net loss per share attributable to ordinary shareholders				
—Basic	20	(51.93)	(61.70)	(8.97)
—Diluted	20	(51.93)	(61.70)	(8.97)

The accompanying notes are an integral part of these consolidated financial statements.

I-MAB
Consolidated Statements of Changes in Shareholders' Equity (Deficit)
For the Years Ended December 31, 2017 and 2018
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Ordinary share (Note 12) (US\$0.001 par value)		Treasury stock RMB	Additional paid-in capital RMB	Accumulated other comprehensive income RMB	Accumulated deficit RMB	Total shareholders' equity (deficit) RMB
	Number of shares	Amount RMB					
Balance as of December 31, 2016	8,363,719	6	(2)	45,331	(227)	(59,620)	(14,512)
Foreign currency translation adjustments	—	—	—	—	5,918	—	5,918
Net loss	—	—	—	—	—	(298,240)	(298,240)
Share-based compensation	—	—	1	7,038	—	—	7,039
Balance as of December 31, 2017	8,363,719	6	(1)	52,369	5,691	(357,860)	(299,795)
Foreign currency translation adjustments	—	—	—	—	53,689	—	53,689
Net loss	—	—	—	—	—	(402,833)	(402,833)
Share-based compensation	—	—	—	3,520	—	—	3,520
Transaction with redeemable non-controlling interests (Note 16)	—	—	—	(55,889)	—	(253,796)	(309,685)
Balance as of December 31, 2018	<u>8,363,719</u>	<u>6</u>	<u>(1)</u>	<u>—</u>	<u>59,380</u>	<u>(1,014,489)</u>	<u>(955,104)</u>

The accompanying notes are an integral part of these consolidated financial statements.

I-MAB
Consolidated Statements of Cash Flows
For the Years Ended December 31, 2017 and 2018
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Year Ended December 31,		
	2017 RMB	2018 RMB	2018 US\$ (Note 2.5)
Cash flows from operating activities			
Net loss	(298,240)	(402,833)	(58,588)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation of property, equipment and software	1,634	6,740	978
Loss on disposal of property, equipment and software	79	—	—
Interest expenses of convertible promissory notes and onshore convertible loans	3,835	6,963	1,013
Fair value change of warrants	14,027	(61,405)	(8,931)
Income from other financial assets	(5,572)	(13,622)	(1,981)
Share-based compensation	7,039	3,520	512
Loss from conversion of 2017 Notes	—	18,375	2,673
Loss from conversion of onshore convertible loans	—	8,548	1,244
Loss from issuance of 2018 Notes	—	5,081	740
Changes in operating assets and liabilities			
Contract assets	—	(11,000)	(1,600)
Prepayments and other receivables	8,830	(76,276)	(11,097)
Accruals and other payables	408	55,641	8,093
Contract liabilities	15,803	(15,803)	(2,298)
Advance from customers	—	14,151	2,058
Research and development funding received	—	178,715	25,993
Deferred subsidy income	—	2,500	364
Net cash used in operating activities	<u>(252,157)</u>	<u>(280,705)</u>	<u>(40,827)</u>
Cash flows from investing activities			
Cash acquired from acquisition of a subsidiary	93,335	—	—
Purchase of property, equipment and software	(20,327)	(14,409)	(2,096)
Cash paid for investments in other financial assets	(369,000)	(30,000)	(4,363)
Cash received from disposal of other financial assets	133,000	40,000	5,818
Cash received on income from other financial assets	5,327	13,909	2,023
Net cash (used in) generated from investing activities	<u>(157,665)</u>	<u>9,500</u>	<u>1,382</u>
Cash flows from financing activities			
Proceeds from issuance of convertible preferred shares, net of issuance cost	346,515	1,306,633	190,042
Proceeds from issuance of redeemable non-controlling interest	161,196	—	—
Proceeds from issuance of convertible promissory notes	75,970	59,704	8,684
Proceeds from issuance of onshore convertible loans	35,341	—	—
Proceeds from issuance of warrants	40,563	—	—
Proceeds from exercise of warrants	—	132,332	19,247
Proceeds from bank borrowings	99,000	80,000	11,636
Repayment of bank borrowings	—	(99,000)	(14,399)
Net cash generated from financing activities	<u>758,585</u>	<u>1,479,669</u>	<u>215,210</u>

I-MAB
Consolidated Statements of Cash Flows (Continued)
For the Years Ended December 31, 2017 and 2018
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Year Ended December 31,		
	2017	2018	
	RMB	RMB	US\$ (Note 2.5)
Effect of exchange rate changes on cash and cash equivalents and restricted cash	(132)	59,754	8,689
Net increase in cash and cash equivalents and restricted cash	348,631	1,268,218	184,454
Cash, cash equivalents, and restricted cash, beginning of year	64,082	412,713	60,027
Cash, cash equivalents, and restricted cash, end of the year	<u>412,713</u>	<u>1,680,931</u>	<u>244,481</u>
Supplemental cash flow disclosures			
Interest paid	1,677	4,862	707
Non-cash activities:			
Exercise of warrants	—	1,314	191
Payables for purchase of property, equipment and software	2,346	—	—
Payables for in-licensed patent rights	—	5,970	868
Convertible preferred shares issued for business combination (Note 3)	289,024	—	—

The accompanying notes are an integral part of these consolidated financial statements.

I-MAB**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

(All amounts in thousands, except for share and per share data, unless otherwise noted)

1. PRINCIPAL ACTIVITIES AND ORGANIZATION

I-Mab (the “Company”) was incorporated in the Cayman Islands on June 30, 2016 as an exempted company with limited liability under the Companies Law of the Cayman Islands. The Company and its subsidiaries (together the “Group”) are principally engaged in discovering and developing transformational biologics in the fields of immuno-oncology and immuno-inflammation diseases in the People’s Republic of China (the “PRC”) and other countries and regions.

Prior to the incorporation of the Company, the Group carried out its operation in the PRC since November 2014 mainly through Third Venture Biopharma (Nanjing) Co., Ltd. (“Third Venture”), which was incorporated on November 17, 2014 in the PRC. For the purpose of introduction of overseas investors and in preparation for a listing of the Company’s shares on the overseas capital markets, the Group underwent a reorganization (the “Reorganization”) in 2016. The Reorganization was approved by the Board of Directors and a restructuring framework agreement was entered into by Third Venture, the Company, and the shareholders of the Company based on Reorganization framework agreement, pursuant to which on July 7, 2016, Third Venture transferred all of its assets and operations to the Company’s wholly owned subsidiary, I-Mab Biopharma Co., Ltd. (“I-Mab Shanghai”), which was a transaction in which shareholders had identical ownership interests before and after the transaction and was accounted for in a manner similar to a common control transaction.

The Reorganization, as described above has been accounted for at historical cost. That Reorganization was reverse merger of Third Venture and Third Venture is the predecessor of the Company. As such, the assets and liabilities of Third Venture are consolidated in the Company’s financial statements at historical cost.

As of December 31, 2018, the Company’s principal subsidiaries are as follows:

Subsidiaries	Place of incorporation	Date of incorporation or acquisition	Percentage of direct or indirect ownership by the Company	Principal activities
I-Mab Biopharma Hong Kong Limited	Hong Kong	July 8, 2016	100%	Investment holding
I-Mab Shanghai	PRC	August 24, 2016	100%	Research and development of innovative medicines
I-Mab Bio-tech (Tianjin) Co., Ltd. (“I-Mab Tianjin”)	PRC	July 15, 2017	100%	Research and development of innovative medicines
I-Mab Biopharma US Ltd.	U.S.	February 28, 2018	100%	Research and development of innovative medicines

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2. PRINCIPAL ACCOUNTING POLICIES

2.1 Basis of presentation

The accompanying consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP").

Significant accounting policies followed by the Group in the preparation of its accompanying consolidated financial statements are summarized below.

2.2 Basis of consolidation

The accompanying consolidated financial statements reflect the accounts of the Company and all of its subsidiaries in which a controlling interest is maintained. All inter-company balances and transactions have been eliminated in consolidation.

2.3 Use of estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosures of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Estimates are used when accounting for amounts recorded in connection with acquisitions, including initial fair value determinations of assets and liabilities and other intangible assets. Additionally, estimates are used in determining items such as useful lives of property, equipment and software, impairment of contract assets and other receivables, impairment of long-lived assets and goodwill, share-based compensation, tax valuation allowances and revenues from licensing and collaboration arrangements. Management bases the estimates on historical experience, known trends and various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results could differ from those estimates.

2.4 Fair value measurements

Financial assets and liabilities of the Group primarily comprise of cash and cash equivalents, restricted cash, other financial assets, contract assets, other receivables, short-term borrowings, accruals and other payables and warrants liabilities. As of December 31, 2017 and 2018, except for other financial assets and warrant liabilities, the carrying values of these financial assets and liabilities approximated their fair values because of their generally short maturities. The Group reports other financial assets and warrant liabilities at fair value at each balance sheet date and changes in fair value are reflected in the consolidated statements of comprehensive loss.

The Group measures its financial assets and liabilities using inputs from the following three levels of the fair value hierarchy. The three levels are as follows:

Level 1 inputs are unadjusted quoted prices in active markets for identical assets that the management has the ability to access at the measurement date.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.4 Fair value measurements (continued)

Level 2 inputs include quoted prices for similar assets in active markets, quoted prices for identical or similar assets in markets that are not active, inputs other than quoted prices that are observable for the asset (i.e., interest rates, yield curves, etc.), and inputs that are derived principally from or corroborated by observable market data by correlation or other means (market corroborated inputs).

Level 3 includes unobservable inputs that reflect the management's assumptions about the assumptions that market participants would use in pricing the asset. The management develops these inputs based on the best information available, including the own data.

Assets and liabilities measured at fair value on a recurring basis

The Group measured its other financial assets and warrant liabilities at fair value on a recurring basis. As the Group's other financial assets and warrants are not traded in an active market with readily observable prices, the Group uses significant unobservable inputs to measure the fair value of other financial assets and warrant liabilities. These instruments are categorized in the Level 3 valuation hierarchy based on the significance of unobservable factors in the overall fair value measurement.

The following table summarizes the Group's financial assets and liabilities measured and recorded at fair value on a recurring basis as of December 31, 2017 and 2018:

	As of December 31, 2017			Total RMB
	Active market (Level 1) RMB	Observable input (Level 2) RMB	Non-observable input (Level 3) RMB	
Assets:				
Other financial assets	—	—	266,245	266,245
Liabilities:				
Warrant liabilities	—	—	65,832	65,832
	As of December 31, 2018			
	Active market (Level 1) RMB	Observable input (Level 2) RMB	Non-observable input (Level 3) RMB	Total RMB
Assets:				
Other financial assets	—	—	255,958	255,958
Liabilities:				
Warrant liabilities	—	—	5,618	5,618

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)**2.4 Fair value measurements (continued)**

The roll forward of major Level 3 financial asset and financial liability are as follows:

	Other financial assets	Warrant liabilities
Fair value of Level 3 financial asset and liability as of		
December 31, 2016	—	(12,931)
Business combination (Note3)	30,000	—
Investment in other financial assets	369,000	—
Issuance of warrants to investors	—	(40,563)
Disposal of other financial assets	(133,000)	—
Fair value change	5,572	(14,027)
Income received from other financial assets	(5,327)	—
Currency translation differences	—	1,689
Fair value of Level 3 financial asset and liability as of		
December 31, 2017	266,245	(65,832)
Investment in other financial assets	30,000	—
Disposal of other financial assets	(40,000)	—
Fair value change	13,622	61,405
Exercise of warrants	—	1,314
Income received from other financial assets	(13,909)	—
Currency translation differences	—	(2,505)
Fair value of Level 3 financial assets and financial as of		
December 31, 2018	<u>255,958</u>	<u>(5,618)</u>

Refer to Note 15 for additional information about Level 3 warrant liabilities measured at fair value on a recurring basis for the years ended December 31, 2017 and 2018.

2.5 Foreign currency translation

The Group uses Chinese Renminbi (“RMB”) as its reporting currency. The United States Dollar (“US\$”) is the functional currency of the Group’s entities incorporated in the Cayman Islands, the United States of America (“U.S.”) and Hong Kong, the Australia Dollar (“AUD”) is the functional currency of the Group’s entity incorporated in Australia and the RMB is the functional currency of the Company’s PRC subsidiaries.

Transactions denominated in other than the functional currencies are translated into the functional currency of the entity at the exchange rates prevailing on the transaction dates. Assets and liabilities denominated in other than the functional currencies are translated at the balance sheet date exchange rate. The resulting exchange differences are recorded in the consolidated statements of comprehensive loss.

The consolidated financial statements of the Group are translated from the functional currency to the reporting currency, RMB. Assets and liabilities of the subsidiaries are translated into RMB using the exchange rate in effect at each balance sheet date. Income and expenses are translated at the average exchange rates prevailing for the year. Foreign currency translation adjustments arising from these are reflected in the accumulated other

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.5 Foreign currency translation (continued)

comprehensive income. The exchange rates used for translation on December 31, 2017 and 2018 were US\$1.00 = RMB6.5342 and RMB6.8632, respectively, representing the index rates stipulated by the People's Bank of China.

Translations of balances in the consolidated balance sheets, consolidated statements of comprehensive loss, consolidated statements of changes in shareholders' equity (deficit) and consolidated statements of cash flows from RMB into US\$ as of and for the year ended December 31, 2018 are solely for the convenience of the readers and were calculated at the rate of US\$1.00=RMB6.8755, representing the noon buying rate in The City of New York for cable transfers of RMB as certified for customs purposes by the Federal Reserve Bank of New York on December 31, 2018. No representation is made that the RMB amounts could have been, or could be, converted, realized or settled into US\$ at that rate on December 31, 2018, or at any other rate. The US\$ convenience translation is not required under U.S. GAAP and all US\$ convenience translation amounts in the accompanying consolidated financial statements are unaudited.

2.6 Cash and cash equivalents

Cash and cash equivalents consist of cash on hand and bank deposits, which are unrestricted as to withdrawal and use. The Company considers all highly liquid investments with an original maturity date of three months or less at the date of purchase to be cash equivalents.

2.7 Restricted cash

Restricted cash consists of the guarantee deposits held in a designated bank account as security deposits under bank borrowing agreements. Such restricted cash will be released when the Group repays the related bank borrowings.

2.8 Property, equipment and software

Property, equipment and software are stated at cost less accumulated depreciation and amortization. Depreciation and amortization is computed using the straight-line method over the following estimated useful lives, taking into account any estimated residual value:

Laboratory equipment	3 to 5 years
Software	2 to 5 years
Office furniture and equipment	5 years
Leasehold improvements	Lesser of useful life or lease term

The Group recognized the gain or loss on the disposal of property, equipment and software in the consolidated statements of comprehensive loss.

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.9 Intangible assets

Intangible assets with definite useful lives are amortized to their estimated residual values over their estimated useful lives and reviewed for impairment if certain events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Amortization is initiated for in-process research and development (IPR&D) intangible assets that are acquired from business combination when their useful lives have been determined. IPR&D intangible assets which are determined to have an impairment in their fair value are adjusted downward and an expense recognized in research and development in the consolidated statements of comprehensive loss. These IPR&D intangible assets are tested at least an annual basis on December 31 or when a triggering event occurs that could indicate a potential impairment. (see Note 7).

2.10 Impairment of long-lived assets

Long-lived assets are reviewed for impairment in accordance with authoritative guidance for impairment or disposal of long-lived assets. Long-lived assets are reviewed for events or changes in circumstances, which indicate that their carrying value may not be recoverable. Long-lived assets are reported at the lower of carrying amount or fair value less cost to sell. For the years ended December 31, 2017 and 2018, there was no impairment of the value of the Group's long-lived assets.

2.11 Goodwill

Goodwill is an asset representing the future economic benefits arising from other assets acquired in a business combination that are not individually identified and separately recognized. The Group allocates the cost of an acquired entity to the assets acquired and liabilities assumed based on their estimated fair values at the date of acquisition. The excess of the purchase price for acquisitions over the fair value of the net assets acquired, including other intangible assets, is recorded as goodwill. Goodwill is not amortized, but impairment of goodwill assessment is performed on at least an annual basis on December 31 or whenever events or changes in circumstances indicate that the carrying value of the asset may not be recoverable.

The Group has elected to first assess qualitative factors to determine whether it is more likely than not that the fair value of the Group's reporting unit is less than its carrying amount, including goodwill. The qualitative assessment includes the Group's evaluation of relevant events and circumstances affecting the Group's single reporting unit, including macroeconomic, industry, market conditions and the Group's overall financial performance. If qualitative factors indicate that it is more likely than not that the Group's reporting unit's fair value is less than its carrying amount, then the Group will perform the quantitative impairment test by comparing the reporting unit's carrying amount, including goodwill, to its fair value. If the carrying amount of the reporting unit exceeds its fair value, an impairment loss will be recognized in an amount equal to that excess. For the years ended December 31, 2017 and 2018, the Group determined that there were no indicators of impairment of the goodwill.

2.12 Deferred subsidy income

Deferred subsidy income consists of deferred income from government grants. Government grants consist of cash subsidies received by the Group's subsidiaries in the PRC from local governments as support on expenses relating to certain projects. Grants received with government specified performance obligations are recognized when all the obligations have been fulfilled. If such obligations are not satisfied, the Group may be required to

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.12 Deferred subsidy income (continued)

refund the subsidy. Cash grants of RMB2,500 was recorded in deferred subsidy income as of December 31, 2018, which will be recognized when the government specified performance obligation is satisfied, which is expected to be more than 12 months after December 31, 2018.

