

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

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

GRACELL BIOTECHNOLOGIES INC.
(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 Number)

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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, please 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 depositary shares, or ADSs, issuable upon deposit of ordinary shares registered hereby will be registered under a separate registration statement on Form F-6 (Registration No. 333-). Each ADS represents ordinary shares.
- (2) Includes the aggregate offering price of additional ordinary shares represented by ADSs that the underwriters have the option to purchase. 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 Class A 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, as amended.

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. We may not sell these securities 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 state where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS
(Subject to Completion) Issued , 2020

AMERICAN DEPOSITARY SHARES



GRACELL BIOTECHNOLOGIES INC.

Representing Ordinary Shares

This is an initial public offering of American depositary shares, or ADSs, representing ordinary shares of Gracell Biotechnologies Inc.

We are offering ADSs. Each ADS represents ordinary shares, US\$0.0001 par value per share. We anticipate the initial public offering price per ADS will be between US\$ and US\$.

Prior to this offering, there has been no public market for the ADSs or our ordinary shares. We have applied to list the ADSs on the Nasdaq Global Market, or Nasdaq, under the symbol “GRCL.”

We are an “emerging growth company” and a “foreign private issuer” under applicable U.S. federal securities laws and are eligible for reduced public company reporting requirements. See “Prospectus Summary—Implications of Being an Emerging Growth Company” and “Prospectus Summary—Implications of Being a Foreign Private Issuer” for additional information.

Investing in the ADSs involves risks. See “Risk Factors” beginning on page 16.

	Per ADS	Total
Public offering price	US\$	US\$
Underwriting discounts and commissions	US\$	US\$
Proceeds, before expenses, to Gracell Biotechnologies Inc.	US\$	US\$

We have granted the underwriters the right to purchase up to an additional ADSs at the initial public offering price, less underwriting discounts and commissions.

Neither the Securities and Exchange Commission nor any other state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the ADSs to purchasers on or about , 2020 through the book-entry facilities of The Depository Trust Company.

Citigroup Jefferies Piper Sandler
, 2020

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No dealer, salesperson or other person is authorized to give any information or to represent as to anything not contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. You must not rely on any unauthorized information or representations. This prospectus is an offer to sell, and we are seeking offers to buy, only the ADSs offered hereby, and only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date, regardless of the time of delivery of this prospectus or any sale of the ADSs.

Neither we nor the underwriters have done anything that would permit this offering or the possession or distribution of this prospectus or any filed free writing prospectus in any jurisdiction where other action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus or any free writing prospectus filed with the U.S. Securities and Exchange Commission, or the SEC, 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 of the United States.

Until _____, 2020 (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. This summary does not contain all of the information that may be important to you in making your investment decision. In addition to this summary, we urge you to read the entire prospectus carefully, especially the risks of investing in the ADSs discussed under “Risk Factors,” before deciding whether to invest in the ADSs.

Overview

We are a global clinical-stage biopharmaceutical company dedicated to discovering and developing breakthrough cell therapies to address major industry challenges and fulfill unmet medical needs in the treatment of cancer. As a leading cell and gene therapy company, we aim to disrupt conventional approaches to CAR-T cell therapies with our proprietary technology platforms—FastCAR and TruUCAR.

- With FastCAR, we are able to deliver younger, less exhausted T cells for autologous cell therapies with greater potency and next-day manufacturing (22 to 36 hours) versus the industry norm of two to six weeks. Our lead FastCAR-enabled autologous product candidate, GC012F, has demonstrated fast, deep and durable responses, including multiple stringent complete responses, or sCR, in relapsed or refractory multiple myeloma, or r/r MM, patients in an ongoing investigator-initiated Phase 1 trial in China.
- With TruUCAR, we are able to derive T cells from non-HLA-matched healthy donors to generate allogeneic CAR-T cell therapies that are readily available off-the-shelf at lower cost for a broad patient base, including those less suitable for autologous CAR-T cell therapies. Our lead TruUCAR-enabled allogeneic product candidate, GC027, has achieved multiple complete responses, or CR, in relapsed or refractory T cell acute lymphoblastic leukemia, or r/r T-ALL, patients with a manageable safety profile in an ongoing investigator-initiated Phase 1 trial in China.

In addition to our technology platforms, we utilize our proprietary genetic engineering techniques, Dual CAR and Enhanced CAR, to generate FastCAR and TruUCAR product candidates with enhanced efficacy and safety. Leveraging our pioneering platforms, know-how and experience, we are developing a rich clinical-stage pipeline of multiple autologous and allogeneic product candidates that we believe will unlock the long-held promise of CAR-T cell therapies for a broad range of patients with advanced hematologic malignancies and solid tumors.

GC012F, our lead FastCAR autologous product candidate, is being studied in an ongoing investigator-initiated Phase 1 trial in China. We enrolled and treated 16 r/r MM patients for this trial with 15, or 93.8%, of these patients exhibiting high-risk features, which represent a subgroup of MM patients that are most difficult to treat. As of the July 2020 data cutoff date, 15 of 16 evaluable r/r MM patients achieved a response, resulting in an overall response rate, or ORR, of 93.8%, with all six patients, or 100%, from the highest dose cohort achieving a sCR, which was maintained through the landmark analysis at six months after CAR-T infusion. The most common adverse event observed was cytokine release syndrome, or CRS, which was managed with standard of care, or SOC, treatment.

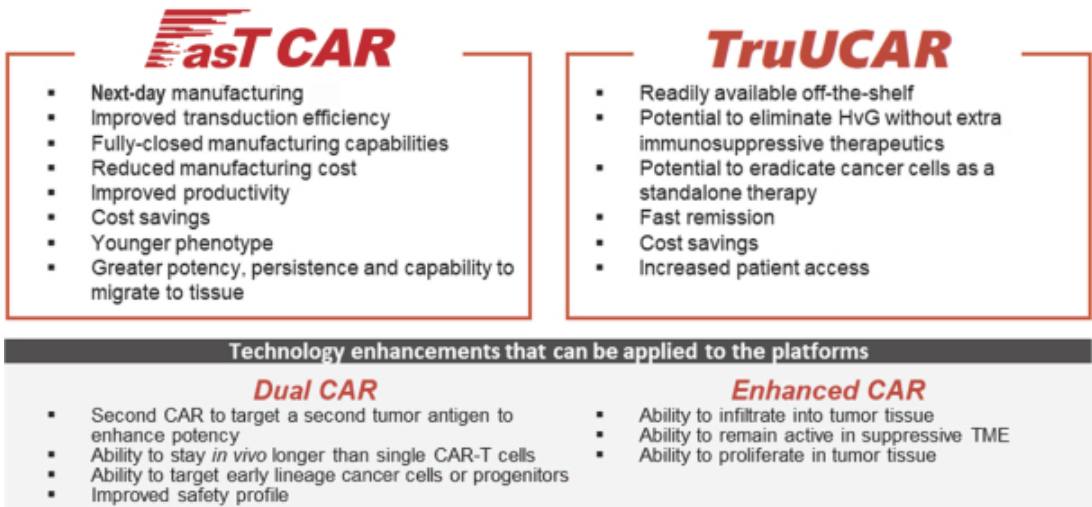
GC027, our lead TruUCAR allogeneic product candidate, has demonstrated in an ongoing investigator-initiated Phase 1 trial in China that all five enrolled adult r/r T-ALL patients, or 100%, achieved a CR or complete response with incomplete hematologic recovery, or CRi, on Day 14 or Day 28 after treatment, as of the February 2020 data cutoff date. All CRS observed was manageable and resolved following treatment and supportive care. No patients developed neurotoxicity, an adverse event commonly observed after CAR-T cell therapy, or graft versus host disease, or GvHD, a potentially fatal condition after allogeneic CAR-T cell therapy.

CAR-T Cell Therapeutics and Industry Challenges

Chimeric antigen receptor T cells, or CAR-T cells, can be classified as either autologous or allogeneic. Autologous CAR-T cells are derived from the T cells of the cancer patient while allogeneic CAR-T cells are derived from the T cells of a healthy donor. Theoretically, CAR-T cells can be engineered to target virtually any tumor-associated antigen. Currently, CAR-T cell therapies are primarily focused on hematologic malignancies. In 2017, the first two CAR-T cell therapies were approved: Kymriah (marketed by Novartis AG) for pediatric B cell acute lymphoblastic leukemia and Yescarta (marketed by Kite Pharma, Inc., acquired by Gilead Sciences, Inc.) for diffuse large B cell lymphoma.

Despite the vast potential of CAR-T cell therapies, major challenges persist for both autologous and allogeneic approaches. Autologous cell therapies are highly personalized, making the manufacturing process time-consuming, complex, costly and difficult to scale. It is also challenging to generate sufficient high-quality T cells as T cells of patients are often compromised from earlier lines of cancer treatment. Allogeneic therapies, including those intended for use off-the-shelf, derive cells from healthy donors but require modifications to reduce or eliminate host versus graft rejection, or HvG, and GvHD. Additionally, despite progress in treating hematologic malignancies, CAR-T cell therapies have had little success with treating solid tumors, primarily as a result of CAR-T cells’ limited ability to penetrate and persist in solid tumors. We believe we can disrupt the conventional approaches to CAR-T cell therapies by leveraging our highly innovative and proprietary technology platforms.

Our Proprietary Technology Platforms



Our pioneering platforms, FasTCAR and TruUCAR, are highly innovative and are designed to provide significant advantages as highlighted below:

- **FasTCAR.** FasTCAR offers a revolutionary approach that tackles the most pressing challenges associated with autologous therapies, such as lengthy manufacturing time, suboptimal manufacturing quality, high therapy cost and poor T cell fitness. We transform the three primary production steps—activation, transduction and expansion—into a single “concurrent activation-transduction” step. This is achieved by utilizing XLenti vectors derived from lentivirus to concurrently activate and transduce resting T cells and enable them to stably express one or more CARs and proliferate potently *in vivo*. In addition, FasTCAR manufactured CAR-T cells are younger, less exhausted and show enhanced proliferation potency, tissue migration and tumor clearance effect as demonstrated in preclinical

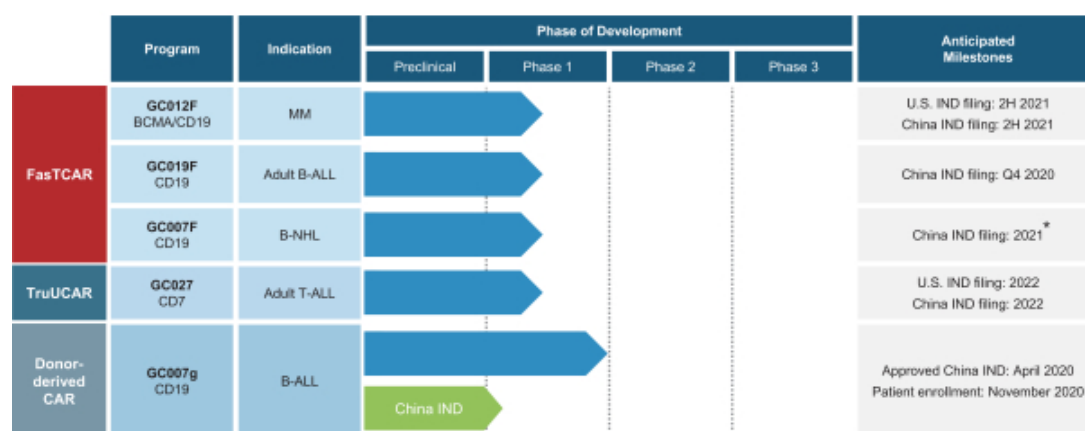
studies, eliminating the need for the *ex vivo* expansion phase in the conventional process. This streamlined process significantly shortens the production time from an industry norm of two to six weeks and achieves next-day manufacturing. Shorter manufacturing time is of particular importance to increasing the widespread utility of CAR-T cell therapies, particularly in the case of rapidly progressing cancers. We established fully-closed production lines designed to produce FasTCAR product candidates while reducing the risk of contamination and optimizing cost-efficiency. Our significantly shorter manufacturing time and highly efficient manufacturing process may result in meaningful cost savings, increasing the accessibility of cell therapies for cancer patients. We are developing our lead autologous product candidate, GC012F, as well as multiple autologous clinical-stage pipeline candidates on our FasTCAR platform.

- **TruUCAR.** TruUCAR is designed to generate high-quality allogeneic CAR-T cell therapies with superior efficacy that can be administered “off-the-shelf” at lower cost. As with FasTCAR, TruUCAR uses a lentivirus to deliver its CAR. TruUCAR has several key design differences when compared to conventional allogeneic CAR-T approaches. TruUCAR is designed to specifically target a patient’s T cells and natural killer, or NK, cells that would otherwise be directed against the foreign, or allogeneic, cells resulting in rejection by the patients. This feature allows our allogeneic cell therapies to survive a patient’s immune system without the need for combination treatment with anti-CD52 antibodies that may leave a patient at increased risk for infection. TruUCAR is designed to avoid GvHD, one of the most severe adverse events of allogeneic CAR-T cell therapies, and rapidly eliminate cancer cells without the need to bridge to hematopoietic stem cell transplantation, or HSCT, which is often used with conventional allogeneic CAR-T cell therapy to strengthen its therapeutic effects but pose a risk of early mortality. As a result, TruUCAR’s monotherapy approach has the potential to significantly reduce the cost and length of treatment by achieving fast remission and avoiding anti-CD52 treatment and potentially HSCT. We believe that TruUCAR may result in meaningful cost savings, further increasing the accessibility of cell therapies for cancer patients. We are developing our lead allogeneic product candidate, GC027, as well as multiple allogeneic pipeline candidates on our TruUCAR platform.

In addition, we have a suite of genetic engineering techniques, Dual CAR and Enhanced CAR, that can be leveraged with FasTCAR and TruUCAR to further enhance the efficacy of our CAR-T cell therapies. Dual CAR has the potential to control relapse by reducing the likelihood of antigen escape and to reduce rejection of the CAR-T cells by patients treated with TruUCAR-enabled allogeneic CAR-T cell therapies. Enhanced CAR further strengthens CAR-T cells’ functionality, for example by overcoming the immunosuppressive tumor microenvironment, or TME, and/or increasing cytokine signaling. We also have an allogeneic donor-derived CAR technique based on HLA-matching to avoid GvHD.

Our Clinical Development Pipeline

We have generated a pipeline of first-in-class autologous and allogeneic cell therapy candidates with the potential to treat both hematologic malignancies and solid tumors. The clinical development strategy that we have established in partnership with top-tier hospitals in China expedites the initial demonstration of safety and efficacy signal for our product candidates through pre-IND investigator-initiated trials. We have generated all our product candidates internally. Our most advanced product candidates are presented in the pipeline diagram below:



* IND filing for either GC007F for B-NHL or GC019F for B-NHL which is currently in earlier-stage development

China IND Investigator-initiated trial in China

MM = multiple myeloma, B-ALL = B cell acute lymphoblastic leukemia, B-NHL = B cell non-Hodgkin's lymphoma, T-ALL = T cell acute lymphoblastic leukemia

Our lead product candidates include:

- GC012F.** GC012F is a FasTCAR-enabled dual BCMA- and CD19-directed autologous CAR-T product candidate, being studied for the treatment of MM in an ongoing investigator-initiated Phase 1 trial across multiple centers in China. As of July 2020, we enrolled and treated 16 r/r MM patients with 93.8% of these patients having high-risk features, which represent a subgroup of MM patients with a poor prognosis and potentially rapid disease progression, making them particularly challenging to treat even with novel agents. All patients in this investigator-initiated Phase I trial had relapsed from, or were refractory to, previous treatments, including the most commonly used agents and SOC treatments. 15 of 16 patients achieved and maintained a response. In the highest dose cohort which is the recommended dosage level, 100% of the six evaluable patients achieved MRD- sCR as best response which was maintained through the landmark analysis at six months after CAR-T infusion. Based on these results, we expect to submit IND applications for GC012F in r/r MM to the FDA and the NMPA by the end of 2021.
- GC019F.** GC019F is a FasTCAR-enabled CD19-directed autologous CAR-T product candidate, being studied for the treatment of adult B-ALL in an ongoing investigator-initiated Phase 1 trial across multiple centers in China. An investigator-initiated trial for GC019F for the treatment of r/r B-NHL is currently in the planning stage and is expected to begin patient enrollment by the end of 2020.
- GC007F.** GC007F is a FasTCAR-enabled CD19-directed autologous CAR-T product candidate being studied for the treatment of B-NHL in an ongoing investigator-initiated Phase 1 trial across multiple centers in China. Based on the clinical results from the investigator-initiated trial, we plan to submit an IND application for either GC019F or GC007 in r/r B-NHL to the NMPA in 2021.

- **GC027.** GC027 is a TruUCAR-enabled CD7-directed allogeneic CAR-T product candidate being studied for the treatment of adult T-ALL in an ongoing investigator-initiated Phase 1 trial across multiple centers in China. As of February 2020, we enrolled and treated five adult r/r T-ALL patients. All patients enrolled had relapsed from, or were refractory to, their prior line of therapy. All five evaluable patients achieved a CR or CRi, resulting in an ORR of 100%, including four patients, or 80%, achieving MRD- CR on Day 28 after treatment. We observed CRS in all treated patients, which was resolved with treatment. No patient developed neurotoxicity or GvHD. We expect to submit an IND application for GC027 in adult r/r T-ALL to the FDA and the NMPA in 2022.
- **GC007g.** GC007g is a donor-derived CD19-directed allogeneic CAR-T cell therapy that has been studied in a completed investigator-initiated Phase 1 trial for the treatment of r/r B-ALL, where CAR-T cells were manufactured using T cells from an HLA-matched healthy donor. We obtained IND approval to study GC007g in B-ALL from the NMPA on April 1, 2020 and are initiating the Phase 1 study in China. We submitted an updated innovative seamless Phase 1b/2 study design for GC007g's registration-enabling clinical trial to the Center for Drug Evaluation, or CDE, in September 2020 which may enable us to roll over the ongoing Phase 1 clinical trial into the seamless Phase 1b/2 registration-enabling clinical trial in the first half of 2021. Our goal is to submit a biologics license application, or BLA, to the NMPA for GC007g upon completion of a registrational trial.

In addition to our lead product candidates, we have a broad portfolio of earlier stage product candidates targeting various cancer indications, such as ovarian cancer, breast cancer, peripheral T cell lymphoma, or PTCL, a subtype of NHL, and T cell lymphoblastic leukemia, or T-LBL.

CAR-T cell manufacturing is a critical component of our clinical development and future commercialization, as CAR-T cell therapies are complex and, in the case of autologous therapies, highly personalized. We control our manufacturing through our two good manufacturing practices, or GMP, compliant manufacturing facilities in Suzhou and Shanghai, making us self-sufficient in the production of CAR-T cells for clinical development and early-stage commercialization. We established fully-closed production lines in our Suzhou and Shanghai facilities, which are designed to produce FastCAR product candidates while reducing contamination risks and optimizing cost-efficiency. With this fully-closed design, we are able to operate multiple systems in one manufacturing cleanroom at the same time, with each system producing CAR-T cells for an individual patient. We believe these advantages, coupled with our ability to achieve next-day manufacturing for autologous CAR-T cells in one production shift, allow us to substantially reduce manufacturing costs, improve productivity and scale up our production in a cost-efficient manner.

Our Strategy

Our goal is to disrupt conventional approaches to CAR-T cell therapy by using our proprietary technology platforms and techniques to discover and develop treatments that deliver fast, deep and durable responses for advanced hematologic malignancies and solid tumors. In order to achieve our goal, the key elements of our strategy include:

- Rapidly advance our lead product candidates through clinical development and regulatory approval by leveraging our global clinical development capabilities.
- Continue to leverage the strength of our revolutionary technology platforms to broaden our pipeline of next-generation autologous and allogeneic CAR-T cell therapies.
- Expand our CAR-T therapies into solid tumor indications.
- Enhance our leadership position within the cell and gene therapy field.
- Expand our proprietary genetic engineering and cell manufacturing capabilities.
- Evaluate strategic partnerships to maximize the value of our technology platforms.

Our Team

We are led by an experienced management team with an unwavering commitment to developing next generation cell and gene therapies. Our Founder and Chief Executive Officer, Dr. William Wei Cao, Ph.D., B.M., has over 30 years of research and development experience in the biotechnology industry and previously co-founded and served as chief executive officer and executive board member of Cellular Biomedicine Group, Inc. (Nasdaq: CBMG), a Nasdaq-listed cell therapy company. Prior to that, Dr. Cao held research positions at Harvard Medical School and Standard University Medical Center, as well as senior roles at Chiron (Novartis and Bayer) and Affymetrix (ThermoFisher). Our Chief Medical Officer, Dr. Martina Sersch, M.D., has over 25 years of academia and industry experience and previously served in senior roles at Amgen, Roche/Genentech and Pfizer. Dr. Sersch also served as Chief Medical Officer of Mustang Bio, Inc. (Nasdaq: MBIO), a Nasdaq-listed CAR-T and gene therapy company where she successfully led the IND approval of a CAR-T cell therapy. Our Chief Financial Officer, Dr. Kevin Xie, Ph.D., has over 18 years of experience in healthcare investment and held various leadership and management positions at Fosun Group, Locust Walk Capital, Scopia Capital, and Great Point Partners. Dr. Xie serves on the board of ViewRay Inc (Nasdaq: VRAY) and Alpha Healthcare Acquisition Corp. (Nasdaq: AHACU).

Summary Risk Factors

Our business is subject to numerous risks and uncertainties that you should be aware of before making a decision to invest in our ADSs. These risks are more fully described in the section titled “Risk Factors” immediately following this prospectus summary. These risks include, among others, the following:

- We are a clinical-stage biopharmaceutical company with limited operating history, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We have incurred significant losses in every year since our inception. We expect to continue to incur losses over the next several years and may never achieve or maintain profitability.
- We will need to obtain funding from time to time to complete the development and any commercialization of our product candidates, which may not be available on acceptable terms, or at all. If we are unable to raise capital when needed, we may be forced to delay, reduce or eliminate our product development programs or other operations.
- If we fail to implement and maintain effective internal controls to remediate our material weakness over financial reporting, our ability to produce accurate financial statements on a timely basis could be impaired.
- All of our product candidates are in early stages of development. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.
- Our product candidates are based on novel technologies, which make it difficult to predict the timing, results and cost of product candidate development and likelihood of obtaining regulatory approval.
- Our future success is highly dependent on the regulatory approval of GC012F, GC027 and our other pipeline programs. All of our product candidates will require significant preclinical study and clinical trial before we can seek regulatory approval for and launch a product commercially.
- Adverse effects or other safety risks associated with our product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials, cause us to abandon product candidates, limit the commercial profile of an approved label or result in significant negative consequences following any potential marketing approval.

- We may not be successful in our efforts to extend our pipeline of product candidates, including identifying or discovering additional product candidates in the future.
- Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these product candidates on a timely basis or at all, which would have an adverse effect on our business.
- As a company currently with substantial operations outside of the United States, our business is subject to economic, political, regulatory and other risks associated with international operations.
- Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. As a result, we cannot predict when or if, and in which territories, we will obtain marketing approval to commercialize a product candidate.
- If we are unable to establish sales, marketing and distribution capabilities for our product candidates, or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing our product candidates, if and when they are approved.
- If we are unable to obtain, maintain, defend and enforce patent and other intellectual property rights for our technologies and product candidates, or if the scope of the patent and other intellectual property rights obtained is not sufficiently broad, our competitors and other third parties could develop and commercialize technology and biologics similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired.
- The audit report included in this prospectus is prepared by an auditor who is not inspected by the Public Company Accounting Oversight Board and, as such, our investors are deprived of the benefits of such inspection.

Implications of Being an Emerging Growth Company

As a company with less than US\$1.07 billion in revenue for the last fiscal year, we qualify as an “emerging growth company” pursuant to the Jumpstart Our Business Startups Act of 2012, or 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, or Section 404, related to the assessment of the effectiveness of the emerging growth company’s internal control over financial reporting. We have elected to take advantage of such exemptions.

We will remain an emerging growth company until the earliest of (a) the last day of our 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 previous 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 Securities Exchange Act of 1934, as amended, or 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.

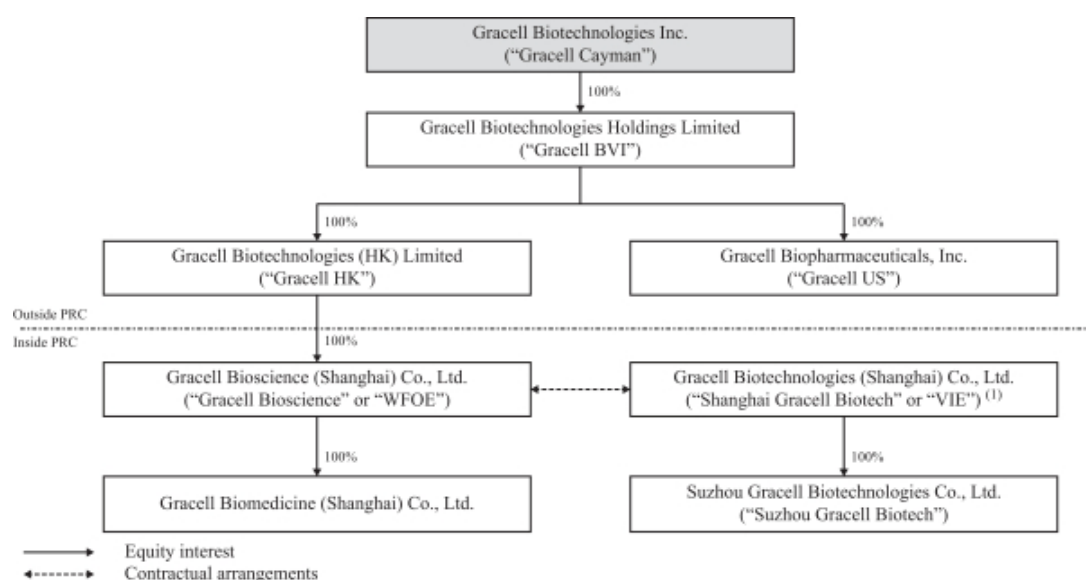
Corporate History and Information

We are an exempted company incorporated in the Cayman Islands with limited liability. We commenced operations in May 2017 through Gracell Biotechnologies (Shanghai) Co., Ltd., a company incorporated in China, which we refer to as Shanghai Gracell Biotech in this prospectus. In April 2018, Shanghai Gracell Biotech incorporated Suzhou Gracell Biotechnologies Co., Ltd., a company incorporated in China, which we refer to as Suzhou Gracell Biotech in this prospectus. Currently, we conduct research and development activities in

biotechnologies and pharmaceutical industries primarily through Suzhou Gracell Biotech and Shanghai Gracell Biotech. In May 2018, we incorporated Gracell Biotechnologies Inc., or Gracell Cayman, under the laws of the Cayman Islands as our offshore holding company. Shortly after its incorporation, Gracell Cayman established a wholly owned subsidiary, Gracell Biotechnologies Holdings Limited, or Gracell BVI, under the laws of the British Virgin Islands in May 2018. Gracell BVI in turn established its wholly owned subsidiaries Gracell Biotechnologies (HK) Limited, or Gracell HK, and Gracell Biopharmaceuticals, Inc., or Gracell US, in June 2018 and February 2020, respectively. In August 2018, Gracell Bioscience (Shanghai) Co., Ltd., which we refer to as Gracell Bioscience or our WFOE in this prospectus, was incorporated as a PRC subsidiary wholly owned by Gracell HK. Our WFOE incorporated its wholly owned PRC subsidiary Gracell Biomedicine (Shanghai) Co., Ltd. in August 2020.

Due to restrictions imposed by PRC laws and regulations on foreign ownership of companies engaged in the development and application of human stem cell or gene diagnostic and therapeutic technologies and other related businesses, our WFOE entered into a series of contractual arrangements, as amended and restated, with Shanghai Gracell Biotech and its shareholders, through which we obtained control over Shanghai Gracell Biotech and its subsidiary. As a result, we are regarded as the primary beneficiary of Shanghai Gracell Biotech and its subsidiary. We treat Shanghai Gracell Biotech and its subsidiary as our consolidated affiliated entities under U.S. GAAP and have consolidated the financial results of these entities in our consolidated financial statements in accordance with U.S. GAAP. We also refer Shanghai Gracell Biotech as our VIE in this prospectus.

The following diagram illustrates our corporate structure as a result of our reorganization mentioned above and as of the date of this prospectus, including our significant subsidiaries and other entities that are material to our business:



(1) Shareholders of Shanghai Gracell Biotech are Dr. William Wei Cao, Suzhou Lirui Equity Investment Center (Limited Partnership) (苏州礼瑞股权投资中心(有限合伙)), Suzhou Private Capital Investment (苏州民营资本投资控股有限公司) and Chengdu Miaoji Medical Technology Co., Ltd. (成都妙济医疗技术有限公司), holding 87.0%, 4.5%, 4.5% and 4.0%, respectively, of the equity interest in the VIE. Dr. Cao is our Founder, Chairman of board of directors and Chief Executive Officer. Suzhou Lirui Equity Investment Center (Limited Partnership), Suzhou Private Capital Investment and Chengdu Miaoji Medical Technology Co., Ltd. are our shareholders.

Our principal executive offices are located at Building 12, Block B, Phase II, Biobay Industrial Park, 218 Sangtian St., Suzhou Industrial Park, People's Republic of China. Our telephone number at this address is

+86-512-6262-6701. Our registered office in the Cayman Islands is located at Sertus Incorporations (Cayman) Limited, Sertus Chambers, Governors Square, Suite # 5-204, 23 Lime Tree Bay Avenue, P.O. Box 2547, Grand Cayman, KY1-1104, Cayman Islands. Investors should submit any inquiries to the address and telephone number of our principal executive offices.

Our main website is www.gracellbio.com. The information contained on this website is not a part of this prospectus. Our agent for service of process in the United States is _____, located at _____.

This prospectus includes our trademarks, trade names and service marks, such as “Gracell”, the Gracell logo and the FasTCAR logo, which are protected under applicable intellectual property laws and are our property. This prospectus also contains trademarks, trade names and service marks of other companies, which are the property of their respective owners. Solely for convenience, trademarks, trade names and service marks referred to in this prospectus may appear without the ®, ™ or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to such trademarks, trade names and service marks. We do not intend our use or display of other parties’ trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

Implications of Being a Foreign Private Issuer

Upon completion of this offering, we will report under the Exchange Act as a non-U.S. company with foreign private issuer status. Even after we no longer qualify as an emerging growth company, as long as we qualify as a foreign private issuer under the Exchange Act we will be exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including:

- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act;
- the sections of the Exchange Act requiring insiders to file public reports of their share ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and
- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events.

Both foreign private issuers and emerging growth companies are also exempt from certain more stringent executive compensation disclosure rules. Thus, even if we no longer qualify as an emerging growth company, but remain a foreign private issuer, we will continue to be exempt from the more stringent compensation disclosures required of companies that are neither an emerging growth company nor a foreign private issuer.

Conventions that Apply to this Prospectus

Unless otherwise indicated or the context otherwise requires, references in this prospectus to:

- “ADSS” are to the American depositary shares, each of which represents _____ of our ordinary shares;
- “ADRs” are to the American depositary receipts that evidence the ADSS;
- “CAR” refers to chimeric antigen receptor;
- “China” or “PRC” refers to the People’s Republic of China, excluding, for the purpose of this prospectus only, the Hong Kong Special Administrative Region, the Macau Special Administrative Region and Taiwan; “Greater China” does not exclude Hong Kong Special Administrative Region, the Macau Special Administrative Region and Taiwan;

- “ordinary shares” are to ordinary shares of our company, par value US\$0.0001 per share;
- “Renminbi” or “RMB” refers to the legal currency of the PRC;
- “Preferred Shares” are to the Series A, Series B-1 and Series B-2 preferred shares, par value \$0.0001 per share; and
- “US\$,” “U.S. dollars,” “\$,” or “dollars” are to the legal currency of the United States.

Our reporting currency is Renminbi. This prospectus contains translations of certain Renminbi amounts into U.S. dollars solely for the convenience of readers. Unless otherwise noted, all translations from Renminbi to U.S. dollars and from U.S. dollars to Renminbi in this prospectus were made at a rate of RMB6.7896 to US\$1.00, the noon buying rate on September 30, 2020 set forth in the H.10 statistical release of the Board of Governors of the Federal Reserve System. We make no representation that any Renminbi or U.S. dollar amounts could have been, or could be, converted into U.S. dollars or Renminbi, as the case may be, at any particular rate, the rates stated below, or at all. On October 9, 2020, the exchange rate set forth in the H.10 statistical release of the Federal Reserve Board was RMB6.6933 to US\$1.00.

THE OFFERING	
ADSs offered by us	ADSs.
Over-allotment option	We have granted to the underwriters an option, exercisable within 30 days from the date of this prospectus, to purchase up to an aggregate of additional ADSs.
ADSs outstanding immediately after this offering	ADSs (or ADSs if the underwriters exercise their over-allotment option in full).
Ordinary shares outstanding immediately after this offering	ordinary shares (or ordinary shares if the underwriters exercise their option to purchase additional ADSs in full).
The ADSs	Each ADS represents ordinary shares.
	The depositary will hold ordinary shares underlying your ADSs. You will have rights as provided in the deposit agreement among us, the depositary and owners and holders of ADSs from time to time.
	We do not expect to pay dividends in the foreseeable future. If, however, we declare dividends on our ordinary shares, the depositary will distribute 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.
	You may surrender your ADSs to the depositary for cancellation in exchange for ordinary shares. The depositary will charge you fees for any cancellation.
	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.
Use of Proceeds	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.
	We expect that we will receive net proceeds of approximately \$ million from the sale of ADSs in this offering, assuming an initial public offering price of \$ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	<p>We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to fund the research and development of GC012F and GC027, the research and development of our other clinical stage and earlier-stage product candidates, the expansion of our manufacturing facilities in China and the construction of our research and development center in the United States as well as for working capital and other general corporate purposes. See “Use of Proceeds” for additional information.</p>
Lock-up	<p>We, our officers and directors, all of our existing shareholders and certain of our option holders have agreed with the underwriters not to sell, transfer or 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. See “Shares and ADSs Eligible for Future Sale” and “Underwriting.”</p>
Risk Factors	<p>See “Risk Factors” and other information included in this prospectus for a discussion of the risks relating to investing in our ADSs. You should carefully consider these risks before deciding to invest in our ADSs.</p>
Directed share program	<p>At our request, the underwriters have reserved up to % of the shares of ADSs for sale at the initial public offering price to persons who are directors, officers or employees, or who are otherwise associated with us through a directed share program. If purchased by these persons, these shares will be subject to a lock-up restriction. Any directed shares not purchased will be offered by the underwriters to the general public on the same basis as all other shares offered. See “Underwriting.”</p>
Listing	<p>We intend to apply to have the ADSs listed on The Nasdaq Global Market. The ADSs and shares will not be listed on any other stock exchange or traded on any automated quotation system.</p>
Proposed Nasdaq Global Market Symbol for the ADSs	<p>GRCL</p>
Payment and settlement	<p>The underwriters expect to deliver the ADSs against payment therefor through the facilities of the Depositary Trust Company on , 2020.</p>
Depository	<p>The number of ordinary shares that will be issued and outstanding immediately after this offering is based on the ordinary shares outstanding prior to giving effect to this offering, which consists of ordinary shares outstanding as of , 2020 and the conversion of all of our issued and outstanding preference shares into ordinary shares immediately prior to the closing of this offering, and excludes:</p> <ul style="list-style-type: none"> • ordinary shares issuable upon the exercise of options outstanding as of , 2020, with a weighted average exercise price of US\$ per ordinary share; and • ordinary shares available for future issuance under our employee stock option plan.

Except as otherwise indicated, all information in this prospectus reflects and assumes:

- no exercise of the outstanding options described above;
- no exercise of the underwriters' over-allotment option to purchase additional ADSs representing ordinary shares; and
- the filing and effectiveness of our Amended and Restated Memorandum and Articles of Association, which will occur immediately prior to the completion of this offering.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables set forth our summary consolidated financial data for the period indicated. We have derived the consolidated statement of comprehensive loss for the years ended December 31, 2018 and 2019 from our audited consolidated financial statements included elsewhere in this prospectus. You should read this 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.

The following table presents our summary consolidated statement of comprehensive loss data for the years ended December 31, 2018 and 2019:

	For the Year Ended December 31,		
	2018 RMB (in thousands, except per share data)	2019 RMB US\$	2019 US\$
Summary consolidated statement of comprehensive loss:			
Expenses			
Research and development expenses	(52,243)	(119,218)	(17,559)
Administrative expenses	(10,261)	(27,362)	(4,030)
Loss from operations	(62,504)	(146,580)	(21,589)
Interest income	1,435	3,932	579
Other income	256	1,449	213
Foreign exchange gain, net	—	2,556	376
Others, net	20	(21)	(3)
Loss before income tax	(60,793)	(138,664)	(20,424)
Income tax expense	—	—	—
Net loss	(60,793)	(138,664)	(20,424)
Deemed dividend to convertible redeemable preferred shareholders	—	(25,390)	(3,740)
Accretion of convertible redeemable preferred shares to redemption value	(12,199)	(36,802)	(5,420)
Net loss attributable to Gracell Biotechnologies Inc.’s ordinary shareholders	(72,992)	(200,856)	(29,584)
Other comprehensive income			
Foreign currency translation adjustments, net of nil tax	—	(3,159)	(465)
Total comprehensive loss attributable to Gracell Biotechnologies Inc.’s ordinary shareholders	(72,992)	(204,015)	(30,049)
Weighted average number of ordinary shares used in per share calculation			
Basic	100,089,552	99,053,363	99,053,363
Diluted	100,089,552	99,053,363	99,053,363
Net loss per share attributable to Gracell Biotechnologies Inc.’s ordinary shareholders			
Basic	(0.73)	(2.03)	(0.30)
Diluted	(0.73)	(2.03)	(0.30)

The following table presents our summary consolidated statement of financial position as of December 31, 2018 and 2019:

	As of December 31,		
	2018	2019	
	Actual RMB	Actual RMB	US\$
(in thousands)			
Summary consolidated statement of financial position data:			
Cash and cash equivalents	11,890	312,058	45,961
Short-term investments	102,000	4,200	619
Property, equipment and software	16,285	48,323	7,117
Total assets	148,518	412,217	60,713
Total liabilities	146,135	156,861	23,103
Total mezzanine equity	83,404	547,843	80,688
Total shareholders' deficit	(81,021)	(292,487)	(43,078)
Ordinary shares	69	68	10
Total liabilities, mezzanine equity and shareholders' deficit	148,518	412,217	60,713

The following table presents our summary consolidated statement of cash flows for the years ended December 31, 2018 and 2019:

	For the Year Ended December 31,		
	2018	2019	
	RMB	RMB	US\$
(in thousands, except per share data)			
Summary consolidated statement of cash flows:			
Net cash used in operating activities	(61,856)	(135,393)	(19,941)
Net cash (used in) generated from investing activities	(113,357)	41,368	6,093
Net cash generated from financing activities	138,695	394,796	58,148
Effect of exchange rate on cash and cash equivalents	—	(603)	(90)
Net (decrease) increase cash and cash equivalents	(36,518)	300,168	44,210
Cash and cash equivalents at the beginning of year	48,408	11,890	1,751
Cash and cash equivalents at the end of year	11,890	312,058	45,961

RISK FACTORS

Investing in our ADSs involves a high degree of risk. Before you invest in our ADSs, you should carefully consider the risks described below together with all of the other information contained in this prospectus, including our financial statements and the related notes included elsewhere in this prospectus. If any of the following risks actually occurs, our business, prospects, operating results and financial condition could suffer materially. In such event, the trading price of our ADSs could decline, which would cause you to lose all or part of your investment. Please also see “Special Note Regarding Forward-Looking Statements.”

Risks Related to Our Limited Operating History, Financial Position and Need for Additional Capital

We are a clinical-stage biopharmaceutical company with limited operating history, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are a clinical-stage biopharmaceutical company with limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. All of our product candidates are in early development and none have been approved for commercial sale. We have not demonstrated an ability to successfully complete late-stage clinical trials, obtain regulatory approvals, manufacture our product candidates at commercial scale or arrange for a third-party to do so on our behalf, conduct sales and marketing activities necessary for successful commercialization, or obtain reimbursement in the countries of sale. We may encounter unforeseen expenses, difficulties, complications, and delays in achieving our business objectives. Our short history as an operating company makes any assessment of our future success or viability subject to significant uncertainty. If we do not address these risks successfully or are unable to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities, then our business will be materially harmed.

We have incurred significant losses in every year since our inception. We expect to continue to incur losses over the next several years and may never achieve or maintain profitability.

We have no products approved for commercial sale, have not generated any revenue from commercial sales of our product candidates, and have incurred net losses each year since we commenced operations in 2017. For the years ended December 31, 2018 and 2019, our net losses were RMB60,793 million and RMB138,664 million (US\$20,424 million), respectively. As of December 31, 2019, we had an accumulated deficit of RMB289,396 (US\$42,623 million).

We have been devoting the majority of our financial resources and efforts to our research and development activities, including pre-clinical testing of our technologies, research and development of our CAR-T cell therapy product candidates as well as building our research and development capabilities. None of our product candidates have received marketing approval, and we may never be successful in obtaining marketing approval and commercializing product candidates. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. These net losses will adversely impact our shareholders’ deficit and net assets and may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially as we:

- continue our ongoing and planned research and development of our pipeline product candidates;
- conduct preclinical studies and clinical trials for any additional product candidates that we may pursue in the future, including ongoing and planned development of additional therapies for the treatment of ovarian cancer, breast cancer, peripheral T-cell lymphoma, or PTCL, a subtype of NHL, and T cell lymphoblastic leukemia, or T-LBL;
- seek to discover and develop additional product candidates and further expand our clinical product pipeline;

- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- continue to scale up manufacturing capacity with the aim of securing sufficient quantities to meet our capacity requirements for clinical trials and potential commercialization;
- establish sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain regulatory approval;
- develop, maintain, expand and protect our intellectual property portfolio; acquire or in-license other product candidates and technologies;
- hire additional clinical, quality control and manufacturing personnel;
- add clinical, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts;
- expand our operations in China and establish our operations in the United States and other geographic regions; and
- incur additional legal, accounting and other expenses associated with operating as a public company.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, obtaining regulatory approval, manufacturing, marketing and selling any products for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with the development, delivery and commercialization of complex autologous and allogeneic cell therapies, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase and profitability could be further delayed.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our ADSs and could impair our ability to raise capital, expand our business, maintain our research and development efforts or continue our operations. A decline in the value of our ADSs could also cause you to lose all or part of your investment.

We will need to obtain funding from time to time to complete the development and any commercialization of our product candidates, which may not be available on acceptable terms, or at all. If we are unable to raise capital when needed, we may be forced to delay, reduce or eliminate our product development programs or other operations.

Since our inception, we have used substantial amounts of cash to fund our operations and expect our expenses to increase substantially during the next few years. The development of biopharmaceutical product candidates is capital intensive. As our product candidates enter and advance through preclinical studies and clinical trials, we will require substantial additional funding to meet our financial needs and to pursue our business objectives.

As of December 31, 2019, we had RMB316.3 million (US\$46.6 million) in cash, cash equivalents and short-term investments. We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. However, we will need to raise additional capital to complete the development and

commercialization of our lead product candidates, GC012F for the treatment of r/r MM and GC027 for the treatment of r/r T-ALL and our other product candidates and in connection with our continuing operations and other planned activities. Our future capital requirements will depend on many factors, including:

- the progress, results and costs of laboratory testing, manufacturing, and preclinical and clinical development for our current product candidates;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials of other product candidates that we may pursue;
- the development requirements of other product candidates that we may pursue;
- the timing and amounts of any milestone or royalty payments we may be required to make under future license agreements, if we enter into such agreements;
- the costs of expanding our research and development capacities and manufacturing infrastructure into the United States, including hiring additional research and development, clinical, quality control and manufacturing personnel;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the amount of revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, obtaining, maintaining, protecting and enforcing our intellectual property rights and defending against any intellectual property-related claims;
- the costs of operating as a public company; and
- the extent to which we acquire or in-license other product candidates and technologies.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. To date, we have no products approved for commercial sale, nor have we generated any revenue from product sales. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish some rights to our technologies or our product candidates on terms that are not favorable to us. Any additional capital-raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current and future product candidates, if approved. If we are unable to raise capital when needed or on acceptable terms, we may be forced to delay, reduce or altogether cease our research and development programs or future commercialization efforts.

Risks Related to the Development of Our Product Candidates

All of our product candidates are in early stages of development. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

We are very early in our development efforts. Except for our allogeneic donor-derived CAR-T product candidate, GC007g, for which we have obtained IND approval from the National Medical Products

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Administration, or the NMPA, and are initiating the Phase 1 study in China, all of our product candidates are in preclinical studies or investigator-initiated Phase 1 trials and have not been advanced into IND studies. There is no assurance that these or any other future clinical trials of our product candidates will be successful or will generate compelling clinical data to support further development. Except for the IND approval we obtained from the NMPA for GC007g in B-ALL, we have not obtained any IND approval from, or submitted any IND application to the U.S. Food and Drug Administration, or the FDA, the NMPA or other regulatory authorities in connection with our product candidates. There is no assurance that the NMPA, the FDA or other regulatory authorities will permit the submitted and future IND applications for our product candidates to go into effect in a timely manner or at all. Even if we successfully obtain IND approvals for our product candidates, there is no assurance that we will receive approvals or clearance for advancing or accelerating our development efforts such as for our recent submission to the Center for Drug Evaluation, or CDE, of an innovative seamless Phase 1b/2 study design for GC007g, and eventually marketing approval from the FDA, the NMPA or other regulatory agencies for any of our product candidates.

Biopharmaceutical development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. Failure to obtain regulatory approval for our product candidates will prevent us from commercializing and marketing our product candidates. The success in the development of our product candidates will depend on many factors, including:

- completing preclinical studies and receiving regulatory approvals or clearance for conducting clinical trials for our preclinical-stage programs;
- obtaining positive results in our clinical trials demonstrating efficacy, safety and durability of effect of our product candidates;
- receiving approvals for commercialization of our product candidates from regulatory authorities;
- manufacturing our product candidates at an acceptable quality and cost; and
- maintaining and growing an organization of scientists, medical professionals and business people who can develop and commercialize our products and technology.

Many of these factors are beyond our control, including the time needed to adequately complete clinical testing and the regulatory submission process. It is possible that none of our product candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, or any other factors impacting the successful development of biopharmaceutical products, we could experience significant delays or an inability to successfully develop our product candidates, which would materially harm our business.

Our product candidates are based on novel technologies, which make it difficult to predict the timing, results and cost of product candidate development and likelihood of obtaining regulatory approval.

We have concentrated our primary research and development efforts on our CAR-T cell therapies using our proprietary technology platforms, FasTCAR and TruUCAR, our in-house know-how, our expertise in tumor biology and cell programming, and our future success is highly dependent on the validity of our technology platforms and the successful development and manufacture of our CAR-T product candidates. We do not currently have any approved or commercialized products. As with other targeted therapies, off-tumor or off-target activity could delay development or require us to reengineer or abandon a particular product candidate. Because CAR-T cell therapies represent a relatively new field of cellular immunotherapy and cancer treatment generally, developing and commercializing our product candidates subjects us to a number of risks and challenges, including:

- obtaining regulatory approval for our product candidates, as the FDA, the NMPA and other regulatory authorities have limited experience with CAR-T therapies for cancer;

- in the case of autologous CAR-T cell therapies, developing and deploying consistent and reliable processes for engineering a patient's T cells *ex vivo* and *infusing the engineered T cells back into the patient*;
- conditioning patients with chemotherapy in conjunction with delivering each of our products, which may increase the risk of adverse effects of our product candidates;
- sourcing clinical and, if approved, commercial supplies of the materials used to manufacture our product candidates;
- developing programming modules with the desired properties, while avoiding adverse reactions;
- creating viral vectors capable of delivering multiple programming modules;
- developing a reliable and consistent *ex vivo* gene modification and manufacturing process;
- establishing manufacturing capacity suitable for the manufacture of our product candidates in line with expanding enrollment in our clinical studies and our projected commercial requirements;
- achieving cost efficiencies in the scale-up of our manufacturing capacity;
- minimizing and avoiding infection and contamination during production of product candidates;
- developing protocols for the safe administration of our product candidates;
- educating medical personnel regarding our CAR-T technologies and the potential side effect profile of each of our product candidates, such as potential adverse effects related to cytokine release syndrome, or CRS, neurotoxicity, including immune effector cell-associated neurotoxicity syndrome, or ICANS, and/or graft versus host disease, or GvHD;
- establishing integrated solutions in collaboration with specialty treatment centers in order to reduce the burdens and complex logistics commonly associated with the administration of T cell therapies;
- establishing sales and marketing capabilities or partnerships to successfully launch and commercialize our product candidates if and when we obtain any required regulatory approvals, and risks associated with gaining market acceptance of a novel therapy if we receive approval; and
- the availability of coverage and adequate reimbursement from third-party payors for our novel and personalized therapies in connection with commercialization of any approved product candidates.

We may not be able to successfully develop our CAR-T product candidates or our technology in a manner that will yield products that are safe, effective, scalable or profitable. Additionally, because our technology involves the genetic modification of patient cells *ex vivo*, we are subject to additional regulatory challenges and risks, including:

- regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future. To date, only three CAR-T cell therapy products that involve the genetic modification of patient cells have been approved in the United States and/or the European Union, and none have been approved in China;
- genetically modified products in the event of improper insertion of a gene sequence into a patient's chromosome could lead to lymphoma, leukemia or other cancers, or other aberrantly functioning cells;
- although our viral vectors are not able to replicate, there is a risk with the use of retroviral or lentiviral vectors that they could lead to new or reactivated pathogenic strains of virus or other infectious diseases; and
- the FDA recommends a 15-year follow-up observation period for all patients who receive treatment using gene therapies and a trial guidance promulgated by NMPA requires a similar follow-up observation period for patients who receive cell therapeutic products, which has to be sufficient and could be as long as life-time, and we may need to adopt an observation period for our product candidates.

Moreover, public perception and awareness of cell therapy safety issues may adversely influence the willingness of subjects to participate in clinical trials of our product candidates, or if approved, of physicians to prescribe our products. Physicians, hospitals and third-party payors often are slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. Treatment centers may not be willing or able to devote the personnel and establish other infrastructure required for the administration of CAR-T cell therapies. Physicians may not be willing to undergo training to adopt this novel and personalized therapy, may decide the therapy is too complex to adopt without appropriate training and may choose not to administer the therapy. Based on these and other factors, hospitals and payors may decide that the benefits of this new therapy do not or will not outweigh its costs.

Our future success is highly dependent on the regulatory approval of GC012F, GC027 and our other pipeline programs. All of our product candidates will require significant development through preclinical studies and/or clinical trials before we can seek regulatory approval for and launch a product commercially.

We do not have any products that have gained regulatory approval for marketing. Our business is substantially dependent on our ability to obtain regulatory approval for, and, if approved, to successfully commercialize our lead product candidates, GC012F for the treatment of r/r MM, and GC027, for the treatment of r/r T-ALL, and our other pipeline programs. We cannot commercialize product candidates in the United States without first obtaining regulatory approval for the product from the FDA; similarly, we cannot commercialize product candidates in China or other countries without obtaining regulatory approval from comparable regulatory authorities in relevant jurisdictions, such as the NMPA in China, the EMA in the European Union and the PMDA in Japan. Before obtaining regulatory approvals for the commercial sale of any product candidate for a particular indication, we must demonstrate with substantial evidence gathered in preclinical and clinical studies that the product candidate is safe and effective for that indication and that the manufacturing facilities, processes and controls comply with regulatory requirements with respect to such product candidate. Prior to seeking approval for any of our product candidates, we will need to confer with the FDA, the NMPA and other regulatory authorities regarding the design of our clinical trials and the type and amount of clinical data necessary to seek and gain approval for our product candidates. In addition, approval policies, regulations, or the type and amount of preclinical and clinical data necessary to gain approval may change during the course of a product candidate's research and development and may vary among jurisdictions. It is possible that none of our existing product candidates or any future product candidates will ever obtain regulatory approval.

Any of the following instances during preclinical studies and clinical trials could cause our product candidates to fail to receive marketing regulatory approval from the FDA, the NMPA or other regulatory authorities:

- disagreement with the design, protocol or conduct of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of a biologics license application, or BLA, or other submission or to obtain regulatory approval;
- failure to obtain approval of the manufacturing processes of our facilities;
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval; or
- lack of adequate funding to complete a clinical trial in a manner that is satisfactory to the applicable regulatory authority.

The FDA, the NMPA or a comparable regulatory authority may require us to provide more information, including additional preclinical or clinical data, to support a regulatory approval. To obtain such data, we may need to perform additional preclinical studies, clinical trials, or both, or modify our manufacturing processes, which may delay or prevent regulatory approval and our commercialization plans, or force us to abandon the development program. If we change our manufacturing processes, we may also be required to conduct additional clinical trials or other studies, which equally could delay or prevent approval of our product candidates.

Depending on the results of the preclinical and clinical trials in our product candidates, we may apply for expedited approval programs for those candidates, such as the breakthrough and conditional approval programs. There is no certainty that the clinical data obtained from trials of our product candidates will be sufficient to qualify for any expedited approval program.

Even if a product candidate were to successfully obtain marketing approval from the FDA, the NMPA or other comparable regulatory authorities in other jurisdictions, any approval might contain significant limitations related to use restrictions for specified indications, specified age groups, warnings, precautions, distribution or contraindications, may be subject to burdensome and costly post-approval trials, risk management requirements or other post-marketing commitments, or may be subject to requirement of a liable that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. If we are unable to obtain regulatory approval for one of our product candidates in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding to continue the development of that product or generate revenue attributable to that product candidate. Also, any regulatory approval of our current or future product candidates, even if obtained, may be withdrawn.

We may not be successful in our efforts to extend our pipeline of product candidates, including identifying or discovering additional product candidates in the future.

A key element of our strategy is to use our proprietary technology platforms, FasTCAR and TruUCAR, our in-house know-how and our expertise in tumor biology and cell programming to develop and deliver what we believe are safer and more effective next-generation CAR-T cell therapies. Our initial focus is on the development of a pipeline of product candidates for the treatment of hematological cancers, including our lead product candidates, GC012F, for the treatment of r/r MM, and GC027, for the treatment of r/r T-ALL, and the progression of these product candidates through clinical development. We also have a broad portfolio of earlier stage candidates targeting various cancer indications, such as ovarian cancer, breast cancer, PTCL, a subtype of NHL, and T-LBL. However, we may not be able to develop product candidates that are safe and effective, or which compare favorably with other commercially available alternatives. Even if we are successful in continuing to build our pipeline and developing first-in-class next-generation product candidates or expanding into solid tumor indications, such as ovarian and breast cancer, the potential product candidates that we identify may not be suitable for clinical development, including as a result of lack of safety, lack of tolerability, lack of anti-tumor activity, or other characteristics that indicate that they are unlikely to be products that will receive marketing approval, achieve market acceptance or obtain reimbursements from third-party payors. There is no assurance that we will be able to successfully advance any of these additional product candidates through the development process. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

- we may not be successful in identifying additional product candidates;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in preclinical or clinical testing;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;

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- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our development program so that the continued development of that product candidate is no longer reasonable;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, discover, develop or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations.

Even if we receive approval from the FDA, the NMPA or other comparable regulatory agencies to market our product candidates, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. Further, because of our limited financial and managerial resources, we are required to focus our research programs on certain product candidates and on specific diseases. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases that may later prove to have greater commercial potential, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights.

If we do not successfully develop and commercialize product candidates or collaborate with others to do so, we will not be able to obtain product revenue in future periods, which could significantly harm our financial position and adversely affect the trading price of our ADSs.

Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these product candidates on a timely basis or at all, which would have an adverse effect on our business.

Most of our product candidates are still in the preclinical development and investigator-initiated clinical stage, and the risk of failure of these programs is high. Before we can commence registrational clinical trials for a product candidate, we must complete extensive preclinical testing and studies to obtain regulatory clearance to initiate registrational human clinical trials, including based on IND applications in the United States and clinical trial applications, or CTAs, in China. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA, the NMPA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit IND applications or similar applications for our preclinical programs on the timelines we expect, or at all, and we cannot be sure that submission of IND applications or similar applications will result in the FDA, the NMPA or other regulatory authorities allowing registrational clinical trials to begin.

Clinical trials are difficult to design and implement, involve uncertain outcomes and may not be successful.

Human clinical trials are difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The design of a clinical trial can determine whether its results will support approval of a product candidate and flaws in the design of a clinical trial may not become apparent until the clinical trial is well

advanced. As an organization, we have limited experience designing clinical trials and may be unable to design and execute clinical trials to support regulatory approval. There is a high failure rate for biologic products proceeding through clinical trials, which may be higher for our product candidates because they are based on new technology and engineered on a patient-by-patient basis. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

Success in preclinical studies or early phases of clinical trials may not be indicative of results in future clinical trials.

Results from preclinical studies are not necessarily predictive of future clinical trial results, and interim results of a clinical trial or an investigator-initiated Phase 1 trial are not necessarily indicative of final results. While we have received some compelling data to date in the investigator-initiated Phase 1 trials for our lead product candidates, such as GC012F, for the treatment of r/r MM, and GC027, for the treatment of r/r T-ALL, these trials are still ongoing except for the completed investigator-initiated Phase 1 trial for GC007g, and there is no assurance that we will be able to generate the same compelling data in the subsequent clinical trials. For example, we are still in the process of producing and gather trial data for GC012F and GC027 in order to support our expected IND applications for GC012F to the FDA and the NMPA by the end of 2021, and for GC027 to the same regulatory authorities in 2022. We also have a broad portfolio of earlier stage product candidates, and because they are in earlier stages of development, we do not know whether these candidates will be effective and safe for the intended indications in humans. Our product candidates may fail to show the desired safety and efficacy in clinical development despite compelling results in preclinical studies or having successfully advanced through initial investigator-initiated Phase 1 trials. Any failure to establish sufficient efficacy and safety could cause us to abandon clinical development of our product candidates.

We depend on enrollment of patients in our clinical trials for our product candidates. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including the COVID-19 pandemic. The timely completion of clinical trials in accordance with the protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the number of patients with the disease or condition being studied;
- the understanding of risks and benefits of the product candidate in the trial;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating or drugs that may be used off-label for these indications;
- the size and nature of the patient population who meet inclusion criteria;
- the proximity of patients to study sites;
- the design of the clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;

- competing clinical trials for similar therapies or other new therapeutics not involving T cell-based immunotherapy;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before completion of their treatment.

In particular, some of our clinical trials are designed to enroll patients with characteristics that are found in a very small population. For example, T cell acute lymphoblastic leukemia, or T-ALL, the lead indication for our lead clinical product candidate GC027 has a low incidence overall and therefore clinical study enrollment will take longer. Other companies are conducting clinical trials with their T cell therapies in multiple myeloma, B cell acute lymphoblastic leukemia or T cell acute lymphoblastic leukemia, and seek to enroll patients in their studies that may otherwise be eligible for our clinical trials, which could lead to slow recruitment and delays in our clinical programs. In addition, since the number of qualified clinical investigators is limited, we will conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which could further reduce the number of patients who are available for our clinical trials in these clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and antibody therapy, rather than participating 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 clinical trials and adversely affect our ability to advance the development of our product candidates. In addition, many of the factors that may lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

We rely, and expect to continue to rely, on independent investigators and other third parties to conduct the preclinical and clinical trials for our product candidates. We do not have full control over the conduct of such trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with applicable regulatory requirements.

We depend and will continue to depend upon top-tier hospitals in China to conduct our preclinical and clinical trials, including both investigator-initiated trials and clinical trials initiated by us. Agreements with such third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, our product development activities would be delayed.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that GC007g's registration-enabling clinical study is conducted in accordance with the general investigational plan and protocols for the trial. Investigator-initiated trials pose similar risks as clinical trials initiated by us. While investigator-initiated trials may provide us with clinical data that can inform our future development strategy, we do not have full control over the protocols, administration, or conduct of the trials and the compliance of the extensive regulatory requirements that the trials are subject to, especially with respect to portions that need to be performed by third parties. As a result, we are subject to risks associated with the way investigator-initiated trials are conducted. Third parties in such investigator-initiated trials may not perform their responsibilities for our clinical trials on our anticipated schedule or consistent with clinical trial protocols or applicable regulations. Furthermore, any data integrity issues or patient safety issues arising out of any of these trials would be beyond our control, yet could adversely affect our reputation and damage the clinical and commercial prospects for our product candidates. Additional risks include difficulties or delays in communicating with investigators or administrators, procedural delays and other timing issues, and difficulties or differences in interpreting data. As a result, our reduced control over the conduct and timing of, and communications with the FDA, the NMPA and other comparable regulatory authorities regarding investigator-initiated trials expose us to additional risks and

uncertainties, many of which are outside our control, and the occurrence of which could adversely affect the prospects for our product candidates.

Moreover, the NMPA, having adopted the International Council for Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use, or ICH, requires us to comply with standards commonly referred to as good laboratory practices and good clinical practices for conducting, recording and reporting the results of preclinical and clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Similar regulatory requirements apply in the United States, where we plan to conduct clinical trials for our product candidates in the future. We are also required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored database within specified time frames. Failure to do so by us or third parties can result in NMPA's refusal to approve applications based on the clinical data, enforcement actions, adverse publicity and civil and criminal sanctions.

Furthermore, the third parties we work with may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the NMPA concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the NMPA. Any such delay or rejection could prevent us from commercializing our clinical-stage product candidates or any future product candidates.

We have studied our product candidates and plan to continue to study our product candidates in investigator-initiated clinical trials, and there is no assurance that the clinical data from these trials will be accepted or considered by the FDA, the NMPA, or other comparable regulatory authorities.

We are currently evaluating certain of our product candidates in investigator-initiated trials. In addition, part of our strategy is to continue to explore new opportunities for cell therapy in investigator-initiated clinical trials in China, where such trials are initiated and conducted under the oversight of the China National Health Commission, or NHC, as a medical practice technology, rather than the NMPA as a medical product. As a general matter, the NMPA will accept, review, and reject or approve a CTA only from the manufacturer of the investigational product as the sponsor of the CTA, rather than from a physician who intends to be the investigator and sponsor of the CTA. The NMPA distinguishes the former as registrational clinical trial, and the latter as non-registrational clinical trial, and normally will not consider the data generated from investigator-initiated non-registrational clinical trials, when it reviews the application for registrational clinical trial from the manufacturer.

In the case of CAR-T cell therapy, however, the NMPA is aware of the large number of investigator-initiated trials in China and the United States, and some reviewers from its CDE have published two articles on its website in February 2018 and October 2018, expressing the view that (1) the mainstream regulatory oversight is to follow the pathway of registrational clinical trial, but that (2) data from investigator-initiated trials may be considered if the non-registrational clinical trials otherwise fully comply with the same requirements applicable to registrational clinical trials, in particularly the requirements related to manufacturing quality control, informed consent, data integrity, data management, and all GCP requirements.

Accordingly, there is risk to part of our strategy to continue to explore new opportunities for cell therapy in investigator-initiated clinical trials in China that the NMPA may refuse to consider the data from the investigator-

initiated clinical trials of our product candidates due to concerns that (1) this does not follow the mainstream regulatory pathway of relying on registrational clinical trial, or that (2) the non-registrational clinical trials of our product candidates may not otherwise fully comply with the same requirements applicable to registrational clinical trials, as further explained below. There is no assurance that the clinical data from any of our investigator-initiated clinical trials in China will be accepted by the FDA or other comparable regulatory authorities outside of China, for any of our product candidates, nor can we assure that the clinical data from any of our investigator-initiated clinical trials in China, where the patients are predominately of Chinese descent, will produce similar results in patients of different races, ethnicities or those of non-Chinese descent.

The market opportunities for certain of our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small, and our projections regarding the size of the addressable market may be incorrect.

Cancer therapies are may be characterized as first line, second line or third line therapy depending options for treatment and prior treatments received, and the NMPA and FDA may approve new therapies initially only for the last line of therapy after SOC treatment. When blood cancers are detected, they are first treated with a curative intent. This approach may consists of chemotherapy, radiation, antibody drugs, tumor-targeted small molecules, or a combination of these. In addition, sometimes a bone marrow transplantation can be used as first treatment approach or first line therapy. If the patient's cancer relapses, then they may be given a second line and thereafter a third or fourth line therapy, which can consist of more chemotherapy, radiation, antibody drugs, tumor-targeted small molecules, or a combination of these, or bone marrow transplant. Generally, the higher the line of therapy, the lower the chance of a cure. With third or higher line, the goal of the therapy in the treatment of lymphoma and myeloma is to control the growth of the tumor and extend the life of the patient.

While we are initially developing GC012F as therapy for patients with r/r MM in later lines of therapy, there is no guarantee that it, or any of our product candidates, even if approved, would be approved for an earlier line of therapy. In addition, we may have to conduct additional large randomized clinical trials prior to gaining approval for the earlier line of therapy.

Our projections of both the number of people who have the cancers we are targeting, as well as the size of the patient population subset of people with these cancers in a position to receive first, second, third and fourth line therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be fewer than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. For example, our ongoing investigator-initiated Phase 1 trial for GC027 is seeking to enroll patients with r/r T-ALL, an indication that has a low incidence overall. Even if we obtain significant market share for our product candidates, because the potential target populations are small, we may never achieve significant revenue without obtaining regulatory approval for additional indications or as part of earlier lines of therapy.

Adverse effects or other safety risks associated with our product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials, cause us to abandon product candidates, limit the commercial profile of an approved label or result in significant negative consequences following any potential marketing approval.

In clinical trials conducted by other companies involving CAR-T cells, the most prominent acute toxicities included symptoms thought to be associated with CRS, such as fever, low blood pressure and kidney dysfunction. Some patients also experienced toxicity of the central nervous system, or neurotoxicity, such as confusion, tremor, cranial nerve dysfunction, seizures and speech impairment. Adverse events with the worst

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grades and attributed to CAR-T cells were severe and life threatening in some patients and often occur in the first two weeks after cell infusion. Although most of such adverse effects would be resolved within three weeks, some may progress to a life-threatening condition and lead to patient deaths.

Our clinical trials include cancer patients who are very sick and whose health is deteriorating. So far, adverse events observed in our clinical studies include but are not limited to CRS, ICANS, cytopenias, infection, bleeding and GvHD. While most of these adverse events were managed with treatment and supportive care, one r/r MM patient in the investigator-initiated Phase 1 trial for GC012F presented with fever and died shortly after Day 78 of unknown cause during the COVID-19 pandemic and one B-ALL patient withdrew treatment from the investigator-initiated Phase 1 trial for GC007g due to severe CRS accompanied with infection. It is possible that patients may continue to experience similar adverse events as were observed in clinical trials conducted by other companies and academic institutions involving CAR-T cells, and that patients may die during our clinical trials for various reasons, including as a result of receiving our product candidates, because the patient's disease is too advanced, or because the patient experiences medical problems that may not be related to our product candidate. Even if the deaths are not related to our product candidate, the deaths could affect perceptions regarding the safety of our product candidate.

Patient deaths and severe adverse effects caused by products or product candidates of other companies that are thought to have similarities with our product candidates, could result in the delay, suspension, clinical hold or termination of clinical trials by us, ethics committee, the FDA, the NMPA or other regulatory authorities for a number of reasons. If we elect or are required to delay, suspend or terminate any clinical trial of any product candidates that we develop, the commercial prospects of such product candidates will be harmed and our ability to generate product revenue from any of these product candidates would be delayed or eliminated. Serious adverse events observed in clinical trials could hinder or prevent market acceptance of the product candidate at issue. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, including during any long-term follow-up observation period recommended or required for patients who receive treatment using our products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a Risk Management Plan, or RMP, or similar risk management plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of the foregoing could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

Preliminary, interim and topline 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.

From time to time, we may publicly disclose interim, preliminary or topline data from our preclinical studies, investigator-initiated trials and clinical trials, and the results and related findings and conclusions, which

are based on a preliminary analysis of then-available data, are subject to change as patient enrollment and treatment continues and more patient data become available. For example, we have reported interim data from our ongoing investigator-initiated Phase 1 trial of GC012F for the treatment of r/r MM, GC019F for the treatment of r/r B-ALL, GC007F for the treatment of r/r B-NHL and GC027 for the treatment of T-ALL elsewhere in this prospectus. Adverse differences between previous preliminary or interim data and future interim or final data could significantly harm our business prospects. We may also announce topline data following the completion of a preclinical study, investigator-initiated Phase 1 trial or clinical trial, which may be subject to change following a more comprehensive review of the data related to the particular study or trial.

We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Regulatory agencies, including the FDA and the NMPA, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general.

As a result, the preliminary, interim or topline results that we report or release may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available.

If the interim, preliminary or topline data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

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

We may not commercialize, market, promote or sell any product candidate without obtaining marketing approval from the FDA, the NMPA or other comparable regulatory authority, and we may never receive such approvals. It is impossible to predict accurately when or if any of our product candidates will prove effective or safe in humans and will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each proposed indication. Clinical trials are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of clinical development.

We may experience numerous unforeseen events prior to, during or as a result of clinical trials that could delay or prevent our ability to receive marketing approval or commercialize any of our product candidates, including:

- the FDA, the NMPA or other comparable regulatory authority may disagree as to the number, design or implementation of our clinical trials, or may not interpret the results from clinical trials as we do;
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may not reach agreement on acceptable terms with prospective clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;

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- clinical trials of our product candidates may produce negative or inconclusive results;
- we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or we may fail to recruit eligible patients to participate in a trial;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators may issue a clinical hold, or regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the FDA, the NMPA or other comparable regulatory authorities may fail to approve our manufacturing processes or facilities;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- our product candidates may have undesirable side effects or other unexpected characteristics, particularly given their novel, first-in-human application, such as cytokine-induced toxicity and T cell aplasia, causing us or our investigators, regulators or institutional review boards to suspend or terminate the clinical trials; and
- the approval policies or regulations of the FDA, the NMPA or other comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

To the extent that the results of the trials are not satisfactory for the FDA, the NMPA or regulatory authorities in other countries or jurisdictions to approve our new drug application, or NDA, BLA or other comparable applications, the commercialization of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

We may not be able to successfully develop or operate our own manufacturing infrastructure for supply of our requirements of programmed CAR-T cell product candidates for use in clinical trials and for commercial sale.

We currently have manufacturing facilities in Suzhou and Shanghai, which meet the supply for the preclinical and clinical development and early-stage commercialization of our pipeline product candidates. We also have the capacity to support our global preclinical and clinical development and early commercialization with our manufacturing facilities.

We expect that operating our own commercial cell manufacturing facilities will provide us with enhanced control of material supply for both preclinical and clinical studies and the commercial market, enable the more rapid implementation of process changes, and allow for better long-term cost margins. However, we have limited experience as a company in designing and operating a commercial manufacturing facility and may never be successful in developing new manufacturing capability either on our own or together with a third-party. We plan to establish a manufacturing facility in the United State and may establish more manufacturing sites as we expand our commercial footprint to multiple geographies, which may lead to regulatory delays or prove costly. Even if we are successful, our manufacturing operations could be affected by cost-overruns, unexpected delays,

equipment failures, labor shortages, natural disasters, power failures and numerous other factors, or we may not be successful in establishing sufficient capacity to produce our product candidates in sufficient quantities to meet the requirements for the potential launch or to meet potential future demand, all of which could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business.

We may not be successful in achieving cost of goods at commercial scale that provide for an attractive margin.

We believe that our current, robust manufacturing processes are fit for commercial scale and we anticipate they will enable commercial supply at an economical cost. However, we have not yet established manufacturing capacity at sufficient commercial scale and may underestimate the cost and time required to do so, or overestimate cost reductions from economies of scale that can be realized with our manufacturing processes. We may ultimately be unable to manage the cost of goods for our product candidates to levels that will allow for a margin in line with our expectations and return on investment if and when those product candidates are commercialized.

Our product candidates are biologics whose manufacture is complex. If we encounter any difficulties in production, particularly with respect to process development or scaling-out of our manufacturing capabilities, supply of our product candidates for clinical trials or for patients, if approved, could be delayed or stopped.

We have developed our proprietary technology platform, FasTCAR, to manufacture autologous CAR-T cells with desired quality, significantly shortening manufacturing time from an industry norm of two to six weeks and achieving next-day manufacturing (22 to 36 hours). While we believe that the manufacture of autologous CAR-T cells using the FasTCAR platform is scalable for commercial production, each manufacturing process must be validated through the performance of process validation runs to guarantee that the facility, personnel, equipment and process work as designed. The other proprietary technology platform, TruUCAR, is designed to manufacture allogeneic CAR-T cells readily available off-the-shelf. We have not yet manufactured or processed our product candidates on a commercial scale using either FasTCAR platform or TruUCAR platform, and may not be able to do so for any of our product candidates.

We, like other manufacturers of biologic products, may encounter various difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process. These problems include delays or breakdowns in logistics and shipping, difficulties with production costs and yields, quality control, product testing, operator error, lack of availability of qualified personnel, as well as failure to comply with strictly enforced regulations.