2.13 Revenue recognition

The Group adopted Accounting Standard Codification (“ASC”) 606, *Revenue from Contracts with Customers* (Topic 606) (“ASC 606”) for all periods presented. Consistent with the criteria of Topic 606, the Group recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to receive in exchange for those goods or services.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Group only applies the five-step model to contracts when it is probable that the entity will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

Once a contract is determined to be within the scope of ASC 606 at contract inception, the Group reviews the contract to determine which performance obligations it must deliver and which of these performance obligations are distinct. The Group recognizes as revenue the amount of the transaction price that is allocated to each performance obligation when that performance obligation is satisfied or as it is satisfied.

Collaboration revenue

At contract inception, the Group analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements* (“ASC 808”) to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Group first determines if the collaboration is deemed to be within the scope of ASC 808 and those that are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606. For the collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently.

The Group’s collaborative arrangements may contain more than one unit of account, or performance obligation, including grants of licenses to intellectual property rights, agreement to provide research and development services and other deliverables. The collaborative arrangements do not include a right of return for any deliverable. As part of the accounting for these arrangements, the Group must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. In developing the stand-alone selling price for a performance obligation, the Group considers competitor pricing for a similar or identical product, market awareness of and perception of the product, expected product life and

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.13 Revenue recognition (continued)

current market trends. In general, the consideration allocated to each performance obligation is recognized when the respective obligation is satisfied either by delivering a good or providing a service, limited to the consideration that is not constrained.

When the timing of the delivery of product is different from the timing of payments made by the customers, the Group recognizes either a contract asset (performance precedes the contractual due date) or a contract liability (customer payment precedes performance). The Group's contractual payment terms are typically due in no more than 30 days from invoicing. In limited situations, certain customer contractual payment terms require the Group to bill in arrears; thus, the Group satisfies some or all of the performance obligations before the Group is contractually entitled to bill the customer. In these situations, billing occurs subsequent to revenue recognition, which results in a contract asset. For example, certain of the contractual arrangements do not permit the Group to bill until the completion of the production of the samples. In other limited situations, certain customer contractual payment terms allow the Group to bill in advance; thus, the Group receives customer cash payment before satisfying some or all of its performance obligations. In these situations, billing occurs in advance of revenue recognition, which results in contract liabilities.

Licenses of Intellectual Property: Upfront non-refundable payments for licensing the Group's intellectual property are evaluated to determine if the license is distinct from the other performance obligations identified in the arrangement. For licenses determined to be distinct, the Group recognizes revenues from non-refundable, up-front fees allocated to the license at a point in time, when the license is transferred to the licensee and the licensee is able to use and benefit from the license.

Research and Development Services: The portion of the transaction price allocated to research and development services performance obligations is deferred and recognized as collaboration revenue over time as delivery or performance of such services occurs.

Milestone Payments: At the inception of each arrangement that includes development, commercialization, and regulatory milestone payments, the Group evaluates whether the milestones are considered probable of being reached and to the extent that a significant reversal of cumulative revenue would not occur in future periods, estimates the amount to be included in the transaction price using the most likely amount method. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Group recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Group re-evaluates the probability of achieving such development milestones and any related constraint, and if necessary, adjust the estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Group recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.14 Value-added-tax (“VAT”) recoverable and surcharges

Value added tax recoverable represent amounts paid by the Group for purchases. The surcharges (i.e., Urban construction and maintenance tax, educational surtax, local educational surtax), vary from 6% to 12% of the value-added-tax depending on the tax-payer’s location.

2.15 Research and development expenses

Elements of research and development expenses primarily include (1) payroll and other related expenses of personnel engaged in research and development activities, (2) in-licensed patent rights fee of exclusive development rights of drugs granted to the Group, (3) expenses related to preclinical testing of the Group’s technologies and clinical trials such as payments to contract research organizations (“CRO”), investigators and clinical trial sites that conduct the clinical studies (4) expenses to develop the product candidates, including raw materials and supplies, product testing, depreciation, and facility related expenses, (5) other research and development expenses. Research and development expenses are charged to expense as incurred when these expenditures relate to the Group’s research and development services and have no alternative future uses.

The Group has acquired rights to develop and commercialize product candidates. Upfront payments that relate to the acquisition of a new drug compound, as well as pre-commercial milestone payments, are immediately expensed as acquired in-process research and development in the period in which they are incurred, provided that the new drug compound did not also include processes or activities that would constitute a “business” as defined under U.S. GAAP, the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no established alternative future use. Milestone payments made to third parties subsequent to regulatory approval would be capitalized as intangible assets and amortized over the estimated remaining useful life of the related product. The conditions enabling capitalization of development expenses as an asset have not yet been met and, therefore, all development expenditures are recognized in profit or loss when incurred.

2.16 Leases

Leases are classified at the inception date as either a capital lease or an operating lease. the Group assesses a lease to be a capital lease if any of the following conditions exist: (1) ownership is transferred to the lessee by the end of the lease term, (2) there is a bargain purchase option, (3) the lease term is at least 75% of the property’s estimated remaining economic life or (4) the present value of the minimum lease payments at the beginning of the lease term is 90% or more of the fair value of the leased property to the lessor at the inception date. A capital lease is accounted for as if there was an acquisition of an asset and an incurrence of an obligation at the inception of the lease. The Group has no capital leases for the years presented.

All other leases are accounted for as operating leases wherein rental payments are expensed on a straight-line basis over the periods of their respective lease terms. Certain of the lease agreements contain rent holidays. Rent holidays are considered in determining the straight-line rent expense to be recorded over the lease term. The lease term begins on the date of initial possession of the lease property for purposes of recognizing lease expense on straight-line basis over the term of the lease.

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.17 Comprehensive loss

Comprehensive loss is defined as the changes in equity of the Group during a period from transactions and other events and circumstances excluding transactions resulting from investments by owners and distributions to owners. Among other disclosures, ASC 220, *Comprehensive Income*, requires that all items that are required to be recognized under current accounting standards as components of comprehensive loss be reported in a financial statement that is displayed with the same prominence as other financial statements. For each of the periods presented, the Group's comprehensive loss includes net loss and foreign currency translation adjustments, which are presented in the consolidated statements of comprehensive loss.

2.18 Share-based compensation

The Company grants restricted shares and stock options to eligible employees and accounts for share-based compensation in accordance with ASC 718, *Compensation—Stock Compensation*.

Employees' share-based compensation awards are measured at the grant date fair value of the awards and recognized as expenses a) immediately at the grant date if no vesting conditions are required; or b) for share-based awards granted with only service conditions, using the graded vesting method net of estimated forfeitures over the vesting period; or c) for share-based awards granted with service conditions and the occurrence of an initial public offering ("IPO") as performance condition cumulative share-based compensation expenses for the options that have satisfied the service condition should be recorded upon the completion of the IPO using the graded vesting method.

A change in any of the terms or conditions of share-based awards is accounted for as a modification of the awards. The Group calculates incremental compensation expense of a modification as the excess of the fair value of the modified awards over the fair value of the original awards immediately before its terms are modified at the modification date. For vested awards, the Group recognizes incremental compensation cost in the period when the modification occurs. For awards not being fully vested, the Group recognizes the sum of the incremental compensation expense and the remaining unrecognized compensation expense for the original awards over the remaining requisite service period after modification.

Share-based compensation in relation to the restricted shares is measured based on the fair market value of the Group's ordinary shares at the grant date of the award. Prior to the listing, estimation of the fair value of the Group's ordinary shares involves significant assumptions that might not be observable in the market, and a number of complex and subjective variables, including discount rate, and subjective judgments regarding the Group's projected financial and operating results, its unique business risks, the liquidity of its ordinary shares and its operating history and prospects at the time the grants are made. Share-based compensation in relation to the share options is estimated using the Binominal Option Pricing Model. The determination of the fair value of share options is affected by the share price of the Group's ordinary shares as well as the assumptions regarding a number of complex and subjective variables, including the expected share price volatility, risk-free interest rate, exercise multiple and expected dividend yield. The fair value of these awards was determined with the assistance from an independent valuation firm.

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.19 Income taxes

The Group accounts for income taxes under the liability method. Under the liability method, deferred income tax assets and liabilities are determined based on the differences between the financial reporting and income tax bases of assets and liabilities and are measured using the tax income rates that will be in effect when the differences are expected to reverse. A valuation allowance is recorded if it is more likely than not that some portion or all of a deferred income tax assets will not be realized in the foreseeable future.

The Group evaluates its uncertain tax positions using the provisions of ASC 740-10, *Income Taxes*, which prescribes a recognition threshold that a tax position is required to meet before being recognized in the financial statements. The Group recognizes in the financial statements the benefit of a tax position which is “more likely than not” to be sustained under examination based solely on the technical merits of the position assuming a review by tax authorities having all relevant information. Tax positions that meet the recognition threshold are measured using a cumulative probability approach, at the largest amount of tax benefit that has a greater than fifty percent likelihood of being realized upon settlement. It is the Group’s policy to recognize interest and penalties related to unrecognized tax benefits, if any, as a component of income tax expense.

2.20 Borrowings

Borrowings are recognized initially at fair value, net of transaction costs incurred. Borrowings are subsequently stated at amortized cost; any difference between the proceeds (net of transaction costs) and the redemption value is recognized in the consolidated statements of comprehensive loss over the period of the borrowings using the effective interest method.

2.21 Business combination

The Group accounts for its business combinations using the acquisition method of accounting in accordance with ASC topic 805, *Business Combinations* (“ASC 805”). The acquisition method of accounting requires all of the following steps: (i) identifying the acquirer, (ii) determining the acquisition date, (iii) recognizing and measuring the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree, and (iv) recognizing and measuring goodwill or a gain from a bargain purchase. The consideration transferred in a business combination is measured as the aggregate of the fair values at the date of exchange of the assets given, liabilities incurred, and equity instruments issued as well as the contingent considerations and all contractual contingencies as of the acquisition date.

The Group allocates the fair value of purchase consideration to the tangible assets acquired, liabilities assumed and intangible assets acquired based on their estimated fair values. The excess of the fair value of purchase consideration over the fair values of these identifiable assets and liabilities is recorded as goodwill. Such valuations require management to make significant estimates and assumptions, especially with respect to intangible assets. Significant estimates in valuing certain intangible assets may include, but are not limited to, future expected cash flows from acquired assets, timing and probability of success of clinical events and regulatory approvals, and assumptions on useful lives of the patents and discount rates. Management’s estimates of fair value are based upon assumptions believed to be reasonable, but which are inherently uncertain and unpredictable and, as a result, actual results may differ from estimates. Additional information, such as that related to income tax and other contingencies, existing as of the acquisition date but unknown to us may become

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.21 Business combination (continued)

known during the remainder of the measurement period, not to exceed one year from the acquisition date, which may result in changes to the amounts and allocations recorded.

Acquisitions that do not meet the accounting definition of a business combination are accounted for as asset acquisitions. For transactions determined to be asset acquisitions, the Group allocates the total cost of the acquisition, including transaction costs, to the net assets acquired based on their relative fair values.

2.22 Segment information

In accordance with ASC 280, *Segment Reporting*, the Group's chief operating decision maker, the Chief Executive Officer, reviews the consolidated results when making decisions about allocating resources and assessing performance of the Group as a whole and hence, the Group has only one reportable segment. The Group does not distinguish between markets or segments for the purpose of internal reporting. As the Group's long-lived assets are substantially located in and derived from the PRC, no geographical segments are presented.

2.23 Loss per share

Basic loss per share is computed by dividing net loss attributable to ordinary shareholders by the weighted average number of ordinary shares outstanding during the period using the two-class method. Under the two-class method, the net loss is allocated between ordinary shares and other participating securities based on their participating rights. Net loss is not allocated to other participating securities if based on their contractual terms they are not obligated to share in the loss. Diluted loss per share is calculated by dividing net loss attributable to ordinary shareholders by the weighted average number of ordinary and dilutive ordinary equivalent shares outstanding during the period. Ordinary equivalent shares consist of shares issuable upon the conversion of the preferred shares using the if-converted method, shares issuable upon the exercise of share options using the treasury stock method, shares issuable upon the conversion of the convertible promissory notes using the if-converted method, and shares issuable upon the exercise of warrants using the treasury stock method. Ordinary equivalent shares are not included in the denominator of the diluted loss per share calculation when inclusion of such shares would be anti-dilutive.

2.24 Recent accounting pronouncements

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842) ("ASU 2016-02"). Under this guidance, an entity is required to recognize right-of-use assets and lease liabilities on its balance sheet and disclose key information about leasing arrangements. This guidance offers specific accounting guidance for a lessee, a lessor and sale and leaseback transactions. Lessees and lessors are required to disclose qualitative and quantitative information about leasing arrangements to enable a user of the financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. In July 2018, the FASB issued ASU 2018-11, Leases (Topic 842): Targeted Improvements ("ASU 2018-11"), which provides entities the option to initially apply ASU 2016-02 at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. ASU 2016-02 and ASU 2018-11 are effective for the annual reporting period beginning after December 15, 2018, including interim periods within that reporting period. The Group adopted the new leasing standards on January 1, 2019, using a modified retrospective transition approach to be applied to

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.24 Recent accounting pronouncements (continued)

leases existing as of, or entered into after, January 1, 2019. The Group have reviewed the existing lease contracts and the impact of the new leasing standards on the consolidated results of operations, financial position and disclosures. Upon adoption of the new leasing standards, the Group expect to recognize a lease liability and related right-of-use asset on the consolidated balance sheets of approximately RMB11,333 and RMB13,100, respectively. The impact of adoption of the new leasing standards will have an immaterial impact to the consolidated statements of comprehensive loss.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments (“ASU 2016-13”). This guidance requires that financial assets measured at amortized cost be presented at the net amount expected to be collected. The measurement of expected credit losses is based on historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability. In November 2018, the FASB issued ASU 2018-19, Codification Improvements to Topic 326, Financial Instruments-Credit Losses (“ASU 2018-19”), which clarifies certain topics included within ASU 2016-13. ASU 2016-13 and ASU 2018-19 are effective for the annual reporting period beginning after December 15, 2019, including interim periods within that reporting period. The Group is currently evaluating the impact on the consolidated financial statements upon the adoption of this guidance.

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230), Classification of Certain Cash Receipts and Cash Payments. ASU 2016-15 provides guidance for targeted changes with respect to how cash receipts and cash payments are classified in the statements of cash flows, with the objective of reducing diversity in practice. The amendments in this update are effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. The Group elected to early adopt this ASU and applied this guidance retrospectively to all periods presented. The impact of this ASU to the consolidated financial statements is immaterial.

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230) (“ASU 2016-18”). This ASU affects all entities that have restricted cash or restricted cash equivalents and are required to present a statement of cash flows under Topic 230. ASU 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. This update was required to be adopted for fiscal years beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2019, and early adoption is permitted in any interim or annual period. The Group elected to early adopt this ASU and applied this guidance retrospectively to all periods presented.

3. BUSINESS COMBINATION

In 2017, the Group acquired 66.67% of the equity interests in I-Mab Tianjin and its subsidiaries including Chengdu Tasgen Bio-Tech Co., Ltd. and Shanghai Tianyunjian Bio-Tech Co., Ltd. (together the “Tasgen Group”) by issuing convertible preferred shares to the then equity holders of I-Mab Tianjin. The acquisition date was determined as July 15, 2017 when the Group controlled the board and business of I-Mab Tianjin from July 15, 2017 accordingly.

I-MAB**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

(All amounts in thousands, except for share and per share data, unless otherwise noted)

3. BUSINESS COMBINATION (CONTINUED)

I-Mab Tianjin and its subsidiaries are principally engaged in the research and development of innovative medicines. The Group acquired I-Mab Tianjin and its subsidiaries for its research team, technical experience, and pipeline assets.

Goodwill is an asset representing the future economic benefits arising from other assets acquired in a business combination that are not individually identified and separately recognized. The Company allocates the cost of an acquired entity to the assets acquired and liabilities assumed based on their estimated fair values at the date of acquisition. The excess of the purchase price for acquisitions over the fair value of the net assets acquired, including other intangible assets, is recorded as goodwill. Goodwill is not amortized but is tested for impairment at least annually or more frequently if events or changes in circumstances would indicate a potential impairment. None of the goodwill recognized is expected to be deductible for income tax purpose.

The Group completed the valuations necessary to assess the fair values of the tangible assets acquired and liabilities assumed, resulting from which the amount of goodwill was determined and recognized as of the date of acquisition. The following table summarizes the estimated aggregate fair values of the assets acquired and liabilities assumed as of the date of acquisition:

	As of July 15, 2017	
	RMB	US\$ (Note 2.5)
Convertible preferred shares to be issued (Note 13)	289,024	42,036
Cash and cash equivalents	93,335	13,575
Other financial assets (Note 5)	30,000	4,363
Intangible assets (*)	148,844	21,648
Prepayments and other receivables	564	82
Equipment and software	43	6
Total assets	272,786	39,674
Accruals and other payables	(1,824)	(265)
Fair value of net assets	270,962	39,409
Redeemable non-controlling interests (Note 16)	144,512	21,018
Goodwill	162,574	23,645

* The intangible assets acquired in the business combination were IPR&D intangible assets, which represented the fair value assigned to research and development assets that the Group acquired.

The acquired business did not contribute any revenues and contributed net loss of RMB14,750 to the Group for the period from July 15, 2017 to December 31, 2017. Unaudited pro forma operating results for the Group, assuming the acquisition of Tasgen Group occurred on January 1, 2017 is as follows:

	For the year ended December 31, 2017	
	RMB	US\$ (Note 2.5)
Net revenues	11,556	1,681
Net loss	(314,489)	(45,741)

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(All amounts in thousands, except for share and per share data, unless otherwise noted)

3. BUSINESS COMBINATION (CONTINUED)

The following summarizes the business combination as presented on the consolidated statement of cash flows:

	For the year ended December 31, 2017	
	RMB	US\$ (Note 2.5)
Investing activities		
Cash acquired for acquisition of a subsidiary	93,335	13,575
Non-cash activities		
Convertible preferred shares issued for business combination	<u>289,024</u>	<u>42,037</u>

4. PREPAYMENTS AND OTHER RECEIVABLES

	As of December 31,		
	2017	2018	
	RMB	RMB	US\$ (Note 2.5)
Prepayments:			
- Prepayments to CRO vendors	5,232	71,894	10,457
- Prepayments for other services	2,553	3,160	460
Value-added tax recoverable	3,073	4,235	616
Rental deposits	747	1,012	147
Interest receivables	704	1,502	218
Others	324	7,169	1,044
	<u>12,633</u>	<u>88,972</u>	<u>12,942</u>

5. OTHER FINANCIAL ASSETS

	As of December 31,		
	2017	2018	
	RMB	RMB	US\$ (Note 2.5)
Financial asset at fair value through profit or loss	266,245	215,571	31,354
Note receivables	—	40,387	5,874
	<u>266,245</u>	<u>255,958</u>	<u>37,228</u>

The Group placed the principal amount for short-term investments through a contractual arrangement with a third party for the period from June 30, 2017 to June 30, 2020 (“Principal Amount”). The Principal Amount can be redeemed from the third party at the discretion of the Group from time to time whereby the Group is expecting to earn an income on the Principal Amount with an average yield in the range from 4.50% to 5.25% per annum. The Group initially records these assets at cost, which approximates its fair value at inception and subsequently records these assets at fair value. Changes in the fair value are reflected in the consolidated statements of comprehensive loss.

I-MAB**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

(All amounts in thousands, except for share and per share data, unless otherwise noted)

5. OTHER FINANCIAL ASSETS (CONTINUED)

Subsequent to December 31, 2018, the Group entered into an agreement with the relevant party involved for early termination of the contractual arrangement with effect from June 22, 2019 (“Termination Agreement”). Pursuant to the Termination Agreement, the Group shall receive cash with an amount of RMB95,056 and commercial bills with a total face value of RMB160,944 (including those commercial bills redeemed during the year ended December 31, 2018 with a face value of RMB40,387). No material gain or loss was arising from such termination.

Up to the issuance of these consolidated financial statements, cash of RMB80,000 was received and an amount of RMB85,374 cash was received upon the maturities of certain commercial bills.

6. PROPERTY, EQUIPMENT AND SOFTWARE

Property, equipment and software consist of the following:

	As of December 31,		
	2017	2018	US\$
	RMB	RMB	(Note 2.5)
Cost			
Laboratory equipment	15,592	20,796	3,025
Leasehold improvement	7,084	10,271	1,494
Software	889	3,632	528
Office furniture and equipment	421	1,350	196
Total property, equipment and software	23,986	36,049	5,243
Less: accumulated depreciation and amortization	(1,650)	(8,390)	(1,220)
Net book value	<u>22,336</u>	<u>27,659</u>	<u>4,023</u>

The total amounts charged to the consolidated statements of comprehensive loss for depreciation and amortization expenses amounted to approximately RMB1,634 and RMB6,740 for the years ended December 31, 2017 and 2018, respectively.

7. INTANGIBLE ASSETS

Intangible assets as of December 31, 2017 and 2018 are summarized as follows:

	As of December 31,		
	2017	2018	US\$
	RMB	RMB	(Note 2.5)
Cost			
IPR&D	148,844	148,844	21,648
Less: accumulated amortization	—	—	—
Net book value	<u>148,844</u>	<u>148,844</u>	<u>21,648</u>

I-MAB**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

(All amounts in thousands, except for share and per share data, unless otherwise noted)

7. INTANGIBLE ASSETS (CONTINUED)

IPR&D represents the fair value assigned to research and development assets that we acquired from business combination of Tasgen Group in 2017 and had not reached technological feasibility at the date of acquisition. Upon commercialization, the Group will determine the estimated useful life and amortize these amounts based upon an economic consumption method.

8. GOODWILL

The goodwill of RMB162,574 (US\$23,645) as of December 31, 2017 and 2018 represented the goodwill generated from the acquisition of Tasgen Group in 2017 (Note 3). The business of Tasgen Group was fully integrated into the Company post acquisition. As of December 31, 2017 and 2018, the Group performed a qualitative assessment by evaluating relevant events and circumstances that would affect the Group's single reporting unit and did not note any indicator that it is more likely than not that the fair value of the Group's reporting unit is less than its carrying amount, and therefore the Group's goodwill was not impaired.

9. SHORT-TERM BORROWINGS

In the third quarter of 2017, I-Mab Biopharma Co., Ltd. borrowed loans with the total amount of RMB99,000 from China Merchant Bank Co., Ltd. for a term of one year and at the interest rate of 4.79% per annum. To facilitate the borrowings, another subsidiary of the Company in Hong Kong placed cash deposits of US\$16,015 (equivalent to approximately RMB104,783) with the bank. The use of such cash deposits and the interest earned thereon are restricted by the bank during the period of the borrowings. The deposits have a one-year term and bear interest at 2.00% per annum. The borrowings were fully repaid in 2018.

In July 2018, I-Mab Bio-tech (Tianjin) Co., Ltd. borrowed a loan of RMB80,000 (equivalent to approximately US\$11,636) from China Merchant Bank Co., Ltd. for a term of one year and at the interest rate of 4.20% per annum. To facilitate these borrowing, another subsidiary of the Company in Hong Kong placed cash deposits of US\$13,500 (equivalent to approximately RMB92,653) with the bank. The use of such cash deposits and the interest earned thereon are restricted by the bank during the period of the borrowing. The deposits have a one-year term and bear interest at 3.26% per annum. The borrowing was fully repaid in 2019.

10. ACCRUALS AND OTHER PAYABLES

	As of December 31,		
	2017	2018	
	RMB	RMB	US\$ (Note 2.5)
Staff salaries and welfare payables	3,164	18,869	2,744
Accrued external research and development activities related expenses	3,798	39,068	5,682
Payables for purchase of equipment	2,346	—	—
Interest payables	130	—	—
Accrued travelling expenses, office expenses and others	5,071	9,737	1,417
	<u>14,509</u>	<u>67,674</u>	<u>9,843</u>

I-MAB

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(All amounts in thousands, except for share and per share data, unless otherwise noted)

11. INCOME TAXES

Cayman Islands

I-Mab is incorporated in the Cayman Islands. Under the current laws of the Cayman Islands, I-Mab is not subject to tax on income or capital gain. Additionally, the Cayman Islands does not impose a withholding tax on payments of dividends to shareholders.

Hong Kong

I-Mab Biopharma Hong Kong Limited is incorporated in Hong Kong. Companies registered in Hong Kong are subject to Hong Kong profits tax on the taxable income as reported in their respective statutory financial statements adjusted in accordance with the relevant Hong Kong tax laws. The applicable tax rate in Hong Kong is 16.5%. For the years ended December 31, 2017 and 2018, I-Mab Biopharma Hong Kong Limited did not make any provisions for Hong Kong profit tax as there were no assessable profits derived from or earnings in Hong Kong for any of the periods presented. Under the Hong Kong tax law, I-Mab Biopharma Hong Kong Limited is exempted from income tax on its foreign-derived income and there are no withholding taxes in Hong Kong on remittance of dividends.

Australia

I-Mab Biopharma Australia Pty Ltd is incorporated in Australia. Companies registered in Australia are subject to Australia profits tax on the taxable income as reported in their respective statutory financial statements adjusted in accordance with the relevant Australia tax laws. The applicable tax rate in Australia is 30%. I-Mab Biopharma Australia Pty Ltd has no taxable income for all periods presented, therefore, no provision for income taxes is required.

United States

I-Mab Biopharma US Ltd. is incorporated in U.S. and is subject to U.S. federal corporate income tax at a rate of 21%. I-Mab Biopharma US Ltd. is also subject to state income tax in Maryland of 8.25%. I-Mab Biopharma US Ltd. has no taxable income for all periods presented, therefore, no provision for income taxes is required.

China

On March 16, 2007, the National People's Congress of PRC enacted a new Enterprise Income Tax Law ("new EIT law"), under which Foreign Investment Enterprises ("FIEs") and domestic companies would be subject to corporate income tax at a uniform rate of 25%. The new EIT law became effective on January 1, 2008. Under the new EIT law, preferential tax treatments will continue to be granted to entities which conduct businesses in certain encouraged sectors and to entities otherwise classified as "High and New Technology Enterprises".

I-Mab Shanghai has been qualified as "High and New Technology Enterprise" and enjoys a preferential income tax rate of 15% from 2018 to 2020.

The Company's other PRC subsidiaries are subject to the statutory income tax rate of 25%.

No provision for income taxes has been made because the Group and all of its subsidiaries are in cumulative loss positions for all the periods presented.

I-MAB**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

(All amounts in thousands, except for share and per share data, unless otherwise noted)

11. INCOME TAXES (CONTINUED)

Reconciliations of the differences between the PRC statutory income tax rate and the Group's effective income tax rate for the years ended December 31, 2017 and 2018 are as follows:

	Year Ended December 31,		
	2017	2018	US\$ (Note 2.5)
	RMB	RMB	
Loss before income tax	(298,240)	(401,111)	(58,338)
Income tax computed at respective applicable tax rate	(37,672)	(56,093)	(8,159)
Non-deductible expenses	3,889	2,548	371
Research and development expenses plus deduction	(2,846)	(6,762)	(983)
Changes in valuation allowance	36,629	62,029	9,022
	—	1,722	251
Effect of tax holidays entitled by the PRC subsidiaries on basic loss per share	—	3.07	0.45

The principal components of the deferred tax assets and liabilities are as follows:

	Year Ended December 31,		
	2017	2018	US\$ (Note 2.5)
	RMB	RMB	
Deferred tax assets:			
Net operating loss carryforward	73,105	92,185	13,408
Depreciation and amortization of property, equipment and software, net	—	18,405	2,677
Accrual expenses	13,647	21,132	3,073
Less: valuation allowance	(49,541)	(94,511)	(13,746)
Total deferred tax assets	37,211	37,211	5,412
Deferred tax liabilities:			
Acquired intangible assets	37,211	37,211	5,412
Total deferred tax liabilities	37,211	37,211	5,412
Deferred tax assets, net	—	—	—

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(All amounts in thousands, except for share and per share data, unless otherwise noted)

11. INCOME TAXES (CONTINUED)

Movement of the valuation allowance is as follows:

	<u>2017</u>	<u>2018</u>	
	RMB	RMB	US\$
			(Note 2.5)
Balance as of January 1	(6,472)	(49,541)	(7,205)
Business combination (Note 3)	(6,440)	—	—
Additions	(36,629)	(62,029)	(9,022)
Decrease due to the change of tax rate	—	17,059	2,481
Balance as of December 31	<u>(49,541)</u>	<u>(94,511)</u>	<u>(13,746)</u>

As of December 31 2018, the Group had net operating losses of approximately RMB462,148 which arose from the subsidiaries established in the PRC. The tax losses carried forward in the PRC will expire during the period from 2019 to 2023.

A valuation allowance is provided to reduce the amount of deferred tax assets if it is considered more likely than not that some portion or all of the deferred tax assets will not be realized in the foreseeable future. In making such determination, the Group evaluates a variety of positive and negative factors including the Group's operating history, accumulated deficit, the existence of taxable temporary differences and reversal periods.

The Group has incurred net accumulated operating losses for income tax purposes since its inception. The Group believes that it is more likely than not that these net accumulated operating losses will not be utilized in the future. Therefore, the Group has provided full valuation allowances for the deferred tax assets as of December 31, 2017 and 2018.

The Group evaluates each uncertain tax position (including the potential application of interest and penalties) based on the technical merits, and measure the unrecognized benefits associated with the tax positions. As of December 31, 2017 and 2018, the Group did not have any significant unrecognized uncertain tax positions.

12. ORDINARY SHARES

As of December 31, 2017 and 2018, 500,000,000 ordinary shares had been authorized by the Company. Each ordinary share is entitled to one vote. The holders of ordinary shares are also entitled to receive dividends whenever funds are legally available and when declared by the Board of Directors of the Company.

13. CONVERTIBLE PREFERRED SHARES

On October 18, 2016, the Company issued 5,141,587 shares of Series A-1 and A-2 Preferred Shares with a consideration of US\$11,282 (equivalent to approximately RMB74,742). In connection with the Series A-1 and A-2 Preferred Shares issuance, the Company also issued 2,246,744 warrant to purchase its Series A-3 Preferred Shares (Series A-3 Warrants and see Note 15).

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(All amounts in thousands, except for share and per share data, unless otherwise noted)

13. CONVERTIBLE PREFERRED SHARES (CONTINUED)

On September 6, 2017, in connection with the Group's acquisition of Tasgen Group (see Note 3), the Company issued 16,723,646 shares of series A-3 Preferred Shares at a price of US\$2.55 per share with a total consideration of US\$42,645 (equivalent to approximately RMB289,024).

Series A-1 Preferred Shares, Series A-2 Preferred Shares and Series A-3 Preferred Shares are also referred to as Series A Preferred Shares.

On September 22, 2017, the Company issued 15,894,594 shares of Series B Preferred Shares with a consideration of US\$52,546 (equivalent to approximately RMB346,515). In connection with the Series B Preferred Shares issuance, the Company also issued convertible promissory notes that are convertible into Series B-1 Preferred Shares (2017 Notes and see Notes 14) and 5,633,780 warrants to purchase its Series B-2 Preferred Shares ("Series B Warrant" and see Note 15).

Concurrently with the Company's issuance of Series B Preferred Shares, the Company also completed a round of onshore financing with respect to the Group's subsidiary I-MAB Tianjin ("Series B Onshore Financing"). Series B Onshore Financing comprised 1) capital injection to I-Mab Tianjin by a number of investors ("Series B Onshore Investors") (see Note 14), 2) I-Mab Tianjin's issuance of convertible loans ("Onshore Convertible Loans" and see Note 14), and 3) the Company's issuance of 2,620,842 warrants to purchase its Series B-2 Preferred Shares ("Series B Warrants" and see Note 15).

On June 29, 2018, the Company issued 2,535,201 shares of Series B-1 Preferred Shares upon conversion of 2017 Notes and issued 2,253,512 shares of Series B-2 Preferred Shares upon exercise of Series B Warrant by Series B preferred shareholders.

On June 29, 2018 and July 6, 2018, the Company issued total 1,179,379 share of Series B-1 Preferred Shares upon exercise of Series B Option held by Series B Onshore Investors (see Note 14) and issued total 1,048,337 shares of Series B-2 Preferred Shares upon exercise of Series B Warrants by Series B Onshore Investors, respectively.

Series B Preferred Shares, Series B-1 Preferred Shares and Series B-2 Preferred Shares are also referred to as Series B Preferred Shares.

On June 28, 2018, the Company issued 31,046,360 shares of Series C Preferred Shares at a price of US\$6.4419 per share with a total consideration of US\$200,000 (equivalent to approximately RMB1,323,363). In connection with the offering of the Series C Preferred Shares, the Company incurred issuance costs of RMB16,730.

Series A Preferred Shares, Series B Preferred Shares and Series C Preferred Shares are collectively referred to as Preferred Shares.

Key terms of the Preferred Shares are summarized as follows:

Dividends

The holders of Preferred Shares are entitled to receive dividends, out of any assets legally available therefor, prior and in preference to any declaration or payment of any dividend on the ordinary shares or any other class or

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(All amounts in thousands, except for share and per share data, unless otherwise noted)

13. CONVERTIBLE PREFERRED SHARES (CONTINUED)

series of shares of the Group at the rate of eight percent (8%) of the original issue price per share per annum on each Preferred Share, payable in US\$ and annually when, as and if declared by the Board. Such distributions shall not be cumulative. No dividend, whether in cash, in property or in shares of the capital of the Group, shall be paid on or declared and set aside for any ordinary shares or any other class or series of shares of the Group unless and until all dividends have been paid in full on the Preferred Shares (on an as-converted basis).

Conversion

Each Preferred Share may be converted at any time into ordinary shares at the option of the preferred shares holders at the then applicable conversion price. The initial conversion ratio is 1:1, subject to adjustment in the event of (i) share splits, share combinations, share dividends or distribution, other dividends, recapitalizations and similar events, or (ii) issuance of ordinary shares (excluding certain events such as issuance of ordinary shares pursuant to a public offering) at a price per share less than the conversion price in effect on the date of or immediately prior to such issuance.

The Preferred Shares shall be automatically converted into ordinary shares immediately upon the closing of a public offering of the Company's shares with an offering price (exclusive of underwriting commissions and expenses) that reflects a market capitalization (immediately prior to the public offering) of not less than US\$1,000,000,000 (the "Qualified Public Offering").

The Group determined that there were no beneficial conversion features ("BCF") identified for any of the Preferred Shares during any of the periods. In making this determination, the Company compared the fair value of the ordinary shares into which the Preferred Shares are convertible with the respective effective conversion price at the issuance date. In all instances, the effective conversion price was greater than the fair value of the ordinary shares. To the extent a conversion price adjustment occurs, as described above, the Group will reevaluate whether or not a beneficial conversion feature should be recognized.