Furthermore, if microbial, viral or other contaminations are discovered in our supply of product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any of these or other issues relating to the manufacture of our product candidates will not occur in the future. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

The manufacture and delivery of CAR-T cell therapies, in particular, autologous CAR-T cell therapies, to patients involves complex, integrated processes, including harvesting T cells from patients, programming the T cells *ex vivo*, multiplying the CAR-T cells to obtain the desired dose, and ultimately infusing the CAR-T cells back into a patient's body. As a result of the complexities, the cost to manufacture biologics in general, and our CAR-T cell product candidates in particular, is generally higher than traditional small molecule chemical compounds, and the manufacturing process is more variable and is more difficult and costly to reproduce. In addition, our manufacturing process will be susceptible to product loss or failure due to logistical issues associated with the collection of white blood cells from the patient, shipping such patient material to the manufacturing site, storing and processing such patient material, shipping the patient material with the CAR-T

cells back to the patient, and infusing the patient with the final product. Other manufacturing issues include the differences in patient starting materials, inconsistency in cell growth, variability in product characteristics, interruptions in the manufacturing process, equipment or reagent failure, improper installation or operation of equipment, and vendor or operator error. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. If we lose, destroy or otherwise impair the patient materials at any point in the vein-to-vein supply chain, the manufacturing process for that patient may need to be restarted and the resulting delay may adversely affect that patient's outcome due to the risk of disease progression. In addition, because our product candidates are manufactured for each particular patient, we will be required to maintain a chain of identity with respect to materials as they move from the patient to the manufacturing facility, through the manufacturing process, and back to the patient. Maintaining such a chain of identity is difficult and complex, and failure to do so could result in adverse patient outcomes, loss of product, or regulatory action including withdrawal of our products from the market.

Our manufacturing facilities also require commissioning and validation activities to demonstrate that they operate as designed, and are subject to government inspections by the FDA, the NMPA and other comparable regulatory authorities. If we are unable to reliably produce products to specifications acceptable to the regulatory authorities, we may not obtain or maintain the approvals we need to manufacture our products. Further, our facilities may fail to pass government inspections prior to or after the commercial launch of our product candidates, which would cause significant delays and additional costs required to remediate any deficiencies identified by the regulatory authorities. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects.

Changes in methods of product candidate manufacturing may result in additional costs or delays.

As product candidates progress through preclinical to late-stage clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs and achieve consistent quality and results. We may also from time to time change our method of manufacturing, including chemistry, manufacturing and control, or CMC, processes, and such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates and generate revenue. In addition, if our technical transfer in connection with CMC is delayed, our efforts in building our research and development capacity in a new geographic area may also be delayed.

We may contract with third parties for the manufacturing and supply of certain of our product candidates for use in preclinical testing and clinical trials or for commercial use in the future, which supply could become limited or interrupted or may not be of satisfactory quality and quantity.

We currently manufacture all of our product candidates for use in preclinical testing and clinical trials, but may rely on third parties for certain manufacturing needs in the future. For example, we intend to partner with a contract research organization, or CRO, as well as contract development and manufacturing organization, or CDMO, in the United States to conduct clinical trials for GC012F in support of a potential BLA submission in the United States, including manufacturing the products to be used in the clinical trials. Any such future reliance may increase the risk that we will not have sufficient quantities of our product candidates or products, if approved, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. Furthermore, all entities involved in the preparation of therapeutics for clinical trials or commercial sale, including any contract manufacturer for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in clinical trials must be manufactured in accordance with cGMP requirements. These regulations govern

manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. Manufacturing in the United States must supply all necessary documentation in support of a BLA on a timely basis and must adhere to the FDA's Good Laboratory Practice regulations and cGMP regulations enforced by the FDA through its facilities inspection program. Manufacturing of our products in the China requires regulatory approvals and is subject to the NMPA's ongoing and periodic inspection to ensure compliance with GMP requirements. Comparable foreign regulatory authorities may require compliance with similar requirements. The facilities and quality systems of us and any of our future third-party contract manufacturers must pass a pre-approval inspection for compliance with the applicable regulations as a condition of marketing approval of our product candidates. We may not be able to control the manufacturing activities of a third-party contract manufacturer for compliance with cGMP regulations.

Our or a third-party's failure to execute on our manufacturing requirements, do so on commercially reasonable terms and comply with cGMP may adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of our product candidates under development;
- delay in submitting regulatory applications, or receiving marketing approvals, for our product candidates;
- loss of the cooperation of future collaborators;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of our product candidates; and
- in the event of approval to market and commercialize our product candidates, an inability to meet commercial demands for our product or any other future product candidates.

Cell-based therapies rely on the availability of reagents, specialized equipment, and other specialty materials, which may not be available to us on acceptable terms or at all. For some of these reagents, equipment, and materials, we rely or may rely on sole source vendors or a limited number of vendors, which could impair our ability to manufacture and supply our products.

Manufacturing our product candidates will require many reagents, which are substances used in our manufacturing processes to bring about chemical or biological reactions, and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. We currently depend on a limited number of vendors for access to facilities and supply of certain materials and equipment used in the manufacture of our product candidates. Some of our suppliers may not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. We also do not have supply contracts with many of these suppliers, and may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we may not be able to obtain key materials and equipment to support clinical or commercial manufacturing.

For some of these reagents, equipment, and materials, we rely and may in the future rely on sole source vendors or a limited number of vendors. An inability to continue to source product from any of these suppliers, which could be due to regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

As we continue to develop and scale our manufacturing process, we may need to obtain rights to and supplies of certain materials and equipment to be used as part of that process. We may not be able to obtain rights to such materials on commercially reasonable terms, or at all, and if we are unable to alter our process in a commercially viable manner to avoid the use of such materials or find a suitable substitute, it would have a material adverse effect on our business.

The process for treating cancer patients using T cell therapy is subject to human and systemic risks.

The “vein-to-vein” cycle for treating cancer patients using autologous T cell therapy involves multiple steps and human participants. In our FasTCAR process, the patient’s T cells are extracted in the treatment center and shipped to the manufacturing site, followed by a “concurrent activation-transduction” step during which T cells are genetically modified to express CARs. The CAR-T cells are then formulated into finished product and delivered back to the treatment center and administered to the patient. Our TruUCAR process for allogeneic T cell therapy involves similar manufacturing steps, such as T cell extraction and modification, and therefore is subject to similar human and systemic risks facing autologous T cell therapy.

In both China and the United States, samples of the final product are subjected to several release tests which must fulfill specified criteria for the drug product to be released for infusion. These include sterility, identity, purity, potency and other tests. We are subject to stringent regulatory and quality standards in the course of a T cell therapy treatment process. We cannot assure you that our quality control and assurance efforts will be successful or that the risk of human or systemic errors in these processes can be eliminated.

Prior treatments can alter the cancer and negatively impact chances for achieving clinical activity with our CAR-T cells.

Patients with hematological cancers typically receive highly toxic chemotherapy as their initial treatment that can impact the viability of the T cells collected from the patient and may contribute to highly variable responses to CAR-T cell therapies. Patients could also have received prior therapies that target the same target antigen on the cancer cells as our intended programmed CAR-T cell product candidate and thereby these patients may have cancer cells with low or no expression of the target. As a result, our CAR-T cell product candidates may not recognize the cancer cell and may fail to achieve clinical activity. Take one of our lead product candidates, GC012F, for example, most of the patients enrolled for our GC012F study are r/r MM patients with high-risk features as assessed by Mayo Stratification for Myeloma and Risk-Adapted Therapy, or mSMART, criteria, who have exhausted other therapeutic options, including radiotherapy and chemotherapy. If any of our product candidates do not achieve a sufficient level of clinical activity, we may discontinue the development of that product candidate, which could have an adverse effect on the value of our ADSs.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or have a greater likelihood of success.

Because we have limited financial and management resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Risks Related to our Business Operations

As a company currently with substantial operations outside of the United States, our business is subject to economic, political, regulatory and other risks associated with international operations.

As a company with substantial operations in China, our business is subject to risks associated with conducting business outside the United States. Many of our suppliers and clinical trial relationships are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- differing and changing regulatory requirements for product approvals;
- differing jurisdictions could present different issues for securing, maintaining or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- foreign exchange risks and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by governments;
- differing reimbursement regimes and price controls in certain non-U.S. markets;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad, including, for example, the variable tax treatment in different jurisdictions of options granted under our employee stock option plan;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- litigation or administrative actions resulting from claims against us by current or former employees or consultants individually or as part of class actions, including claims of wrongful terminations, discrimination, misclassification or other violations of labor law or other alleged conduct;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- 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, health epidemics, or natural disasters including earthquakes, typhoons, floods and fires.

See “—Risks Related to Doing Business in China” for additional risks related to our operations in China.

We are a fast-growing emerging company and may experience difficulties in managing this growth.

As of September 30, 2020, we had 160 full-time employees. As our development and commercialization plans and strategies to expand and develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, financial and other personnel, including personnel to support our

product development and planned future commercialization efforts. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, NMPA, FDA review processes for our product candidates; and
- improving our operational, financial and management controls, reporting systems and procedures.

There are a small number of individuals with experience in cell therapy and the competition for these individuals is high. Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

If we are not able to effectively expand our organization by hiring new employees, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

In addition to expanding our organization, we are increasing the size of our facilities and building out our development and manufacturing capabilities, which requires significant capital expenditures and technology. If these capital expenditures are higher than expected, it may adversely affect our financial condition and capital resources. In addition, if the increase in the size of our facilities is delayed, it may limit our ability to rapidly expand the size of our organization in order to meet our corporate goals.

Our future success depends on our ability to retain key members of senior management and to attract, retain and motivate qualified personnel.

Our ability to compete in the highly competitive biopharmaceutical industry depends upon our ability to attract and retain highly qualified management, research and development, clinical, financial and business development personnel. We are highly dependent on our management, scientific and medical personnel, including Dr. William Wei Cao, our Founder and Chief Executive Officer, Dr. Martina A. Sersch, our Chief Medical Officer and Dr. Yili Kevin Xie, our Chief Financial Officer. Although we have entered into employment arrangements with the members of our senior management, other than Dr. Cao, each of them may currently terminate their employment with us at any time and will continue to be able to do so after the closing of this offering. We do not maintain “key person” insurance for any of our employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of any of our product candidates, commercialization, manufacturing and sales and marketing personnel, will be critical to our success. The loss of the services of members of our senior management 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. Furthermore, replacing members of our senior management 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 our product candidates. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers, as well as junior, mid-level and senior scientific and medical personnel. Competition to hire from this limited candidate 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 pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

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

From time to time, we may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses, as we may deem appropriate to carry out our business plan. Any potential acquisition or strategic collaboration may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- 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 programs and initiatives in pursuing such a strategic partnership, 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 other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

Additionally, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large onetime expenses and acquire intangible assets that could result in significant future amortization expenses. 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.

Our internal information technology systems, or those of our third-party vendors, collaborators or other contractors or consultants, may fail or suffer security breaches or other unauthorized or improper access, which could result in a significant disruption of our product development programs, give rise to significant liability, subject us to costly and protracted litigation, cause significant reputational harm and impact our ability to operate our business effectively.

We are increasingly dependent upon information technology systems, infrastructure, and data to operate our business. In the ordinary course of business, we collect, store, and transmit confidential information (including but not limited to intellectual property, proprietary business information, and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party vendors and other contractors and consultants who have access to our confidential information.

Our internal information technology systems and those of our current and any future third-party vendors, collaborators and other contractors or consultants may be vulnerable to a variety of disruptive elements, including data breaches, cyber-attacks by malicious third parties (including the deployment of computer viruses, harmful malware, ransomware, denial-of-service attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information), unauthorized access, natural disasters, terrorism, war, telecommunication and electrical failures and persons with access to systems inside our organization. In particular, the risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective

against all such security threats. Because the techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates or terrorist organizations, we and our partners may be unable to anticipate these techniques or implement adequate preventative measures. Further, we do not have any control over the operations of the facilities or technology of third parties that collect, process and store personal data on our behalf.

While we have not experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations or a loss of, or damage to, our data or applications, or those of our third-party vendors and other collaborators, contractors and consultants, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other confidential, personal or proprietary information, significant delays or setbacks in our research, or other similar disruptions. 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. 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, personal or proprietary information, we could incur significant liability, our competitive position could be harmed, our reputation could be damaged, and the further development and commercialization of our product candidates could be delayed.

Unauthorized disclosure of sensitive or confidential data, including personal information, whether through a breach of computer systems, systems failure, employee negligence, fraud or misappropriation, or otherwise, or unauthorized access to or through our information systems and networks, whether by our employees or third parties, could result in negative publicity, damage to our reputation and/or compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. The costs related to significant security breaches or disruptions could be material. If the information technology systems of our third-party vendors and other collaborators, contractors and consultants become subject to disruptions or security breaches, we may be exposed to material liability and have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. Any of the foregoing could adversely affect our business, financial condition, results of operations or prospects.

We are or may become subject to a variety of privacy and data security laws, policies and contractual obligations, and our failure or failure of our third-party vendors, collaborators, contractors or consultants to comply with them could harm our business.

We collect, maintain and process, and our third-party vendors, collaborators, contractors and consultants collect, maintain and process on our behalf, sensitive information, including confidential business and personal information, including health information in connection with our preclinical and clinical studies and information regarding our employees, and are subject to federal, state and foreign laws and regulations governing the privacy and security of such information. Failure by us, our third-party vendors, collaborators, contractors and consultants to comply with any of these laws and regulations could result in enforcement action against us, including fines, imprisonment of company officers and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

In China, regulatory authorities have implemented and are considering a number of legislative and regulatory proposals concerning data protection. For example, the Cyber Security Law of PRC, or the Cyber Security Law, which became effective in June 2017, created China's first national-level data protection for "network operators" which may include all network service providers in China. 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

Cyberspace Administration of China in 2017, which if enacted, may require security review before transferring human health-related data out of China. Furthermore, the Data Security Law of the PRC (Draft) was published on July 3, 2020 by the National People's Congress for public comment. The draft law consists of seven chapters, namely General Provisions, Data Security and Development, Data Security System, Data Security Protection Obligation, Security and Openness of Government Data, Legal Liability and Supplementary Provisions. However, the relationship between the Data Security Law of the PRC and the implemented National Security Law of the PRC, the Cyber Security Law of the PRC, the Confidentiality Law of the PRC and the ongoing Personal Information Protection Law of the PRC needs to be carefully clarified. In addition, certain industry-specific laws and regulations affect the collection and transfer of personal data in China. The regulations of the People's Republic of China on the Administration of Human Genetic Resources promulgated by the State Council on May 28, 2019 and implemented on July 1, 2019 stipulates that in order to obtain marketing authorization for relevant drugs and medical devices in China, no approval is required in international clinical trial cooperation using China's human genetic resources, or the HGR at clinical institutions without export of HGR materials. However, the two parties among international clinical trial cooperation shall file the type, quantity and usage of the HGR to be used with the administrative department of science and technology under the State Council before clinical trials. 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. Many statutory requirements include obligations for companies to notify individuals of security breaches involving certain personal information, which could result from breaches experienced by us or our third-party service providers. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. We also may be contractually required to notify customers or other counterparties of a security breach. Any contractual protections we may have from our third-party service providers, contractors or consultants may not be sufficient to adequately protect us from such liabilities and losses, and we may not be able to enforce any such contractual protections. Moreover, governments have been frequently amending existing laws and implementing regulations, requiring attention to changing regulatory requirements. We expect that there will continue to be new proposed laws and regulations concerning data privacy and security, and we cannot yet determine the impact such future laws, regulations and standards may have on our business. New laws, amendments to or re-interpretations of existing laws, regulations, standards and other obligations may require us to incur additional costs and restrict our business operations. Because the interpretation and application of health-related and data protection laws, regulations, standards and other obligations are still uncertain, and often contradictory and in flux, it is possible that the scope and requirements of these laws may be interpreted and applied in a manner that is inconsistent with our practices and our efforts to comply with the evolving data protection rules may be unsuccessful. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business.

In the United States, where we expect to commence our operations and clinical trials in the future, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws, and federal and state consumer protection laws. Each of these constantly evolving laws can be subject to varying interpretations. For example, regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996, or HIPAA, establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. The U.S. Department of Health and Human Services, or HHS, has the discretion to impose penalties without attempting to first resolve violations. HHS enforcement activity can result in financial

liability and reputational harm, and responses to such enforcement activity can consume significant internal resources.

In addition, states in the United States are constantly adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements. For example, the California Consumer Privacy Act, or CCPA, which went into effect on January 1, 2020, gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. Although there are limited exemptions for certain health-related information, including certain clinical trial data, the precise application and scope of these exemptions as well as how they would apply to our business is not yet clear. As currently written, the CCPA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business.

In May 2018, a new privacy regime, the General Data Protection Regulation, or the GDPR, took effect in the European Economic Area, or the EEA, into which we may expand our business. The GDPR governs the collection, use, disclosure, transfer or other processing of personal data of European persons. Among other things, the GDPR imposes requirements regarding the security of personal data and notification of data processing obligations to the competent national data processing authorities, changes the lawful bases on which personal data can be processed, expands the definition of personal data and requires changes to informed consent practices, as well as more detailed notices for clinical trial subjects and investigators. In addition, the GDPR imposes substantial fines for breaches and violations (up to the greater of €20 million or 4% of our consolidated annual worldwide gross revenue) and increases the scrutiny of transfers of personal data from clinical trial sites located in the EEA to the United States and other jurisdictions that the European Commission does not recognize as having “adequate” data protection laws. The efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain. For example, in 2016, the EU and United States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR. Further, while the United Kingdom enacted the Data Protection Act 2018 in May 2018 that supplements the GDPR and has publicly announced that it will continue to regulate the protection of personal data in the same way post-Brexit, Brexit has created uncertainty with regard to the future of regulation of data protection in the United Kingdom. Some countries also are considering or have passed legislation requiring local storage and processing of data, or similar requirements, which could increase the cost and complexity of delivering our products and services.

Many statutory requirements, in China, the United States, Europe and elsewhere, include obligations for companies to notify individuals of security breaches involving certain personal information, which could result from breaches experienced by us or our third-party service providers. For example, laws in all 50 states of the United States and the District of Columbia require businesses to provide notice to consumers whose personal information has been disclosed as a result of a data breach. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. Moreover, states have been frequently amending existing laws, requiring attention to changing regulatory requirements. We also may be contractually required to notify customers or other counterparties of a security breach. Any contractual protections we may have from our third-party service providers, contractors or consultants may not be sufficient to adequately protect us from any such liabilities and losses, and we may be unable to enforce any such contractual protections.

We expect that there will continue to be new proposed laws and regulations concerning data privacy and security, and we cannot yet determine the impact such future laws, regulations and standards may have on our

business. New laws, amendments to or re-interpretations of existing laws, regulations, standards and other obligations may require us to incur additional costs and restrict our business operations. Because the interpretation and application of health-related and data protection laws, regulations, standards and other obligations are still uncertain, and often contradictory and in flux, it is possible that the scope and requirements of these laws may be interpreted and applied in a manner that is inconsistent with our practices and our efforts to comply with the evolving data protection rules may be unsuccessful. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy regulations may differ from country to country and may vary based on where testing is performed. Our operations or business practices may not comply with these regulations in each country.

Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we or our third-party vendors, collaborators, contractors and consultants fail to comply with any such laws or regulations, we may face regulatory investigations, significant fines and penalties, reputational damage or be required to change our business practices, all of which could adversely affect our business, financial condition and results of operations.

The COVID-19 coronavirus could adversely impact our business, including our clinical trials.

In December 2019, a novel strain of coronavirus, COVID-19, was first reported to have surfaced in Wuhan, China. Since then, the COVID-19 coronavirus has spread globally. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked. As a result, we may experience disruptions that could severely impact our business and clinical trials, including:

- limitation in patient enrollment, disruptions to patient follow-up during the lockdown periods, and curtailed screening visits;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by governments, employers and others;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people.
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations as part of a response to the COVID-19 coronavirus outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and

- refusal of the relevant regulatory authorities to accept data from clinical trials in these affected geographic regions.

The extent to which the COVID-19 coronavirus may impact our business and clinical trials is highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak and social distancing regulations, travel restrictions, business closures or business disruptions and the effectiveness of actions taken to contain and treat the disease.

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

Our operations, and those of our vendors and suppliers, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We currently rely on third-party suppliers to produce and process our product candidates on a patient-by-patient basis. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters

Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. As a result, we cannot predict when or if, and in which territories, we will obtain marketing approval to commercialize a product candidate.

Our product candidates and the activities associated with their development and commercialization, including their design, research, testing, manufacture, safety, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale, distribution, import, export, and reporting of safety and other post-market information, are subject to comprehensive regulation by the FDA, the NMPA and other comparable regulatory authorities in other jurisdictions. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and may rely on third-party CROs to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. If any of our product candidates receives marketing approval, the accompanying label may limit its approved use, which could limit sales of the product.

The process of obtaining marketing approvals in China, the United States and elsewhere is expensive and may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA, the NMPA or other regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or

have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

In addition, changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenue will be impaired.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

In order to market and sell our products in the United States or other jurisdictions outside of China in the future, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in China, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions.

The time required to obtain approval may differ substantially from that required to obtain approval from the NMPA. The regulatory approval process outside China generally includes all of the risks associated with obtaining approval from the NMPA. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the NMPA grants marketing approval of a product candidate, comparable regulatory authorities in other jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. If we fail to comply with the regulatory requirements in international markets and/or to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

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

Even if marketing approval of a product candidate is granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulatory requirements for manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, sampling, and recordkeeping, including the potential requirements to implement a Risk Management Plan, or RMP, or to conduct costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the

product. We must also comply with requirements concerning advertising and promotion for any of our product candidates for which we obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved. In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive regulatory requirements of the FDA, the NMPA and other regulatory authorities, including ensuring that quality control and manufacturing procedures conform to cGMP and other comparable regulations and standards, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We or our suppliers could be subject to periodic unannounced inspections by the FDA, the NMPA or other regulatory authorities to monitor and ensure compliance with cGMP.

Accordingly, assuming we receive marketing approval for one or more of our product candidates, we and our suppliers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Thus, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Any product candidate for which we obtain marketing approval will be subject to various post-approval regulatory requirements, and we may be subject to significant penalties, sanctions and other damages if we fail to comply with regulatory requirements.

The FDA and other federal and state agencies, including the U.S. Department of Justice, or DOJ, closely regulate compliance with all requirements governing prescription drug products, including requirements pertaining to marketing and promotion of products in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our products for their approved indications, or if other of our marketing claims are deemed false or misleading, we may be subject to enforcement action. Violations of such requirements may lead to investigations alleging violations of the Food, Drug and Cosmetic Act and other statutes, including the False Claims Act and other federal and state health care fraud and abuse laws as well as state consumer protection laws.

Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various results, including:

- litigation involving patients taking our products;
- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;

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- suspension or withdrawal of marketing approvals;
- suspension of any ongoing clinical trials;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Noncompliance by us or any future collaborator with regulatory requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with regulatory requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Likewise, the NMPA and other relevant PRC regulatory authorities closely regulate the manufacture, labeling, marketing and promotion of product candidates that have received a marketing approval. Approved products must be manufactured in compliance with GMP and other applicable standards and regulatory requirements. The NMPA and other PRC regulatory authorities may conduct periodic inspections of the manufacturers and raw material suppliers that are involved in the manufacturing of the approved products to ensure compliance with standards on quality control, quality assurance, recordkeeping and reporting. Further, we are prohibited from marketing and promoting our approved products outside of their approved indications and uses. Promotions of prescription drugs, in particular, must be consistent with the information in the labelling approved for such drugs. In addition, we may be required in certain circumstances to conduct post-marketing studies, clinical trials or other actions to continuously monitor the safety and efficacy of the product. If we fail to comply with post-approval regulatory requirements, the marketing approvals we obtain for our product candidates could be withdrawn by regulatory authorities and our abilities to market any future products could be limited.

In addition, noncompliance with EU requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, also can result in significant financial penalties. Similarly, failure to comply with the European Union's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could adversely affect our business, financial condition and results of operations.

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

We are exposed to the risk of employee and third-party fraud or other misconduct or failure to comply with applicable regulatory requirements. Misconduct by employees and independent contractors, such as principal investigators, consultants, commercial partners, and vendors, could include failures to comply with regulations of the FDA, the NMPA and other comparable regulatory authorities, to provide accurate information to such regulators, to comply with manufacturing standards we have established, to comply with healthcare fraud and abuse laws, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of business activities, including, but not limited

to, research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee and independent contractor misconduct could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation.

It is not always possible to identify and deter employee and independent contractor misconduct, and any precautions we take to detect and prevent improper activities 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 be in compliance with such laws. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement of profits, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, or other government supported healthcare in other jurisdictions, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of noncompliance with the law and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.

Our product candidates are subject to government price controls in certain jurisdictions that may affect our revenue.

There has been heightened governmental scrutiny in China and other jurisdictions of pharmaceutical pricing practices in light of the rising cost of prescription drugs. In the United States, such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, Congressional leadership and the Trump administration have each indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly enacted legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, 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 China, the government has recently announced their intention to revise and introduce more measures on the centralized procurement of drugs, price management and setting up standards on charges for medical consultants and prescriptions, all for the purpose of reducing people's medical expenses. In the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

Recently enacted and future legislation in the United States and other countries may affect the prices we may obtain for our product candidates and increase the difficulty and cost for us to commercialize our product candidates.

In the United States and many other countries, rising healthcare costs have been a concern for governments, patients and the health insurance sector, which resulted in a number of changes to laws and regulations, and may result in further legislative and regulatory action regarding the healthcare and health insurance systems that could affect our ability to profitably sell any product candidates for which we obtain marketing approval. For a detailed discussion of healthcare reform initiatives of importance to the pharmaceutical industry, see the section titled "Regulation—United States Regulation—Healthcare Reform."

For example, the ACA was enacted in the United States in March 2010 with the stated goals of containing healthcare costs, improving quality and expanding access to healthcare, and includes measures to change healthcare delivery, increase the number of individuals with insurance, ensure access to certain basic healthcare services, and contain the rising cost of care. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. H.R. 1: An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018, or the Tax Cuts and Jobs Act of 2017, 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 that is commonly referred to as the “individual mandate.” Additionally, the 2020 federal spending package permanently eliminates, effective January 1, 2020, the ACA-mandated “Cadillac” tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax.

On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of the Tax Cuts and Jobs Act. Further, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA.

Further, the Bipartisan Budget Act of 2018, among other things, amended the ACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole.” Congress may consider other legislation to repeal or replace elements of the ACA. These executive orders and legislative actions are expected to result in increased health insurance premiums and reduce the number of people with health insurance in the United States, and have other effects that adversely affect U.S. health insurance markets and the ability of patients to have access to therapies that our product candidates can provide.

In addition, other federal health reform measures have been proposed and adopted in the United States. For example, as a result of the Budget Control Act of 2011, providers are subject to Medicare payment reductions of 2% per fiscal year through 2029 unless additional Congressional action is taken. Further, the American Taxpayer Relief Act of 2012 reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments from providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015 ended the use of the statutory formula, also referred to as the Sustainable Growth Rate, for clinician payment and established a quality payment incentive program, also referred to as the Quality Payment Program. This program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models, or APMs, and the Merit-based Incentive Payment System, or MIPS. In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. At this time, it is unclear how the introduction of the quality payment program will impact overall physician reimbursement under the Medicare program. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration’s budget proposal for fiscal year 2021 includes a US\$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs

for patients, and increase patient access to lower-cost generic and biosimilar drugs. Additionally, 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. The HHS has solicited feedback on some of these measures and, at the same time, has implemented others under its existing authority. For example, in May 2019, the Centers for Medicare & Medicaid Services, or CMS, issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS’s policy change that was effective January 1, 2019. Although a number of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, 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.

The combination of healthcare cost containment measures, increased health insurance costs, reduction of the number of people with health insurance coverage, as well as future legislation and regulations focused on reducing healthcare costs by reducing the cost of or reimbursement and access to pharmaceutical products, may limit or delay our ability to generate revenue, attain profitability, or commercialize our products.

Our product candidates may face competition sooner than anticipated from biosimilar products.

Even if we are successful in achieving regulatory approval to commercialize a product candidate faster than our competitors, our product candidates may face competition from biosimilar products. In the United States, our product candidates are regulated by the FDA as biologic products and we intend to seek approval for these product candidates pursuant to the BLA pathway. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated pathway for the approval of biosimilar and interchangeable biologic products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our product candidates.

There is a risk that any exclusivity we may be afforded if any of our product candidates are approved as a biologic product under a BLA could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic or biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar product, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. In addition, a competitor could decide to forego the biosimilar approval path and submit a full BLA after completing its own preclinical studies and clinical trials. In such cases, any exclusivity to which we may be eligible under the BPCIA would not prevent the competitor from marketing its product as soon as it is approved.

In Europe, the European Commission has granted marketing authorizations for several biosimilar products pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In Europe, a competitor may reference data supporting approval of an innovative biological product, but will not be able to market it until 10 years after the time of approval of the innovative product. This 10-year

marketing exclusivity period may be extended to 11 years if, during the first eight of those 10 years, the marketing authorization holder obtains an approval for one or more new therapeutic indications that bring significant clinical benefits compared with existing therapies. In addition, companies may be developing biosimilar products in other countries that could compete with our products, if approved.

If competitors are able to obtain marketing approval for biosimilars referencing our product candidates, if approved, such products may become subject to competition from such biosimilars, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which our product candidates may have received approval.

We are subject to certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Any violation of such laws and regulations may subject us to criminal liability and other serious consequences.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous materials, including chemicals 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 for failure to comply with such laws and regulations. In addition, in connection with the construction of certain research and development facilities in China, we have not completed all required fire prevention and safety-related procedures and filings in a timely manner, which could subject us to fines and other administrative penalties.

Although we maintain insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of 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 or disposal of biological or hazardous materials.

In addition, we may incur substantial costs in order 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. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our business operations and relationships with healthcare professionals, principal investigators, consultants, customers and third-party payors in the United States and elsewhere are subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, physician payment transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to substantial penalties.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may expose us to broadly applicable healthcare laws, including, without limitation, the U.S. federal Anti-Kickback Statute and the U.S. federal False Claims Act, that may constrain the business or financial arrangements and relationships through which we sell, market and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to physician payment transparency laws and privacy and security regulation by the U.S. federal government and by the states and foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws that may affect our ability to operate include the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, 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 federal and state healthcare programs such as Medicare and Medicaid. The term “remuneration” has been broadly interpreted to include anything of value. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration that are alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the federal Anti-Kickback Statute has been violated;
- U.S. federal civil and criminal false claims laws, including the federal False Claims Act, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalty laws, which, among other things, impose criminal and civil penalties, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Further, pharmaceutical manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to “cause” the

submission of false or fraudulent claims. Criminal prosecution is also possible for making or presenting a false, fictitious or fraudulent claim to the federal government;

- HIPAA, which contains new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of whether the payor is public or private, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose obligations on “covered entities,” including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective “business associates” that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. Additionally, HITECH also contains four new tiers of civil monetary penalties; amends 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 U.S. federal courts to enforce the federal HIPAA laws and to seek attorneys’ fees and costs associated with pursuing federal civil actions;
- the U.S. federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. federal Physician Payments Sunshine Act, created under Section 6002 of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, and its implementing regulations, created annual reporting requirements for certain 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 information related for certain payments and “transfers of value” provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and analogous state laws and regulations and foreign laws, 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 and foreign 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 to adopt compliance programs as prescribed by state laws and regulations, or that otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign 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.

Further, the ACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute and certain criminal statutes governing healthcare fraud. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the ACA provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Because of the breadth of these laws and the narrowness of their exceptions and safe harbors, it is possible that our business activities can be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Efforts to ensure that our internal operations and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. If our operations are found to be in violation of 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, including, without limitation, damages, monetary fines, imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of noncompliance with the law and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including future collaborators, are found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also affect our business.

Risks Related to the Commercialization of Our Product Candidates

If we are unable to establish sales, marketing and distribution capabilities for our product candidates, or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing our product candidates, if and when they are approved.

We may not be successful in locating suitable medical centers or partners or enter into an agreement on commercially reasonable terms or at all. We would have limited control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively.

For the future potentially partnered product candidates, we would not market our products alone once they have obtained marketing authorization. The risks inherent in entry into these contracts are as follows:

- the negotiation and execution of these agreements is a long process that may not result in an agreement being signed or that can delay the development or commercialization of the product candidate concerned;
- these agreements are subject to cancellation or nonrenewal by our collaborators, or may not be fully complied with by our collaborators;
- in the case of a license granted by us, we lose control of the development of the product candidate licensed;
- in such cases we would have only limited control over the means and resources allocated by our partner for the commercialization of our product; and
- collaborators may not properly obtain, maintain, enforce, or defend our intellectual property or proprietary rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation.

Should any of these risks materialize, or should we fail to find suitable collaborators, this could have a material adverse effect on our business, prospects, financial condition and results of operations.

We operate in a rapidly changing industry and face significant competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new biopharmaceutical products is highly competitive and subject to rapid and significant technological advancements. We face competition from major multi-national pharmaceutical companies, biotechnology companies and specialty pharmaceutical companies with respect to our current and future product candidates that we may develop and commercialize in the future. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of cancer. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Potential competitors also include academic institutions, government agencies and other public and private research organizations. Due to their promising clinical therapeutic effect in clinical exploratory trials, engineered T cell therapies, redirected T cell therapies in general and antibody-drug conjugates are being pursued by multiple biotechnology and pharmaceutical companies. Our competitors may succeed in developing, acquiring or licensing technologies and products that are more effective, more effectively marketed and sold or less costly than any product candidates that we may develop, which could render our product candidates noncompetitive and obsolete.

Our potential CAR-T cell therapy competitors include, among others, companies developing autologous and allogeneic CAR-T treatments, discovering dual or novel antigens, developing transposon or gene editing technologies to improve manufacturing. In addition, we may compete with cell therapies companies that are focused on development in Asia. See “Business—Competition” for more details.

Many of our competitors, either alone or with their strategic collaborators, have substantially greater financial, technical and human resources than we do. Accordingly, our competitors may be more successful than we are in obtaining approval for treatments and achieving widespread market acceptance, which may render our treatments obsolete or noncompetitive. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive or better reimbursed than any products that we may commercialize. Our competitors also may obtain NMPA, FDA or other regulatory approval for their products more rapidly than we do, which could result in our competitors establishing a strong market position for either the product or a specific indication before we are able to enter the market.

Due to the novelty of our technologies, our new and emerging CAR-T cell therapies may have difficulty or encounter significant delays in achieving the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if we obtain approvals from the FDA, the NMPA or other comparable regulatory agencies and are able to initiate commercialization of our clinical-stage product candidates or any other product candidates we develop, the product candidate may not achieve market acceptance among physicians, patients, hospitals, including pharmacy directors, and third-party payors and, ultimately, may not be commercially successful. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers, and patients considering our product candidates as a safe and effective treatment;

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- hospitals and cancer treatment centers establishing the infrastructure required for the administration of redirected CAR-T cell therapies;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA, the NMPA or other comparable regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA, the NMPA or other comparable regulatory authorities;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the amount of upfront costs or training required for physicians to administer our product candidates;
- the availability of coverage, adequate reimbursement, and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of comprehensive coverage and reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts and distribution support.

Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of our products, if approved, may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our product candidates. Because we expect sales of our product candidates, if approved, to generate substantially all of our product revenue for the foreseeable future, the failure of our product candidates to find market acceptance would harm our business and could require us to seek additional financing.

In addition, although we are not utilizing embryonic stem cells or replication competent vectors, adverse publicity due to the ethical and social controversies surrounding the therapeutic use of such technologies, and reported side effects from any clinical trials using these technologies or the failure of such trials to demonstrate that these therapies are safe and effective, may limit market acceptance of our product candidates. If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue.

Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

Coverage and adequate reimbursement may not be available for our current or any future product candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any product candidates that we commercialize, if approved, will depend in part on the extent to which reimbursement for these products and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels.

In China, the Ministry of Human Resources and Social Security of China or provincial or local human resources and social security authorities, together with other government authorities, review the inclusion or

removal of drugs from the China's National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance, or the National Reimbursement Drug List, or the NRDL, or provincial or local medical insurance catalogues for the National Medical Insurance Program, or the PRDL, regularly, and the tier under which a drug will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs. There can be no assurance that any of our future approved drug candidates will be included in the NRDL or the PRDL. Products included in the NRDL or the PRDL are typically generic and essential drugs. Innovative drugs similar to our drug candidates have historically been more limited on their inclusion in the NRDL or the PRDL due to the affordability of the government's Basic Medical Insurance. If we were to successfully launch commercial sales of our products in China but fail in our efforts to have our products included in the NRDL or PRDL, our revenue from commercial sales in China will be highly dependent on patient self-payment, which can make our products less competitive. Additionally, even if the Ministry of Human Resources and Social Security of the PRC or any of its local counterparts accepts our application for the inclusion of products in the NRDL or PRDL, our potential revenue from the sales of these products in China could still decrease as a result of the significantly lowered prices we may be required to charge for our products to be included in the NRDL or PRDL.

Third-party payors in the United States often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. One payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage and adequate reimbursement for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. These pressures are further compounded by significant controversies and intense political debate and publicity about prices for pharmaceuticals that some consider excessive, including government regulatory efforts, funding restrictions, legislative proposals, policy interpretations, investigations and legal proceedings regarding pharmaceutical pricing practices. Global pressures on pricing may negatively impact, in parallel, both our product pricing and our market access. We may incur significant costs to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective.

Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its list of covered drugs, or formulary, it will be placed. The position on a payor's formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products, and providers are unlikely to prescribe our products, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products and their administration. Therefore, coverage and adequate reimbursement is critical to new medical product acceptance.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Even if favorable coverage and reimbursement status is attained for one or more product candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our current and any future product candidates that we develop.

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We cannot be sure that coverage and reimbursement in China, the United States or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- reduced resources of our management to pursue our business strategy;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant costs to defend the resulting litigation;
- substantial monetary awards paid to clinical trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

While we maintain clinical trial insurance, which covers certain bodily injury or damage in connection with our clinical trials and investigator-initiated trials for our product candidates, our insurance coverage may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical and investigator-initiated trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

We may enter into partnership agreements with third parties for the development and commercialization of our product candidates, which may adversely affect our ability to generate revenue.

We may seek to enter into collaborations or partnerships with third parties for the development and potential commercialization of our product candidates. We face competition in seeking partners and may not be able to locate a suitable partner or to enter into an agreement on commercially reasonable terms or at all. Even if we succeed in securing partners for the development and commercialization of our product candidates, we will have limited control over the time and resources that our partners may dedicate to the development and commercialization of our product candidates. These partnerships pose a number of risks, including the following:

- partners may not have sufficient resources or decide not to devote the necessary resources due to internal constraints such as budget limitations, lack of human resources or a change in strategic focus;
- partners may believe our intellectual property is not valid or is unenforceable or the product candidate infringes on the intellectual property rights of others;
- partners may dispute their responsibility to conduct development and commercialization activities pursuant to the applicable collaboration, including the payment of related costs or the division of any revenue;

- partners may decide to pursue a competitive product developed outside of the collaboration arrangement;
- partners may not be able to obtain, or believe they cannot obtain, the necessary regulatory approvals; or
- partners may delay the development or commercialization of our product candidates in favor of developing or commercializing another party's product candidate.

Thus, partnership agreements may not lead to development, regulatory approval or successful commercialization of product candidates in the most efficient manner or at all and we may not be able to advance our product candidates or generate meaningful revenue.

Risks Related to Our Intellectual Property

If we are unable to obtain, maintain, defend and enforce patent and other intellectual property rights for our technologies and product candidates, or if the scope of the patent and other intellectual property rights obtained is not sufficiently broad, our competitors and other third parties could develop and commercialize technology and biologics similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired.

Our success depends, in large part, on our ability to obtain, maintain, defend and enforce patent protection in the United States, China and other countries with respect to our product candidates and technology. We seek to protect our proprietary position by filing patent applications related to our technology and product candidates in the major pharmaceutical markets, including China and the United States. As of the date of this prospectus, our patent portfolio for our lead product candidates and technology platforms is currently comprised of three Patent Cooperation Treaty applications (which have entered into the national stage in the U.S.), one patent application in China, and three patent applications in Taiwan. We own five Patent Cooperation Treaty applications (which have entered into the national stage in the U.S.), five issued invention patents in China and ten issued utility model patents in China, 23 patent applications in China, two patent applications in Europe, and one patent application in Taiwan related to our other products and/or technologies. We currently do not own or license any issued patents that cover any of our platforms or product candidates. If we are unable to obtain or maintain patent protection with respect to our proprietary product candidates and technology or do not otherwise adequately obtain, maintain and protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage that we may have, which could harm our business and ability to achieve profitability. Our ability to stop unauthorized third parties from making, using, selling, offering to sell, importing or otherwise commercializing our product candidates we may develop is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

To protect our proprietary positions, we file patent applications in the United States, China and other countries related to our novel technologies and product candidates that are important to our business. The patent application and prosecution process is expensive, complex and time-consuming. We may not be able to file, prosecute, maintain, defend, enforce or license all necessary or desirable patent applications in all potential jurisdictions at a reasonable cost or in a timely manner. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. The patent applications that we own may fail to result in issued patents with claims that cover our current and future product candidates in China or elsewhere. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, a patent issues from such applications, and then only to the extent the issued claims cover the technology. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. In addition, under the PRC patent law, if an applicant applies for a patent in a jurisdiction outside of China for an invention or utility model invented within China, such applicants must concurrently report to the National Intellectual Property

Administration, or the NIPA, for confidentiality examination of such invention or utility model. If an applicant fails to make such reporting but files a patent application in China for the same invention or utility model at a later time, a patent will not be granted to such applicant. If the patent applications we hold with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our current and future product candidates, it could threaten our ability to commercialize our product candidates. Any such outcome could have a negative effect on our business. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Any of these outcomes could impair our ability to prevent competition from third parties.

In some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain and defend the patents, related to technology that we license from third parties. If any current or future licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent, such patent could be compromised and we might not be able to prevent third parties from making, using and selling competing products. We cannot be certain that patent prosecution and maintenance activities by our licensors have been or will be conducted in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such patent applications. If our licensors fail to do so, this could cause us to lose rights in any applicable intellectual property that we in-license, and as a result, our ability to develop and commercialize products or product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

Prosecution of our patent portfolio is at a very early stage. Much of our patent portfolio consists of pending applications (including priority applications) in China, United States, Europe, and under the Patent Cooperation Treaty, or PCT, that have not been examined. Neither priority applications nor PCT applications can themselves give rise to issued patents. Rather, protection for the inventions disclosed in these applications must be further pursued by applicable deadlines via non-provisional or national stage applications that are subject to examination. As applicable deadlines for the priority and PCT applications become due, we will need to decide whether and in which countries or jurisdictions to pursue patent protection for the various inventions claimed in these applications, and we will only have the opportunity to pursue and obtain patents in those jurisdictions where we pursue protection. Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-license may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, we do not know whether any of our platform advances and product candidates we may develop will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain. Changes in either the patent laws or interpretation of the patent laws in China, the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the protections offered by laws of different countries vary. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in China, the United States or in other jurisdictions. In addition, the determination of patent rights with respect to pharmaceutical compounds and technologies commonly involves complex legal and factual questions, which 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. Furthermore, recent changes in patent laws in the United States, may affect the scope, strength, validity and enforceability of our patent rights or the nature of proceedings that may be brought by or against us related to our patent rights. Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. For example, in the case, *Assoc. for Molecular Pathology v. Myriad*

Genetics, Inc., the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. 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. Depending on decisions by the U.S. Congress, the U.S. federal courts, and the U.S. Patent and Trademark Office, or USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain patents or to enforce any patents that we might obtain in the future. Furthermore, the complexity and uncertainty of European patent laws have also increased in recent years.

We may not be aware of all third-party intellectual property rights potentially relating to our current and future product candidates. 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. Similarly, should we own or in-license any patents or patent applications in the future, we may not be certain that we or the applicable licensor were the first to file for patent protection for the inventions claimed in such patents or patent applications. As a result, the issuance, scope, validity and commercial value of our patent rights cannot be predicted with any certainty.

We may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, reexamination, post-grant, *inter partes* review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, hold unenforceable or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights, which could significantly harm our business and results of operations. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in the courts or patent offices in the United States or elsewhere, that challenge priority of invention or other features of patentability. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

Our pending and future patent applications may not result in patents being issued that protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection against competing products or processes sufficient to achieve our business objectives, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to circumvent our patents, should they issue, by developing similar or alternative technologies or products in a non-infringing manner. Our competitors or other third parties may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid and/or unenforceable. Consequently, we do not know whether any of our technologies and product candidates will be protectable or remain protected by valid and enforceable patents.

In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others

from commercializing products similar or identical to ours. Any of the foregoing could have a material adverse effect on our business.

The intellectual property landscape around technology involving cellular therapies, including CAR-T cell therapies, is highly dynamic, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could significantly harm our business.

Our commercial success depends, in part, on our ability and/or the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary and modular CAR-T cell technology without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. There has been extensive patenting activity in the field of CAR-T cellular therapies, and pharmaceutical companies, biotechnology companies, and academic institutions are competing with us or are expected to compete with us in the in this field and filing patent applications potentially relevant to our business. We are aware of several third-party patents, and patent applications, that if issued, may be construed to cover our proprietary and modular CAR-T cell technology and product candidates, including GC012F and GC027. We are in the process of negotiating licenses with certain third-party holders of such patent rights and we may find it necessary or prudent to obtain additional such licenses. However, we may be unable to secure such licenses on commercially reasonable terms, or at all, or otherwise acquire or in-license any compositions, methods of use, processes, or other intellectual property rights from third parties that we identify as necessary for product candidates we may develop and base editing technology. Even if we obtain a license, it may only be non-exclusive, which may limit our ability to stop others from using or commercializing technology and products similar or identical to ours. If we are unable to obtain a license, such third parties may seek to enforce their patent rights against us claiming that our product candidates infringe such patent rights and may obtain injunctive or other equitable relief against us, which could effectively block our ability to further develop and commercialize one or more of our product candidates in the countries where such patent protection exists. Defense of these claims, including demonstrating non-infringement, invalidity or unenforceability of the respective patent rights in question, regardless of their merit, is time-consuming, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We cannot guarantee that a court of competent jurisdiction will hold in our favor in any such proceeding. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing product candidates or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our ADSs.

The field of CAR-T cell therapies is still in its infancy, and only a few product candidates have reached the market. Due to the intense research and development that is taking place by several companies, including us and our competitors, in this field, the intellectual property landscape is evolving and in flux, and it may remain uncertain for the coming years. There may be significant intellectual property related litigation and proceedings relating to our owned and in-licensed, and other third party, intellectual property and proprietary rights in the future. Numerous third-party issued patents exist in this area of biotechnology, including relating to the modification of T cells and the production of CAR-T cells, and including patents held or controlled by our competitors, such as Nanjing Legend Biotech, bluebird Bio, Inc., Allogene, Inc. Juno Therapeutics, Inc. (acquired by Celgene Corporation), Kite Pharma, Inc. (a Gilead Sciences, Inc. company), Poseida Therapeutics, Celyad, Novartis AG and other companies or academic institutions. Because of the large number of patents issued and patent applications filed in our field, these and other third parties could allege they have patent rights encompassing our product candidates, technologies or methods.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding

intellectual property rights with respect to our technology or product candidates, including interference proceedings, post-grant review, *inter partes* review and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions. Intellectual property disputes arise in a number of areas including with respect to patents, use of other proprietary rights and the contractual terms of license arrangements. Third parties may assert claims against us based on existing or future intellectual property rights and claims may also come from competitors against whom our own patent portfolio may have no deterrent effect. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. Other parties may allege that our product candidates or the use of our technologies infringes patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. As we continue to develop and, if approved, commercialize our current and future product candidates, competitors may claim that our technology infringes, misappropriates or otherwise violates their intellectual property rights as part of business strategies designed to impede our successful commercialization. There are and may in the future be additional third-party patents or patent applications with claims to, for example, materials, compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of any one or more of our product candidates. Moreover, we may fail to identify relevant third-party patents or patent applications, or we may incorrectly conclude that the claims of an issued patent are invalid, unenforceable or are not infringed by our activities.

Because patent applications can take many years to issue, third parties may have currently pending patent applications which may later result in issued patents that any of our product candidates may infringe, or which such third parties claim to be infringed by our technologies. As the CAR-T therapy field expands and more patents are issued, the risk increases that our proprietary and modular CAR-T cell technology and product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of therapies, products or their methods of use or manufacture. Because of the large number of patents issued and patent applications filed in our field, third parties may allege they have patent rights encompassing our product candidates, technologies or methods. Third parties may assert that we are employing their proprietary technology without authorization and may file patent infringement claims or lawsuit against us, and if we are found to infringe such third-party patents, we may be required to pay damages, cease commercialization of the infringing technology, or obtain a license from such third parties, which may not be available on commercially reasonable terms or at all.

Even if we would have valid defenses against any assertion of such patents against us, such defenses may be unsuccessful. There is no assurance that a court would find in our favor on questions of infringement, validity, enforceability, or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any product candidates we may develop and any other product candidates or technologies covered by the asserted third party patents. If any of our products is found to infringe any of these patents, we could be required to obtain a license from the respective patent owners, or, if applicable, their licensees, to continue developing, manufacturing, marketing, selling and commercializing such products. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving the licensor and other third parties the right to use the same technologies licensed to us, and it could require us to make substantial licensing, royalty and other payments. We also could be forced, including by court order, to permanently cease development, manufacturing, marketing and commercializing the applicable products. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willingly infringed any such patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative effect on our business. Even if successful, the defense of any claim of infringement or misappropriation is time-consuming, expensive and diverts the attention of our management from our ongoing business operations. Some third-parties may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if

securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our ADSs. Any of the foregoing could have a material adverse effect on our business.

Changes in United States and Chinese patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotech and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of our issued patents.

Intellectual property laws in China are constantly evolving, with efforts being made to improve intellectual property protection in China. For example, a draft amendment to the PRC Patent Law (“Draft Amendment to the PRC Patent Law”) was released in July 2020 and proposes to introduce patent extensions to eligible innovative drug patents. If adopted, the patents owned by third parties may be extended, which may in turn affect our ability to commercialize our product candidates (if approved) without facing infringement risks. The adoption of this Draft Amendment to the PRC Patent Law may enable the patent owner to submit applications for a patent term extension. The length of any such extension is uncertain. If we are required to delay commercialization for an extended period of time, technological advances may develop and new products may be launched, which may render our product non-competitive. We also cannot guarantee that other changes to Chinese intellectual property laws would not have a negative impact on our intellectual property protection.

In the United States, changes in either the patent laws or interpretation of the patent laws could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents and may affect the scope, strength and enforceability of our patent rights or the nature of proceedings that may be brought by or against us related to our patent rights. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either file any patent application related to our technology or product candidates or invent any of the inventions claimed in our patents or patent applications. The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

The life of patent protection is limited, and third parties could develop and commercialize products and technologies similar or identical to ours and compete directly with us after our patent expires, which could materially and adversely affect our ability to commercialize our products and technologies.

The life of a patent and the protection it affords is limited. For example, in the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. In China, the expiration of an invention patent is 20 years from its filing date and the expiration of a utility model patent or industrial design is ten years from its filing date. The Draft Amendment to the PRC Patent Law proposed to introduce patent extensions to patents of new drugs that launched in the PRC, the adoption of which may enable the patent owner to submit applications for a patent term extension. The length of any such extension is uncertain. Even if we successfully obtain patent protection for an approved drug candidate, it may face competition from generic or biosimilar medications. Manufacturers of generic or biosimilar drugs may challenge the scope, validity or enforceability of our patents in court or before a patent office, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would materially adversely affect any potential sales of that product.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Even if we believe that we are eligible for certain patent term extensions, there can be no assurance that the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, will agree with our assessment of whether such extensions are available, and such authorities may refuse to grant extensions to our patents, or may grant more limited extensions than we request. For example, depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during 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 product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or 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 could be harmed.

The pending patent applications, if issued, for our product candidates are expected to expire on various dates as described in “Business—Intellectual Property.” Upon the expiration of our patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors, which would materially adversely affect our business, financial condition, results of operations and prospects.

We may be subject to claims challenging the inventorship or ownership of our patent rights and other intellectual property.

We generally enter into confidentiality and intellectual property assignment arrangements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors. However, these agreements may be breached and may not effectively assign intellectual property rights to us. For example, disputes may arise from conflicting obligations of consultants or others who are involved in developing our technology and product candidates. Litigation may be necessary to defend against these and other claims

challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe, misappropriate or otherwise violate our patents, trademarks, copyrights, trade secrets or other intellectual property. In addition, our patents also are, and may in the future become, involved in inventorship or priority disputes. To counter or defend against infringement, misappropriation, violation or unauthorized use, we may be required to file claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringed, misappropriated or otherwise violated their patents, trademarks, copyrights, trade secrets or other intellectual property. In addition, in a patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patents do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, could put one or more of our owned patents at risk of being invalidated or interpreted narrowly and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

In any infringement or other intellectual property-related litigation, any award of monetary damages we receive may not be commercially valuable. 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 litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our ADSs. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement, misappropriation or violation claims, which typically last for years before they are concluded. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent or other intellectual property litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel for significant periods of time during such litigation could outweigh any benefit we receive as a result of the proceedings. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating, violating or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent or other intellectual property litigation or other proceedings could have a negative impact on our ability to compete in the marketplace.

If we initiate legal proceedings against a third-party to enforce a patent covering a product candidate we may develop or our technologies, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory

requirements, including 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, or made a misleading statement, during prosecution. Third parties may raise challenges to the validity of certain of our patent claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our technologies or product candidates that we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our licensing partners and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technologies or product candidates that we may develop. Such a loss of patent protection would have a material adverse impact on our business.

Conversely, we may choose to challenge the patentability of claims in a third-party's U.S. patent by requesting that the USPTO review the patent claims in re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). We may also in the future choose to challenge, third party patents in patent opposition proceedings in the EPO or another foreign patent office. Even if successful, the costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates, proprietary and modular CAR-T cell technology or other or proprietary technologies.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. 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. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our ADSs. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent and trademark protection for our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Trade secrets and know-how can be difficult to protect. We seek to protect our trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality arrangement with parties who have access to them, such as our employees, CROs and other third parties. We also enter into confidentiality and invention or intellectual property assignment arrangement with our employees, CROs and other third parties. We cannot guarantee that we have entered into such arrangement with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the arrangements and disclose our proprietary information, including our trade secrets.

Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the United States or in other jurisdictions are less willing or unwilling to protect trade secrets.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information through other appropriate precautions, such as physical and technological security measures. However, trade secrets and know-how can be difficult to protect. These measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and any recourse we might take against this type of misconduct may not provide an adequate remedy to protect our interests fully.

Moreover, our competitors or other third parties may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors or other third parties could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third parties, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third parties, our competitive position would be harmed.

In addition, some courts inside and outside the United States are sometimes less willing or unwilling to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. Even if we are successful, these types of lawsuits may consume our time and other resources. Any of the foregoing could have a material adverse effect on our business

We are currently party to several in-license agreements under which we have the rights to use, develop, manufacture and/or commercialize certain of our technology platforms and resulting product candidates. If we breach our obligations under these agreements, we may be required to pay damages, lose our rights to these technologies or both, which would adversely affect our business and prospectus.

We rely, in part, on license and other strategic agreements, which subject us to various obligations, including diligence obligations with respect to development and commercialization activities, payment obligations for achievement of certain milestones and royalties on product sales, negative covenants and other material obligations. For example, we received a license from ProMab Biotechnologies, Inc. to develop and commercialize certain CAR-T technology related to our GC007g product candidate in the field of human therapeutics in Greater China. If we fail to comply with the obligations under our license agreements, including as a result of COVID-19 impacting our operations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and our licensors may have the right to terminate the license. If our license agreements are terminated, we may not be able to develop, manufacture, market or sell the products covered by our agreements and those being tested or approved in combination with such products. Such an occurrence could materially adversely affect the value of the product candidates being developed under any such agreement.

Disputes may arise regarding intellectual property subject to, and any of our rights and obligations under, any license or other strategic 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 the intellectual property of the licensor that is not subject to the license agreement;

- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the sublicensing of patent and other rights to third parties under any such agreement or collaborative relationships;
- 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 to or 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 product candidates.

Our business also would suffer if any current or future licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing, misappropriating or otherwise violating the licensor's rights.

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 seek alternative options, such as developing new product candidates with design-around technologies, which may require more time and investment, or abandon development of the relevant research programs or product candidates and our business, financial condition, results of operations and prospects could suffer.

We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms or at all.

A third-party may hold intellectual property rights, including patent rights, that are important or necessary to the development or manufacture of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, and we could be forced to accept unfavorable contractual terms. In that event, we may be required to expend significant time and resources to redesign our technology, product 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, our business could be harmed.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue 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, capital 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 product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may wish to form collaborations in the future with respect to our product candidates, but may not be able to do so or to realize the potential benefits.

The development and potential commercialization of our product candidates will require substantial additional capital to fund expenses. We may, in the future, decide to collaborate with other biopharmaceutical companies for the development and potential commercialization of those product candidates, including in territories outside the United States or for certain indications. We will face significant competition in seeking appropriate collaborators. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at a stage of development too early for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third-party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third-party. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of our technologies, product candidates and market opportunities. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under any license agreements from entering into agreements on certain terms or at all with potential collaborators.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators and changes to the strategies of the combined company. As a result, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such product candidate, reduce or delay one or more of our other development programs, delay the potential commercialization or reduce the scope of any planned sales or marketing activities for such product candidate, or increase our expenditures and undertake development, manufacturing or commercialization activities at our own expense. If we elect to increase our expenditures to fund development, manufacturing or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Additionally, we may collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Even if we hold such an option, we may be unable to negotiate a license from the institution within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program.

Our product candidates may also require specific components to work effectively and efficiently, and rights to those components may be held by others. We may be unable to in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms or at all, which would harm our business. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

We may be subject to claims by third parties asserting that we or our employees, consultants or advisors have misappropriated, wrongfully used or disclosed their trade secrets or other intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of third parties in their work for us, we may be subject to claims that we or these individuals have inadvertently or otherwise used intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. We may also in the future be subject to claims that we have caused such individual to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these potential claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception, development or reduction to practice 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, conceives, develops or reduces to practice intellectual property that we regard as our own or such employees and contractors may breach the agreement and claim the developed intellectual property as their own. Our assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A court could prohibit us from using technologies or features that are essential to our product candidates if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and could be a distraction to management. In addition, any litigation or threat thereof may adversely affect our ability to hire employees or contract with independent service providers. Moreover, a loss of key personnel or their work product could hamper or prevent our ability to commercialize our products.

Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. We have not yet selected trademarks for our product candidates and have not yet begun the process of applying to register trademarks for our product candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

In addition, any proprietary name we propose to use with our clinical-stage product candidates or any other product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. The NMPA may also object to our proposed proprietary product name that infringes the existing rights of third parties.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and growth prospects.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. In some cases, we may not be able to obtain patent protection for certain technology outside the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, even in jurisdictions where we do pursue patent protection or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

Competitors may use our technologies in jurisdictions where we have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and preclinical programs and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign 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, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents, if pursued and obtained, or marketing of competing products in violation of our intellectual property and other proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions 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 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. Moreover, the initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. 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, and our business, financial condition, results of operations, and prospects may be adversely affected.

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, renewal fees, annuity fees and various other government fees on patents and applications are due to be paid to the USPTO and patent agencies outside the United States in several stages over the lifetime of the patent and applications. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products or product candidates, our competitors might be able to enter the market, which would harm our business.

Intellectual property rights do not necessarily address all potential threats.

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

- any product candidates we may develop will eventually become commercially available in generic or biosimilar product forms;
- others may be able to make products that are similar to any product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we may own or license now or in the future;
- we, or any future license partners or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or license now or in the future;
- we, or any future license partners or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications or those that we may own in the future will not lead to issued patents;
- it is possible that there are prior public disclosures that could invalidate our issued patents, or parts of our issued patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our product candidates or technology similar to ours;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- the claims of our patent applications, if and when issued, may not cover our product candidates;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- the laws of foreign countries may not protect our proprietary rights or the proprietary rights of license partners or current or future collaborators to the same extent as the laws of the United States;

- the inventors of our patent applications may become involved with competitors, develop products or processes that design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- we engage in scientific collaborations and will continue to do so in the future, and our collaborators may develop adjacent or competing products that are outside the scope of our patents;
- any product candidates we develop may be covered by third parties' patents or other exclusive rights;
- the patents of others may harm our business;
- we may not develop additional proprietary technologies that are patentable; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third-party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Our Corporate Structure

The uncertainties in the PRC legal system may subject our contractual arrangements to different interpretations or enforcement challenges, or subject us to severe penalties or force us to relinquish our interests in our operations.

We are a Cayman Islands exempted company and we obtain control over our VIE, Gracell Biotechnologies (Shanghai) Co., Ltd., or Shanghai Gracell Biotech, through our wholly owned PRC subsidiary, Gracell Bioscience (Shanghai) Co., Ltd., or Gracell Bioscience or our WFOE, by entering into a series of contractual arrangements by and among our WFOE, our VIE, and its shareholders, which enable us to (i) exercise effective control over our VIE, (ii) receive economic benefits from our VIE that potentially could be significant to our VIE, and (iii) have an exclusive option to purchase all or part of the equity interests and assets in our VIE, when and to the extent permitted by PRC laws. As a result of these contractual arrangements, we have control over and are the primary beneficiary of our VIE and hence consolidate its financial results under U.S. GAAP. See "Corporate History and Structure" for further details.

Our PRC legal counsel, AllBright Law Offices, based on its understanding of the relevant laws and regulations, is of the opinion that (i) the ownership structure of our WFOE, our VIE and its subsidiary are in compliance with applicable PRC laws or regulations and (ii) such contractual arrangements constitute valid, legal and binding obligations enforceable against each party of such agreements in accordance with the terms of each agreement, and will not result in any violation of PRC laws or regulations currently in effect. However, our PRC legal counsel has also advised us that there are substantial uncertainties regarding the interpretation and application of current and future PRC laws, regulations and rules. Accordingly, the PRC regulatory authorities may take a view that is contrary to the opinion of our PRC legal counsel.

If we or our VIE are found to be in violation of any existing or future PRC laws or regulations, or fail to obtain or maintain any of the required permits or approvals, the relevant PRC regulatory authorities would have broad discretion to take action in dealing with such violations or failures, including:

- revoking the business licenses and/or operating licenses of such entities;
- discontinuing or placing restrictions or onerous conditions on our operation through any transactions between our WFOE and our VIE;
- imposing fines, confiscating the income from our WFOE or our VIE, or imposing other requirements with which we or our VIE may not be able to comply;

- requiring us to restructure our ownership structure or operations, including terminating the contractual arrangements with our VIE and deregistering the equity pledges of our VIE, which in turn would affect our ability to consolidate, derive economic interests from, or exert effective control over our VIE;
- restricting or prohibiting our use of the proceeds of this offering to finance our business and operations in China, and taking other regulatory or enforcement actions that could be harmful to our business;
- confiscating any of our income deemed to be obtained through illegal operations;
- discontinuing or placing restrictions or onerous conditions on our operations;
- imposing additional conditions or requirements with which we may not be able to comply; or
- taking other regulatory or enforcement actions against us that could be harmful to our business.

The imposition of any of these penalties would result in a material and adverse effect on our ability to conduct our business. In addition, it is unclear what impact the PRC government actions would have on us and on our ability to consolidate the financial results of our VIE in our consolidated financial statements, if the PRC government authorities were to find our legal structure and contractual arrangements to be in violation of PRC laws and regulations. If the imposition of any of these government actions causes us to lose our right to direct the activities of our VIE or our right to receive substantially all the economic benefits and residual returns from our VIE and we are not able to restructure our ownership structure and operations in a satisfactory manner, we would no longer be able to exert effective control over or consolidate the financial results of our VIE in our consolidated financial statements. Either of these results, or any other significant penalties that might be imposed on us in this event, would have a material adverse effect on our financial condition and results of operations.

We rely on contractual arrangements with our VIE to use, or otherwise benefit from, the foreign restricted licenses and permits, which may not be as effective as direct ownership in providing operational control.

We have relied and expect to continue to rely on contractual arrangements with Shanghai Gracell Biotech, our VIE, and its shareholders, and its subsidiary to operate our business in China. These contractual arrangements may not be as effective as direct ownership in providing us with control over our VIE. For example, our VIE and its shareholders could breach their contractual arrangements with us by, among other things, failing to conduct their operations in an acceptable manner or taking other actions that are detrimental to our interests.

Currently, none of our equity pledge is registered with the local branches of the Administration for Market Regulation in accordance with the PRC Property Rights Law. Under the PRC laws, if the registration of the pledge of equity interests fails to be completed, we may not be able to enforce our equity pledge agreement and other contractual arrangements that provide us control over our VIE, especially against third parties.

If we had direct ownership of our VIE, we would be able to exercise our rights as a shareholder to effect changes in the board of directors of our VIE, which in turn could implement changes, subject to any applicable fiduciary obligations, at the management and operational level. However, under the current contractual arrangements, we rely on the performance by our VIE and its shareholders of their respective obligations under the contracts to exercise control over our VIE. The shareholders of our VIE may not act in the best interests of our company or may not perform their obligations under these contracts. Such risks exist throughout the period in which we intend to operate certain portion of our business through the contractual arrangements with our VIE. If any dispute relating to these contracts remains unresolved, we will have to enforce our rights under these contracts through arbitration, litigation or other legal proceedings and therefore will be subject to uncertainties in the PRC legal system. Therefore, our contractual arrangements with our VIE may not be as effective in controlling our business operations as direct ownership.

Uncertainties exist with respect to the interpretation and implementation of the newly enacted Foreign Investment Law and how it may impact the viability of our current structure, our business, financial condition and results of operations.

On March 15, 2019, the Standing Committee of the National People's Congress of the PRC passed the Foreign Investment Law of the People's Republic of China ("Foreign Investment Law"), which took effect on January 1, 2020 and replaced three existing laws regulating foreign investment in China, namely, the PRC Equity Joint Venture Law, the PRC Cooperative Joint Venture Law and the Wholly Foreign-owned Enterprise Law, together with their implementation rules and ancillary regulations. Among other things, the Foreign Investment Law defines the "foreign investment" as the investment activities in China conducted by foreign individuals, enterprises and other organizations (collectively, the "Foreign Investors") in a direct or indirectly manner, including any of the following circumstances: (1) the foreign investor establishes a foreign-invested enterprise within the territory of China, independently or jointly with any other investor; (2) the foreign investor acquires shares, equities, property shares or any other similar rights and interests of an enterprise within the territory of China; (3) the foreign investor makes investment to initiate a new project within the territory of China, independently or jointly with any other investor; and (4) the foreign investor makes investment in any other way stipulated by laws, administrative regulations or provisions of the State Council. The Foreign Investment Law leaves uncertainty with respect to whether Foreign Investors control PRC onshore variable interest entities via contractual arrangements will be recognized as "foreign investment". PRC governmental authorities will administrate foreign investment by applying the principal of pre-entry national treatment together with a "negative list" (the "Negative List", which shall be promulgated by or promulgated with approval by the State Counsel), to be specific, Foreign Investors are prohibited from making any investments in the fields which are catalogued into prohibited industries for foreign investment based on the Negative List, while Foreign Investors are allowed to make investments in the restricted industries provided that all the requirements and conditions as set forth in the Negative List have been satisfied; when Foreign Investors make investments in the fields other than those included in the Negative List, the national treatment principle shall apply. Besides, certain approval and/or filing requirements shall be fulfilled in accordance with applicable foreign investment laws and regulations.

The operations that we conduct through our VIE and its subsidiary may be subject to the latest version of the "negative list", namely, the Special Management Measures (Negative List) for the Access of Foreign Investment (2020), which became effective on July 23, 2020 (the "2020 Negative List"), or any successor regulations. If our control over our VIE through contractual arrangements are deemed as foreign investment in the future, and any business of our VIE is restricted or prohibited from foreign investment under the "negative list" effective at the time, we may be deemed to be in violation of the Foreign Investment Law, the contractual arrangements that allow us to have control over our VIE may be deemed as invalid and illegal, and we may be required to unwind such contractual arrangements and/or restructure our business operations, any of which may have a material adverse effect on our business operation.

The shareholders of our VIE may have actual or potential conflicts of interest with us and fail to perform their obligations under our contractual arrangements, which, in turn, may adversely affect our business and financial condition.

The shareholders of our VIE may have potential conflicts of interest with us. For example, Dr. William Wei Cao is one of the shareholders of our VIE. Dr. Cao is also our founder, chairman and chief executive officer. Any shareholder of our VIE may breach, or cause our VIE to breach, or refuse to renew, the existing contractual arrangements we have with any of them and our VIE, which would have a material and adverse effect on our ability to effectively control our VIE and receive substantially all the economic benefits from them. For example, the shareholders may be able to cause our agreements with our VIE to be performed in a manner adverse to us by, among other things, failing to remit payments due under the contractual arrangements to us on a timely basis. There can be no assurance that when conflicts of interest arise, any or all of these shareholders will act in the best interests of our company or such conflicts will be resolved in our favor.

Currently, we do not have any arrangements to address potential conflicts of interest between these shareholders and our company, except that we could exercise our purchase option under the exclusive option agreements with these shareholders to request them to transfer all of their equity interests in our VIE to a PRC entity or individual designated by us, to the extent permitted by PRC laws. For the shareholders who are also our directors and executive officers, we rely on them to abide by the laws of the Cayman Islands and China, which provide that directors owe a fiduciary duty to the company that requires them to act in good faith and in what they believe to be the best interests of the company and not to use their position for personal gain. There is currently no specific and clear guidance under PRC laws that addresses any conflict between PRC laws and laws of Cayman Islands in respect of any conflict relating to corporate governance. The shareholders of our VIE have executed powers of attorney to appoint our WFOE to vote on their behalf and exercise voting rights as shareholders of our VIE. If we cannot resolve any conflicts of interest or disputes between us and the shareholders of our VIE, we would have to rely on legal proceedings, which may be expensive, time-consuming and disruptive to our operations. There is also substantial uncertainty as to the outcome of any such legal proceedings.

Under our current contractual arrangements, (i) the spouse of the individual shareholders of our VIE has executed a spousal consent letter, under which such spouse agrees that she will not raise any claims against the equity interest, and will take every action to ensure the performance of the contractual arrangements, and (ii) the VIE and its shareholders shall not assign any of their respective rights or obligations to any third party without the prior written consent of our WFOE. However, we cannot assure you that these undertakings and arrangements will be complied with or effectively enforced. The shareholders of our VIE may be involved in personal disputes with third parties or other incidents that may have an adverse effect on their respective equity interests in our VIE and the validity or enforceability of our contractual arrangements with its shareholders. For example, in the event that any of the shareholders of our VIE divorces his or her spouse, the spouse may claim that the equity interest of our VIE held by such shareholder is part of their community property and should be divided between such shareholder and his or her spouse. If such claim is supported by the court, the relevant equity interest may be obtained by the shareholder's spouse or another third-party who is not subject to obligations under our contractual arrangements, which could result in a loss of the effective control over our VIE by us. Similarly, if any of the equity interests of our VIE is inherited by a third-party with whom the current contractual arrangements are not binding, we could lose our control over our VIE or have to maintain such control by incurring unpredicted costs, which could cause significant disruption to our business and operations and harm our financial condition and results of operations.

Contractual arrangements in relation to our VIE may be subject to scrutiny by the PRC tax authorities and they may determine that we or our VIE owes additional taxes, which could negatively affect our financial condition and the value of your investment.

Under applicable PRC laws and regulations, arrangements and transactions among related parties may be subject to audit or challenge by the PRC tax authorities. The Enterprise Income Tax Law requires every enterprise in China to submit its annual enterprise income tax return together with a report on transactions with its related parties to the relevant tax authorities. The tax authorities may impose reasonable adjustments on taxation if they have identified any related party transactions that are inconsistent with arm's length principles. We may face material and adverse tax consequences if the PRC tax authorities determine the contractual arrangements among our WFOE, our VIE and VIE's shareholders were not entered into on an arm's length basis in such a way as to result in an impermissible reduction in taxes under applicable PRC laws, rules and regulations, and adjust the income of our VIE in the form of a transfer pricing adjustment. A transfer pricing adjustment could, among other things, result in a reduction of expense deductions recorded by our VIE for PRC tax purposes, which could increase our tax expenses. In addition, the PRC tax authorities may impose late payment fees and other penalties on our VIE for the adjusted but unpaid taxes according to the applicable regulations. Our financial position could be materially and adversely affected if our VIE's tax liabilities increase or if it is required to pay late payment fees and other penalties.

We may lose the ability to use and enjoy assets held by our VIE and its subsidiary that are important to our business if our VIE and its subsidiary declare bankruptcy or become subject to a dissolution or liquidation proceeding.

As part of our contractual arrangements with our VIE, our VIE and its subsidiary hold certain assets that are material to the operation of certain portion of our business, including permits, domain names and certain of our IP rights. If our VIE and its subsidiary declare bankrupt and all or part of their assets become subject to liens or rights of third-party creditors, we may be unable to continue some or all of our business activities, which could materially and adversely affect our business, financial condition and results of operations. Under the contractual arrangements, our VIE may not, in any manner, sell, transfer, mortgage or dispose of its assets or legal or beneficial interests in the business without our prior consent. If our consolidated affiliated entity undergoes a voluntary or involuntary liquidation proceeding, the independent third-party creditors may claim rights to some or all of these assets, thereby hindering our ability to operate our business, which could materially and adversely affect our business, financial condition and results of operations.

If the chops of our PRC subsidiary, our VIE and its subsidiary, are not kept safely, are stolen or are used by unauthorized persons or for unauthorized purposes, the corporate governance of these entities could be severely and adversely compromised.

In China, a company chop or seal serves as the legal representation of the company towards third parties even when unaccompanied by a signature. Each legally registered company in China is required to maintain a company chop, which must be registered with the local Public Security Bureau. In addition to this mandatory company chop, companies may have several other chops which can be used for specific purposes. The chops of our WFOE and VIE are generally held securely by personnel designated or approved by us in accordance with our internal control procedures. To the extent those chops are not kept safely, are stolen or are used by unauthorized persons or for unauthorized purposes, the corporate governance of these entities could be severely and adversely compromised and those corporate entities may be bound to abide by the terms of any documents so chopped, even if they were chopped by an individual who lacked the requisite power and authority to do so. In addition, if the chops are misused by unauthorized persons, we could experience disruption to our normal business operations. We may have to take corporate or legal action, which could involve significant time and resources to resolve while distracting management from our operations.

Our contractual arrangements are governed by PRC law. Accordingly, these contracts would be interpreted in accordance with PRC law, and any disputes would be resolved in accordance with PRC legal procedures, which may not protect you as much as those of other jurisdictions, such as the United States.

All the agreements under our contractual arrangements with our VIE and its equity owners are governed by PRC law and provide for the resolution of disputes through arbitration in China. Accordingly, these contracts would be interpreted in accordance with PRC law and any disputes would be resolved in accordance with PRC legal procedures. The legal system in the PRC is not as developed as in some other jurisdictions, such as the United States. As a result, uncertainties in the PRC legal system could limit our ability to enforce these contractual arrangements. Meanwhile, there are very few precedents and little formal guidance as to how contractual arrangements in the context of a VIE should be interpreted or enforced under PRC law. There remain significant uncertainties regarding the ultimate outcome of such arbitration should legal action become necessary. In addition, under PRC law, rulings by arbitrators are final, parties cannot appeal the arbitration results in courts, and if the losing parties fail to carry out the arbitration awards within a prescribed time limit, the prevailing parties may only enforce the arbitration awards in PRC courts through arbitration award recognition proceedings, which would require additional expenses and delay. In the event we are unable to enforce these contractual arrangements, or if we suffer significant delay or other obstacles in the process of enforcing these contractual arrangements, we may not be able to exert effective control over our VIE, and our ability to conduct our business may be negatively affected.

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.

Currently, a material portion of 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—PRC Regulation” for a discussion of the regulatory requirements that are applicable to our current and planned business activities in China. For example, under PRC law, before we or our subsidiaries commence a clinical trial with a PRC partner, an approval or filing, as the case may be, needs to be obtained in advance for any projects involving international collaboration in respect of human genetic resources in order to collect any biological samples that contain the genetic material of Chinese human subjects. Any failure to obtain such approval or filing could cause relevant collaboration projects to be suspended by governing authorities, may result in fines and also may constitute a breach under our agreements with certain CROs. Investigator-initiated trials cannot be implemented in a medical and healthcare institution without first being approved by such medical and healthcare institution. Such medical and healthcare institution shall file such approval to the medical and healthcare authority which issues its operating license for record. Furthermore, under relevant PRC laws, a license for use of laboratory animals is required for performing experimentation on animals. Any failure of fully comply with such requirement may result in the invalidation of our experimental data. 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.

The Chinese economy differs from the economies of most developed countries in many respects, including a higher level of government involvement, the ongoing development of a market-oriented economy, a higher level of control over foreign exchange, and a less efficient allocation of resources.

While the PRC economy has experienced significant growth since the late 1970s, 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. These measures are intended to benefit the overall PRC economy, but may also have a negative effect on us. For example, our business, financial condition and results of operations could be adversely affected by PRC government control over capital investments or changes in regulations that are applicable to us.

The PRC economy has been transitioning from a centrally planned economy to a more market-oriented economy. Although the PRC government has implemented measures since the late 1970s that emphasize the utilization of market forces for economic reform, the PRC government continues to play a significant role in regulating industry development by imposing industrial policies. The PRC government also exercises significant control over China’s economic growth through the allocation of resources, controlling payment of foreign currency-denominated obligations, setting monetary policy and providing preferential treatment to particular industries or companies.

The PRC legal system contains uncertainties, which could limit the legal protections available to you and to us.

In 1979, the PRC government began to promulgate a comprehensive system of laws and regulations governing economic matters in general. The overall effect of legislation over the past four decades has significantly enhanced the protections afforded to various forms of foreign investment in China. Our PRC subsidiary is subject to laws and regulations applicable to foreign-invested enterprises in China. In particular, they are subject to PRC laws, rules and regulations governing foreign companies' ownership and operation of pharmaceutical businesses. Such laws and regulations are subject to change, and their interpretation and enforcement involve uncertainties, which could limit the legal protections available to us and our investors. In addition, we cannot predict the effect of future developments in the PRC legal system, including the promulgation of new laws, changes to existing laws or the interpretation or enforcement of such laws, or the preemption of local regulations by PRC laws, rules and regulations.

Moreover, China has a civil law system based on written statutes, which, unlike common law systems, is a system in which decided judicial cases have little precedential value. Furthermore, interpretation of statutes and regulations may be subject to government policies reflecting domestic political changes. The relative inexperience of China's judiciary in many cases creates additional uncertainty as to the outcome of litigation. In addition, enforcement of existing laws or contracts based on existing laws may be uncertain and sporadic, and it may be difficult to obtain swift and equitable enforcement within China. All such uncertainties 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. It may also be difficult for overseas regulators or you to conduct investigations or collect evidence within China.

We are an exempted company incorporated under the laws of the Cayman Islands. We conduct a material portion of our operations in China and a material portion of our assets are located in China. In addition, many of our senior executive officers and directors 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. In addition, there is uncertainty as to whether the courts of the Cayman Islands or the PRC would (i) recognize or enforce judgments of U.S. courts against us or our directors or officers that are predicated upon the civil liability provisions of the securities laws of the United States or any state in the United States, or (ii) 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.

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 and other applicable laws, regulations and interpretations 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.

It may also be difficult for you or overseas regulators to conduct investigations or collect evidence within China. For example, in China, there are significant legal and other obstacles to obtaining information, documents and materials needed for regulatory investigations or litigation outside China or otherwise with respect to foreign

entities. Although the authorities in China may establish a regulatory cooperation mechanism with the securities regulatory authorities of another country or region to implement cross-border supervision and administration, such regulatory cooperation with the securities regulatory authorities in the United States may not be efficient in the absence of mutual and practical cooperation mechanism. Furthermore, according to Article 177 of the PRC Securities Law, which became effective in March 2020, no overseas securities regulator is allowed to directly conduct investigation or evidence collection activities within the territory of the PRC. Accordingly, without the consent of the competent PRC securities regulators and relevant authorities, no entity or individual may provide the documents and materials relating to securities business activities to overseas parties. While detailed interpretation of or implementing rules under Article 177 have yet to be promulgated, the inability for an overseas securities regulator to directly conduct investigation or evidence collection activities within China may further increase difficulties faced by you in protecting your interests.

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, researchers conducting research funded, at least in part, by the PRC government may be 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 United States 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.

Our business benefits from certain financial incentives and discretionary policies granted by local governments. Expiration of, or changes to, these incentives or policies would have an adverse effect on our operations.

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

Dividends we receive from our subsidiaries located in the PRC may be subject to PRC withholding tax, which could materially and adversely affect the amount of dividends, if any, we may pay our shareholders.

The PRC Enterprise Income Tax Law classifies enterprises as resident enterprises and non-resident enterprises. The PRC Enterprise Income Tax Law provides that an income tax rate of 20% may be applicable to dividends payable to non-resident investors, which (i) do not have an establishment or place of business in the PRC, or (ii) have an establishment or place of business in the PRC 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 State Council of the PRC reduced such rate to 10% through the implementation regulations of the PRC Enterprise Income Tax Law. Further, pursuant to the Double Tax Avoidance Arrangement between Hong Kong and Mainland China, or the Double Tax Avoidance Arrangement, and the Notice on Certain Issues with Respect to the Enforcement of Dividend Provisions in Tax Treaties issued in February 2009 by the State Administration of Taxation of the PRC, or the SAT, if a Hong Kong resident enterprise owns more than 25% of the equity interest in a company in China at all times during the 12-month period immediately prior to obtaining a dividend from such company, the 10% withholding tax on dividends is reduced to 5% provided that certain other conditions and requirements under the Double Tax Avoidance Arrangement and other applicable PRC laws are satisfied at the discretion of relevant PRC tax authority.

If our British Virgin Island subsidiary and our Hong Kong subsidiary are considered as non-resident enterprises and our Hong Kong subsidiary is considered as a Hong Kong resident enterprise under the Double Tax Avoidance Arrangement and is determined by the competent PRC tax authority to have satisfied relevant conditions and requirements, then the dividends paid to our Hong Kong subsidiary by its PRC subsidiary may be subject to the reduced income tax rate of 5% under the Double Tax Avoidance Arrangement. However, based on the Notice on Certain Issues with Respect to the Enforcement of Dividend Provisions in Tax Treaties, if the relevant PRC tax authorities determine, in their discretion, that a company benefits from such reduced income tax rate due to a structure or arrangement that is primarily tax-driven, such PRC tax authorities may adjust the preferential tax treatment. In addition, based on the Announcement of the State Administration of Taxation on Issues Relating to Beneficial Owner in Tax Treaties, effective from April 1, 2018, under certain conditions a company cannot be defined as a beneficial owner under the treaty and thus are not entitled to the abovementioned reduced income tax rate of 5% under the Double Tax Avoidance Arrangement. If we are required under the PRC Enterprise Income Tax Law to pay income tax for any dividends we receive from our subsidiaries in China, or if our Hong Kong subsidiary is determined by PRC government authority as receiving benefits from reduced income tax rate due to a structure or arrangement that is primarily tax-driven, it would materially and adversely

affect the amount of dividends, if any, we may pay to our shareholders and may also have an adverse impact on the value of our ADSs or ordinary shares.

If we are classified as a “resident enterprise” of China under the PRC Enterprise Income Tax Law, we and our non-PRC shareholders could be subject to unfavorable tax consequences, and our business, financial condition and results of operations could be materially and adversely affected.

Under the PRC Enterprise Income Tax Law and its implementation rules, an enterprise established outside the PRC with “de facto management body” within the PRC 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, SAT issued a circular, known as 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 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 the PRC; (ii) decisions relating to the enterprise’s financial and human resource matters are made or are subject to approval by organizations or personnel in the PRC; (iii) the enterprise’s primary assets, accounting books and records, company seals, and board and shareholder resolutions, are located or maintained in the PRC; and (iv) at least 50% of board members with voting rights or senior executives habitually reside in the PRC.

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 may be required to withhold a 10% tax from dividends we pay to our shareholders that are non-resident enterprises, including the holders of the ADSs. In addition, non-resident enterprise shareholders, including our ADS holders, may be subject to PRC tax at a rate of 10% on gains realized on the sale or other disposition of ADSs or ordinary shares, if such income is treated as sourced from within the PRC. Furthermore, if we are deemed a PRC resident enterprise, dividends paid 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 20%, which in the case of dividends may be withheld at source. Any PRC tax liability may be reduced by an applicable tax treaty. However, 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 our ADSs or ordinary shares.

In addition to the uncertainty as to the application of the “resident enterprise” classification, we cannot assure you that the PRC government will not amend or revise the taxation laws, rules and regulations to impose stricter tax requirements or higher tax rates. Any of such changes could materially and adversely affect our financial condition and results of operations.

Governmental control of currency conversion may affect the value of your investment.

Currently, the RMB cannot be freely converted into any foreign currency. The PRC government imposes controls on the convertibility of RMB into foreign currencies and, in certain cases, the remittance of currency out of China. Shortages in the availability of foreign currency may restrict the ability of our PRC subsidiary to remit

sufficient foreign currency to pay dividends or other payments to us, or otherwise satisfy their foreign currency dominated obligations. Under existing PRC foreign exchange regulations, payments of current account items, including profit distributions, interest payments and expenditures from trade-related transactions, can be made in foreign currencies without prior approval from the PRC State Administration of Foreign Exchange, or SAFE, by complying with certain procedural requirements. However, for most capital account items, 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 bank loans denominated in foreign currencies. The PRC government may also at its discretion restrict access in the future to foreign currencies for current account transactions. If the foreign exchange control system prevents us from obtaining sufficient foreign currency to satisfy our currency demands, we may not be able to pay dividends in foreign currencies to our shareholders, including holders of the ADSs.

Fluctuation in exchange rates could have a negative effect on our results of operations and the value of your investment.

The value of the 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. Since June 2010, the 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, or IMF, 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, the 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. Since the fourth quarter of 2016, the RMB has depreciated significantly in the backdrop of a surging U.S. dollar and persistent capital outflows of China. With the development of the foreign exchange market and progress toward 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 the 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 the RMB and the U.S. dollar in the future.

Significant revaluation of the RMB may have a negative 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 the 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 the 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. As of the date of this prospectus, 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. In addition, our currency exchange losses may be magnified by PRC exchange control regulations that restrict our ability to convert RMB into foreign currency or to convert foreign currency into RMB.

PRC regulations relating to offshore investment activities by PRC residents and enterprises may increase our administrative burden and restrict our overseas and cross-border investment activity. If our PRC resident and enterprise shareholders fail to make any required applications and filings under such regulations, we may be unable to distribute profits to such shareholders and may become subject to liability under PRC law.

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, which replaces the Notice on Relevant Issues Concerning Foreign Exchange Administration for PRC Residents to Engage in Financing and Round-tripping Investment via Overseas Special Purpose, or SAFE Circular 75. SAFE Circular 37 requires PRC residents, including PRC individuals and PRC corporate entities, to register with SAFE or its local branches in connection with their direct or indirect offshore investment activities. SAFE Circular 37 is applicable to our shareholders who are PRC residents and may be applicable to any offshore acquisitions that we may make in the future.

Under SAFE Circular 37, PRC residents who make, or have prior to the implementation of SAFE Circular 37 made, direct or indirect investments in offshore special purpose vehicles, or SPVs, are required to register such investments with SAFE or its local branches. In addition, any PRC resident who is a direct or indirect shareholder of an SPV, is required to update its registration with the local branch of SAFE with respect to that SPV, to reflect any change of basic information or material events. If any PRC resident shareholder of such SPV fails to make the required registration or to update the registration, the subsidiary of such SPV in China may be prohibited from distributing its profits or the proceeds from any capital reduction, share transfer or liquidation to the SPV, and the SPV may also be prohibited from making additional capital contributions into its subsidiaries in China. In February 2015, SAFE promulgated a Notice on Further Simplifying and Improving Foreign Exchange Administration Policy on Direct Investment, or SAFE Notice 13. Under SAFE Notice 13, applications for foreign exchange registration of inbound foreign direct investments and outbound direct investments, including those required under SAFE Circular 37, shall be filed with qualified banks instead of SAFE. Qualified banks should examine the applications and accept registrations under the supervision of SAFE. Due to the inherent uncertainty in PRC government authorities' implementation of the regulations, SAFE Circular 37 registration may not always be practically available under all circumstances prescribed in these regulations.

We may not be aware of the identities of all of our beneficial owners who are PRC residents. To our knowledge, some of our beneficial owners have not complied with SAFE registration requirements under SAFE Circular 37 and subsequent implementation rules on time or at all. However, we do not have control over our beneficial owners and cannot compel them to comply with SAFE Circular 37 and subsequent implementation rules. Therefore, we cannot assure you that any required registration under SAFE Circular 37 and any amendment has been or will be completed in a timely manner, or at all. The failure of our beneficial owners who are PRC residents to register or amend their foreign exchange registrations pursuant to SAFE Circular 37 and subsequent implementation rules, or the failure of future beneficial owners of our company who are PRC residents to comply with the registration procedures set forth in SAFE Circular 37 and subsequent implementation rules, may subject such beneficial owners or our PRC subsidiary to fines and legal sanctions, or could result in liability under PRC laws for evasion of applicable foreign exchange restrictions, including (i) the requirement by SAFE to return the foreign exchange remitted overseas or into the PRC within a period of time specified by SAFE, with a fine of up to 30% of the total amount of foreign exchange remitted overseas or into PRC and deemed to have been evasive or illegal and (ii) in circumstances involving serious violations, a fine of no less than 30% of and up to the total amount of remitted foreign exchange deemed evasive or illegal. Failure to register or comply with relevant requirements may also limit our ability to contribute additional capital to our PRC subsidiary and limit our PRC subsidiary's ability to distribute dividends to us. These risks may have a material adverse effect on our business, financial condition and results of operations.

Furthermore, as these foreign exchange and outbound investment related regulations and their interpretation and implementation have been constantly evolving, it is unclear how these regulations, and any future regulation concerning offshore or cross-border investments and transactions, will be interpreted, amended and implemented by the relevant government authorities. For example, we may be subject to a more stringent review and approval process with respect to our foreign exchange activities, such as remittance of dividends and foreign-currency-denominated borrowings, which may adversely affect our financial condition and results of operations. We cannot assure you that we have complied or will be able to comply with all applicable foreign exchange and outbound investment related regulations. In addition, if we decide to acquire a PRC domestic company, we cannot assure you that we or the owners of such company, as the case may be, will be able to obtain the necessary approvals or complete the necessary filings and registrations required by the foreign exchange

regulations. This may restrict our ability to implement our acquisition strategy and could adversely affect our business and prospects.

PRC regulation of loans and direct investment by offshore holding companies to PRC entities may delay or prevent us from making loans or additional capital contributions to our PRC operating subsidiary.

As an offshore holding company of our PRC operating subsidiary, we may make loans or additional capital contributions to our PRC subsidiary, subject to satisfaction of applicable governmental registration and approval requirements.

Any loans we extend to our PRC subsidiary, which is treated as a foreign-invested enterprise under PRC law, cannot exceed the statutory limit and must be registered with the local counterpart of the SAFE.

We may also decide to finance our PRC subsidiary by means of capital contributions. According to the relevant PRC regulations on foreign-invested enterprises in China, these capital contributions are subject to registration with State Administration for Market Regulation or its local counterparts. In addition, the PRC government also restricts the convertibility of foreign currencies into RMB and use of the proceeds. On March 30, 2015, SAFE promulgated the Notice on Reforming the Management Method for the Settlement of Foreign Exchange Capital of Foreign-invested Enterprises, or SAFE Circular 19, which took effect and replaced certain previous SAFE regulations from June 1, 2015. SAFE further promulgated the Circular on Reforming and Regulating Policies on the Management of Foreign Exchange Settlement of Capital Accounts, or SAFE Circular 16, effective on June 9, 2016, which, among other things, amends certain provisions of SAFE Circular 19. According to SAFE Circular 19 and SAFE Circular 16, the flow and use of the 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 business beyond its business scope or to provide loans to persons other than affiliates unless otherwise permitted under its business scope. Violations of the applicable circulars and rules may result in severe penalties, including substantial fines as set forth in the Foreign Exchange Administration Regulations. These circulars may limit our ability and speed to transfer the net proceeds from this offering to our PRC subsidiary. On October 23, 2019, SAFE promulgated the Circular to Further Facilitating Cross-border Trade and Investment, or SAFE Circular 28, which took effect on the same day. SAFE Circular 28 cancels restrictions on domestic equity investments made with capital funds by non-investing foreign-funded enterprises. If a non-investing foreign-funded enterprise makes domestic equity investment with capital funds obtained from foreign exchange settlement, the investee shall undergo registration formalities for accepting domestic reinvestment and open the “capital account—account for settled foreign exchange to be paid” to receive the corresponding funds according to relevant provisions. However, it still remains unclear how SAFE and competent banks will carry this out in practice. Despite the restrictions and procedural requirements under these SAFE circulars, our PRC subsidiary may use RMB funds converted from foreign currency registered capital to carry out any activities within their normal course of business and business scope, including to fund operational needs, and to make equity investments in domestic companies.

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 have completed or will be able to complete the necessary government registrations, meet the relevant government requirements or obtain the necessary government approvals on a timely basis, or at all, with respect to existing or future loans to our PRC subsidiary or future capital contributions by us to our PRC subsidiary. If we fail to complete such registrations or obtain such approvals, our ability to use the proceeds we expect to receive from this offering to 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.

Failure to comply with PRC regulations regarding the registration requirements for employee stock ownership plans or share option plans may subject the PRC plan participants or us to fines and other legal or administrative sanctions.

Under the applicable regulations and SAFE rules, PRC citizens who participate in an employee stock ownership plan or a stock option plan in an overseas publicly listed company are required to register with SAFE and complete certain other procedures. In February 2012, SAFE promulgated the Notices on Issues concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies, or the Stock Option Rules, which replaced the Application Procedures of Foreign Exchange Administration for Domestic Individuals Participating in Employee Stock Ownership Plan or Stock Option Plans of Overseas Publicly Listed Companies issued by SAFE in March 2007. Pursuant to the Stock Option Rules, if a PRC resident participates in any stock incentive plan of an overseas publicly listed company, a qualified PRC domestic agent must, among other things, file on behalf of such participant an application with SAFE to conduct the SAFE registration with respect to such stock incentive plan and obtain approval for an annual allowance with respect to the purchase of foreign exchange in connection with the exercise or sale of stock options or stock such participant holds. Such participating PRC residents' foreign exchange income received from the sale of stock and dividends distributed by the overseas publicly listed company must be fully remitted into a PRC collective foreign currency account opened and managed by the PRC agent before distribution to such participants. We and our PRC resident employees who have been granted stock options or other share-based incentives of ours will be subject to the Stock Option Rules when our company becomes an overseas listed company upon the completion of this offering. If we or our PRC resident participants fail to comply with these regulations, we and/or our PRC resident participants may be subject to fines and legal sanctions. In addition, the State Administration of Taxation has issued certain circulars concerning employee share options and restricted shares. Under these circulars, our employees working in China who exercise share options and/or are granted restricted shares in the future will be subject to PRC individual income tax. Our PRC subsidiaries have obligations to file documents related to employee share options and/or restricted shares with tax authorities and to withhold individual income taxes of those employees who exercise their share options. If our employees fail to pay or we fail to withhold their income taxes according to laws and regulations, we may face sanctions imposed by the tax authorities or other PRC government authorities.

We may be required to obtain prior approval from the China Securities Regulatory Commission for the listing and trading of the ADSs on Nasdaq.

On August 8, 2006, six PRC regulatory agencies, including the China Securities Regulatory Commission, or the CSRC, promulgated the Provisions on the Merger or Acquisition of Domestic Enterprises by Foreign Investors, or the M&A Rules, which became effective on September 8, 2006 and was amended on June 22, 2009. This regulation, among other things, requires offshore SPVs formed for the purpose of an overseas listing and controlled by PRC companies or individuals, to obtain the CSRC approval prior to listing their securities on an overseas stock exchange. The application of this regulation remains unclear. Our PRC legal counsel has advised us that, based on their understanding of the current PRC laws, the CSRC approval is not required under the M&A Rules in the context of this offering because (i) the ownership structure of our PRC subsidiary was established by direct investment instead of through acquisition of equity interests or assets of any PRC domestic company by foreign entities using equity as consideration as defined under the M&A Rules; and (ii) no explicit provision in the M&A Rules classifies the contractual arrangement as a type of acquisition transaction falling under the M&A Rules.

However, we have been advised by our PRC legal counsel that there are uncertainties regarding the interpretation and application of the PRC laws and regulations, and there can be no assurance that the PRC government will ultimately take a view that is not contrary to the above opinion of our PRC legal counsel. If it is determined that the CSRC approval is required for this offering, we may face sanctions by the CSRC or other PRC regulatory agencies for failure to seek the CSRC approval for this offering. These sanctions may include fines and penalties on our operations in the PRC although, to our knowledge, no definitive rules or interpretations

have been issued to determine or quantify such fines or penalties, delays 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 PRC subsidiary, or other actions that may have a material adverse effect on our business and the trading price of the ADSs. The CSRC or other PRC regulatory agencies may also take actions requiring us, or making it advisable to 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.

The M&A Rules and certain other PRC regulations establish complex procedures for some acquisitions of PRC companies by foreign investors, which could make it more difficult for us to pursue growth through acquisitions in China.

The M&A Rules and relevant regulations and rules concerning mergers and acquisitions established additional procedures and requirements that could make merger and acquisition activities by foreign investors more time-consuming and complex. The M&A Rules require that the Ministry of Commerce, or the MOFCOM, be notified in advance of any change-of-control transaction in which a foreign investor takes control of a PRC domestic enterprise, if (i) any important industry is concerned, (ii) such transaction involves factors that have or may have an impact on the 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. The approval from MOFCOM shall be obtained in circumstances where overseas companies established or controlled by PRC enterprises or residents acquire affiliated domestic companies.

The Anti-Monopoly Law promulgated by the Standing Committee of the National People's Congress, or NPC, which became effective in August 2008, requires that when a concentration of undertakings occurs and reaches statutory thresholds, the undertakings concerned shall file a prior notification with the anti-monopoly enforcement agency of the State Council. Without the clearance from such agency, no concentration of undertakings shall be implemented and effected. Mergers, acquisitions or contractual arrangements that allow one market player to take control of or to exert decisive impact on another market player must also be notified in advance to the anti-monopoly enforcement agency of the State Council, when the threshold under the Provisions on Thresholds for Prior Notification of Concentrations of Undertakings, or the Prior Notification Rules, issued by the State Council in August 2008 and amended in September 2018 is triggered. If such prior notification is not obtained, the anti-monopoly enforcement agency may order the concentration to cease its operations, dispose of shares or assets, transfer the business of the concentration within a time limit, take any other necessary measures to restore the situation as it was before the concentration, and may impose administrative fines.

In addition, the Implementing Rules Concerning Security Review on the Mergers and Acquisitions by Foreign Investors of Domestic Enterprises, issued by the MOFCOM in August 2011, specify that mergers and acquisitions by foreign investors involved in "an industry related to national security" are subject to strict review by the MOFCOM, and prohibit any activities attempting to bypass such security review, including by structuring the transaction through a proxy or contractual control arrangement. In the future, we may grow our business by acquiring complementary businesses. Complying with the requirements of the abovementioned regulations and other relevant rules to complete such transactions could be time-consuming, and any required approval processes, including obtaining approval from the MOFCOM or its local counterparts may delay or inhibit our ability to complete such transactions.

We cannot preclude the possibility that the MOFCOM or other government agencies may publish explanations contrary to our understanding or broaden the scope of such security reviews in the future, in which case our future acquisitions in the PRC, including those by way of entering into contractual control arrangements with target entities, may be closely scrutinized or prohibited. Our ability to expand our business or maintain or expand our market share through future acquisitions would as such be materially and adversely affected.

We and our shareholders face uncertainty with respect to indirect transfers of equity interests in PRC resident enterprises, assets attributed to a PRC establishment of a non-PRC company or immovable properties located in China owned by non-PRC companies.

In February 2015, SAT issued a Public Notice Regarding Certain Corporate Income Tax Matters on Indirect Transfer of Properties by Non-Tax Resident Enterprises, or SAT Public Notice 7. SAT Public Notice 7 extends its tax jurisdiction to transactions involving transfer of other taxable assets through offshore transfer of a foreign intermediate holding company. In addition, SAT Public Notice 7 provides clear criteria for assessment of reasonable commercial purposes and has introduced safe harbors for internal group restructurings and the purchase and sale of equity through a public securities market. SAT Public Notice 7 also brings challenges to both foreign transferor and transferee (or other person who is obligated to pay for the transfer) of taxable assets. In October 2017, SAT issued the Announcement of the State Administration of Taxation on Issues Concerning the Withholding of Non-resident Enterprise Income Tax at Source, or SAT Bulletin 37, which came into effect on December 1, 2017. The Bulletin 37 further clarifies the practice and procedure of the withholding of nonresident enterprise income tax. Where a non-resident enterprise transfers taxable assets indirectly by disposing of the equity interests of an overseas holding company, which is an indirect transfer, the non-resident enterprise as either transferor or transferee, or the PRC entity that directly owns the taxable assets, may report such Indirect Transfer to the relevant tax authority. Using a “substance over form” principle, the PRC tax authority may disregard the existence of the overseas holding company if it lacks a reasonable commercial purpose and was established for the purpose of reducing, avoiding or deferring PRC tax. As a result, gains derived from such indirect transfer other than transfer of shares of ADSs acquired and sold on public markets may be subject to PRC enterprise income tax, and the transferee or other person who is obligated to pay for the transfer is obligated to withhold the applicable taxes, currently at a rate of 10% for the transfer of equity interests in a PRC resident enterprise. Both the transferor and the transferee may be subject to penalties under PRC tax laws if the transferee fails to withhold the taxes and the transferor fails to pay the taxes.

We face uncertainties as to the reporting and other implications of certain past and future transactions that involve PRC taxable assets, such as offshore restructuring, sale of the shares in our offshore subsidiaries and investments. Our company may be subject to filing obligations or taxed if our company is the transferor in such transactions, and may be subject to withholding obligations if our company is the transferee in such transactions, under SAT Public Notice 7 or Bulletin 37, or both.

The audit report included in this prospectus is prepared by an auditor who is not inspected by the Public Company Accounting Oversight Board and, as such, our investors are deprived of the benefits of such inspection.

Our independent registered public accounting firm that issued the audit report included in our prospectus filed with the SEC, as an auditor of companies that are traded publicly in the United States and a firm registered with the U.S. Public Company Accounting Oversight Board, or PCAOB, is required by the laws of the United States to undergo regular inspections by the PCAOB to assess its compliance with the laws of the United States and applicable professional standards. Because our auditor is located in, and organized under the laws of, the PRC, a jurisdiction where the PCAOB is currently unable to conduct inspections without the approval of the Chinese authorities, our auditors are not currently inspected by the PCAOB.

On May 24, 2013, the PCAOB announced that it had entered into a Memorandum of Understanding on Enforcement Cooperation with the China Securities Regulatory Commission, or 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 the PCAOB, the CSRC or the PRC Ministry of Finance in the United States and the PRC, respectively. The PCAOB continues to be in discussions with the CSRC and the PRC Ministry of Finance to permit joint inspections in the PRC of audit firms that are registered with the 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

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of financial statement audits of U.S.-listed companies with significant operations in China. On April 21, 2020, the SEC and the PCAOB issued another joint statement reiterating the greater risk that disclosures will be insufficient in many emerging markets, including China, compared to those made by U.S. domestic companies. In discussing the specific issues related to the greater risk, the statement again highlighted the PCAOB's inability to inspect audit documentation and practices of accounting firms in China, with respect to their audit work of U.S. reporting companies. These statements reflect a heightened interest in an issue that has vexed U.S. regulators in recent years. However, it remains unclear what further actions the SEC and PCAOB will take to address the problem.

Inspections of other firms that the PCAOB has conducted outside of China have identified deficiencies in those firms' audit procedures and quality control procedures, which may be addressed as part of the inspection process to improve future audit quality. This lack of PCAOB inspections in China prevents the PCAOB from regularly evaluating our auditor's audits and its quality control procedures. As a result, investors may be deprived of the benefits of PCAOB inspections.

The inability of the PCAOB to conduct inspections of auditors in China makes it more difficult to evaluate the effectiveness of our auditor's audit procedures or quality control procedures as compared to auditors outside China that are subject to PCAOB inspections. Investors may lose confidence in our reported financial information and procedures and the quality of our financial statements.

As part of a continued regulatory focus in the United States on access to audit and other information currently protected by national law, in particular China's, in June 2019, a bipartisan group of lawmakers introduced bills in both houses of the U.S. Congress, which, if passed, would require the SEC to maintain a list of issuers for which the PCAOB is not able to inspect or investigate an auditor report issued by a foreign public accounting firm. On May 20, 2020, the U.S. Senate approved the Holding Foreign Companies Accountable Act, or the HFCA Act, which includes requirements for the SEC to identify issuers whose audit reports are prepared by auditors that the PCAOB is unable to inspect or investigate because of restrictions imposed by non-U.S. authorities. The HFCA Act would also require public companies on this SEC list to certify that they are not owned or controlled by a foreign government and make certain additional disclosures in their SEC filings. In addition, for issuers on the SEC list for three consecutive years, the SEC would be required to prohibit the securities of these companies from being traded on a U.S. national securities exchange, such as The Nasdaq Global Market, or in U.S. over-the-counter markets. Both pieces of proposed legislation would require issuers on the SEC list to make certain disclosures on foreign ownership and control of the issuer.

On June 4, 2020, the U.S. President issued a memorandum ordering the President's Working Group on Financial Markets, or the PWG, to submit a report to the President within 60 days of the memorandum that includes recommendations for actions that can be taken by the executive branch and by the SEC or PCAOB to further protect investors in Chinese companies listed in the United States in response to the PCAOB's lack of access to the work of such companies' auditors. In August 2020, the PWG, released the Report on Protecting United States Investors from Significant Risks from Chinese Companies, which outlined the PWG's five recommendations to the SEC. In particular, the PWG recommends that the SEC work to enhance U.S. exchanges' listing standards to address the concern over the PCAOB's lack of access to audit work papers. This would require, as a condition to initial and continued exchange listing, PCAOB access to work papers of the principal audit firm for the audit of the listed company. The PWG proposed a concept under which Companies that are unable to satisfy this standard as a result of governmental restrictions on access to audit work papers and practices in non-cooperating jurisdictions, or NCJs, may satisfy this standard by providing a co-audit from an audit firm with comparable resources and experience where the PCAOB determines it has sufficient access to audit work papers and practices to conduct an appropriate inspection of the co-audit firm. To reduce market disruption, the new listing standards could provide for a transition period until January 1, 2022 for currently listed companies. The report also recommends to require enhanced and prominent issuer disclosures of the risks of investing in NCJs such as China. After this transition period, if currently listed companies were unable to meet the enhanced listing standards, then they would become subject to securities exchange rules and processes that

could lead to possible de-listing if not cured. The measures in the PWG report are presumably subject to the standard SEC rulemaking process before becoming effective. On August 10, 2020, the SEC announced that SEC Chairman Jay Clayton had directed the SEC staff to prepare proposals in response to the PWG report, and that the SEC was soliciting public comments and information with respect to these proposals.

It is unclear if these legislative proposals would be enacted. However, enactment of one or more of these bills or other efforts to increase U.S. regulatory access to audit information could cause investor uncertainty for affected issuers, including us, and the market price of the ADSs could be adversely affected. In addition, enactment of these legislative proposals may result in prohibitions on the trading of the ADSs on The Nasdaq Global Market or other U.S. exchange if our auditor fails to be inspected by the PCAOB for three consecutive years.

Proceedings instituted by the SEC against the “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.

In late 2012, the SEC commenced administrative proceedings under Rule 102(e) of its Rules of Practice and also under the Sarbanes-Oxley Act of 2002 against the “big four” PRC-based accounting firms (including our auditors). The Rule 102(e) proceedings initiated by the SEC relate to these firms’ inability to produce documents, including audit work papers, in response to the request of the SEC pursuant to Section 106 of the Sarbanes-Oxley Act of 2002, as the auditors located in China are not in a position lawfully to produce documents directly to the SEC because of restrictions under PRC laws and specific directives issued by the China Securities Regulatory Commission, or the CSRC. The issues raised by the proceedings are not specific to our auditors or to us, but affect equally all audit firms based in China and all China-based businesses with securities listed in the United States.

In January 2014, the administrative judge reached an initial decision that each of these firms should be barred from practicing before the SEC for six months. Thereafter, the accounting firms filed a petition for review of the initial decision, prompting the SEC commissioners to review the initial decision, determine whether there had been any violation and, if so, determine the appropriate remedy to be placed on these audit firms.

In February 2015, “big four” PRC-based accounting firms (including our auditors) each agreed to censure and pay a fine to the SEC to settle the dispute and avoid suspension of their ability to practice before the SEC and audit U.S. listed companies. The settlement requires the firms to follow detailed procedures and to seek to provide the SEC with access to the Chinese firms’ audit documents via the CSRC. 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 the accounting firms are subject to additional remedial measures, our ability to file our financial statements in compliance with SEC requirements could be impacted. A determination that we have not timely filed financial statements in compliance with SEC requirements could ultimately lead to the delisting of our ADSs or the termination of the registration of our ADSs under the Exchange Act, or both, which would substantially reduce or effectively terminate the trading of our ADSs in the United States.

In the event that the SEC restarts the administrative proceedings, 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, and could result in delisting. Moreover, any negative news about the proceedings against these audit firms may cause investor uncertainty regarding China-based,

United States-listed companies and the market price of our shares may be adversely affected. If our independent registered public accounting firm was denied, 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 to not be in compliance with the requirements of the Exchange Act.

Our business may be significantly affected by the newly enacted Foreign Investment Law and the “negative list.”

The Foreign Investment Law grants foreign invested entities the same treatment as PRC domestic entities, except for those foreign invested entities that operate in industries deemed to be either “restricted” or “prohibited” in the “negative list” published by the State Council. We are a Cayman Islands exempted company and our PRC subsidiary, Gracell Bioscience (Shanghai) Co., Ltd., or Gracell Bioscience, is currently considered to be a foreign invested entity in China.

The 2020 Negative List provides that foreign investment is prohibited in the development and application of human stem cell or gene diagnostic and therapeutic technologies. As of the date of this prospectus, there has been no official interpretation of the scope of “human stem cell or gene diagnostic and therapeutic technologies” and the application of this regulation remains unclear. If our CAR-T cell therapies or other technologies that are being researched and developed are deemed by relevant PRC regulatory agencies as falling into the category of “human stem cell or gene diagnostic and therapeutic technologies,” Gracell Bioscience would be prohibited from engaging in the research or development of such technologies. For risks relating to the “negative list” in connection with our VIE structure, see “—Uncertainties exist with respect to the interpretation and implementation of the newly enacted Foreign Investment Law and how it may impact the viability of our current structure, our business, financial condition and results of operations.”

Our leased property interest may be defective and our right to lease the properties may be challenged, which could cause significant disruption to our business.

In China, we lease certain premises used in our operations from third parties. We lease our research and development site in Shanghai from a third-party landlord who was granted the land use right on this site from the local government authority for free. According to the relevant regulations in the PRC, approval of the relevant government department is required for leasing allocated land. The third-party landlord for this particular leased site has not made the required filing. If a granted land use right for free is assigned, leased or mortgaged without approval, such landlord maybe subject to the confiscation of the illegal revenue and fine in the light of the seriousness of the case. As a result, our lease may be negatively affected. Certain lessors have not provided us with valid ownership certificates, or authorization of sublease for our leased properties. Under the relevant PRC laws and regulations, if the lessors are unable to obtain certificates of title because such properties were built illegally or failed to pass the inspection or other reasons, or relevant lease has not been approved by competent government authority in accordance with applicable law, such lease contracts may be recognized as void and, as a result, we may be required to vacate the relevant properties. In addition, if our lessors are not the owners of the properties and they have not obtained consents from the owners or their lessors, our leases could be invalidated. If this occurs, we may have to renegotiate the leases with the owners or the parties who have the right to lease the properties, and the terms of the new leases may be less favorable to us, or we may be required to vacate the relevant properties if the terms of the new leases are not reached.

Under PRC laws, all lease agreements are required to be registered with the local housing authorities. We have not registered certain of our lease agreements with the relevant government authorities. Failure to complete these required registrations may expose our landlords, lessors and us to potential monetary fines.

Increases in labor costs and enforcement of stricter labor laws and regulations in the PRC may adversely affect our business and our profitability.

China's overall economy and the average wage level in China have increased in recent years and are expected to continue to grow. The average wage level for our employees has also increased in recent years. We expect that our labor costs, including wages and employee benefits, will continue to increase.

In addition, we have been subject to stricter regulatory requirements in terms of entering into labor contracts with our employees, protecting occupational health and safety, and paying various statutory employee benefits, including pensions, housing funds, medical insurance, work-related injury insurance, unemployment insurance and maternity insurance to designated government agencies for the benefit of our employees. We cannot assure you that we have complied or will be able to comply with all labor-related laws and regulations including those relating to obligations to make social insurance payments and contribute to the housing provident funds. We have not fully paid the housing provident funds for all of our employees as required by applicable PRC regulations. We may be required to make up the contributions for our employees, resulting in financial conditions and results of operations to be adversely affected. Furthermore, certain overseas employee of our PRC subsidiary has not obtained required work permit or residence permit, which may subject our PRC subsidiary to fines and penalty.

We have granted, and may continue to grant, options and other types of awards under our employee stock option plan, which may result in significant share-based compensation expenses and you will incur immediate and substantial dilution.

We adopted our employee stock option plan in April 2019 for the purpose of granting share-based compensation awards to employees, directors and consultants to incentivize their performance and align their interests with ours. As of the date of this prospectus, options to purchase a total of 7,017,599 ordinary shares have been granted and outstanding under our employee stock option plan. See "Management—Employee Stock Option Plan." As of the date of this prospectus, we have not incurred any share-based compensation expenses relating to awards granted under our employee stock option plan. Pursuant to our employee stock option plan, the performance condition for options granted thereunder will be satisfied upon completion of this offering; and as a result, we will, upon the date of the completion of this offering, record a significant amount of cumulative share-based compensation expenses for those options for which the vesting conditions have been satisfied as of such date. 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 awards 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 employee stock option 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.

Risks Related to this Offering, Our Securities and Our Status as a Public Company

An active trading market for our ADSs may not develop and you may not be able to resell your ADSs at or above the initial offering price, or at all.

This offering constitutes the initial public offering of our ADSs, and no public market has previously existed for our ADSs. Any delay in the commencement of trading of our ADSs on Nasdaq would impair the liquidity of the market for the ADSs and make it more difficult for holders to sell the ADSs. There can be no assurance that an active trading market for the ADSs will develop or be sustained after this offering is completed. The lack of an active trading market may also reduce the fair market value of the ADSs. The initial offering price was determined by negotiations among the lead underwriters and us. Among the factors considered in determining the initial public offering price were our future prospects and the prospects of our industry in general, our revenue, net income and certain other financial and operating information in recent periods, and the market prices of securities and certain financial and operating information of companies engaged in activities similar to ours.

However, there can be no assurance that, following the completion of this offering, the ADSs will trade at a price equal to or greater than the initial public offering price.

The trading price of our ADSs may be volatile, and you could lose all or part of your investment.

The trading price of our ADSs following this offering is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their ADSs at or above the price paid for the ADSs. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this prospectus, these factors include:

- the commencement, enrollment or results of our planned and future clinical trials;
- positive or negative results from, or delays in, testing and clinical trials by us, collaborators or competitors;
- the loss of any of our key scientific or management personnel;
- regulatory or legal developments in the United States, China and other countries;
- the success of competitive products or technologies;
- adverse actions taken by regulatory agencies with respect to our clinical trials or manufacturers;
- changes or developments in laws or regulations applicable to our product candidates and preclinical program;
- changes in the structure of healthcare payment systems;
- changes to our relationships with collaborators, manufacturers or suppliers;
- concerns regarding the safety of our product candidates or CAR-T cells in general;
- announcements concerning our competitors or the pharmaceutical industry in general;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- potential acquisitions, financing, collaborations or other corporate transactions;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates;
- the trading volume of our ADSs on Nasdaq;
- sales of our ADSs or ordinary shares by us, members of our senior management and directors or our shareholders or the anticipation that such sales may occur in the future;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States or China;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- investors’ general perception of us and our business; and
- other events and factors, many of which are beyond our control.

These and other market and industry factors may cause the market price and demand for our ADSs to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from

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selling their ADSs at or above the price paid for the ADSs and may otherwise negatively affect the liquidity of our ADSs. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms.

Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming, and could divert our management's attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our ADSs.

If you purchase ADSs in this offering, you will suffer immediate dilution of your investment.

The initial public offering price of our ADSs is substantially higher than the pro forma as adjusted net tangible book value per ADS. Therefore, if you purchase ADSs in this offering, you will pay a price per ADS that substantially exceeds our pro forma as adjusted net tangible book value per ADS after this offering. Based on the initial public offering price of US\$ per ADS, you will experience immediate dilution of US\$ per ADS, representing the difference between our pro forma as adjusted net tangible book value per ADS after this offering and the initial public offering price per ADS. After this offering, we will also have outstanding options under our employee stock option plan to purchase ordinary shares with exercise prices lower than the initial public offering price. To the extent these outstanding options are exercised, there will be further dilution to investors in this offering. For further information regarding the dilution resulting from this offering, see the section titled "Dilution" in this prospectus.

A significant portion of our total outstanding shares are restricted from immediate resale, but may be sold into the market in the near future. This could cause the market price of our ADSs to drop significantly, even if our business is doing well.

Sales of a substantial number of our ordinary shares or ADSs in the public market could occur at any time. If our shareholders sell, or the market perceives that our shareholders intend to sell, substantial amounts of our ordinary shares or ADSs in the public market following this offering, the market price of our ADSs could decline significantly.

Upon completion of this offering, we will have ordinary shares outstanding, including ordinary shares represented by ADSs, based on the number of shares outstanding as of December 31, 2019. Of these shares, the ADSs sold in this offering will be freely tradable immediately. Up to ordinary shares underlying ADSs will be available for sale in the public market beginning 180 days after the date of this prospectus following the expiration of lock-up agreements entered into by our shareholders in connection with the offering. The representatives of the underwriters may agree to release these shareholders from their lock-up agreements at any time and without notice, which would allow for earlier sales of shares in the public market. Sales of a substantial number of such shares upon expiration of the lock-up agreements, the perception that such sales may occur, or early release of restrictions in the lock-up agreements, could cause the market price of our ADSs to fall or make it more difficult for you to sell your ADSs at a time and price that you deem appropriate.

In addition, promptly following the completion of this offering, we intend to file one or more registration statements registering the issuance of approximately ordinary shares (which may be in the form of ADSs) subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements will be available for sale in the public market subject

to vesting arrangements and exercise of options, the lock-up agreements described above and, in the case of our affiliates, the restrictions of Rule 144 under the Securities Act.

Additionally, after this offering, the holders of an aggregate of approximately _____ of our ordinary shares, or their transferees, will have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other shareholders. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our ADSs could decline.

If we fail to implement and maintain effective internal controls to remediate our material weakness over financial reporting, our ability to produce accurate financial statements on a timely basis could be impaired.

Upon becoming a public company, we will be subject to reporting obligations under U.S. securities laws, including the Sarbanes-Oxley Act. Section 404(a) of the Sarbanes-Oxley Act, or Section 404(a), will require that, beginning with our second annual report following our initial public offering, management assess and report annually on the effectiveness of our internal controls over financial reporting and identify any material weaknesses in our internal controls over financial reporting. Although Section 404(b) of the Sarbanes-Oxley Act, or Section 404(b), requires our independent registered public accounting firm to issue an annual report that addresses the effectiveness of our internal controls over financial reporting, we have opted to rely on the exemptions provided in the JOBS Act, and consequently will not be required to comply with SEC rules that implement Section 404(b) until such time as we are no longer an emerging growth company.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and 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 and procedures and we were never required to evaluate our internal control within a specified period, and, as a result, we have experienced and may experience difficulty in meeting these reporting requirements in a timely manner.

During the audit of our financial statements for the years ended December 31, 2018 and 2019, one material weakness was identified in our internal control over financial reporting. Under standards established by the PCAOB, 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 annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness that has been identified relate to our lack of sufficient and competent financial reporting and accounting personnel with appropriate knowledge of U.S. GAAP and SEC reporting and compliance requirements.

We are in the process of implementing a number of measures to address the material weakness that has been identified including: (i) hiring additional accounting and financial reporting personnel with U.S. GAAP and SEC reporting experience and qualifications, (ii) expanding the capabilities of existing accounting and financial reporting personnel through continuous training and education in the accounting and reporting requirements under U.S. GAAP, and SEC rules and regulations, and (iii) enhancing internal audit function as well as engaging an external consulting firm to assist us in assessing compliance with the SEC requirements and improve overall internal control.

We may incur significant costs in the implementation of such measures. We cannot assure you that all these measures will be sufficient to remediate our material weakness in time, or at all. Additionally, we cannot assure you that we have identified all, or that we will not in the future have additional, material weaknesses. 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.

The presence of material weaknesses could result in financial statement errors which, in turn, could lead to errors in our financial reports or delays in our financial reporting, which could require us to restate our operating results or result in our auditors issuing a qualified audit report. In order to establish and maintain effective disclosure controls and procedures and internal controls over financial reporting, we will need to expend significant resources and provide significant management oversight. Developing, implementing and testing changes to our internal controls may require specific compliance training of our directors and employees, entail substantial costs in order to modify our existing accounting systems, take a significant period of time to complete and divert management's attention from other business concerns. These changes may not, however, be effective in establishing and maintaining adequate internal controls.

If either we are unable to conclude that we have effective internal controls over financial reporting or, at the appropriate time, our independent auditors are unwilling or unable to provide us with an unqualified report on the effectiveness of our internal controls over financial reporting as required by Section 404(b), investors may lose confidence in our operating results, the price of our ADSs could decline and we may be subject to litigation or regulatory enforcement actions. In addition, if we are unable to meet the requirements of Section 404, we may not be able to remain listed on the Nasdaq.

We will have broad discretion in the use of proceeds from this offering and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.

Our management will have broad discretion in the application of our cash and cash equivalents, including the net proceeds from this offering, and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our ADSs. The failure by our management to apply these funds effectively could result in financial losses that could have a negative impact on our business, cause the price of our ADSs to decline and delay the development of our product candidates and preclinical program. Pending their use, we may invest our cash and cash equivalents, including the net proceeds from this offering, in a manner that does not produce income or that loses value. See the section titled "Use of Proceeds" for additional information.

Raising additional capital may cause dilution to our holders, including purchasers of our ADSs in this offering, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through any or a combination of securities offerings, debt financings, license and collaboration agreements and research grants. If we raise capital through securities offerings, such sales may also result in material dilution to our existing shareholders, and new investors could gain rights, preferences and privileges senior to the holders of our ADSs or ordinary shares, including ADSs sold in this offering.

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 of these securities may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing and preferred equity financing, if available, could result in fixed payment obligations, and we may be required to accept terms that restrict our ability to incur additional indebtedness, force us to maintain specified liquidity or other ratios or restrict our ability to pay dividends or make acquisitions.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. In addition, we could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable. If we raise funds through research grants, we may be subject to

certain requirements, which may limit our ability to use the funds or require us to share information from our research and development. 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 a third-party to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Raising additional capital through any of these or other means could adversely affect our business and the holdings or rights of our shareholders, and may cause the market price of our ADSs to decline.

Holders of our ADSs have fewer rights than our shareholders and must act through the depositary to exercise their rights.

Holders of our ADSs do not have the same rights as our shareholders and may only exercise their voting rights with respect to the underlying ordinary shares in accordance with the provisions of the deposit agreement. Holders of the ADSs will appoint the depositary or its nominee as their representative to exercise the voting rights attaching to the ordinary shares represented by the ADSs. When a general meeting is convened, if you hold ADSs, you may not receive sufficient notice of a shareholders' meeting to permit you to withdraw the ordinary shares underlying your ADSs to allow you to vote with respect to any specific matter. We will make all commercially reasonable efforts to cause the depositary to extend voting rights to you in a timely manner, but we cannot assure you 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. Furthermore, the depositary will not be liable for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, you may not be able to exercise your right to vote and you may lack recourse if your ADSs are not voted as you request. In addition, in your capacity as an ADS holder, you will not be able to call a shareholders' meeting.

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

The deposit agreement governing the ADSs representing our shares provides that holders and beneficial owners of ADSs irrevocably waive the right to a trial by jury in any legal proceeding arising out of or relating to the deposit agreement, our shares or the ADSs or the transactions contemplated thereby, including claims under federal securities laws, against us or the depositary to the fullest extent permitted by applicable law. If this jury trial waiver provision is prohibited by applicable law, an action could nevertheless proceed under the terms of the deposit agreement with a jury trial. To our knowledge, the enforceability of a jury trial waiver under the federal securities laws has not been finally adjudicated by a federal court. However, we believe that a jury trial waiver provision is generally enforceable under the laws of the State of New York, which govern the deposit agreement, by a court of the State of New York or a federal court in New York, which have non-exclusive jurisdiction over matters arising under the deposit agreement, applying such law. In determining whether to enforce a jury trial waiver provision, New York courts and federal courts will consider whether the visibility of the jury trial waiver provision within the agreement is sufficiently prominent such that a party has knowingly waived any right to trial by jury. We believe that this is the case with respect to the deposit agreement, our shares and the ADSs and the transactions contemplated thereby. In addition, New York courts will not enforce a jury trial waiver provision in order to bar a viable setoff or counterclaim sounding in fraud or one which is based upon a creditor's negligence in failing to liquidate collateral upon a guarantor's demand, or in the case of an intentional tort claim (as opposed to a contract dispute), none of which we believe are applicable in the case of the deposit agreement, our shares or the ADSs or the transactions contemplated thereby. 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 depositary of compliance with any provision of the federal securities laws. If you or any other holder or beneficial owner of ADSs brings a claim against us or the depositary in connection with matters arising under the deposit agreement, our shares or the ADSs or the transactions contemplated thereby, 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 depositary. If a lawsuit is brought against us and/or the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may augur different results than a trial by jury would have had, including results that could be less favorable to the plaintiff(s) in any such action, depending on, among other things, the nature of the claims, the judge or justice hearing such claims, and the venue of the hearing.

You may not receive distributions on our ordinary shares represented by the ADSs or any value for them if it is illegal or impractical to make them available to holders of ADSs.

Although we do not have any present plans to declare or pay any dividends on our ordinary shares after this offering, in the event we declare and pay any dividends, the depositary for the 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 our ordinary shares your ADSs represent. However, in accordance with the limitations set forth in the deposit agreement, it may be unlawful or impractical to make a distribution available to holders of ADSs. We have no obligation to register under U.S. securities laws any offering of ADSs, ordinary shares or other securities received through such distributions. We also have no obligation to take any other action to permit distribution on the ADSs, ordinary shares, rights or anything else to holders of the ADSs. This means that you may not receive the distributions we make on our ordinary shares or any value from them if it is unlawful or impractical to make them available to you. These restrictions may have an adverse effect on the value of your ADSs.

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 the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. Also, under the deposit agreement, the depositary bank will not make rights available to you unless either both the rights and any related securities are registered under the Securities Act, or the distribution of them to ADS holders is exempted 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. Moreover, we may not be able to establish an exemption from registration under the Securities Act. If the depositary does not distribute the rights, it may, under the deposit agreement, either sell them, if possible, or allow them to lapse. Accordingly, you may be unable to participate in our rights offerings and may experience dilution in your holdings.

Because we do not anticipate paying any cash dividends on our ADSs in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.

We have never declared or paid a dividend on our ordinary shares in the past, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. Therefore, you should not rely on an investment in our ADSs to provide dividend income. Our board of directors has complete discretion as to whether to distribute dividends, subject to certain restrictions under Cayman Islands law, namely that our company may only pay dividends out of profits or out of the credit standing in our company's share premium account, and provided always that in no circumstances may a dividend be paid if this would result in our company being unable to pay its debts as they fall due in the ordinary course of business. In addition, our shareholders may, subject to our memorandum and articles of association, by ordinary resolution declare a dividend, but no dividend may exceed the amount recommended by our board of directors. Even if our board of directors decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on, among other things, 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. As a result, capital appreciation, if any, on our ADSs will be your sole source of gains for the foreseeable future. Investors seeking cash dividends should not purchase our ADSs in this offering.

If we are or become classified as a passive foreign investment company, our U.S. shareholders may suffer adverse tax consequences as a result.

Generally, for any taxable year, if at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. For purposes of these tests, passive income includes dividends, interest, gains from commodities and securities transactions, the excess of gains over losses from the disposition of assets which produce passive income (including amounts derived by reason of the temporary investment of funds raised in offerings of our shares) and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. If we are characterized as a PFIC, our U.S. shareholders may suffer adverse tax consequences, including having gains realized on the sale of our ordinary shares treated as ordinary income, rather than capital gain, the non-availability of the preferential rate applicable to dividends received by U.S. non-corporate holders, and having interest charges apply to distributions by us and gains from the sales of our shares.

Based on our operating history and the projected composition of our income and valuation of our assets, including goodwill, we may be a PFIC for the taxable year ending December 31, 2020. The determination of whether we are a PFIC is a fact-intensive determination made on an annual basis and the applicable law is subject to varying interpretation. In particular, the characterization of our assets as active or passive may depend in part on our current and intended future business plans, which are subject to change. Our status as a PFIC will depend on the nature and composition of our income and the nature, composition and value of our assets (which may be determined based on the fair market value of each asset, with the value of goodwill and going concern value determined in large part by reference to the market value of our ADSs, which may be volatile). Therefore, declines in our market capitalization could adversely affect our PFIC status for any taxable year. Our status may also depend, in part, on how quickly we utilize our current cash balances and the cash proceeds from this offering in our business. Furthermore, prior to the commercialization of any of our product candidates, for any taxable year interest or other passive income may constitute 75% or more of our total gross income. Moreover, it is not entirely clear how the contractual arrangements between us, our VIE and its nominal shareholders will be treated for purposes of the PFIC rules, and we may be or become a PFIC if our VIE is not treated as owned by us for these purposes. Even if we determine that we are not a PFIC for a taxable year, there can be no assurance that the Internal Revenue Service, or IRS, will agree with our conclusion and that the IRS would not successfully challenge our position. Accordingly, our U.S. counsel expresses no opinion with respect to our PFIC status for our taxable year ending December 31, 2019, and also expresses no opinion with regard to our expectations regarding our PFIC status for the current taxable year or any future taxable year.

The tax consequences that would apply if we are classified as a PFIC will be different from those described above if a U.S. shareholder were able to make a valid qualified electing fund, or QEF, election. At this time, we do not expect to provide U.S. holders with the information necessary for a U.S. shareholder to make a QEF election. Prospective investors should assume that a QEF election will not be available.

Tax authorities may disagree with our positions and conclusions regarding certain tax positions, resulting in unanticipated costs, taxes or non-realization of expected benefits.

A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, the IRS or another tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies, including amounts paid with respect to our intellectual property development.

Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a “permanent establishment” under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. A tax authority may take the position that material income tax liabilities, interest and penalties are payable by us, in which case, we expect that we might contest such assessment. Contesting such an assessment may be lengthy and costly, and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable.

We will incur significantly increased costs as a result of operating as a company whose ADSs are publicly traded in the United States, and our management will be required to devote substantial time to new compliance initiatives.

As a public company in the United States, we will incur significant legal, accounting and other expenses that we did not incur previously. These expenses will likely be even more significant after we no longer qualify as an emerging growth company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies in the United States, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our senior management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors.

However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404, we will be required to furnish a report by our senior management on our internal controls over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal controls over financial reporting issued by our independent registered public accounting firm. To prepare for eventual compliance with Section 404, we will be engaged in a process to document and evaluate our internal controls over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal controls over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal controls over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed time frame or at all, that our internal controls over financial reporting is effective as required by Section 404.

We are an “emerging growth company” and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our ADSs may be less attractive to investors.

We are an “emerging growth company” as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. As an emerging growth company, we are required to report only two years of financial results and selected financial data compared to three and five years, respectively, for comparable data

reported by other public companies. We may take advantage of these exemptions until we are no longer an emerging growth company. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if the aggregate market value of our ordinary shares, including ordinary shares represented by ADSs, held by non-affiliates exceeds US\$700 million as of the end of our second fiscal quarter before that time, in which case we would no longer be an emerging growth company as of the following December 31st (the last day of our fiscal year). We cannot predict if investors will find our ADSs less attractive because we may rely on these exemptions. If some investors find our ADSs less attractive as a result, there may be a less active trading market for our ADSs and the price of our ADSs may be more volatile.

We qualify as a foreign private issuer and, as a result, we will not be subject to U.S. proxy rules and will be subject to Exchange Act reporting obligations that permit less detailed and frequent reporting than that of a U.S. domestic public company.

Upon the closing of this offering, we will report under the Exchange Act as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act; (ii) 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 (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K upon the occurrence of specified significant events. In addition, foreign private issuers are not required to file their annual report on Form 20-F until 120 days after the end of each fiscal year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year.

Foreign private issuers also are exempt from Regulation FD, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

If we lose our status as a foreign private issuer, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and Nasdaq rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time-consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors.

As an exempted company incorporated in Cayman Islands, we are permitted to adopt certain home country practices in relation to corporate governance matters that differ significantly from the Nasdaq corporate governance listing standards. These practices may afford less protection to shareholders than they would enjoy if we complied fully with Nasdaq corporate governance listing standards.

We are entitled to rely on a provision in Nasdaq's corporate governance rules that allows us to follow Cayman Island's corporate law with regard to certain corporate governance matters. This allows us to follow certain corporate governance practices that differ in significant respects from the corporate governance

requirements applicable to U.S. companies listed on the Nasdaq. The corporate governance practice in our home country, the Cayman Islands, does not require a majority of our board to consist of independent directors or the implementation of a nominating and corporate governance committee. Since a majority of our board of directors will not consist of independent directors as long as we rely on the foreign private issuer exemption, fewer board members will be exercising independent judgment and the level of board oversight on the management of our company may decrease as a result.

Since shareholder rights under Cayman Islands law differ from those under U.S. law, you may have difficulty protecting your shareholder rights.

We are an exempted company limited by shares incorporated under the laws of the Cayman Islands. Our corporate affairs are governed by our memorandum and articles of association, the Companies Law (as amended) of the Cayman Islands 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 responsibilities of our directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from 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 responsibilities 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, other than the memorandum and articles of association and any special resolutions passed by such companies, and the registers of mortgages and charges of such companies. The Registrar of Companies of the Cayman Islands shall make available the list of the names of the current directors of the Company (and where applicable the current alternate directors of the Company) for inspection by any person upon payment of a fee by such person. Our directors have discretion under our post-offering memorandum and articles of association 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.

Certain corporate governance practices in the Cayman Islands, which is our home country, differ significantly from requirements for companies incorporated in other jurisdictions such as the United States. Currently, we do not plan to rely on home country practice with respect to any corporate governance matter. However, if we choose to follow home country practice in the future, our shareholders may be afforded less protection than they otherwise would under rules and regulations applicable to U.S. domestic issuers.

As a result of all of the above, public shareholders may have more difficulty in protecting their interests in the face of actions taken by our management, members of our board of directors or our 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 (as amended) of the Cayman Islands and the laws applicable to companies incorporated in the United States and their shareholders, see “Description of Share Capital—Differences in Corporate Law.”

Provisions in our amended and restated memorandum and articles of association to be effective in connection with the closing of this offering may prevent or frustrate attempts by our shareholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our ADSs may be lower as a result.

There are provisions in our amended and restated memorandum and articles of association to be effective in connection with the closing of this offering that may make it difficult for a third-party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by you and other shareholders. For example, our board of directors will have the authority to issue up to 1,000,000 shares of an additional class or classes of shares, which could include preference shares. The board of directors can fix the price, rights, preferences, privileges, and restrictions of the other classes of shares without any further vote or action by our shareholders. The issuance of such shares may delay or prevent a change of control transaction. As a result, the market price of our ADSs and the voting and other rights of our shareholders may be adversely affected. An issuance of other classes of shares may result in the loss of voting control to other shareholders.

Our charter documents will also contain other provisions that could have an anti-takeover effect, including:

- only one of our three classes of directors will be elected each year;
- shareholders will be entitled to remove directors only for cause;
- shareholders will not be permitted to take actions by written consent;
- shareholders must give advance notice to nominate directors or submit proposals for consideration at annual general meetings.

These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our ADSs.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, the price and trading volume of our ADSs could decline.

The trading market for our ADSs will be influenced by the research and reports that equity research analysts publish about us and our business. We do not currently have and may never obtain research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our ADSs after the completion of this offering, and such lack of research coverage may adversely affect the market price of our ADSs. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our ADSs could decline if one or more equity research analysts downgrade our ADSs or issue other unfavorable commentary or research about us. If one or more equity research analysts cease coverage of us or fail to publish reports on us regularly, demand for our ADSs could decrease, which in turn could cause the trading price or trading volume of our ADSs to decline.

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

Your ADSs are transferable on the books of the depository. However, the depository may close its transfer books at any time or from time to time when deemed necessary or advisable by it in good faith in connection with the performance of its duties or at our reasonable written request, subject in all cases to compliance with applicable U.S. securities laws. In addition, the depository may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depository are closed, or at any time if we or the depository 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.

We may be subject to securities litigation, which is expensive and could divert management's attention.

The market price of our ADSs may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

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 ability of our investigator-initiated trials and clinical trials to demonstrate acceptable safety and efficacy of our product candidates, and other positive results;
- the timing, progress and results of preclinical studies, investigator-initiated trials and clinical trials for product candidates we may develop, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
- the timing, scope and likelihood of regulatory filings and approvals, including final regulatory approval of our product candidates;
- our ability to develop and advance our current product candidates and programs into, and successfully complete, clinical trials;
- our manufacturing, commercialization, and marketing capabilities and strategy;
- our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and sales strategy;
- the need to hire additional personnel and our ability to attract and retain such personnel;
- the size of the market opportunity for our product candidates, including our estimates of the number of patients who suffer from the diseases we are targeting;
- our expectations regarding the approval and use of our product candidates as first, second or subsequent lines of therapy or in combination with other drugs;
- our ability to implement measures to address the material weakness that has been identified;
- our competitive position and the success of competing therapies that are or may become available;
- our estimates of the number of patients that we will enroll in our clinical trials;
- the beneficial characteristics, safety, efficacy and therapeutic effects of our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our plans relating to the further development of our product candidates, including additional indications we may pursue;
- our intellectual property position, including our ability to obtain, maintain, expand, protect and enforce our intellectual property rights covering product candidates we may develop, including the extensions of existing patent terms where available, the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- our continued reliance on third parties to conduct additional clinical trials of our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials;

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- our ability to obtain, and negotiate favorable terms of, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- the pricing and reimbursement of our product candidates we may develop, if approved;
- the rate and degree of market acceptance and clinical utility of our product candidates we may develop;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements;
- the impact of laws and regulations;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act; and
- our anticipated use of our existing resources and the proceeds from this offering.

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,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Business,” 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.

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.

MARKET, INDUSTRY AND OTHER DATA

This prospectus contains estimates, projections and other information concerning our industry, our business and the markets for our product candidates, including data regarding the estimated size of such markets and the incidence of certain medical conditions. We obtained the industry, market and similar data set forth in this prospectus from our internal estimates and research and from academic and industry research, publications, surveys and studies conducted by third parties, including governmental agencies. In some cases, we do not expressly refer to the sources from which this data is derived. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. While we believe that the data we use from third parties are reliable, we have not separately verified this data. Further, while we believe that our internal research is reliable, such research has not been verified by any third party. You are cautioned not to give undue weight to any such information, projections and estimates.

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 over-allotment option in full, after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us. These estimates are based upon an assumed initial public offering price of US\$ per ADS, which is the midpoint of the price range shown on the front page of this prospectus.

A US\$1.00 increase or decrease in the assumed initial public offering price of US\$ per ADS would increase or decrease, as applicable, the net proceeds to us from this offering by US\$ million, assuming the number of ADSs offered by us, as set forth on the front cover of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase or decrease of million in the number of ADSs we are offering would increase or decrease, as applicable, the net proceeds to us from this offering by US\$ million, assuming the assumed initial public offering price of US\$ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to obtain additional capital to support our operations, establish a public market for our ADSs and facilitate our future access to the public capital markets.

We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows:

- approximately US\$ million to US\$ million to fund the research and development of our lead FasTCAR-enabled product candidate, GC012F, for the treatment of r/r MM;
- approximately US\$ million to US\$ million to fund the research and development of our lead TruUCAR-enabled product candidate, GC027, for the treatment of r/r T-ALL;
- approximately US\$ million to US\$ million to fund the research and development of our other clinical-stage and earlier-stage product candidates;
- approximately US\$ million to US\$ million to fund the expansion of our manufacturing facilities in China and the construction of our research and development center in the United States;
- the remaining amounts for working capital and other general corporate purposes.

Based on our current operating plan, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our planned operating expenses and capital expenditures through at least the next 12 months. The net proceeds from this offering, together with our existing cash and cash equivalents, may be insufficient to fund any of our product candidates through regulatory approval, and we anticipate needing to raise additional capital to complete the development of and commercialize our product candidates. It is difficult to predict the cost and timing required to complete development and obtain regulatory approval of, and commercialize, our product candidates due to, among other factors, the relatively short history of our experience with initiating, conducting and completing clinical trials, obtaining regulatory approval and commercializing our product candidates, the rate of subject enrollment in our clinical trials, filing requirements with various regulatory agencies, clinical trial results and the actual costs of manufacturing and supplying our product candidates.

Our expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we

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will actually spend on the uses set forth above. We believe that opportunities may exist from time to time to expand our current business through licenses with or acquisitions of, or investments in, complementary businesses, products or technologies. While we have no current agreements, commitments or understandings for any specific in-licensing, acquisition or investments at this time, we may use a portion of the net proceeds for these purposes.

Our management will have broad discretion over the use of the net proceeds from this offering. The amounts and timing of our expenditures will depend upon numerous factors, including the results of our research and development efforts, the timing, cost and success of preclinical studies and any ongoing clinical trials or clinical trials we may commence in the future, the timing of regulatory submissions, our ability to obtain additional financing, the amount of cash obtained through our existing collaborations and future collaborations, if any, and any unforeseen cash needs.

Pending any use described above, we intend to invest the net proceeds of this offering in short- and intermediate-term interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

DIVIDEND POLICY

Our board of directors has discretion on whether to distribute dividends, subject to the amended and restated memorandum and articles of association of our company and 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 board of directors. In either case, all dividends are subject to certain restrictions under Cayman Islands law, namely that our company may only pay dividends out of profits or the credit standing in our company's share premium account, and provided always that in no circumstances may a dividend be paid if this would result in our company being unable to pay its debts as they fall due in the ordinary course of business immediately following the date on which the distribution or dividend is paid. Even if we decide to pay dividends, 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 the 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—Other PRC National- and Provincial-Level Laws and Regulations—Regulations Relating to Dividend Distributions."

If we pay any dividends on our ordinary shares, we will pay those dividends, which are payable in respect of the ordinary shares underlying the 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, 2019:

- 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 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 upon the completion of this offering and (ii) the sale of ordinary shares in the form of 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 front cover of this prospectus, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, assuming the underwriters do not exercise the over-allotment option.

The pro forma as adjusted information set forth below is illustrative only and will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this information in conjunction with our financial statements and the related notes appearing elsewhere in this prospectus, as well as the sections of this prospectus titled “Selected Consolidated Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

Summary consolidated statement of financial position data:

	As of December 31,					
	2018	2019				
	Actual RMB	Actual RMB	US\$ (in thousands)	Pro Forma(1) RMB	US\$	Pro Forma As Adjusted(1)(2) RMB US\$
Convertible loans	138,695	138,695	20,428	138,695	20,428	
Mezzanine equity:						
Series A convertible redeemable preferred shares (US\$ 0.0001 par value; 36,567,163 and 31,343,282 shares authorized, issued and outstanding as of December 31, 2018 and 2019, respectively)	83,404	82,334	12,126	—	—	
Series B-2 convertible redeemable preferred shares (US\$ 0.0001 par value; Nil and 59,327,653 shares authorized, issued and outstanding as of December 31, 2018 and 2019, respectively)	—	465,509	68,562	—	—	
Total mezzanine equity	83,404	547,843	80,688	—	—	
Shareholders’ deficit	(81,021)	(292,487)	(43,078)	255,356	37,610	
Ordinary shares (par value of US\$0.0001 per share; 500,000,000 and 500,000,000 shares authorized; 100,089,552 and 99,044,776 shares issued and outstanding as of December 31, 2018 and 2019, respectively; 189,715,711 shares issued and outstanding on a pro forma basis as of December 31, 2019)	69	68	10	77	11	
Accumulated other comprehensive loss	—	(3,159)	(465)	(544,675)	(80,222)	
Accumulated deficit	(81,090)	(289,396)	(42,623)	(289,396)	(42,623)	
Total shareholders’ deficit	(81,021)	(292,487)	(43,078)	255,356	37,610	
Total mezzanine equity and shareholders’ equity	2,383	255,356	37,610	255,356	37,610	
Total capitalization	141,078	394,051	58,038	394,051	58,038	

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- (1) The unaudited pro forma and pro forma as adjusted information does not include the impact of share-based compensation expense for share options which we expect to record upon the completion of this offering.
- (2) The pro forma as adjusted information discussed above is illustrative only. Our additional paid-in capital and total shareholders' (deficit)/ equity following the completion of this offering are subject to adjustment based on the actual initial public offering price and other terms of this offering determined at pricing. Assuming the number of ADSs offered by us as set forth on the cover page of this prospectus remains the same, and after deduction of underwriting discounts and commissions and the estimated offering expenses payable by us, a US\$1.00 change in the assumed initial public offering price of US\$ per ADS would, in the case of an increase, increase and, in the case of a decrease, decrease each of additional paid-in capital and total shareholders' (deficit)/ equity by US\$ million.

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 and holders of our preferred shares which will automatically convert into our ordinary shares upon the completion of this offering.

Our historical net tangible book value as of December 31, 2019, was approximately US\$ per ordinary share, equivalent to US\$ per ADS. Each ADS represents ordinary shares. Historical net tangible book value per ordinary share represents the amount of total tangible assets, minus the amount of total liabilities and mezzanine equity, divided by the total number of ordinary shares outstanding. Pro forma net tangible book value per ordinary share is calculated after giving effect to the automatic conversion of all of our outstanding preferred shares on a one-for-one basis into ordinary shares immediately prior to the completion of this offering. Dilution is determined by subtracting pro forma net tangible book value per ordinary share from the assumed public offering price per ordinary share. If the underwriters exercise their over-allotment option in full, the pro forma as adjusted net tangible book value immediately upon the completion of this offering would be US\$ per ordinary share and US\$ per ADS, and the dilution in pro forma as adjusted net tangible book value to new investors in this offering would be US\$ per ordinary share and US\$ per ADS.