Liquidation

In the event of any liquidation (unless waived by the preferred shareholders) including deemed liquidation, dissolution or winding up of the Company, holders of the Preferred Shares shall be entitled to receive a per share amount equal to one hundred percent (100%) of the original issue price on each Preferred Share, plus an amount representing an internal rate of return of twelve percent (12%) per annum on the original issue price as adjusted for share dividends, share splits, combinations, recapitalizations or similar events, plus all accrued and declared but unpaid dividends thereon, in the sequence of Series C Preferred Shares, Series B Preferred Shares and Series A Preferred Shares. After such liquidation amounts have been paid in full, any remaining funds or assets of the Company legally available for distribution to shareholders shall be distributed on a pro rata basis among the holders of the Preferred Shares, on an as-converted basis, together with the holders of the ordinary shares.

Accounting of preferred shares

The Preferred Shares are redeemable by the holders upon a liquidation event, including a deemed liquidation event (e.g., change in control), and as such are presented as mezzanine equity on the consolidated balance sheets. In accordance with ASC 480-10-S99, each issuance of the convertible preferred shares should be recognized at the date of issuance after deducting fair value allocated to the detachable warrants and issuance costs.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(All amounts in thousands, except for share and per share data, unless otherwise noted)

13. CONVERTIBLE PREFERRED SHARES (CONTINUED)

Accounting of preferred shares (continued)

The Company assesses whether an amendment to the terms of its convertible preferred shares is an extinguishment or a modification using the fair value model. When convertible preferred shares are extinguished, the difference between the fair value of the consideration transferred to the convertible preferred shareholders and the carrying amount of the convertible preferred shares (net of issuance costs) is treated as deemed dividends to the preferred shareholders. The Company considers that a significant change in fair value after the change of the terms to be substantive and thus triggers extinguishment. A change in fair value which is not significant immediately after the change of the terms is considered non-substantive and thus is subject to modification accounting.

The Company's convertible preferred shares activities for the years ended December 31, 2017 and 2018 are summarized below:

	Series A Shares			Series B Shares			Series C Shares		
	Number of shares	Amount US\$	Amount RMB	Number of shares	Amount US\$	Amount RMB	Number of shares	Amount US\$	Amount RMB
Balance as of January 1, 2017	5,141,587	11,282	74,742	—	—	—	—	—	—
Issuance of Series A Preferred Shares	16,723,646	42,645	289,024	—	—	—	—	—	—
Issuance of Series B Preferred Shares	—	—	—	15,894,594	52,546	346,515	—	—	—
Balance as of December 31, 2017	21,865,233	53,927	363,766	15,894,594	52,546	346,515	—	—	—
Issuance of Series A Preferred Shares upon exercise of Series A-3 Option	8,361,823	48,925	323,716	—	—	—	—	—	—
Issuance of Series B Preferred Shares upon exercise of Series B Option	—	—	—	7,394,189	44,083	291,677	—	—	—
Issuance of Series B Preferred Shares upon conversion of 2017 Notes	—	—	—	2,535,201	15,401	101,906	—	—	—
Issuance of Series B Preferred Shares upon Onshore Convertible Loans	—	—	—	1,179,379	7,165	47,407	—	—	—
Issuance of Series B Preferred Shares upon exercise of Tranche I of Series B Warrants	—	—	—	3,301,849	20,212	133,738	—	—	—

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(All amounts in thousands, except for share and per share data, unless otherwise noted)

13. CONVERTIBLE PREFERRED SHARES (CONTINUED)
Accounting of preferred shares (continued)

	Series A Shares			Series B Shares			Series C Shares		
	Number of shares	Amount US\$	Amount RMB	Number of shares	Amount US\$	Amount RMB	Number of shares	Amount US\$	Amount RMB
Issuance of Series C Preferred Shares, net of issuance costs	—	—	—	—	—	—	31,046,360	197,478	1,306,633
Balance as of December 31, 2018	<u>30,227,056</u>	<u>102,852</u>	<u>687,482</u>	<u>30,305,212</u>	<u>139,407</u>	<u>921,243</u>	<u>31,046,360</u>	<u>197,478</u>	<u>1,306,633</u>

14. CONVERTIBLE PROMISSORY NOTES AND ONSHORE CONVERTIBLE LOANS
2017 Notes

On September 25, 2017, the Company issued US\$11,520 convertible promissory notes (“2017 Notes”) to investors of Series B Preferred Shares (see Note 13) at a compound interest rate of 8% per annum, maturing on 36 months after the issuance date. Under the agreement, the holder of the 2017 Notes may convert the outstanding principal amount into Series B-1 Preferred Shares at the conversion price of US\$5.38 per share or a lower price as may be agreed by the investors and the Company at any time from six months prior to the maturity date and prior to the repayment in full of the 2017 Note. No interest shall be accrued if the 2017 Notes have been converted into Series B-1 Preferred Shares.

As the fair value of the Company’s ordinary shares on September 25, 2017 of US\$2.95 was lower than the effective conversion price of US\$5.38, the Company did not record a BCF.

On June 29, 2018, the Company’s 2017 Notes were converted into the Company’s 2,535,201 Series B-1 Preferred Shares at the nominal conversion price of US\$5.38 per share.

2018 Notes

On February 3, 2018, the Company issued US\$9,000 (equivalent to approximately RMB59,704) convertible promissory notes (“2018 Notes”) to an investor of Series A-3 Preferred Shares at an annual interest rate of 0%, maturing on 36 months after the issuance date. Under the agreement, the holder of the 2018 Notes may convert the 2018 Notes outstanding principal amount into Series B-1 Preferred Shares at the conversion price being lower of US\$10 per share and fair market value at any time prior to the maturity date. Alternatively, the 2018 Notes shall be automatically converted into the Company’s Series B Preferred Shares upon the maturity. As the fair value of the Company’s ordinary shares on February 3, 2018 of US\$3.96 was equal to the effective conversion price (being lower of US\$10 per share and fair market value), the Company did not record a BCF.

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14. CONVERTIBLE PROMISSORY NOTES AND ONSHORE CONVERTIBLE LOANS (CONTINUED)

Onshore Convertible Loans

On September 25, 2017, I-Mab Tianjin issued US\$5,359 convertible loans to Series B Onshore Investors at a compound interest rate of 8% per annum, maturing on 36 months after the issuance date. Under the agreement, the holder of the Onshore Convertible Loans may convert the outstanding principal amount into I-Mab Tianjin's equity interest at a stipulated conversion price at any time from 6 months prior to the maturity date and prior to the repayment in full of the Onshore Convertible Loans. No interest shall be accrued if the Onshore Convertible Loans have been converted into I-Mab Tianjin's equity interest. As the fair value of the I-Mab's ordinary shares on September 25, 2017 of US\$2.05 was lower than the effective conversion price of US\$4.31, the Company did not record a BCF.

In June and July 2018, the Company reached agreements with holders of Onshore Convertible Loans and the principal amount of Onshore Convertible Loans were then effectively converted into 1,179,379 Series B-1 Preferred Shares of the Company and the accrued interests were waived, resulting in an extinguishment loss of RMB8,548.

15. WARRANTS

In connection with the issuance of the Series A-1 and A-2 Preferred Shares on October 18, 2016, 2,246,744 Series A-3 Warrants were issued to Series A-1 and A-2 preferred shareholder, which provided the holder the right to purchase Series A-3 Preferred Shares. The Series A-3 Warrants were later terminated on September 6, 2017 without being exercised.

In connection with the issuance of the Series B Preferred Shares on September 22, 2017, 15,894,594 Series B Warrants were issued to Series B preferred shareholders, which provided the holders the right to purchase Series B-2 Preferred Shares.

In connection with the Company's Series B Onshore Financing that took place on September 25, 2017, 8,254,622 Series B Warrants were issued to Series B Onshore Investors, which provided the holders the right to purchase Series B-2 Preferred Shares.

During the period from June 29, 2018 to July 6, 2018, 3,301,849 Series B Warrants (representing Tranche I of Series B Warrants) were exercised to purchase 3,301,849 Series B-2 Preferred Shares with proceeds of US\$20,000 (equivalent to approximately RMB132,332).

On July 6, 2018, the Series B Warrants holders agreed that the Series B Warrants shall be divided into two tranches and exercisable in accordance with different time schedules, such that: (i) the holders have exercised part of the Series B Warrants in the total consideration of US\$20,000 ("Tranche I of Series B Warrants") and 3,301,849 Series B-2 Preferred Shares of the Company in aggregate have been newly issued to such holders on a pro rata basis; (ii) only when the Company fails to submit a Qualified Public Offering application at an internationally recognized securities exchange by March 31, 2019, the Warrant Holders may exercise the remaining part of Series B Warrants, in the total consideration of US\$30,000,000 ("Tranche II of Series B Warrants") and 4,952,773 Series B-2 Preferred Shares of the Company in aggregate will be issued to such holders on a pro rata basis; (iii) provided that the Company successfully submits a Qualified Public Offering application at an internationally recognized securities exchange by March 31, 2019, the holders shall unconditionally and irrevocably waive and cancel Tranche II of Series B Warrants; and (iv) the Tranche II of Series B Warrants may only be concurrently exercised by all the Warrant Holders in one lump. This is considered to be a modification to Series B Warrants.

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15. WARRANTS (CONTINUED)

According to the confirmations issued by the Company's Series B Warrants holders in July 2019, the holders of Series B Warrants has unconditionally and irrevocably waived and cancelled the Tranche II of Series B Warrants.

Accounting of warrants

The warrant is a freestanding instrument and is recorded as liability in accordance with ASC 480, *Distinguishing Liabilities from Equity*.

As the Company's issuance of warrants were bundled with other instruments (such as convertible preferred shares, convertible promissory notes, etc.), out of total considerations, the warrants are initially recognized at fair value and the remaining were allocated to other instruments on a relative fair value basis (if applicable). The fair value changes of the warrants (including the fair value changes arising from modification of warrants) up to the time of exercise or termination were recognized in earnings. Upon exercise, the total carrying value of the associated warrant liabilities was reclassified into the carrying value of the Preferred Shares into which it was converted.

The Company determined the fair value of the warrants with the assistance of an independent third party valuation firm.

The Group has measured the warrant liabilities at fair values on a recurring basis using significant unobservable inputs (Level 3) for the years ended December 31, 2017 and 2018. The Group used the binomial model to estimate the fair value of warrant liabilities using the following assumptions:

	As of December 31,	
	2017	2018
Risk-free rate of return	1.84%	2.49%
Maturity date	September 25, 2019	September 25, 2019
Estimated volatility rate	49.3%	50.9%
Exercise price	US\$6.06	US\$6.06
Fair value of underlying convertible preferred shares	US\$5.42	US\$6.91

The model requires the input of highly subjective assumptions including the risk-free rate of return, maturity date, estimated volatility rate and fair value of underlying preferred shares. The risk-free rate for periods within the contractual life is based on the US treasury strip bond with maturity similar to the maturity of the warrants as of valuation dates plus a China country risk premium. For expected volatilities, the Group has made reference to the historical daily stock prices volatilities of ordinary shares of several comparable companies in the same industry as the Group. The estimated fair value of the preferred shares was determined with assistance from an independent third party valuation firm. The Group's management is ultimately responsible for the determination of the estimated fair value of its preferred shares.

The significant unobservable inputs used in the fair value measurement of the warrant liabilities include risk-free rate of return, interval between valuation date and maturity date, estimated volatility rate and fair value of

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15. WARRANTS (CONTINUED)

Accounting of warrants (continued)

underlying preferred shares. Significant decreases in interval between valuation date and maturity date, estimated volatility rate and fair value of underlying preferred shares would result in a significantly lower fair value measurement. Significant increases in risk-free rate of return would result in a significantly lower fair value measurement.

16. REDEEMABLE NON-CONTROLLING INTERESTS

In connection with the Company's acquisition of Tasgen Group (see Note 3), on September 6, 2017, the Company also entered into an option agreement with the third party investor of I-Mab Tianjin, pursuant to which the Company granted the third party investor an option to subscribe for certain number of Series A-3 Preferred Shares of the Company at a price that stipulated in the agreement, and at the same time, the third party investor shall transfer its equity interests in I-Mab Tianjin to the Company at the same price ("Series A-3 Option"). This Series A-3 can be exercised at any time at the holder's own discretion or upon the request of the Company if the shareholders of the Company approve an initial public offering. In addition, in the event that the exercise of Series A-3 Option has not been completed within 6 months after the option holder delivers the share purchase option notice, the Company shall purchase the third party investor's equity interest in I-Mab Tianjin and the Series A-3 Option at a price that stipulated in the agreement.

Concurrently with the Company's issuance of Series B Preferred Shares (see Note 13), on September 25, 2017, the Group's subsidiary I-MAB Tianjin entered into a capital increase subscription agreement with Series B Onshore Investors, pursuant to which Series B Onshore Investors subscribed for additional equity in I-MAB Tianjin of US\$24,444 (equivalent to RMB161,196). On September 25, 2017 and in tandem with the aforementioned I-Mab Tianjin's capital increase subscription agreement, the Company also entered into option agreements with Series B Onshore Investors, pursuant to which the Company granted Series B Onshore Investors options to subscribe for certain numbers of Series B-1 Preferred Shares of the Company at a price that stipulated in the agreements, and at the same time, the Series B Onshore Investors shall transfer their equity interests in I-Mab Tianjin to the Company at the same price ("Series B Option"). The Series B Option can be exercised at any time at the holders' own discretion or upon the request of the Company if the shareholders of the Company approve an initial public offering. In addition, in the event that the exercise of Series B Option has not been completed within 6 months after the option holders deliver the share purchase option notice, the Company shall purchase the third party investor's equity interest in I-Mab Tianjin and the Series B Option at a price that stipulated in the agreements.

Based on the accounting assessments, the Company considers that the aforementioned Series A-3 and Series B Options are embedded features of the non-controlling interests that are not required to be bifurcated. Since the aforementioned non-controlling interests in I-Mab Tianjin are redeemable at a determinable price, upon occurrence of an event that is not solely within the control of I-Mab Tianjin, the aforementioned non-controlling interests in I-Mab Tianjin are accounted for as redeemable non-controlling interests in the Group's consolidated balance sheets. Subsequently, the redeemable non-controlling interests should be carried at the higher of (1) the carrying amount after the attribution of net income of the Company and (2) the expected redemption value.

The Series A-3 Option and Series B Option were exercised by respective holders on June 29, 2018 and July 6, 2018 to acquire 8,361,823 Series A-3 Preferred Shares and 7,394,189 Series B Preferred Shares, respectively. The transactions were accounted for as equity transactions, and the differences between the carrying amount of redeemable non-controlling interests of RMB305,708 and the fair value of convertible preferred shares of RMB615,393 that issued were recognized in additional paid-in capital.

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16. REDEEMABLE NON-CONTROLLING INTERESTS (CONTINUED)

The Group's redeemable non-controlling interest activities for the years ended December 31, 2017 and 2018 is summarized as follows:

	Year Ended December 31		
	2017	2018	
	RMB	RMB	US\$
Beginning balance	—	305,708	44,463
Capital injection by Series B Onshore Investors	161,196	—	—
Redeemable non-controlling interests arising from business combination (Note 3)	144,512	—	—
Exercise of Series A-3 Option	—	(144,512)	(21,018)
Exercise of Series B Option	—	(161,196)	(23,445)
Ending balance	<u>305,708</u>	<u>—</u>	<u>—</u>

17. SHARE-BASED COMPENSATION

(a) Restricted shares

During the year ended December 31, 2016, the Company issued 4,019,554 ordinary shares to Mr. Zang Jingwu Zhang, Ms. Qian Lili, Mr. Wang Zhengyi and Mr. Fang Lei (collectively the "Founders"), including the 369,301 shares which represented the equity interests of Third Venture held by the Founders, and the Company recorded share-based compensation expense of RMB18.7 million for issuance and grant of 3,650,253 ordinary shares to the Founders in June 2016.

In October 2016, the Founders entered into an arrangement with other investors of the Company, and the 87,441 ordinary shares issued to the Founders in June 2016 were canceled and out of the remaining 3,932,113 ordinary shares held by the Founders, 70% became restricted and subject to service vesting conditions, that shall vest 20%, 20% and 30% over the next three years, respectively. There shall be no acceleration of the vesting schedule except that, in case of a change of control of the Company or a Qualified Public Offering, or the termination of the Founder's employment with the Group without cause.

Deferred share-based compensation was measured for the restricted shares using the estimated fair value of the Company's ordinary shares of US\$0.77 at the date of imposition of the restriction in October 2016, and was amortized to the consolidated statements of comprehensive loss by using graded vesting method over the vesting term of 3 years.

The following table summarizes the Group's Founders' restricted shares activities:

	Numbers of shares	Weighted-average grant date fair value
Outstanding at December 31, 2016	2,752,479	0.77
Vested	(786,423)	
Outstanding at December 31, 2017	1,966,056	0.77
Vested	(786,423)	
Outstanding at December 31, 2018	<u>1,179,633</u>	0.77

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17. SHARE-BASED COMPENSATION (CONTINUED)*(a) Restricted shares (continued)*

The amounts of share-based compensation expense in relation to the restricted shares recognized in the years ended December 31, 2017 and 2018 were RMB7,039 and RMB3,520, respectively.