Without taking into account any other changes in such net tangible book value after December 31, 2019, other than to give effect to our issuance and sale of ADSs in this offering at an assumed initial public offering price of US\$ per ADS, the midpoint of the estimated public offering price range, and after deduction of underwriting discounts and commissions and estimated offering expenses payable by us (assuming the over-allotment option is not exercised), our pro forma as adjusted net tangible book value as of December 31, 2019 would have been US\$ per outstanding ordinary share, including ordinary shares underlying our outstanding ADSs, or US\$ per ADS. This represents an immediate increase in net tangible book value of US\$ per ordinary share, or US\$ per ADS, to existing shareholders and an immediate dilution in net tangible book value of US\$ per ordinary share, or US\$ per ADS, to purchasers of ADSs in this offering. The following table illustrates such dilution:

Assumed initial public offering price per ADS	US\$
Historical net tangible book value per ADS as of December 31, 2019	US\$
Increase per ADS attributable to the issuance and sale of preferred shares and conversion of such shares into ordinary shares	US\$
Pro forma net tangible book value per ADS as of December 31, 2019	US\$
Pro forma increase in net tangible book value per ADS as adjusted to investors participating in this offering, as of December 31, 2019	US\$
Pro forma as adjusted net tangible book value per ADS following this offering	US\$
Amount of dilution in net tangible book value per ADS to investors participating in this offering	US\$

A US\$1.00 change in the assumed public offering price of US\$ per ADS would, in the case of an increase, increase and, in the case of a decrease, decrease our pro forma as adjusted net tangible book value after giving effect to the offering by US\$ million, 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

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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 estimated offering expenses. The pro forma 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 following table summarizes, on a pro forma as adjusted basis as of December 31, 2019, the differences between our shareholders as of December 31, 2019 and the new investors with respect to the number of ordinary shares purchased from us, the total consideration paid and the average price per ordinary share paid at an assumed initial public offering price of US\$ per ADS before deducting estimated underwriting discounts and commissions and estimated offering expenses.

	Ordinary Shares Purchased		Total Consideration		Average Price Per Ordinary Share	Average Price Per ADS
	Number	Percent	Amount	Percent		
Existing shareholders						
New investors						
Total				100%		

A US\$1.00 change in the assumed public offering price of US\$ per ADS would, in the case of an increase, increase and, in the case of a decrease, decrease total consideration paid by new investors, total consideration paid by all shareholders, average price per ordinary share and average price per ADS paid by all shareholders by US\$, US\$, US\$ and US\$, respectively, 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 estimated offering expenses payable by us.

The discussion and tables above also assume no exercise of any outstanding stock options outstanding as of the date of this prospectus. As of the date of this prospectus, there were ordinary shares issuable upon exercise of outstanding stock options at a weighted average exercise price of US\$ per ordinary share, and there were ordinary shares available for future issuance upon exercise of future grants under our employee stock option plan. 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 to take advantage of certain benefits associated with being a Cayman Islands exempted company, such as:

- political and economic stability;
- an effective judicial system;
- tax neutrality;
- the absence of exchange control or currency restrictions; and
- the availability of professional and support services.

However, certain disadvantages accompany incorporation in the Cayman Islands. These disadvantages include but are not limited to:

- the Cayman Islands has a less developed body of securities laws as compared to the United States and these securities laws provide significantly less protection to investors as compared to those of the United States; and
- Cayman Islands companies may not have standing to sue before the federal courts of the United States.

Our constituent documents do not contain provisions requiring that disputes, including those arising under the securities laws of the United States, between us, our officers, directors and shareholders, be arbitrated.

Certain of our directors are nationals or residents of jurisdictions other than the United States and most of their assets are located outside the United States. As a result, it may be difficult for a shareholder to effect service of process within the United States upon these individuals, or to bring an action against us or these individuals in the United States, or to enforce against us or them judgments obtained in United States courts, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any state in the United States.

Harney Westwood & Riegels, our counsel as to Cayman Islands law, has advised us that there is uncertainty as to whether the courts of the Cayman Islands would (i) 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 (ii) 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.

Harney Westwood & Riegels has informed us that although there is no statutory enforcement in the Cayman Islands of judgments obtained in the federal or state courts of the United States (and the Cayman Islands are not a party to any treaties for the reciprocal enforcement or recognition of such judgments), the courts of the Cayman Islands would recognize as a valid judgement, a final and conclusive judgement in personam obtained in federal or state courts in 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, a fine or a penalty or similar fiscal or revenue obligations) 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 the natural justice of 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.

AllBright Law Offices, our counsel as to PRC law, has advised us that there is uncertainty as to whether the courts of the PRC would (i) 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, and (ii) entertain original actions brought in the PRC 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.

AllBright Law Offices has advised us that the recognition and enforcement of foreign judgments are provided for under the PRC Civil Procedure Law. PRC courts may recognize and enforce foreign judgments in accordance with the requirements of the PRC Civil Procedure Law. AllBright Law Offices has advised us further that under PRC law, a foreign judgment that does not otherwise violate basic legal principles, state sovereignty, safety or social public interest may be recognized and enforced by a PRC court, based either on bilateral treaties or international conventions contracted by China and the country where the judgment is made or on reciprocity between jurisdictions. As there currently exists no bilateral treaty, international convention or other form of reciprocity between China and the United States governing the recognition of judgments, including those predicated upon the liability provisions of the U.S. federal securities laws, it would be highly unlikely that a PRC court would enforce judgments rendered by U.S. courts.

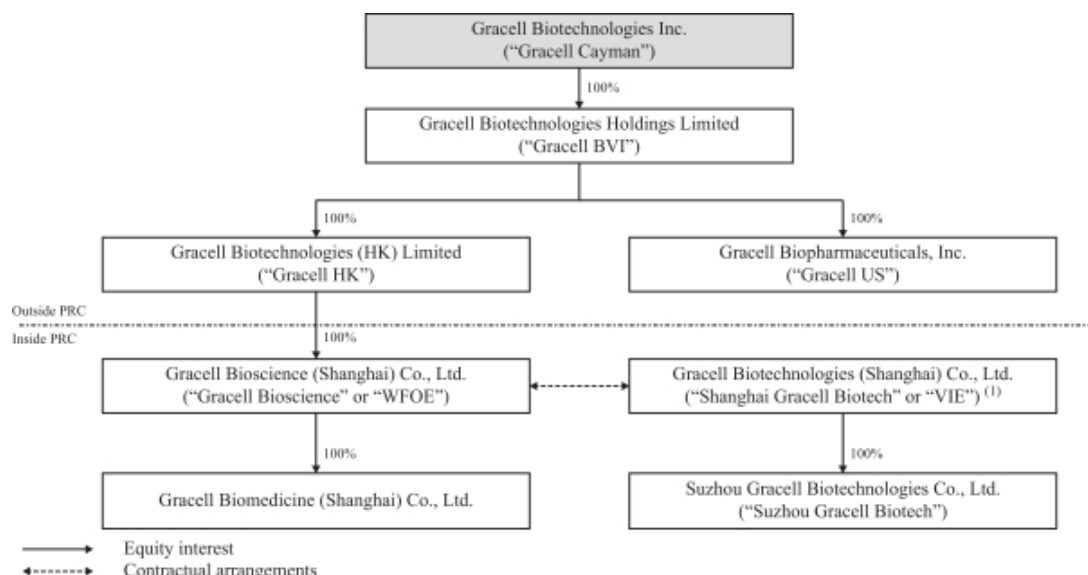
CORPORATE HISTORY AND STRUCTURE

We commenced operations in May 2017 through Gracell Biotechnologies (Shanghai) Co., Ltd., a company incorporated in China, which we refer to as Shanghai Gracell Biotech in this prospectus. In April 2018, Shanghai Gracell Biotech incorporated Suzhou Gracell Biotechnologies Co., Ltd., a company incorporated in China, which we refer to as Suzhou Gracell Biotech in this prospectus. Currently, we conduct research and development activities in biotechnologies and pharmaceutical industries primarily through Suzhou Gracell Biotech and Shanghai Gracell Biotech.

In May 2018, we incorporated Gracell Biotechnologies Inc., or Gracell Cayman, under the laws of the Cayman Islands as our offshore holding company. Shortly after its incorporation, Gracell Cayman established a wholly owned subsidiary, Gracell Biotechnologies Holdings Limited, or Gracell BVI, under the laws of the British Virgin Islands in May 2018. Gracell BVI in turn established its wholly owned subsidiaries Gracell Biotechnologies (HK) Limited, or Gracell HK, and Gracell Biopharmaceuticals, Inc., or Gracell US, in June 2018 and February 2020, respectively. In August 2018, Gracell Bioscience (Shanghai) Co., Ltd., which we refer to as Gracell Bioscience or our WFOE in this prospectus, was incorporated as a PRC subsidiary wholly owned by Gracell HK. Our WFOE incorporated its wholly owned PRC subsidiary Gracell Biomedicine (Shanghai) Co., Ltd. in August 2020.

Due to restrictions imposed by PRC laws and regulations on foreign ownership of companies engaged in the development and application of human stem cell or gene diagnostic and therapeutic technologies and other related businesses, our WFOE entered into a series of contractual arrangements, as amended and restated, with Shanghai Gracell Biotech and its shareholders, through which we obtained control over Shanghai Gracell Biotech and its subsidiary. As a result, we are regarded as the primary beneficiary of Shanghai Gracell Biotech and its subsidiary. We treat Shanghai Gracell Biotech and its subsidiary as our consolidated affiliated entities under U.S. GAAP and have consolidated the financial results of these entities in our consolidated financial statements in accordance with U.S. GAAP. We also refer Shanghai Gracell Biotech as our VIE in this prospectus. For more details and risks related to our variable interest entity structure, please see “—Contractual Agreements with our VIE and its Shareholders” and “Risk Factors—Risks Related to Our Corporate Structure.”

The following diagram illustrates our corporate structure as a result of our reorganization mentioned above and as of the date of this prospectus, including our significant subsidiaries and other entities that are material to our business:



- (1) Shareholders of Shanghai Gracell Biotech are Dr. William Wei Cao, Suzhou Lirui Equity Investment Center (Limited Partnership) (苏州礼瑞股权投资中心(有限合伙)), Suzhou Private Capital Investment (苏州民营资本投资控股有限公司) and Chengdu Miaoji Medical Technology Co., Ltd. (成都妙济医疗技术有限公司), holding 87.0%, 4.5%, 4.5% and 4.0%, respectively, of the equity interest in the VIE. Dr. Cao is our Founder, Chairman of board of directors and Chief Executive Officer. Suzhou Lirui Equity Investment Center (Limited Partnership), Suzhou Private Capital Investment and Chengdu Miaoji Medical Technology Co., Ltd. are our shareholders.

Contractual Agreements with Our VIE and Its Shareholders

The following is a summary of the currently effective contractual arrangements by and among our WFOE, our VIE and its shareholders. These contractual arrangements enable us to (i) exercise effective control over our VIE and its subsidiary; (ii) receive substantially all of the economic benefits of our VIE and its subsidiary; and (iii) have an exclusive option to purchase all or part of the equity interests in and assets of our VIE and its subsidiary when and to the extent permitted by PRC law.

Agreements That Provide Us Effective Control over Our VIE

Voting Rights Proxy Agreement and Power of Attorney. On January 3, 2019, each shareholder of our VIE entered into a voting rights proxy agreement with our WFOE and our VIE and executed a power of attorney to irrevocably authorize our WFOE to act as his or its attorney-in-fact to exercise all of his or its rights as a shareholder of our VIE, including, but not limited to, the right to (i) propose to hold and attend shareholders' meetings, (ii) vote on any resolution that requires a shareholder vote pursuant to the applicable laws and article of association of our VIE, such as designation and appointment of directors, the chief executive officer and other senior management members of our VIE, and (iii) exercise other shareholder's rights, such as the sale or transfer of all or part of the equity interests owned by such shareholder. The voting rights proxy agreement will remain effective for 20 years. Prior to the expiration of the term, our WFOE may extend the term through written notification at its sole discretion. On December 20, 2019, Dr. William Wei Cao entered into an amended voting rights proxy agreement and power of attorney with our WFOE and our VIE, which contain terms substantially similar to the voting rights proxy agreement and power of attorney described above.

Equity Pledge Agreements. On January 3, 2019, each shareholder of our VIE entered into an equity pledge agreement with our WFOE and our VIE, pursuant to which such shareholder pledges all of his or its equity interest in our VIE to our WFOE to guarantee the performance by such shareholder and our VIE of their obligations under the contractual arrangements, including the technical consultation and service agreement, the business cooperation agreement, the call option agreement, the voting rights proxy agreement and the power of attorney. In the event of a breach by any of our VIE's shareholders of their contractual obligations under these agreements, our WFOE, as pledgee, will have the right to dispose of the pledged equity interests in our VIE. Each shareholder of our VIE agrees that, during the term of the equity pledge agreement, he or it will not dispose of the pledged equity interests or create or allow any encumbrance on the pledged equity interests without the prior written consent of our WFOE, except for the performance of the call option agreement. The equity pledge agreements will remain effective until our VIE and its shareholders discharge all of their obligations under the contractual arrangements. On March 6, 2020, Dr. William Wei Cao entered into an amended equity pledge agreement with our WFOE and our VIE, which contains terms substantially similar to the equity pledge agreement described above. Currently, none of our equity pledge is registered with the local branches of the Administration for Market Regulation in accordance with the PRC Property Rights Law. For more information on the risks related to failing to register the equity pledge, see "Risk Factors – We rely on contractual arrangements with our VIE to use, or otherwise benefit from, the foreign restricted licenses and permits, which may not be as effective as direct ownership in providing operational control."

Spouse Consent Letter. On January 3, 2019, the spouse of Dr. William Wei Cao, a shareholder of our VIE, unconditionally and irrevocably agreed that the equity interest in our VIE held by Dr. Cao will be disposed of pursuant to the equity pledge agreement, the voting rights proxy agreement and the call option agreement. The spouse agreed not to make any assertions in connection with the equity interest in our VIE held by Dr. Cao.

Agreements That Allow Us to Receive Economic Benefits from Our VIE

Technical Consultation and Service Agreement. Pursuant to the technical consultation and service agreement between our WFOE and our VIE, dated January 3, 2019, our WFOE has the exclusive right to provide to our VIE consultation and services related to, among other things, training and technical support, marketing, management and operation. Without our WFOE's written consent, our VIE shall not accept any consultation or services covered by this agreement from any third party. Our WFOE has the sole and exclusive ownership of intellectual property rights created as a result of the performance of this agreement. Our VIE agrees to pay our WFOE an annual service fee at an amount agreed by our WFOE. This agreement will remain effective for a 20-year term and then can be renewed at our WFOE's sole discretion.

Business Cooperation Agreement. Pursuant to the business cooperation agreement between our WFOE and our VIE, dated January 3, 2019, our WFOE has the exclusive right to provide to our VIE technical support, business support and related consulting services. Our WFOE has exclusive right and interests in all intellectual properties arising out of or created during the performance of this agreement. Our VIE agrees to pay our WFOE a monthly service fee at an amount agreed by our WFOE. Our VIE has no right of early termination while our WFOE may terminate this agreement upon a 30-day prior written notice at any time.

Agreements That Provide Us the Option to Purchase the Equity Interests in Our VIE

Call Option Agreement. Our WFOE, our VIE and each shareholder of our VIE entered into a call option agreement on January 3, 2019, pursuant to which each shareholder of our VIE irrevocably grants our WFOE an exclusive option to purchase, or have its designated person or persons to purchase, at its discretion, to the extent permitted by PRC law, all or part of such shareholder's equity interests in our VIE, and such option may be exercised at the lowest price permitted by applicable PRC law. Any proceeds received by the shareholder of our VIE from the exercise of the option shall be remitted to our WFOE or its designated party, to the extent permitted by applicable PRC law. Each of the shareholders of our VIE undertakes that without our WFOE's prior written consent, he shall not take any actions that may have material effects on our VIE's assets, businesses and liabilities, nor shall they appoint or replace any directors of our VIE. On December 20, 2019, Dr. William Wei Cao entered into an amended call option agreement with our WFOE and our VIE, which contains terms substantially similar to the call option agreement described above.

In the opinion of AllBright Law Offices, our PRC legal counsel:

- the ownership structures of our VIE and our WFOE, both currently and immediately after giving effect to this offering, do not and will not result in any violation of PRC laws or regulations currently in effect; and
- the contractual arrangements among our WFOE, our VIE and the shareholders of our VIE governed by PRC law both currently and immediately after giving effect to this offering are valid, binding and enforceable, and will not result in any violation of PRC laws or regulations currently in effect.

However, we have been further advised by our PRC legal counsel that there are substantial uncertainties regarding the interpretation and application of current and future PRC laws, regulations and rules, and there can be of no assurance that the PRC government will ultimately take a view that is consistent with the above opinions of our PRC legal counsel. It is also uncertain whether any new PRC laws or regulations relating to the VIE structures will be adopted or if adopted, what they would provide. If we or the VIE is found to be in violation of any existing or future PRC laws or regulations, or fail to obtain or maintain any of the required permits or approvals, the relevant PRC regulatory authorities would have broad discretion to take action in dealing with such violations or failures. See "Risk Factors—Risks Related to Our Corporate Structure—The uncertainties in the PRC legal system may subject our contractual arrangements to different interpretations or enforcement challenges, or subject us to severe penalties or force us to relinquish our interests in our operations" and "Risk Factors—Risks Related to Our Corporate Structure—Uncertainties exist with respect to the interpretation and implementation of the newly enacted Foreign Investment Law and how it may impact the viability of our current structure, our business, financial condition and results of operations."

SELECTED CONSOLIDATED FINANCIAL DATA

The following tables present our selected consolidated financial data as of the dates and for the periods indicated. We have derived the consolidated statement of profit or loss data for the years ended December 31, 2018 and 2019 and the consolidated statement of financial position data as of December 31, 2018 and 2019 from our audited consolidated financial statements appearing in this prospectus.

Our historical results are not necessarily indicative of results expected for future periods. You should read this 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.

The following table presents our selected consolidated statement of comprehensive loss data for the years ended December 31, 2018 and 2019:

	For the Year Ended December 31,		
	2018 RMB	2019 RMB	US\$
(in thousands, except per share data)			
Selected consolidated statement of comprehensive loss:			
Expenses			
Research and development expenses	(52,243)	(119,218)	(17,559)
Administrative expenses	(10,261)	(27,362)	(4,030)
Loss from operations	(62,504)	(146,580)	(21,589)
Interest income	1,435	3,932	579
Other income	256	1,449	213
Foreign exchange gain, net	—	2,556	376
Others, net	20	(21)	(3)
Loss before income tax	(60,793)	(138,664)	(20,424)
Income tax expense	—	—	—
Net loss	(60,793)	(138,664)	(20,424)
Deemed dividend to convertible redeemable preferred shareholders	—	(25,390)	(3,740)
Accretion of convertible redeemable preferred shares to redemption value	(12,199)	(36,802)	(5,420)
Net loss attributable to Gracell Biotechnologies Inc.’s ordinary shareholders	(72,992)	(200,856)	(29,584)
Other comprehensive income			
Foreign currency translation adjustments, net of nil tax	—	(3,159)	(465)
Total comprehensive loss attributable to Gracell Biotechnologies Inc.’s ordinary shareholders	(72,992)	(204,015)	(30,049)
Weighted average number of ordinary shares used in per share calculation			
Basic	100,089,552	99,053,363	99,053,363
Diluted	100,089,552	99,053,363	99,053,363
Net loss per share attributable to Gracell Biotechnologies Inc.’s ordinary shareholders			
Basic	(0.73)	(2.03)	(0.30)
Diluted	(0.73)	(2.03)	(0.30)

The following table presents our selected consolidated statement of financial position as of December 31, 2018 and 2019:

	As of December 31,		
	2018	2019	
	Actual	Actual	
	RMB	RMB	US\$
	(in thousands)		
Selected consolidated statement of financial position data:			
Cash and cash equivalents	11,890	312,058	45,961
Short-term investments	102,000	4,200	619
Property, equipment and software	16,285	48,323	7,117
Total assets	148,518	412,217	60,713
Total liabilities	146,135	156,861	23,103
Total mezzanine equity	83,404	547,843	80,688
Total shareholders' deficit	(81,021)	(292,487)	(43,078)
Ordinary shares (par value of US\$0.0001 per share; 500,000,000 and 500,000,000 shares authorized; 100,089,552 and 99,044,776 shares issued and outstanding as of December 31, 2018 and 2019, respectively)	69	68	10
Total liabilities, mezzanine equity and shareholders' deficit	148,518	412,217	60,713

The following table presents our selected consolidated statement of cash flows for the years ended December 31, 2018 and 2019:

	For the Year Ended December 31,		
	2018	2019	
	RMB	RMB	US\$
	(in thousands, except per share data)		
Selected consolidated statement of cash flows:			
Net cash used in operating activities	(61,856)	(135,393)	(19,940)
Net cash (used in) generated from investing activities	(113,357)	41,368	6,093
Net cash generated from financing activities	138,695	394,796	58,148
Effect of exchange rate on cash and cash equivalents	—	(603)	(89)
Net (decrease) increase cash and cash equivalents	(36,518)	300,168	44,210
Cash and cash equivalents at the beginning of year	48,408	11,890	1,751
Cash and cash equivalents at the end of year	11,890	312,058	45,961

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 together with our consolidated financial statements and the related notes and other financial information included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" section of this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a global clinical-stage biopharmaceutical company dedicated to discovering and developing breakthrough cell therapies to address major industry challenges and fulfill unmet medical needs in the treatment of cancer. As a leading cell and gene therapy company, we aim to disrupt conventional approaches to CAR-T cell therapies with our proprietary technology platforms—FasTCAR and TruUCAR.

- With FasTCAR, we are able to deliver younger, less exhausted T cells for autologous cell therapies with greater potency and next-day manufacturing (22 to 36 hours) versus the industry norm of two to six weeks. Our lead FasTCAR-enabled autologous product candidate, GC012F, has demonstrated fast, deep and durable responses, including multiple stringent complete responses, or sCR, in relapsed or refractory multiple myeloma, or r/r MM, patients in an ongoing investigator-initiated Phase 1 trial in China.
- With TruUCAR, we are able to derive T cells from non-HLA-matched healthy donors to generate allogeneic CAR-T cell therapies that are readily available off-the-shelf at lower cost for a broad patient base, including those less suitable for autologous CAR-T cell therapies. Our lead TruUCAR-enabled allogeneic product candidate, GC027, has achieved multiple complete responses, or CR, in relapsed or refractory T cell acute lymphoblastic leukemia, or r/r T-ALL, patients with a manageable safety profile in an ongoing investigator-initiated Phase 1 trial in China.

In addition to our technology platforms, we utilize our proprietary genetic engineering techniques, Dual CAR and Enhanced CAR, to generate FasTCAR and TruUCAR product candidates with enhanced efficacy and safety. Leveraging our pioneering platforms, know-how and experience, we are developing a rich clinical-stage pipeline of multiple autologous and allogeneic product candidates that we believe will unlock the long-held promise of CAR-T cell therapies for a broad range of patients with advanced hematologic malignancies and solid tumors.

We commenced operations in May 2017. Since our inception, our operations have focused on organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio, developing and manufacturing our product candidates, conducting research and development activities, including preclinical studies and clinical trials, and providing general and administrative support for these operations. We do not have any product candidates approved for commercialization and have not generated any revenue from product sales.

We have funded our operations to date primarily through a combination of equity and debt financing. Through the date of this prospectus, we have received proceeds of RMB2.4 million from sale of ordinary shares, RMB648.0 million from sale of preferred shares, and RMB64.9 million from our term loan facility with commercial banks. As of December 31, 2019, we had RMB316.3 million (US\$46.6 million) in cash and cash equivalents and short-term investments, which does not include the proceeds from term loan facilities that were received in 2020.

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Since inception, we have incurred significant operating losses. Our net losses were RMB60.8 million and RMB138.7 million (US\$20.4 million) for the years ended December 31, 2018 and 2019, respectively. We expect to continue to incur net losses for the foreseeable future, and we expect that our research and development expenses, administrative expenses and capital expenditures will continue to increase substantially for the foreseeable future in connection with our ongoing activities, as we:

- continue our ongoing and planned research and development of our lead product candidates, GC012F for the treatment of relapsed or refractory multiple myeloma, or r/r MM, and GC027 for the treatment of relapsed or refractory T cell acute lymphoblastic leukemia, or r/r T-ALL;
- continue our ongoing and planned clinical activities for our other product candidates, including those we are developing for the treatment of B-cell acute lymphoblastic leukemia, or B-ALL, and B-cell non-Hodgkin's lymphoma, or B-NHL;
- continue our ongoing and planned research and development activities;
- seek to discover and develop additional product candidates and further expand our clinical product pipeline;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- continue to scale up manufacturing capacity with the aim of securing sufficient quantities to meet our capacity requirements for clinical trials and potential commercialization;
- establish sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain regulatory approval;
- develop, maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, quality control, manufacturing and administrative personnel;
- expand our operations globally; and
- incur additional legal, accounting, investor relations, insurance and other expenses associated with operating as a public company following the completion of this offering.

Based upon our current operating plan, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents as of December 31, 2019, will enable us to fund our operating expenses and capital expenditure requirements through at least the next 12 months from the date of this offering. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

We do not expect to generate any revenue from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years. As a result, until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic and otherwise. If we fail to raise additional funds or enter into such other arrangements when needed on favorable terms or at all, it could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies.

Impact of COVID-19

The global COVID-19 pandemic continues to rapidly evolve, and we have been monitoring the COVID-19 situation closely. To date, the impact of the COVID-19 on our business, operations and timelines and plans of our preclinical studies and clinical trials is immaterial. However, the ultimate impact of the COVID-19 pandemic is highly uncertain, and will depend on certain developments, including the duration and spread of the outbreak and its impact on our trial sites, GMP facilities, CROs and other third parties with whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. We are generally conducting business as usual, with necessary or advisable modifications to employee travel with the exception of our U.S. employees who are currently working remotely. We will continue to actively monitor the rapidly evolving situation related to COVID-19 and may take further actions that alter our operations, including those that may be required by government authorities, or that we determine are in the best interests of our employees and other third parties with whom we do business. At this point, the extent to which the COVID-19 pandemic may affect our business, operations and timelines and plans of our preclinical studies and clinical trials, including the resulting impact on our expenditures and capital needs, remains uncertain.

Significant Components of Our Results of Operations

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with our research activities and include:

- cost of personnel engaged in research and development activities, including salaries, benefits and share-based compensation expense, if any;
- costs of funding research performed by third parties including laboratory, contract research organization, and other investigator and vendor expenses related to the execution of preclinical and clinical trials;
- costs related to production of preclinical and clinical materials;
- facilities and other expenses, which include expenses for rent and maintenance of facilities, depreciation and amortization expense and other supplies;
- expenses related to regulatory activities, including filing fees paid to regulatory agencies; and
- fees for maintaining licenses under our third-party licensing agreements.

Research and development costs are expensed as incurred. Costs for certain activities, such as manufacturing and preclinical studies and clinical trials, are generally recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and investigators.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase over the next several years as our existing clinical programs progress and as we seek to initiate clinical trials of additional product candidates. We also expect to incur increased research and development expenses as we selectively identify and develop additional product candidates. However, it is difficult to determine with certainty the duration and completion costs of our current or future preclinical programs and clinical trials of our product candidates.

The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors that include, but are not limited to, the following:

- per patient trial costs;

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- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up;
- the efficacy and safety profile of the product candidates;
- the cost and timing of manufacturing of our product candidates;
- the number of trials required for regulatory approval;
- the receipt of regulatory approvals from applicable regulatory authorities;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities; and
- the extent to which we establish collaboration, licensing or similar arrangements and the performance of any related third parties.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate's commercial potential. Because our product candidates are still in clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of product candidates or whether, or when, we may achieve profitability.

Administrative Expenses

Administrative expenses consist primarily of personnel expenses, including salaries, benefits and share-based compensation expense, if any, for personnel in executive, finance, accounting, business development, legal and human resource functions. Administrative expenses also include corporate facility costs not otherwise included in research and development expenses, legal fees related to intellectual property and corporate matters and fees for accounting and consulting services. Administrative costs are expensed as incurred, and we accrue for services provided by third parties related to the above expenses by monitoring the status of services provided and adjusting our accruals as actual costs become known.

We expect our administrative expenses to increase in the foreseeable future to support our continued research and development activities, manufacturing activities, potential commercialization of our product candidates and operating as a public company. These increased costs are anticipated to be related to the hiring of additional personnel, developing commercial infrastructure, fees to outside consultants, lawyers and accountants, and costs associated with being a public company such as accounting, audit, legal, regulatory, compliance and director and officer insurance costs, as well as investor and public relations expenses.

Other Income

Other income primarily consists of government subsidies that we receive from local government in the PRC.

Results of Operations

Comparison of Years Ended December 31, 2018 and 2019

The following table summarizes our results of operations for the years ended December 31, 2018 and 2019:

	For the Year Ended December 31,			Year-Over-Year	
	2018	2019		Change	
	RMB	RMB	US\$	RMB	US\$
(in thousands)					
Consolidated Statement of Operations Data:					
Operating expenses:					
Research and development expenses	(52,243)	(119,218)	(17,559)	(66,975)	(9,864)
Administrative expenses	(10,261)	(27,362)	(4,030)	(17,101)	(2,519)
Loss from operation	(62,504)	(146,580)	(21,589)	(84,076)	(12,383)
Interest income	1,435	3,932	579	2,497	368
Other income	256	1,449	213	1,193	176
Foreign exchange gain, net	—	2,556	376	2,556	376
Others, net	20	(21)	(3)	(41)	(6)
Loss before income tax	(60,793)	(138,664)	(20,424)	(77,871)	(11,469)
Income tax expense	—	—	—	—	—
Net loss	(60,793)	(138,664)	(20,424)	(77,871)	(11,469)

Operating Expenses

Research and Development Expenses

Research and development expenses for the year ended December 31, 2019 were RMB119.2 million (US\$17.6 million), compared to RMB52.2 million for the year ended December 31, 2018. This increase of RMB67.0 million (US\$9.9 million) was primarily due to an increase of RMB40.3 million (US\$5.9 million) in costs related to preclinical studies and clinical trials, which mainly resulted from increased manufacturing costs along with the progression of our preclinical studies and clinical trials, an increase of RMB11.0 million (US\$1.6 million) in payroll and other personnel expenses, and an increase in RMB9.4 million (US\$1.4 million) in rental expenses related to our research and development activities incurred as two of our PRC operating entities, Shanghai Gracell Biotech and Suzhou Gracell Biotech, commenced operation in 2019.

Administrative Expenses

Administrative expenses for the year ended December 31, 2019 were RMB27.4 million (US\$4.0 million), compared to RMB10.3 million for the year ended December 31, 2018. This increase of RMB17.1 million (US\$2.5 million) was primarily due to an increase of RMB7.7 million (US\$1.1 million) in cost related to professional service fees, and an increase of RMB5.9 million (US\$0.9 million) in personnel expenses and labor outsourcing cost as a few of our subsidiaries commenced operation in 2019.

Interest Income, Other Income and Foreign Exchange Gain

Interest income for the year ended December 31, 2019 was RMB3.9 million (US\$0.6 million), compared to RMB1.4 million for the year ended December 31, 2018. This increase of RMB2.5 million (US\$0.3 million) was primarily attributable to proceeds from issuance of Series B-2 preferred shares. Other income for the year ended December 31, 2019 was RMB1.5 million (US\$0.2 million), compared to RMB0.3 million for the year ended December 31, 2018. This increase of RMB1.2 million (US\$0.2 million) was primarily due to an increase in subsidies we received from the PRC local government in 2019. Foreign exchange gain for the year ended December 31, 2019 was RMB2.6 million (US\$0.4 million), compared to nil for the year ended December 31,

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2018. This increase of RMB2.6 million (US\$0.4 million) was primarily attributable to increase in United States dollars received and favorable foreign exchange fluctuation during the year ended December 31, 2019.

Income Tax Expense

We incurred no income tax expense in the years ended December 31, 2018 and 2019.

Liquidity and Capital Resources

We do not currently have any approved products and have not generated any revenue from product sales. We have funded our operations to date primarily through a combination of equity and debt financing. Through the date of this prospectus, we have received proceeds of RMB2.4 million from sale of ordinary shares, RMB648.0 million from sale of preferred shares, and RMB64.9 million from our term loan facility with commercial banks. As of December 31, 2019, we had RMB316.3 million (US\$46.6 million) in cash and cash equivalents and short-term investments, which does not include the proceeds from term loan facilities that were received in 2020.

Cash Flows

The following table shows a summary of our cash flow:

	For the Year Ended December 31,		
	2018	2019	
	RMB	RMB	US\$
	(in thousands)		
Net cash used in operating activities	(61,856)	(135,393)	(19,940)
Net cash (used in)/ generated from investing activities	(113,357)	41,368	6,093
Net cash generated from financing activities	138,695	394,796	58,148
Net (decrease)/increase in cash and cash equivalents	(36,518)	300,168	44,210
Cash and cash equivalents at the beginning of the year	48,408	11,890	1,751
Cash and cash equivalents at the end of the year	11,890	312,058	45,961

Operating Activities

Net cash used in operating activities for the year ended December 31, 2019 was RMB135.4 million (US\$19.9 million), primarily attributable to a net loss of RMB138.7 million (US\$20.4 million) and an increase of RMB10.0 million (US\$1.5 million) in prepayments and other current assets, which were partially offset by an increase of RMB6.7 million (US\$1.0 million) in salary and welfare payables, RMB5.2 million (US\$0.8 million) in accrued external research and development activities related expenses and RMB5.1 million (US\$0.8 million) in depreciation and amortization.

Net cash used in operating activities for the year ended December 31, 2018 was RMB61.9 million, primarily attributable to a net loss of RMB60.8 million and an increase of RMB10.6 million in prepayments and other current assets, which were partially offset by an increase of RMB3.9 million in salary and welfare payables, RMB2.0 million in accrued external research and development activities related expenses and RMB3.0 million in depreciation and amortization.

Investing Activities

Net cash provided by investing activities for the year ended December 31, 2019 was RMB41.4 million (US\$6.1 million), attributable to RMB178.0 million (US\$26.2 million) in proceeds from the disposal of short-

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term investments, partially offset by an increase of RMB80.2 million (US\$11.8 million) in short-term investments and RMB56.4 million (US\$8.3 million) in purchase of property and equipment.

Net cash used in investing activities for the year ended December 31, 2018 was RMB113.4 million, attributable to an increase of RMB335.0 million in short-term investments and RMB11.4 million in purchase of property and equipment, partially offset by RMB233.0 million in proceeds from the disposal of short-term investments.

Financing Activities

Net cash provided by financing activities in the year ended December 31, 2019 was RMB394.8 million (US\$58.1 million), attributable to RMB439.5 million (US\$64.7 million) in proceeds from issuance of Series B-2 convertible redeemable preferred shares, partially offset by the payment of RMB44.7 million (US\$6.6 million) in repurchasing Series A preferred shares.

Net cash provided by financing activities in the year ended December 31, 2018 was RMB138.7 million, attributable to the proceeds we received from issuance of Series B-1 convertible redeemable preferred shares.

Loan Agreements

Loan Agreement with Bank of China

On January 15, 2020, one of our PRC operating entities Suzhou Gracell Biotech entered into a loan agreement with Suzhou Industrial Park Branch of Bank of China, under which Suzhou Gracell Biotech may borrow an aggregate principal amount of RMB69.0 million in the form of a term loan with a term of 72 months commencing from the first drawdown date. Interest on the outstanding loan balance accrues at a variable annual rate equal to the five-year loan prime rate plus 0.2%. We are required to make interest payments on the loan on a quarterly basis and payments of principal according to the agreed repayment schedule which will commence from the end of the 42nd month after the first drawdown date. The loan agreement contains customary covenants that, among other things, require Suzhou Gracell Biotech to obtain written approval from Suzhou Industrial Park Branch of Bank of China for merger, consolidation or division, reducing registered capital, making investments, disposing of assets, increasing debt financing or other transactions that may adversely affect its ability to make payments under the loan. The loan agreement also contains customary events of default relating to, among other things, payment defaults or breaches of the terms of the loan, upon which the bank may declare all or a portion of our outstanding obligations payable to be immediately due and payable. As of September 30, 2020, RMB40.0 million was outstanding under the loan agreement.

Loan Agreements with China Construction Bank

On May 11, 2020, Suzhou Gracell Biotech entered into a loan agreement with Suzhou Industrial Park Sub-branch of China Construction Bank, under which Suzhou Gracell Biotech borrowed an aggregate principal amount of RMB5.0 million in the form of a term loan for 12 months. Interest on the outstanding loan balance accrues at a fixed annual rate equal to the one-year loan prime rate plus 0.5%. We are required to make interest payments on the loan on a monthly basis and repay principal at the end of the loan term. The loan agreement contains customary covenants that, among other things, require Suzhou Gracell Biotech to obtain written approval from Suzhou Industrial Park Sub-branch of China Construction Bank for merger, consolidation or division, reducing registered capital, making investments, disposing of assets, increasing debt financing or other transactions that may adversely affect its ability to make payments under the loan. The loan agreement also contains customary events of default relating to, among other things, payment defaults or breaches of the terms of the loan, upon which the bank may declare all or a portion of our outstanding obligations payable to be immediately due and payable.

On June 4, 2020, Suzhou Gracell Biotech entered into another loan agreement with Suzhou Industrial Park Sub-branch of China Construction Bank, under which Suzhou Gracell Biotech borrowed additional

RMB5.0 million for a term of 12 months at an interest rate equal to the one-year loan prime rate plus 0.15%. On July 16, 2020, Suzhou Gracell Biotech entered into the third loan agreement with Suzhou Industrial Park Sub-branch of China Construction Bank, under which Suzhou Gracell Biotech borrowed additional RMB5.0 million for a term of 12 months at an interest rate equal to the one-year loan prime rate minus 0.2%. On September 10, 2020, Suzhou Gracell Biotech entered into the fourth loan agreement with Suzhou Industrial Park Sub-branch of China Construction Bank, under which Suzhou Gracell Biotech borrowed additional RMB5.0 million for a term of 12 months at an interest rate equal to the one-year loan prime rate. Other than the interest rate, these loan agreements have substantially the same terms and conditions as the loan agreement signed on May 11, 2020.

As of September 30, 2020, RMB20.0 million was outstanding under the loan agreements with China Construction Bank.

Loan Agreement with China Merchants Bank

On July 24, 2020, Suzhou Gracell Biotech entered into a loan agreement with Suzhou Branch of China Merchants Bank, under which Suzhou Gracell Biotech obtained a term loan facility of RMB29.0 million for a term of 60 months commencing from June 2, 2020 and ending on June 1, 2025. During the term, Suzhou Gracell Biotech may make multiple drawdowns within the facility limit. Interest on the outstanding loan balance accrues quarterly at a variable annual rate equal to the one-year loan prime rate plus 1%. We are required to make payments of principal and interest on the loan on a semi-annual basis unless otherwise agreed by the parties. The loan agreement contains customary covenants that, among other things, require Suzhou Gracell Biotech to obtain written approval from Suzhou Branch of China Merchants Bank for merger, consolidation or division, reducing registered capital, making investments, disposing of assets, increasing debt financing or other transactions that may adversely affect its ability to make payments under the loan. The loan agreement also contains customary events of default relating to, among other things, payment defaults or breaches of the terms of the loan, upon which the bank may declare all or a portion of our outstanding obligations payable to be immediately due and payable. As of September 30, 2020, RMB4.9 million was outstanding under the loan agreement.

Funding Requirements

We do not currently have any approved products and have not generated any revenue from product sales. We have funded our operations to date primarily through a combination of equity and debt financing. Through the date of this prospectus, we have received proceeds of RMB2.4 million from sale of ordinary shares, RMB648.0 million from sale of preferred shares, and RMB64.9 million from our term loan facilities with commercial banks. As of December 31, 2019, we had RMB316.3 million (US\$46.6 million) in cash and cash equivalents and short-term investments, which does not include the proceeds from term loan facilities that were received in 2020.

Since our inception, we have incurred significant operating losses. We expect to incur significant expenses and operating losses for the foreseeable future as we advance the preclinical and clinical development of our research programs and product candidates. We expect that our research and development and general and administrative expenses will increase in connection with conducting additional clinical trials and preclinical studies for our current and future research programs and product candidates, contracting with CROs to support clinical trials and preclinical studies, expanding our intellectual property portfolio, and providing general and administrative support for our operations. As a result, we expect that we will need additional capital to fund our operations.

Based upon our current operating plan, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents as of December 31, 2019, will enable us to fund our operating expenses and capital expenditure requirements through at least the next 12 months from the date of this offering. We do not expect to generate any revenue from product sales unless and until we successfully complete development and

obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years. As a result, until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements.

However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing shareholders, including investors in this offering, will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our shareholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise capital, we will need to delay, reduce or terminate planned activities to reduce costs.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the timing, receipt and amount of sales of any future approved or cleared products, if any;
- the scope, progress, results and costs of researching and developing our existing product candidates or any future product candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals or clearances for our existing product candidates or any future product candidates;
- the time and costs involved in obtaining regulatory approval for our product candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of these product candidates;
- the number and characteristics of any additional product candidates we develop or acquire;
- the cost of manufacturing our product candidates and any products we successfully commercialize, including costs associated with developing our manufacturing capabilities;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other product candidates and technologies;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of any such agreements that we may enter into;
- the expenses needed to attract and retain skilled personnel and senior management; and
- the costs associated with being a public company.

Further, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development activities. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated product development programs.

Capital Expenditure

We incurred capital expenditure of RMB11.4 million and RMB56.4 million (US\$8.3 million) in the years ended December 31, 2018 and 2019, respectively, primarily in connection with our expenditure for the purchase of property and equipment. We intend to fund our future capital expenditure through our existing cash balance, proceeds from this offering and other financing alternatives. We will continue to incur capital expenditure to support the growth of our business.

Contractual Obligations and Commitments

The following is our contractual obligations and commitments as of December 31, 2019:

	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	Total
(in RMB thousands)					
Operating Lease obligations	10,564	27,069	—	—	37,633

Our operating lease obligations related to our leases of offices and GMP facilities. For the years ended December 31, 2018 and 2019, total rental related expenses for all operating leases amounted to RMB4.2 million and RMB13.0 million (US\$1.9 million), respectively.

Internal Control Over Financial Reporting

During the audit of our financial statements for the years ended December 31, 2018 and 2019, one material weakness was identified in our internal control over financial reporting. Under standards established by the PCAOB, 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 annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness that has been identified relate to our lack of sufficient and competent financial reporting and accounting personnel with appropriate knowledge of U.S. GAAP and SEC reporting and compliance requirements.

We are in the process of implementing a number of measures to address the material weakness that has been identified including: (i) hiring additional accounting and financial reporting personnel with U.S. GAAP and SEC reporting experience and qualifications, (ii) expanding the capabilities of existing accounting and financial reporting personnel through continuous training and education in the accounting and reporting requirements under U.S. GAAP, and SEC rules and regulations, and (iii) enhancing internal audit function as well as engaging an external consulting firm to assist us in assessing compliance with the SEC requirements and improve overall internal control.

We may incur significant costs in the implementation of such measures. We cannot assure you that all these measures will be sufficient to remediate our material weakness in time, or at all. Additionally, we cannot assure you that we have identified all, or that we will not in the future have additional, material weaknesses. 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.

Off-Balance Sheet Arrangements

We have not entered into any financial guarantees or other commitments to guarantee the payment obligations of any third parties. 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.

Holding Company Structure

Gracell Cayman is a holding company with no material operations of its own. We currently conduct our operations primarily through our PRC subsidiaries, our variable interest entity and its subsidiary in China. As a result, Gracell Cayman's ability to pay dividends primarily 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 subsidiary 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 laws, each of our subsidiaries, our variable interest entity and its 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 its registered capital. In addition, our wholly foreign owned subsidiaries in China may allocate a portion of its after-tax profits based on PRC accounting standards to enterprise expansion funds and staff bonus and welfare funds at its discretion, and our variable interest entity may allocate a portion of its after-tax profits based on PRC accounting standards to a discretionary surplus fund at its 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.

As a Cayman Islands exempted company and offshore holding company, we are permitted under PRC laws and regulations to provide funding to our PRC subsidiary only through loans or capital contributions, subject to the approval of government authorities and limits on the amount of capital contributions and loans. This may delay us from using the proceeds from this offering to make loans or capital contribution to our PRC subsidiary. See "Risk Factors—Risks Relating to Doing Business in China— PRC regulation of loans and direct investment by offshore holding companies to PRC entities may delay or prevent us from making loans or additional capital contributions to our PRC operating subsidiary."

Taxation

Cayman Islands

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. In addition, the Cayman Islands does not impose withholding tax on dividend payments.

British Virgin Islands

Under the current laws of the British Virgin Islands, our British Virgin Islands subsidiary, Gracell Biotechnologies Holdings Limited, is not subject to income or capital gain taxes. In addition, dividend payments are not subject to withholding tax in the British Virgin Islands.

Hong Kong

Under the current Hong Kong Inland Revenue Ordinance, our Hong Kong subsidiary, Gracell Biotechnologies (HK) Limited, is subject to a two-tiered profits tax rate where the first HK\$2 million of the

taxable income generated from operations in Hong Kong will be taxed at a rate of 8.25% while the remainder will be taxed at 16.5%. For the years ended December 31, 2018 and 2019, our Hong Kong subsidiary did not make any provisions for Hong Kong profit tax as there were no assessable profits derived from or earnings in Hong Kong. Under the Hong Kong tax law, our Hong Kong subsidiary is exempt from Hong Kong profit tax on its foreign-derived income and dividend payments are not subject to withholding tax in Hong Kong.

PRC

Generally, our PRC subsidiaries, VIE and VIE's subsidiary are subject to corporate income tax on their taxable income in the PRC at a rate of 25%. Enterprise engaged in research and development activities are entitled to claim a tax deduction at an amount equal to 50%, or 75% in the years of 2018 to 2020 for corporate income tax purpose, of the qualified research and development expenses.

Dividends paid by our wholly owned subsidiary in China to our intermediary holding company in Hong Kong will be subject to a withholding tax rate of 10%, unless they qualify for treaty benefit. If our Hong Kong subsidiary is qualified as a Hong Kong tax resident and satisfies all other requirements under the Arrangement between the Mainland China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Tax Evasion on Income, then dividends paid by our wholly foreign owned subsidiary in China will be subject to a reduced withholding tax rate of 5% instead. See "Risk Factors—Risks Relating to Doing Business in China—Dividends we receive from our subsidiaries located in the PRC may be subject to PRC withholding tax, which could materially and adversely affect the amount of dividends, if any, we may pay our shareholders."

If our holding company in the Cayman Islands or any of our subsidiaries outside of China were deemed to be a "resident enterprise" under the PRC Enterprise Income Tax Law, it would be subject to corporate income tax on its worldwide income at a rate of 25%. See "Risk Factors—Risks Relating to Doing Business in China—If we are classified as a "resident enterprise" of China under the PRC Enterprise Income Tax Law, we and our non-PRC shareholders could be subject to unfavorable tax consequences, and our business, financial condition and results of operations could be materially and adversely affected."

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 December 2018 and 2019 were increases of 1.9% and 4.5%, 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. For example, certain operating expenses, such as employee compensation and rental and related expenses for office space may increase as a result of higher inflation. Additionally, because a substantial portion of our assets consists of cash and cash equivalents and short-term investments, high inflation could significantly reduce the value and purchasing power of these assets. We are not able to hedge our exposure to higher inflation in China.

Qualitative and Quantitative Disclosures about Market Risk

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily the result of fluctuations in foreign exchange and interest rate risk.

Foreign Exchange Risk

Most of our expenses are denominated in Renminbi and, therefore, we are exposed to risks related to movements between Renminbi and U.S. dollars. To date, we have not used any derivative financial instruments to hedge exposure to foreign exchange risk. Although we do not believe that we currently have any significant direct foreign exchange risk and the value of your investment in the ADSs will be affected by the exchange rate between U.S. dollar and Renminbi because the value of our business is effectively denominated in Renminbi, while the ADSs will be traded in U.S. dollars.

The value of the Renminbi 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. For U.S. dollar against Renminbi, there was appreciation of approximately 5.7% and 1.3% in the years ended December 31, 2018 and 2019, respectively. It is difficult to predict how market forces or PRC or U.S. government policy may impact the exchange rate between the Renminbi and the U.S. dollar. To the extent that we need to convert U.S. dollars into Renminbi for our operations, appreciation of the Renminbi against the U.S. dollar would have an adverse effect on the Renminbi amount we receive from the conversion. Conversely, if we decide to convert Renminbi 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 the Renminbi would have a negative effect on the U.S. dollar amounts available to us.

We estimate that we will receive net proceeds of approximately US\$ million from this offering if the underwriters do not exercise their option to purchase additional ADSs, after deducting underwriting discounts and commissions and the estimated offering expenses payable by us, based on the initial offering price of US\$ per ADS, the midpoint of the estimated initial public offering price range shown on the cover page of this prospectus. Assuming that we convert the full amount of the net proceeds from this offering into Renminbi, a 10% appreciation of the U.S. dollar against the Renminbi, from the exchange rate of RMB6.7896 for US\$1.00 as of September 30, 2020 to a rate of RMB7.4686 to US\$1.00, would result in an increase of RMB million in our net proceeds from this offering. Conversely, a 10% depreciation of the U.S. dollar against the Renminbi, from the exchange rate of RMB6.1106 for US\$1.00 as of December 31, 2019 to a rate of RMB6.2656 to US\$1.00, would result in a decrease of RMB million in our net proceeds from this offering.

Interest Rate Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. We held cash and cash equivalents and short-term investments of RMB316.3 million (US\$46.6 million) as of December 31, 2019. We generally hold our cash in interest-bearing money market accounts. Due to the short-term maturities of our cash equivalents and short-term investments and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents and short-term investments.

Critical Accounting Policies, Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP.

Our consolidated financial statements include the financial statements of Gracell Biotechnologies Inc. and its subsidiaries. All significant intercompany balances and transactions have been eliminated upon consolidation. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the balance sheet dates, as well as the reported expenses incurred during the reporting periods. Significant estimates and assumptions reflected in our consolidated financial statements include, but not limited to, the useful lives and impairment of long-lived assets, deferred tax valuation allowance, share-based compensation expenses and the valuation of our convertible redeemable preferred shares. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Research and Development Expenses

Research and development expenses primarily include (i) payroll and other related costs of personnel engaged in research and development activities, (ii) costs related to pre-clinical testing of our technologies under development and clinical trials such as payments to contract research organizations, investigators and clinical trial sites that conduct our clinical studies; (iii) costs to develop the product candidates, including raw materials and supplies, product testing, depreciation and amortization, and facility related expenses, and (iv) other research and development expenses.

We expense research and development costs as incurred when the expenditures relate to our research and development services and have no alternative future uses in accordance with ASC 730, Research and Development. The contracts with contract research organizations are generally cancellable at our option with notice. We did not record any accrued expenses related to cancellation of contracts with contract research organizations as of December 31, 2019 as we did not have any plan to cancel the existing contracts with contract research organizations.

Accounting and Modification of Preferred Shares

Our Preferred Shares are classified as mezzanine equity in the consolidated balance sheets because they are contingently redeemable upon the occurrence of an event outside of our control, for example us not achieving a qualified initial public offering or a deemed liquidation event before February 22, 2024, or the Target QIPO Date. Our Preferred Shares were determined to be mezzanine equity with no embedded feature to be bifurcated and no beneficial conversion features to be recognized. Our Preferred Shares are initially recorded at their respective issuance date fair value, net of issuance cost. We did not incur material issuance cost for any Preferred Shares issued. The cumulative undeclared dividends are not recorded in the consolidated balance sheet as we do not have the obligation to pay the cumulative dividend before it is declared by our board of directors.

Our Preferred Shares are not currently redeemable, but are probable to become redeemable. We accreted changes in the redemption value over the period from the date of issuance to the earliest redemption date using the effective interest method. The accretion is recorded against retained earnings, or in the absence of retained earnings, by charges against additional paid-in-capital, or in the absence of additional paid-in-capital, by charges to accumulated deficit. The accretion of the Preferred Shares was US\$12,198,769 and US\$36,802,418 for the years ended December 31, 2018 and 2019.

On January 3, 2019, the Target QIPO Date was extended from November 15, 2022 to February 22, 2024 upon issuance of series B-2 preferred shares. The amendment is accounted for as modifications rather than extinguishments as the fair values of these Preferred Shares immediately after the amendments were not significantly different from their respective fair values immediately before the amendment. When Preferred Shares are modified and such modification results in value transfer between the holders of the Preferred Shares and the holders of ordinary shareholders, the value transferred is treated as a deemed dividend to or deemed contribution from the holders of the Preferred Shares.

Share-Based Compensation

We adopted an employee stock option plan in April 2019 for the purpose of providing incentives and rewards to eligible participants who contributed to the success of our operations. We follow ASC 718 *Compensation—Stock Compensation* to determine whether a share option should be classified and accounted for as a liability award or equity award. We have early adopted Accounting Standards Update 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting* from the earliest period presented to recognize the effect of forfeiture in compensation cost when they occur.

We recognize share-based compensation costs related to share incentive awards based on the estimated fair value of the awards on the date of grant. The fair value of options was determined using the binomial option

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valuation model. The binomial model requires the input of highly subjective assumptions, including the expected volatility, the exercise multiple, the risk-free rate and the dividend yield. For expected volatility, we have referred to historical volatility of several comparable companies in the same industry. The exercise multiple was estimated as the average ratio of the stock price to the exercise price of when employees would decide to voluntarily exercise their vested options. The risk-free rate for periods within the contractual life of the options is based on market yield of U.S. Treasury Strips plus China country risk premium with a maturity life equal to the remaining maturity life of the options as of the valuation date, sourced from Bloomberg. The dividend yield is based on our expected dividend policy over the contractual life of the options.

The assumptions used to estimate the fair value of the share options granted are as follows:

	For the year ended December 31,	
	2018	2019
Risk-free interest rate	3.7%-4.0%	2.9%-3.1%
Dividend yield	0%	0%
Expected volatility range	55.0%-56.2%	53.7%-54.3%
Exercise multiple	2.20	2.20
Contractual life	10 years	10 years

Share-based compensation costs are recognized as expenses immediately on the grant date if no vesting conditions are required. If the options are subject to a vesting schedule, then the share-based compensation costs are recognized as expenses using the straight-line method over the vesting period. If the options are subject to a vesting schedule and an exercise condition, which requires the listing of our shares on a recognized stock exchange, the cumulative share-based compensation expenses for the then vested options will be recorded upon the listing of our shares on a recognized stock exchange using the graded vesting method.

Since the exercisability is dependent upon the listing of our shares, and it is not probable that this performance condition can be achieved until the completion of our initial public offering, no share-based compensation expense relating to our employee stock option plan was recorded for the years ended December 31, 2018 and 2019. We will recognize compensation expenses relating to options vested cumulatively upon the listing of our shares on a recognized stock exchange.

Fair Value Measurements

We apply ASC 820, *Fair Value Measurements and Disclosures*. ASC 820 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. ASC 820 requires disclosures to be provided for fair value measurements. ASC 820 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1—Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2—Includes other inputs that are directly or indirectly observable in the marketplace.

Level 3—Unobservable inputs which are supported by little or no market activity.

ASC 820 describes three main approaches to measuring the fair value of assets and liabilities: (1) market approach; (2) income approach; and (3) cost approach. The market approach uses prices and other relevant information generated from market transactions involving identical or comparable assets or liabilities. The income approach uses valuation techniques to convert future amounts to a single present value amount. The measurement is based on the value indicated by current market expectations about those future amounts. The cost approach is based on the amount that would currently be required to replace an asset.

The carrying amounts of cash and cash equivalent, short-term investments, other current assets, accruals and other current liabilities and convertible loans approximate their fair values because of their generally short maturities.

Recent Accounting Pronouncement

For detailed discussion on recent accounting pronouncements, see Note 2 to our consolidated financial statements included elsewhere in this prospectus.

Emerging Growth Company Status

We are an “emerging growth company,” as defined in the JOBS Act, and we may take advantage of reduced reporting requirements that are otherwise applicable to public companies. Section 107 of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies are required to comply with those standards. The JOBS Act also exempts us from having to provide an auditor attestation of internal control over financial reporting under Sarbanes-Oxley Act Section 404(b).

We will remain an “emerging growth company” until the earliest of (1) the last day of the fiscal year in which we have total annual gross revenues of US\$1.07 billion or more, (2) the last day of the fiscal year in which the fifth anniversary of the completion of this initial public offering occurs, (3) the date on which we have issued more than US\$1.0 billion in nonconvertible debt during the previous three years or (4) the last day of the fiscal year in which we are deemed to be a large accelerated filer under the rules of the SEC, which generally is when we have more than US\$700.0 million in market value of our stock held by non-affiliates as of the prior June 30th and we have been a public company for at least 12 months and have filed one annual report.

BUSINESS

Overview

We are a global clinical-stage biopharmaceutical company dedicated to discovering and developing breakthrough cell therapies to address major industry challenges and fulfill unmet medical needs in the treatment of cancer. As a leading cell and gene therapy company, we aim to disrupt conventional approaches to CAR-T cell therapies with our proprietary technology platforms—FasTCAR and TruUCAR.

- With FasTCAR, we are able to deliver younger, less exhausted T cells for autologous cell therapies with greater potency and next-day manufacturing (22 to 36 hours) versus the industry norm of two to six weeks. Our lead FasTCAR-enabled autologous product candidate, GC012F, has demonstrated fast, deep and durable responses, including multiple stringent complete responses, or sCR, in relapsed or refractory multiple myeloma, or r/r MM, patients in an ongoing investigator-initiated Phase 1 trial in China.
- With TruUCAR, we are able to derive T cells from non-HLA-matched healthy donors to generate allogeneic CAR-T cell therapies that are readily available off-the-shelf at lower cost for a broad patient base, including those less suitable for autologous CAR-T cell therapies. Our lead TruUCAR-enabled allogeneic product candidate, GC027, has achieved multiple complete responses, or CR, in relapsed or refractory T cell acute lymphoblastic leukemia, or r/r T-ALL, patients with a manageable safety profile in an ongoing investigator-initiated Phase 1 trial in China.

In addition to our technology platforms, we utilize our proprietary genetic engineering techniques, Dual CAR and Enhanced CAR, to generate FasTCAR and TruUCAR product candidates with enhanced efficacy and safety. Leveraging our pioneering platforms, know-how and experience, we are developing a rich clinical-stage pipeline of multiple autologous and allogeneic product candidates that we believe will unlock the long-held promise of CAR-T cell therapies for a broad range of patients with advanced hematologic malignancies and solid tumors.

GC012F, our lead FasTCAR autologous product candidate, is being studied in an ongoing investigator-initiated Phase 1 trial in China. We enrolled and treated 16 r/r MM patients for this trial with 15, or 93.8%, of these patients exhibiting high-risk features, which represent a subgroup of MM patients that are most difficult to treat. As of the July 2020 data cutoff date, 15 of 16 evaluable r/r MM patients achieved a response, resulting in an overall response rate, or ORR, of 93.8%, with all six patients, or 100%, from the highest dose cohort achieving a sCR, which was maintained through the landmark analysis at six months after CAR-T infusion. The most common adverse event observed was cytokine release syndrome, or CRS, which was managed with standard of care, or SOC, treatment.

GC027, our lead TruUCAR allogeneic product candidate, has demonstrated in an ongoing investigator-initiated Phase 1 trial in China that all five enrolled adult r/r T-ALL patients, or 100%, achieved a CR or complete response with incomplete hematologic recovery, or CRi, on Day 14 or Day 28 after treatment, as of the February 2020 data cutoff date. All CRS observed was manageable and resolved following treatment and supportive care. No patients developed neurotoxicity, an adverse event commonly observed after CAR-T cell therapy, or graft versus host disease, or GvHD, a potentially fatal condition after allogeneic CAR-T cell therapy.

Despite the vast potential of CAR-T cell therapies, major challenges persist for both autologous and allogeneic approaches. Autologous cell therapies are highly personalized, making the manufacturing process time-consuming, complex, costly and difficult to scale. It is also challenging to generate sufficient high-quality T cells as T cells of patients are often compromised from earlier lines of cancer treatment. Allogeneic therapies, including those intended for use off-the-shelf, derive cells from healthy donors but require modifications to reduce or eliminate host versus graft rejection, or HvG, and GvHD. Additionally, despite progress in treating hematologic malignancies, CAR-T cell therapies have had little success with treating solid tumors, primarily as a result of CAR-T cells' limited ability to penetrate and persist in solid tumors.

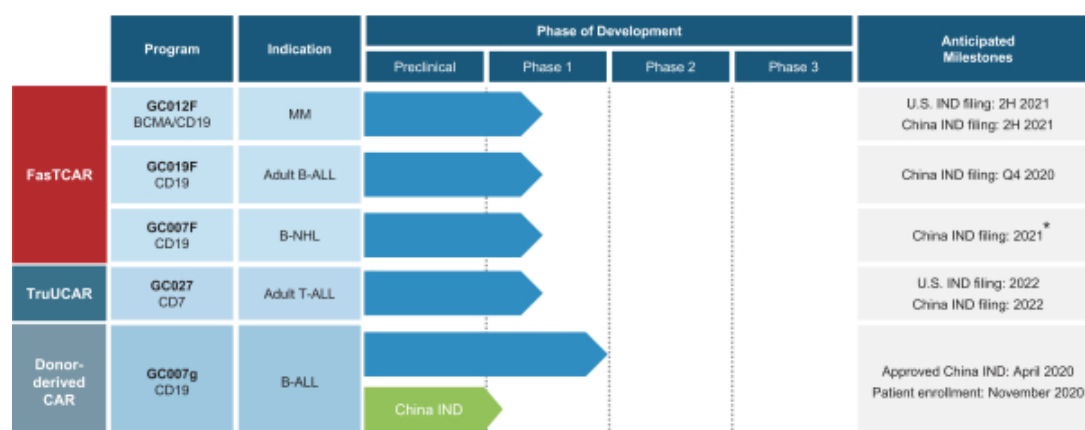
Our pioneering platforms, FasTCAR and TruUCAR, are highly innovative and are designed to provide significant advantages as highlighted below:

- **FasTCAR.** FasTCAR offers a revolutionary approach that tackles the most pressing challenges associated with autologous therapies, such as lengthy manufacturing time, suboptimal manufacturing quality, high therapy cost and poor T cell fitness. We transform the three primary production steps—activation, transduction and expansion—into a single “concurrent activation-transduction” step. This is achieved by utilizing XLenti vectors derived from lentivirus to concurrently activate and transduce resting T cells and enable them to stably express one or more CARs and proliferate potently *in vivo*. In addition, FasTCAR manufactured CAR-T cells are younger, less exhausted and show enhanced proliferation potency, tissue migration and tumor clearance effect as demonstrated in preclinical studies, eliminating the need for the *ex vivo* expansion phase in the conventional process. This streamlined process significantly shortens the production time from an industry norm of two to six weeks and achieves next-day manufacturing. Shorter manufacturing time is of particular importance to increasing the widespread utility of CAR-T cell therapies, particularly in the case of rapidly progressing cancers. We established fully-closed production lines designed to produce FasTCAR product candidates while reducing the risk of contamination and optimizing cost-efficiency. Our significantly shorter manufacturing time and highly efficient manufacturing process may result in meaningful cost savings, increasing the accessibility of cell therapies for cancer patients. We are developing our lead autologous product candidate, GC012F, as well as multiple autologous clinical-stage pipeline candidates on our FasTCAR platform.
- **TruUCAR.** TruUCAR is designed to generate high-quality allogeneic CAR-T cell therapies with superior efficacy that can be administered “off-the-shelf” at lower cost. As with FasTCAR, TruUCAR uses a lentivirus to deliver its CAR. TruUCAR has several key design differences when compared to conventional allogeneic CAR-T approaches. TruUCAR is designed to specifically target a patient’s T cells and natural killer, or NK, cells that would otherwise be directed against the foreign, or allogeneic, cells resulting in rejection by the patients. This feature allows our allogeneic cell therapies to survive a patient’s immune system without the need for combination treatment with anti-CD52 antibodies that may leave a patient at increased risk for infection. TruUCAR is designed to avoid GvHD, one of the most severe adverse events of allogeneic CAR-T cell therapies, and rapidly eliminate cancer cells without the need to bridge to hematopoietic stem cell transplantation, or HSCT, which is often used with conventional allogeneic CAR-T cell therapy to strengthen its therapeutic effects but pose a risk of early mortality. As a result, TruUCAR’s monotherapy approach has the potential to significantly reduce the cost and length of treatment by achieving fast remission and avoiding anti-CD52 treatment and potentially HSCT. We believe that TruUCAR may result in meaningful cost savings, further increasing the accessibility of cell therapies for cancer patients. We are developing our lead allogeneic product candidate, GC027, as well as multiple allogeneic pipeline candidates on our TruUCAR platform.

In addition, we have a suite of genetic engineering techniques, Dual CAR and Enhanced CAR, that can be leveraged with FasTCAR and TruUCAR to further enhance the efficacy of our CAR-T cell therapies. Dual CAR has the potential to control relapse by reducing the likelihood of antigen escape and to reduce rejection of the CAR-T cells by patients treated with TruUCAR-enabled allogeneic CAR-T cell therapies. Enhanced CAR further strengthens CAR-T cells’ functionality, for example by overcoming the immunosuppressive tumor microenvironment, or TME, and/or increasing cytokine signaling. We also have an allogeneic donor-derived CAR technique based on HLA-matching to avoid GvHD.

We have generated a pipeline of first-in-class autologous and allogeneic cell therapy candidates with the potential to treat both hematologic malignancies and solid tumors. The clinical development strategy that we have established in partnership with top-tier hospitals in China expedites the initial demonstration of safety and efficacy signal for our product candidates through pre-IND investigator-initiated trials. We have generated all our

product candidates internally. Our most advanced product candidates are presented in the pipeline diagram below:



MM = multiple myeloma, B-ALL = B cell acute lymphoblastic leukemia, B-NHL = B cell non-Hodgkin's lymphoma, T-ALL = T cell acute lymphoblastic leukemia

Our lead product candidates include:

- GC012F.** GC012F is a FasTCAR-enabled dual BCMA- and CD19-directed autologous CAR-T product candidate, being studied for the treatment of MM in an ongoing investigator-initiated Phase 1 trial across multiple centers in China. As of July 2020, we enrolled and treated 16 r/r MM patients with 93.8% of these patients having high-risk features, which represent a subgroup of MM patients with a poor prognosis and potentially rapid disease progression, making them particularly challenging to treat even with novel agents. All patients in the trial had relapsed from, or were refractory to, previous treatments, including most commonly used agents and SOC treatments. 15 of 16 patients achieved and maintained a response. In the highest dose cohort which is the recommended dosage level, 100% of the six evaluable patients achieved MRD- sCR as best response which was maintained through the landmark analysis at six months after CAR-T infusion. Based on these results, we expect to submit IND applications for GC012F in r/r MM to the FDA and the NMPA by the end of 2021.
- GC019F.** GC019F is a FasTCAR-enabled CD19-directed autologous CAR-T product candidate, being studied for the treatment of adult B-ALL in an ongoing investigator-initiated Phase 1 trial across multiple centers in China. An investigator-initiated trial for GC019F for the treatment of r/r B-NHL is currently in the planning stage and is expected to begin patient enrollment by the end of 2020.
- GC007F.** GC007F is a FasTCAR-enabled CD19-directed autologous CAR-T product candidate being studied for the treatment of B-NHL in an ongoing investigator-initiated Phase 1 trial across multiple centers in China. Based on the clinical results from the investigator-initiated trial, we plan to submit an IND application for either GC019F or GC007 in r/r B-NHL to the NMPA in 2021.
- GC027.** GC027 is a TruUCAR-enabled CD7-directed allogeneic CAR-T product candidate being studied for the treatment of adult T-ALL in an ongoing investigator-initiated Phase 1 trial across multiple centers in China. As of February 2020, we enrolled and treated five adult r/r T-ALL patients. All patients enrolled had relapsed from, or were refractory to, their prior line of therapy. All five evaluable patients achieved a CR or CRi, resulting in an ORR of 100%, including four patients, or 80%, achieving MRD- CR on Day 28 after treatment. We observed CRS in all treated patients, which was resolved with treatment. No patient developed neurotoxicity or GvHD. We expect to submit an IND application for GC027 in adult r/r T-ALL to the FDA and the NMPA in 2022.

- **GC007g.** GC007g is a donor-derived CD19-directed allogeneic CAR-T cell therapy that has been studied in a completed investigator-initiated Phase 1 trial for the treatment of r/r B-ALL, where CAR-T cells were manufactured using T cells from an HLA-matched healthy donor. We obtained IND approval to study GC007g in B-ALL from the NMPA on April 1, 2020 and are initiating the Phase 1 study in China. We submitted an updated innovative seamless Phase 1b/2 study design for GC007g's registration-enabling clinical trial to the Center for Drug Evaluation, or CDE, in September 2020 which may enable us to roll over the ongoing Phase 1 clinical trial into the seamless Phase 1b/2 registration-enabling clinical trial in the first half of 2021. Our goal is to submit a biologics license application, or BLA, to the NMPA for GC007g upon completion of a registrational trial.

In addition to our lead product candidates, we have a broad portfolio of earlier stage product candidates targeting various cancer indications, such as ovarian cancer, breast cancer, peripheral T cell lymphoma, or PTCL, a subtype of NHL, and T cell lymphoblastic leukemia, or T-LBL.

CAR-T cell manufacturing is a critical component of our clinical development and future commercialization, as CAR-T cell therapies are complex and, in the case of autologous therapies, highly personalized. We control our manufacturing through our two good manufacturing practices, or GMP, compliant manufacturing facilities in Suzhou and Shanghai, making us self-sufficient in the production of CAR-T cells for clinical development and early stage commercialization. We established fully-closed production lines in our Suzhou and Shanghai facilities, which are designed to produce FastCAR product candidates while reducing contamination risks and optimizing cost-efficiency. With this fully-closed design, we are able to operate multiple systems in one manufacturing cleanroom at the same time, with each system producing CAR-T cells for an individual patient. We believe these advantages, coupled with our ability to achieve next-day manufacturing for autologous CAR-T cells in one production shift, allow us to substantially reduce manufacturing costs, improve productivity and scale up our production in a cost-efficient manner. Our Suzhou facility supports an annual production of 3,200 autologous samples using FastCAR and 12,000 allogeneic samples using TruUCAR. Our Shanghai facility supports high-quality engineering runs for IND preparations.

We are led by an experienced management team with an unwavering commitment to developing next generation cell and gene therapies. Our Founder and Chief Executive Officer, Dr. William Wei Cao, Ph.D., B.M., has over 30 years of research and development experience in the biotechnology industry and previously co-founded and served as chief executive officer and executive board member of Cellular Biomedicine Group, Inc. (Nasdaq: CBMG), a Nasdaq-listed cell therapy company. Prior to that, Dr. Cao held research positions at Harvard Medical School and Standard University Medical Center, as well as senior roles at Chiron (Novartis and Bayer) and Affymetrix (ThermoFisher). Our Chief Medical Officer, Dr. Martina Sersch, M.D., has over 25 years of academia and industry experience and previously served in senior roles at Amgen, Roche/Genentech and Pfizer. Dr. Sersch also served as Chief Medical Officer of Mustang Bio, Inc. (Nasdaq: MBIO), a Nasdaq-listed CAR-T and gene therapy company where she successfully led the IND approval of a CAR-T cell therapy. Our Chief Financial Officer, Dr. Kevin Xie, Ph.D., has over 18 years of experience in healthcare investment and held various leadership and management positions at Fosun Group, Locust Walk Capital, Scopia Capital, and Great Point Partners. Dr. Xie serves on the board of ViewRay Inc (Nasdaq: VRAY) and Alpha Healthcare Acquisition Corp. (Nasdaq: AHACU). Since our inception, we have raised approximately US\$95 million from a group of strategic and life sciences focused institutional investors who support our mission. Our key investors include Temasek, Lilly Asia Ventures, OrbiMed and Kington Capital.

Our Strategy

Our goal is to disrupt conventional approaches to CAR-T cell therapy by using our proprietary platforms and techniques to discover and develop treatments that deliver fast, deep and durable responses for advanced hematologic malignancies and solid tumors. In order to achieve our goal, the key elements of our strategy include:

- ***Rapidly advance our lead product candidates through clinical development and regulatory approval by leveraging our global clinical development capabilities.*** We seek to develop our product candidates by leveraging our relationships with clinicians and key opinion leaders in China, the United States and Europe. We partner with top-tier hospitals in China to streamline the safety and efficacy testing of our innovative pipeline product candidates in investigator-initiated trials that are conducted in accordance with international standards to support future global regulatory filings and clinical development. Our lead FasTCAR-enabled autologous product candidate, GC012F, in r/r MM has demonstrated fast, deep and durable responses in an ongoing investigator-initiated Phase 1 trial in China. In addition, our lead TruUCAR-enabled allogeneic product candidate, GC027, has achieved multiple CRs in r/r T-ALL in an ongoing investigator-initiated Phase 1 trial in China. We plan to submit IND applications to the FDA and the NMPA for GC012F by the end of 2021 and for GC027 in 2022.
- ***Continue to leverage the strength of our revolutionary technology platforms to broaden our pipeline of next-generation autologous and allogeneic CAR-T cell therapies.*** We believe our FasTCAR platform positions us as the only company that currently has achieved next-day manufacturing (22 to 36 hours) for autologous CAR-T cells and can be applied broadly to any CAR-T target. We believe our TruUCAR platform, through its rapid monotherapy approach, has the potential to produce allogeneic therapies that will extend the reach of CAR-T cell therapies to more patients. We believe our technology platforms and in-house expertise will enable us to continue discovering and developing novel autologous and allogeneic CAR-T cell therapies with greater efficacy and safety than existing CAR-T cell therapies that, together with the substantial cost savings achieved, could increase the accessibility of these therapies for patients.
- ***Expand our CAR-T therapies into solid tumor indications.*** CAR-T cell therapies have not been able to show meaningful efficacy in treating solid tumors, possibly due to CAR-T cells' limited ability to infiltrate and proliferate in solid tumors as well as CAR-T cells' poor resistance against the immunosuppressive TME. Our proprietary platforms and techniques are designed to address these significant challenges. Utilizing FasTCAR, Enhanced CAR and Dual CAR, we are developing a portfolio of highly differentiated CAR-T product candidates for the treatment of solid tumors with high unmet needs.
- ***Enhance our leadership position within the cell and gene therapy field.*** Our proprietary technology platforms, know-how, and scientific expertise have enabled us to discover and develop cell therapies with significant advantages over other CAR-T cell therapies and have established us as leaders in the field. We plan to continue our leadership position in cell therapy by innovating and expanding upon our suite of proprietary platforms and techniques. In addition, we continually survey the scientific and industry landscape for opportunities to in-license or acquire new technologies.
- ***Expand our proprietary genetic engineering and cell manufacturing capabilities.*** We believe the quality, reliability, cost effectiveness and scalability of our proprietary cell manufacturing platforms and techniques, together with our know-how, are important to our competitive advantage over current CAR-T therapies and critical to our long-term success. We currently have two GMP-compliant manufacturing facilities in China that enable us to be self-sufficient in the production of CAR-T cells for our clinical development and early-stage commercialization. We will continue to invest in developing our manufacturing capabilities and plan to establish our own manufacturing facility in the United States to support future clinical trials and commercialization.
- ***Evaluate strategic partnerships to maximize the value of our technology platforms.*** We may strategically enter into collaborations or other partnerships with leading biopharmaceutical companies

to accelerate our development timelines and maximize the commercial potential of our product candidates. We may also explore strategic alliances to identify additional targets and develop pipeline product candidates.

CAR-T Cell Therapy and Industry Challenges

Cancer originates from individual cells that have developed mutations in essential cellular programs, driving increased cell division and growth. T cells are a type of white blood cell used by the human immune system to defend the body against cancerous cells and infectious pathogens. If, using its T cell receptor, a T cell recognizes an altered cell, it becomes activated and kills that particular cell. For a cancer to grow, cancer cells evolve mechanisms to evade recognition by, or establish other defenses against the immune system and in particular, T cells. However, T cells may not always be able to launch an effective defense due to a number of reasons, such as tumor antigen escape and T cell exhaustion. The two most common engineered T cells, CAR-T cells and TCR-T cells, are genetically modified T cells that express either chimeric antigen receptors or naturally occurring T cell receptors, or TCRs, that recognize antigen on a patient's tumors.

Chimeric antigen receptors, or CARs, are genetically engineered cell surface receptors that provide specific immunological properties to an immune effector cell, such as a lymphocyte T cell. CARs result from a coding sequence for the receptor when transferred into the cell by viral vectors, either retroviral or lentiviral, or non-viral gene engineering technologies. These CARs provide immune effector cells with the tumor targeting specificity of a monoclonal antibody. By redirecting the immune system to eliminate malignant cells, CAR-T cells act as a living drug, expanding in the patient and enabling long-term antitumor memory.


CAR-T cells can be classified as either autologous or allogeneic. Autologous CAR-T cells are derived from the T cells of the cancer patient while allogeneic CAR-T cells are derived from the T cells of a healthy donor. Theoretically, CAR-T cells can be engineered to target virtually any tumor-associated antigen. Currently, CAR-T cell therapies are primarily focused on hematologic malignancies. In 2017, the first two CAR-T cell therapies were approved: Kymriah (marketed by Novartis AG) for pediatric B cell acute lymphoblastic leukemia and Yescarta (marketed by Kite Pharma, Inc., acquired by Gilead Sciences, Inc.) for diffuse large B cell lymphoma. Despite the vast potential of CAR-T cell therapies, there are major challenges for both autologous and allogeneic CAR-T cell therapies, as presented below:

- **Manufacturing Time – Industry norm of two to six weeks.** Patients must wait for a few weeks to be treated with their engineered cells, primarily due to the lengthy manufacturing time of two to six weeks, which is the current industry norm. Lengthy manufacturing time can prove suboptimal for those patients with rapidly progressing cancer who may die while waiting for the therapy.
- **Production Quality – High failure risks.** The complex, multistep process of generating autologous CAR T cells increases the risk of manufacturing failure, including failure to generate a sufficient density of viable T cells or batch failures resulting from infection or contamination during production. Reported failure rates of autologous CAR-T cell manufacturing range from 5% to 14%. Manufacturing failure results in an inability to provide therapy.
- **Cost / Access – High manufacturing cost and lengthy hospitalization.** High manufacturing cost and highly personalized nature of CAR-T cell therapies result in an average cost of US\$1.5 million per patient per therapy. The long manufacturing time for conventional CAR-T cell therapies results in lengthy hospitalization that requires a dedicated infrastructure for in-patient care from specialized medical centers, further increasing costs to patients.
- **Poor T Cell Fitness – Exhausted T cells.** T cells of patients used for the autologous CAR-T therapy are often compromised from earlier lines of treatment, resulting in decreased survival, proliferation, differentiation, homing and tumor killing ability. The T cells are further weakened during the activation and expansion phases in conventional CAR-T manufacturing processes, affecting the quality of CAR-T cells.


- **Limited Durability – Need for combination therapy.** It is challenging to maintain response in relapsed or refractory patients for various reasons. For example, infused allogeneic CAR-T cells may be rejected by a patient’s immune system via HvG, which harms the durability and efficacy of the treatment. Anti-CD52 therapies are often co-administered to avoid HvG. Additionally, CAR-T cell therapies are often coupled with or bridged into HSCT to strengthen the therapeutic effects and improve response durability.
- **Relapse – Antigen escape.** CAR-T cell therapies targeting a single antigen have been shown to lose efficacy due to antigen escape, which occurs when expression of a CAR-T target on a malignant cell is lost or reduced, resulting in an expansion of the malignant cells that have escaped the ability of the CAR-T cells to kill them. Antigen escape poses a significant risk of failure for CAR-T cell therapy and may result in response rates declining from the initial response level.
- **Limited Efficacy – Solid tumors.** Despite progress in the treatment of blood cancers with CAR-T cells, achieving success in solid tumors is significantly more challenging due to a variety of factors, including inefficient trafficking of CAR-T cells to tumor sites, immunosuppressive TME, limited ability of CAR-T cells to penetrate and remain alive in solid tumors, target antigen heterogeneity, and the inability of *ex vivo* expanded CAR-T cells to persist and proliferate following infusion into patients.

In view of the major challenges facing current autologous and allogeneic CAR-T therapies, there remains a critical unmet medical need for improved CAR-T cell therapies. We believe we can disrupt the conventional approaches to CAR-T cell therapies by leveraging our highly innovative technology platforms, proprietary techniques, in-house expertise, clinical development strategy and high-quality and scalable manufacturing facilities. Below are tables summarizing our proprietary platforms, techniques and their advantages over conventional autologous and allogeneic CAR-T therapies:


Challenges and FasTCAR’s Advantages to Conventional Autologous CAR-T Approaches

Challenges	Conventional Autologous CAR-T Approach	
MANUFACTURING TIME	<ul style="list-style-type: none"> • Industry norm being two to six weeks • Less suitable for patients with rapidly progressing cancer 	<ul style="list-style-type: none"> • Next-day manufacturing (22 to 36 hours) • Increased speed to patients • Access to a broad patient base
PRODUCTION QUALITY	<ul style="list-style-type: none"> • Time-consuming multi-step process • High risk of contamination • High production variation 	<ul style="list-style-type: none"> • Fully-closed manufacturing design <ul style="list-style-type: none"> - Reduced risk of contamination - Improved operational consistency
COST / ACCESS	<ul style="list-style-type: none"> • Costly to manufacture • Difficulty to scale (one sample in single space) • Lengthy hospitalization 	<ul style="list-style-type: none"> • Significantly reduced manufacturing cost • High scalability (multiple samples in single space) • Potential cost-savings to the healthcare system
POOR T CELL FITNESS	<ul style="list-style-type: none"> • Weakened CAR-T cells with decreased survival, proliferation, differentiation, homing and tumor killing ability 	<ul style="list-style-type: none"> • Greater T cell potency • Younger, less exhausted CAR-T cells with enhanced proliferation potency, tissue migration and tumor clearance effect

Challenges and TruUCAR's Advantages to Conventional Allogeneic CAR-T Approaches

Challenges	Conventional Allogeneic CAR-T Approach	 TruUCAR
LIMITED DURABILITY	<ul style="list-style-type: none"> • Anti-CD52 therapies are co-administered to avoid HvG • Often coupled with or bridged into HSCT 	<ul style="list-style-type: none"> • Designed to specifically target a patient's T cells and NK cells to avoid HvG without extra antibody therapy • Potential to eradicate cancer cells as a standalone therapy
COST / ACCESS	<ul style="list-style-type: none"> • Anti-CD52 therapy carries infection risk • HSCT carries risk of early mortality • Severe adverse events and combination therapies increase cost and length of treatment, limiting patient access 	<ul style="list-style-type: none"> • Potential to achieve fast remission and avoid anti-CD52 therapy and potentially HSCT • Monotherapy approach provides meaningful cost savings, increasing patient access

Challenges and Advantages of Other Proprietary Techniques to Conventional CAR-T Approaches

Challenges	Conventional CAR-T Approach	 Other Techniques
RELAPSE	<ul style="list-style-type: none"> • Lower efficacy due to antigen escape • Increased risk of therapy failure and disease relapse 	<p>Dual CAR enables dual antigen targeting CAR-T cells with the potential to:</p> <ul style="list-style-type: none"> • Enhance potency • Stay <i>in vivo</i> longer than single CAR-T cells • Target early lineage cells that will develop into cancer cells • Improve safety profile
LIMITED EFFICACY IN SOLID TUMORS	<ul style="list-style-type: none"> • Inefficient trafficking to tumor sites • Inability to resist the suppressive TME • Difficulty penetrating and remaining alive in solid tumors 	<p>Enhanced CAR strengthens CAR-T cells' ability to:</p> <ul style="list-style-type: none"> • Infiltrate into tumor tissue • Remain active in suppressive TME • Proliferate in tumor tissue
POOR T CELL FITNESS	<ul style="list-style-type: none"> • Collection of T cells from patients may be difficult due to their poor health or existing infection • Low quality of T cells given prior treatment and disease characteristics 	<p>Donor-derived CAR derives T cells from HLA-matched healthy donors to:</p> <ul style="list-style-type: none"> • Treat patients less suitable for autologous therapies • Improve tumor clearance ability for higher response rate and persistence of efficacy • Reduce manufacturing failure given higher quality donor T cells

Our Proprietary Technologies

We believe our proprietary technology platforms, FastCAR and TruUCAR, represent game changing advances in the CAR-T industry. With FastCAR, we are able to deliver younger, less exhausted T cells for autologous cell therapies with greater potency and next-day manufacturing (22 to 36 hours) versus the industry norm of two to six weeks. With TruUCAR, we are able to derive T cells from non-HLA-matched healthy donors to generate allogeneic CAR-T cell therapies that are readily available off-the-shelf at lower cost for a broad range of patients, including those less suitable for autologous CAR-T cell therapies. In addition, we have a suite of genetic engineering techniques, Dual CAR and Enhanced CAR, that can be leveraged with FastCAR and TruUCAR technology platforms to further enhance the efficacy of our CAR-T cell therapies. Dual CAR is designed to control relapse by reducing the likelihood of antigen escape and to reduce rejection of the CAR-T cells by patients treated with TruUCAR-enabled allogeneic CAR-T cell therapies. Enhanced CAR further strengthens CAR-T cells' functionality, for example by overcoming the immunosuppressive TME and/or increasing cytokine signaling. We also have an allogeneic donor-derived CAR technique based on HLA-matching to avoid GvHD.

Our platforms and techniques are designed to produce therapies with significant advantages over conventional approaches as highlighted below:

asT CAR

- Next-day manufacturing
- Improved transduction efficiency
- Fully-closed manufacturing capabilities
- Reduced manufacturing cost
- Improved productivity
- Cost savings
- Younger phenotype
- Greater potency, persistence and capability to migrate to tissue

TruUCAR

- Readily available off-the-shelf
- Potential to eliminate HvG without extra immunosuppressive therapeutics
- Potential to eradicate cancer cells as a standalone therapy
- Fast remission
- Cost savings
- Increased patient access

Technology enhancements that can be applied to the platforms

Dual CAR

- Second CAR to target a second tumor antigen to enhance potency
- Ability to stay *in vivo* longer than single CAR-T cells
- Ability to target early lineage cancer cells or progenitors
- Improved safety profile

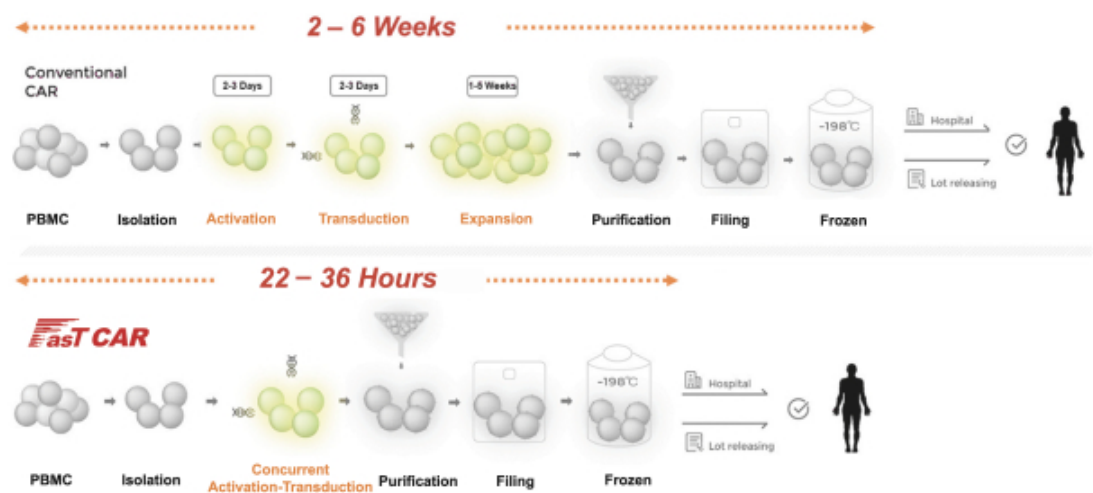
Enhanced CAR

- Ability to infiltrate into tumor tissue
- Ability to remain active in suppressive TME
- Ability to proliferate in tumor tissue

FasTCAR – Our Autologous CAR-T Platform

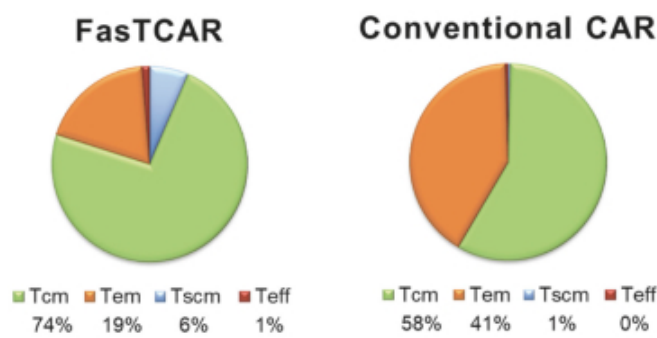
FasTCAR is our revolutionary autologous CAR-T platform that tackles the most pressing challenges associated with autologous therapies, such as lengthy manufacturing time, suboptimal manufacturing quality, high therapy cost and poor T cell fitness. In the conventional CAR-T manufacturing process, the first and most essential step is activating a patients’ T cells using CD3 and/or CD28 antibodies. As the next step, activated T cells will be transduced by virus vectors to express one or more CARs. Engineered CAR-T cells will then need to be expanded *ex vivo* before they can be administered into the human body. As depicted in the figure below, the conventional process can take about two to six weeks. Our ability to revolutionize the autologous CAR-T manufacturing process relies on several proprietary technological innovations, including our system of concurrently activating and transducing T cells in a single step with no extra *ex vivo* T cell expansion phase and the use of XLenti vectors, our viral vectors with higher transduction efficiency. We developed a proprietary system of concurrently activating and transducing resting T cells using XLenti vectors derived from lentivirus, that are of high-quality and exhibit high gene transduction efficiency. As a result, after transduction, one or more CARs are integrated in the T cell genome and expressed stably. Based on our preclinical studies, these transduced T cells are highly potent in proliferation and tumor clearance, as shown below, and therefore can be administered into the human body without the need for *ex vivo* cell expansion. With these innovations, FasTCAR transforms the activation, transduction and expansion steps into a single “concurrent activation-transduction” step, as depicted in the figure below, significantly reducing the autologous CAR-T cell manufacturing time from an industry norm of two to six weeks and achieving next-day manufacturing (22 to 36 hours).

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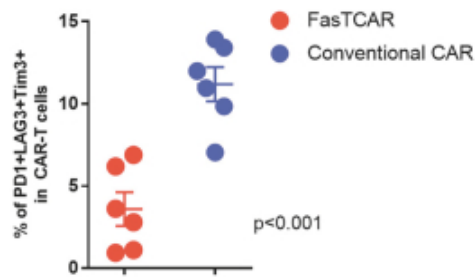
As exemplified by the preclinical studies for FasTCAR T cells targeting CD19, FasTCAR T cells are younger, less exhausted and show enhanced proliferation potency, tissue migration and tumor clearance effect, as compared to conventional CAR-T cells targeting CD19, as demonstrated by the figures below. We conducted a preclinical study in which the percentages of stem cell memory T cells, or Tscm cells, and central memory T cell, or Tcm cells, in FasTCAR T cells were compared to those in conventional CAR-T cells *in vitro*. Memory T cells, such as Tscm cells and Tcm cells, are indicators of T cell youth, and are associated with CAR-T cell efficacy. Effector memory T cells, or Tem cells, and effector T cells, or Teff cells, are late-differentiated T cells that attack the tumor cells. As depicted in the figure below, we observed that FasTCAR T cells were younger than conventional CAR-T cells as demonstrated by the larger percentage of Tscm and Tcm cells in the FasTCAR T cells.

FasTCAR T Cells Are Younger than Conventional CAR-T Cells, As Demonstrated by the Percentage of Tscm and Tcm Cells *In Vitro*



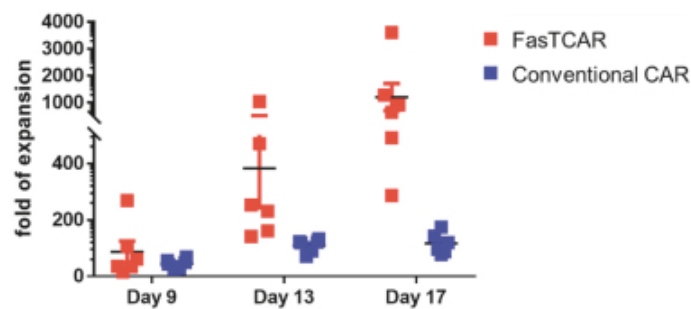
FasTCAR T cells targeting CD19 are also less exhausted than conventional CAR-T cells *in vitro* upon antigen re-stimulation based on the percentage of PD-1+Lag3+Tim3+ in CAR-T cells, as depicted in the figure below.

FasTCAR T Cells Are Less Exhausted than Conventional CAR-T Cells



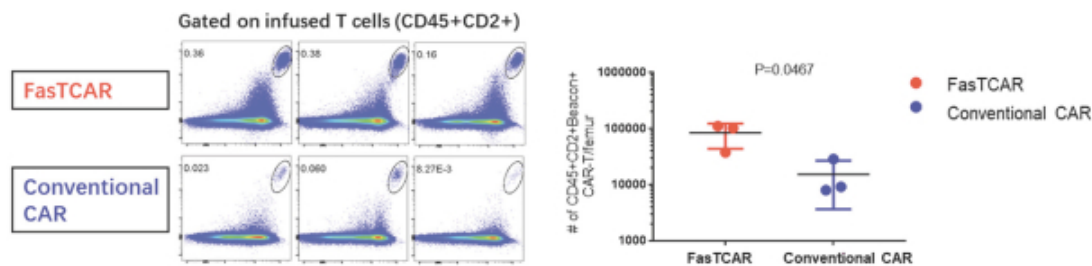
FasTCAR-T cells targeting CD19 also demonstrated more robust and potent proliferation than conventional CAR-T cells *in vitro* upon antigen re-stimulation, as depicted in the figure below.

FasTCAR T Cells Are More Robust and Potent in Proliferation than Conventional CAR-T Cells



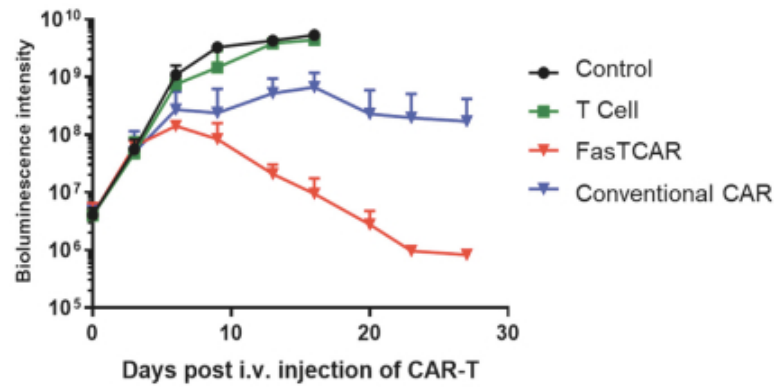
We also assessed the CAR-T cell migration to the bone marrow after infusion. As depicted in the figure below, significantly more FasTCAR T cells targeting CD19 were found in the bone marrow than conventional CAR-T cells ten days after CAR-T cell infusion.

FasTCAR T Cells Infiltrate into Bone Marrow Better than Conventional CAR-T Cells



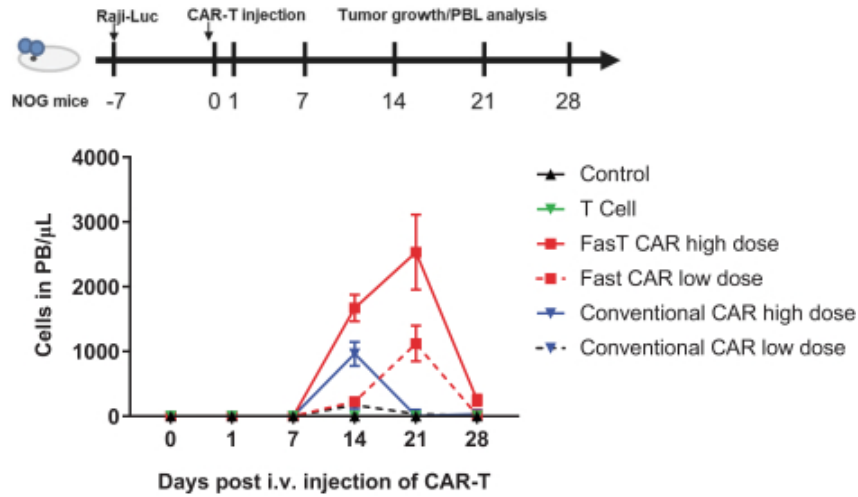
Additionally, FasTCAR T cells targeting CD19 demonstrated significantly more potent and sustained anti-leukemia efficacy *in vivo* in a Raji xenograft mouse model, or Raji-Luc, as depicted in the figure below. Immunocompromised mice were implanted intravenously with tumor cells and the tumors were established for seven days before injection with a dose of 5.0x10⁵ total CAR-T cells. FasTCAR T cells targeting CD19 exhibited more potent and sustained anti-tumor efficacy than conventional CAR-T cells at the same dose.

FasTCAR T Cells Exhibit Significantly More Potent and Sustained Anti-Tumor Efficacy than Conventional CAR-T Cells in A B Cell Malignancy Xenograft Mouse Model



The *in vivo* expansion of FasTCAR T cells targeting CD19 was more robust than conventional CAR-T cells, as depicted in the figure below, which could be evidence of the enhanced potency of FasTCAR T cells.

Enhanced Anti-Tumor Capacity of FasTCAR T Cells Was, at Least Partly, Attributable to Increased Proliferation Potential of FasTCAR T Cells Observed *In Vivo*



We believe our autologous CAR-T manufacturing process has the potential to reduce contamination risk, lower manufacturing cost and improve productivity. We established fully-closed production lines in our Suzhou and Shanghai facilities, which are designed to produce FasTCAR product candidates while reducing contamination risks and optimizing cost-efficiency. With this fully-closed design, we are able to operate multiple systems in one manufacturing cleanroom at the same time, with each system producing CAR-T cells for an individual patient. On the contrary, autologous CAR-T cell therapy producers without a fully-closed system can only produce one batch of CAR-T cells for a single patient in one manufacturing cleanroom at one time in order to avoid potential cross-contamination. Our fully-closed system reduces reagent consumable costs, labor costs, workshop equipment operations and depreciation. We believe these advantages, coupled with our ability to achieve next-day manufacturing for autologous CAR-T cells in one production shift, allow us to substantially

reduce manufacturing cost, improve productivity and scale up our production in a cost-efficient manner. We currently manufacture our lead product candidates, GC019F and GC007F, on the fully-closed production lines.

Given the number of patients with these fast-progressing diseases our autologous CAR-T product candidates are currently being developed to treat, the time saved by our faster and more reliable manufacturing process alone could make a large difference in clinical outcomes and, together with the substantial cost savings, could improve accessibility of cell therapies for patients. We believe that FasTCAR can be applied broadly to any CAR-T antigens and a variety of tumor markers, based on our clinical and preclinical studies. With FasTCAR, we are currently developing our lead autologous product candidates, GC012F, GC019F and GC007F, targeting hematologic malignancies, such as MM, B-ALL and B-NHL, as well as earlier-stage autologous product candidates targeting a variety of indications, such as ovarian cancer and breast cancer.

TruUCAR – Our Off-the-Shelf Allogeneic CAR-T Platform

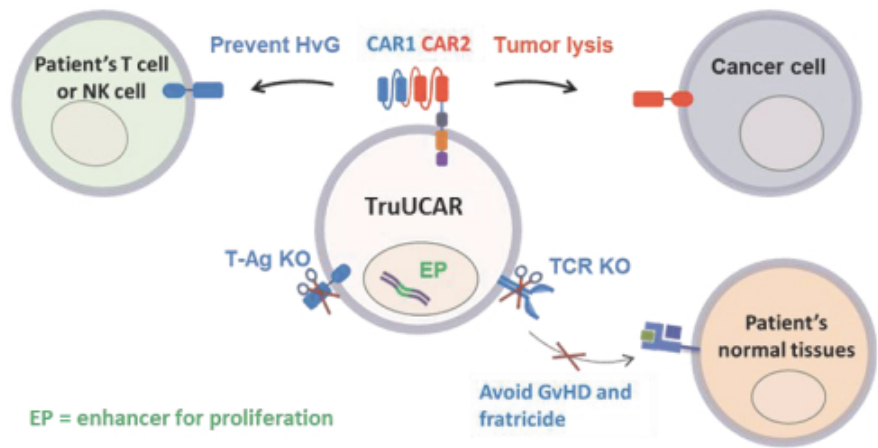
TruUCAR is our proprietary and innovative technology platform for generating high-quality allogeneic CAR-T therapies with superior efficacy that can be administered “off-the-shelf” at lower cost. Unlike autologous CAR-T therapies, these product candidates use T cells from non-HLA-matched healthy donors, making them readily available to treat cancer patients, including those who are less suitable for, or have relapsed after, autologous CAR-T cell therapy as well as those with rapidly progressing cancer. Allogeneic CAR-T cell therapies that are derived from higher quality T cells from healthy donors have the potential to be superior to T cells derived from cancer patients in multiple attributes, including fitness, proliferation, differentiation, homing and tumor clearance ability *in vivo*.

Despite these advantages, allogeneic cell therapy approaches are often limited by HvG and GvHD, which limit the therapeutic potential of these therapies by reducing potential efficacy and posing significant safety challenges. HvG occurs when a patient’s immune cells recognize infused non-HLA-matched donor cells as foreign and reject them. The most common method used for mitigating the potential for HvG is to suppress the patient’s own alloreactive killer cells, including T cells and NK cells. We believe the only clinically proven strategy to achieve such suppression of T and NK cells to date is to administer anti-CD52 antibodies as part of the preconditioning regimen. Since CD52 is broadly expressed on the surface of many immune cells including not only T and NK cells, but also monocytes and granulocytes, depletion of these cell types increases the risk of infections. GvHD is a potentially fatal condition, where transplanted cells, or specifically allogeneic CAR-T cells in this case, recognize the patient’s normal tissues as foreign and cause potentially lethal tissue damage. GvHD associated with allogeneic CAR-T cell therapies can be addressed by knocking out, or making functionally inactive, TCRs, and this approach has been validated by our and others’ early results observed in clinical trials. Due to the limited monotherapy efficacy, the current-generation of off-the-shelf allogeneic cell therapies are often coupled with or bridged into HSCT to strengthen the therapeutic effects that may leave a patient at risk of neutropenia and early mortality. Antibody therapies and HSCT, as well as the risks associated with each of them together, result in increased treatment timeframes and medical costs.

TruUCAR is designed to avoid HvG and GvHD as a standalone therapy and has the potential to significantly reduce the cost and length of treatment by achieving fast remission and avoiding anti-CD52 treatment and potentially HSCT. As depicted in the figure below, to reduce HvG, we engineer T cells to express a CAR that specifically targets a patient’s own T cells and NK cells that would otherwise be directed against the foreign, or allogeneic, CAR-T cells, resulting in rejection by the patient without affecting the recovery of other immune cell compartments, such as monocytes and granulocytes, during treatment. This feature allows our allogeneic cell therapies to survive in a patient’s immune system without the need for combination treatment with anti-CD52 antibodies that may leave the patient at risk for infection. To reduce the possibility of GvHD from allogeneic T cells, we utilize CRISPR/Cas9 to disrupt the T cell receptor alpha constant, or TRAC, locus to eliminate surface expression of the TCR complex of our TruUCAR product candidates. Furthermore, to eliminate potential fratricide, or self-killing of CAR-T cell during the production process, we utilize CRISPR/Cas9 to disrupt CD7, a pan T and NK marker on the CAR-T cells. To enable TruUCAR T cell therapies to function as a standalone therapy, our proprietary enhancer for proliferation, or EP, is implanted in TruUCAR T cells utilizing a

lentivirus-based gene delivery system, to strengthen cell expansion and *in vivo* engraftment. We believe these differentiating design features of TruUCAR can work together to enable the creation of allogeneic CAR-T cell therapies with greater efficacy and safety.

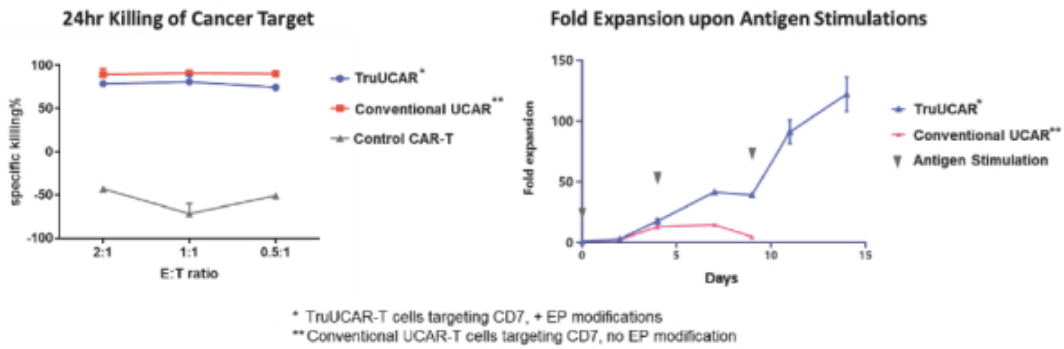
Mechanism of Action of TruUCAR



Since TruUCAR is modular, alternative CAR constructs targeted against different antigens can be applied to TruUCAR to achieve similar therapeutic effects. For example, the anti-HvG and anti-GvHD functions can be carried out by a dual CAR design or a single CAR design for dual functions. In the case of a dual CAR design, as depicted in the figure above, one CAR serves a “defensive” purpose, targeting the patient’s own alloreactive killer T cells and NK cells while the second CAR serves an “attack” purpose, targeting tumor antigen to eradicate tumor cells. In the case of a single CAR design, as in the case of GC027, our CD7-directed allogeneic CAR-T product candidate, the CAR targeting CD7 carries out dual functions, targeting both alloreactive killer T cells and NK cells, as well as T leukemia cells. No GvHD symptoms were observed as of the February 2020 data cutoff date in the first-in-human trial of GC027 when administered to five adult patients.

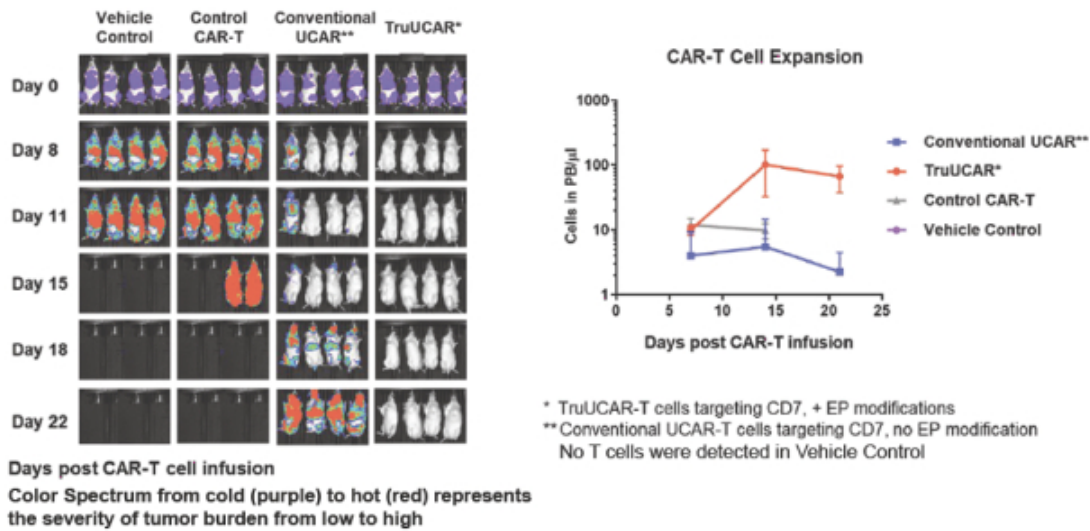
We believe TruUCAR’s monotherapy approach has the potential to significantly reduce cost and length of treatment by achieving fast remission and avoiding anti-CD52 treatment and potentially HSCT, which carries a risk of early mortality and may require lengthy hospitalization. By avoiding combination therapy, we believe that TruUCAR can result in meaningful cost savings, further increasing the accessibility of CAR-T cell therapies for cancer patients. In the preclinical studies we conducted for TruUCAR T cells targeting CD7, TruUCAR T cells demonstrated comparable short-term cancer cell killing *in vitro* and superior long-term expansion over conventional UCAR T cells targeting CD7 without EP modifications.

TruUCAR T Cells Exhibited Comparable *In Vitro* Cancer Cell Killing and Superior Expansion over Conventional UCAR T Cells



Additionally, TruUCAR-T cells targeting CD7 demonstrated superior engraftment and anti-leukemia efficacy *in vivo* in a highly malignant xenograft murine model for T-ALL. As depicted in the figures below, immunocompromised NOG mice were implanted intravenously with 2.0×10^6 CCRF-CEM leukemia cells and leukemia were established for six days before injection with 1.0×10^6 CAR-T cells. CCRF-CEM is an aggressive, highly malignant T-ALL cell line. Mice in the control groups all succumbed to death within two weeks post CAR-T infusion. TruUCAR T cells exhibited more potent and sustained anti-leukemia efficacy than conventional UCAR T cells. TruUCAR T cells also demonstrated superior *in vivo* proliferation as well as duration of expansion in the peripheral blood of treated animals, which was correlated with its robust anti-leukemia efficacy.

In Murine Xenograft Model of Human T-ALL, TruUCAR-T Cells Demonstrated Superior *In Vivo* Engraftment and Anti-Leukemia Efficacy Compared to Conventional UCAR-T Cells



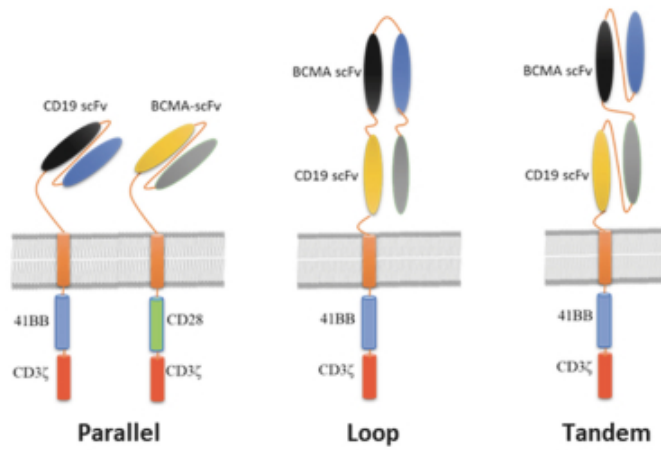
Technology Enhancements

We also have a suite of proprietary genetic engineering techniques, Dual CAR and Enhanced CAR, that can be leveraged with FasTCAR and TruUCAR technology platforms to further enhance the efficacy and safety of our CAR-T product candidates.

Dual CAR

Dual CAR is designed to control relapse in patients in FasTCAR by reducing the likelihood of antigen escape and to reduce rejection of the CAR-T cells by patients treated with TruUCAR-enabled allogeneic CAR-T cell therapies. Stimulated by two CARs, dual antigen targeting CAR-T cells have the potential to maintain *in vivo* longer than single antigen targeting CAR-T cells. The second CAR can be designed to target early lineage cells or progenitors that will ultimately develop into cancer cells. A Dual CAR construct can come in a parallel design, a loop design or a tandem design, as depicted in the figures below. The final designs for our dual antigen targeting product candidates are determined through *in vivo* and *in vitro* screening. For example, our lead product candidate, GC012F, adopts a loop design.

Dual CAR Construct Designs



Enhanced CAR

Enhanced CAR further strengthens CAR-T cells’ functionality, for example by overcoming the immunosuppressive TME and/or increasing cytokine signaling. Working on the hypothesis that PD-1 mediated immunosuppression causes CAR-T cell hypofunction, we utilize CRISPR/Cas9 to knock out PD-1 expressed on CAR-T cells to release potential suppression from programmed death-ligand 1, or PD-L1, expressed on tumor cells and other suppressive immune cells in tumor tissue. With Enhanced CAR, we can also enable CAR-T cells to achieve intended functions by regulating the expression of one or a combination of cytokine, cytokine receptors or checkpoint ligands.

Donor-derived CAR

Donor-derived CAR technique produces allogeneic CAR-T cells based on HLA-matching, offering an alternative CAR-T cell therapy option for patients who are less suitable for autologous CAR-T cell therapies due to various reasons. Autologous CAR-T cells are produced from T cells of patients. Due to repeated radiotherapy and chemotherapy, the survival, proliferation, differentiation, homing and tumor killing ability of T cells in cancer patients are often compromised, thus affecting the quality of autologous CAR-T products. Our donor-derived CAR technique is designed to derive higher quality T cells from healthy donors to manufacture CAR-T cells that demonstrate better tumor clearance ability as well as improved response rate and persistence of efficacy. GC007g, enabled by our allogeneic donor-derived CAR, is our most clinically advanced product candidate. GC007g has shown favorable safety and efficacy results and obtained IND approval from the NMPA on April 1, 2020.

Our Clinical Development Pipeline and Strategy

Leveraging our pioneering FastCAR and TruUCAR platforms, proprietary techniques, in-house know-how, and experience, we are developing a rich clinical-stage pipeline of multiple autologous and allogeneic product candidates with the potential for clear differentiation compared to current CAR-T cell therapies. We seek to bridge the gap between research and development and patient treatments by leveraging our relationships with clinicians and key opinion leaders in China, the United States and Europe. In particular, clinical development strategy that we have established in partnership with top-tier hospitals in China expedites the initial demonstration of safety and efficacy signal for our product candidates through pre-IND investigator-initiated trials. Our clinical product pipeline is presented in the diagram below:



FasTCAR Autologous Product Candidates

GC012F: BCMA-CD19-directed Autologous Dual CAR-T for the Treatment of Multiple Myeloma

Overview

GC012F, our FastCAR-enabled autologous dual CAR-T product candidate, is being studied in an ongoing investigator-initiated Phase 1 trial across multiple centers in China for the treatment of MM. The goal of GC012F is to deliver fast, deep and durable response in MM patients. As of July 17, 2020, we enrolled and treated 16 r/r MM patients. All patients in the trial had relapsed from, or were refractory to, previous treatments including commonly used agents and SOC treatments. Notably, the majority of this study population belong to a subgroup of MM patients with high-risk features, a poor prognosis and potentially rapid disease progression. These patients often, in later lines, do not respond to therapy or soon progress after a short initial response, making them particularly challenging to treat even with novel agents. Despite this, 15 of 16 patients treated with GC012F derived treatment benefit by achieving and maintaining a response. In the highest dose cohort, 100% of the six evaluable patients achieved MRD- sCR/CR as best response, which was maintained through the landmark analysis at six months post CAR-T infusion. GC012F demonstrated a manageable safety profile, with only two patients experiencing Grade 3 or higher CRS and no patient experiencing neurotoxicity, such as immune effector cell associated neurotoxicity, or ICANS.

Background on Multiple Myeloma

Multiple myeloma is the third most common type of blood cancer in the United States, originating from plasma cells, a type of immune cell that is typically responsible for secreting antibodies to fight infection. DNA damage can turn these plasma cells into cancerous cells known as myeloma cells. Often asymptomatic initially, in later stages of the disease patients experience a number of different signs and symptoms that can greatly vary.

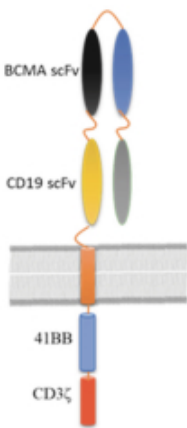
Multiple myeloma patients may experience severe bone pain, anemia, kidney dysfunction, easy bruising and bleeding and infections as the disease progresses. Myeloma cells produce high levels of single antibodies, resulting in dysfunction of the immune system and kidneys and other organs. Overproduction of abnormal plasma cells are also a hallmark of MM. The underlying cause of the disease is still unknown. In recent years, many advances have been made to treat MM, however, the disease is still considered incurable. Globally, approximately 160,000 patients are diagnosed with MM every year with over 32,000 expected to be diagnosed in the United States in 2020.

Multiple myeloma patients with certain cytogenetic and other abnormalities are classified by the International Myeloma Working Group, or IMWG, and Mayo Stratification for Myeloma and Risk-Adapted Therapy, or mSMART, criteria as high-risk patients. They represent a smaller portion of the overall MM patient population accounting for approximately 20-30% of MM patients. High-risk patients have a much higher risk of early relapse and shorter progression free and overall survival. These patients are considered the most difficult to treat MM patients, typically with a poor prognosis. Novel antibody therapy has not yet shown to add any significant benefit to this subgroup of patients when added to SOC therapy in early lines of therapy. This challenge was recently discussed in the Hematologic Malignancies-Plasma Cell Dyscrasia session at the 2020 American Society of Clinical Oncology Annual Meeting (ASCO 2020, Highlights of the Day Session, Suzanne Lentzsch). High-risk MM continues to represent a high unmet medical need in all stages of the disease and through all lines of therapy. We believe that regulatory pathways for this subgroup of patients may enable us to adopt a fast-to-market strategy.

Dual Antigen Targeting with GC012F

CAR-T cell therapy directed at BCMA, a well-established MM target, has provided an encouraging modality for the management of r/r MM. However, CAR-T cells targeting a single antigen may not be sufficient to control the relapse resulting from antigen escape or auto-antibody, an antibody produced by the immune system that is directed against self-antigens that can induce the immune system to attack a patient’s tissues. According to a 2016 study of BCMA expression after CAR-T treatment, BCMA loss occurred in approximately 10% of MM patients after BCMA-targeted therapy. Additionally, it has been demonstrated that CD19-directed CAR-T cell therapy was effective in certain MM patients, likely due to CD19 expression on subsets of MM cells, including early-stage MM cells, known as progenitor cells. In order to improve the efficacy and duration of responses to CAR-T cell therapy for r/r MM, we designed GC012F with dual CARs targeting both BCMA and CD19. As depicted in the figure below, in the GC012F construct, BCMA and CD19 scFv are linked, and joined by a hinge, a transmembrane domain, a co-stimulatory domain and CD3z intracellular domain.

GC012F Structure



Ongoing Investigator-Initiated Phase 1 Trial and Preliminary Evidence of Clinical Benefit

GC012F is being studied in an ongoing investigator-initiated Phase 1 trial across multiple centers in China, for the treatment of MM. The primary endpoint of this first-in-human, single-arm, open-label trial is safety, as determined by the occurrence of treatment-related adverse events, such as CRS and neurotoxicity. CRS is the most significant treatment-related toxicity, and may result from rapid immune activation induced by CAR-T cell therapies. CRS initially manifests with fever, depending on grade hypoxia and hypotension and can progress to a life-threatening condition. Another common toxicity observed after CAR-T cell therapy is neurotoxicity, including ICANS which may manifest as delirium, encephalopathy, aphasia and lethargy among other symptoms.

A secondary endpoint is efficacy, as determined by clinical response, such as sCR, CR in accordance with the IMWG uniform response criteria for MM. The IMWG uniform response criteria has been utilized in registrational trials of approved drugs, including as a primary endpoint. As such, ORR and depth of response such as MRD and sCR are important parameters to establish efficacy in MM. ORR, the percentage of patients achieving a response to therapy, is also a secondary endpoint for this trial, and an approvable endpoint for MM in later line settings.

As of July 2020, we had enrolled 16 patients and expect to enroll up to a total of 20 patients by the end of 2020. Patients enrolled in the trial had r/r MM and were heavily pre-treated with previous therapies. These patients had failed a median of five prior lines of therapy, with a range of two to seven prior therapies. In addition, 15 patients, representing 93.8% of total patients enrolled, had high-risk features as assessed by mSMART 3.0 guidelines. Our trial is distinguished by the high percentage of high-risk patients, making the demonstration of a high ORR and a longer lasting response particularly challenging. As such, based on the data observed, GC012F may represent a highly competitive new treatment approach to high-risk MM and beyond.

According to study protocol, all patients in this investigator-initiated Phase 1 trial were preconditioned with fludarabine and cyclophosphamide. Following preconditioning, patients enrolled in the study were treated with a single infusion of GC012F. As of July 17, 2020, all 16 patients were evaluable for efficacy and safety assessment.

Efficacy Results. As of July 17, 2020, 15 of 16 patients responded to therapy, resulting in an ORR of 93.8%, including nine patients, or 56.3%, achieving MRD- CR/sCR as best response. Response was observed in all dosage levels and the earliest response was observed on Day 28 after treatment. In dosage level 3, or DL3, the recommended dosage level, all six patients, or 100%, achieved sCR, and three patients had been confirmed by PET/CT, a highly sensitive imaging technique to detect any remaining disease, as of the July 2020 data cutoff date. The median follow-up time was 7.3 months and the longest follow-up time was ten months post infusion, as of the July 2020 data cut-off date.

At one month, three months and six months after treatment, 14, 11 and ten patients, respectively, were evaluable for efficacy assessment. 11 of 14 evaluable patients, or 78.6%, were MRD- at one month after treatment, all 11 evaluable patients, or 100%, were MRD- at three months after treatment, and all ten evaluable patients, or 100%, were MRD- at six months after treatment. Of the overall 16 patients, seven patients were measured by flow cytometry with a sensitivity level of 10^{-4} , and nine patients were measured by EuroFlow, a standardized procedure designed to measure MRD, with a sensitivity level of 10^{-6} and at least 1.08×10^7 cells analyzed. At the landmark analysis at six months post treatment, treatment of all six patients in DL3, or 100%, had achieved and maintained MRD- sCR, which includes patients heavily pretreated with Daratumumab. Five of these six patients in DL3, or 83.3%, had high-risk features according to mSMART criteria.

Safety Results. As of July 17, 2020, 16 patients experienced CRS, including 14 patients, or 87.5%, experiencing Grade 1 or Grade 2 CRS and two patients, or 12.5%, experiencing Grade 3 CRS. The median duration of CRS was four days, with a range of one to eight days. CRS symptoms were managed with treatment.

No neurotoxicity of any grade was observed. One patient at dosage level 2, or DL2, presented with fever and died shortly after Day 78 of unknown cause during the COVID-19 pandemic.

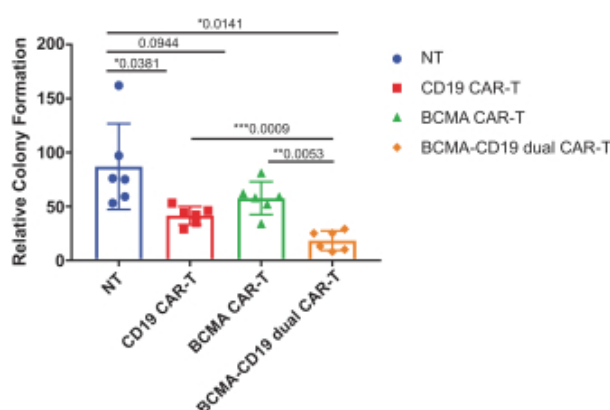
GC012F Future Clinical Plans

The ongoing investigator-initiated Phase 1 trial has demonstrated GC012F's potential to deliver deep, fast and durable responses and a favorable safety profile in r/r MM patients, including high-risk MM patients who have exhausted other therapeutic options. We intend to use DL3 as the recommended Phase 2 dose for dose expansion studies. Based on these results, we intend to conduct clinical trials of GC012F in r/r MM and potentially in earlier lines of therapy. We expect to submit IND applications for GC012F to the FDA and the NMPA by the end of 2021. We plan to use the data from the investigator-initiated Phase 1 trial as supportive evidence in our IND applications. If the data remains as compelling for high-risk patients, we expect to discuss options for clinical development in earlier lines of therapy and accelerated regulatory pathways for GC012F with the FDA and the NMPA.

Preclinical Data

As demonstrated in a preclinical study, our GC012F, dual CAR-T cells targeting both BCMA and CD19 (BCMA-CD19 dual CAR-T as labeled in the figure below) were effective in killing BCMA+ and/or CD19+ target cells including MM cell lines both *in vitro* and *in vivo*. More importantly, BCMA-CD19 dual CAR-T cells were shown to be more effective than single CAR-T cells targeting either BCMA or CD19 (CD19-CAR-T and BCMA-CAR-T as labeled in the figure below) in eliminating bone marrow MM progenitors, as depicted in the figure below.

BCMA-CD19 Dual CAR-T Cells Eliminate MM Progenitors More Effectively than BCMA and CD19 Single CAR-T Cells



GC019F: CD19-directed Autologous CAR-T for the Treatment of Adult B Cell Acute Lymphoblastic Leukemia and B Cell Non-Hodgkin's Lymphoma

Overview

GC019F, our FastCAR-enabled autologous CAR-T product candidate, is being studied in an ongoing investigator-initiated Phase 1 trial in China, for the treatment of r/r B-ALL. An investigator-initiated trial for GC019F for the treatment of B-NHL is currently in the planning stage and is expected to begin patient enrollment by the end of 2020.

Background on B Cell Acute Lymphoblastic Leukemia

Acute lymphoblastic leukemia, or ALL, is characterized by the proliferation of immature lymphocytes in the bone marrow. Symptoms may include fatigue, pale skin, fever, easy bleeding or bruising, enlarged lymph nodes and bone pain. ALL progresses rapidly and, if left untreated, is generally fatal within weeks or months. ALL can involve either the T lymphocytes, referred to as T-ALL, or the B lymphocytes, referred to as B-ALL. B-ALL occurs mainly in children and adolescents, with two-thirds of affected patients being male. A second peak incidence occurs later in life, among people over 40 years of age. SOC treatment for T-ALL includes chemotherapy, radiation therapy and stem cell transplantation. Globally, approximately 64,000 patients are diagnosed with ALL every year with over approximately 6,000 expected to be diagnosed in the United States in 2020. B-ALL accounts for 85%-88% of ALL diagnoses.

Ongoing Investigator-initiated Phase 1 Trial and GC019F Future Clinical Plans

GC019F is being studied in an ongoing investigator-initiated Phase 1 trial across multiple centers in China, for the treatment of r/r B-ALL. We have entered into discussions with the CDE with respect to our IND application for GC019F for the treatment of r/r B-ALL. We expect to submit an IND application for GC019F to the NMPA by the end of 2020. Additionally, patient enrollment in an investigator-initiated first-in-human trial in China for GC019F for the treatment of B-NHL is expected to start by the end of 2020. Safety and efficacy of both GC019F and GC007F in the treatment of r/r B-NHL will be studied in first-in-human trials and, if the results support further development, we plan to advance one of the two product candidates into the IND stage.

GC007F: CD19-directed Autologous CAR-T for the Treatment of B Cell Non-Hodgkin's Lymphoma

Overview

GC007F, our FastCAR-enabled autologous CAR-T product candidate, is being studied in an ongoing investigator-initiated Phase 1 trial across multiple centers in China for the treatment of r/r B-NHL.

Background on B Cell Non-Hodgkin's Lymphoma

Lymphomas are a group of blood malignancies that develop from lymphocytes, a type of white blood cell. Symptoms of lymphoma include enlarged lymph nodes, fever, night sweats, weight loss and fatigue. Lymphomas associated with a cell type known as Reed–Sternberg cells, are known as Hodgkin's lymphoma and they account for 15% of lymphomas. All other lymphomas are known as non-Hodgkin's lymphoma. Non-Hodgkin's lymphomas can be further categorized by the predominant lymphocyte type involved. B cell Non-Hodgkin's lymphoma, or B-NHL, is the most common type of adult B cell lymphoma, and includes several sub-types, based on various histologic and cytogenetic factors. Some forms are slow-growing, while others may be more aggressive. SOC treatment of B-NHL includes chemotherapy, radiation therapy, and stem cell transplantation. CAR-T cell therapy targeting CD19 has shown some success in treating B-NHL. However, relapse rate is high and the long-term patient survival is not satisfactory, which is in part due to the limited expansion and persistence of CAR-T cells manufactured using a conventional process. Globally, approximately 510,000 patients are diagnosed with NHL every year with over 77,000 patients expected to be diagnosed in the United States in 2020. B-NHL accounts for approximately 85% of NHL diagnoses.

Ongoing Investigator-initiated Phase 1 Trial and GC007F Future Clinical Plans

GC007F is being studied in an ongoing investigator-initiated Phase 1 trial across multiple centers in China for the treatment of B-NHL. This trial is expected to enroll 12 more patients to further evaluate the safety and efficacy of GC007F in treating r/r B-NHL patients. If the clinical data from this trial or from the future investigator-initiated Phase 1 trial of GC019F for r/r B-NHL support further development, we plan to submit an IND application for either GC007F or GC019F to the NMPA in 2021 and advance that candidate into further clinical trials, including potentially registrational trials.

TruUCAR Off-the-Shelf Allogeneic Product Candidate

GC027: CD7-directed Allogeneic CAR-T for the Treatment of Adult T Cell Acute Lymphoblastic Leukemia

Overview

GC027, our TruUCAR-enabled allogeneic CAR-T product candidate, is being studied in an ongoing investigator-initiated Phase 1 trial across multiple centers in China, for the treatment of adult T-ALL. As of February 2020, we enrolled and treated five adult r/r T-ALL patients. All five evaluable patients achieved a CR or CRi, resulting in an ORR of 100%, including four patients, or 80%, achieving MRD- CR on Day 28 after treatment. The safety profile has been acceptable given the risk benefit in T-ALL and all CRS observed were manageable and resolved with treatment and supportive care. No patient developed neurotoxicity (ICANS) or GvHD.

Background on T Cell Malignancies and T Cell Acute Lymphoblastic Leukemia

T cell malignancies are a group of cancers involving T lymphocytes, including acute T cell lymphoblastic leukemia or T-ALL. Like B-ALL, T-ALL occurs mainly in children, with most affected patients being male. The symptoms of T-ALL are also similar to B-ALL, including fatigue, pallor, fever, easy bleeding or bruising, enlarged lymph nodes and bone pain. SOC treatment for T-ALL includes chemotherapy, radiation therapy and stem cell transplantation. Patients with T cell malignancies usually have high relapse and mortality rates. Due to shared common surface antigen and potential contamination by malignant cells, development of CAR-T cell therapies is lagged behind. In addition, no new therapies have been approved for the treatment of T-ALL since the approval of Nelarabine (marketed by GlaxoSmithKline) by the FDA in 2005. Globally, approximately 64,000 patients are diagnosed with ALL every year with over approximately 6,000 expected to be diagnosed in the United States in 2020. T-ALL accounts for approximately 12-15% of ALL diagnoses.

Dual Functions Single Antigen Targeting with GC027

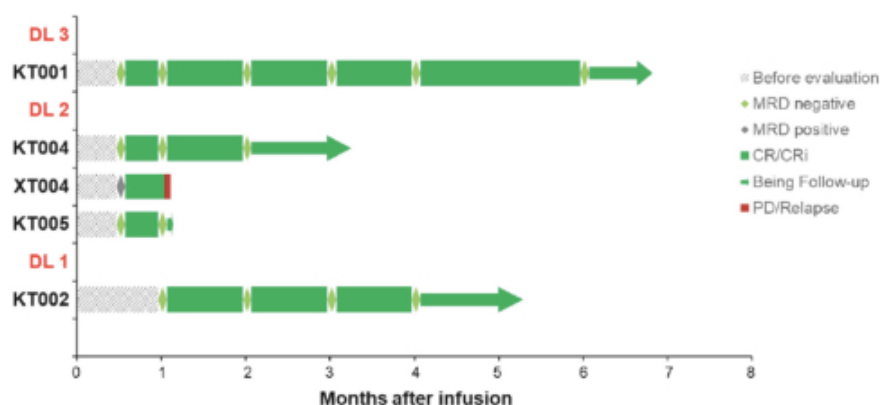
To avoid the potential for HvG, which may lead to rejection of allogeneic CAR-T cells by patients' own immune system, we have designed GC027 with a CD7-directed single CAR that carries out dual functions, targeting both the patient's own alloreactive killer T cells and NK cells as well as tumor antigen to eradicate tumor cells. To alleviate the potential of GvHD, which causes tissue damage in the recipient patient, we utilize CRISPR/Cas9 to disrupt the TRAC locus to eliminate surface expression of the TCR complex of GC027. To eliminate potential fratricide, we utilize CRISPR/Cas9 to disrupt CD7, a pan T and NK marker on the CAR-T cells. In addition, an enhancer is implanted in the CAR-T cells utilizing a lentivirus-based gene delivery system, to strengthen cell expansion and *in vivo* engraftment.

Ongoing Investigator-initiated Phase 1 Trial and Preliminary Evidence of Clinical Benefit

GC027 is being studied in an ongoing investigator-initiated Phase 1 trial across multiple centers in China, for the treatment of adult T-ALL. The primary endpoint of this first-in-human, single-arm and open-label trial is safety, as determined by the occurrence of treatment-related adverse events, such as CRS, neurotoxicity (ICANS) and GvHD. The secondary endpoint is efficacy as determined by clinical response, such as ORR, CR and CRi.

As of February 2020, we had enrolled five adult r/r T-ALL patients. Patients in this trial had failed a median of five prior lines of therapy, with a range of one to nine prior therapies. All patients enrolled had relapsed from, or were refractory to, their prior line of therapy. According to study protocol, all patients in our trial were preconditioned with a multi-drug regimen including fludarabine and cyclophosphamide. No other biologics such as anti-CD52 antibody was given as immune suppressant. Following preconditioning, we treated all patients with a single infusion of GC027, including one patient at dosage level 1, or DL1 (0.6×10^7 CAR+ cells/kg), three patients at dosage level 2, or DL2 (1.0×10^7 CAR+ cells/kg) and one patient at dosage level 3, or DL3 (1.5×10^7 CAR+ cells/kg). As of February 2020, all five patients were evaluable for safety and efficacy assessment.

Response, Duration of Remission and Adverse Events, as of February 2020



Efficacy Results. During the observation period, all five evaluable patients achieved a CR or CRi on Day 14 or Day 28 after treatment, representing an ORR of 100%. Of these patients, three patients achieved MRD- CR on Day 28 after treatment and remained MRD- at follow-up re-evaluations on Day 61, 118 and 161, respectively, without bridging into HSCT and one patient just achieved MRD- CR on Day 28 after treatment, as of the February 2020 data cut-off date. One patient (XT004 as labeled in the figure above) achieved MRD+ CR on Day 14 after treatment, but such patient's disease progressed on Day 29 and deceased due to relapse. No patient has been bridged into HSCT.

Safety Results. During the observation period, all five evaluable patients tolerated their dose levels. Of the five patients, four patients experienced Grade 3 CRS and one patient experienced Grade 4 CRS. CRS symptoms were managed and resolved after treatment and supportive care. No neurotoxicity nor GvHD was observed.

GC027 Future Clinical Plans

We expect to submit IND applications for GC027 to the FDA and the NMPA in 2022. We intend to use the data from this investigator-initiated Phase 1 trial as supportive evidence in our IND applications.

Donor-derived Allogeneic Product Candidate

GC007g: CD19-directed Allogeneic CAR-T for the Treatment of B Cell Acute Lymphoblastic Leukemia

Overview

GC007g, our donor-derived allogeneic CAR-T product candidate, has been studied in a completed investigator-initiated Phase 1 trial across multiple centers in China, for the treatment of B-ALL patients who relapsed after receiving allogeneic stem cell transplantation. We submitted our interim results as of the June 17, 2019 data cutoff date from this trial to the CDE as part of our IND application for GC007g. As of June 17, 2019, we enrolled and treated 14 patients. 11 of 13 evaluable patients achieved a CR, resulting in an ORR of 84.6%, including ten patients, or 76.9%, achieving an MRD- CR on Day 28 after treatment. CRS and neurotoxicity observed were manageable and resolved after treatment and supportive care, except for one early withdrawal due to CRS.

We obtained IND approval to study GC007g in B-ALL from the NMPA on April 1, 2020 and are initiating the Phase 1 trial in China. We submitted an updated innovative seamless Phase 1b/2 study design for GC007g's registration-enabling clinical trial to the CDE in September 2020 which may enable us to roll over the ongoing

Phase 1 clinical trial into the seamless Phase 1b/2 registration-enabling clinical trial in the first half of 2021. Our goal is to submit a BLA to the NMPA for GC007g upon completion of a registrational trial.

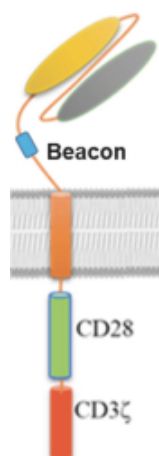
Background

There are a significant portion of B-ALL patients who are not suitable for the autologous CAR-T cell therapy due to various reasons, including but not limited to existing viral infections, high tumor burden, poor quality of their own T cells, conditions prohibitive to leukapheresis and failure to prior autologous CAR-T cell therapies. Reported failure rates of autologous CAR-T cell manufacturing range from 5% to 14%. Under certain circumstances, collection of autologous T cells directly from cancer patients may be difficult due to poor general condition or concomitant viral infections. Donor-derived CAR technology has the potential to resolve the T cell fitness issue associated with autologous CAR-T cell therapies and offer an alternative treatment options for B-ALL patients.

Beacon Tag Monitoring with GC007g

To improve our ability to precisely monitor the number of CAR-T cells in the body and effectively control toxicity in CAR-T cells without compromising efficacy, we inserted a Beacon tag into CD19 CAR construct. As depicted in the figure below, in the GC007g construct, CD19 scFv is joined by a hinge, a transmembrane domain and CD3z intracellular domain. A Beacon tag was inserted to allow precise monitoring of the number of CAR-T cells in the body in using the antibodies against the Beacon tag. Studies both *in vivo* and *ex vivo* have demonstrated that Beacon tag monitoring technology enables accurate calculation of the number of viable CAR-T cells in patients and effectively controls toxicity in CAR-T cells without compromising efficacy.

GC007g Structure



Interim Results from Completed Investigator-Initiated Phase 1 Trial and Preliminary Evidence of Clinical Benefit

We have studied GC007g in an investigator-initiated Phase 1 trial across three independent centers in China, for the treatment of r/r B-ALL. The primary endpoint of this first-in-human, single-arm and open-label trial was safety, as measured by the occurrence of treatment-related adverse events, such as CRS, neurotoxicity (ICANS), GvHD and acute GvHD, or aGvHD. The secondary endpoint was efficacy, as determined by clinical response, such as ORR, CR, PFS and overall survival, or OS.

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We submitted our interim results as of the June 17, 2019 data cutoff date from this investigator-initiated Phase 1 trial to the CDE as part of our IND application for GC007g. As of June 17, 2019, we had enrolled 14 patients. Patients enrolled in the trial had r/r B-ALL and had relapsed after receiving allogeneic stem cell transplantation as the last line of therapy. The study protocol varied across sites, allowing us to explore multiple treatment protocols within a single trial. The study protocol was standardized to the extent possible across sites; however, some variation in methodologies may have occurred due to the flexible nature of this first-in-human study. According to study protocol, patients were preconditioned with fludarabine and cyclophosphamide. Following preconditioning, we administered all patients with a single infusion of GC007g, including three patients at dosage level 1, or DL1 (1.0×10^5 CAR+ cells/kg), nine patients at dosage level 2, or DL2 (2.0×10^6 CAR+ cells/kg) and two patients at dosage level 3, or DL3 (4.2×10^6 CAR+ cells/kg). As of June 17, 2019, all 14 patients were evaluable for safety assessment and 13 patients were evaluable for efficacy assessment. One patient (GG001 as labeled in the figure below) withdrew on Day 8 after treatment due to severe CRS accompanied with infection and the patient failed to receive the efficacy evaluation before such withdrawal.

Efficacy Results. During the observation period, 11 of the 13 evaluable patients responded, resulting in an ORR of 84.6%, including ten patients, or 76.9%, achieving MRD- CR on Day 28 after treatment. 11 patients, or 84.6%, achieved PFS one month after treatment and seven patients, or 77.8%, achieved PFS three months after treatment. The remaining four patients have not reached the three months follow-up time point after GC007g infusion.

Efficacy Results by Dosage, as of June 2019

Efficacy	DL1 (n=3)	DL2 (n=9)	DL3 (n=1)	Overall (n=13)
ORR (Day 28)	3 (100%)	7 (77.8%)	1 (100%)	11 (84.6%)
MRD- (Day 28)	3 (100%)	6 (66.7%)	1 (100%)	10 (76.9%)

Safety Results. During the observation period, 12 patients, or 85.7%, experienced CRS, including one patient, or 7.1%, experiencing Grade 3 or higher CRS. No patient experienced Grade 3 or higher neurotoxicity and two patients, or 14.3%, experienced aGvHD. CRS and GvHD symptoms were managed with SOC treatment.

Safety Results by Dosage, as of June 2019

Safety	DL1 (n=3)	DL2 (n=9)	DL3 (n=2)	Overall (n=14)
CRS	1 (33.3%)	9 (100%)	2 (100%)	12 (85.7%)
Grade 3 or higher CRS	0	1 (11.1%)	0	1 (7.1%)
Neurotoxicity	0	0	0	0
Grade 3 or higher neurotoxicity	0	0	0	0
aGvHD	0	2 (22.2%)	0	2 (14.3%)

GC007g Future Clinical Plans

We obtained the IND approval to study GC007g in B-ALL from the NMPA on April 1, 2020 and are initiating the Phase 1 study in China. We expect to enroll up to nine patients by the first half of 2021. The primary endpoint of this trial is to evaluate the safety and tolerability of GC007g injection in patients with r/r B-ALL after allogeneic transplantation. The secondary endpoint is to evaluate the efficacy of GC007g injection in patients with r/r B-ALL after allogeneic transplantation. We submitted an updated innovative seamless Phase 1b/2 study design for GC007g's registration-enabling clinical trial to the CDE in September 2020 which may enable us to roll over the ongoing Phase 1 clinical trial into the seamless Phase 1b/2 registration-enabling clinical trial in the first half of 2021 and further streamline the clinical development process of GC007g. Our goal is to submit a BLA to the NMPA for GC007g upon completion of a registrational trial.

Preclinical Data

Data from a preclinical study of GC007g demonstrate that CAR-T cells derived from healthy donor T cells showed potency to kill tumor cells expressing CD19 specifically *in vitro* and to eliminate tumor cell very fast in animal model. Co-cultured GC007g CAR-T cells with Hela cells or Hela-CD19 cells can be specifically eliminated. In tumor bearing mice, high dose GC007g eliminated tumor cells on Day 10 after infusion, and no weight loss and other side effects were observed. These data indicate GC007g is a safe and effective CAR-T therapy against CD19+ B cell malignancy.

Early Pipeline and Potential Additional Programs

While we have leveraged our technology platforms to currently pursue the development of CAR-T cell product candidates targeting MM, B-ALL, T-ALL, and B-NHL, we believe our technology platforms have broad applicability across a wide array of cell therapeutic modalities and diseases. We are developing a broad portfolio of preclinical programs beyond our current clinical pipeline. The following table highlights preclinical programs that we are prioritizing:

	Program	Indication	Investigator-initiated trial in China
FasTCAR	GC019F	NHL	4Q2020
	GC122	NHL	2H2021
	GC008E	Ovarian Cancer	2H2021
		Breast Cancer	1H2022
TruUCAR	GC198	B cell malignancies	1H2021
	GC202	PTCL	2H2021
	GC207	T-ALL, T-LBL	1H2022
	GC212	MM	1H2022

NHL = Non-Hodgkin's lymphoma, PTCL = Peripheral T cell lymphoma (a subtype of NHL), T-ALL = T cell acute lymphoblastic leukemia, T-LBL = T cell lymphoblastic leukemia/lymphoma, MM = multiple myeloma

Our lead FasTCAR-enabled preclinical programs include:

- **GC019F.** GC019F is an autologous CAR-T product candidate. An investigator-initiated trial for GC019F for the treatment of B-NHL is currently in the planning stage and is expected to begin patient enrollment by the end of 2020.
- **GC122.** GC122 is an autologous CAR-T product candidate for the treatment of NHL. To further improve the efficacy and reduce relapse rate, we plan to develop this new product candidate with three novel components, namely, a dual CAR-T which targets a new NHL marker, a newly developed scFv which has shown improved activity in pre-clinical studies, and a new molecule to improve persistence. With these novel components, we believe GC122 can provide a new therapeutic modality for NHL.
- **GC008E.** GC008E is a highly differentiated solid tumor CAR-T program designed to address the most significant challenges in treating solid tumors with CAR-T cell therapies. Utilizing FasTCAR and genetic engineering techniques, Enhanced CAR and Dual CAR, GC008E is engineered to enable CAR-T cells to infiltrate, survive and proliferate against immunosuppressive TME. We are developing a portfolio of solid CAR-T product candidates under this program to target mesothelin positive solid tumors, such as ovarian cancer and breast cancer.

Additionally, a significant portion of cancer patients cannot benefit from autologous CAR-T cell therapies due to medical reasons or product quality issues. To address these unmet needs, we plan to advance the following lead TruUCAR-enabled preclinical programs:

- **GC198.** GC198 is a CD19-directed allogeneic CAR-T product candidate for the treatment of B cell malignancies, including B-ALL and B-NHL.
- **GC202.** GC202 is an allogeneic CAR-T product candidate for the treatment of PTCL. PTCL develops from mature T cells and is a subtype of NHL with a high unmet medical need. PTCL patients represent approximately 7-10% and 10-15% of the NHL patient populations in the United States and China. Patients with r/r PTCL usually have poor prognosis and high long-term mortality rates.
- **GC207.** GC207 is an allogeneic CAR-T product candidate for the treatment of T-ALL or T-LBL.
- **GC212.** GC212 is an allogeneic CAR-T product candidate for the treatment of r/r MM. While autologous CAR-T cell therapies for MM have achieved significant success, there are still more than 10% of the MM patient population who are not suitable for autologous CAR-T cell therapy. We are developing this program with additional modifications designed to produce TruUCAR T cells that are more potent and capable to deliver safer and more durable responses.

Our Global Clinical Development Strategy

We seek to bridge the gap between research and development and patient treatments by leveraging our relationships with clinicians and key opinion leaders in China, the United States and Europe. In particular, the clinical development strategy that we have established in partnership with top-tier hospitals in China expedites the initial demonstration of safety and efficacy signal for our product candidates through pre-IND investigator-initiated trials.