Share-based compensation expenses related to restricted shares were included in:

	Year Ended December 31,		
	2017	2018	
	RMB	RMB	US\$
Research and development expenses	2,112	1,056	154
Administrative expenses	4,927	2,464	358
	<u>7,039</u>	<u>3,520</u>	<u>512</u>

(b) 2017 Employee Stock Option Plan ("2017 Plan")

In October 2017, the Company adopted the 2017 Plan. Under the 2017 Plan, a maximum aggregate number of 13,376,865 shares that may be issued pursuant to all awards granted were approved. Stock options granted to an employee under the 2017 Plan will be exercisable upon the Company completes a listing and the employee renders service to the Company in accordance with a stipulated service schedule starting from the employee's date of employment. Employees are generally subject to a three-year service schedule, under which an employee earns an entitlement to vest in 50% of the option grants on the second anniversary of the grant date, a vesting of the remaining 50% on the third anniversary of the applicable grant date. The stock option under 2017 Plan, to the extent then vested, shall become exercisable only upon the earlier of (i) a listing, and (ii) occurrence of a change in control.

Prior to the Company completes a listing, all stock options granted to an employee shall be forfeited at the time the employee terminates his employment with the Group. After the Company completes a listing, vested options not exercised by an employee shall be exercised until later of: (i) 90 days after the date when the options become exercisable, or (ii) 30 days after the date of cessation of employment or directorship, or such longer period as the Board of Directors may otherwise determine.

The Group granted 10,646,783 and 1,470,000 stock options to employees, all with an exercise price of US\$1, for the years ended December 31, 2017 and 2018, respectively. No options are exercisable as of December 31, 2017 and 2018 and prior to the Group completes a listing.

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17. SHARE-BASED COMPENSATION (CONTINUED)

(b) 2017 Employee Stock Option Plan (“2017 Plan”) (continued)

The following table sets forth the stock options activities for the years ended December 31, 2017 and 2018:

	Number of shares	Weighted average exercise price US\$	Weighted average remaining contractual term	Aggregate intrinsic value US\$
Outstanding as of December 31, 2016	—	—	—	—
Granted	11,051,230	—	—	—
Other addition (note)	710,366	—	—	—
Outstanding as of December 31, 2017	11,761,596	1.00	8.50	4,890
Granted	1,470,000	—	—	—
Forfeited	(226,000)	—	—	—
Outstanding as of December 31, 2018	13,005,596	1.00	8.61	10,129
Exercisable as of December 31, 2018	—	—	—	—

note: Other addition represented the modified share options that originally granted to two senior management employees in October 2016 (see (c) Other share-based compensation)

Stock options granted to the employees were measured at fair value on the dates of grant using the Binomial Option Pricing Model with the following assumptions:

	Year ended December 31,	
	2017	2018
Expected volatility	62.34%	61.32%-62.13%
Risk-free interest rate (per annum)	2.32%	2.81%-3.06%
Exercise multiple	2.8	2.8
Expected dividend yield	—	—
Contractual term (in years)	10	10

The expected volatility was estimated based on the historical volatility of comparable peer public companies with a time horizon close to the expected term of the Group’s options. The risk-free interest rate was estimated based on the yield to maturity of U.S. treasury bonds denominated in US\$ for a term consistent with the expected term of the Group’s options in effect at the option valuation date. The expected exercise multiple was estimated as the average ratio of the stock price to the exercise price when employees would decide to voluntarily exercise their vested options. As the Group did not have sufficient information of past employee exercise history, it was estimated by referencing to a widely-accepted academic research publication. Expected dividend yield is zero as the Group has never declared or paid any cash dividends on its shares, and the Group does not anticipate any dividend payments in the foreseeable future. Expected term is the contract life of the option.

The fair value of stock options granted to employees for the years ended December 31, 2017 and 2018 amounted to RMB99.0 million and RMB45.2 million, respectively. Since the exercisability is dependent upon the listing, and it is not probable that this performance condition can be achieved until a listing, no share-based compensation expense relating to the 2017 Plan was recorded for the years ended December 31, 2017 and 2018. The Group will recognize compensation expenses relating to options vested cumulatively upon the completion of the Company’s listing.

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17. SHARE-BASED COMPENSATION (CONTINUED)

(c) Other share-based compensation

For the year ended December 31, 2016, the Group recorded share-based compensation expense of RMB3.3 million for issuance and grant of 710,366 stock options to two senior management employees in October 2016, as rewards for their services they had performed in the past and in exchange for their full-time devotion and professional expertise. Stock options granted to the two employees were exercisable once granted, with an exercise price of US\$0.06.

In October 2017, in connection with the adoption of 2017 Plan, the Group amended the stock option agreement with the two aforementioned employees, under which the stock options would become exercisable only upon the earlier of (i) a listing, and (ii) occurrence of a change in control that defined in the stock option agreements. As the modification of terms and conditions of share-based compensation were not beneficial to its employees, no further accounting impact was resulting from it.

18. LICENSING AND COLLABORATION ARRANGEMENTS

The following is a description of the Group's significant licensing and collaboration agreements entered into for the years ended December 31, 2017 and 2018.

A. In-Licensing Arrangements

Licensing Agreement with MorphoSys AG ("MorphoSys")

In November 2017, the Group entered into a license and collaboration agreement with MorphoSys, with respect to the development and commercialization of MOR202/TJ202, MorphoSys's proprietary investigational antibody against CD38 (the "CD38 product").

Under this agreement, MorphoSys granted to the Group an exclusive, royalty-bearing, sublicensable license to exploit MOR202/TJ202 for any human therapeutic or diagnostic purpose in the licensed territory, namely mainland China, Hong Kong, Macau and Taiwan (collectively "Greater China").

Pursuant to this agreement, the Group granted to MorphoSys an exclusive license to its rights in any inventions that the Group make while exploiting the CD38 product under this agreement, solely to exploit the CD38 product outside of Greater China.

Pursuant to this agreement, the Group paid to MorphoSys an upfront license fee of US\$20.0 million (equivalent to approximately RMB132.7 million). The Group also agreed to make milestone payments to MorphoSys, conditioned upon the achievement of certain development, regulatory and commercial milestones, in the aggregate amount of US\$98.5 million (equivalent to approximately RMB653.5 million). Such milestones include first patient dosed in human clinical trials, marketing approval, and first annual net sales of CD38 products covered by the agreement in excess of a certain amount.

In addition, the Group is required to pay tiered low-double-digit royalties to MorphoSys on a country-by-country and product-by-product basis during the term, commencing with the first commercial sale of a relevant licensed product in Greater China. Unless terminated earlier in accordance with the terms thereof, this agreement will remain in effect until the expiration of the Group's last payment obligation under the agreement.

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18. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

A. In-Licensing Arrangements (continued)

For the year ended December 31, 2017, the Group paid a US\$20.0 million (equivalent to approximately RMB132.7 million) upfront fee to MorphoSys, which was recorded as research and development expense in the consolidated statements of comprehensive loss. Due to the uncertainty involved in meeting these development and commercialization based targets, the Group evaluated and concluded that the remaining milestones are still not probable as of December 31, 2017 and 2018.

Summarized financial information related to the above agreement is presented below:

	Years Ended December 31,			Amortization of prepaid research and development	As of
	Research and Development Expense				December 31,
	Upfront Fees	Milestones	Extension/ Termination of agreements		Intangible asset balance
2018	—	—	—	—	—
2017	US\$20,000	—	—	—	—

Licensing Agreement with Genexine, Inc. (“Genexine”)

In December 2017, the Group entered into an intellectual property license agreement with Genexine with respect to GX-I7/TJ107, a long-acting IL-7 cytokine. Under this agreement, the Group obtained an exclusive, sublicensable and transferable license to use and otherwise exploit certain intellectual property in connection with the pre-clinical and clinical development, manufacturing, sale and distribution of GX-I7 to treat cancer in Greater China.

Under the terms of the agreement, the Group made an upfront payment of US\$12.0 million (equivalent to approximately RMB79.6 million) to Genexine which was recorded as a research and development expense in 2018. The Group also agreed to make milestone payments in the aggregate amount of US\$23.0 million (equivalent to approximately RMB152.6 million), conditioned upon the achievement of certain development milestones, including completion of Phase 2 and Phase 3 clinical studies and new drug application (“NDA”) or biologic license application (“BLA”) approval in Greater China.

Further, the Group agreed to make milestone payments in the aggregate amount of US\$525.0 million (equivalent to approximately RMB3,482.7 million), conditioned upon the achievement of certain cumulative net sales of GX-I7 up to US\$2,000 million. The Group also is required to pay Genexine a low-single-digit percentage royalty in respect of the total annual net sales of GX-I7. The aforesaid milestones and royalties (other than the upfront payment) will be reduced by 50% following the entry of a generic version of GX-I7 in China, Hong Kong, Macau and Taiwan without the consent or authorization of us or any of our sublicensees.

Unless terminated earlier in accordance with the terms thereof, this agreement will remain in effect until the later of (i) the expiry of the last to expire patent of the licensed intellectual property that includes a valid claim for Greater China and that covers the composition of GX-I7; and (ii) 15 years from the date of the first commercial sale of GX-I7.

For the year ended December 31, 2018, the Group paid a US\$12.0 million (equivalent to approximately RMB79.6 million) upfront fee to Genexine, which was recorded as research and development expense in the consolidated statements of comprehensive loss. Due to the uncertainty involved in meeting these development and commercialization based targets, the Group evaluated and concluded that the remaining milestones are still not probable as of December 31, 2018.

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18. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

A. In-Licensing Arrangements (continued)

Summarized financial information related to the above agreement is presented below:

	Years Ended December 31,				As of
	Research and Development Expense				December 31,
	Upfront Fees	Milestones	Extension/ Termination of agreements	Amortization of prepaid research and development	Intangible asset balance
2018	<u>US\$12,000</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>

Licensing Agreement with MorphoSys

In November 2018, the Group entered into a license and collaboration agreement with MorphoSys for MorphoSys’s proprietary antibody (MOR210/TJ210) directed against C5aR (the “C5aR Agreement”). Under this agreement, the Group obtained an exclusive, royalty-bearing license to explore, develop and commercialize certain anti-C5aR antibodies in Greater China and South Korea.

The Group will perform and fund all global development activities related to the development of MOR210/TJ210 in Greater China and South Korea, including all relevant clinical trials (including in the U.S. and China) and all development activities required for IND filing in the US as well as CMC development of manufacturing processes. MorphoSys retains rights in respect of development and commercialization of MOR210/TJ210 in the rest of the world.

Under the terms of the agreement, the Group also agreed to make milestone payments conditioned upon the achievement of certain development milestones and certain annual net sales of anti-C5aR antibodies. The Group is also required to pay to MorphoSys tiered mid-single-digit royalties on annual net sales of anti-C5aR antibody products within the licensed territory.

For the year ended December 31, 2018, the Group paid a US\$3.5 million (equivalent to approximately RMB23.2 million) upfront fee to MorphoSys, which was recorded as research and development expense in the consolidated statements of comprehensive loss. Due to the uncertainty involved in meeting these development and commercialization based targets, the Group evaluated and concluded that the remaining milestones are still not probable as of December 31, 2018.

Summarized financial information related to the above agreement is presented below:

	Years Ended December 31,				As of
	Research and Development Expense				December 31,
	Upfront Fees	Milestones	Extension/ Termination of agreements	Amortization of prepaid research and development	Intangible asset balance
2018	<u>US\$3,500</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>

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18. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

A. In-Licensing Arrangements (continued)

Other In-Licensing Arrangements

In addition to the above arrangements, the Group has entered into other various in-licensing and collaboration agreements with third party licensors to develop and commercialize drug candidates. Based on the terms of these agreements the Group is contingently obligated to make additional material payments upon the achievement of certain contractually defined milestones. The Group made US\$0.6 million (equivalent to approximately RMB4.0 million) upfront and US\$0.3 million (equivalent to approximately RMB2.0 million) milestone payment under these agreements for the year ended December 31, 2018. Under the terms of the agreements, the licensors are eligible to receive from the Group up to an aggregate of approximately US\$164.4 million (equivalent to approximately RMB1,090.6 million) in milestone payments upon the achievement of contractually specified development milestones, such as regulatory approval for the drug candidates, which may be before the Group has commercialized the drug or received any revenue from sales of such drug candidate, which may never occur.

B. Out-Licensing and collaboration Arrangements

Licensing Agreement among HDYM, I-Mab and Hangzhou HealSun Biopharm Co., Ltd. (“HealSun”)

In April 2017, one of the Company’s subsidiaries, I-Mab Shanghai, entered into a technology transfer agreement with HDYM and HealSun with respect to anti-PD-L1 humanized monoclonal antibodies. Under the agreement, I-Mab Shanghai agreed to grant to HDYM exclusive, worldwide and sublicenseable rights to develop, manufacture, have manufactured, use, sell, have sold, import, or otherwise exploit certain PD-L1 related patents, patent applications, know-hows, data and information of I-Mab Shanghai, relevant cell lines as well as any anti-PD-L1 monoclonal antibody arising from such cell lines for the treatment of diseases. Further, I-Mab Shanghai and its cooperative party, HealSun agreed to provide subsequent research and development services on such intellectual property to HDYM, including the selection and examination of innovative anti-PD-L1 humanized monoclonal antibodies, cultivation and selection of stable cell lines, establishment of cell bank, research and development of manufacturing processes and preparation of samples, toxicological and pharmacological testing, pre-clinical pharmaceutical experiment report drafting, and application for and registration of clinical trials. HDYM agreed to make milestone payments conditioned upon achieving certain contractually defined milestones.

The Group determined that this collaboration is more reflective of a vendor-customer relationship and therefore within the scope of ASC 606. Under this agreement, due to the early stage nature of the development, the Group determined the license to the intellectual property and research and development services are not distinct and thus were accounted for as a single performance obligation that is satisfied over time. The Group would receive RMB51.0 million (inclusive of VAT) milestone payments under this agreement, and considered that the achievements of milestone II, III, IV are constrained such that the transaction price shall initially only include the milestones payment which have been achieved (that means when uncertainty associated with the variable consideration is subsequently resolved), the additional milestone payment shall be included in the total transaction price when it is no longer probable that a significant reversal of cumulative revenue would occur in future periods.

The Group used a cost-to-cost input method to measure progress as that method best depicts its performance under the agreement. For the year ended December 31, 2017, the Group achieved milestones I and II and received milestone payments totalling of RMB29.0 million (inclusive of VAT). The cumulative percentage complete in the cost-to-cost input method related to this agreement as of December 31, 2017 is estimated to

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18. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

B. Out-Licensing and collaboration Arrangements (continued)

approximate 42%, the Group recognized RMB11.6 million (exclusive of VAT of RMB0.7 million) of revenue in the consolidated statements of comprehensive loss, and RMB15.8 million (exclusive of VAT of RMB0.9 million) were deferred as contract liability related to this arrangement.

For the year ended December 31, 2018, the Group achieved milestones III and IV and received milestone III payment of RMB11.0 million (inclusive of VAT), and the milestone IV payment of RMB11.0 million (inclusive of VAT) was received in June 2019 and recognized as contract assets. As of December 31, 2018, the cumulative percentage complete in the cost-to cost input method related to this arrangement is estimated to approximate 100%. The Group recognized RMB36.5 million (exclusive of VAT of RMB1.3 million) of revenue in the consolidated statements of comprehensive loss for the year ended December 31, 2018.

Collaboration Agreement with Everest Medicines Limited (“Everest”)

In January 2018, the Group entered into a collaboration agreement with Everest, which is controlled by the ultimate controlling party of a principal shareholder of the Group. Under the agreement, both parties agreed to collaborate on programs to co-develop MorphoSys’ proprietary anti-CD38 antibody for all indications in hematologic oncology and commercialize of MOR202/TJ202 in Greater China.

A joint steering committee with equal representation from each party was established to coordinate and oversee the development and commercialization of the CD38 product. All decisions of the joint steering committee shall be made by unanimous vote.

Under the agreement, the Group is primarily responsible for carrying out the development, manufacture and supply of the CD38 product, as well as seeking regulatory approval of the CD38 product. Everest is primarily responsible for sharing the development costs of the CD38 product, including payments due to MorphoSys under the Licensing Agreement, dated November 30, 2017, in the proportion of 75% by Everest and 25% by the Group.

The joint steering committee will decide which party shall be responsible for conducting the commercialization of the CD38 product pursuant to the commercialization plan approved by the committee. If Everest is selected to be responsible for commercialization, the Group shall grant an exclusive royalty-free license to Everest to commercialize the CD38 product for all indications in hematologic oncology in Greater China.

The Group and Everest will share the profit and loss and out-license revenue derived from the CD 38 product in proportion to the costs that each party incur in developing the product.

Upon any termination of this arrangement, the terminating party has the right to continue the development and commercialization of CD38 product. If Everest is the rightful terminating party, the Group shall (i) assign the MorphoSys license to Everest (subject to the terms and conditions of such license); (ii) grant to Everest an exclusive license to all intellectual property rights that the Group owns or controls to further develop, manufacture, and commercialize the CD38 product; (iii) transfer the development, manufacture and commercialization of the CD38 product to Everest. The terminating party shall be solely responsible for the cost and expense of such development and commercialization after termination. In the event that such continuing party successfully develops and commercializes the CD38 product, it shall pay to the other party a percentage of the product profit and out-license revenue generated therefrom in accordance with the terms of this agreement.

The US\$26.0 million (equivalent to approximately RMB178.7 million) in aggregate proceeds from Everest under the agreement represented the full funding available under the agreement, and was recorded as a research and

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(All amounts in thousands, except for share and per share data, unless otherwise noted)

18. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

B. Out-Licensing and collaboration Arrangements (continued)

development funding received liability on the consolidated balance sheet as of December 31, 2018, in accordance with ASC 730, Research and Development. Because there is a significant related party relationship between the Company and Everest, the Company is treating its obligation to make payments under the commercialization stage as an implicit obligation to repay the funds advanced by Everest (see Note 28).