Our CAR-T Manufacturing Capacity and Strategy

We control our manufacturing through our two GMP compliant manufacturing facilities in Suzhou and Shanghai with high productivity. The over 66,000 square feet Suzhou GMP facility supports an annual production of 3,200 autologous samples from FasTCAR and 12,000 allogeneic samples from TruUCAR. We have also completed dozens of engineering runs for IND preparation in our Shanghai GMP facility, achieving high product quality and good production repeatability. We have produced hundreds of samples for our product candidates to be used with patients in the ongoing investigator-initiated Phase 1 trials in China.

Our Suzhou and Shanghai manufacturing facilities established fully-closed production lines, designed to produce FasTCAR product candidates while reducing contamination risks and optimizing cost-efficiency. With this fully-closed design, we are able to operate multiple systems in one manufacturing cleanroom at the same time, with each system producing CAR-T cells for an individual patient. This fully-closed system is designed to reduce reagent consumable costs, labor costs, workshop equipment operations and depreciation. We believe these advantages, coupled with our ability to achieve next-day manufacturing for autologous CAR-T cells in one production shift, allow us to substantially reduce manufacturing cost, improve productivity and scale up our production in a cost-efficient manner. We currently produce GC019F and GC007F on our fully-closed production lines. We are self-sufficient in the production of CAR-T cells for clinical development and early stage commercialization. We have the capacity to support our global preclinical and clinical development and early commercialization with our GMP facilities. We also plan to expand our manufacturing capabilities to the United States to enable a local supply of high-quality novel cell therapies.

Competition

The biotechnology industry, and specifically the CAR-T cell therapy sciences, are characterized by intense and rapidly changing competition to develop new technologies and proprietary products. While we believe that

our pioneering technology platforms, know-how and scientific expertise in cell therapies provide us with competitive advantages, we face potential competition from many different sources, including biopharmaceutical companies, academic research institutions, government agencies and public and private research institutions, in addition to SOC treatments. Smaller or early-stage companies may compete with us through collaborative arrangements with more established companies.

Due to the promising clinical therapeutic effect of CAR-T product candidates in clinical trials, we anticipate direct competition from other organizations development advanced T cell therapies and other types of oncology therapies. This would include companies in the CAR-T space, including Nanjing Legend Biotech, bluebird Bio, Inc., Allogene, Inc. Juno Therapeutics, Inc. (acquired by Celgene Corporation), Kite Pharma, Inc. (acquired by Gilead Sciences, Inc.), Poseida Therapeutics, Inc., Celyad Oncology AG, and Novartis AG. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, safer, have fewer or less severe side effects, and more convenient, or cost less than any products that we may develop. Our competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient enrollment for clinical trials.

Intellectual Property

Intellectual property is of vital importance in our field and in biotechnology generally. We seek to protect and enhance proprietary technology, inventions, and improvements that are commercially important to the development of our business by seeking, maintaining, and defending patent rights, whether developed internally, acquired or licensed from third parties.

As of the date of this prospectus, our patent portfolio for our lead product candidates and technology platforms is currently comprised of three Patent Cooperation Treaty applications (which have entered into the national stage in the U.S.), one patent application in China, and three patent applications in Taiwan. We currently do not own or license any issued patents that cover any of our platforms or product candidates. We have applied for patents for our technology platforms, FasTCAR and TruUCAR, and expect to file additional patent applications in support of current and new product candidates and technologies. Our commercial success will depend in part on obtaining and maintaining patent, trade secret and other intellectual property protection for our current and future product candidates and the methods used to develop and manufacture them, as well as successfully defending such intellectual property rights against third-party challenges and operating without infringing, misappropriating or violating the intellectual property rights of others. Furthermore, our ability to develop and commercialize our product candidates, including GC012F and GC027, in certain jurisdictions will depend on our ability to acquire or license intellectual property owned by third parties. In addition, our ability to stop third parties from making, using, selling, offering to sell or importing our products depends on the extent to which we have rights under valid and enforceable patents, trade secrets or other intellectual property rights that cover these activities.

The area of patent and other intellectual property rights in biotechnology is an evolving one with many risks and uncertainties. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting any of our platforms, product candidates, discovery programs and processes. Furthermore, the term of individual patents depends upon the legal term of the patents in the countries in which they are obtained and extend for varying periods depending on the date of filing of the patent application or the date of patent issuance. In most countries in which we file, the patent term is 20 years from the earliest non-provisional filing date. The life of a patent, and the protection it affords, is therefore limited and once the patent life of our issued patents has expired, we may face competition, including from other competing technologies. In China, the expiration of an invention patent is 20 years from its filing date and the expiration of a utility model patent or industrial design is ten years from its filing date. The Draft Amendment to the PRC Patent Law proposed to introduce patent extensions to patents of new drugs that launched in the PRC, the adoption of which may enable the patent owner to submit applications for a patent term extension. The length of any such extension is uncertain. For more information

regarding the risks related to our intellectual property, see “Risk Factors—Risks Related to Our Intellectual Property.”

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. We have not yet selected trademarks for our product candidates and have not yet begun the process of applying to register trademarks for our product candidates. The period of validity for a registered trademark in China 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 canceled. For more comprehensive regulations related to intellectual property protection in the China, see “Regulation—PRC Regulation—Regulatory Protections.” For more information regarding the risks related to trademarks, see “Risk Factors—Risks Related to Our Intellectual Property—Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.”

Furthermore, we rely upon trade secrets, know-how, confidential information, unpatented technologies, continuing technological innovation and other proprietary information to develop, protect and maintain our competitive position and aspects of our business that are not amenable to, or that we do not presently consider appropriate for, patent protection and prevent competitors from reverse engineering or copying our technologies. However, the foregoing rights, technologies and information are difficult to protect. We seek to protect them by, in part, using confidentiality agreements with our employees and consultants and any potential commercial partners and collaborators and invention assignment agreements with our employees. We also have implemented or intend to implement confidentiality agreements or invention assignment agreements with our selected consultants and any potential commercial partners. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any breach. There can be no assurance that these agreements will be self-executing or otherwise provide meaningful protection for our trade secrets or other intellectual property or proprietary information. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. For this and more comprehensive risks related to our intellectual property, see “Risk Factors—Risks Related to Our Intellectual Property.”

Employees

As of September 30, 2020, we had 160 full time employees, 144 of whom hold medical, technical or scientific credentials and qualifications, including 61 holding Ph.D. and/or M.D. degrees. Of these 61 employees, 55 are engaged in research and development activities and six are engaged in business development, finance, information systems, facilities, human resources or administrative support. Substantially all of our employees are located in Suzhou and Shanghai, China. None of our employees are subject to a collective bargaining agreement. We believe that we maintain a good working relationship with our employees, and we have not experienced any material disputes with our employees in our history.

Facilities

Our principal research and development center is located at Building 3, 418 Guilin Road, XuHui District, Shanghai, with approximately 7,700 square meters of office space. We opened our Beijing office in level 14, 126 Jianguo Road, Chaoyang District in January 2020 to support clinical study. We believe that our current facilities are suitable and adequate to meet our current needs. If we need to add new facilities or expand existing facilities

as we add employees, we believe that suitable additional space will be available to accommodate any such expansion of our operations.

Legal Proceedings

We are currently not a party to any material legal or administrative proceedings. We have been, and may from time to time in the future, be subject to various legal and administrative proceedings arising in the ordinary course of our business. Such claims or legal actions, even if without merit, could result in the expenditure of significant financial and management resources and potentially result in civil liability for damages. For risks related to legal proceedings, see “Risk Factors—Risk Related to Our Intellectual Property—We may become involved in lawsuits to protect or enforce our patents and other intellectual property, which could be expensive, time-consuming and unsuccessful” and “Risk Factors—Risk Related to Our Intellectual Property—Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could significantly harm our business.”

REGULATION

United States Regulation

The FDA and other regulatory authorities 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, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, 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 product candidates.

In the United States, the FDA regulates biologic products under the Federal Food, Drug and Cosmetic Act, its implementing regulations and other laws, including, in the case of biologics, the Public Health Service Act. Our product candidates are subject to regulation by the FDA as biologics. Biologics require the submission of a BLA and licensure, which constitutes approval, by the FDA before being marketed in the United States. None of our product candidates has been approved by the FDA for marketing in the United States, and we currently have no BLAs pending. Failure to comply with applicable FDA or other requirements at any time during product development, clinical testing, the approval process or after approval may result in administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, suspension or revocation of approved applications, warning letters, product recalls, product seizures, total or partial suspensions of manufacturing or distribution, injunctions, fines, civil penalties or criminal prosecution.

The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's good laboratory practices, or GLP, regulations;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety and effectiveness of the proposed biologic product candidate for its intended indications;
- preparation of and submission to the FDA of a BLA when adequate data are obtained from pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA to accept the application for review;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with Good Clinical Practices, or GCP regulations; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical and Clinical Development

Prior to beginning the first clinical trial with a product candidate in the United States, we must submit an IND application to the FDA. An IND application is a request for authorization from the FDA to administer an

investigational new drug product to humans. The central focus of an IND application is on the general investigational plan and the protocol(s) for clinical studies. The IND application also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls, or CMC, information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. If the IND sponsor is not able to address FDA's concerns satisfactorily within the 30-day time frame, the IND may be placed on clinical hold. The IND sponsor and the FDA must resolve any outstanding concerns or questions before the IND is cleared by the FDA and the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, 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. Generally, 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. 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 studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, or DSMB, which provides recommendation on whether or not a study should move forward at designated check points based on access to certain data from the study. The DSMB may recommend halting of the clinical trial if it determines that there is an unacceptable safety risk for subjects or on other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- **Phase 1.** The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. For investigational products developed for oncology indications, the Phase 1 trials are normally conducted in patients with serious or life-threatening diseases without other treatment alternatives.
- **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. For certain indications in patients with serious or life-threatening diseases and with no available therapies, it may be possible to obtain BLA approval based on data from Phase 2 trials if a positive benefit risk profile is demonstrated.
- **Phase 3.** The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

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. These so-called Phase 4 studies may be made a condition to approval of the BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must 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 product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's CMC, and proposed labeling, among other things. The submission of a BLA requires payment of a substantial application user fee to the FDA unless a waiver or exemption applies.

Once an original BLA has been submitted, FDA has 60 days to determine whether the application can be filed. If FDA determines that an application to be deficient, on its face, in a way that precludes a complete review, FDA may not accept the application for review and may issue a refuse-to-file letter to the sponsor. If FDA determines the application is fillable, the FDA's goal is to review standard applications within ten months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facilities in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued 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 are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. 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.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the commercial product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter 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 Complete Response letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. 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. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, 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. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. The fast track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for frequent interactions with the review team during product development and, once a BLA is submitted, the product may be eligible for priority review. A fast track product may also be eligible for rolling review, in which case the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A product intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product, including involvement of senior managers.

Any marketing application for a biologic submitted to the FDA for approval, including a product with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition compared to marketed products. For products containing new molecular entities, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (compared with ten months under standard review).

Additionally, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the

FDA will generally require the sponsor to perform adequate and well- controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

In 2017, FDA established a new regenerative medicine advanced therapy, or RMAT, designation as part of its implementation of the 21st Century Cures Act, which was signed into law in December 2016. The RMAT designation program is intended to fulfill the 21st Century Cures Act requirement that FDA facilitate an efficient development program for, and expedite review of, any drug that meets the following criteria: (1) it qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. Like fast track and breakthrough therapy designation, RMAT designation provides potential benefits that include more frequent meetings with the FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review.

Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. Once approved, when appropriate, the FDA can permit fulfillment of post-approval requirements under accelerated approval through the submission of clinical evidence, clinical studies, patient registries, or other sources of real-world evidence such as electronic health records; through the collection of larger confirmatory datasets; or through post-approval monitoring of all patients treated with the therapy prior to approval.

Fast track designation, breakthrough therapy designation, priority review, accelerated approval, and RMAT designation do not change the standards for approval but may expedite the development or approval process.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making available a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record keeping, reporting of adverse experiences, periodic reporting, 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 prior FDA review and approval. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior 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 and other aspects of regulatory compliance.

The FDA may withdraw 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-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning 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; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. 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 and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product be biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered to a patient more than once, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the FDA may not approve a biosimilar product until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of the competing product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate implementation and impact of the BPCIA is subject to significant uncertainty.

Other Healthcare Laws and Compliance Requirements

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation: the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under any federal healthcare program; federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment to the federal government, including federal healthcare programs, that are false or fraudulent; the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes which prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters, and which, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, also imposes certain requirements on HIPAA covered entities and their business associates relating to the privacy, security and transmission of individually identifiable health information; the U.S. federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to the federal government, information related to payments or other transfers of value made to physicians, as defined by such law, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and U.S. state and foreign law equivalents of each of the above federal laws, which, in some cases, differ from each other in significant ways, and may not have the same effect, thus complicating compliance efforts. If their operations are found to be in violation of any of such laws or any other governmental regulations that apply, they may be subject to significant penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare

programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product for which we obtain regulatory approval. Sales of any product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. As there is no uniform policy of coverage and reimbursement for drug products among third-party payors in the United States, coverage and reimbursement policies for drug products can differ significantly from payor to payor. There may be significant delays in obtaining coverage and reimbursement as the process of determining coverage and reimbursement is often time-consuming and costly which will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage or adequate reimbursement will be obtained. It is difficult to predict at this time what government authorities and third-party payors will decide with respect to coverage and reimbursement for our drug products. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical or biological products, medical devices and medical services, in addition to questioning safety and efficacy.

Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of reform proposals to change the healthcare system. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state legislative initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded healthcare programs, and increased governmental control of drug pricing.

In March 2010, the ACA was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The ACA contains a number of provisions of particular import to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs, 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, and annual fees based on pharmaceutical

companies' share of sales to federal healthcare programs. Since its enactment, there have been judicial, Congressional, and executive branch challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, the 2020 federal spending package permanently eliminates, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. In addition, the Tax Act was enacted, which, among other things, removes penalties for not complying with ACA's individual mandate to carry health insurance. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how this decision, future decisions, subsequent appeals, if any, and other efforts to repeal and replace the ACA will impact the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year and reduced payments to several types of Medicare providers, which will remain in effect through 2029 unless additional Congressional action is taken. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration's budget proposal for fiscal year 2021 includes a US\$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. Further, the Trump administration released a "Blueprint," or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug 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. The Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, the Centers for Medicare & Medicaid Services, or CMS, issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. While some of measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, 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.

PRC Regulation

In the PRC, we operate in an increasingly complex legal and regulatory environment. 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.

PRC Drug Regulation

Introduction

China strictly supervises and regulates the development, approval, manufacturing and distribution of drugs, including biologics. The specific regulatory requirements applicable depend on whether the drug is made and

finished in China, which is referred to as a domestically manufactured drug, or made abroad and imported into China in finished form, which is referred to as an imported drug, as well as the approval or “registration” category of the drug. For both imported and domestically manufactured drugs, China typically requires regulatory approval for a clinical trial application, or CTA, to conduct clinical trials in China and submit China clinical trial data, prior to submitting an application for marketing approval. For a domestically manufactured drug, there is also a requirement to have a drug manufacturing license for a facility in China.

In 2017, the drug regulatory system entered a new and significant period of reform. The General Office of the State Council and the General Office of the Central Committee of the Communist Party of China jointly issued the Opinion on Deepening the Reform of the Evaluation and Approval System to Encourage Innovation in Drugs and Medical Devices, or the Innovation Opinion in October 2017. The expedited programs and other advantages under this and other recent reforms encourage drug manufacturers to seek marketing approval in China first, manufacture domestically, and develop drugs in high priority disease areas, such as oncology.

To implement the regulatory reform introduced by the Innovation Opinion, the NPC and the NMPA has been revising the fundamental laws, regulations and rules regulating pharmaceutical products and the industry, which include the framework law known as the PRC Drug Administration Law, or Drug Administration Law. Drug Administration Law was promulgated by the Standing Committee of the NPC on September 20, 1984 and last amended on August 26, 2019 and took effect as of December 1, 2019. The Drug Administration Law is implemented by a high-level regulation issued by the State Council referred to as the Implementing Regulations of the PRC Drug Administration Law. The NMPA has its own set of regulations further implementing Drug Administration Law; the primary one governing CTAs, marketing approval, and post-approval amendment and renewal is known as the Drug Registration Regulation, or DRR. The DRR was promulgated by the State Food and Drug Administration (the predecessor of CFDA and NMPA), or SFDA on February 28, 2005 and the latest amendment of DRR promulgated by the State Administration for Market Regulation (the “SAMR”) in January 2020 took effect as of July 1, 2020. Although the NMPA has issued several notices and proposed regulations in 2018 and 2019 to implement the reforms, the implementing regulations for many of the reforms in the Innovation Opinion have not yet been finalized and issued, and therefore, the details regarding the implementation of the regulatory changes remained uncertain in some respects.

Regulatory Authorities and Recent Government Reorganization

In the PRC, the NMPA is the primary regulatory agency for pharmaceutical products and businesses. The agency was formed from the prior China Food and Drug Administration, or CFDA, in 2018 as part of a government reorganization. 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 CFDA’s functions with respect to drug supervision has been transferred to NMPA, a newly established regulatory authority responsible for registration and supervision of drugs, cosmetics and medical equipment under the supervision of the SAMR, which are responsible for consumer protection, advertising, anticorruption, pricing and fair competition matters. The CFDA was canceled following the structure reform of administrative organs led by the State Council.

Like the CFDA, the NMPA is still the primary drug regulatory agency and implements the same laws, regulations, rules, and guidelines as the CFDA, and it regulates almost all of the key stages of the life-cycle of pharmaceutical products, including nonclinical studies, clinical trials, marketing approvals, manufacturing, advertising and promotion, distribution, and pharmacovigilance (i.e., post-marketing safety reporting obligations). The Center for Drug Evaluation, or CDE, which remains under the NMPA, conducts the technical evaluation of each drug and biologic application to assess safety and efficacy.

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

hospitals and other medical personnel. NHC plays a significant role in drug reimbursement. Furthermore, the NHC and its local counterparts at or below the provincial level of local government also oversee and organize public medical institutions' centralized bidding and procurement process for pharmaceutical products, through which public hospitals and their pharmacies acquire drugs.

Also, as part of the 2018 reorganization, the PRC government formed the National Healthcare Security Administration which focuses on regulating reimbursement under the state-sponsored insurance plans.

Non-Clinical Research and Animal Experiment

The NMPA requires preclinical data to support registration applications for imported and domestic drugs. According to the DRR, nonclinical safety studies must comply with the Administrative Measures for Good Laboratories Practice of Non-clinical Laboratory. On August 6, 2003, the SFDA (the predecessor of CFDA and NMPA) promulgated the Administrative Measures for Good Laboratories Practice of Nonclinical 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 SFDA on April 16, 2007, the SFDA 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 SFDA 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 SFDA if all the relevant requirements are satisfied, which will also be published on the SFDA'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 Ministry of Science and Technology and other regulatory authorities on December 5, 2001, using and breeding experimental animals shall be subject to some rules and performing experimentation on animals requires a Certificate for Use of Laboratory Animals.

Registration Categories

Prior to engaging with the NMPA on research and development and approval, an applicant will need to determine the registration category for its drug candidate (which will ultimately need to be confirmed with the NMPA), which will determine the application requirements for its clinical trial and marketing application. In March 2016, the CFDA issued the Reform Plan for Registration Category of Chemical Medicine, according to which, there are five categories for small molecule drugs: Category 1, or innovative drugs, refers to drugs that have a new chemical entity that has not been marketed anywhere in the world, Category 2, or improved new drugs, refers to drugs with a new indication, dosage form, route of administration, combination, or certain formulation changes not approved in the world, Category 3 is for domestic generics that reference an innovator drug marketed abroad but not in China, Category 4 is for domestic generics that reference an innovator drug marked in China, and Category 5 refers to an application to import into China innovative or generic drugs that have already been marketed abroad. As a support policy and implementing rule of the Registration Measures newly amended in 2020, the NMPA issued the Chemical Drug Registration Classification and Application Data Requirements in June 2020, effective in July 2020, which reaffirmed the principles of the classification of chemical drugs set forth by the Reform Plan for Registration Category of Chemical Medicine, and made minor adjustments to the subclassifications of Category 5. According to such rule, Category 5.1 are innovative chemical

drugs and improved new chemical drugs while Category 5.2 are generic chemical drugs, all of which shall have been already marketed abroad but not yet approved in China.

Therapeutic biologics follow a somewhat similar categorization, with three out of the 15 categories depending on marketing approval status: Category 1 is for innovative biologics that have not been approved inside or outside of China, Category 7 for biologics that have been marketed abroad but not in China, and Category 15 for biologics that have been marketed in China, and the rest of the 15 categories depending on products characteristics. All biologics follow the new drug application pathway, but a tentative guideline on the development and evaluation of biosimilar drugs was issued by the CFDA in 2015.

Expedited Programs

Priority Evaluation and Approval Programs to Encourage Innovation

The NMPA and its predecessors has adopted several expedited review and approval mechanisms since 2009 and created additional expedited programs in recent years that are intended to encourage innovation. Applications for these expedited programs can be submitted together with the registration package or after the registration submission is admitted for review by the CDE. The Announcement of Three Documents Including “Working Procedures for Review of Breakthrough Therapeutics (Trial)” promulgated by NMPA on July 7, 2020 clarifies that during clinical trials of drugs, innovative drugs or improved new drugs that are used to prevent and treat severely life threatening diseases which no effective prevention and treatment methods are available or there is sufficient evidence to show such drugs have obvious clinical advantages compared with existing treatment methods, etc., applicant can apply for breakthrough therapeutic drug program in Phase 1 and Phase 2 clinical trials, usually no later than the start of Phase 3 clinical trials.

If admitted to one of these expedited programs, an applicant will be entitled to more frequent and timely communication with reviewers at the CDE, expedited review and approval, and more agency resources throughout the review approval process.

NMPA also permits conditional approval of certain medicines based on early phase China clinical trial data or only on foreign approval clinical data. Post-approval the applicant may need to conduct one or more post-market studies. The agency has done this for drugs that meet unmet clinical needs for life-threatening illnesses and also for drugs that treat orphan indications. In 2018, NMPA and NHC established a conditional approval program for drugs designated by the CDE that have been approved in the US, EU and Japan within the last 10 years.

Clinical Trials and Marketing Approval

Upon completion of preclinical studies, a sponsor typically needs to conduct clinical trials in China for registering a new drug. The materials required for this application and the data requirements are determined by the registration category. The NMPA has taken a number of steps to increase efficiency for approving CTAs, and it has also significantly increased monitoring and enforcement of the Administrative Regulations of Quality of Drug Clinical Practice, or the PRC’s GCP to ensure data integrity. The PRC’s GCP was initially promulgated by the SFDA on August 6, 2003 and the latest version came into force on July 1, 2020.

Trial Approval

The clinical trials conducted in China for new drug registration purposes must be approved and conducted at pharmaceutical clinical trial institutions which shall be under the filing administration. In October 2014, the CDFA, National Health and Family Planning Commission and National Administration for Chinese Medicine issued Administration Rule for the Project of Clinical Trial Conducted by Medical and Healthcare Institution, pursuant to which, clinical trials conducted by medical and healthcare institution shall only be implemented in

medical and healthcare institution upon project approved by such medical and healthcare institution, and after the approval of such clinical trial project, such medical and healthcare institution shall file such approval with the medical and healthcare authority that issues its operating license for records. 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 China trial to support development, imported drug applicants may establish a site in China that is part of an international multi-center trial, or IMCT, at the outset of the global trial. Domestically manufactured drugs are not subject to foreign approval requirements, and in contrast to prior practice, the NMPA has recently decided to permit those drugs to conduct development via an IMCT as well.

In 2015, the CFDA began to issue an umbrella approval for all phases (typically three) of a new drug clinical trial, instead of issuing approval phase by phase. For certain types of new drug candidates, CTAs may be prioritized over other applications and put in a separate expedited queue for approval.

The NMPA has now adopted a system for clinical trials of new drugs where trials can proceed if after 60 business days, the applicant has not received any objections from the CDE. China is also expanding the number of trial sites by changing from a clinical trial site certification procedure into a notification procedure.

Drug Clinical Trial Registration

According to the DRR, after the completion of the pharmaceutical, pharmacological and toxicological research of the drug clinical trial, the applicant may submit relevant research materials to CDE for applying for the approval to conduct drug clinical trial. The CDE will organize pharmaceutical, medical and other technicians to review the application and to decide whether to approve the drug clinical trial within 60 days of the date of acceptance of the application. Once the decision is made, the result will be notified to the applicant through the website of the CDE and if no notice of decision is issued within the aforementioned time limit, the application of clinical trial shall be deemed as approval. The Registration Measures further requires that the applicant shall, prior to conducting the drug clinical trial, register the information of the drug clinical trial plan, etc. on the Drug Clinical Trial Information Platform. During the drug clinical trials, the applicant shall update registration information continuously, and register information of the outcome of the drug clinical trial upon completion. The applicant shall be responsible for the authenticity of the drug clinical trial information published on the platform. On September 6, 2013, the CDFA released the Announcement on Drug Clinical Trial Information Platform, pursuant to which, 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 be annulled.

Human Genetic Resources Approval

According to the Interim Measures for the Administration of Human Genetic Resources, jointly promulgated by the Ministry of Science and Technology and the MOH on June 10, 1998, an additional approval is required for any foreign companies or foreign affiliates that conduct trials in China. Prior to beginning a trial, the foreign sponsor and the Chinese clinical trial site are required to obtain approval from the Human Genetic Resources Administration of China, or the HGRAC, which is an agency under the Ministry of Science and Technology, to collect any biological samples that contain the genetic material of Chinese human subjects, and to transfer any cross-border transfer of the samples or associated data. Furthermore, one of the key review points for the HGRAC review and approval process is the IP sharing arrangement between Chinese and foreign parties. The parties are required to share patent rights to inventions arising from the samples. Conducting a clinical trial in China without obtaining the relevant HGRAC preapproval will subject the sponsor and trial site to administrative liability, including confiscation of HGRAC samples and associated data, and administrative fines.

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 the sampling, collecting or research activities of human genetic resources by a foreign-invested sponsor fall within the scope of international cooperation, and the cooperating organization of China shall apply for approval of the HGRAC through the 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 May 28, 2019, the State Council of PRC issued the Administration Regulations on Human Genetic Resources, which became effective on July 1, 2019. The Administration Regulations on Human Genetic Resources formalized the approval requirements pertinent to research collaborations between Chinese and foreign-owned entities. Pursuant to the 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 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 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, or 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 consistent with the relevant requirements under the GCP of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, or ICH. 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 the need for pre-approval clinical trials inside China. Specifically, on October 23, 2018, the NMPA and the NHC jointly issued the Procedures for Reviewing and Approval of Clinical Urgently Needed Overseas New Drugs, which established a program permitting drugs that have been approved within the last ten years in the United States, EU or Japan and that i) treat orphan diseases, ii) prevent or treat serious life-threatening illnesses for which there is either no effective therapy or prevention in China, or iii) prevent or treat serious life-threatening illnesses and 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 is marketed.

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 to further verify the drug candidate's therapeutic efficacy and safety in 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. The NMPA requires that the different phases of clinical trials in China receive ethics committee approval and comply with the PRC's GCP. The NMPA conducts inspections to assess the PRC's GCP compliance and will cancel the CTA if it finds substantial issues.

On August 6, 2003, the SFDA promulgated the PRC's GCP to improve the quality of clinical trials. According to the latest PRC's GCP jointly issued by NMPA and MHC and came into effect on July 1, 2020, the

sponsor shall provide insurance to the subjects participating in the clinical trial and bear the cost of the treatment and the corresponding financial compensation for the subjects who suffer harm or death related to the trial. The sponsor shall provide legal and economic guarantee compatible with the nature and degree of risk of clinical trials to the investigator and clinical trial institution, but harm or death caused by the fault or negligence of the investigator or clinical trial institution shall be excluded. Pursuant to the Innovation Opinion, the accreditation of the institutions for drug clinical trials shall be subject to record-filing administration. The conduct of clinical trials must adhere to the PRC's GCP, and the protocols must be approved by the ethics committees of each study site. Pursuant to the newly amended Drug Administration Law, and the Regulations on the Administration of Drug Clinical Trial Institution jointly promulgated by NMPA and NHC on November 29, 2019 and effective from December 1, 2019, drug clinical trial institutions shall be under filing administration. Entities that only conduct analysis of biological samples related to clinical trials of drugs do not need to be filed.

New Drug Application and Approval

Upon completion of clinical trials, a sponsor may submit clinical trial data to support marketing approval for the drug. For imported drugs, this means issuance of an import license. Again, the applicant must submit evidence of foreign approval, unless it is an innovative drug that has never been approved anywhere in the world.

New drug application, or NDA, sponsors must submit data derived from domestically manufactured drugs in support of a drug approval. Under the current regime, upon approval of the registration application, the NMPA will first issue a new drug certificate to the applicant. Only when the applicant is equipped with relevant manufacturing capability will the NMPA issue a Drug Approval Serial Number, which is effectively the marketing approval allowing the holder to market/commercialize the drug in China.

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.

Pursuant to the newly amended Drug Administration Law, under the drug marketing authorization holder mechanism, an enterprise or a research and development institution which has obtained a drug registration certificate is eligible to be a pharmaceutical marketing authorization holder, and this pharmaceutical marketing authorization holder shall be responsible for nonclinical laboratory studies, clinical trials, production and distribution, post-market studies, and the monitoring, reporting, and handling of adverse reactions in connection with pharmaceuticals in accordance with the provisions of the Drug Administration Law. The pharmaceutical marketing authorization holder may engage contract manufacturers for manufacturing, provided that the contract manufacturers are licensed and may engage pharmaceutical distribution enterprises with drug distribution license for the distribution activities. Upon the approval of the medical products administrative department under the State Council, a drug marketing authorization holder may transfer the drug marketing license and the transferee shall have the capability of quality management, risk prevention and control, and liability compensation to ensure the safety, effectiveness and quality controllability of drugs, and fulfill the obligations of the drug marketing license holder.

Manufacturing and Distribution

According to the newly amended Drug Administration Law and the implementing Measures of the Drug Administration Law, all facilities that manufacture drugs in China must receive a Drug Manufacturing License with an appropriate "scope of manufacturing" from the local drug regulatory authority. This license must be renewed every five years.

Similarly, to conduct sales, importation, shipping and storage, or distribution activities, a company must obtain a Drug Distribution License with an appropriate "scope of distribution" from the local drug regulatory authority, subject to renewal every five years.

China has formed a “Two Invoice System” to control distribution of drugs. The “Two-Invoice System” generally requires that no more than two invoices may be issued throughout the distribution chain, with 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 their exclusive distributor, or from a distributor to its wholly owned or controlled subsidiary (or between the 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 will become a prerequisite for pharmaceutical companies to participate in procurement processes with public hospitals, which currently provide most of China’s healthcare. Manufacturers and distributors that fail to implement the Two-Invoice System may lose their qualifications to participate in the bidding process for centralized purchasing. 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 that are involved in pilot comprehensive medical reforms, but the program has expanded to nearly all provinces, which have their own individual rules for the program.

Human Cell Therapy

On March 20, 2003, the State Drug Administration (the predecessor of the SFDA), or the SDA, published the Technical Guidelines for Research on Human Cell Therapy and Quality Control of Preparations, which set some principles for the research of human cell therapy.

Pursuant to the DRR promulgated by the SFDA on July 10, 2007 and effective from October 1, 2007, human cell therapy and its products belong to biological products and the application for biological products shall be submitted as the process of new drug application.

On March 2, 2009, the MOH published the Management Measures for Clinical Application of Medical Technology, which came into effect on May 1, 2009 and prescribed that cell immunotherapy belongs to the Category 3 medical technology of which the clinical application shall be subject to the additional provisions of the MOH. In May, 2009, the MOH published the First List of Category 3 Medical Technologies Allowed for Clinical Application, or the Category 3 Medical Technologies which prescribed cell immunotherapy technology as Category 3 medical technologies were allowed for clinical application, and was abolished by the Notice on the Relevant Work Concerning Cancellation of the Category Three of Medical Technology Entry Approval of Clinical Application on June 29, 2015. The Notice on the Relevant Work Concerning Cancellation of the Category Three of Medical Technology Entry Approval of Clinical Application also cancelled the approval of Category 3 medical technology clinical application.

On November 30, 2017, the CFDA promulgated the Notice of Guidelines for Acceptance and Examination of Drug Registration (Trial), the application of clinical trials of therapeutic biological products and the production and listing application of therapeutic biological products shall be subject to the provisions thereof. On December 18, 2017, the CFDA promulgated the Technical Guiding Principles for Research and Evaluation of Cell Therapy Products (Trial) to regulate and guide the research and evaluation of cell therapy products that are researched on, developed and registered as drugs.

Post-Marketing Surveillance

Pursuant to the newly amended Drug Administration Law, the drug marketing authorization holder shall be responsible for the monitoring, reporting and handling of adverse reactions in connection with pharmaceuticals in accordance with the provisions of Drug Administration Law. Marketing authorization holders, pharmaceutical manufacturer, pharmaceutical distributors and medical institutions shall regularly inspect the quality, efficacy and adverse reactions of drugs manufactured, distributed and used by them. Cases of suspected adverse reactions

shall be promptly reported to the drug administrative authorities and the competent health administrative authority. The drug marketing authorization holder shall forthwith stop selling, notify the relevant pharmaceutical distributors and medical institutions to stop sales and use, recall sold drugs, promptly announce recall information if the drugs have quality issues or other safety hazards.

Advertising and Promotion of Pharmaceutical Products

China has a strict regime for the advertising of approved drugs. No unapproved drugs may be advertised. The definition of an advertisement is very broad, and it can be any media that directly or indirectly introduces the product to end users. There is no clear line between advertising and any other type of promotion.

Each advertisement for drugs requires an approval from a local drug regulatory authority, and the content of an approved advertisement may not be altered without filing a new application for approval. An enterprise seeking to advertise a prescription drug may do so only in medical journals jointly designated by NMPA and the NHC, and the advertisement for a prescription drug shall tag “this advertisement is for medical and pharmaceutical professionals reading only.” Drug advertisements are subject to strict content restrictions, which prohibit recommendations by doctors and hospitals and guarantees of effectiveness. Advertising that includes content that is outside of the drug’s approval documentation, off-label content, is prohibited. False advertising can result in civil suits from end users and administrative liability, including fines. In addition to advertisements, non-promotional websites that convey information about a drug must go through a separate approval process by a local drug regulatory authority.

Product Liability

The Product Quality Law of the PRC, or the Product Quality Law 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.

On May 28, 2020, the Third Session of the 13th National People’s Congress passed the Civil Code of the People’s Republic of China which will take effect on January 1, 2021, and will replace the current Tort Liability Law of the PRC. According to the Civil Code of the People’s Republic of China, patients have the right to claim compensation from the drug marketing authorization holder, medical institution or manufacturer for damage caused by drug defects.

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 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 were promulgated by the NHFPC on December 25, 2013 and 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. 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.

Regulatory Protections

Non-Patent Exclusivities

New Drug Monitoring Period

According to the DRR and the Implementing Regulations of Drug Administration Law, the NMPA may, for the purpose of protecting public health, provide for an administrative monitoring period of five years for new drugs approved to be manufactured, commencing from the date of approval, to continually monitor the safety of those new drugs. During the monitoring period, the NMPA will not approve another CTA from another applicant for the same type of drug, except if another sponsor has an approved CTA at the time that the monitoring period is initiated it may proceed with its trial and once approved become another drug that is part of the monitoring period.

Regulatory Data Protection

The Innovation Opinion also lays the foundation for the establishment of a system for regulatory data protection to protect innovators. This protection will be available to the undisclosed clinical trial data of drugs falling into the following categories: innovative drugs, innovative therapeutic biologics, drugs that treat orphan diseases, pediatric drugs, and drugs for which there has been a successful patent challenge.

On April 25, 2018, NMPA published a draft on Implementing Regulations for Pharmaceutical Study Data Protection for public comment that would set regulatory data protection for innovative small molecule drugs at six years and for innovative therapeutic biologics at 12 years; pediatric and orphan drugs would receive six years to run concurrently from their approval dates. Full terms of protection would require reliance on local trials or sites of multi-center trials in China and simultaneous submissions of marketing applications in China and other countries. Submissions in China that are up to six years after those made abroad would result in the term being reduced to 1-5 years. Submissions made in China over six years after those made abroad may not receive protection.

Furthermore, the Data Security Law of the PRC (Draft) was published on July 3, 2020 by the Standing Committee of the National People's Congress for public comment. The draft law consists of seven chapters, namely General Provisions, Data Security and Development, Data Security System, Data Security Protection Obligation, Security and Openness of Government Data, Legal Liability and Supplementary Provisions.

Patent-Related Protections

Patent Linkage

The Innovation Opinion also sets forth the basic elements of a patent linkage system to protect innovators, in which a follow-on applicant will be required to specify patents that are relevant to its application and notify relevant patent holders (including, innovators) within a specified period after filing its application, permitting them to sue to protect their rights. The system will require that the NMPA continue to review the potentially infringing follow-on application during any lawsuit by the innovator. However, the NMPA may not approve the follow-on application pending resolution of the patent litigation in favor of the follow-on application or for a specified period of time, whichever is shorter. This reform will require implementing regulations. To date, the NMPA has not issued the relevant implementing regulations.

Patent Term Extension

In early 2019, pursuant to the Innovation Opinion, the NPC issued a proposal for patent term extension as part of a proposed amendment to the Patent Law. Under this proposal, the State Council may grant a patent term extension of up to five years to compensate for delays in the review process for innovative drugs that are applying simultaneously for marketing approval in both China and abroad. The patent term may not be extended to more than 14 years post-marketing. It is not clear when this will be finalized.

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, August 30, 2013 and April 23, 2019, respectively and became effective from 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 canceled. 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 Administrative Measures on China Internet Domain Names promulgated by the Ministry of Information Industry 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, or the MIIT, 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 25 September 2002 which came into effect on 1 December 2002 and last amended on May 28, 2012, which became effective on May 29, 2012. The MIIT is the main regulatory authority 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.

Reimbursement and Pricing

China's national medical insurance program was adopted pursuant to the Decision of the State Council on the Establishment of the Urban Employee Basic Medical Insurance Program issued by the State Council in 1998, under which all employers in urban cities are required to enroll their employees in the basic medical insurance

program. The insurance premium is jointly contributed by the employers and employees. In 2007, the State Council promulgated Guiding Opinions of the State Council about the Pilot Urban Resident Basic Medical Insurance, under which urban residents of the pilot district, rather than urban employees, may voluntarily join Urban Resident Basic Medical Insurance. Participants of the national medical insurance program and their employers, if any, are required to contribute to the payment of insurance premiums on a monthly basis. Program participants are eligible for full or partial reimbursement of the cost of medicines included in the NRDL. A pharmaceutical product listed in the NRDL must be clinically needed, safe, effective, reasonably priced, easy to use, and available in sufficient quantity.

Factors that affect the inclusion of a pharmaceutical product in the NRDL include whether the product is consumed in large volumes and commonly prescribed for clinical use in the PRC and whether it is considered to be important in meeting the basic healthcare needs of the general public. Since 2016, special consideration has been given to, among others, innovative drugs with high clinical value and drugs for serious diseases. In addition, the PRC Ministry of Human Resources and Social Security has also been negotiating with manufacturers of expensive drugs with high clinical demands and proven effectiveness for price cuts in exchange for inclusion into the NRDL.

Government Price Controls

On May 4, 2015, the National Development and Reform Commission, or 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, including drugs reimbursed by government medical insurance funds, patented drugs, and some other drugs. The government regulates prices mainly by establishing a consolidated procurement mechanism, restructuring medical insurance reimbursement standards and strengthening regulation of medical and pricing practices as discussed below.

Centralized Procurement and Tenders

Under 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 must comply with 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.

According to the Notice of Issuing Pilot Program of the Centralized Procurement and Use of Drugs Organized by the State issued by the General Office of the State Council in January 2019, 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.

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. The privacy of human subjects in clinical trials is also protected under regulations. For example, the case report forms must avoid disclosing names of the human subjects.

These laws and regulations governing both the disclosure and the use of confidential patient medical information may become more restrictive in the future, including restrictions on transfer of healthcare data. The Cybersecurity Law that took effect in 2017 designates healthcare as a priority area that is part of critical information infrastructure, and China's cyberspace administration is working to finalize a draft rule on cross-border transfer of personal information.

PRC Regulation of Foreign Investment

On March 15, 2019, the NPC approved the Foreign Investment Law of the PRC, or the Foreign Investment Law, which became effective on January 1, 2020 and replaced the three old rules 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 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" refers 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.

The Foreign Investment Law grants foreign invested entities the same treatment as PRC domestic entities, except for those foreign invested entities that operate in industries deemed to be either "restricted" or "prohibited" in the Negative List. The Foreign Investment Law provides that foreign invested entities operating in foreign restricted or prohibited industries will require market entry clearance and other approvals from relevant PRC governmental authorities.

On December 26, 2019, the State Council promulgated the Implementation Rules to the Foreign Investment Law, which became effective on January 1, 2020. The implementation rules further clarified that the state encourages and promotes foreign investment, protects the lawful rights and interests of foreign investors, regulates foreign investment administration, continues to optimize foreign investment environment, and advances a higher-level opening.

On December 30, 2019, the MOFCOM and the SAMR jointly promulgated Measures for Information Reporting on Foreign Investment, which became effective on January 1, 2020. Pursuant to the Measures for Information Reporting on Foreign Investment, where a foreign investor carries out investment activities in China, the foreign investor or the foreign-invested enterprise shall submit the investment information to the competent commerce department.

In addition, on June 28, 2017, the Ministry of Commerce of the People's Republic of China, or the MOFCOM, and the NDRC, jointly promulgated the Guidance Catalogue of Industries for Foreign Investment

(Revised in 2017), or the Catalogue, which came into effect on July 28, 2017. The Catalogue includes the Catalogue of Industries for Encouraging Foreign Investment, or the Encouraged Catalogue, and the Special Administrative Measures for Access of Foreign Investment (Negative List), or the Negative List. The Encourage Catalogue sets forth the industries and economic activities that foreign investment in China is encouraged to be engaged in. The Negative List sets forth the prohibited or restricted industries or economic activities for foreign investment in China. The Encouraged Catalogue was amended on June 30, 2019, and the Negative List was amended on June 28, 2018, June 30, 2019 and June 23, 2020. Any industry not listed in the Encouraged Catalogue and the Negative List is a permitted industry.

M&A Rules

According to the M&A Rules jointly issued by the MOFCOM, the State Assets Supervision and Administration Commission of the State Council, the SAT, the State Administration for Industry and Commerce (now known as the SAMR), the CSRC and 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 M&A Rules. 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.

Regulations Relating to Employee Stock Incentive Plan

On February 15, 2012, the SAFE promulgated the Stock Option Rules. 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, or 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

The PRC Foreign Exchange Administration Regulations promulgated by the State Council on January 29, 1996, which was amended on January 14, 1997 and August 1, 2008, respectively, are the principal regulations governing foreign currency exchange in China. Under the PRC foreign exchange regulations, payments of current account items, such as profit distributions and trade and service-related foreign exchange transactions, may be made in foreign currencies without prior approval from the State Administration of Foreign Exchange, or SAFE, by complying with certain procedural requirements. In contrast, approval from or registration with appropriate government authorities or designated banks is required when RMB is to be converted into a foreign currency and remitted out of China to pay capital expenses such as the repayment of foreign currency-denominated loans.

Under current regulations, the capital of a foreign-invested enterprise and capital in RMB obtained by the foreign-invested enterprise from foreign exchange settlement must not be used for the following purposes: directly or indirectly used for the payment beyond the business scope of the enterprises or the payment prohibited by relevant laws and regulations; directly or indirectly used for investment in securities, unless otherwise provided by relevant laws and regulations; extending loans to non-related parties, unless permitted by the scope of business; and/or paying the expenses related to the purchase of real estate that is not for self-use, except for the real estate enterprises.

In 2017, new regulations were adopted which, among other things, relax the policy restriction on foreign exchange inflow to further enhance trade and investment facilitation and tighten genuineness and compliance verification of cross-border transactions and cross-border capital flows.

In 2019, SAFE promulgated SAFE Circular 28, which cancelled restrictions on domestic equity investments made with capital funds by non-investing foreign-funded enterprises. If a non-investing foreign-funded enterprise makes domestic equity investment with capital funds obtained from foreign exchange settlement, the investee shall undergo registration formalities for accepting domestic reinvestment and open the “capital account — account for settled foreign exchange to be paid” to receive the corresponding funds according to relevant provisions.

SAFE Circular 37

In July 2014, SAFE promulgated SAFE Circular 37, which replaces the previous SAFE Circular 75. SAFE Circular 37 requires PRC residents, including PRC individuals and PRC corporate entities, to register with SAFE or its local branches in connection with their direct or indirect offshore investment activities. SAFE Circular 37 is applicable to our shareholders who are PRC residents and may be applicable to any offshore acquisitions that we may make in the future.

Under SAFE Circular 37, PRC residents who make, or have prior to the implementation of SAFE Circular 37 made, direct or indirect investments in offshore special purpose vehicles, or SPVs, are required to register such investments with SAFE or its local branches. In addition, any PRC resident who is a direct or indirect shareholder of an SPV, is required to update its registration with the local branch of SAFE with respect to that SPV, to reflect any change of basic information or material events. If any PRC resident shareholder of such SPV fails to make the required registration or to update the registration, the subsidiary of such SPV in China may be prohibited from distributing its profits or the proceeds from any capital reduction, share transfer or liquidation to the SPV, and the SPV may also be prohibited from making additional capital contributions into its subsidiaries in China. In February 2015, SAFE promulgated SAFE Notice 13. Under SAFE Notice 13, applications for foreign exchange registration of inbound foreign direct investments and outbound direct investments, including those required under SAFE Circular 37, must be filed with qualified banks instead of SAFE. Qualified banks should examine the applications and accept registrations under the supervision of SAFE.

Regulations Relating to Dividend Distributions

The principal laws, rules and regulations governing dividend distributions by foreign-invested enterprises in the PRC are the PRC Company Law, promulgated in 1993 and last amended in 2018 and the Foreign Investment Law and its Implementing Regulations, both came into effect on January 1, 2020. Under these requirements, foreign-invested enterprises may pay dividends only out of their accumulated profit, if any, as determined in accordance with PRC accounting standards and regulations. A PRC company is required to allocate at least 10% of their respective accumulated after-tax profits each year, if any, to fund certain capital reserve funds until the aggregate amount of these reserve funds have reached 50% of the registered capital of the enterprises. A PRC company is not permitted to distribute any profits until any losses from prior fiscal years have been offset. Profits retained from prior fiscal years may be distributed together with distributable profits from the current fiscal year.

Labor Laws and Labor Contract Law

Pursuant to the PRC Labor Law promulgated by the Standing Committee of the NPC on July 5, 1994 and last amended on December 29, 2018 and the PRC Labor Contract Law promulgated by the Standing Committee of the NPC on June 29, 2007 and amended on December 28, 2012, employers must execute written labor contracts with full-time employees. All employers must comply with local minimum wage standards. Employers must establish a comprehensive management system to protect the rights of their employees, including a system governing occupational health and safety to provide employees with occupational training to prevent occupational injury, and employers are required to truthfully inform prospective employees of the job description, working conditions, location, occupational hazards and status of safe production as well as remuneration and other conditions. Violations of the PRC Labor Contract Law and the PRC Labor Law may result in the imposition of fines and other administrative and criminal liability in the case of serious violations.

Regulations Relating to Social Insurance and Housing Provident Funds

In addition, according to the PRC Social Insurance Law promulgated on October 28, 2010 by the Standing Committee of the NPC and amended on December 29, 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 like our PRC subsidiaries in China must provide employees with welfare schemes covering pension insurance, unemployment insurance, maternity insurance, work-related injury insurance, medical insurance and housing 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 PRC Enterprise Income Tax Law 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 PRC Enterprise Income Tax Law, the State Council promulgated the Implementation Rules of the Enterprise Income Tax Law on December 6, 2007, which was amended and became effective on April 23, 2019. Under the PRC Enterprise Income Tax Law and the Implementation Rules of the PRC Enterprise Income Tax Law, enterprises are classified as either “resident enterprises” or “non-resident enterprises.” Aside from enterprises established within the PRC, enterprises established outside of China whose “de facto management bodies” are located in China are considered “resident enterprises” and are subject to the uniform 25% enterprise income tax rate for their global income. In addition, the PRC 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 PRC 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.

Rest of World Regulation

For other countries outside of PRC and the United States, the requirements governing the conduct of clinical trials, drug licensing, pricing and reimbursement vary from country to country. In all cases the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles having their origin in the Declaration of Helsinki.

MANAGEMENT**Directors and Executive Officers**

The following table sets forth certain information relating to our directors and executive officers as of the date of this prospectus.

Name	Age	Position
William Wei Cao, Ph.D. B.M.	62	Founder, Chairman of the Board and Chief Executive Officer
Jieyu Zou	31	Director
Ye Shen	47	Director
Guotong Xu M.D., Ph.D.	63	Director
David Guowei Wang M.D., Ph.D.	59	Director
Martina A. Sersch, M.D.	48	Chief Medical Officer
Yili Kevin Xie, Ph.D.	50	Chief Financial Officer

William Wei Cao, Ph.D. B.M., has served as our Chairman of the Board and Chief Executive Officer since May 2017. Dr. Cao has over 30 years of research and development experience in the biotechnology industry. Prior to founding our company, Dr. Cao co-founded Cellular Biomedicine Group, Inc. (Nasdaq: CBMG), a Nasdaq-listed company engaging in developing proprietary cell therapies for the treatment of cancer and degenerative diseases, and served several positions at CBMG, such as chief operating officer, chief executive officer and director, from August 2010 to January 2016. Dr. Cao has extensive research experience in the immune-pharmacology field at Harvard Medical School and Stanford University Medical Center. Dr. Cao holds a Bachelor's degree in Medicine from Fudan University Medical College, Shanghai China, and a Ph.D. in Pharmacology from Medical College of Virginia, Richmond Virginia.

Jieyu Zou, has served as our director since February 2019. Ms. Zou is a Principal with Lilly Asia Ventures, or LAV, primarily focuses on biotechnology investments. Prior to joining LAV in June 2015, she served as investment manager in Fosun healthcare group and was responsible for investment project management. From July 2012 to February 2014, Ms. Zou served as a research associate in Michael Allen Company, where she was primarily responsible for providing consulting services. Ms. Zou holds a Bachelor's degree Biology and Psychology from Peking University, and an M.P.H. degree from Yale University School of Public Health.

Ye Shen, has served as our director since February 2019. Ms. Shen serves as the Managing Director of China at Temasek, covering Temasek's investment efforts in China, including areas such as healthcare, transportation, logistics, industrials and business services. Prior to joining Temasek in February 2014, Ms. Shen served as Investment Director of Goldstone Investment Co. Ltd., the direct investment arm of CITIC Securities from October 2011 to March 2013. From June 2008 to September 2011, Ms. Shen served as a director at Crimson Investment and primarily engaged in private equities investments. From May 2005 to June 2008, she served as Director, Chief Representative of Shanghai office of Merrill Lynch. Ms. Shen served at McKinsey & Company for seven years from September 1996 to April 2005, focusing on advising clients from financial institution and healthcare sectors. Ms. Shen holds a Bachelor's degree in Economics from Peking University and an M.B.A. from Colombia University.

Guotong Xu, M.D., Ph.D., has served as our director since February 2019. Dr. Xu has over 30 years of academia and industry experience in both China and the United States. Dr. Xu has been a professor of Ophthalmology and Pharmacology at Tongji University School of Medicine, or TUSM, since 2008 and a director of The East China Stem Cell Bank located inside TUSM, a center for stem cell research and clinical application in China. From March 2008 to July 2016, Dr. Xu served as dean of Tongji University School of Medicine. Dr. Xu has been an independent director of Guangzheng Group Co., Ltd., a company listed on the Shenzhen Stock Exchange (Stock Code: 002524) and Zhejiang Shapuaisi Pharmaceutical Co., Ltd., a company listed on the Shanghai Stock Exchange (Stock Code: 603168), from June 2018 and August 2020, respectively. Prior to that,

Dr. Xu served as an independent director of Cellular Biomedicine Group Inc. (Nasdaq: CBMG) from November 2014 to November 2016. Dr. Xu holds a Bachelor's degree in Medicine from Harbin Medical University, an M.D. and a Master of Medical Sciences from Peking Union Medical College, Chinese Academy of Medical Sciences, and a Ph.D. in Pharmacology from University of North Texas Health Science Center, Fort Worth, Texas.

David Guowei Wang, M.D., Ph.D., has served as our director since March 2020. Dr. Wang has over 20 years of experience in the healthcare industry. Dr. Wang has served as Partner and Senior Managing Director, Asia, of OrbiMed Advisors LLC, since August 2011. He has served as director of AK Medical Holdings Limited, a company listed on the Hong Kong Stock Exchange (Stock Code: 1789) since April 2016, and as director of Edan Instruments, Inc., a company listed in the Shenzhen Stock Exchange (Stock Code: 300206) since March 2010. Prior to that, Dr. Wang served as Managing Director of Healthcare Investment of WI Harper Group from April 2006 to July 2011. Dr. Wang holds a Bachelor's degree in basic medicine and an M.D. from Peking University School of Medicine, and a Ph.D. in Developmental Biology from California Institute of Technology.

Martina A. Sersch, M.D., has served as our Chief Medical Officer since April 2020. Dr. Sersch has over 25 years of academia and industry experience and extensive experience in cell and gene therapy, immune-oncology, mAb and small molecules in multi-national companies and biotechnology companies. Prior to joining us, Dr. Sersch served as chief medical officer of Mustang Bio, Inc. (Nasdaq: MBIO), a Nasdaq-listed CAR-T and gene therapy company, from October 2018 to September 2019, where she led the clinical development of rare diseases and orphan drug indications and accomplished the successful IND approval of a CAR-T cell therapy in hematology. From December 2016 to September 2018, Dr. Sersch served as executive medical director at Amgen Inc. leading the clinical development and hematology portfolio including global filing activities and regional development strategies. Prior to that, she served as a senior medical director at Roche Genentech from 2011 to 2016, as global biologics strategy leader and global development leader leading global and regional clinical development activities including Europe, Asia and as well as successful global filing activities. Dr. Sersch holds an M.D. from the University of Heidelberg in Germany.

Yili Kevin Xie, Ph.D., has served as our Chief Financial Officer since July 2020. Dr. Xie has over 18 years of experience in healthcare investment. Prior to joining our company, Dr. Xie served in various leadership positions in Fosun Group from March 2015 to July 2020, including as the President of Fosun Healthcare Holdings and Chief Representative of Fosun, New York. Dr. Xie has served as director of ViewRay Inc (Nasdaq: VRAY) since October 2019 and director of Alpha Healthcare Acquisition Corp (Nasdaq: AHACU) since September 2020. From February 2012 to March 2015, Dr. Xie served as Managing Partner for Kinglington Capital, an investment company. He co-founded and served as Portfolio Manager for Locust Walk Capital from April 2010 to February 2012. From January 2009 to January 2010, Dr. Xie served as Healthcare Sector Head for Scopia Capital, a global hedge fund. From 2005 to 2008, he served as Principal and subsequently Managing Director for Great Point Partners, a healthcare hedge fund. Dr. Xie served as an Equity Analyst for Delaware Investments, an asset management firm, from June 2002 to July 2005. Dr. Xie holds a Bachelor's degree from Tianjin University in China, a Ph.D. from The City University in New York, and an M.B.A. from The Wharton School, University of Pennsylvania.

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 is 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 (i) such director, if his interest in such contract or arrangement is material, has declared the nature of his interest at the earliest meeting of the board at which it is practicable for him to do so, either specifically or by way of a general notice, (ii) such director has not been disqualified by the chairman of the relevant board meeting, and (iii) if such contract or arrangement is a transaction with a related party, such transaction has been approved by the audit committee in accordance with

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the Nasdaq rules. The directors may exercise all the powers of the 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 the company or of any third party. None of our non-executive directors has a service contract with us that provides for benefits upon termination of service.

Duties of Directors

Under Cayman Islands law, our directors have a fiduciary duty to act honestly and in good faith with a view to our best interests. Our directors also have a duty to exercise the care, diligence and skill that a reasonably prudent person would exercise in comparable circumstances. In fulfilling their duty of care to us, our directors must ensure compliance with our amended and restated memorandum and articles of association. A shareholder has the right to seek damages if a duty owed by our directors is breached.

The functions and powers of our board of directors include, among others:

- conducting and managing the business of our company;
- representing our company in contracts and deals;
- appointing attorneys for our company;
- selecting and removing senior management;
- providing employee benefits and pensions;
- managing our company's finance and bank accounts;
- evaluating the performance and determining the compensation level of chief executive officer;
- exercising the borrowing powers of our company and mortgaging the property of our company; and
- exercising any other powers conferred by the shareholders meetings or under our amended and restated memorandum and articles of association.

Terms of Directors and Executive Officers

Our directors may be elected by a resolution of our board of directors or by an ordinary resolution of our shareholders. Unless otherwise determined by our company in general meeting, our company shall have not less than directors, and there shall be no maximum number of directors. Our directors are not subject to a term of office and hold office until such time as they are removed from office by ordinary resolution of the shareholders or by the board. A director will be removed from office automatically if the director (i) becomes bankrupt or makes any arrangement or composition with his creditors; (ii) dies or is found by our company to be or becomes of unsound mind; (iii) resigned his office by notice in writing to the company; (iv) without special leave of absence from our board, is absent from three consecutive board meetings; or (v) is removed from office pursuant to any other provisions of the company's post-offering amended and restated memorandum and articles of association.

Our officers are elected by and serve at the discretion of the board of directors.

Board Committees

Our board of directors intends to establish an audit committee, a compensation committee and a nominating and corporate governance committee prior to the completion of this offering. We have adopted a charter for each of the committees. Each committee's members and functions are described below.

Audit Committee

Our audit committee will initially consist of _____, _____ and _____ . _____ will be the chairperson of our audit committee. _____ satisfies the criteria of an audit committee financial expert as set

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forth under the applicable rules of the SEC. Each of _____, _____ and _____ satisfies the requirements for an “independent director” within the meaning of Rule 5605(a)(2) of the Listing Rules of the Nasdaq and will meet the criteria for independence set forth in Rule 10A-3 of the Exchange Act.

The audit committee will oversee our accounting and financial reporting processes and the audits of our financial statements. Our audit committee will be responsible for, among other things:

- selecting the independent auditor;
- pre-approving auditing and non-auditing services permitted to be performed by the independent auditor;
- annually reviewing the independent auditor’s report describing the auditing firm’s internal quality control procedures, any material issues raised by the most recent internal quality control review, or peer review, of the independent auditors and all relationships between the independent auditor and our company;
- review responsibilities, budget, compensation and staffing of our internal audit function;
- reviewing with the independent auditor any audit problems or difficulties and management’s response;
- reviewing and, if material, approving all related party transactions on an ongoing basis;
- reviewing and discussing the annual audited financial statements with management and the independent auditor;
- reviewing and discussing with management and the independent auditors major issues regarding accounting principles and financial statement presentations;
- reviewing reports prepared by management or the independent auditors relating to significant financial reporting issues and judgments;
- discussing earnings press releases with management, as well as financial information and earnings guidance provided to analysts and rating agencies;
- reviewing with management and the independent auditors the effect of regulatory and accounting initiatives, as well as off-balance sheet structures, on our financial statements;
- discussing policies with respect to risk assessment and risk management with management and internal auditors;
- timely reviewing reports from the independent auditor regarding all critical accounting policies and practices to be used by our company, all alternative treatments of financial information within IFRS that have been discussed with management and all other material written communications between the independent auditor and management;
- establishing procedures for the receipt, retention and treatment of complaints received from our employees regarding accounting, internal accounting controls or auditing matters and the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters;
- such other matters that are specifically delegated to our audit committee by our board of directors from time to time; and
- meeting separately, periodically, with management, internal auditors and the independent auditor.

Compensation Committee

Our compensation committee will initially consist of _____, _____ and _____. _____ will be the chairperson of our compensation committee. Each of _____, _____ and _____ satisfies the requirements for an “independent director” within the meaning of Rule 5605(a)(2) of the Listing Rules of the Nasdaq.

Our compensation committee will be responsible for, among other things:

- reviewing, evaluating and, if necessary, revising our overall compensation policies;
- reviewing and evaluating the performance of our directors and relevant senior officers and determining the compensation of relevant senior officers;
- reviewing and approving our senior officers' employment agreements with us;
- setting performance targets for relevant senior officers with respect to our incentive compensation plan and equity-based compensation plans;
- administering our equity-based compensation plans in accordance with the terms thereof; and
- such other matters that are specifically delegated to the compensation committee by our board of directors from time to time.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee will initially consist of _____, _____ and _____. _____ will be the chairperson of our nominating and corporate governance committee.

The nominating and corporate governance committee will be responsible for, among other things:

- selecting and recommending to our board of directors nominees for election by the shareholders or appointment by the board;
- reviewing annually with our board of directors the current composition of our board of directors with regards to characteristics such as independence, knowledge, skills, experience and diversity;
- making recommendations on the frequency and structure of our board of directors meetings and monitoring the functioning of the committees of our board of directors; and
- advising our board of directors 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.

Compensation of Directors and Executive Officers

For the year ended December 31, 2019, we paid an aggregate of approximately RMB2.4 million (US\$0.4 million) in cash and benefits to our executive officers. During the year ended December 31, 2019, we did not pay our non-employee directors. For stock option grants to our executive officers and directors, see “—Employee Stock Option Plan.” We have not set aside or accrued any amount to provide pension, retirement or other similar benefits to our executive officers and 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 three-month advance 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.

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 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 agents, developers, real estate buyers 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.

Employee Stock Option Plan

We adopted an employee stock option plan in April 2019. As of the date of this prospectus, the maximum aggregate number of ordinary shares that may be granted under our employee stock option plan is 7,388,060 ordinary shares. As of the date of this prospectus, awards to purchase a total of 7,017,599 ordinary shares have been granted and are outstanding, excluding awards that were forfeited or cancelled after the relevant grant dates. The following paragraphs summarize the principal terms of our employee stock option plan.

- **Types of Awards.** Our employee stock option plan permits awards of options or similar rights.
- **Plan Administration.** With respect to grants of awards to our directors and officers, our employee stock option plan is administered by our board of directors or a committee designated by our board of directors. With respect to grants of awards to employees, consultants and other eligible persons, our employee stock option plan will be administered by our chief executive officer.
- **Stock Option Award Agreement.** Awards granted under our employee stock option plan are evidenced by a stock option award agreement that sets forth terms, conditions and limitations for each award which may include the term of an award, the provisions applicable in the event the grantee's employment or service terminates, and our authority to unilaterally or bilaterally amend, modify, suspend, cancel or rescind an award.
- **Exercisability.** Unless otherwise agreed by our board of directors, no option granted under our employee stock option plan may be exercised prior to the occurrence of, among other things, an admission of all or any part of our share capital to a recognized stock exchange or the grant of permission by any stock exchange to deal in the same.
- **Exercise Price.** The exercise price of an award will be determined by our board of directors.

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- **Eligibility.** We may grant awards to our employees, officers, directors, contractors, advisors or consultants, as determined by our chief executive officer, provided that prior approval of our board of directors shall be obtained for grants to our officers and directors.
- **Term of the Awards.** The term of each share award granted under our employee stock option plan will be determined by our board of directors.
- **Vesting Schedule.** Unless otherwise approved by our board of directors, the vesting schedule shall be a 48-month vesting schedule consisting of monthly vesting in equal instalments over the 48 months.
- **Transfer Restrictions.** Awards may not be transferred in any manner by the recipient other than by will or the laws of descent and distribution, except as otherwise approved by the board of directors.
- **Termination.** Our employee stock option plan will terminate ten years after its adoption, provided that our board of directors may terminate the plan at any time.

The following table summarizes, as of the date of this prospectus, the options granted under our employee stock option plan to several of our executive officers, excluding awards that were forfeited or cancelled after the relevant grant dates.

Name	Ordinary Shares Underlying Options Awarded	Exercise Price (US\$/Share)	Date of Grant	Date of Expiration
William Wei Cao	—	—	—	—
Jieyu Zou	—	—	—	—
Ye Shen	—	—	—	—
Guotong Xu	*	0.30	September 1, 2017	August 31, 2027
David Guowei Wang	—	—	—	—
Martina A. Sersch	*	1.06	June 15, 2020	June 14, 2030
Yili Kevin Xie	3,000,000	1.06	July 16, 2020	July 15, 2030
Other grantees	2,967,599	0.30 (August 8, 2017 through January 2, 2019) 1.06 (On or after January 3, 2019)	From August 8, 2017	Ten years from date of award
Total	7,017,599			

* Less than 1% of our total outstanding ordinary shares on an as-converted basis.

PRINCIPAL SHAREHOLDERS

Except as specifically noted, the following table sets forth information with respect to the beneficial ownership of our ordinary shares as of the date of this prospectus:

- each of our directors and executive officers;
- all of our directors and executive officers as a group; and
- each person known to us to beneficially own more than 5% of our ordinary shares.

The calculations in the table below are based on 211,451,434 ordinary shares on an as-converted basis outstanding as of the date of this prospectus and ordinary shares issued and 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 of the date of this prospectus, 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 After This Offering	
	Number	%	Number	%
Directors and Executive Officers**:				
William Wei Cao ⁽¹⁾	92,090,000	43.6		
Jieyu Zou	—	—		
Ye Shen	—	—		
Guotong Xu	*	*		
David Guowei Wang	—	—		
Martina A. Sersch.	*	*		
Yili Kevin Xie ⁽²⁾	3,000,000	1.4		
All Directors and Executive Officers as a Group	96,140,000	44.6		
Principal Shareholders:				
Gracell Venture Holdings Limited ⁽¹⁾	92,090,000	43.6		
TLS Beta Pte. Ltd. ⁽³⁾	37,668,351	17.8		
Entities affiliated with LAV ⁽⁴⁾	17,406,346	8.2		
OrbiMed Asia Partners III, L.P. ⁽⁵⁾	26,795,880	12.7		
Entities affiliated with Kington ⁽⁶⁾	19,125,740	9.0		

* Less than 1% of our total ordinary shares on an as-converted basis outstanding as of the date of this prospectus.

** Business address of Dr. William Wei Cao, Dr. Martina A. Sersch and Dr. Yili Kevin Xie is Building 12, Block B, Phase II, Biobay Industrial Park, 218 Sangtian St., Suzhou Industrial Park, Jiangsu Province, China. Ms. Jieyu Zou's business address is Room 2909, 168 Hubin Road, Huangpu District, Shanghai, China. Ms. Ye Shen's business address is Floor 45, Tower 2, Jing An Kerry Center, Nanjing West Road, Shanghai, China. Dr. Guotong Xu's business address is Room 102, No.18, Lane 29, Lingling Road, XuHui District, Shanghai, China. Dr. David Guowei Wang's business address is Unit 4706, Raffles City Shanghai Office Tower, 268 Middle Xizang Road, Huangpu District, Shanghai, China.

(1) Represents 98,000,000 ordinary shares held by Gracell Venture Holdings Limited, a company incorporated in the British Virgin Islands. Gracell Venture Holdings Limited is wholly owned by Land Blossom Limited, a company incorporated in the British Virgin Islands. Land Blossom Limited, under The Cao Family Trust, or the Trust, established under the law of Republic of Singapore and managed by VISTRA Trust (Singapore) Pte. Limited, or the Trustee, is wholly owned and managed by the Trustee. Dr. William Wei Cao is the Settlor of the Trust and Dr. Cao and his family members are the Trust's beneficiaries. Under the terms of the Trust, Dr. Cao has the power to direct the Trustee with respect to the retention or disposal of, and the exercise of any voting and other rights attached to the shares held by Gracell Venture Holdings Limited in our company. The registered address of Gracell Venture Holdings Limited is Sertus Chambers, P.O. Box 905, Quastisky Building, Road Town, Tortola, British Virgin Islands.

(2) Represents 3,000,000 ordinary shares issuable upon exercise of options exercisable within 60 days after the date of this prospectus held by Dr. Xie. Dr. Xie is our Chief Financial Officer.

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- (3) Represents 37,668,351 ordinary shares issuable upon the conversion of 37,668,351 series B-2 preferred shares held by TLS Beta Pte. Ltd., a Singapore corporation. TLS Beta Pte. Ltd. is a direct wholly-owned subsidiary of Temasek Life Sciences Private Limited. Temasek Life Sciences Private Limited, is a direct wholly-owned subsidiary of Fullerton Management Pte Ltd, or FMPL, which in turn is a direct wholly-owned subsidiary of Temasek Holdings (Private) Limited. Temasek Life Sciences Private Limited, FMPL and Temasek Holdings (Private) Limited may be deemed to beneficially own the shares held by TLS Beta Pte. Ltd. The principal business address of Temasek Holdings (Private) Limited, FMPL, Temasek Life Sciences Private Limited and TLS Beta Pte. Ltd. is 60B Orchard Road #06-18 Tower 2, The Atrium@Orchard, Singapore 238891.
- (4) Represents (i) 78,214 and 27,616 ordinary shares held by LAV Biosciences Fund V, L.P., a Cayman Islands limited partnership, and LAV Granite Limited, a British Virgin Island company, respectively and (ii) 17,300,516 ordinary shares issuable upon the conversion of 2,346,402 series A preferred shares held by LAV Biosciences Fund V, L.P., 828,482 series A preferred shares held by LAV Granite Limited, and 14,125,632 series B-2 preferred shares held by LAV Granite Limited. LAV Corporate V GP, Ltd. is the general partner of LAV GP V, L.P., which is the general partner of LAV Biosciences Fund V, L.P. Dr. Yi Shi is a Managing Partner of LAV Corporate V GP, Ltd and has voting power and investment discretion with regard to the shares held of record by LAV Biosciences Fund V, L.P. LAV Granite Limited is wholly owned by LAV Biosciences Fund IV, LP. Dr. Yi Shi is the managing partner of LAV Corporate IV GP, Ltd the general partner of LAV GP IV, L.P., which is the general partner of LAV Biosciences Fund IV, LP. The voting and investment power of shares held by LAV Granite Limited is exercised by Dr. Yi Shi. The registered address of LAV Biosciences Fund V, L.P. is 75 Fort Street, PO Box 1350, Grand Cayman KY1-1108, Cayman Islands. The registered address of LAV Granite Limited is PO Box 4301, Road Town, Tortola, British Virgin Islands.
- (5) Represents (i) 864,383 ordinary shares held by OrbiMed Asia Partners III, L.P., or OPA III, a Cayman Islands exempted limited partnership and (ii) 25,931,497 ordinary shares issuable upon the conversion of 25,931,497 series A preferred shares held by OPA III. OrbiMed Asia GP III, L.P., or OAP GP III, a Cayman Islands exempted limited partnership, is the general partner of OAP III. OrbiMed Advisors III Limited, or Advisors III, a Cayman Islands exempted company, is the general partner of OAP GP III. OrbiMed Advisors LLC, or OrbiMed Advisors, acts as the investment manager to OAP III. By virtue of such relationships, OrbiMed Advisors may be deemed to have voting power and investment power over the securities held by OAP III and as a result, may be deemed to have beneficial ownership over such securities. OrbiMed Advisors exercises voting and investment power through a management committee comprised of Carl L. Gordon, Sven H. Borho, and Jonathan T. Silverstein, each of whom disclaims beneficial ownership of the shares held by OAP III. The principal business address of OAP III is c/o OrbiMed Advisors LLC, 601 Lexington Avenue, 54th Floor, New York, NY 10022.
- (6) Represents (i) 55,232 ordinary shares held by King Star Med LP and (ii) 19,070,508 ordinary shares issuable upon the conversion of 1,656,965 series A preferred shares held by King Star Med LP, 7,533,670 series B-2 preferred shares held by King Star Med LP and 9,879,873 series B-1 preferred shares held by Suzhou Kington Capital Holdings Co., Ltd. King Star Med Management Limited, a company incorporated in the Cayman Islands, is the general partner of King Star Med LP. The voting and investment power of shares held by King Star Med LP is exercised by the two directors, Xianghong Lin and Bin Yu, of King Star Med Management Limited, no one of whom may act alone to vote or dispose of the shares. The voting and investment power of shares held by Suzhou Kington Capital Holdings Co., Ltd. is exercised by the five members of investment committee authorized by its board, no one of whom may act alone to vote or dispose of the shares. The registered address of King Star Med LP is P.O. Box 309 Ugland House, South Church Street, George Town, Grand Cayman KY1-1104, Cayman Island. The registered address of Suzhou Kington Capital Holdings Co., Ltd. is Unit 801, North Building, Suyue Commercial Plaza, 118 West Suzhou Avenue, Suzhou Industrial Park, Suzhou City, Jiangsu Province, China.

As of the date of this prospectus, none of our shares are held by record holders in the United States. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a summary of transactions since January 1, 2018 to which we have been a participant in which the amount involved exceeded or will exceed US\$120,000, and in which any of our then directors, executive officers or holders of more than 5% of any class of our voting securities at the time of such transaction, or any members of their immediate family, had or will have a direct or indirect material interest.

Contractual Arrangements with Our Variable Interest Entities and Their Shareholders

See “Corporate History and Structure—Contractual Arrangements with our VIEs and Their Shareholders.”

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 Incentives

See “Management—Employee Stock Option Plan.”

Other Related Party Transactions

Transactions with Unitex Capital Ltd. In the year ended December 31, 2019, we paid RMB1,358 thousand (US\$200 thousand) to obtain an exclusive license from Unitex Capital Ltd., an entity controlled by Dr. William Wei Cao.

DESCRIPTION OF SHARE CAPITAL

We are a Cayman Islands exempted company incorporated with limited liability and our affairs are governed by our memorandum and articles of association, the Companies Law (as amended) of the Cayman Islands, which we refer to as the Companies Law below and the common law of the Cayman Islands.

Upon the closing of this offering, our authorized share capital will be US\$ divided into shares, of which (i) are designated as ordinary shares of a par value of US\$0.0001 each (the “Ordinary Shares”) and (ii) of such class or classes (however designated) of shares, par value each, as our board of directors may determine in accordance with our amended and restated memorandum and articles of association. All of our issued and outstanding ordinary shares are fully paid.

As of the date of this prospectus, we had (i) Ordinary Shares issued and outstanding, (ii) Series A Preferred Shares, (iii) Series B-1 Preferred Shares, and (iv) Series B-2 Preferred Shares issued and outstanding. All of our shares issued and outstanding prior to the completion of the offering will be fully paid, and all of our shares to be issued in the offering will be issued as fully paid.

Based on the assumed initial offering price of US\$ per ADS, which is the midpoint of the price range set forth on the cover page of this prospectus, we expect these shares and the Preferred Shares will convert into ordinary shares immediately prior to the closing of this offering. However, if our initial offering price is below US\$ per ADS, the number of our ordinary shares to be issued upon the conversion of our Preferred Shares will increase and will depend on the initial public offering price per ADS.

The ratio at which each Preferred Share automatically converts into our ordinary shares in connection with this offering is its original issue price of US\$ per share divided by a conversion price shall equal the lower of (i) the conversion price at the time in effect for such Preferred Share and (ii) the price per share that equals % of our initial offering price per ADS.

Upon the completion of this offering, our board of directors may, without further action by our stockholders, fix the rights, preferences, privileges, and restrictions of up to an aggregate of other shares, including preferred shares, in one or more classes or series and authorize their issuance. These rights, preferences, and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms, and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of our ordinary shares. The issuance of our other shares, including potentially preferred shares, could adversely affect the voting power of holders of ADSs and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of other shares, including preferred shares, could have the effect of delaying, deferring, or preventing a change of control or other corporate action. Upon the completion of this offering, no preferred shares will be outstanding, and we have no present plan to issue any preferred shares.

Our Amended and Restated Memorandum and Articles of Association

Our shareholders intend to 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. The following are summaries of material provisions of the amended and restated memorandum and articles of association that we expect will become effective immediately prior to completion of this offering, and of the Companies Law, insofar as they relate to the material terms of our ordinary shares.

Objects of Our Company. Under our amended and restated 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 law of the Cayman Islands.

Ordinary Shares. Our ordinary shares are issued in registered form and are issued when registered in our register of shareholders. We may not issue shares to bearer. Our shareholders who are nonresidents of the Cayman Islands may freely hold and vote their shares.

Dividends. The holders of our ordinary shares are entitled to such dividends as may be declared by our board of directors. In addition, our shareholders may declare dividends by ordinary resolution, but no dividend shall exceed the amount recommended by our directors. Our amended memorandum and restated articles of association provide that the directors may, before recommending or declaring any dividend, set aside out of the funds legally available for distribution such sums as they think proper as a reserve or reserves which shall, in the absolute discretion of the directors, be applicable for meeting contingencies or for equalizing dividends or for any other purpose to which those funds may be properly applied. Under the laws of the Cayman Islands, our company may pay a dividend out of either profit or the credit standing in our company's share premium account, provided that in no circumstances may a dividend be paid if this would result in our company being unable to pay its debts as they fall due in the ordinary course of business immediately following the date on which the distribution or dividend is paid.

Voting Rights. Holders of our ordinary shares shall be entitled to one vote per ordinary share. Voting at any shareholders' meeting is by show of hands unless a poll is demanded (before or on the declaration of the result of the show of hands). A poll may be demanded by the chairman of such meeting or any one or more shareholders who together hold not less than 10% of the votes attaching to the total ordinary shares which are present in person or by proxy at the meeting.

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 no less than two-thirds of the votes cast attaching to the 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 amended and restated memorandum and articles of association. Holders of the ordinary shares 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 amended and restated 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 a majority of our board of directors. Advance notice of at least ten calendar 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 least one shareholder present or by proxy, representing not less than one-third of all votes attaching to all of our shares in issue and entitled to vote.

The Companies Law does not provide shareholders with an express right to put forth any proposal before an annual meeting of the shareholders. However, the Companies Law may provide shareholders with limited rights to requisition a general meeting, but such rights must be stipulated in the articles of association of our company.

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.

The registration of transfers may, after compliance with any notice required 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 capital paid up at the commencement of the winding up on the shares held by them, respectively 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 the whole of the share capital, the assets will be distributed so that the losses are borne by our shareholders in proportion to the capital paid up at the commencement of the winding up on the shares held by them, respectively.

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. Subject to the Companies Law, our amended and restated memorandum and articles of association and to any applicable requirements imposed from time to time by the Nasdaq, the Securities and Exchange Commission, or by any other recognized stock exchange on which our securities are listed, 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 by our board of directors or by an ordinary resolution of our shareholders. Under the Companies Law, the redemption or repurchase of any share may be paid out of our profits or out of the proceeds of a fresh issue of shares made for the purpose of such redemption or repurchase, or out of capital (including share premium account and capital redemption reserve) if our company can, immediately following such payment, pay its debts as they fall due in the ordinary course of business. In addition, under the Companies Law no such share may be redeemed or repurchased (a) unless it is fully paid up, (b) if such redemption or repurchase would result in there being no shares outstanding or (c) if the company has commenced liquidation. In addition, our company may accept the surrender of any fully paid share for no consideration.

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Variations of Rights of Shares. If at any time our share capital is divided into different classes or series of shares, the rights attached to any class or series of shares (unless otherwise provided by the terms of issue of the shares of that class or series), whether or not our company is being wound-up, may be varied with the consent in writing of the holders of two-thirds of the issued shares of that class or series or with the sanction of a special resolution passed at a separate meeting of the holders of the shares of the class or series. The rights conferred upon the holders of the shares of any class issued shall not, unless otherwise expressly provided by the terms of issue of the shares of that class, be deemed to be varied by the creation or issue of further shares ranking *pari passu* with such existing class of shares.

Issuance of Additional Shares. Our amended and restated memorandum of association authorizes our board of directors to issue additional ordinary shares from time to time as our board of directors shall determine, to the extent of available authorized but unissued shares.

Our amended and restated memorandum of association also authorizes our board of directors to establish from time to time one or more series of preferred shares and to determine, with respect to any series of preferred shares, the terms and rights of that series, including:

- the designation of the series;
- the number of shares of the series;
- the dividend rights, dividend rights, conversion rights, voting rights;
- the rights and terms of redemption and liquidation preferences; and
- any other powers, preferences and relative, participating, optional and other special rights.

Our board of directors may issue preference shares without action by our shareholders to the extent authorized but unissued. Issuance of these shares may dilute the voting power of holders of ordinary shares.

Inspection of Books and Records. Holders of our ordinary shares will have no general right under Cayman Islands law to inspect or obtain copies of our corporate records. However, we will provide our shareholders with annual audited financial statements. See “Where You Can Find Additional Information.”

Anti-Takeover Provisions. Some provisions of our amended and restated 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 amended and restated 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;

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- 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 (except in exceptional circumstances, such as involving fraud, the establishment of an agency relationship or an illegal or improper purpose or other circumstances in which a court may be prepared to pierce or lift the corporate veil).

Differences in Corporate Law

The Companies Law is derived, to a large extent, from the older Companies Acts of England but does not follow recent English statutory enactments and accordingly there are significant differences between the Companies Law and the current Companies Act of England. In addition, the Companies Law differs from laws applicable to U.S. corporations and their shareholders. Set forth below is a summary of certain 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, (i) “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 (ii) 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 written plan of merger or consolidation must be filed with the Registrar of Companies of the Cayman Islands together with a declaration as to the solvency of the consolidated or surviving company, a list of the assets and liabilities of each constituent company and an undertaking that a copy of the certificate of merger or consolidation will be given to the members and creditors of each constituent company and that notification of the merger or consolidation will be published in the Cayman Islands Gazette. 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 of that Cayman subsidiary 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 shares (which, if not agreed between the

parties, will be determined by the Cayman Islands court) upon dissenting to the merger or consolidation, provide 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 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.

The Companies Law also contains a statutory power of compulsory acquisition which may facilitate the “squeeze out” of dissentient minority shareholder upon a tender offer. When a tender offer is made and accepted by holders of 90.0% of the shares affected 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 by way of scheme of arrangement is thus approved and sanctioned, or if a tender 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 to sue for a wrong done to us as a company, 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 court can be expected to follow and apply the common law principles (namely the rule in *Foss v. Harbottle* and the exceptions thereto) so that a non-controlling shareholder may be permitted to commence a class action against or derivative actions in the name of the company to challenge actions where:

- a company acts or proposes to act illegally or ultra vires;
- the act complained of, although not ultra vires, could only be effected duly if authorized by more than a simple majority vote that has not been obtained; and
- those who control the company are perpetrating a “fraud on the minority.”

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 amended and restated memorandum and articles of association provide that we shall indemnify our officers and directors against all actions, proceedings, costs, charges, expenses, losses, damages or liabilities incurred or sustained by such directors or officer, other than by reason of such person's 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 duties, powers, authorities or discretions, including without prejudice to the generality of the foregoing, any costs, expenses, losses or liabilities incurred by such director or officer 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. This standard of conduct is generally the same as permitted under the Delaware General Corporation Law for a Delaware corporation.

In addition, we intend to enter into indemnification agreements with our directors and executive officers prior to the completion of this offering, that provide such persons with additional indemnification beyond that provided in our amended and restated 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 reasonably believes to be in the best interests of the corporation. He must not use his corporate position for personal gain or advantage. This duty prohibits self-dealing by a director and mandates that the best interest 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 exempted company is in the position of a fiduciary with respect to the company and therefore it is considered that he owes the following duties to the company—a duty to act bona fide in the best interests of the company, a duty not to make a profit based on his position as director (unless the company permits him to do so), a duty not to put himself in a position where the interests of the company conflict with his personal interest or his 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 exempted 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 duties a greater degree of skill than may reasonably be expected from a person of his 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 Resolution. 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 amended and restated 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 provides shareholders with only limited rights to requisition a general meeting. However, these rights may be provided in a company's articles of association. Our amended and restated articles of association allow our shareholders holding in aggregate not less than one-third of all votes attaching to the issued and 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. As a Cayman Islands exempted company, we may but are not obliged by law to call shareholders' annual general meetings. See "-Our Amended and Restated Memorandum and Articles of Association-General Meetings of Shareholders" for more information on the rights of our shareholders' rights to put proposals before the annual general meeting.

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 for 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 amended and restated 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 amended and restated articles of association, directors may be removed only for cause by an ordinary resolution of our shareholders. In addition, a director's office shall be vacated if the director (i) becomes bankrupt or makes any arrangement or composition with his creditors; (ii) is found to be or becomes of unsound mind or dies; (iii) resigns his 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 office be vacated; or (v) is removed from office pursuant to any other provisions of our amended and restated 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 amended and restated 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 amended and restated 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 two-thirds 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, unless the certificate of incorporation provides otherwise. Under the Companies Law and our amended and restated memorandum and articles of association, our memorandum and articles of association may only be amended by a special resolution of our shareholders.

Rights of Non-resident or Foreign Shareholders. There are no limitations imposed by our amended and restated memorandum and articles of association on the rights of non-resident or foreign shareholders to hold or exercise voting rights on our shares. In addition, there are no provisions in our post-offering amended and restated memorandum and articles of association governing the ownership threshold above which shareholder ownership must be disclosed.

History of Securities Issuances

The following is a summary of our securities issuances in the past three years:

Ordinary Shares

On March 10, 2018, we issued (i) 1 ordinary share to Sertus Nominees (Cayman) Limited at par value of US\$0.0001 and (ii) 9,999 ordinary shares to Gracell Venture Holdings Limited at par value of US\$0.0001 as part of our reorganization.

On February 22, 2019, we issued (i) 1,044,776 ordinary shares to Voyager Biosciences IV Limited at par value of US\$0.0001 (all of which were subsequently repurchased by us on March 6, 2020) and (ii) 97,990,000 ordinary shares to Gracell Venture Holdings Limited at par value of US\$0.0001 as part of our reorganization.

On March 6, 2020, we issued 1,044,776 ordinary shares to Suzhou Tonghe Venture Investment Partnership II (L.P.) at par value of US\$0.0001 as part of our reorganization.

As part of our reorganization, Dr. William Wei Cao and Suzhou Tonghe Venture Investment Partnership II (L.P.) also relinquished an aggregate of 9,904,477 ordinary shares in our VIE.

Preferred Shares

On February 22, 2019, we issued 31,343,284 series A preferred shares to Voyager Biosciences IV Limited at par value of US\$0.0001 as part of our reorganization.

On March 6, 2020, we issued (i) 18,283,584 series A preferred shares to Suzhou Tonghe Venture Investment Partnership II (L.P.) at par value of US\$0.0001 and (ii) 13,059,700 series A preferred shares to Suzhou Tonghe Yucheng Investment Partnership (L.P.) at par value of US\$0.0001 as part of our reorganization.

As part of our reorganization, certain investors also relinquished an aggregate of 3,656,716 series A preferred shares in our VIE.

On February 22, 2019, we issued (i) 7,533,670 series B-2 preferred shares to King Star Med LP for a purchase price of US\$8.0 million, (ii) 14,125,632 series B-2 preferred shares to LAV Granite Limited for a purchase price of US\$15.0 million and (iii) 37,668,351 series B-2 preferred shares to TLS Beta Pte. Ltd. for a purchase price of US\$40.0 million.

On July 2, 2020, we issued 1,975,975 series B-1 preferred shares to Chengdu Miaoji Medical Technology Co., Ltd. for a purchase price of approximately RMB12.6 million in equivalent U.S. dollars.

On August 25, 2020, we issued 9,879,873 series B-1 preferred shares to Suzhou Kington Capital Holdings Co., Ltd. for a purchase price of approximately RMB63.0 million in equivalent U.S. dollars.

On September 9, 2020, we issued 9,879,873 series B-1 preferred shares to Suzhou Lirui Equity Investment Center (Limited Partnership) for a purchase price of approximately RMB63.0 million in equivalent U.S. dollars.

In October 2020, we entered into a Series C Preferred Share Subscription Agreement with certain investors that the number of series C preferred shares to be issued by us and purchased by these investors is a maximum of 73,379,643 series C preferred shares and the aggregate purchase price amounts to approximately US\$120 million assuming the issuance and purchase with respect to all series C preferred shares available for issuance.

Options

We have granted options to purchase our ordinary shares to certain of our directors, executive officers, employees and consultants. See “Management—Employee Stock Option Plan.”

Shareholders Agreement

We entered into our second amended and restated shareholders agreement on _____ with our shareholders, which consisted of holders of ordinary shares and preferred shares.

The shareholders agreement provides for certain preferential rights, including right of first refusal, co-sale rights and provisions governing the board of directors and other corporate governance matters. Those preferential rights, as well as the corporate governance provisions, will automatically terminate upon the completion of this offering.

Registration Rights

Pursuant to our second amended and restated shareholders agreement dated _____, 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. If at any time beginning six (6) months following the effective date of the registration statement, we receive a written request from the holders of at least 20% of the registrable securities then outstanding that we file a registration statement under the Securities Act covering the registration of the registrable securities of such holders with aggregate gross proceeds (prior to selling expenses) expected to be in excess of US\$25,000,000, then we shall, within ten (10) business days after the receipt of such written request, give written notice of such request ("Request Notice") to all the holders, and use our best efforts to effect, as soon as practicable, the registration under the Securities Act of all the registrable securities that the holders request to be registered and included in such registration by written notice given by such holders to us within twenty (20) days after receipt of the Request Notice. We shall not be obligated to effect more than two (2) such demand registrations.

If the holders requesting registration intend to distribute the registrable securities covered by their request by means of an underwriting, if the underwriter(s) advise(s) us in writing that marketing factors require a limitation of the number of securities to be underwritten, then we shall so advise all holders of registrable securities which would otherwise be registered and underwritten pursuant hereto, and the number of registrable securities that may be included in the underwriting shall be reduced as required by the underwriter(s) and allocated among the holders of registrable securities on a pro rata basis according to the number of registrable securities then outstanding held by each holder requesting registration.

Notwithstanding the foregoing, if we shall furnish to the holders requesting registration a certificate signed by the President or Chief Executive Officer stating that in the good faith judgment of the Board, it would be materially detrimental to us and our Shareholders for such registration statement to be filed at such time, then we shall have the right to defer such filing for a period of not more than ninety (90) days after receipt of the request of the holders.

Registration on Form F-3 or Form S-3. If we receive from any holder of at least five percent (5%) of the registrable securities then outstanding a written request or requests that we effect a registration on Form F-3 or Form S-3 for which the reasonably anticipated aggregate offering price to the public would exceed US\$2,500,000 and any related qualification or compliance with respect to all or a part of the registrable securities owned by such holder, we should promptly give a written notice to all other holders of registrable securities, and effect such registration and all such qualifications and compliances as may be so requested with twenty (20) days after we provided such notice, except in certain circumstances.

Piggyback Registration Rights. If we propose to register for our own account any of our equity securities in connection with the public offering, we shall offer holders of our registrable securities an opportunity to be included in such registration. If a holder decides not to include all of its registrable securities in such registration, such holder will continue to have the right to include any registrable securities in any subsequent registration statement as may be filed by us, subject to certain limitations.

Expenses of Registration. We will bear all registration expenses, other than the underwriting discounts and selling commissions applicable to the sale of registrable securities, incurred in connection with registrations pursuant to the shareholders agreement. Each holder participating in the registration shall bear such holder's proportionate share (based on the total number of shares sold in such registration other than for our account) of all the selling expenses or other amounts payable to underwriter(s) or brokers in connection with such offering by the holders.

Termination of Obligations. The registration rights set forth above will terminate upon the earliest of (a) the fourth (4th) anniversary of consummation of this offering, (b) the termination, liquidation or dissolution of our Company and (c) if and when, in the opinion of our counsel, all such registrable securities proposed to be sold by each holder may be sold without registration in any ninety (90) day period pursuant to Rule 144 promulgated under the Securities Act.

DESCRIPTION OF AMERICAN DEPOSITARY SHARES

American Depositary Receipts

, as depositary, will issue the ADSs which you will be entitled to receive in this offering. Each ADS will represent an ownership interest in a designated number of shares which we will deposit with the custodian, as agent of the depositary, under the deposit agreement among ourselves, the depositary, yourself as an ADR holder and all other ADR holders, and all beneficial owners of an interest in the ADSs evidenced by ADRs from time to time.

The depositary's office is located at .

The ADS to share ratio is subject to amendment as provided in the form of ADR (which may give rise to fees contemplated by the form of ADR). 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.

A beneficial owner is any person or entity having a beneficial ownership interest ADSs. A beneficial owner need not be the holder of the ADR evidencing such ADS. If a beneficial owner of ADSs is not an ADR holder, it must rely on the holder of the ADR(s) evidencing such ADSs in order to assert any rights or receive any benefits under the deposit agreement. A beneficial owner shall only be able to exercise any right or receive any benefit under the deposit agreement solely through the holder of the ADR(s) evidencing the ADSs owned by such beneficial owner. The arrangements between a beneficial owner of ADSs and the holder of the corresponding ADRs may affect the beneficial owner's ability to exercise any rights it may have.

An ADR holder shall be deemed to have all requisite authority to act on behalf of any and all beneficial owners of the ADSs evidenced by the ADRs registered in such ADR holder's name for all purposes under the deposit agreement and ADRs. The depositary's only notification obligations under the deposit agreement and the ADRs is to registered ADR holders. Notice to an ADR holder shall be deemed, for all purposes of the deposit agreement and the ADRs, to constitute notice to any and all beneficial owners of the ADSs evidenced by such ADR holder's ADRs.

Unless certificated ADRs are specifically requested, 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.

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 or beneficial owner, we will not treat you as a shareholder of ours and you will not have any shareholder rights. Cayman Island 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 or of a beneficial owner. Such rights derive from the terms of the deposit agreement to be entered into among us, the depositary and all holders and beneficial owners from time to time of ADRs issued under the deposit agreement and, in the case of a beneficial owner, from the arrangements between the beneficial owner and the holder of the corresponding ADRs. 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 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 a part. 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, DC 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 (if it determines such conversion may be made on a reasonable basis) and, in all cases, making any necessary deductions provided for in the deposit agreement. The depositary may utilize a division, branch or affiliate of _____ to direct, manage and/or execute any public and/or private sale of securities under the deposit agreement. Such division, branch and/or affiliate may charge the depositary a fee in connection with such sales, which fee is considered an expense of the depositary. 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 and/or its agents' 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. *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 timely 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 timely furnish such evidence, the depositary may: (i) sell such rights if practicable and distribute the net proceeds in the same manner as cash to the ADR holders entitled thereto; or (ii) if it is not practicable to sell such rights by reason of the non-transferability of the rights, limited markets therefor, their short duration or otherwise, do nothing and allow such rights to lapse, in which case ADR holders will receive nothing and the rights may lapse.

- *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 in its discretion 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 fails to determine that any distribution or action is lawful or reasonably practicable.

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. All purchases and sales of securities will be handled by the depositary in accordance with its then current policies, which are currently set forth in the "Depositary Receipt Sale and Purchase of Security" section of <https://www.adr.com/Investors/FindOutAboutDRs>, the location and contents of which the depositary shall be solely responsible for.

Deposit, Withdrawal and Cancellation

How does the depositary issue ADSs?

The depositary will issue ADSs if you or your broker deposit shares or evidence of rights to receive shares with the custodian and pay 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 and to the order of the depositary, in each case for the benefit of ADR holders. ADR holders and beneficial owners 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."

Deposited securities are not intended to, and shall not, constitute proprietary assets of the depositary, the custodian or their nominees. Beneficial ownership in deposited securities is intended to be, and shall at all times during the term of the deposit agreement continue to be, vested in the beneficial owners of the ADSs representing such deposited securities. Notwithstanding anything else contained herein, in the deposit agreement, in the form of ADR and/or in any outstanding ADSs, the depositary, the custodian and their respective nominees are intended to be, and shall at all times during the term of the deposit agreement be, the record holder(s) only of the

deposited securities represented by the ADSs for the benefit of the ADR holders. The depositary, on its own behalf and on behalf of the custodian and their respective nominees, disclaims any beneficial ownership interest in the deposited securities held on behalf of the ADR holders.

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. Delivery of deposited securities in certificated form will be made at the custodian's office. 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 (which, to the extent applicable, shall be as near as practicable to any corresponding record dates set by us) 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 deposited securities,
- to give instructions for the exercise of voting rights at a meeting of holders of shares, or
- to pay the fee assessed by the depositary for administration of the ADR program and for any expenses as provided for in the ADR,
- 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 receipt from us of notice of any meeting at which the holders of shares are entitled to vote, or of our solicitation of consents or proxies from holders of shares, the depositary shall fix the ADS record date in accordance with the provisions of the deposit agreement, provided that if the depositary receives a written request from us in a timely manner and at least 30 days prior to the date of such vote or meeting, the depositary shall, at our expense, distribute to the registered ADR holders a “voting notice” stating (i) final information particular to such vote and meeting and any solicitation materials, (ii) that each ADR holder on the record date set by the depositary will, subject to any applicable provisions of Cayman Islands law, be entitled to instruct the depositary as to the exercise of the voting rights, if any, pertaining to the deposited securities represented by the ADSs evidenced by such ADR holder’s ADRs and (iii) the manner in which such instructions may be given, or deemed to be given pursuant to the terms of the deposit agreement, including instructions for giving a discretionary proxy to a person designated by us. Each ADR holder shall be solely responsible for the forwarding of voting notices to the beneficial owners of ADSs registered in such ADR holder’s name. There is no guarantee that ADR holders and beneficial owners generally or any holder or beneficial owner in particular will receive the notice described above with sufficient time to enable such ADR holder or beneficial owner to return any voting instructions to the depositary in a timely manner.

Following actual receipt by the ADR department responsible for proxies and voting of ADR holders’ instructions (including, without limitation, instructions of any entity or entities acting on behalf of the nominee for DTC), the depositary shall, in the manner and on or before the time established by the depositary for such purpose, endeavor to vote or cause to be voted the deposited securities represented by the ADSs evidenced by such ADR holders’ ADRs in accordance with such instructions insofar as practicable and permitted under the provisions of or governing deposited securities.

To the extent that (A) we have provided the depositary with at least 35 days’ notice of the proposed meeting, (B) the voting notice will be received by all ADR holders and beneficial owners no less than 10 days prior to the date of the meeting and/or the cut-off date for the solicitation of consents, and (C) the depositary does not receive instructions on a particular agenda item from an ADR holder (including, without limitation, any entity or entities acting on behalf of the nominee for DTC) in a timely manner, such ADR holder shall be deemed, and in the deposit agreement the depositary is instructed to deem such ADR holder, to have instructed the depositary to give a discretionary proxy for such agenda item(s) to a person designated by us to vote the deposited securities represented by the ADSs for which actual instructions were not so given by all such ADR holders on such agenda item(s), provided that no such instruction shall be deemed given and no discretionary proxy shall be given unless (1) we inform the depositary in writing (and we agree to provide the depositary with such instruction promptly in writing) that (a) we wish such proxy to be given with respect to such agenda item(s), (b) there is no substantial opposition existing with respect to such agenda item(s) and (c) such agenda item(s), if approved, would not materially or adversely affect the rights of holders of shares, and (2) the depositary has obtained an opinion of counsel, in form and substance satisfactory to the depositary, confirming that (i) the granting of such discretionary proxy does not subject the depositary to any reporting obligations in the Cayman Islands, (ii) the granting of such proxy will not result in a violation of the laws, rules, regulations or permits of the Cayman Islands, (iii) the voting arrangement and deemed instruction as contemplated herein will be given effect under the laws, rules and regulations of the Cayman Islands, and (iv) the granting of such discretionary proxy will not under any circumstances result in the shares represented by the ADSs being treated as assets of the depositary under the laws, rules or regulations of the Cayman Islands.

The depositary may from time to time access information available to it to consider whether any of the circumstances described above exist, or request additional information from us in respect thereto. By taking any such action, the depositary shall not in any way be deemed or inferred to have been required, or have had any duty or responsibility (contractual or otherwise), to monitor or inquire whether any of the circumstances described above existed. In addition to the limitations provided for in the deposit agreement, ADR holders and beneficial owners are advised and agree that (a) the depositary will rely fully and exclusively on us to inform it of any of the circumstances set forth above, and (b) neither the depositary, the custodian nor any of their respective agents shall be obliged to inquire or investigate whether any of the circumstances described above exist and/or

whether we complied with our obligation to timely inform the depositary of such circumstances. Neither the depositary, the custodian nor any of their respective agents shall incur any liability to ADR holders or beneficial owners (i) as a result of our failure to determine that any of the circumstances described above exist or our failure to timely notify the depositary of any such circumstances or (ii) if any agenda item which is approved at a meeting has, or is claimed to have, a material or adverse effect on the rights of holders of shares. Because there is no guarantee that ADR holders and beneficial owners will receive the notices described above with sufficient time to enable such ADR holders or beneficial owners to return any voting instructions to the depositary in a timely manner, ADR holders and beneficial owners may be deemed to have instructed the depositary to give a discretionary proxy to a person designated by us in such circumstances, and neither the depositary, the custodian nor any of their respective agents shall incur any liability to ADR holders or beneficial owners in such circumstances.

ADR holders are strongly encouraged to forward their voting instructions to the depositary as soon as possible. For instructions to be valid, the ADR department of the depositary that is responsible for proxies and voting must receive them in the manner and on or before the time specified, notwithstanding that such instructions may have been physically received by the depositary prior to such time. The depositary will not itself exercise any voting discretion in respect of deposited securities. The depositary and its agents will not be responsible for any failure to carry out any instructions to vote any of the deposited securities, for the manner in which any voting instructions are given, or deemed to be given pursuant to the terms of the deposit agreement, including instructions to give a discretionary proxy to a person designated by us, for the manner in which any vote is cast, including, without limitation, any vote cast by a person to whom the depositary is instructed to grant a discretionary proxy (or deemed to have been instructed pursuant to the terms of the deposit agreement), or for the effect of any such vote. Notwithstanding anything contained in the deposit agreement or any ADR, the depositary may, to the extent not prohibited by any law, regulation, or requirement 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 ADR holders with or otherwise publicizes to such ADR 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).

We have advised the depositary that under 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) demanded. 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 received by the depositary from ADR holders shall lapse. The depositary will not demand a poll or join in demanding a poll, whether or not requested to do so by ADR holders or beneficial owners.

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, canceled or surrendered, or upon which a share distribution or elective distribution is made or offered, 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 also be incurred by the ADR holders, the beneficial owners, by any party depositing or withdrawing shares or by any party surrendering ADSs and/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 ADSs 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 US\$ or less per ADS held for any cash distribution made, or for any elective cash/stock dividend offered, pursuant to the deposit agreement;
- an aggregate fee of US\$ or less 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);
- a fee for the reimbursement of such fees, charges and expenses as are incurred by the depositary and/or any of its agents (including, without limitation, the custodian and expenses incurred on behalf of ADR 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 deposited securities, the sale of securities (including, without limitation, 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 fees and charges shall be assessed on a proportionate basis against ADR 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 ADR 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 US\$ per ADS issuance 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) but which securities or the net cash proceeds from the sale thereof are instead distributed by the depositary to those ADR holders entitled thereto;
- 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, ADRs or deposited securities;
- 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
- fees of any division, branch or affiliate of the depositary utilized by the depositary to direct, manage and/or execute any public and/or private sale of securities under the deposit agreement.

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To facilitate the administration of various depositary receipt transactions, including disbursement of dividends or other cash distributions and other corporate actions, the depositary may engage the foreign exchange desk within and/or its affiliates in order to enter into spot foreign exchange transactions to convert foreign currency into U.S. dollars. For certain currencies, foreign exchange transactions are entered into with the Bank or an affiliate, as the case may be, acting in a principal capacity. For other currencies, foreign exchange transactions are routed directly to and managed by an unaffiliated local custodian (or other third-party local liquidity provider), and neither the Bank nor any of its affiliates is a party to such foreign exchange transactions.

The foreign exchange rate applied to a foreign exchange transaction will be either (a) a published benchmark rate, or (b) a rate determined by a third-party local liquidity provider, in each case plus or minus a spread, as applicable. The depositary will disclose which foreign exchange rate and spread, if any, apply to such currency on the “Disclosure” page (or successor page) of www.adr.com. Such applicable foreign exchange rate and spread may (and neither the depositary, the Bank nor any of their affiliates is under any obligation to ensure that such rate does not) differ from rates and spreads at which comparable transactions are entered into with other customers or the range of foreign exchange rates and spreads at which the Bank or any of its affiliates enters into foreign exchange transactions in the relevant currency pair on the date of the foreign exchange transaction. Additionally, the timing of execution of a foreign exchange transaction varies according to local market dynamics, which may include regulatory requirements, market hours and liquidity in the foreign exchange market or other factors. Furthermore, the Bank and its affiliates may manage the associated risks of their position in the market in a manner they deem appropriate without regard to the impact of such activities on the depositary, us, holders or beneficial owners. *The spread applied does not reflect any gains or losses that may be earned or incurred by the Bank and its affiliates as a result of risk management or other hedging related activity.*

Notwithstanding the foregoing, to the extent we provide U.S. dollars to the depositary, neither the Bank nor any of its affiliates will execute a foreign exchange transaction as set forth herein. In such case, the depositary will distribute the U.S. dollars received from us.

Further details relating to the applicable foreign exchange rate, the applicable spread and the execution of foreign exchange transactions will be provided by the depositary on ADR.com. Each holder and beneficial owner by holding or owning an ADR or ADS or an interest therein, and we, each acknowledge and agree that the terms applicable to foreign exchange transactions disclosed from time to time on ADR.com will apply to any foreign exchange transaction executed pursuant to the deposit agreement.

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 right of the depositary to receive payment of fees, charges and expenses survives the termination of the deposit agreement, and shall extend for those fees, charges and expenses incurred prior to the effectiveness of any resignation or removal of the depositary.

The fees and charges described above may be amended from time to time by agreement between us and the depositary. The depositary may make available to us a set amount or a portion of the depositary fees charged in respect of the ADR program or otherwise upon such terms and conditions as we and the depositary may agree from time to 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 ADR holders that have not paid those fees and expenses owing until such fees and expenses have been paid. At the discretion of the

depository, all fees and charges owing under the deposit agreement are due in advance and/or when declared owing by the depository.

Payment of Taxes

ADR holders or beneficial owners must pay any tax or other governmental charge payable by the custodian or the depository on any ADS or ADR, deposited security or distribution. 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 depository with respect to any ADR, any deposited securities represented by the ADSs evidenced thereby or any distribution thereon, including, without limitation, any Chinese Enterprise Income Tax owing if the SAT Circular 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 ADR holder thereof to the depository and by holding or owning, or having held or owned, an ADR or any ADSs evidenced thereby, the ADR holder and all beneficial owners thereof, and all prior ADR holders and beneficial owners thereof, jointly and severally, agree to indemnify, defend and save harmless each of the depository and its agents in respect of such tax or other governmental charge. Notwithstanding the depository's right to seek payment from current and former beneficial owners, by holding or owning, or having held or owned, an ADR, the ADR holder thereof (and prior ADR holder thereof) acknowledges and agrees that the depository has no obligation to seek payment of amounts owing from any current or former beneficial owner. If an ADR holder owes any tax or other governmental charge, the depository 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. 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) in such amounts and in such manner as the depository deems necessary and practicable to pay such taxes and distribute any remaining net proceeds or the balance of any such property after deduction of such taxes to the ADR holders entitled thereto.

As an ADR holder or beneficial owner, you will be agreeing to indemnify us, the depository, its custodian and any of our or their respective officers, 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 of shares or other property 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, and shall if reasonably requested by us:

- 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 depositary 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, SWIFT, cable, telex or facsimile transmission costs, delivery costs or other such expenses), or otherwise prejudices any substantial existing right of ADR holders or beneficial owners. Such notice need not describe in detail the specific amendments effectuated thereby, but must identify to ADR holders and beneficial owners 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 and any beneficial owner are deemed to agree to such amendment and to be bound by the deposit agreement as so amended. 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.

Any amendments or supplements which (i) are reasonably necessary (as agreed by us and the depositary) in order for (a) the ADSs to be registered on Form F-6 under the Securities Act of 1933 or (b) the ADSs or shares to be traded solely in electronic book-entry form and (ii) do not in either such case impose or increase any fees or charges to be borne by ADR holders, shall be deemed not to prejudice any substantial rights of ADR holders or beneficial owners. 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 depositary may amend or supplement the deposit agreement and the ADR at any time in accordance with such changed laws, rules or regulations. Such amendment or supplement to the deposit agreement in such circumstances may become effective before a notice of such amendment or supplement is given to ADR holders or within any other period of time as required for compliance.

Notice of any amendment to the deposit agreement or form of ADRs shall not need to describe in detail the specific amendments effectuated thereby, and failure to describe the specific amendments in any such notice shall not render such notice invalid, provided, however, that, in each such case, the notice given to the ADR holders identifies a means for ADR holders and beneficial owners to retrieve or receive the text of such amendment (*i.e.*, upon retrieval from the SEC's, the depositary's or our website or upon request from the depositary).

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 ADR holders unless a successor depositary shall not be operating under the deposit agreement within 60 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 60th day after our notice of removal was first provided to the depositary.

After the date so fixed for termination, (a) all direct registration ADRs shall cease to be eligible for the direct registration system and shall be considered ADRs issued on the ADR register maintained by the depositary and (b) the depositary shall use its reasonable efforts to ensure that the ADSs cease to be DTC eligible so that neither DTC nor any of its nominees shall thereafter be a registered holder of ADRs. At such time as the ADSs cease to be DTC eligible and/or neither DTC nor any of its nominees is a registered holder of ADRs, the depositary shall (a) instruct its custodian to deliver all shares to us along with a general stock power that refers to the names set forth on the ADR register maintained by the depositary and (b) provide us with a copy of the ADR

register maintained by the depositary. Upon receipt of such shares and the ADR register maintained by the depositary, we have agreed to use our best efforts to issue to each registered ADR holder a Share certificate representing the Shares represented by the ADSs reflected on the ADR register maintained by the depositary in such registered ADR holder's name and to deliver such Share certificate to the registered ADR holder at the address set forth on the ADR register maintained by the depositary. After providing such instruction to the custodian and delivering a copy of the ADR register to us, the depositary and its agents will perform no further acts under the deposit agreement or the ADRs and shall cease to have any obligations under the deposit agreement and/or the ADRs.

Notwithstanding anything to the contrary, in connection with any such termination, the depositary may, in its sole discretion and without notice to us, establish an unsponsored American depositary share program (on such terms as the depositary may determine) for our shares and make available to ADR holders a means to withdraw the shares represented by the ADSs issued under the deposit agreement and to direct the deposit of such shares into such unsponsored American depositary share program, subject, in each case, to receipt by the depositary, at its discretion, of the fees, charges and expenses provided for under the deposit agreement and the fees, charges and expenses applicable to the unsponsored American depositary share program.

Limitations on Obligations and Liability to ADR 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 in the case of the production of proofs as described below, 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 or other ownership of, or interest in, 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, ourselves and our respective agents, provided, however, that no disclaimer of liability under the Securities Act of 1933 is intended by any of the limitations of liabilities provisions of the deposit agreement. The deposit agreement provides that each of us, the depositary and our respective agents will:

- incur or assume no liability (including, without limitation, to holders or beneficial owners) if any present or future law, rule, regulation, fiat, order or decree of the Cayman Islands, Hong Kong, the

People's Republic of China, the United States or any other country or jurisdiction, or of any governmental or regulatory authority or securities exchange or market or automated quotation system, the provisions of or governing any deposited securities, any present or future provision of our charter, any act of God, war, terrorism, nationalization, expropriation, currency restrictions, work stoppage, strike, civil unrest, revolutions, rebellions, explosions, computer failure or circumstance beyond our, the depositary's or our respective agents' direct and immediate 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);

- incur or assume no liability (including, without limitation, to holders or beneficial owners) by reason of any non-performance or delay, caused as aforesaid, in the performance of any act or things which by the terms of the deposit agreement it is provided shall or may be done or performed or any exercise or failure to exercise discretion under the deposit agreement or the ADRs including, without limitation, any failure to determine that any distribution or action may be lawful or reasonably practicable;
- incur or assume no liability (including, without limitation, to holders or beneficial owners) if it performs its obligations under the deposit agreement and ADRs without gross negligence or willful misconduct;
- in the case of the depositary and its agents, be under no obligation to appear in, prosecute or defend any action, suit or other proceeding in respect of any deposited securities the ADSs or the ADRs;
- in the case of us and our agents, be under no obligation to appear in, prosecute or defend any action, suit or other proceeding in respect of any deposited securities the ADSs or the ADRs, which in our or our agents' opinion, as the case may be, may involve it in expense or liability, unless indemnity satisfactory to us or our agent, as the case may be against all expense (including fees and disbursements of counsel) and liability be furnished as often as may be requested;
- not be liable (including, without limitation, to holders or beneficial owners) for any action or inaction by it in reliance upon the advice of or information from any legal counsel, any accountant, 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 and/or, in the case of the depositary, us; or
- may rely and shall be protected in acting upon any written notice, request, direction, instruction or document believed by it to be genuine and to have been signed, presented or given 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, the ADSs 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, the ADSs 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, or the insolvency of, any securities depositary, clearing agency or settlement system. 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 . Notwithstanding anything to the contrary contained in the deposit agreement or any ADRs, the depositary shall not be responsible for, and shall incur no liability in connection with or arising from, any act or omission to act on the part of the custodian except to the extent that any registered ADR holder has incurred liability directly as a result of the custodian having (i) committed fraud or willful misconduct in the provision of custodial services to

the depositary or (ii) failed to use reasonable care in the provision of custodial services to the depositary as determined in accordance with the standards prevailing in the jurisdiction in which the custodian is located. The depositary and the custodian(s) may use third party delivery services and providers of information regarding matters such as, but not limited to, 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 services such as, but not limited to, attendance at any meetings of security holders of issuers. 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. The depositary shall not have any liability for the price received in connection with any sale of securities, the timing thereof or any delay in action or omission to act nor shall it be responsible for any error or delay in action, omission to act, default or negligence on the part of the party so retained in connection with any such sale or proposed sale.

The depositary has no obligation to inform ADR holders or beneficial owners about the requirements of the laws, rules or regulations or any changes therein or thereto of the Cayman Islands, Hong Kong, the People's Republic of China, the United States or any other country or jurisdiction or of any governmental or regulatory authority or any securities exchange or market or automated quotation system.

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 or refunds of non-U.S. tax paid against such ADR holder's or beneficial owner's income tax liability. The depositary is under no obligation to provide the ADR holders and beneficial owners, or any of them, with any information about our tax status. Neither we nor the depositary shall incur any liability for any tax or tax consequences that may be incurred by registered ADR holders or beneficial owners on account of their ownership or disposition 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 voting instructions are given, or deemed to be given pursuant to the terms of the deposit agreement, including instructions to give a discretionary proxy to a person designated by us, for the manner in which any vote is cast, including, without limitation, any vote cast by a person to whom the depositary is instructed to grant a discretionary proxy (or deemed to have been instructed pursuant to the terms of the deposit agreement), or for the effect of any such vote. The depositary may rely upon instructions from us or our counsel in respect of any approval or license required for any currency conversion, transfer or distribution. The depositary shall not incur any liability for the content of any information submitted to it by us or on our behalf for distribution to ADR holders or for any inaccuracy of any translation thereof, for any investment risk associated with acquiring an interest in the deposited securities, for the validity or worth of the deposited securities, for the credit-worthiness of any third party, for allowing any rights to lapse upon the terms of the deposit agreement or for the failure or timeliness of any notice from us. The depositary shall not be liable for any acts or omissions made by a successor depositary whether in connection with a previous act or omission of the depositary or in connection with any matter arising wholly after the removal or resignation of the depositary. Neither the depositary nor any of its agents shall be liable for any indirect, special, punitive or consequential damages (including, without limitation, legal fees and expenses) or lost profits, in each case of any form incurred by any person or entity (including, without limitation holders or beneficial owners of ADRs and ADSs), 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 ADR holder and beneficial owner) irrevocably waives, to the fullest extent permitted by applicable law, any right it may have to a trial by jury in any suit, action or proceeding against the depositary and/or us 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). No provision of the deposit agreement or the ADRs is intended to constitute a waiver or limitation of any rights which an ADR holder or any beneficial owner may have under the Securities Act of 1933 or the Securities Exchange Act of 1934, to the extent applicable.

The depositary and its agents may own and deal in any class of securities of our company and our affiliates and in ADRs.

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, or interest in, deposited securities, other shares and other securities and may provide for blocking transfer, voting or other rights to enforce such disclosure or limits, you as ADR holders or beneficial owners agree to comply with all such disclosure requirements and ownership limitations and to comply with any reasonable instructions we may provide in respect thereof.

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 ADR holders in the interest of the business of our company or a matter relating to the deposit agreement. Such register may be closed at any time or from time to time, when deemed expedient by the depositary or, in the case of the issuance book portion of the ADR Register, when reasonably requested by the Company solely in order to enable the Company to comply with applicable law.

The depositary will maintain facilities for the delivery and receipt of ADRs.

Appointment

In the deposit agreement, each registered holder of ADRs and each beneficial owner, upon acceptance of any ADSs or ADRs (or any interest in any of them) 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,
- appoint the depositary 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 depositary in its sole discretion may deem necessary or appropriate to carry out the purposes of the deposit agreement and the applicable ADR or ADRs, the taking of such actions to be the conclusive determinant of the necessity and appropriateness thereof; and
- acknowledge and agree that (i) nothing in the deposit agreement or any ADR shall give rise to a partnership or joint venture among the parties thereto, nor establish a fiduciary or similar relationship among such parties, (ii) the depositary, its divisions, branches and affiliates, and their respective agents, may from time to time be in the possession of non-public information about us, ADR holders, beneficial owners and/or their respective affiliates, (iii) the depositary and its divisions, branches and affiliates may at any time have multiple banking relationships with us, ADR holders, beneficial owners and/or the affiliates of any of them, (iv) the depositary and its divisions, branches and affiliates may, from time to time, be engaged in transactions in which parties adverse to us, ADR holders, beneficial owners and/or their respective affiliates may have interests, (v) nothing contained in the deposit agreement or any ADR(s) shall (A) preclude the depositary or any of its divisions, branches or affiliates from engaging in any such transactions or establishing or maintaining any such relationships, or (B) obligate the depositary or any of its divisions, branches or affiliates to disclose any such transactions or relationships or to account for any profit made or payment received in any such transactions or relationships, (vi) the depositary shall not be deemed to have knowledge of any information held by any branch, division or affiliate of the depositary and (vii) notice to an ADR holder

shall be deemed, for all purposes of the deposit agreement and the ADRs, to constitute notice to any and all beneficial owners of the ADSs evidenced by such ADR holder's ADRs. For all purposes under the deposit agreement and the ADRs, the ADR holders thereof shall be deemed to have all requisite authority to act on behalf of any and all beneficial owners of the ADSs evidenced by such ADRs.

Governing Law

The deposit agreement, the ADSs and the ADRs are governed by and construed in accordance with the internal laws of the State of New York. In the deposit agreement, we have submitted to the non-exclusive jurisdiction of the courts of the State of New York and appointed an agent for service of process on our behalf. Any action based on the deposit agreement, the ADSs, the ADRs or the transactions contemplated therein or thereby may also be instituted by the depositary against us in any competent court in the Cayman Islands, Hong Kong, the People's Republic of China, the United States and/or any other court of competent jurisdiction.

Under the deposit agreement, by holding or owning an ADR or ADS or an interest therein, ADR holders and beneficial owners each irrevocably agree that any legal suit, action or proceeding against or involving ADR holders or beneficial owners brought by us or the depositary, arising out of or based upon the deposit agreement, the ADSs, the ADRs or the transactions contemplated thereby, may be instituted in a state or federal court in New York, New York, irrevocably waive any objection which you may have to the laying of venue of any such proceeding, and irrevocably submit to the non-exclusive jurisdiction of such courts in any such suit, action or proceeding. By holding or owning an ADR or ADS or an interest therein, ADR holders and beneficial owners each also irrevocably agree that any legal suit, action or proceeding against or involving the depositary brought by ADR holders or beneficial owners, arising out of or based upon the deposit agreement, the ADSs, the ADRs or the transactions contemplated thereby, may only be instituted in a state or federal court in New York, New York.

Notwithstanding the foregoing, (i) the depositary may, in its sole discretion, elect to institute any dispute, suit, action, controversy, claim or proceeding directly or indirectly based on, arising out of or relating to the deposit agreement, the ADSs, the ADRs or the transactions contemplated therein or thereby, including without limitation any question regarding its or their existence, validity, interpretation, performance or termination, against any other party or parties to the deposit agreement (including, without limitation, against ADR holders and beneficial owners of interests in ADSs), by having the matter referred to and finally resolved by an arbitration conducted under the terms described below, and (ii) the depositary may in its sole discretion require, by written notice to the relevant party or parties, that any dispute, suit, action, controversy, claim or proceeding against the depositary by any party or parties to the deposit agreement (including, without limitation, by ADR holders and beneficial owners of interests in ADSs) shall be referred to and finally settled by an arbitration conducted under the terms described below. Any such arbitration shall be conducted in the English language 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).

Jury Trial Waiver

In the deposit agreement, each party thereto (including, for the avoidance of doubt, each holder and beneficial owner of, and/or holder of interests in, ADSs or ADRs) irrevocably waives, to the fullest extent permitted by applicable law, any right it may have to a trial by jury in any suit, action or proceeding against the depositary and/or us 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), including any claim under the U.S. federal securities laws.

If we or the depositary were to oppose a jury trial demand based on such waiver, the court would determine whether the waiver was enforceable in the facts and circumstances of that case in accordance with applicable state and federal law, including whether a party knowingly, intelligently and voluntarily waived the right to a jury trial. The waiver to right to a jury trial in the deposit agreement is not intended to be deemed a waiver by any holder or beneficial owner of ADSs of our or the depositary's compliance with the U.S. federal securities laws and the rules and regulations promulgated thereunder.

SHARES AND ADSs ELIGIBLE FOR FUTURE SALE

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 to purchase additional ADSs. 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 the ADSs in the public market could adversely affect prevailing market prices of the ADSs. Prior to this offering, there has been no public market for our ordinary shares or the ADSs. We have applied 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

For a period of 180 days after the date of this prospectus, we have agreed, subject to certain exceptions, not to directly or indirectly 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, except in this offering, any of our ordinary shares or ADSs or securities convertible into or exercisable or exchangeable for our ordinary shares or ADSs subject to certain exceptions, without the prior written consent of Citigroup Global Markets Inc., Jefferies LLC and Piper Sandler & Co. See “Underwriting” for additional information.

Furthermore, each of our officers, directors, other stockholders and certain option holders has also entered into a similar lock-up agreement for a period of 180 days from the date of this prospectus, subject to certain exceptions, with respect to our ordinary shares, ADSs and securities convertible into or exercisable or exchangeable for our ordinary shares or ADSs. These restrictions also apply to any ADSs acquired by our directors and executive officers in the offering, if any.

Other than this offering, we are not aware of any plans by any significant shareholders to dispose of significant numbers of the ADSs or ordinary shares. However, one or more existing shareholders or owners of securities convertible or exchangeable into or exercisable for the ADSs or ordinary shares may dispose of significant numbers of the ADSs or ordinary shares in the future. We cannot predict what effect, if any, future sales of the ADSs or ordinary shares, or the availability of ADSs or ordinary shares for future sale, will have on the trading price of the ADSs from time to time. Sales of substantial amounts of the ADSs or ordinary shares in the public market, or the perception that these sales could occur, could adversely affect the trading price of the ADSs.

Rule 144

All of our ordinary shares that will be outstanding upon the completion of this offering, other than those ordinary shares represented by 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 180 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 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, in the form of ADSs or otherwise, which immediately after this offering will equal approximately _____ ordinary shares, assuming the underwriters do not exercise their over-allotment option; or

- the average weekly trading volume of our ordinary shares of the same class, in the form of 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 share 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.

Regulation S

Regulation S provides generally that sales made in offshore transactions are not subject to the registration or prospectus-delivery requirements of the Securities Act. Accordingly, restricted securities may be sold in offshore transactions in compliance with Regulation S.

TAXATION

The following is a general summary of certain Cayman Islands, People's Republic of China and United States federal income tax consequences relevant to an investment in our ADSs and ordinary shares. To the extent that the discussion below relates to matters of Cayman Islands tax law, it is the opinion of Harney Westwood & Riegels, our Cayman Islands counsel. To the extent that the discussion below relates to matters of People's Republic of China tax law, it is the opinion of AllBright Law Offices, our PRC counsel. The discussion is not intended to be, nor should it be construed as, legal or tax advice to any particular prospective purchaser. The discussion is based on laws and relevant interpretations thereof in effect as of the date of this prospectus, all of which are subject to change or different interpretations, possibly with retroactive effect. The discussion does not address U.S. state or local tax laws, or tax laws of jurisdictions other than the Cayman Islands, the People's Republic of China and the United States. You should consult your tax advisors with respect to the consequences of acquisition, ownership and disposition of our ADSs and ordinary shares.

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.

No other taxes are 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 after execution brought within, the jurisdiction of the Cayman Islands. The Cayman Islands is not party to any double tax treaties which are applicable to any payments made to or by our company. There are no exchange control regulations or currency restrictions in the Cayman Islands.

Payments of dividends and capital in respect of our ordinary shares and ADSs will not be subject to taxation in the Cayman Islands and no withholding will be required on the payment of dividends or capital to any holder of our ordinary shares or ADSs, nor will gains derived from the disposal of our ordinary shares or ADSs be subject to Cayman Islands income or corporation tax.

No stamp duty is payable in respect of the issue of our ordinary shares or on an instrument of transfer in respect of our ordinary shares, unless the relevant instruments are executed in, or after execution brought within, the jurisdiction of the Cayman Islands or our company holds interests in land in the Cayman Islands.

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 is considered as a Tax Resident Enterprise for PRC enterprise income tax purposes and is generally subject to a uniform 25% enterprise income tax rate on its worldwide income. The implementation rules of the PRC Enterprise Income Tax Law 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 SAT issued 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 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 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 board members with voting rights or senior executives habitually reside in China.

We believe that we should not be considered as a PRC resident enterprise for PRC tax purposes as (i) we are incorporated outside of China and not controlled by a PRC enterprise or PRC enterprise group; and (ii) we do not meet all of the conditions above. 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.” There can be no assurance that PRC tax authorities will ultimately not take a different view.

If the PRC tax authorities determine that we are a PRC resident enterprise for enterprise income tax purposes, our worldwide income could be subject to 25% enterprise income tax; and any dividends payable to non-resident enterprise holders of our ordinary shares or ADSs may be treated as income derived from sources within China and therefore, and therefore could be subject to a 10% withholding tax (or 20% in the case of non-resident individual holders) unless an applicable income tax treaty provides otherwise. In addition, capital gains realized by non-resident enterprise shareholders (including our ADS holders) upon the disposition of our ordinary shares or ADSs may be treated as income derived from sources within PRC and therefore, subject to 10% income tax (or 20% in the case of non-resident individual shareholders or ADS holders) unless an applicable income tax treaty provides otherwise. It is unclear whether non-PRC shareholders of our company would be able to obtain 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. Provided that we are not deemed to be a PRC resident enterprise, holders of the ADSs and ordinary shares who are not PRC residents will not be subject to PRC income tax on dividends distributed by us or gains realized from the sale or other disposition of our shares or ADSs. SAT Public Notice 7 further clarifies that, if a non-resident enterprise derives income by acquiring and selling shares in an offshore listed enterprise in the public market, such income will not be subject to PRC tax. However, there is uncertainty as to the application of SAT Bulletin 37 and SAT Public Notice 7, we and our non-PRC resident investors may be at risk of being required to file a return and being taxed under SAT Bulletin 37 and SAT Public Notice 7 and we may be required to expend valuable resources to comply with SAT Bulletin 37 and SAT Public Notice 7 or to establish that we should not be taxed under SAT Bulletin 37 and SAT Public Notice 7. See “Risk Factors—Risks Related to Doing Business in China—If we are classified as a “resident enterprise” of China under the PRC Enterprise Income Tax Law, we and our non-PRC shareholders could be subject to unfavorable tax consequences, and our business, financial condition and results of operations could be materially and adversely affected.”

Material U.S. Federal Income Tax Consequences to U.S. Holders

The following discussion is a summary of certain material U.S. federal income tax considerations generally applicable to the ownership and disposition of the ADSs or ordinary shares by a U.S. Holder (as defined below) that holds the ADSs or ordinary shares 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 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, moreover, does not address the U.S. federal estate, gift, Medicare, and alternative minimum tax considerations, or any state, local or non-U.S. tax considerations, relating to the ownership or disposition of the ADSs or ordinary shares. The following summary also does not address all aspects of U.S. federal income taxation that may be important to particular investors in light of their individual circumstances or to persons in special tax situations such as:

- banks and other financial institutions;
- insurance companies;
- pension plans;
- cooperatives;
- regulated investment companies;

- real estate investment trusts;
- broker-dealers;
- dealers or traders 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);
- governmental organizations;
- 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 that have a functional currency other than the U.S. dollar;
- investors required to accelerate the recognition of any item of gross income with respect to their ADSs or ordinary shares as a result of such income being recognized on an applicable financial statement;
- investors that actually or constructively own 10% or more of our stock (by vote or value); or
- partnerships or other entities taxable as partnerships for U.S. federal income tax purposes, or persons holding ADSs or ordinary shares through such entities.

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 application of U.S. federal taxation to its particular circumstances, and the state, local, non-U.S. and other tax considerations of the ownership and disposition of the ADSs or ordinary shares.

General

For purposes of this discussion, a “U.S. Holder” is a beneficial owner of the ADSs or ordinary shares that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- 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;
- an estate the income of which is includible in gross income for U.S. federal income tax purposes regardless of its source; or
- 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 the 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 partnership. Partnerships holding the ADSs or ordinary shares and their partners are urged to consult their tax advisors regarding an investment in the 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 the ADSs will be treated in this manner. Accordingly, deposits or withdrawals of ordinary shares for ADSs will generally not be subject to U.S. federal income tax.

Dividends

Subject to the discussion below under “—Passive Foreign Investment Company Rules,” distributions paid on the 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, in the case of ordinary shares, or by the depositary, in the case of ADSs. 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 treated as a “dividend” for U.S. federal income tax purposes. Dividends received on the 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. The amount of any dividend income paid in foreign currency will be the U.S. dollar amount calculated by reference to the spot rate in effect on the date of receipt, regardless of whether the payment is in fact converted into U.S. dollars on such date. If the dividend is converted into U.S. dollars on the date of receipt, a U.S. Holder generally should not be required to recognize foreign currency gain or loss in respect of the amount received. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt.

Individuals and other non-corporate U.S. Holders may be subject to tax on dividend income from a “qualified foreign corporation” at a lower capital gains rate rather than the marginal tax rates generally applicable to ordinary income, provided that certain holding period and other requirements are met. A non-U.S. corporation (other than a corporation that is classified as a PFIC for the taxable year in which the dividend is paid or the preceding taxable year) will generally be considered to be a qualified foreign corporation (i) if it is eligible for the benefits of a comprehensive tax treaty with the U.S. which the Secretary of the Treasury of the U.S. determines is satisfactory for purposes of this provision and which includes an exchange of information program, or (ii) with respect to any dividend it pays on stock (or ADSs in respect of such stock) which is readily tradable on an established securities market in the U.S. We expect the ADSs (but not our ordinary shares) will be readily tradeable on an established securities market in the United States. Since we do not expect that our ordinary shares will be listed on an established securities market, it is unclear whether 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 that, the ADSs will continue to be considered readily tradeable on an established securities market in later years. Non-corporate U.S. Holders should consult their tax advisers regarding the availability of these reduced tax rates in their particular circumstances and in light of our possible PFIC status for any taxable year.

Dividends will generally be treated as income from foreign sources for United States 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 the ADSs or ordinary shares (see “—People’s Republic of China Taxation”). For U.S. federal income tax purposes, the amount of the dividend income will include amounts withheld in respect of PRC withholding tax, if any. 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 the 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

Subject to the discussion below under “—Passive Foreign Investment Company Rules,” a U.S. Holder will generally recognize gain or loss upon the sale or other disposition of the 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. The gain or loss will generally be capital gain or loss. Any capital gain or loss will be long-term capital gain or loss if the ADSs or ordinary shares have been held for more than one year. The deductibility of a capital loss is subject to limitations. Any such gain or loss that the U.S. Holder recognizes will

generally be treated as U.S.-source income or loss for foreign tax credit limitation purposes, which will generally limit the availability of foreign tax credits. However, we may be deemed to be a PRC resident enterprise under the PRC Enterprise Income Tax Law. In such event, if PRC tax were to be imposed on any gain from the disposition of the ADSs or ordinary shares, a U.S. Holder that is eligible for the benefits of the United States-PRC income tax treaty may elect to treat such gain as PRC source income. If a U.S. Holder is not eligible for the benefits of the United States-PRC income tax 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). Each U.S. Holder is advised to consult their tax advisors regarding the tax consequences if a foreign tax is imposed on a disposition of the ADSs or ordinary shares, including the availability of the foreign tax credit under its particular circumstances.

Passive Foreign Investment Company Rules

A non-U.S. corporation, such as our company, will be a PFIC if, in the case of any particular taxable year, 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 (generally 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 categorized as passive assets and the company’s goodwill and other unbooked intangibles associated with active business activities may generally be classified as active assets. Passive income generally includes, among other things, dividends, interest, rents, royalties, and gains from the disposition of passive assets. For purposes of these rules, 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, more than 25% (by value) of the stock.

Based on our operating history and the projected composition of our income and valuation of our assets, including goodwill, we may be a PFIC for the taxable year ending December 31, 2020. The determination of whether we are a PFIC is a fact-intensive determination made on an annual basis and the applicable law is subject to varying interpretation. In particular, the characterization of our assets as active or passive may depend in part on our current and intended future business plans, which are subject to change. Our status as a PFIC will depend on the nature and composition of our income and the nature, composition and value of our assets (which may be determined based on the fair market value of each asset, with the value of goodwill and going concern value determined in large part by reference to the market value of our ADSs, which may be volatile). Therefore, declines in our market capitalization would adversely affect our PFIC status for any taxable year. Our status may also depend, in part, on how quickly we utilize our current cash balances and the cash proceeds from this offering in our business. Furthermore, prior to the commercialization of any of our product candidates, for any taxable year interest or other passive income may constitute 75% or more of our total gross income. Moreover, it is not entirely clear how the contractual arrangements between us, our VIE and its nominal shareholders will be treated for purposes of the PFIC rules, and we may be or become a PFIC if our VIE is treated as owned by us for these purposes. Even if we determine that we are not a PFIC for a taxable year, there can be no assurance that the Internal Revenue Service, or IRS, will agree with our conclusion and that the IRS would not successfully challenge our position. Accordingly, our U.S. counsel expresses no opinion with respect to our PFIC status for our taxable year ending December 31, 2019, and also expresses no opinion with regard to our expectations regarding our PFIC status for the current taxable year or any future taxable year.

If we are a PFIC for any taxable year during which a U.S. Holder holds the 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 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;
- 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; and
- the interest charge generally applicable to underpayments of tax will be imposed on the tax attributable to each prior taxable year, other than a pre-PFIC year.

If we are a PFIC for any taxable year during which a U.S. Holder holds the ADSs or ordinary shares and any of the entities in which we hold equity interests (including generally, our VIE or any of the entities in which our VIE holds equity interests) is also a PFIC (in each case, a "lower-tier 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 the entities in which we hold equity interests, our VIE or any of the entities in which our VIE holds equity interests.

If we were a PFIC for any taxable year during which a U.S. Holder owned ADSs or ordinary shares, we would generally continue to be treated as a PFIC with respect to the U.S. Holder for all succeeding years during which the U.S. Holder owned the ADSs or ordinary shares, even if we ceased to meet the threshold requirements for PFIC status, unless the U.S. Holder made a timely "deemed sale" election, in which case any gain on the deemed sale would be taxed under the PFIC rules described above.

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 with respect to the ADSs, 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 in each such taxable year 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 the ADSs and we cease to be classified as a PFIC, the U.S. Holder will not be required to take into account the gain or loss described above during any period that we are 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 the 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.

The mark-to-market election is available only for "marketable stock," which is stock that is regularly traded on a qualified exchange or other market as defined in applicable U.S. Treasury regulations. The ADSs will be treated as "regularly traded" for any calendar year in which more than a *de minimis* quantity of the ADSs are traded on a qualified exchange for at least 15 days during each calendar quarter. The Nasdaq Global Market, where our ADSs are listed, is a qualified exchange for this purpose.

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.

If we are a PFIC (or with respect to a particular U.S. Holder are treated as a PFIC) for a taxable year of ours in which we pay a dividend or the prior taxable year, the favorable tax rate described above with respect to dividends paid to certain non-corporate U.S. Holders would not apply.

At this time, we do not expect to provide U.S. shareholders with the information necessary for a U.S. shareholder to make a QEF election. Prospective investors should assume that a QEF election will not be available.

If a U.S. Holder owns the ADSs or ordinary shares during any taxable year that we are a PFIC, the holder must generally file an annual IRS Form 8621 or such other form as is required by the U.S. Treasury Department. Each U.S. Holder is advised to consult its tax advisor regarding the potential tax consequences to such holder if we were, are or become a PFIC, including the possibility of making a mark-to-market election.

Information Reporting and Backup Withholding

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries may be subject to information reporting and backup withholding, unless (i) the U.S. Holder is a corporation or other “exempt recipient” and (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding.

The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the U.S. Holder’s U.S. federal income tax liability and may entitle it to a refund, provided that the required information is timely furnished to the IRS. Certain U.S. Holders who are individuals (or certain specified entities) may be required to report information relating to their ownership of ADSs or ordinary shares, unless the ADSs or ordinary shares are held in accounts at financial institutions (in which case the accounts may be reportable if maintained by non-U.S. financial institutions). U.S. Holders should consult their tax advisers regarding their reporting obligations with respect to the ADSs or ordinary shares.

UNDERWRITING

Citigroup Global Markets, Inc., Jefferies LLC and Piper Sandler & Co. are acting as joint book-running managers of this offering and as representatives of the underwriters named below. Subject to the terms and conditions stated in the underwriting agreement dated the date of this prospectus, the underwriters named below have severally agreed to purchase, and we have agreed to sell to them, the number of ADSs indicated below:

<u>Underwriter</u>	<u>Number of ADS</u>
Citigroup Global Markets Inc.	
Jefferies LLC	
Piper Sandler & Co.	
Total	

The underwriting agreement provides that the obligations of the underwriters to purchase the ADSs included in this offering are subject to approval of legal matters by counsel and to other conditions. The underwriters are obligated to purchase all of the ADSs (other than those covered by the over-allotment option described below) if they purchase any.

ADSs sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any ADSs sold by the underwriters to securities dealers may be sold at a discount from the initial public offering price not to exceed US\$ per ADS. After the initial public offering of the ADSs, if all the ADSs are not sold at the initial public offering price, the underwriters may change the offering price and the other selling terms. The representatives have advised us that the underwriters do not intend to make sales to discretionary accounts.

The address of Citigroup Global Markets Inc. is 390 Greenwich Street, New York, New York 10013, the address of Jefferies LLC is 520 Madison Avenue, New York, NY 10022, and the address of Piper Sandler & Co. is 800 Nicollet Mall, Minneapolis, MN 55402.

If the underwriters sell more ADSs than the total number set forth in the table above, we have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to additional ADSs at the initial public offering price less the underwriting discount. The underwriters may exercise the option solely for the purpose of covering over-allotments, if any, in connection with this offering. To the extent the option is exercised, each underwriter must purchase a number of additional ADSs approximately proportionate to that underwriter's initial purchase commitment set forth in the table above. Any ADSs issued or sold under the option will be issued and sold on the same terms and conditions as the other ADSs that are the subject of this offering.

We and our officers, directors, other stockholders and certain option holders have agreed that, subject to specified limited exceptions, for a period of 180 days from the date of this prospectus, or the Restricted Period, we and they will not, without the prior written consent of Citigroup Global Markets, Inc., Jefferies LLC and Piper Sandler & Co., offer, sell, contract to sell, pledge or otherwise dispose of, including the filing of a registration statement in respect of, or hedge any ordinary shares or ADSs or any securities convertible into, or exercisable or exchangeable for, our ordinary shares or ADSs, collectively referred to as lock-up securities. Citigroup Global Markets, Inc., Jefferies LLC and Piper Sandler & Co. in their sole discretion may release any of the securities subject to these lock-up agreements at any time, which, in the case of officers and directors, shall be with notice.

At our request, the underwriters have reserved up to % of the shares of ADSs for sale at the initial public offering price to persons who are directors, officers or employees, or who are otherwise associated with us through a directed share program. The number of shares available for sale to the general public will be reduced

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by the number of directed shares purchased by participants in the program. For certain officers, directors and employees purchasing shares through the directed share program, the lock-up agreements contemplated in the immediately preceding paragraph shall govern with respect to their purchases. Any directed shares not purchased will be offered by the underwriters to the general public on the same basis as all other shares offered. We have agreed to indemnify the underwriters against certain liabilities and expenses, including liabilities under the Securities Act, in connection with the sales of the directed shares.

The lock-up restrictions relating to our officers, directors, other stockholders and certain option holders described in the immediately preceding paragraph are subject to specified exceptions, including the following:

- a. transactions relating to ordinary shares, ADSs or other securities acquired in the offering or in open market transactions after the completion of the offering, provided that no filing under Section 16(a) of the Exchange Act shall be required or shall be voluntarily made in connection with subsequent sales of ordinary shares, ADSs or other securities acquired in such open market transactions;
- b. transfers of ordinary shares to a depository, solely for the purpose of converting such ordinary shares into restricted ADSs that are not freely tradeable in open market, whose restrictive legend shall not be removed prior to the end of the Restricted Period and whose holder shall have agreed to the same lock-up restrictions as those binding on the transferor;
- c. transfer of ordinary shares, ADSs or any security convertible into or exercisable or exchangeable for ordinary shares or ADSs as bona fide gifts, or through will or intestacy, or to “immediate family members” (as defined in Rule 16a-1(e) under the Exchange Act), to any trust for the direct or indirect benefit of the undersigned or any immediate family member of the undersigned, or to any entity beneficially owned and controlled by the undersigned, provided that any such transfer shall not involve a disposition of value;
- d. distributions of ordinary shares, ADSs or any security convertible into or exercisable or exchangeable for ordinary shares or ADSs to limited partners, stockholders or “affiliates” (as defined in Rule 12b-2 under the Exchange Act) of the undersigned; provided that any such transfer shall not involve a disposition of value;
- e. the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of ordinary shares or ADSs;

provided that:

- in the case of any transfer or distribution pursuant to clauses (c) and (d) above, each done, transferee or distributee shall agree in writing to be bound by the same restrictions in place for the transferor for the duration that such restrictions remain in effect at the time of transfer;
- in the case of any transfer or distribution pursuant to clause (e) above, (i) such plan does not provide for the transfer of ordinary shares or ADSs during the Restricted Period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by or on behalf of the undersigned or the Company regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of ordinary shares or ADSs may be made under such plan during the Restricted Period;

Prior to this offering, there has been no public market for the ADSs in the United States. The initial public offering price for the ADSs will be determined by negotiations between us and the representatives. Among the factors considered in determining the initial public offering price will be our stage of development, our results of operations, our current financial condition, our future prospects, our markets, the economic conditions in and future prospects for the industry in which we compete, our management, and currently prevailing general conditions in the equity securities markets, including current market valuations of publicly traded companies considered comparable to our company. We cannot assure you, however, that the price at which the ADSs will sell in the public market after this offering will not be lower than the initial public offering price or that an active trading market in our shares of ADSs will develop and continue after this offering.

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We have applied for listing of the ADSs listed on the Nasdaq Global Market under the symbol “GRCL.”

The following table shows the per ADS and total underwriting discounts and commissions that we are to pay to the underwriters and proceeds to us, before estimated offering expenses, in connection with this offering. These amounts are shown assuming both no exercise and full exercise of the underwriters’ over-allotment option:

	Per ADS	Total	
		No exercise	Full exercise
Public offering price	US\$	US\$	US\$
Underwriting discounts paid by us	US\$	US\$	US\$
Proceeds to us, before expenses	US\$	US\$	US\$

We estimate that expenses payable by us in connection with this offering, exclusive of underwriting discounts, will be approximately US\$. We have also agreed to reimburse the underwriters for expenses in an amount up to US\$.

In connection with this offering, the underwriters may purchase and sell ADSs in the open market. Purchases and sales in the open market may include short sales, purchases to cover short positions, which may include purchases pursuant to the underwriters’ over-allotment option, and other transactions that would stabilize, maintain or otherwise affect the price of the ADSs.

- Short sales involve secondary market sales by the underwriters of a greater number of ADSs than they are required to purchase in this offering:
 - “Covered” short sales are sales of ADSs in an amount up to the number of ADSs represented by the underwriters’ over-allotment option.
 - “Naked” short sales are sales of ADSs in an amount in excess of the number of ADSs represented by the underwriters’ over-allotment option.
- The underwriters can close out a short position by purchasing additional ADSs, either pursuant to the underwriters’ over-allotment option or in the open market.
 - To close a naked short position, the underwriters must purchase 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 this offering.
 - To close a covered short position, the underwriters must purchase ADSs in the open market or exercise their over-allotment option. In determining the source of ADSs to close 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 ADSs through their over-allotment option.
- As an additional means of facilitating this offering, the underwriters may bid for, and purchase, ADSs on the Nasdaq Global Market, as long as such bids do not exceed a specified maximum, to stabilize the price of the ADSs.

Purchases to cover short positions and stabilizing purchases, 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 shares. They may also cause the price of the ADSs to be higher than the price that would otherwise prevail in the open market in the absence of these transactions. The underwriters may conduct these transactions on the Nasdaq Global Market, in the over-the-counter market or otherwise. The underwriters are not required to engage in any of these transactions and may discontinue them at any time.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make because of any of those liabilities.

A prospectus in electronic format may be made available on websites maintained by one or more of the underwriters or their respective affiliates. The representatives may agree with us to allocate a number of ADSs to underwriters for sale to their online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' or their respective affiliates' websites and any information contained in any other website maintained by any of the underwriters or their respective affiliates is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors in this offering.

Other Relationships

The underwriters 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 and brokerage activities. The underwriters and their respective affiliates may, from time to time, engage in transactions with and perform services for us in the ordinary course of their business for which they may receive customary fees and reimbursement of expenses. 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 (which may include bank loans and/or credit default swaps) 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 investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Notice to Prospective Investors in the European Economic Area and the United Kingdom

In relation to each member state of the European Economic Area and the United Kingdom that has implemented the Prospectus Directive (each, a relevant state), with effect from and including the date on which the Prospectus Directive is implemented in that relevant state (the relevant implementation date), an offer of ADSs described in this prospectus may not be made to the public in that relevant state other than:

- to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- to fewer than 100 or, if the relevant 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), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the relevant Dealer or Dealers nominated by us for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of ADSs shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive.