Licensing Agreement with ABL Bio

In July 2018, the Group entered into a license and collaboration agreement with ABL Bio, under which the Group granted to ABL Bio exclusive, worldwide (excluding Greater China), royalty-bearing rights to develop and commercialize a bispecific antibodies (“BsAbs”).

The Group agreed to share costs fifty-fifty (50:50) with ABL Bio through the completion of in vivo studies, with ABL Bio responsible for all costs and activities following that time.

In consideration of the license, ABL Bio agreed to pay the Group an upfront fee of US\$2.5 million (equivalent to approximately RMB17.2 million), and milestone payments in the aggregate amount of US\$97.5 million (equivalent to approximately RMB646.8 million) conditioned upon achieving certain research, clinical development and sales milestones. These include research milestones of up to US\$2.5 (equivalent to approximately RMB17.2) million, clinical milestones of up to US\$30 million (equivalent to approximately RMB199.0 million) and sales milestones of up to US\$65 million (equivalent to approximately RMB431.2 million). Further, ABL Bio agreed to pay the Group royalties at mid-single-digit percentages in respect of the total annual net sales of the licensed BsAbs product.

In addition, ABL Bio granted to the Group an exclusive, royalty-free, sublicensable license to use the BsAbs technology solely to exploit the licensed BsAbs product for all indications in Greater China.

The Group determined that this collaboration is more reflective of a vendor-customer relationship and therefore within the scope of ASC 606. Under this agreement, the only one performance obligation was to grant the BsAbs license to ABL, considering that the achievements of milestones are constrained such that the transaction price shall initially only include upfront payment and subsequently, once another milestone was achieved (that means when uncertainty associated with the variable consideration is subsequently resolved), the additional milestone payment shall be included in the total transaction price when it is no longer probable that a significant reversal of cumulative revenue would occur in future periods.

As of December 31, 2018, no milestone has been achieved, and the Group recognized revenue of US\$2.5 million (equivalent to RMB17.2 million) of revenue in the consolidated statements of comprehensive loss, which was upfront fee related to the grant of the rights of BsAbs to ABL Bio as mentioned above.

Collaboration Agreement with ABL Bio

In July 2018, the Group and ABL Bio entered into a collaboration agreement (the “ABL Bio Collaboration”) whereby both parties agreed to collaborate to develop three PD-L1 based bispecific antibodies by using ABL Bio’s proprietary BsAb technology and commercialize them in their respective territories, which, collectively, include Greater China and South Korea, and other territories throughout the rest of the world if both parties agree to do so in such other territories during the performance of the agreement.

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(All amounts in thousands, except for share and per share data, unless otherwise noted)

18. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

B. Out-Licensing and collaboration Arrangements (continued)

At contract inception, as both I-Mab and ABL participate actively in the research and development activity. Also, they share the risk of failure of the bio-sequence products and share the income of licensing, so this contract meet the criteria of the definition of a collaborative arrangement, the Group categorized this agreement within the scope ASC 808. Prior to commercialization, the Group recorded the share of the expenses incurred by the collaboration for the development of three PD-L1 based bispecific antibodies products in research and development expense in the consolidated statements of comprehensive loss. For the year ended December 31, 2018, RMB1.0 million expenses were incurred by the Group and ABL did not incurred any expenses. According to the terms set out in the agreement, the Group recorded RMB0.5 million (50% cost sharing) of expenses in the Group's consolidated statements of comprehensive loss for the year ended December 31, 2018.

Collaboration Agreements with Tracon Pharmaceuticals, Inc. ("Tracon")

In November 2018, the Group entered into collaboration agreements with Tracon, under which both parties agreed to co-develop the Group's proprietary CD73 antibody, TJD5 (the "TJD5 Agreement") and co-develop up to five BsAbs (the "BsAbs Agreement").

Given the early preclinical stage of development of these assets as of December 31, 2018, there was no significant financial impact to the Group for the year ended December 31, 2018.

Licensing Agreement with CSPC Pharmaceutical Group Limited ("CSPC")

In December 2018, the Group entered into a product development agreement with CSPC. The Group granted to CSPC exclusive, non-transferable, non-irrevocable and sublicensable rights in the PRC (excluding Hong Kong, Macau and Taiwan) to develop and commercialize TJ103 for treating type 2 diabetes.

CSPC is responsible for developing, obtaining market approval and commercializing the licensed products. The Group is responsible for transferring the manufacturing technology of the licensed products to CSPC and assisting CSPC in the continued optimization of such manufacturing technology thereafter.

In consideration of the license, CSPC agreed to pay the Group an upfront fee of RMB15.0 million (inclusive of VAT) and milestone payments in an aggregate amount of RMB135.0 million conditioned upon achieving certain clinical development and regulatory approval milestones. In addition, the Group is also entitled to royalties of up to low-double-digit percentages in respect of the total annual net sales of the products after its commercialization in the PRC.

The Group determined that this collaboration is more reflective of a vendor-customer relationship and therefore within the scope of ASC 606. Under this agreement, the only one performance obligation was to grant TJ103 license to CSPC. considering that the achievements of milestones are constrained such that the transaction price shall initially only include upfront payment and subsequently, once another milestone was achieved (that means when uncertainty associated with the variable consideration is subsequently resolved), the additional milestone payment shall be included in the total transaction price when it is no longer probable that a significant reversal of cumulative revenue would occur in future periods. As of December 31, 2018, RMB14.2 million upfront fee received and was recorded as advance from customers in the consolidated balance sheets. The license was approved by china intellectual property office subsequently in June 2019, and accordingly, RMB14.2 million (inclusive of VAT) was recognized as revenue in the consolidated statements of comprehensive loss.

I-MAB**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

(All amounts in thousands, except for share and per share data, unless otherwise noted)

19. OTHER INCOME (EXPENSES), NET

The following table summarizes other income (expense) recognized for the years ended December 31, 2017 and 2018:

	Notes	Year Ended December 31		
		2017 RMB	2018 RMB	US\$
Loss from conversion of 2017 Notes	14	—	(18,375)	(2,673)
Loss from conversion of Onshore Convertible Loans	14	—	(8,548)	(1,243)
Loss from issuance of 2018 Notes	14	—	(5,081)	(740)
Income from other financial assets		5,572	13,622	1,981
Net foreign exchange gains (losses)		(3,873)	742	108
Subsidy income		—	750	109
Others		(172)	110	17
		<u>1,527</u>	<u>(16,780)</u>	<u>(2,441)</u>

20. NET LOSS PER SHARE

Basic and diluted net loss per share for each of the years presented are calculated as follows:

	Year Ended December 31		
	2017 RMB	2018 RMB	US\$ (Note 2.5)
	(in thousands, except for loss per shares)		
Numerator:			
Net loss attributable to ordinary shareholders	(298,240)	(402,833)	(58,588)
Denominator:			
Weighted average number of ordinary shares outstanding - basic and diluted	<u>5,742,669</u>	<u>6,529,092</u>	<u>6,529,092</u>
Net loss per share - basic and diluted	<u>(51.93)</u>	<u>(61.70)</u>	<u>(8.97)</u>

For the years ended December 31, 2017 and 2018, the effects of all outstanding convertible preferred shares, convertible promissory notes and restricted shares have also been excluded from the computation of diluted loss per share for the years ended December 31, 2017 and 2018 as their effects would be anti-dilutive.

For the year ended December 31, 2018, the Company has the dilutive potential stock options. Share options which can not be exercised until the Company completes its listing are not included in the computation of diluted earnings per shares as such contingent event had not taken place.

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(All amounts in thousands, except for share and per share data, unless otherwise noted)

20. NET LOSS PER SHARE (CONTINUED)

The potentially dilutive securities that have not been included in the calculation of diluted net loss per share as their inclusion would be anti-dilutive are as follows:

	Year Ended December 31	
	2017	2018
Convertible preferred shares	14,811,182	64,389,968
Convertible promissory notes	673,738	—
Restricted shares	414,429	181,504

21. EMPLOYEE BENEFITS

Full time employees of the Group in the PRC participate in a government mandated defined contribution plan, pursuant to which certain pension benefits, medical care, employee housing fund and other welfare benefits are provided to the employees. Chinese labor regulations require that the PRC subsidiaries of the Group make contributions to the government for these benefits based on certain percentage of the employees' salaries, up to a maximum amount specified by the government. The Group has no legal obligation for the benefits beyond the contribution made. The total amounts charged to the consolidated statements of comprehensive loss for such employee benefits amounted to approximately RMB5,120 and RMB9,294 for the years ended December 31, 2017 and 2018.

22. COMMITMENTS AND CONTINGENCIES*Operating lease commitments*

The Group leases offices under non-cancelable operating lease agreements. Future minimum lease payments under non-cancelable operating lease agreements with initial terms of one year or more consist of the following:

	As of December 31, 2018	
	RMB	US\$ (Note 2.5)
No later than 1 year	5,754	837
Later than 1 year and no later than 2 years	8,785	1,278
Later than 2 years and no later than 5 years	120	17
Later than 5 years	276	40
	<u>14,935</u>	<u>2,172</u>

The total amounts charged to the consolidated statements of comprehensive loss for rental expense amounted to approximately RMB3,127 and RMB4,659 for the years ended December 31, 2017 and 2018, respectively.

Capital commitments

	As of December 31,		
	2017	2018	
	RMB	RMB	US\$ (Note 2.5)
Property, equipment and software			
Leasehold improvements	<u>408</u>	<u>—</u>	<u>—</u>

I-MAB**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

(All amounts in thousands, except for share and per share data, unless otherwise noted)

22. COMMITMENTS AND CONTINGENCIES (CONTINUED)*Contingencies*

The Group is a party to or assignee of license and collaboration agreements that may require it to make future payments relating to milestone fees and royalties on future sales of licensed products (Note 18).

The Group did not have significant capital and other commitments, long-term obligations, or guarantees as of December 31, 2017 and 2018.

23. RELATED PARTY BALANCES AND TRANSACTIONS

The table below sets forth the major related parties and their relationships with the Group as of December 31, 2017 and 2018:

Name of related parties	Relationship with the Group
Everest	Controlled by the ultimate controlling party of a principal shareholder of the Group
CMAB Biopharma (Suzhou) Inc.	Controlled by the ultimate controlling party of a principal shareholder of the Group

Details of related party balance as of December 31, 2017 and 2018 are as follows:

Research and development funding received

	As of December 31,		
	2017 RMB	2018 RMB	US\$ (Note 2.5)
Everest (Note 18)	—	178,715	25,993

Details of related party transaction for the years ended December 31, 2017 and 2018 are as follows:

Receipt of CRO services - recognized in research and development expenses

	For the year ended December 31,		
	2017 RMB	2018 RMB	US\$ (Note 2.5)
CMAB Biopharma (Suzhou) Inc.	—	2,786	405

24. CONCENTRATION OF CREDIT RISK

Financial instruments that are potentially subject to significant concentration of credit risk consist of cash and cash equivalents, restricted cash, other financial assets, contract assets and other receivables. The carrying amounts of cash and cash equivalents, restricted cash and other financial assets represent the maximum amount of loss due to credit risk. As of December 31, 2017 and 2018, all of the Group's cash and cash equivalents and restricted cash were held by major financial institutions located in the PRC and international financial institutions outside of the PRC which management believes are of high credit quality and continually monitors the credit

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(All amounts in thousands, except for share and per share data, unless otherwise noted)

24. CONCENTRATION OF CREDIT RISK (CONTINUED)

worthiness of these financial institutions. With respect to the contract assets, other receivables and other financial assets, the Group performs on-going credit evaluations of the financial condition of its customers and counterparties.

25. SUBSEQUENT EVENTS

- (a) On February 22, 2019, the Group adopted the 2018 equity incentive plan (“2018 Plan”). Under 2018 Plan, the maximum aggregate number of ordinary shares which may be issued pursuant to all awards is 14,005,745, subject to further amendment. If the Group successfully lists on an internationally recognized securities exchange for a Qualified Public Offering by December 31, 2019, the maximum aggregate number of ordinary shares which may be issued shall be 15,452,620. Accordingly, 10,893,028 stock options granted to the Group’s Chief Executive Officer under 2018 Plan were fully vested and exercisable upon the adoption of 2018 Plan.

On February 22, 2019, the amendment and restated 2017 equity incentive plan was approved by the Board of Directors of the Company, pursuant to which 3,435,215 stock options held by the Group’s Chief Executive Officer under the 2017 equity incentive plan became fully vested and exercisable on February 22, 2019.

In addition, the Group repurchased 3,890,155 stock options held by the Group’s Chief Executive Officer, including 3,435,215 stock options under the amendment and restated 2017 equity incentive plan and 454,940 stock options under the 2018 equity incentive plan, at the total consideration of US\$21,902 (equivalent to approximately RMB148,308).

In July 2019, the Group granted 647,269 stock options and 3,112,717 stock options to the employees under 2017 Plan and 2018 Plan, respectively.

- (b) On July 25, 2019, the Group entered into a share purchase agreement with certain third party investors, under which these investors will subscribe for an aggregate of 3,857,143 Series C-1 convertible preferred shares of the Company for an aggregate purchase price of US\$27.0 million. Up to the issuance of these consolidated financial statements, this transaction has not been consummated.
- (c) According to the confirmations issued by the Company’s Series B Warrants holders in July 2019, the holders of Series B Warrants has unconditionally and irrevocably waived and cancelled the Tranche II of Series B Warrants.
- (d) In July, 2019, the Group entered into an in-licensing and collaboration agreement with MacroGenics, Inc. for development and commercialization of an Fc-optimized antibody known as enoblituzumab that targets B7-H3, including in combination with other agents, such as the anti-PD-1 antibody known as MGA012, in Greater China.

26. UNAUDITED PRO FORMA BALANCE SHEETS AND NET LOSS PER SHARE

The unaudited pro forma balance sheet information as of December 31, 2018 assumes the automatic conversion of all of the outstanding Preferred Shares into ordinary shares at a conversion ratio of 1:1 and forfeiture of Tranche II of Series B Warrants, as if the conversion and expiry had occurred as of December 31, 2018.

The unaudited pro forma net loss per ordinary share is computed using the weighted-average number of ordinary shares outstanding and assumes forfeiture of Tranche II of Series B Warrants and the automatic conversion of

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(All amounts in thousands, except for share and per share data, unless otherwise noted)

26. UNAUDITED PRO FORMA BALANCE SHEETS AND NET LOSS PER SHARE (CONTINUED)

all of the Group's outstanding mezzanine equity into ordinary shares upon the closing of the Group's Qualified Public Offering, as if it had occurred on January 1, 2018. The Group believes the unaudited pro forma net loss per share provides material information to investors, as the automatic conversion of the Group's outstanding mezzanine equity and forfeiture of Tranche II of Series B Warrants. The disclosure of pro forma net loss per ordinary share provides an indication of net loss per ordinary share that is comparable to what will be reported by the Group as a public company following the closing of the Qualified Public Offering.

The following table summarizes the unaudited pro forma net loss per share attributable to ordinary shareholders:

	For the year ended December 31, 2018	
	RMB	US\$
	(in thousands, except for loss per shares)	
Numerator		
Net loss attributable to ordinary shareholders	(402,833)	(58,588)
Add back fair value change of Tranche II of Series B Warrants (Note 15)	(33,881)	(4,928)
Numerator for pro-forma basic and diluted net loss per share	(436,714)	(63,516)
Denominator		
Weighted average number of ordinary shares outstanding	6,529,092	6,529,092
Pro-forma effect of the conversion of Series A Preferred Shares	26,103,417	26,103,417
Pro-forma effect of the conversion of Series B Preferred Shares	23,146,134	23,146,134
Pro-forma effect of the conversion of Series C Preferred Shares	15,140,417	15,140,417
Denominator for pro-forma basic and diluted net loss per share	70,919,060	70,919,060
Pro-forma net loss per share:		
- Basic	<u>(6.16)</u>	<u>(0.90)</u>
- Diluted	<u>(6.16)</u>	<u>(0.90)</u>

The unaudited pro forma balance sheets and loss per share excluded the impacts of the Group's share-based awards that subject to IPO conditions.

27. RESTRICTED NET ASSETS

The Group's ability to pay dividends may depend on the Group receiving distributions of funds from its PRC subsidiary. Relevant PRC statutory laws and regulations permit payments of dividends by the Group's PRC subsidiary only out of its retained earnings, if any, as determined in accordance with PRC accounting standards and regulations. The results of operations reflected in the consolidated financial statements prepared in accordance with U.S. GAAP differ from those reflected in the statutory financial statements of the Group's PRC subsidiary.

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(All amounts in thousands, except for share and per share data, unless otherwise noted)

27. RESTRICTED NET ASSETS (CONTINUED)

In accordance with the Company law of the PRC, a domestic enterprise is required to provide statutory reserves of at least 10% of its annual after-tax profit until such reserve has reached 50% of its respective registered capital based on the enterprise's PRC statutory accounts. A domestic enterprise is also required to provide discretionary surplus reserve, at the discretion of the Board of Directors, from the profits determined in accordance with the enterprise's PRC statutory accounts. The aforementioned reserves can only be used for specific purposes and are not distributable as cash dividends. The Group's PRC subsidiary was established as domestic invested enterprise and therefore is subject to the above mentioned restrictions on distributable profits.

For the years ended December 31, 2017 and 2018, no appropriation to statutory reserves was made because the PRC subsidiary had substantial losses during such periods.