For purposes of this provision, the expression an "offer of securities to the public" in any relevant 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 for any ADSs, as the expression may be varied in that relevant state by any measure implementing the Prospectus Directive in that relevant state, and the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto,

including the 2010 PD Amending Directive, to the extent implemented in the relevant state) and includes any relevant implementing measure in the relevant state. The expression “2010 PD Amending Directive” means Directive 2010/73/EU.

The sellers of the ADSs have not authorized and do not authorize the making of any offer of ADSs through any financial intermediary on their behalf, other than offers made by the underwriters with a view to the final placement of the ADSs as contemplated in this prospectus. Accordingly, no purchaser of the ADSs, other than the underwriters, is authorized to make any further offer of the ADSs on behalf of the sellers or the underwriters.

Notice to Prospective Investors in the United Kingdom

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (1) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, or the Order, or (2) high net worth entities, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order (each such person being referred to as a relevant person).

This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

Notice to Prospective Investors in Australia

No prospectus or other disclosure document (as defined in the Corporations Act 2001 (Cth) of Australia, or Corporations Act) in relation to the ADSs has been or will be lodged with the Australian Securities & Investments Commission, or ASIC. This document has not been lodged with ASIC and is only directed to certain categories of exempt persons. Accordingly, if you receive this document in Australia:

- you confirm and warrant that you are either:
 - a “sophisticated investor” under Section 708(8)(a) or (b) of the Corporations Act;
 - a “sophisticated investor” under Section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant’s certificate to us which complies with the requirements of Section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;
 - a person associated with the company under Section 708(12) of the Corporations Act; or
 - a “professional investor” within the meaning of Section 708(11)(a) or (b) of the Corporations Act, and to the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this document is void and incapable of acceptance; and
- you warrant and agree that you will not offer any of the ADSs for resale in Australia within 12 months of that ADSs being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under Section 708 of the Corporations Act.

Notice to Prospective Investors in Canada

The securities 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 securities 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 (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.

Notice to Prospective Investors in France

Neither this prospectus nor any other offering material relating to the ADSs described in this prospectus has been submitted to the clearance procedures of the *Autorité des Marchés Financiers* or of the competent authority of another member state of the European Economic Area and notified to the *Autorité des Marchés Financiers*. The ADSs have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France.

Neither this prospectus nor any other offering material relating to the ADSs has been or will be:

- released, issued, distributed or caused to be released, issued or distributed to the public in France; or
- used in connection with any offer for subscription or sale of the ADSs to the public in France.

Such offers, sales and distributions will be made in France only:

- to qualified investors (*investisseurs qualifiés*) and/or to a restricted circle of investors (*cercle restreint d'investisseurs*), in each case investing for their own account, all as defined in and in accordance with articles L.411-2, D.411-1, D.411-2, D.734-1, D.744-1, D.754-1 and D.764-1 of the French Code monétaire et financier;
- to investment services providers authorized to engage in portfolio management on behalf of third parties; or
- in a transaction that, in accordance with article L.411-2-II-1° -or-2° -or 3° of the French Code monétaire et financier and article 211-2 of the General Regulations (*Règlement Général*) of the *Autorité des Marchés Financiers*, does not constitute a public offer (*appel public à l'épargne*).

The ADSs may be resold directly or indirectly, only in compliance with articles L.411-1, L.411-2, L.412-1 and L.621-8 through L.621-8-3 of the French Code monétaire et financier.

Notice to Prospective Investors in 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 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.

Notice to Prospective Investors in Hong Kong

The ADSs may not be offered or sold in Hong Kong by means of any document other than (1) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong), or (2) to "professional investors" within the meaning of the Securities and

Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder, or (3) 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.

Notice to Prospective Investors in the State of Israel

In the State of Israel, this prospectus shall not be regarded as an offer to the public to purchase shares of ADSs under the Israeli Securities Law, 5728—1968, which requires a prospectus to be published and authorized by the Israel Securities Authority, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728—1968, including, inter alia, if: (1) the offer is made, distributed or directed to not more than 35 investors, subject to certain conditions, or the Addressed Investors; or (2) the offer is made, distributed or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728—1968, subject to certain conditions, or Qualified Investors. The Qualified Investors shall not be taken into account in the count of the Addressed Investors and may be offered to purchase securities in addition to the 35 Addressed Investors. We have not and will not take any action that would require us to publish a prospectus in accordance with and subject to the Israeli Securities Law, 5728—1968. We have not and will not distribute this prospectus or make, distribute or direct an offer to subscribe for the ADSs to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors.

Qualified Investors may have to submit written evidence that they meet the definitions set out in of the First Addendum to the Israeli Securities Law, 5728—1968. In particular, we may request that Qualified Investors will each represent, warrant and certify to us and/or to anyone acting on our behalf: (1) that it is an investor falling within one of the categories listed in the First Addendum to the Israeli Securities Law, 5728—1968; (2) which of the categories listed in the First Addendum to the Israeli Securities Law, 5728—1968 regarding Qualified Investors is applicable to it; (3) that it will abide by all provisions set forth in the Israeli Securities Law, 5728—1968 and the regulations promulgated thereunder in connection with this offering; (4) that the shares of ADSs that it will be issued are, subject to exemptions available under the Israeli Securities Law, 5728 -1968: (a) for its own account; (b) for investment purposes only; and (c) not issued with a view to resale within the State of Israel, other than in accordance with the provisions of the Israeli Securities Law, 5728 -1968; and (5) that it is willing to provide further evidence of its Qualified Investor status. Addressed Investors may have to submit written evidence in respect of their identity and may have to sign and submit a declaration containing, inter alia, the Addressed Investor’s name, address and passport number or Israeli identification number.

Notice to Prospective Investors in Japan

The ADSs offered in this prospectus have not been and will not be registered under the Financial Instruments and Exchange Law of Japan. The ADSs have not been offered or sold and will not be offered or sold, directly or indirectly, in Japan or to or for the account of any resident of Japan (including any corporation or other entity organized under the laws of Japan), except (1) pursuant to an exemption from the registration requirements of the Financial Instruments and Exchange Law and (2) in compliance with any other applicable requirements of Japanese law.

Notice to Prospective Investors in 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 (1) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (2) 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 (3) 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 party 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 ADSs 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 ADSs and debentures of that corporation or such rights and interest in that trust are acquired at a consideration of not less than \$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.

Notice to Prospective Investors in Switzerland

This document is not intended to constitute an offer or solicitation to purchase or invest in the ADSs described herein. The ADSs may not be publicly offered, sold or advertised, directly or indirectly, in, into or from Switzerland and will not be listed on the SIX Swiss Exchange or on any other exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the ADSs constitutes a prospectus as such term is understood pursuant to article 652a or article 1156 of the Swiss Code of Obligations or a listing prospectus within the meaning of the listing rules of the SIX Swiss Exchange or any other regulated trading facility in Switzerland, and neither this document nor any other offering or marketing material relating to the ADSs may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, nor the Company nor the ADSs have been or will be filed with or approved by any Swiss regulatory authority. The ADSs are not subject to the supervision by any Swiss regulatory authority, e.g., the Swiss Financial Markets Supervisory Authority FINMA (FINMA), and investors in the ADSs will not benefit from protection or supervision by such authority.

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, or FINRA, filing fee, and The Nasdaq Global Market, or Nasdaq, entry and listing fee, all amounts are estimates.

	US\$
SEC Registration Fee	
FINRA Filing Fee	
Nasdaq Global Market Entry and Listing Fee	
Printing and Engraving Expenses	
Legal Fees and Expenses	
Accounting Fees and Expenses	
Miscellaneous	
Total	US\$

LEGAL MATTERS

We are being represented by Cooley 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 offered in this offering and legal matters as to Cayman Islands law will be passed upon for us by Harney Westwood & Riegels. Certain legal matters as to the People's Republic of China, or PRC, law will be passed upon for us by AllBright Law Offices and the underwriters by Zhong Lun Law Firm. Cooley LLP may rely upon Harney Westwood & Riegels with respect to matters governed by Cayman Islands law and AllBright Law Offices with respect to matters governed by PRC law.

EXPERTS

The consolidated financial statements as of December 31, 2018 and 2019 and for the years then ended 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 11/F PricewaterhouseCoopers Center, Link Square 2, 202 Hu Bin Road, Huangpu District, Shanghai 200021, 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 the ADSs. Statements made in this prospectus concerning the contents of any contract, agreement or other document are summaries of all material information about the documents summarized, but are not complete descriptions of all terms of these documents. If we file any of these documents as an exhibit to the registration statement, we refer you to the copy of the document that has been filed for a complete description of its terms. Each statement in this prospectus relating to a document filed as an exhibit is qualified in all respects by the filed exhibit.

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. All information filed with the SEC can be obtained over the internet at the SEC's website at www.sec.gov.

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 combined financial statements prepared in conformity with IFRS, 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.

We maintain a corporate website at www.gracellbio.com. Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus and our website address is included in this prospectus as an inactive textual reference only.

GRACELL BIOTECHNOLOGIES INC.

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Gracell Biotechnologies Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Gracell Biotechnologies Inc. and its subsidiaries (the “Company”) as of December 31, 2019 and 2018, and the related consolidated statements of comprehensive loss, of changes in shareholders’ 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, 2019 and 2018, 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
October 19, 2020

We have served as the Company’s auditor since 2020.

GRACELL BIOTECHNOLOGIES INC.
CONSOLIDATED BALANCE SHEETS
AS OF DECEMBER 31, 2018 AND 2019

(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Notes	As of December 31,			Pro forma as of December 31,	
		2018	2019	US\$ (Note 2)	2019	
		RMB	RMB		RMB Unaudited (Note 12)	US\$ Unaudited (Note 12)
ASSETS						
Current assets:						
Cash and cash equivalents		11,890	312,058	45,961	312,058	45,961
Short-term investments		102,000	4,200	619	4,200	619
Prepayments and other current assets	3	14,072	24,095	3,549	24,095	3,549
Total current assets		127,962	340,353	50,129	340,353	50,129
Property, equipment and software	4	16,285	48,323	7,117	48,323	7,117
Other non-current assets	5	4,271	23,541	3,467	23,541	3,467
TOTAL ASSETS		148,518	412,217	60,713	412,217	60,713
LIABILITIES, MEZZANINE EQUITY AND SHAREHOLDERS' DEFICIT						
Current liabilities:						
Accruals and other current liabilities	6	7,440	18,166	2,675	18,166	2,675
Total current liabilities		7,440	18,166	2,675	18,166	2,675
Convertible loans	8	138,695	138,695	20,428	138,695	20,428
TOTAL LIABILITIES		146,135	156,861	23,103	156,861	23,103
Commitments and contingencies	14					
Mezzanine equity:						
Series A convertible redeemable preferred shares (US\$ 0.0001 par value; 36,567,163 and 31,343,282 shares authorized, issued and outstanding as of December 31, 2018 and 2019, respectively)	8	83,404	82,334	12,126	—	—
Series B-2 convertible redeemable preferred shares (US\$ 0.0001 par value; Nil and 59,327,653 shares authorized, issued and outstanding as of December 31, 2018 and 2019, respectively)	8	—	465,509	68,562	—	—
Total mezzanine equity		83,404	547,843	80,688	—	—
Shareholders' deficit:						
Ordinary shares (par value of US\$0.0001 per share; 500,000,000 and 500,000,000 shares authorized; 100,089,552 and 99,044,776 shares issued and outstanding as of December 31, 2018 and 2019, respectively; 189,715,711 shares issued and outstanding on a pro forma basis as of December 31, 2019 (unaudited))	7	69	68	10	77	11
Accumulated other comprehensive loss		—	(3,159)	(465)	544,675	80,222
Accumulated deficit		(81,090)	(289,396)	(42,623)	(289,396)	(42,623)
Total shareholders' deficit		(81,021)	(292,487)	(43,078)	255,356	37,610
TOTAL LIABILITIES, MEZZANINE EQUITY AND SHAREHOLDERS' DEFICIT		148,518	412,217	60,713	412,217	60,713

The accompanying notes are an integral part of these consolidated financial statements.

GRACELL BIOTECHNOLOGIES INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Notes	For the years ended December 31,		
		2018	2019	US\$
		RMB	RMB	(Note 2)
Expenses				
Research and development expenses		(52,243)	(119,218)	(17,559)
Administrative expenses		(10,261)	(27,362)	(4,030)
Loss from operations		(62,504)	(146,580)	(21,589)
Interest income		1,435	3,932	579
Other income		256	1,449	213
Foreign exchange gain, net		—	2,556	376
Others, net		20	(21)	(3)
Loss before income tax		(60,793)	(138,664)	(20,424)
Income tax expense	10	—	—	—
Net loss		(60,793)	(138,664)	(20,424)
Deemed dividend to convertible redeemable preferred shareholders		—	(25,390)	(3,740)
Accretion of convertible redeemable preferred shares to redemption value	8	(12,199)	(36,802)	(5,420)
Net loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders		(72,992)	(200,856)	(29,584)
Other comprehensive loss				
Foreign currency translation adjustments, net of nil tax		—	(3,159)	(465)
Total comprehensive loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders		(72,992)	(204,015)	(30,049)
Weighted average number of ordinary shares used in per share calculation:				
—Basic	11	100,089,552	99,053,363	99,053,363
—Diluted	11	100,089,552	99,053,363	99,053,363
Net loss per share attributable to Gracell Biotechnologies Inc.'s ordinary shareholders				
—Basic	11	(0.73)	(2.03)	(0.30)
—Diluted	11	(0.73)	(2.03)	(0.30)

The accompanying notes are an integral part of these consolidated financial statements.

GRACELL BIOTECHNOLOGIES INC.
CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' DEFICIT
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Ordinary shares		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total shareholders' deficit
	Number of shares	Amount RMB	RMB	RMB	RMB	RMB
Balance as of January 1, 2018	100,089,552	69	876	—	(8,974)	(8,029)
Net loss	—	—	—	—	(60,793)	(60,793)
Accretion of convertible redeemable preferred shares to redemption value	—	—	(876)	—	(11,323)	(12,199)
Balance as of December 31, 2018	100,089,552	69	—	—	(81,090)	(81,021)
Net loss	—	—	—	—	(138,664)	(138,664)
Repurchase of ordinary shares (Note 7)	(1,044,776)	(1)	—	—	(7,450)	(7,451)
Repurchase of convertible redeemable preferred shares (Note 8)	—	—	—	—	(25,390)	(25,390)
Accretion of convertible redeemable preferred shares to redemption value	—	—	—	—	(36,802)	(36,802)
Foreign currency translation adjustment	—	—	—	(3,159)	—	(3,159)
Balance as of December 31, 2019	99,044,776	68	—	(3,159)	(289,396)	(292,487)

The accompanying notes are an integral part of these consolidated financial statements.

GRACELL BIOTECHNOLOGIES INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

(All amounts in thousands, except for share and per share data, unless otherwise noted)

	For the years ended December 31,		
	2018	2019	
	RMB	RMB	US\$ (Note 2)
Cash flows from operating activities:			
Net loss	(60,793)	(138,664)	(20,424)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	2,992	5,124	755
Foreign exchange gain, net	—	(2,556)	(376)
Changes in operating assets and liabilities:			
Prepayments and other current assets	(10,612)	(10,023)	(1,476)
Accrued liabilities and other current liabilities	6,557	10,726	1,580
Net cash used in operating activities	(61,856)	(135,393)	(19,941)
Cash flows from investing activities:			
Purchase of property, equipment and software	(11,357)	(56,432)	(8,312)
Investments in short-term investments	(335,000)	(80,200)	(11,812)
Proceeds from disposal of short-term investments	233,000	178,000	26,217
Net cash (used in) generated from investing activities	(113,357)	41,368	6,093
Cash flows from financing activities:			
Proceeds from issuance of convertible loans	138,695	—	—
Proceeds from issuance of convertible redeemable preferred shares	—	439,501	64,732
Repurchase of ordinary shares and preferred shares	—	(44,705)	(6,584)
Proceeds from bank borrowings	10,000	—	—
Repayments of bank borrowings	(10,000)	—	—
Net cash generated from financing activities	138,695	394,796	58,148
Effect of exchange rate on cash and cash equivalents	—	(603)	(90)
Net increase (decrease) cash and cash equivalents	(36,518)	300,168	44,210
Cash and cash equivalents at the beginning of year	48,408	11,890	1,751
Cash and cash equivalents at the end of year	11,890	312,058	45,961
Supplemental cashflow disclosures:			
Non-cash activities:			
Accretion of convertible redeemable preferred shares to redemption value	12,199	36,802	5,420

The accompanying notes are an integral part of these consolidated financial statements.

GRACELL BIOTECHNOLOGIES INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019

(All amounts in thousands, except for share and per share data, unless otherwise noted)

1. ORGANIZATION AND BASIS OF PRESENTATION

(a) Nature of operations

Gracell Biotechnologies Inc. (the “Company”), an exempted company with limited liability, was incorporated in Cayman Islands on May 22, 2018. The Company, through its consolidated subsidiaries and variable interest entity (“VIE”) (collectively referred to as the “Group”) engaged primarily in the business of discovering and developing cell therapies to resolve industry challenges and fulfill unmet medical needs in the treatment of cancer (collectively referred to as the “Gracell Business”). The Group’s principal operation and geographic market is in the People’s Republic of China (“PRC”).

(b) Reorganization

The Group carried out its principal business in the People’s Republic of China (the “PRC”) since May 22, 2017 mainly through Gracell Biotechnologies (Shanghai) Co., Ltd. (“Gracell Biotechnologies” or the “VIE”) in the PRC. In connection with the Company’s planned initial public offering on the overseas capital market and facilitate offshore financing, the Group underwent a reorganization through which Gracell Biotechnologies (HK) Limited and Gracell Bioscience (Shanghai) Co., Ltd., (the “WFOE”), were established. The Company then entered into a series of contractual arrangements among the WFOE, the VIE and the VIE’s shareholders in January 2019 and the VIE’s shareholders swapped their shares in the VIE for shares in the Company to establish the Company as the ultimate holding company and the VIE became the variable interest entity of the Group (“Reorganization”).

As of December 31, 2019, the Company’s principal subsidiaries are as follows:

	<u>Date of incorporation</u>	<u>Place of incorporation</u>	<u>Percentage of legal ownership by the Company</u>	<u>Principal activities</u>
<u>Subsidiaries</u>				
Gracell Biotechnologies Holdings Limited (“Gracell BVI”)	May 22, 2018	British Virgin Islands	100%	Investment holding
Gracell Biotechnologies (HK) Limited	June 7, 2018	Hong Kong	100%	Investment holding
Gracell Bioscience (Shanghai) Co., Ltd.	August 24, 2018	The PRC	100%	Research and development of innovative medicines
<u>VIE</u>				
Gracell Biotechnologies (Shanghai) Co., Ltd.	May 22, 2017	The PRC	—	Research and development of innovative medicines
<u>VIE’s subsidiary</u>				
Suzhou Gracell Biotechnologies Co., Ltd. (“Suzhou Gracell”)	April 23, 2018	The PRC	—	Research and development of innovative medicines

GRACELL BIOTECHNOLOGIES INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019
(All amounts in thousands, except for share and per share data, unless otherwise noted)

1. ORGANIZATION AND BASIS OF PRESENTATION (CONTINUED)

(c) Basis of Presentation for the Reorganization

The Reorganization consists of transferring the Gracell Business to the Group, which is controlled by the founder immediately before and after the Reorganization. The Reorganization was a recapitalization with no substantial changes in the shareholding of the Company. Accordingly, the Reorganization is accounted for as a transaction under common control. Therefore, the accompanying consolidated financial statements include the assets, liabilities, revenue, expenses and cash flows of the Gracell Business for the periods presented and are prepared on a carryover basis as if the corporate structure of the Group after the Reorganization had been in existence throughout the periods presented. Accordingly, the effect of the ordinary shares and the preferred shares issued by the Company pursuant to the Reorganization have been presented retrospectively as of the beginning of the earliest period presented on the consolidated financial statements or the original issue date, whichever is later, as if such shares were issued by the Company when the Group issued such interests.

(d) Contractual agreements with the VIE

Due to restrictions imposed by PRC laws and regulations on foreign ownership of companies engaged in the development and application of human stem cell or gene diagnostic and therapeutic technologies and other related businesses, the Group operates its restricted businesses in the PRC through its VIE, whose equity interests are ultimately held by the founder and other shareholders of the Group through the VIE's nominee shareholder. The Company obtained control over the VIE by entering into a series of contractual arrangements with the VIE's legal shareholder who is also referred to as nominee shareholder. The nominee shareholder is the legal owner of the VIE. However, the rights of the nominee shareholder have been transferred to the Group through the contractual arrangements.

The contractual arrangements used to control the VIE are the voting rights proxy agreement, call option agreement, technology consultation and service agreement, business cooperation agreement and equity pledge agreement. The Company's management concluded that the Company, through the contractual arrangements, has the power to direct the activities that most significantly impact the VIE's economic performance and bears the risks of and enjoys the rewards normally associated with ownership of the VIE. Therefore, the Company is the ultimate primary beneficiary of the VIE. As such, the Company consolidates the financial statements of the VIE and its subsidiary, and the financial results of the VIE were included in the Group's consolidated financial statements in accordance with the basis of presentation as stated in Note 2 (a).

The following is a summary of the principal terms of the contractual agreements entered into by and among the WFOE, the VIE and the nominee shareholders of the VIE are described below:

Voting rights proxy agreement

The WFOE, the Group's VIE and the nominee shareholders of the VIE have entered into an voting rights proxy agreement, pursuant to which the nominee shareholders of the Group's VIE irrevocably appointed WFOE or its designated persons as their attorney-in-fact to exercise all of their rights as a shareholder of the VIE, including, but not limited to, propose to hold a shareholders' meeting, exercise all shareholder's voting rights with respect to all matters to be discussed and voted in the shareholders' meeting including but not limited to designate and appoint the director, the chief executive officer and other senior management members of the Company and exercise other voting rights the shareholders are entitled to.

GRACELL BIOTECHNOLOGIES INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019
(All amounts in thousands, except for share and per share data, unless otherwise noted)

1. ORGANIZATION AND BASIS OF PRESENTATION (CONTINUED)

(d) Contractual agreements with the VIE (Continued)

Voting rights proxy agreement (Continued)

The agreement will remain in force for twenty (20) years and can be extended only if the WFOE gives its written notice of the extension of this agreement before the expiration of this agreement and the other parties shall agree with this extension without reserve.

On December 20, 2019, William Wei Cao entered into an amended voting rights proxy agreement and power of attorney with the WFOE and the VIE, which contain terms substantially similar to the voting rights proxy agreement and power of attorney described above.

Call option agreement

The WFOE, the Group's VIE and the nominee shareholders of the VIE have entered into a call option agreement, pursuant to which the shareholders of the VIE irrevocably granted the WFOE an exclusive option to purchase, or have its designated person to purchase, at its discretion, to the extent permitted under PRC law, all or part of their equity interests in the VIE and the purchase price shall be the lowest price permitted by applicable PRC law. The shareholders undertake that, without the prior written consent of the WFOE, they shall not sell, transfer, mortgage or otherwise dispose of its equity interests in the VIE or allow the encumbrance thereon of any security interest, increase or decrease the registered capital of the VIE, appoint or replace any directors of the VIE, sell, transfer, mortgage or dispose of the VIE's assets or beneficial interest in the business or revenues, conduct any merger, acquisition or investments, declare or distribution any dividend; change or amend articles of association or incur any debts or guarantee liabilities. The exclusive option agreement will remain effective until all equity interests in the VIE are transferred or assigned to the WFOE or its designated representative(s).

Technology consultation and service agreement

The WFOE and the VIE entered into a technology consultation and service agreement under which the WFOE engages the VIE as its exclusive consultant and provider of fund, human, technology and intellectual properties service and technical support, consulting services and other commercial services on exclusive basis in relation to the principal business. The WFOE has exclusive and proprietary rights and interests in all rights, ownership, interests and intellectual properties arising out of or created during the performance of this agreement. During the term of the agreement, the VIE may not enter into any agreement with third parties for the provision of identical or similar service without prior consent of the WFOE. In exchange, WFOE agrees to pay an annual service fee to the VIE and such fee is determined by WFOE based on its services provided including various factors such as WFOE's incurred technology support and consulting services fees, performance data and the VIE's revenues. The agreement will remain in force for twenty (20) years and can be extended with WFOE's written notice of the extension before the expiration of this agreement and the VIE shall agree with this extension without reserve.

Business cooperation agreement

Under the business cooperation agreement entered between the VIE and WFOE, WFOE has the exclusive right to provide to the VIE technology support, consulting services and other commercial services including market analysis and consultation, products research and development, training and operation management consultation services. The VIE can't sell, dispose, pledge the intellectual property rights created by the performance of this agreement which should be exclusively owned by WFOE. In exchange, WFOE agrees to pay an annual service fee to VIE based on the services provided including various factors such as WFOE's incurred technology support

GRACELL BIOTECHNOLOGIES INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
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1. ORGANIZATION AND BASIS OF PRESENTATION (CONTINUED)

(d) Contractual agreements with the VIE (Continued)

Business cooperation agreement (Continued)

and consulting services fees, performance data and VIE's profit. The agreement shall maintain effective unless terminated under applicable PRC laws and regulations.

Equity Pledge Agreement

Pursuant to the share pledge agreement entered between the VIE and its shareholders and WFOE, the shareholders of VIE have to pledge all of their equity interests in the VIE to WFOE to guarantee the performance by the VIE and its shareholders' performance of their respective obligations under the call option agreement, technology consultation and service agreement, and voting rights proxy agreement. If the VIE and/or its shareholders breach their contractual obligations under those agreements, WFOE, as pledgee, will be entitled to certain rights, including the right to sell the pledged equity interests. The shareholders of VIE also undertakes that, during the term of the equity pledge agreements, they shall not dispose of the pledged equity interests or create or allow any encumbrance on the pledged equity interests. During the term of the equity pledge agreement, WFOE has the right to receive all of the dividends and profits distributed on the pledged equity interests. The pledge will remain binding until the VIE and their shareholders discharge all their obligations under the contractual arrangements.

Spouse Consent Letter

On January 3, 2019, the spouse of the founder, unconditionally and irrevocably agreed that the equity interest in the VIE held by the founder will be disposed of pursuant to the equity pledge agreement, the voting rights proxy agreement and the call option agreement. The spouse agreed not to make any assertions in connection with the equity interest in the VIE held by the founder.

Risks in relation to the VIE structure

A significant part of the Group's business is conducted through the VIE of the Group, of which the Company is the ultimate primary beneficiary. In the opinion of the management, the contractual arrangements with the VIE and the nominee shareholder are in compliance with PRC laws and regulations and is legally binding and enforceable. Nominee shareholders indicate that they will not act contrary to the contractual arrangements. However, there are substantial uncertainties regarding the interpretation and application of the PRC laws and regulations including those that govern the contractual arrangements, which could limit the Group's ability to enforce these contractual arrangements and if nominee shareholders of the VIE was to reduce their interests in the Group, their interest may diverge from that of the Group and that may potentially increase the risk that they would seek to act contrary to the contractual arrangements.

It is possible that the Group's operation of certain of its operations and businesses through the VIE could be found by PRC authorities to be in violation of PRC law and regulations prohibiting or restricting foreign ownership of companies that engage in such operations and businesses. While the Group's management considers the possibility of such a finding by PRC regulatory authorities under current law and regulations to be remote, on March 15, 2019, the National People's Congress adopted the Foreign Investment Law of the PRC,

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FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019
(All amounts in thousands, except for share and per share data, unless otherwise noted)

1. ORGANIZATION AND BASIS OF PRESENTATION (CONTINUED)

(d) Contractual agreements with the VIE (Continued)

Risks in relation to the VIE structure (Continued)

which became effective on January 1, 2020 and replaces three laws regulating foreign investment in China, namely, the Wholly Foreign-Invested Enterprise Law of the PRC, the Sino-Foreign Cooperative Joint Venture Enterprise Law of the PRC and the Sino-Foreign Equity Joint Venture Enterprise Law of the PRC, together with their implementation rules and ancillary regulations. The Foreign Investment Law of the PRC 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 investments. However, since it is relatively new, uncertainties still exist in relation to its interpretation and implementation. For example, the Foreign Investment Law of the PRC adds a catch-all clause to the definition of “foreign investment” so that foreign investment, by its definition, includes “investments made by foreign investors in China through other means defined by other laws or administrative regulations or provisions promulgated by the State Council” without further elaboration on the meaning of “other means.” It leaves leeway for the future legislations promulgated by the State Council to provide for contractual arrangements as a form of foreign investment. It is therefore uncertain whether the Group’s corporate structure will be seen as violating the foreign investment rules as the Group are currently leveraging the contractual arrangements to operate certain businesses in which foreign investors are prohibited from or restricted to investing. Furthermore, if future legislations prescribed by the State Council mandate further actions to be taken by companies with respect to existing contractual arrangement, the Group may face substantial uncertainties as to whether the Group can complete such actions in a timely manner, or at all. If the Group fails to take appropriate and timely measures to comply with any of these or similar regulatory compliance requirements, the Group’s current corporate structure, corporate governance and business operations could be materially and adversely affected.

If the Group’s corporate structure or the contractual arrangements with the VIE were found to be in violation of any existing or future PRC laws and regulations, the PRC regulatory authorities could, within their respective jurisdictions:

- revoking the business licenses and/or operating licenses of such entities;
- discontinuing or placing restrictions or onerous conditions on the Group’s operation through any transactions between the PRC subsidiary and the VIE;
- imposing fines, confiscating the income from the PRC subsidiary or the VIE, or imposing other requirements with which the VIE may not be able to comply;
- requiring the Group to restructure the ownership structure or operations, including terminating the contractual arrangements with the VIE and deregistering the equity pledges of the VIE, which in turn would affect the Group’s ability to consolidate, derive economic interests from, or exert effective control over the VIE;
- restricting or prohibiting the Group’s use of the proceeds of this offering to finance the Group’s business and operations in China; or
- taking other regulatory or enforcement actions that could be harmful to the Group’s business.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019
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1. ORGANIZATION AND BASIS OF PRESENTATION (CONTINUED)

(d) Contractual agreements with the VIE (Continued)

Risks in relation to the VIE structure (Continued)

The imposition of any of these restrictions or actions could result in a material adverse effect on the Group's ability to conduct its business. In such case, the Group may not be able to operate or control the VIE, which may result in deconsolidation of the VIE in the Group's consolidated financial statements. In the opinion of the management, the likelihood for the Group to lose such ability is remote based on current facts and circumstances. The Group believes that the contractual arrangements among each of the VIE, their respective shareholders and relevant wholly foreign owned enterprise are in compliance with PRC law and are legally enforceable. The Group's operations depend on the VIE to honor their contractual arrangements with the Group. These contractual arrangements are governed by PRC law and disputes arising out of these agreements are expected to be decided by arbitration in the PRC. The Company's management believes that each of the contractual arrangements constitutes valid and legally binding obligations of each party to such contractual arrangements under the PRC laws. However, the interpretation and implementation of the laws and regulations in the PRC and their application on the legality, binding effect and enforceability of contracts are subject to the discretion of competent PRC authorities, and therefore there is no assurance that relevant PRC authorities will take the same position as the Group herein in respect of the legality, binding effect and enforceability of each of the contractual arrangements. Meanwhile, since the PRC legal system continues to evolve, the interpretations of many laws, regulations and rules are not always uniform and enforcement of these laws, regulations and rules involve uncertainties, which may limit legal protections available to the Group to enforce the contractual arrangements should the VIE or the nominee shareholders of the VIE fail to perform their obligations under those arrangements.

The contractual arrangements cannot be unilaterally terminated. Management concluded that the Company, through the WFOE and the contractual arrangements, has the power and control to direct the activities that most significantly impact the VIE's economic performance, bears the risks and enjoys the rewards normally associated with ownership of the VIE, receive substantially all of the economic benefits and residual returns, and absorb substantially all the risks and expected losses from the VIE as if it was their sole shareholder and therefore the Company is the ultimate primary beneficiary of the VIE. As such, the Group consolidates the financial results of the VIE which are prepared in accordance with the basis of presentation as stated in Note 2 below.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
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1. ORGANIZATION AND BASIS OF PRESENTATION (CONTINUED)

(d) Contractual agreements with the VIE (Continued)

Risks in relation to the VIE structure (Continued)

The following financial information of the Group's VIE and the VIE's subsidiary as of December 31, 2018 and 2019 and for the years ended December 31, 2018 and 2019 is included in the accompanying consolidated financial statements of the Group as follows:

	As of December 31,		
	2018 RMB	2019 RMB	US\$ (Note 2)
ASSETS			
Current assets:			
Cash and cash equivalents	11,890	42,153	6,208
Short-term investments	102,000	4,200	619
Amounts due from related parties	3,980	51,835	7,634
Prepayments and other current assets	10,230	17,912	2,638
Total current assets	128,100	116,100	17,099
Property, equipment and software	16,285	36,350	5,354
Other non-current assets	4,272	17,682	2,604
TOTAL ASSETS	148,657	170,132	25,057
LIABILITIES			
Current liabilities:			
Amounts due to related parties	138,695	218,719	32,214
Accruals and other current liabilities	6,369	7,886	1,161
Total current liabilities	145,064	226,605	33,375
Amounts due to related parties	—	23,000	3,388
TOTAL LIABILITIES	145,064	249,605	36,763

	For the years ended December 31,		
	2018 RMB	2019 RMB	US\$ (Note 2)
Total revenue from related parties	130	6,604	973
Net loss	(59,582)	(83,066)	(12,234)

	For the years ended December 31,		
	2018 RMB	2019 RMB	US\$ (Note 2)
Net cash used in operating activities	(61,856)	(87,277)	(12,855)
Net cash generated from (used in) investing activities	(113,358)	59,281	8,731
Net cash generated from financing activities	138,695	58,259	8,581

GRACELL BIOTECHNOLOGIES INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2019
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1. ORGANIZATION AND BASIS OF PRESENTATION (CONTINUED)

(d) Contractual agreements with the VIE (Continued)

Risks in relation to the VIE structure (Continued)

The Company's involvement with the VIE is through the contractual arrangements disclosed in Note 1. All recognized assets held by the VIE are disclosed in the table above.

In accordance with various contractual agreements, the Company has the power to direct the activities of the VIE and can have assets transferred out of the VIE. Therefore, the Company considers that there are no assets in the respective VIE that can be used only to settle obligations of the respective VIE, except for the registered capital of the VIE. As the respective VIE is incorporated as limited liability company under the PRC Company Law, creditors do not have recourse to the general credit of the Company for the liabilities of the respective VIE. There is currently no contractual arrangement that would require the Company to provide additional financial support to the VIE. As the Group is conducting certain businesses in the PRC through the VIE, the Group may provide additional financial support on a discretionary basis in the future, which could expose the Group to a loss. There is no VIE in the Group where the Company or any subsidiary has a variable interest but is not the primary beneficiary.

The Group believes that the contractual arrangements among the VIE shareholders, the VIE and the WFOE comply with PRC law and are legally enforceable. However, uncertainties in the PRC legal system could limit the Company's ability to enforce these contractual arrangements and if the shareholders of the VIE were to reduce their interest in the Company, their interests may diverge from that of the Company and that may potentially increase the risk that they would seek to act contrary to the contractual terms.

The Company's ability to control the VIE also depends on the voting rights proxy and the effect of the share pledge under the Equity Pledge Agreement and the WFOE has to vote on all matters requiring shareholders' approval in the VIE. As noted above, the Company believes this voting right proxy is legally enforceable but may not be as effective as direct equity ownership.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

Principal accounting policies followed by the Company in the preparation of the accompanying consolidated financial statements are summarized below.

Principles of Consolidation

The Group's consolidated financial statements include the financial statements of the Company, its subsidiaries and the VIE for which the Company is the primary beneficiary. All transactions and balances among the Company, its subsidiaries, and the VIE have been eliminated upon consolidation.

A subsidiary is an entity in which the Company, directly or indirectly: (1) controls more than one half of the voting power; (2) has the power to appoint or remove the majority of the members of the board of directors;

GRACELL BIOTECHNOLOGIES INC.
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2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Principles of Consolidation (Continued)

(3) casts a majority of votes at the meeting of the board of directors; or (4) governs the financial and operating policies of the investee under a statute or agreement among the shareholders or equity holders.

The Company applies the guidance codified in Accounting Standard Codification (“ASC”) 810, Consolidations, which contains guidance of accounting for VIEs. The guidance requires certain variable interest entities to be consolidated by the primary beneficiary of the entity in which it has a controlling financial interest. A consolidated VIE is an entity in which the Company, or its subsidiary, through contractual arrangements, bears the risks of, and enjoys the rewards normally associated with, ownership of the entity, and therefore the Company or its subsidiary is the primary beneficiary of the entity.

Use of estimates

The preparation of 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, disclosures of contingent assets and liabilities at the balance sheet dates and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in the Group’s consolidated financial statements include, but are not limited to, the useful lives and impairment of long-lived assets, deferred tax valuation allowance, share-based compensation expenses. Management bases the estimates on historical experience 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 materially differ from those estimates.

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, Hong Kong, 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 as foreign currency translation adjustments.

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 during the fiscal year. Foreign currency translation adjustments arising from these are reflected in the accumulated other comprehensive income.

Translations of balances in the consolidated balance sheets, consolidated statements of comprehensive loss, consolidated statements of changes in shareholders’ deficit and consolidated statements of cash flows from RMB

GRACELL BIOTECHNOLOGIES INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
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2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Foreign currency translation (Continued)

into US\$ as of and for the year ended December 31, 2019 are solely for the convenience of the readers and were calculated at the rate of US\$1.00=RMB6.7896, 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 September 30, 2020. 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, 2019, 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.

Cash and cash equivalents

Cash and cash equivalents primarily consist of cash and demand deposits which are highly liquid. The Group considers highly liquid investments that are readily convertible to known amounts of cash and with original maturities from the date of purchase of three months or less to be cash equivalents. All cash and cash equivalents are unrestricted as to withdrawal and use.

Short-term investments

Short-term investments are deposits at bank with maturities of greater than three months, but less than twelve months. Short-term investments are stated at cost, which approximates fair value. Interest earned is included in interest income.

Fair value measurements

The Group applies ASC 820, *Fair Value Measurements and Disclosures*. ASC 820 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. ASC 820 requires disclosures to be provided for fair value measurements. ASC 820 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1—Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2—Includes other inputs that are directly or indirectly observable in the marketplace.

Level 3—Unobservable inputs which are supported by little or no market activity.

ASC 820 describes three main approaches to measuring the fair value of assets and liabilities: (1) market approach; (2) income approach; and (3) cost approach. The market approach uses prices and other relevant information generated from market transactions involving identical or comparable assets or liabilities. The income approach uses valuation techniques to convert future amounts to a single present value amount. The measurement is based on the value indicated by current market expectations about those future amounts. The cost approach is based on the amount that would currently be required to replace an asset.

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2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Fair value measurements (Continued)

The carrying amounts of cash and cash equivalent, short-term investments, other current assets, accrued liabilities and other current liabilities and convertible loans approximate their fair values because of their generally short maturities.

Property, equipment and software

Property and equipment and software are stated at cost less accumulated depreciation and amortization. Depreciation and amortization is computed using the straight-line method over the estimated useful lives of the assets as follows:

Category	Estimated Useful Life
Machinery and laboratory equipment	5 years
Vehicles	4 years
Furniture and tools	3-5 years
Electronic equipment	3 years
Computer software	3-5 years
Leasehold improvements	Lesser of lease terms or estimated useful lives of the assets

Repair and maintenance costs are charged to expense as incurred, whereas the cost of renewals and betterments that extend the useful lives of property, equipment and software are capitalized as additions to the related assets. Retirements, sales and disposals of assets are recorded by removing the cost and accumulated depreciation and amortization from the asset and accumulated depreciation and amortization accounts with any resulting gain or loss reflected in the consolidated statements of comprehensive loss.

Impairment of long-lived assets

The Group evaluates the recoverability of its long-lived assets, including fixed assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable. When these events occur, the Group measures impairment by comparing the carrying amount of the assets to the estimated undiscounted future cash flows expected to result from the use of the assets and their eventual disposition. If the sum of the expected undiscounted cash flows is less than the carrying amount of the assets, the Group recognizes an impairment loss based on the excess of the carrying amount of the assets over their fair value. Fair value is generally determined by discounting the cash flows expected to be generated by the assets, when the market prices are not readily available. The adjusted carrying amount of the assets is the new cost basis and is depreciated over the assets' remaining useful lives. Long-lived assets are grouped with other assets and liabilities at the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and liabilities.

No impairment loss was recorded for the years ended December 31, 2018 and 2019.

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2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Segment reporting

In accordance with ASC 280, *Segment Reporting*, the Group's chief operating decision maker ("CODM") has been identified as the Chief Executive Officer. The Group's CODM reviews the consolidated results of operations when making decisions about allocating resources and assessing performance of the Group. The Group operates and manages its business as a single segment. The Group does not distinguish between markets for the purpose of making decisions about resources allocation and performance assessment. Hence, the Group has only one operating segment and one reportable segment. No geographical segments are presented as substantially all of the Group's long-lived assets are located in the PRC.

Research and development expenses

Elements of research and development expenses primarily include (1) payroll and other related costs of personnel engaged in research and development activities, (2) costs related to pre clinical testing of the Group's technologies under development and clinical trials such as payments to contract research organizations ("CRO") and contract manufacturing organizations ("CMO"), investigators and clinical trial sites that conduct the clinical studies; (3) costs to develop the product candidates, including raw materials and supplies, product testing, depreciation and amortization, and facility related expenses, (4) 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 in accordance with ASC 730, *Research and Development*. As of December 31, 2019, the Group has several ongoing clinical studies in various clinical trial stages. The contracts with CRO and CMO are generally cancellable, with notice, at the Group's option. The Group did not record any accrued expenses related to cancellation of CRO or CMO contracts as of December 31, 2019 as the Group did not have any plan to cancel the existing CRO or CMO contracts.

Government subsidies

Government subsidies primarily consist of financial subsidies received from provincial and local governments for operating a business in their jurisdictions and compliance with specific policies promoted by the governments. The Group's PRC based subsidiaries received government subsidies from certain local governments. The Group's government subsidies consist of specific subsidies and other subsidies. Specific subsidies are subsidies that the local government has set certain conditions for the subsidies. Other subsidies are the subsidies that the local government has not set any conditions and are not tied to future trends or performance of the Group, receipt of such subsidy income is not contingent upon any further actions or performance of the Group and the amounts do not have to be refunded under any circumstances. For the years ended December 31, 2018 and 2019, no specific subsidies were received by the Group. Other subsidies are recognized as other income upon receipt as further performance by the Group is not required.

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 exists: a) ownership is transferred to the lessee by the end of the lease term, b) there is a bargain purchase option, c) the lease term is at least 75% of the property's estimated remaining economic life or d) the present value of the minimum lease payments at the beginning of the

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2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Leases (Continued)

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 had no capital leases for the years ended December 31, 2018 and 2019.

All other leases are accounted for as operating leases wherein rental payments are expensed on a straight-line basis over their respective lease terms. The Group leases certain office space under non-cancelable operating lease agreements. Certain 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 leased property for purpose of recognizing lease expense on straight-line basis over the term of the lease.

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 shareholders and distributions to shareholders. Accumulated other comprehensive loss of the Group includes foreign currency translation adjustments.

Income taxes

The Group follows the liability method of accounting for income taxes in accordance with ASC 740, *Income Taxes* ("ASC 740"). Under this method, deferred tax assets and liabilities are determined based on the difference between the financial reporting and tax bases of assets and liabilities using enacted tax rates that will be in effect in the period in which the differences are expected to reverse. The Group records a valuation allowance to offset deferred tax assets if based on the weight of available evidence, it is more likely than not that some portion, or all, of the deferred tax assets will not be realized. The effect on deferred taxes of a change in tax rate is recognized in tax expense in the period that includes the enactment date of the change in tax rate.

The Group evaluates its uncertain tax positions using the provisions of ASC 740, which prescribes a recognition threshold that a tax position is required to meet before being recognized in the consolidated financial statements.

The Group recognizes in the consolidated 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.

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.

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2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Share-based compensation

The Company grants share options to eligible employees and consultants and accounts for share-based compensation in accordance with ASC 718, *Compensation—Stock Compensation*.

The Company follows ASC 718 to determine whether a share option should be classified and accounted for as a liability award or equity award. All grants of share-based awards to employees, management and nonemployees classified as equity awards are recognized in the financial statements based on their grant date fair values which are calculated using the binomial option pricing model.

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 straight-line method, 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.

The Company early adopted Accounting Standards Update ("ASU") 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting* from the earliest period presented to recognize the effect of forfeiture in compensation cost when they occur.

Net loss per share

In accordance with ASC 260, *Earnings Per Share*, basic net loss per share is computed by dividing net loss attributable to ordinary shareholders by the weighted average number of unrestricted ordinary shares outstanding during the year using the two-class method. Under the two-class method, net loss is allocated between ordinary shares and other participating securities based on dividends declared (or accumulated) and participating rights in undistributed earnings as if all the earnings for the reporting period had been distributed. The Company's convertible redeemable preferred shares are participating securities because they are entitled to receive dividends or distributions on an as converted basis. Diluted net loss per share is calculated by dividing net loss attributable to ordinary shareholders, as adjusted for the effect of dilutive ordinary equivalent shares, if any, by the weighted average number of ordinary and dilutive ordinary equivalent shares outstanding during the period. Ordinary equivalent shares include ordinary shares issuable upon the conversion of the convertible redeemable preferred shares using the if-converted method, and ordinary shares issuable upon the exercise of share options, using the treasury stock method. Ordinary share equivalents are excluded from the computation of diluted earnings per share if their effects are anti-dilutive. For the periods presented herein, the computation of basic net loss per share using the two-class method is not applicable as the Group is in a net loss position and the participating securities do not have contractual rights and obligations to share in the losses of the Group.

Employee defined contribution plan

As stipulated by the regulations of the PRC, full-time employees of the Group are entitled to staff welfare benefits including medical care, welfare subsidies, unemployment insurance and pension benefits through a PRC government-mandated multi-employer defined contribution plan. The Group is required to accrue for these benefits based on certain percentages of the qualified employees' salaries. The Group is required to make contributions to the plans out of the amounts accrued. The PRC government is responsible for the medical

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2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Employee defined contribution plan (Continued)

benefits and the pension liability to be paid to these employees and the Group's obligations are limited to the amounts contributed. The Group has no further payment obligations once the contributions have been paid. The Group recorded employee benefit expenses of RMB 19,967 and RMB 35,157 for the years ended December 31, 2018 and 2019, respectively.

Concentration of risks

Concentration of credit risk

As of December 31, 2018 and 2019, the aggregate amount of cash and cash equivalents and short-term investments of RMB 113,890 and RMB 221,568 respectively, were held at major financial institutions located in the PRC, and nil and RMB 94,690, respectively, were deposited with major financial institutions located outside the PRC. These financial institutions are of high credit quality and management continually monitors the credit worthiness of these financial institutions.

Business and economic risk

The Group believes that changes in any of the following areas could have a material adverse effect on the Group's future consolidated financial position, results of operations or cash flows: changes in the overall demand for services; competitive pressures due to new entrants; advances and new trends in new technologies and industry standards; changes in certain strategic relationships; regulatory considerations and risks associated with the Group's ability to attract employees necessary to support its growth. The Group's operations could also be adversely affected by significant political, regulatory, economic and social uncertainties in the PRC.

Foreign currency exchange rate risk

A significant portion of the Group's businesses are transacted in RMB, which is not a freely convertible currency. On January 1, 1994, the PRC government abolished the dual rate system and introduced a single rate of exchange as quoted daily by the People's Bank of China (the "PBOC"). However, the unification of the exchange rates does not imply that the RMB may be readily convertible into US\$ or other foreign currencies. All foreign exchange transactions continue to take place either through the PBOC or other banks authorized to buy and sell foreign currencies at the exchange rates quoted by the PBOC. Approval of foreign currency payments by the PBOC or other institutions requires submitting a payment application form together with suppliers' invoices, shipping documents and signed contracts.

From July 21, 2005, the RMB is permitted to fluctuate within a narrow and managed band against a basket of certain foreign currencies. For U.S. dollar against RMB, there was appreciation of approximately 5.7% and 1.3% in the years ended December 31, 2018 and 2019, respectively. It is difficult to predict how market forces or PRC or U.S. government policy may impact the exchange rate between the RMB and the U.S. dollar in the future.

Recently issued accounting pronouncements

In February 2016, the FASB issued ASU No. 2016-02 ("ASU 2016-02"), Leases (Topic 842), which modifies lease accounting for lessees to increase transparency and comparability by recording lease assets and liabilities

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2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Recently issued accounting pronouncements (Continued)

for operating leases and disclosing key information about leasing arrangements. In July 2018, the FASB issued ASU No. 2018-10 (“ASU 2018-10”), Codification Improvements to Topic 842, Leases, which clarifies certain aspects of the guidance issued in ASU 2016-02; and ASU No. 2018-11 (“ASU 2018-11”), Leases (Topic 842): Targeted Improvements, which provides entities with an additional (and optional) transition method to adopt the new leases standard. Under this new transition method, an entity initially applies the new leases standard at the adoption date and recognizes a cumulative effect adjustment to the opening balance of retained earnings in the period of adoption. Consequently, an entity’s reporting for the comparative periods presented in the financial statements in which it adopts the new leases standard will continue to be in accordance with current GAAP (Topic 840, Leases). In November 2019, the FASB issued ASU No. 2019-10, Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842), Effective Dates (“ASU 2019-10”), which extends the adoption date for certain registrants. The updated guidance is effective for the Group for annual reporting periods beginning January 1, 2021 and interim periods within annual periods beginning January 1, 2022. The Group will adopt ASU 2016-02 in its first quarter of 2021 utilizing the modified retrospective transition method. While the Group is currently evaluating the impact of adopting ASU 2016-02, based on the lease portfolio as of December 31, 2019, the Group anticipates recording lease assets and liabilities of approximately RMB 30 million to RMB 40 million on its consolidated balance sheets, with no material impact to its consolidated statements of comprehensive loss and consolidated statements of cash flows. However, the ultimate impact of adopting ASU 2016-02 will depend on the Group’s lease portfolio as of the adoption date.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments (“ASU 2016-13”). ASU 2016-13 is intended to improve financial reporting by requiring timelier recording of credit losses on loans and other financial instruments held by financial institutions and other organizations. This ASU requires the measurement of all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. This ASU requires enhanced disclosures to help investors and other financial statement users better understand significant estimates and judgments used in estimating credit losses, as well as the credit quality and underwriting standards of the Group’s portfolio. These disclosures include qualitative and quantitative requirements that provide additional information about the amounts recorded in the financial statements. In November 2019, the FASB issued ASU 2019-10, which extends the adoption date for certain registrants. The amendments in ASU 2016-13 are effective for fiscal years beginning after December 15, 2023, including interim periods within fiscal years beginning after December 15, 2023 for the Group. The Group does not plan to early adopt ASU 2016-13 and is currently in the process of evaluating the impact of adoption of this guidance on its consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, Compensation—Stock Compensation (Topic 718): Improvements to nonemployee share based payment accounting (“ASU 2018-07”). The amendments in this update expand the scope of Topic 718 to include share based payment transactions for acquiring goods and services from nonemployees. The amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted, but no earlier than an entity’s adoption date of Topic 606. The Group adopted the ASU on January 1, 2018 and there was not a material impact on the consolidated financial statements.

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2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Recently issued accounting pronouncements (Continued)

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement (“ASU 2018-13”). ASU 2018-13 modifies the disclosure requirements for fair value measurements by removing, modifying, or adding certain disclosures. The amendments in ASU 2018-13 are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. Early adoption is permitted upon issuance of ASU 2018-13. An entity is permitted to early adopt any removed or modified disclosures upon issuance of ASU 2018-13 and delay adoption of the additional disclosures until their effective date. The Group does not plan to early adopt ASU 2018-13 and is currently in the process of evaluating the impact of adoption of this guidance on its consolidated financial statements but anticipates the impact would be immaterial.

In November 2018, the FASB issued ASU 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606. This update clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer and precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue from contracts with customers if the counterparty is not a customer for that transaction. The update is effective in fiscal years beginning after December 15, 2021, and interim periods therein, and early adoption is permitted for entities that have adopted ASC 606. This guidance should be applied retrospectively to the date of initial application of Topic 606. The Group elected to early adopt this ASU and the impact of this ASU to the consolidated financial statements is immaterial, as no revenue was recorded for the years ended December 31, 2019 and 2018.

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes. This update simplifies the accounting for income taxes as part of the FASB’s overall initiative to reduce complexity in accounting standards. The amendments include removal of certain exceptions to the general principles of ASC 740, Income taxes, and simplification in several other areas such as accounting for a franchise tax (or similar tax) that is partially based on income. The update is effective in fiscal years beginning after December 15, 2022, and interim periods therein, and early adoption is permitted. Certain amendments in this update should be applied retrospectively or modified retrospectively, all other amendments should be applied prospectively. The Group does not plan to early adopt ASU 2019-12 and is currently evaluating the impact on its financial statements of adopting this guidance.

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3. PREPAYMENTS AND OTHER CURRENT ASSETS

Prepayments and other current assets consist of the following:

	As of December 31,		
	2018	2019	US\$
	RMB	RMB	(Note 2)
Deductible value-added tax input	6,200	13,770	2,028
Prepayments for CRO and other services	4,521	5,427	799
Deposits	3,181	3,959	583
Others	170	939	139
	<u>14,072</u>	<u>24,095</u>	<u>3,549</u>

4. PROPERTY, EQUIPMENT AND SOFTWARE

Property, equipment and software consist of the following:

	As of December 31,		
	2018	2019	US\$
	RMB	RMB	(Note 2)
Machinery and laboratory equipment	11,956	20,281	2,987
Leasehold improvements	3,317	5,654	833
Construction in Progress	2,673	28,515	4,200
Vehicles	1,066	1,088	160
Others	485	1,121	165
Total property, equipment and software	19,497	56,659	8,345
Less: accumulated depreciation and amortization	(3,212)	(8,336)	(1,228)
Property, equipment and software, net	<u>16,285</u>	<u>48,323</u>	<u>7,117</u>

Depreciation and amortization expenses recognized for the years ended December 31, 2018 and 2019 were RMB2,992 and RMB5,124, respectively.

5. OTHER NON-CURRENT ASSETS

Other non-current assets consist of the following:

	As of December 31,		
	2018	2019	US\$
	RMB	RMB	(Note 2)
Prepayment for property, equipment and software	<u>4,271</u>	<u>23,541</u>	<u>3,467</u>

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6. ACCRUALS AND OTHER CURRENT LIABILITIES

Accruals and other current liabilities consist of the following:

	2018	As of December 31, 2019	
	RMB	RMB	US\$ (Note 2)
Salary and welfare payables	3,885	6,720	990
Accrued external research and development related expenses	2,002	6,942	1,022
Professional service fees	3	2,092	308
Rental fees	1,072	2,072	305
Others	478	340	50
	<u>7,440</u>	<u>18,166</u>	<u>2,675</u>

7. ORDINARY SHARES

As at December 31, 2018 and 2019, 500,000,000 ordinary shares with a par value of \$0.0001 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. In 2017, the VIE issued 9,800,000 ordinary shares to William Wei Cao with total consideration of RMB2,150 and 208,955 ordinary shares to Shanghai Guidance Capital Ltd. (“Shanghai Zhaoheng”) and Suzhou Tonghe Venture Investment Partnership II (L.P.) (“Tonghe II”) for a total consideration of RMB200. On January 3, 2019, the VIE repurchased 104,478 shares of ordinary shares held by Shanghai Zhaoheng. As part of the Reorganization in January 2019, the former ordinary shares were exchanged for ordinary shares of the Company on a 1:10 basis. As at December 31, 2019, 99,044,776 shares of ordinary shares were issued and outstanding.

8. CONVERTIBLE REDEEMABLE PREFERRED SHARES

On August 8, 2017, the VIE issued 3,656,716 shares of Series A convertible redeemable preferred shares (“Series A Preferred Shares”) to certain investors at US\$3.032 per share for a total consideration of US\$11,087 (equivalent to approximately RMB69,800).

On August 14, 2018, the Company, the VIE and certain investors entered into a convertible loan agreement and a warrant agreement. Prior to the obtaining of requisite overseas direct investment approvals (“ODI approval”), the investors agreed to provide a convertible loan in an aggregate principal amount of US\$22,000 (equivalent to approximately RMB138,695) to the VIE, with no interest and acquire warrants to subscribe for a total number of 21,735,721 Series B1 Preferred Shares of the Company at US\$1.0122 per share.

On January 3, 2019, the VIE repurchased 104,478 shares of ordinary shares and 522,388 shares of Series A Preferred Shares for an aggregate price of US\$6,657 (equivalent to approximately RMB44,705). The consideration exceeded the carrying value of repurchased ordinary shares and Series A Preferred Shares by RMB32,840, which was recorded as deemed dividend to the ordinary and preferred shareholders.

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8. CONVERTIBLE REDEEMABLE PREFERRED SHARES (CONTINUED)

As part of the Reorganization in January 2019, the former Series A Preferred Shares were exchanged for 31,343,284 Series A Convertible Redeemable Preferred Shares of the Company (“Series A Preferred Shares”) on a 1:10 basis at US\$0.3032 per share.

On February 22, 2019, the Company issued 59,327,653 shares of Series B-2 convertible redeemable preferred shares (“Series B-2 Preferred Shares”) to certain investors at US\$1.0619 per share for total consideration of US\$63,000 (equivalent to approximately RMB439,501). Series B-1 Preferred Shares and Series B-2 Preferred Shares are collectively referred to as the Series B Preferred Shares.

As disclosed in Note 1(b), the Group had undergone the Reorganization and changed the issuer of the Series A Preferred Shares to be the reporting entity through share swaps. The major terms and number of shares of the Series A Preferred Shares have remained the same. Thus, there is no accounting impact as a result of the Reorganization at the consolidated level. As further discussed in Note 1(b), the Reorganization was a transaction by Group entities under common control. The equity section of the Company after the Reorganization is assumed to have existed from the earliest period presented in the consolidated financial statements.

The key features of the Series A and Series B Preferred Shares (collectively the “Preferred Shares”) are as follows:

Dividends right

Each Preferred Share shall have the right to receive non-cumulative dividends, *pari passu* with Ordinary Shares, on an as-converted basis, when, as and if declared by the Board.

Liquidation preference

In the event of any liquidation, dissolution or winding up of the Company, either voluntarily or involuntarily, all assets and funds of the Company legally available for distribution (after satisfaction of all creditors’ claims and claims that may be preferred by law) shall be distributed in the following preference order:

- (i) Holders of the Series B Preferred Shares shall be entitled to receive a per share amount equal to 140% of the issue price of Series B Preferred Shares, respectively, plus all declared but unpaid dividends.
- (ii) Holders of the Series A Preferred Shares shall be entitled to receive a per share amount equal to 150% of the issue price of Series A Preferred Shares, respectively, plus all declared but unpaid dividends.

Conversion right

Each Preferred Share may be converted at any time into ordinary shares at the option of the preferred shareholders based on the then-effective conversion price. The initial conversion ratio is 1:1, subject to adjustment in the event of share splits and combinations, ordinary share dividends and distributions, reorganizations, mergers, consolidations, exchanges, substitutions, or dilutive issuance.

All Preferred Shares are converted automatically into ordinary shares at the then effective applicable conversion price upon a Qualified Public Offering (public offering of the Company’s shares with an offering price (exclusive

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8. CONVERTIBLE REDEEMABLE PREFERRED SHARES (CONTINUED)

Conversion right (Continued)

of underwriting discounts and registration expenses) that reflects the minimum market capitalization and other conditions set forth in the Company's articles).

Redemption right

At any time following the first occurrence of any redemption event specified in the shareholders' agreement ("Redemption Events"), the outstanding preferred shareholders may request a redemption up to all of the outstanding shares held.

The Redemption Events shall mean:

- (i) the Company fails to complete a Qualified Public Offering within five (5) years from February 22, 2019;
- (ii) any material breach or violation by any Group Company, the Founder or the Founder Holding Company of any of its representations, warranties or covenants contained in the Transaction Documents made to any Investor alone or together with any other Person and such breach or violation is not curable or is not cured within thirty (30) days from the date of occurrence;
- (iii) the Founder ceases to hold the offices of Chairman and president of the Company or ceases to be in full-time employment by any Group Company in any other capacity within five (5) years from February 22, 2019 unless otherwise approved by the Board (including all Investor Directors);
- (iv) the exercise of redemption right by any holders with redemption right.

The price at which each Preferred Share shall be redeemed equals to:

- (i) in respect of each Series B Preferred Share, 140% of the original issue price on each preferred share, plus all declared but unpaid dividends on such Series B Preferred Share accrued as of the redemption payment date; and
- (ii) in respect of each Series A Preferred Share, 150% of the original issue price on each preferred share, plus the interest at an annual compound rate of eight percent (8%) on the original issue price on each preferred share accrued August 8, 2017 to the redemption payment date minus all paid dividends on such Series A Preferred Share.

After the liquidation amounts of all series of the Preferred Shares have been paid in full, any remaining funds or assets of the Company legally available for distribution to shareholders shall be distributed ratably 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 classified as mezzanine equity in the consolidated balance sheets because they are contingently redeemable upon the occurrence of an event outside of the Company's control (e.g. the Company

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8. CONVERTIBLE REDEEMABLE PREFERRED SHARES (CONTINUED)

Accounting of preferred shares (Continued)

not achieving a Qualified Public Offering or a deemed liquidation event before February 22, 2024 (“Target QIPO Date”). The Preferred Shares were determined to be mezzanine equity with no embedded feature to be bifurcated and no beneficial conversion features to be recognized. The Preferred Shares are initially recorded at their respective issuance date fair value, net of issuance cost. The Company did not incur material issuance cost for any Preferred Shares issued. The cumulative undeclared dividends are not recorded in the consolidated balance sheet as the Company does not have the obligation to pay the cumulative dividend before it is declared by the board of directors.

The Company concluded that the Preferred Shares are not currently redeemable, but are probable to become redeemable. The Company accreted changes in the redemption value over the period from the date of issuance to the earliest redemption date using the effective interest method. The accretion is recorded against retained earnings, or in the absence of retained earnings, by charges against additional paid-in-capital, or in the absence of additional paid-in-capital, by charges to accumulated deficit. The accretion of the Preferred Shares was RMB 12,199 and RMB 36,802 for the years ended December 31, 2018 and 2019.

The convertible loans and warrants were issued contemporaneously and in contemplation of each other. The warrants cannot be separately exercised; hence, they are not freestanding financial instruments. The convertible loans are accounted for as liabilities recorded using amortized cost.

Modification of Preferred Shares

On January 3, 2019, the Target QIPO Date was extended from November 15, 2022 to February 22, 2024 upon issuance of Series B-2 Preferred Shares. The amendment is accounted for as modifications rather than extinguishments as the fair values of these Preferred Shares immediately after the amendments were not significantly different from their respective fair values immediately before the amendment. When Preferred Shares are modified and such modification results in value transfer between preferred shareholders and ordinary shareholders, the value transferred is treated as a deemed dividend to or deemed contribution from the preferred shareholders.

The Company’s Preferred Shares activities for the periods presented are summarized below:

<u>Mezzanine equity</u>	<u>Series A</u> <u>RMB</u>	<u>Series B-2</u> <u>RMB</u>	<u>Total</u> <u>RMB</u>
Balance as of December 31, 2017	71,205	—	71,205
Accretion of Series A Preferred Shares to redemption value	12,199	—	12,199
Balance as of December 31, 2018	83,404	—	83,404
Issuance of Series B-2 Preferred Shares	—	439,501	439,501
Repurchase of Series A Preferred Shares	(11,864)	—	(11,864)
Accretion of Series A Preferred Shares to redemption value	10,794	—	10,794
Accretion of Series B-2 Preferred Shares to redemption value	—	26,008	26,008
Balance as of December 31, 2019	<u>82,334</u>	<u>465,509</u>	<u>547,843</u>

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9. SHARE-BASED COMPENSATION

On August 8, 2017, the Company adopted the 2017 Employee Stock Option Plan (“PRC Plan” or “2017 Plan”), which was replaced by the Amended and Restated 2017 Employee Stock Option Plan (“Global Plan”) on April 15, 2019 to reserve a pool of 4,388,060 shares of the Company’s ordinary shares to be granted to the officers, directors, employees and consultants of the Company as part of the Reorganization. The replacement of PRC Plan with Global Plan and revocation of the original 2017 Plan are viewed as having no accounting impacts as the 2017 Plan has remained effective throughout and there’s essentially no change but merely just to change the form of the plan due to the Reorganization.

Share options granted under the 2017 Plan or Global Plan will be exercisable upon the Company completes a listing and the guarantee renders service to the Company in accordance with a stipulated service. Guarantees are generally subject to a 48-month service schedule, under which the shares vest in 48 equal instalments over the 48 months. The share option under 2017 Plan or Global Plan, to the extent then vested, shall become exercisable only upon the earlier of (i) a listing, and (ii) a sale of all or substantially all of the issued share capital of the Company, or (iii) a sale by the Company of all or substantially all of its assets (but excluding any internal reorganization).

Prior to the Company completes a listing, all share options granted to a guarantee shall be forfeited at the time the guarantee terminates his service with the Group. After the Company completes a listing, vested options not exercised by a guarantee shall be exercised until later of: (i) 90 days after the date when the options become exercisable, or (ii) 3 months after the date of cessation of employment or directorship, or such longer period as the Board may determine. The share option awards shall expire no more than 10 years from their grant dates.

The Company granted 1,375,500 and 941,814 share options to guarantees, with an exercise price of US\$0.30 and US\$1.06, for the years ended December 31, 2018 and 2019, respectively. No options are exercisable as of December 31, 2018 and 2019 and prior to the Group completes a listing.

The awards are equity classified. 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.

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9. SHARE-BASED COMPENSATION (CONTINUED)

The following table sets forth the share options activities for the years ended December 31, 2018 and 2019:

	Number of Options	Weighted- Average Exercise Price US\$ per option	Weighted- Average Grant Date Fair Value RMB per option	Weighted Average Remaining Contractual Term Years	Aggregate intrinsic value RMB
Outstanding at January 1, 2018	532,000	0.30	0.61	9.69	—
Granted	1,375,500	0.30	1.97	—	—
Outstanding at January 1, 2019	1,907,500	0.30	1.59	9.33	3,798
Granted	941,814	1.06	2.65	—	—
Forfeited	(92,190)	0.71	2.06	—	—
Outstanding at December 31, 2019	2,757,124	0.55	1.93	8.67	7,728
Vested and expected to vest at December 31, 2019	2,757,124	0.55	1.93	8.67	7,728
Exercisable at December 31, 2019	—	—	—	—	—

Fair value of share options

The fair value of options was determined using the binomial option valuation model, with the assistance from an independent third-party appraiser. The binomial model requires the input of highly subjective assumptions, including the expected volatility, the exercise multiple, the risk-free rate and the dividend yield. For expected volatility, the Group has made reference to historical volatility of several comparable companies in the same industry. The exercise multiple was estimated as the average ratio of the stock price to the exercise price of when employees would decide to voluntarily exercise their vested options. The risk-free rate for periods within the contractual life of the options is based on the market yield of U.S. Treasury Strips plus China country risk premium with a maturity life equal to the remaining maturity life of the options as of the valuation date, sourced from Bloomberg. The dividend yield is based on our expected dividend policy over the contractual life of the options.

The assumptions used to estimate the fair value of the share options granted are as follows:

	For the year ended December 31, 2018	For the year ended December 31, 2019
Risk-free interest rate	3.7%-4.0%	2.9%-3.1%
Dividend yield	0%	0%
Expected volatility range	55.0%-56.2%	53.7%-54.3%
Exercise multiple	2.20	2.20
Contractual life	10 years	10 years

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, 2018 and 2019. The Group will recognize compensation expenses relating to options vested cumulatively upon the completion of the Company's listing.

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10. INCOME TAX EXPENSE

PRC

Effective from January 1, 2008, the PRC's statutory, Enterprise Income Tax ("EIT") rate is 25%. According to a policy promulgated by the State Tax Bureau of the PRC and effective from 2008 onwards, enterprises engaged in R&D activities are entitled to claim an additional tax deduction amounting to 50% of the qualified R&D expenses incurred in determining its tax assessable profits for that year. The additional tax deduction amount of the qualified R&D expenses has been increased from 50% to 75%, effective from 2018 to 2020, according to a new tax incentives policy promulgated by the State Tax Bureau of the PRC in September 2018 ("Super Deduction").

Cayman Islands

Gracell Biotechnologies Inc. is incorporated in the Cayman Islands. Under the current laws of the Cayman Islands Gracell Biotechnologies Inc. 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.

British Virgin Islands

Gracell BVI is incorporated in the British Virgin Islands. Under the current laws of the British Virgin Islands, Gracell Biotechnologies Inc. is not subject to tax on income or capital gains. In addition, upon payments of dividends by the Company to its shareholders, no British Virgin Islands withholding tax is imposed.

Hong Kong

Gracell HK 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, 2019, Gracell HK 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, Gracell HK is exempted from income tax on its foreign-derived income and there are no withholding taxes in Hong Kong on remittance of dividends.

Reconciliation between the income tax expense computed by applying the statutory tax rate to loss before income tax and the actual provision for income tax is as follows:

	For the years ended December 31,		
	2018	2019	
	RMB	RMB	US\$ (Note 2)
Loss before income tax	(60,793)	(138,664)	(20,424)
Income tax computed at respective applicable tax rate	(15,198)	(32,091)	(4,727)
Research and development super-deduction	(6,862)	(16,996)	(2,503)
Non-deductible expenses	23	346	51
Changes in valuation allowance	22,037	48,741	7,179
Income tax expense	—	—	—

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10. INCOME TAX EXPENSE (CONTINUED)

Deferred tax assets

Deferred taxes were measured using the enacted tax rates for the periods in which the temporary differences are expected to be reversed. The tax effects of temporary differences that give rise to the deferred tax balances as of December 31, 2018 and 2019 are as follows:

	For the years ended December 31,		
	2018	2019	US\$
	RMB	RMB	(Note 2)
Deferred tax assets:			
Net operating loss carry forward	22,651	70,374	10,365
Depreciation and amortization of property, equipment and software	1,777	2,795	412
Gross deferred tax assets	24,428	73,169	10,777
Less: valuation allowance	(24,428)	(73,169)	(10,777)
Total deferred tax assets, net	—	—	—

Movement of the valuation allowance is as follows:

	For the years ended December 31,		
	2018	2019	US\$
	RMB	RMB	(Note 2)
Balance as of January 1	2,391	24,428	3,598
Addition	22,037	48,741	7,179
Balance as of December 31	24,428	73,169	10,777

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, 2018 and 2019.

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, 2018 and 2019, the Group did not have any significant unrecognized uncertain tax positions.

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11. NET LOSS PER SHARE

Basic and diluted net loss per share for the years ended December 31, 2018 and 2019 are calculated as follows:

	For the years ended December 31,		
	2018	2019	
	RMB	RMB	US\$ (Note 2)
Numerator:			
Net loss attributable to Gracell Biotechnologies Inc.'s shareholders	(60,793)	(138,664)	(20,424)
Deemed dividend to convertible redeemable preferred shareholders	—	(25,390)	(3,740)
Accretion of convertible redeemable preferred shares to redemption value	(12,199)	(36,802)	(5,420)
Net loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders	(72,992)	(200,856)	(29,584)
Denominator:			
Weighted-average number of ordinary shares outstanding—basic and diluted	100,089,552	99,053,363	99,053,363
Net loss per share attributable to Gracell Biotechnologies Inc.'s ordinary shareholders—basic and diluted	(0.73)	(2.03)	(0.30)

For the years ended December 31, 2018 and 2019, assumed conversion of the Preferred Shares has not been reflected in the dilutive calculations pursuant to ASC 260, "Earnings Per Share," due to the anti-dilutive effect.

For the years ended December 31, 2018 and 2019, the Company also has certain share options, which cannot be exercised until the Company completes its listing, that are not included in the computation of diluted losses per shares as such contingent event had not taken place.

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:

	For the years ended December 31,	
	2018	2019
	shares	shares
Convertible redeemable preferred shares	36,567,163	90,670,935

12. UNAUDITED PRO FORMA BALANCE SHEET AND LOSS PER SHARE FOR CONVERTIBLE REDEEMABLE PREFERRED SHARES

Immediately prior to the completion of a Qualified IPO, the Preferred Shares of the Company will be automatically converted into ordinary shares on a one-for-one basis. The unaudited pro forma balance sheet as of December 31, 2019 assumes a Qualified IPO has occurred and presents an adjusted financial position as if the Preferred Shares had been converted into ordinary shares on December 31, 2019 at the conversion ratio of one for one.

The unaudited pro forma net loss per ordinary share is computed using the weighted-average number of ordinary shares outstanding and the automatic conversion of all of the Group's outstanding mezzanine equity into ordinary

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12. UNAUDITED PRO FORMA BALANCE SHEET AND LOSS PER SHARE FOR CONVERTIBLE REDEEMABLE PREFERRED SHARES (CONTINUED)

shares upon the closing of the Group's Qualified Public Offering, as if it had occurred on January 1, 2019. 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. 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 unaudited basic and diluted pro forma net loss per share is calculated as follows:

	For the year ended December 31, 2019	
	RMB (Unaudited)	US\$ (Unaudited)
Numerator:		
Net loss attributable to ordinary shareholders in computing pro forma net loss per share—basic and diluted	(200,856)	(29,584)
Add back deemed dividend to convertible redeemable preferred shareholders	25,390	