As a result of these PRC laws and regulations subject to the limit discussed above that require annual appropriations of 10% of after-tax income to be set aside, prior to payment of dividends, as general reserve fund, the Group's PRC subsidiary is restricted in their ability to transfer a portion of their net assets to the Group.

Foreign exchange and other regulations in the PRC further restrict the Company's PRC subsidiaries from transferring funds to the Company in the form of dividends, loans and advances.

Since the Group has a consolidated shareholders' deficit, its net asset base for purposes of calculating the proportionate share of restricted net assets of consolidated subsidiaries should be zero. Therefore, the restrictions placed on the net assets of the Company's PRC subsidiaries with positive equity would result in the 25 percent threshold being exceeded and a corresponding requirement to provide parent company financial information (Note 28).

28. CONDENSED FINANCIAL INFORMATION OF THE PARENT COMPANY

The Company performed a test on the restricted net assets of consolidated subsidiaries in accordance with Securities and Exchange Commission Regulation S-X Rule 4-08 (e)(3), "General Notes to Financial Statements" and concluded that it was applicable for the Company to disclose the financial statements for the parent company.

The subsidiaries did not pay any dividends to the Company for the years presented. For the purpose of presenting parent company only financial information, the Company records its investments in its subsidiaries under the equity method of accounting. Such investments are presented on the separate condensed balance sheets of the Company as "Investments (deficit) in subsidiaries" and the loss of the subsidiaries is presented as "share of losses of subsidiaries". Certain information and footnote disclosures generally included in financial statements prepared in accordance with U.S. GAAP have been condensed and omitted. The footnote disclosures contain supplemental information relating to the operations of the Company, as such, these statements should be read in conjunction with the notes to the consolidated financial statements of the Company.

The Company did not have significant capital and other commitments, long-term obligations, other long-term debt, or guarantees as of December 31, 2017 and 2018.

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(All amounts in thousands, except for share and per share data, unless otherwise noted)

28. CONDENSED FINANCIAL INFORMATION OF THE PARENT COMPANY (CONTINUED)

Balance sheets

	As of December 31,		
	2017	2018	
	RMB	RMB	US\$ (Note 2.5)
Assets			
Current assets			
Cash and cash equivalents	34,229	603,234	87,737
Total current assets	34,229	603,234	87,737
Investments in subsidiaries	148,688	—	—
Receivables due from subsidiaries	371,211	1,455,048	211,628
Total assets	554,128	2,058,282	299,365
Liabilities, mezzanine equity and shareholders' equity (deficit)			
Current liabilities			
Warrant liabilities	65,832	5,618	817
Total current liabilities	65,832	5,618	817
Convertible promissory notes	77,810	67,026	9,749
Deficit in subsidiaries	—	25,384	3,692
Total liabilities	143,642	98,028	14,258
Mezzanine equity			
Series A convertible preferred shares (US\$0.0001 par value, 21,865,233 and 30,227,056 shares authorized, issued and outstanding as of December 31, 2017 and 2018, respectively)	363,766	687,482	99,990
Series B convertible preferred shares (US\$0.0001 par value, 15,894,594 and 30,305,212 shares authorized, issued and outstanding as of December 31, 2017 and 2018, respectively)	346,515	921,243	133,989
Series C convertible preferred shares (US\$0.0001 par value, 31,046,360 shares authorized, issued and outstanding as of December 31, 2018)	—	1,306,633	190,042
Total mezzanine equity	710,281	2,915,358	424,021

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(All amounts in thousands, except for share and per share data, unless otherwise noted)

28. CONDENSED FINANCIAL INFORMATION OF THE PARENT COMPANY (CONTINUED)

Balance sheets (continued)

	As of December 31,		
	2017 RMB	2018 RMB	US\$ (Note 2.5)
Shareholders' deficit			
Ordinary shares (US\$0.0001 par value, 500,000,000 shares authorized as of December 31, 2017 and 2018, 8,363,719 shares authorized, issued and outstanding as of December 31, 2017 and 2018, respectively)	6	6	1
Treasury stock	(1)	(1)	—
Additional paid-in capital	52,369	—	—
Accumulated other comprehensive income	5,691	59,380	8,636
Accumulated deficit	(357,860)	(1,014,489)	(147,551)
Total shareholders' deficit	(299,795)	(955,104)	(138,914)
Total liabilities, mezzanine equity and shareholders' deficit	554,128	2,058,282	299,365

Statements of comprehensive loss

	Year Ended December 31,		
	2017 RMB	2018 RMB	US\$ (Note 2.5)
Operating expenses			
Research and development expenses	(128,721)	(121,734)	(17,705)
Administrative expenses	—	(15,373)	(2,236)
Total operating expenses	(128,721)	(137,107)	(19,941)
Interest expenses, net	(3,892)	(7,467)	(1,086)
Share of losses of subsidiaries	(151,600)	(319,664)	(46,492)
Fair value change of warrants	(14,027)	61,405	8,931
Loss before income tax expense	(298,240)	(402,833)	(58,588)
Net loss	(298,240)	(402,833)	(58,588)
Other comprehensive income (loss)			
Foreign currency translation adjustments, net of nil tax	5,918	53,689	7,809
Total comprehensive loss	(292,322)	(349,144)	(50,779)

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(All amounts in thousands, except for share and per share data, unless otherwise noted)

28. CONDENSED FINANCIAL INFORMATION OF THE PARENT COMPANY (CONTINUED)

Statements of cash flows

	Year Ended December 31,		
	2017	2018	
	RMB	RMB	US\$ (Note 2.5)
Net cash (used in) generated from operating activities	<u>(132,732)</u>	<u>40,232</u>	<u>5,852</u>
Net cash used in investing activities	<u>(356,635)</u>	<u>(1,032,483)</u>	<u>(150,168)</u>
Net cash generated from financing activities	<u>475,224</u>	<u>1,498,669</u>	<u>217,972</u>
Effect of exchange rate changes on cash and cash equivalents	<u>4,697</u>	<u>62,587</u>	<u>9,103</u>
Net (decrease) increase in cash and cash equivalents	<u>(9,446)</u>	<u>569,005</u>	<u>82,759</u>
Cash and cash equivalents at beginning of the year	<u>43,675</u>	<u>34,229</u>	<u>4,978</u>
Cash and cash equivalents at end of the year	<u><u>34,229</u></u>	<u><u>603,234</u></u>	<u><u>87,737</u></u>

Report of Independent Auditors

To the Board of Directors and Shareholders of I-Mab Bio-tech (Tianjin) Co., Ltd.

We have audited the accompanying consolidated financial statements of I-Mab Bio-tech (Tianjin) Co., Ltd. and its subsidiaries, which comprise the consolidated balance sheet as of July 15, 2017 and the related consolidated statement of comprehensive loss, of changes in shareholders' equity and of cash flows for the period from January 1, 2017 to July 15, 2017.

Management's Responsibility for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of the consolidated financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

Auditors' Responsibility

Our responsibility is to express an opinion on the consolidated financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on our judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, we consider internal control relevant to the Company's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the I-Mab Bio-tech (Tianjin) Co., Ltd. and its subsidiaries as of July 15, 2017 and the results of their operations and their cash flows for the period from January 1, 2017 to July 15, 2017 in accordance with accounting principles generally accepted in the United States of America.

/s/ PricewaterhouseCoopers Zhong Tian LLP
Shanghai, the People's Republic of China
July 29, 2019

I-Mab Bio-tech (Tianjin) Co., Ltd. (“I-Mab Tianjin”)

CONSOLIDATED BALANCE SHEET

As of July 15, 2017

(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Note	As of July 15, 2017	
		RMB	US\$ (Note 2.5)
Assets			
Current assets			
Cash and cash equivalents		93,335	13,575
Other financial assets		30,000	4,363
Prepayments and other receivables		564	82
Total current assets		123,899	18,020
Equipment and software	3	43	6
Total assets		123,942	18,026
Liabilities and shareholders' equity			
Current liabilities			
Accruals and other payables		1,824	265
Total current liabilities		1,824	265
Commitments and contingencies	4		
Shareholders' equity			
Paid-in capital		294,390	42,817
Additional paid-in capital		4,500	654
Accumulated deficit		(176,772)	(25,710)
Total shareholders' equity		122,118	17,761
Total liabilities and shareholders' equity		123,942	18,026

The accompanying notes are an integral part of these consolidated financial statements.

I-MAB TIANJIN
CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS
For the Period from January 1, 2017 to July 15, 2017
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	For the Period from January 1 to July 15, 2017	
	RMB	US\$ (Note 2.5)
Operating expenses		
Research and development expenses	(10,882)	(1,583)
Administrative expenses	(3,745)	(545)
Total operating expenses	(14,627)	(2,128)
Loss from operations		
Other expenses, net	(1,622)	(236)
Loss before income tax expense	(16,249)	(2,364)
Income tax expense	—	—
Net loss	(16,249)	(2,364)
Other comprehensive income	—	—
Total comprehensive loss	(16,249)	(2,364)

The accompanying notes are an integral part of these consolidated financial statements.

I-MAB TIANJIN
CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY
For the Period from January 1, 2017 to July 15, 2017
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	<u>Paid-in capital</u> RMB	<u>Additional paid-in capital</u> RMB	<u>Accumulated deficit</u> RMB	<u>Total Shareholders' Equity</u> RMB
Balances as of January 1, 2017	294,390	4,500	(160,523)	138,367
Loss for the period	—	—	(16,249)	(16,249)
Balances as of July 15, 2017	<u>294,390</u>	<u>4,500</u>	<u>(176,772)</u>	<u>122,118</u>

The accompanying notes are an integral part of these consolidated financial statements.

I-MAB TIANJIN
CONSOLIDATED STATEMENT OF CASH FLOWS
For the Period from January 1, 2017 to July 15, 2017
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	For the Period from	
	January 1 to July 15, 2017	
	RMB	US\$
		(Note 2.5)
Cash flows from operating activities		
Net loss	(16,249)	(2,364)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation of equipment and software	22	3
Income from short-term investment	(482)	(70)
Changes in operating assets and liabilities		
Prepayments and other receivables	255	37
Accruals and other payables	(1,304)	(189)
Net cash used in operating activities	<u>(17,758)</u>	<u>(2,583)</u>
Cash flows from investing activities		
Cash paid for investments in other financial assets	(30,000)	(4,363)
Cash received from disposal of short-term investment	45,000	6,545
Cash received on income from short-term investment	482	70
Net cash generated from investing activities	<u>15,482</u>	<u>2,252</u>
Net cash generated from financing activities	<u>—</u>	<u>—</u>
Net decrease in cash and cash equivalents	<u>(2,276)</u>	<u>(331)</u>
Cash and cash equivalents at beginning of the period	95,611	13,906
Cash and cash equivalents at end of the period	<u>93,335</u>	<u>13,575</u>

The accompanying notes are an integral part of these consolidated financial statements.

I-MAB TIANJIN**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

(All amounts in thousands, except for share and per share data, unless otherwise noted)

1. PRINCIPAL ACTIVITIES AND ORGANIZATION

I-Mab Bio-tech (Tianjin) Co., Ltd. (previously known as Tasgen Bio-tech (Tianjin) Co., Ltd.) (the “Company”) and its subsidiaries, Chengdu Tasgen Bio-Tech Co., Ltd. and Shanghai Tianyunjian Bio-Tech Co., Ltd., (together the “Group”) are principally engaged in the research and development of innovative medicines in the People’s Republic of China (the “PRC”).

As of July 15, 2017, the Company’s subsidiaries are as follows

Subsidiaries	Place of incorporation	Date of incorporation	Percentage of direct or indirect ownership by the Company	Principal activities
Chengdu Tasgen Bio-Tech Co., Ltd.	PRC	May 30, 2016	100%	Research and development of innovative medicines
Shanghai Tianyunjian Bio-Tech Co., Ltd.	PRC	June 28, 2016	100%	Research and development of innovative medicines

2. PRINCIPAL ACCOUNTING POLICIES**2.1 Basis of presentation**

The accompanying consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (“U.S. GAAP”).

Significant accounting policies followed by the Group in the preparation of its accompanying consolidated financial statements are summarized below.

2.2 Basis of consolidation

The accompanying consolidated financial statements reflect the accounts of the Company and all of its subsidiaries in which a controlling interest is maintained. All inter-company balances and transactions have been eliminated in consolidation.

2.3 Use of estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosures of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Estimates are used in determining items such as useful lives of equipment and software, impairment of other receivables, impairment of long-lived assets, taxes on income, tax valuation allowances. Management bases the estimates on historical experience, known trends and various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results could differ from those estimates.

I-MAB TIANJIN

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(All amounts in thousands, except for share and per share data, unless otherwise noted)

2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)**2.4 Fair value measurements**

Financial assets and liabilities of the Group primarily comprise of cash and cash equivalents, other financial assets, other receivables, accruals and other payables. As of July 15, 2017, except for other financial assets the carrying values of these financial assets and liabilities approximated their fair values because of their generally short maturities. The Group reports other financial assets at fair value at each balance sheet date and changes in fair value are reflected in the consolidated statements of comprehensive loss.

The Group measures its financial assets and liabilities using inputs from the following three levels of the fair value hierarchy. The three levels are as follows:

Level 1 inputs are unadjusted quoted prices in active markets for identical assets that the management has the ability to access at the measurement date.

Level 2 inputs include quoted prices for similar assets in active markets, quoted prices for identical or similar assets in markets that are not active, inputs other than quoted prices that are observable for the asset (i.e., interest rates, yield curves, etc.), and inputs that are derived principally from or corroborated by observable market data by correlation or other means (market corroborated inputs).

Level 3 includes unobservable inputs that reflect the management's assumptions about the assumptions that market participants would use in pricing the asset. The management develops these inputs based on the best information available, including the own data.

Assets measured at fair value on a recurring basis

The Group measured its other financial assets at fair value on a recurring basis. As the Group's other financial assets are not traded in an active market with readily observable prices, the Group uses significant unobservable inputs to measure the fair value. These instruments are categorized in the Level 3 valuation hierarchy based on the significance of unobservable factors in the overall fair value measurement.

The following table summarizes the Group's financial assets measured and recorded at fair value on recurring basis as of July 15, 2017:

	As of July 15, 2017			Total RMB
	Active market (Level 1)	Observable input (Level 2)	Non-observable input (Level 3)	
	RMB	RMB	RMB	
Assets:				
Other financial assets	—	—	30,000	30,000

2.5 Foreign currency translation

Translations of balances in the consolidated balance sheet, consolidated statement of comprehensive loss, consolidated statement of changes in shareholders' equity and consolidated statement of cash flows from RMB into US\$ as of and for the year ended December 31, 2018 are solely for the convenience of the readers and were calculated at the rate of US\$1.00=RMB6.8755, representing the noon buying rate in The City of New York for

I-MAB TIANJIN

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(All amounts in thousands, except for share and per share data, unless otherwise noted)

2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.5 Foreign currency translation (continued)

able transfers of RMB as certified for customs purposes by the Federal Reserve Bank of New York on December 31, 2018. No representation is made that the RMB amounts could have been, or could be, converted, realized or settled into US\$ at that rate on December 31, 2018, or at any other rate. The US\$ convenience translation is not required under U.S. GAAP and all US\$ convenience translation amounts in the accompanying consolidated financial statements are unaudited.

2.6 Cash and cash equivalents

Cash and cash equivalents consist of cash on hand and bank deposits, which are unrestricted as to withdrawal and use. The Company considers all highly liquid investments with an original maturity date of three months or less at the date of purchase to be cash equivalents.

2.7 Equipment and software

Equipment and software are stated at cost less accumulated depreciation, amortization and impairment (if any). Depreciation and amortization is computed using the straight-line method over the following estimated useful lives, taking into account any estimated residual value:

Laboratory equipment	3 to 5 years
Software	2 to 5 years

The Group recognized the gain or loss on the disposal of equipment and software in the consolidated statement of comprehensive loss.

2.8 Research and development expenses

Elements of research and development expenses primarily include (1) payroll and other related expenses of personnel engaged in research and development activities, (2) in-licensed patent rights fee of exclusive development rights of drugs granted to the Group, (3) expenses related to preclinical testing of the Group's technologies and clinical trials such as payments to contract research organizations ("CRO"), investigators and clinical trial sites that conduct the clinical studies (4) expenses to develop the product candidates, including raw materials and supplies, product testing, depreciation, and facility related expenses, (5) other research and development expenses. Research and development expenses are charged to expense as incurred when these expenditures relate to the Group's research and development services and have no alternative future uses.

The Group has acquired rights to develop and commercialize product candidates. Upfront payments that relate to the acquisition of a new drug compound, as well as pre-commercial milestone payments, are immediately expensed as acquired in-process research and development in the period in which they are incurred, provided that the new drug compound did not also include processes or activities that would constitute a "business" as defined under U.S. GAAP, the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no established alternative future use. Milestone payments made to third parties subsequent to regulatory approval would be capitalized as intangible assets and amortized over the estimated remaining useful life of the related product. The conditions enabling capitalization of development expenses as an asset have not yet been met and, therefore, all development expenditures are recognized in profit or loss when incurred.

I-MAB TIANJIN**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

(All amounts in thousands, except for share and per share data, unless otherwise noted)

2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)**2.9 Income taxes**

The Group accounts for income taxes under the liability method. Under the liability method, deferred income tax assets and liabilities are determined based on the differences between the financial reporting and income tax bases of assets and liabilities and are measured using the tax income rates that will be in effect when the differences are expected to reverse. A valuation allowance is recorded when it is more likely than not that some portion or all of a deferred income tax asset will not be realized.

The Group evaluates its uncertain tax positions using the provisions of ASC 740, *Income Taxes*, which prescribes a recognition threshold that a tax position is required to meet before being recognized in the financial statements. The Group recognizes in the financial statements the benefit of a tax position which is “more likely than not” to be sustained under examination based solely on the technical merits of the position assuming a review by tax authorities having all relevant information. Tax positions that meet the recognition threshold are measured using a cumulative probability approach, at the largest amount of tax benefit that has a greater than fifty percent likelihood of being realized upon settlement. It is the Group’s policy to recognize interest and penalties related to unrecognized tax benefits, if any, as a component of income tax expense.

3. EQUIPMENT AND SOFTWARE

Equipment and software, net, consist of the following:

	As of July 15, 2017	
	RMB	US\$ (Note 2.5)
Cost		
Laboratory equipment	66	10
Software	19	3
Total equipment and software	85	13
Less: accumulated depreciation and amortization	(42)	(7)
Net book value	<u>43</u>	<u>6</u>

The total amounts charged to the consolidated statement of comprehensive loss for depreciation and amortization expenses amounted to approximately RMB22 for the period from January 1, 2017 to July 15, 2017.

4. COMMITMENTS AND CONTINGENCIES*Operating lease commitments*

The Group leases offices under non-cancelable operating lease agreements. Future minimum lease payments under non-cancelable operating lease agreements with initial terms of one year or more consist of the following:

	For the period from January 1 to July 15, 2017	
	RMB	US\$ (Note 2.5)
Within 1 year	<u>231</u>	<u>34</u>

I-MAB TIANJIN

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(All amounts in thousands, except for share and per share data, unless otherwise noted)

4. COMMITMENTS AND CONTINGENCIES (CONTINUED)

Contingencies

The Group is a party to or assignee of license and collaboration agreements that may require it to make future payments relating to milestone fees and royalties on future sales of licensed products.

5. RELATED PARTY TRANSACTIONS

The table below sets forth the major related party and its relationships with the Group as of December 31, 2017 and 2018:

<u>Name of related party</u>	<u>Nature of relationship</u>
Tasly Pharmaceutical Group Co., Ltd.	Controlled by the ultimate controlling party of a principal shareholder of the Group

For the period from January 1 to July 15, 2017, transaction with related party was as follows:

Receipt of CRO services- recognized in research and development expenses

	<u>For the period from January 1 to July 15, 2017</u>	
	<u>RMB</u>	<u>US\$ (Note 2.5)</u>
Tasly Pharmaceutical Group Co., Ltd.	<u>752</u>	<u>109</u>

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PART II**INFORMATION NOT REQUIRED IN PROSPECTUS****Item 6. INDEMNIFICATION OF DIRECTORS AND OFFICERS.**

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, such as to provide indemnification against civil fraud or the consequences of committing a crime.

The post-offering memorandum and articles of association that we expect to adopt and to become effective immediately prior to the completion of this offering provide that we shall indemnify our directors and officers (each, an indemnified person) against all actions, proceedings, costs, charges, expenses, losses, damages or liabilities incurred or sustained by such indemnified person, other than by reason of such person's own dishonesty, willful default or fraud, in or about the conduct of our company's business or affairs (including as a result of any mistake of judgment) or in the execution or discharge of his or her duties, powers, authorities or discretions, including, without prejudice to the generality of the foregoing, any costs, expenses, losses or liabilities incurred by such indemnified person in defending (whether successfully or otherwise) any civil proceedings concerning our company or its affairs in any court whether in the Cayman Islands or elsewhere.

Pursuant to the indemnification agreements the form of which is filed as Exhibit 10.3 to this registration statement, we agree to indemnify our directors and executive officers against certain liabilities and expenses incurred by such persons in connection with claims made by reason of their being such a director or officer.

The underwriting agreement, the form of which will be filed as Exhibit 1.1 to this registration statement, will also provide indemnification for us and our officers and directors for certain liabilities.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Item 7. RECENT SALES OF UNREGISTERED SECURITIES.

During the past three years, we have issued the following securities. We believe that each of the following issuances was exempt from registration under the Securities Act pursuant to Section 4(2) of the Securities Act regarding transactions not involving a public offering or in reliance on Regulation S under the Securities Act regarding sales by an issuer in offshore transactions. No underwriters were involved in these issuances of securities.

<u>Securities/Purchaser</u>	<u>Date of Sale or Issuance</u>	<u>Number of Securities</u>	<u>Consideration</u>
Ordinary shares			
Offshore Incorporations (Cayman)			
Limited	June 30, 2016	1	US\$0.0001
Mabcore Limited	June 30, 2016	4,019,553	US\$401.9553
BioScikin Co., Ltd.	October 18, 2016	2,215,803	RMB1,000,000
Hangzhou Tigermed Consulting Co., Ltd	October 18, 2016	2,215,803	RMB15,000,000
Convertible promissory notes			
CBC Investment I-Mab Limited	September 25, 2017	1	US\$12,100,000 (due September 2020)

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Securities/Purchaser	Date of Sale or Issuance	Number of Securities	Consideration
C-Bridge II Investment Ten Limited	February 9, 2018	1	US\$1,550,000 (due September 2020)
Qianhai Ark (Cayman) Investment Co. Limited	July 6, 2018	1	US\$1,250,000 (due July 2021)
Genexine Inc.	February 5, 2018	1	US\$9,000,000 (due February 2021)
Series A-1 preferred shares			
IBC Investment Seven Limited	October 18, 2016	4,629,231	US\$4,629,231
Series A-2 preferred shares			
IBC Investment Seven Limited	October 18, 2016	512,356	US\$8,447,692
Series A-3 preferred shares			
CBC SPVII LIMITED	September 6, 2017	8,361,823	US\$15,000,000
Genexine, Inc.	September 6, 2017	8,361,823	US\$15,000,000
Tasly Biopharm Limited	June 29, 2018	8,361,823	Tasly Biopharm Limited's equity interest in I-Mab Hong Kong
Series B preferred shares			
CBC Investment I-Mab Limited	September 22, 2017	14,089,714	US\$48,400,000
C-Bridge II Investment Ten Limited	February 9, 2018	1,804,880	US\$6,200,000
Tasly Biopharm Limited	June 29, 2018	5,938,640	Tasly Biopharm Limited's equity interest in I-Mab Hong Kong
Qianhai Ark (Cayman) Investment Co. Limited	July 6, 2018	1,455,549	US\$2,035,667
Series B-1 preferred shares			
CBC Investment I-Mab Limited	June 29, 2018	2,247,321	Conversion of US\$12,100,000 convertible promissory note due September 2020
C-Bridge II Investment Ten Limited	June 29, 2018	287,880	Conversion of US\$1,550,000 convertible promissory note due September 2020
Tasly Biopharm Limited	June 29, 2018	947,218	Tasly Biopharm Limited's equity interest in I-Mab Hong Kong
Qianhai Ark (Cayman) Investment Co. Limited	July 6, 2018	232,161	Conversion of US\$1,250,000 convertible promissory note due July 2021
Series B-2 preferred shares			
CBC Investment I-Mab Limited	June 29, 2018	1,997,618	US\$12,100,000
C-Bridge II Investment Ten Limited	June 29, 2018	255,894	US\$1,550,000
Rainbow Horizon Limited	July 6, 2018	841,971	US\$5,100,000

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Securities/Purchaser	Date of Sale or Issuance	Number of Securities	Consideration
Qianhai Ark (Cayman) Investment Co. Limited	July 6, 2018	206,366	US\$1,250,000
Series C preferred shares			
Fortune Eight Jogging Limited	July 6, 2018	8,537,749	US\$55,000,000
C-Bridge II Investment Seven Limited	July 6, 2018	6,209,272	US\$40,000,000
HH IMB Holdings Limited	July 6, 2018	3,104,636	US\$20,000,000
Ally Bridge LB Precision Limited	July 6, 2018	3,104,636	US\$20,000,000
Marvey Investment Company Limited	July 6, 2018	3,104,636	US\$20,000,000
Mab Health Limited	July 6, 2018	1,862,782	US\$12,000,000
Casiority H Limited	July 6, 2018	1,241,854	US\$8,000,000
Southern Creation Limited (formerly known as Ally Bridge LB-Sunshine Limited)	July 6, 2018	1,552,318	US\$10,000,000
Tasly International Capital Limited	July 6, 2018	1,552,318	US\$10,000,000
Parkway Limited	July 6, 2018	776,159	US\$5,000,000
Options and Warrants			
IBC Investment Seven Limited	October 18, 2016	Warrant to purchase up to 2,246,744 Series A-3 preferred shares*	N/A
Shanghai Tasly Pharmaceutical Co., Ltd.	September 6, 2017	Option to purchase up to 8,361,823 Series A-3 preferred shares	N/A
Shanghai Tasly Pharmaceutical Co., Ltd.	September 25, 2017	Option to purchase up to 5,938,640 Series B preferred shares and 947,218 Series B-1 preferred shares	N/A
Qianhai Equity Investment Fund (Limited Partnership)	September 25, 2017	Option to purchase up to 1,455,549 Series B preferred shares and up to 232,161 Series B-1 preferred shares	N/A
Tianjin Kangshijing Biopharmaceutical Technology Partnership (Limited Partnership)	September 25, 2017	Option to purchase up to 1,804,880 Series B preferred shares and up to 287,880 additional Series B-1 preferred Shares**	N/A
CBC Investment I-Mab Limited	September 25, 2017	Warrant to purchase up to 4,994,046 Series B-2 preferred shares	N/A
Shanghai Tasly Pharmaceutical Co., Ltd.	September 25, 2017	Warrant to purchase up to 2,104,928 Series B-2 preferred shares	N/A
Qianhai Equity Investment Fund (Limited Partnership)	September 25, 2017	Warrant to purchase up to 515,914 Series B-2 preferred shares	N/A

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<u>Securities/Purchaser</u>	<u>Date of Sale or Issuance</u>	<u>Number of Securities</u>	<u>Consideration</u>
C-Bridge II Investment Ten Limited	September 25, 2017	Warrant to purchase up to 639,734 Series B-2 preferred shares	N/A
Certain directors, officers and employees and consultants	October 2017 to February 2019	Options to purchase 24,939,330 ordinary shares	Past and future services to us

* This warrant was cancelled on September 6, 2017.

** This option was terminated on February 9, 2018.

Item 8. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a) Exhibits

See Exhibit Index beginning on page II-4 of this registration statement.

The agreements included as exhibits to this registration statement contain representations and warranties by each of the parties to the applicable agreement. These representations and warranties were made solely for the benefit of the other parties to the applicable agreement and (i) were not intended to be treated as categorical statements of fact, but rather as a way of allocating the risk to one of the parties if those statements prove to be inaccurate; (ii) may have been qualified in such agreement by disclosure that was made to the other party in connection with the negotiation of the applicable agreement; (iii) may apply contract standards of “materiality” that are different from “materiality” under the applicable securities laws; and (iv) were made only as of the date of the applicable agreement or such other date or dates as may be specified in the agreement.

We acknowledge that, notwithstanding the inclusion of the foregoing cautionary statements, we are responsible for considering whether additional specific disclosure of material information regarding material contractual provisions is required to make the statements in this registration statement not misleading.

(b) Financial Statement Schedules

Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the Consolidated Financial Statements or the Notes thereto.

Item 9. UNDERTAKINGS.

The undersigned registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the provisions described in Item 6, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

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The undersigned registrant hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

I-MAB

Exhibit Index

<u>Exhibit Number</u>	<u>Description of Document</u>
1.1*	Form of Underwriting Agreement
3.1*	Fourth Amended and Restated Memorandum and Articles of Association of the Registrant, as currently in effect
3.2*	Form of Fifth Amended and Restated Memorandum and Articles of Association of the Registrant (effective upon the closing of this offering)
4.1*	Registrant's Specimen American Depositary Receipt (included in Exhibit 4.3)
4.2*	Registrant's Specimen Certificate for Ordinary Shares
4.3*	Form of Deposit Agreement, among the Registrant, the depositary and holder of the American Depositary Receipt
4.4*	Third Amended and Restated Shareholders Agreement, dated as of July 6, 2018, between the Registrant and other parties thereto
5.1*	Opinion of Conyers Dill & Pearman regarding the validity of the ordinary shares being registered and certain Cayman Islands tax matters
8.1*	Opinion of Conyers Dill & Pearman regarding certain Cayman Islands tax matters (included in Exhibit 5.1)
8.2*	Opinion of JunHe LLP regarding certain PRC tax matters (included in Exhibit 99.2)
10.1*	Amended and Restated 2017 Employee Stock Option Plan
10.2*	2018 Employee Stock Option Plan
10.3*	Form of Indemnification Agreement, between the Registrant and its directors and executive officers
10.4*	Form of Employment Agreement, between the Registrant and its executive officers
10.5*	Series C-1 Share Purchase Agreement, dated as of July 25, 2019, between the Registrant and the other parties thereto
10.6*	Series C Share Purchase Agreement, dated as of June 28, 2018, between the Registrant and the other parties thereto
10.7*	Series B Share Purchase Agreement, dated as of May 26, 2017, between the Registrant and the other parties thereto
10.8*	Executed form of warrants between the Registrant and certain investors as currently in effect, and a schedule of all executed warrants adopting the same form in respect of each of the investors
10.9*	Framework Agreement, dated as of May 26, 2017, among the Registrant and the other parties thereto
10.10*	Re-organization Framework Agreement, dated as of April 18, 2018, among the Registrant and the other parties thereto
10.11*	Supplement to the Re-organization Framework Agreement, dated as of May 31, 2018, among the Registrant and the other parties thereto
10.12*	Re-organization Framework Agreement, dated April 4, 2018, among the Registrant and the other parties thereto

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<u>Exhibit Number</u>	<u>Description of Document</u>
10.13*	Supplement to the Re-organization Framework Agreement, dated as of May 31, 2018, among the Registrant and the other parties thereto
10.14*	License and Collaboration Agreement, dated as of November 30, 2017, between the Registrant and MorphoSys AG
10.15*	Intellectual Property Assignment and License Agreement, dated as of October 16, 2015, between Tasgen Bio-tech (Tianjin) Co., Ltd. and Genexine, Inc.
10.16*	Intellectual Property License Agreement, dated as of December 22, 2017, between the Registrant and Genexine, Inc.
10.17*	License and Sublicense Agreement, dated as of November 4, 2016, between the Registrant and Ferring International Center SA
10.18*	Collaboration Agreement, dated as of July 9, 2019, between I-Mab Biopharma, US Limited and MacroGenics, Inc.
10.19*	License and Collaboration Agreement, dated as of July 26, 2018, between the Registrant and ABL Bio
10.20*	English translation of Product Development Agreement, dated as of December 10, 2018, between I-Mab Shanghai and CSPC Baike (Shandong) Biopharmaceutical Co., Ltd.
10.21*	CD38 Product Collaboration Agreement, dated as of January 22, 2018, between the Registrant and Everest Medicines Limited
10.22*	Supplemental Agreement to CD38 Product Collaboration Agreement, dated as of November 7, 2018, between the Registrant and Everest Medicines Limited
21.1*	Principal Subsidiaries of the Registrant
23.1*	Consent of PricewaterhouseCoopers, an independent registered public accounting firm
23.2*	Consent of Conyers Dill & Pearman (included in Exhibit 5.1)
23.3*	Consent of JunHe LLP (included in Exhibit 99.2)
24.1*	Powers of Attorney (included on signature page)
99.1*	Code of Business Conduct and Ethics of the Registrant
99.2*	Opinion of JunHe LLP regarding certain PRC law matters
99.3*	Consent of Frost & Sullivan

* To be filed by amendment.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Shanghai, China, on _____, 2019.

I-MAB

By: _____
Name:
Title:

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints each of _____ and _____ as attorneys-in-fact with full power of substitution for him or her in any and all capacities to do any and all acts and all things and to execute any and all instruments which said attorney and agent may deem necessary or desirable to enable the registrant to comply with the Securities Act of 1933, as amended (the “Securities Act”), and any rules, regulations and requirements of the Securities and Exchange Commission thereunder, in connection with the registration under the Securities Act of ordinary shares of the registrant (the “Shares”), including, without limitation, the power and authority to sign the name of each of the undersigned in the capacities indicated below to the Registration Statement on Form F-1 (the “Registration Statement”) to be filed with the Securities and Exchange Commission with respect to such Shares, to any and all amendments or supplements to such Registration Statement, whether such amendments or supplements are filed before or after the effective date of such Registration Statement, to any related Registration Statement filed pursuant to Rule 462(b) under the Securities Act, and to any and all instruments or documents filed as part of or in connection with such Registration Statement or any and all amendments thereto, whether such amendments are filed before or after the effective date of such Registration Statement; and each of the undersigned hereby ratifies and confirms all that such attorney and agent shall do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
_____ Jingwu Zhang Zang	Director	, 2019
_____ Zheru Zhang	Director	, 2019
_____ Huaqiong Shen (Joan)	Director	, 2019
_____ Jielun Zhu	Director and Chief Financial Officer (Principal Financial and Accounting Officer)	, 2019
_____ Wei Fu	Director	, 2019
_____ Mengjiao Jiang	Director	, 2019
_____ Jie Yu	Director	, 2019
_____ Lin Li	Director	, 2019
_____ 	Chief Executive Officer (Principal Executive Officer)	, 2019

SIGNATURE OF AUTHORIZED REPRESENTATIVE IN THE UNITED STATES

Pursuant to the Securities Act of 1933, the undersigned, the duly authorized representative in the United States of I-MAB has signed this registration statement or amendment thereto in Newark, Delaware, United States on _____, 2019.

Authorized U.S. Representative

By: _____
Name:
Title: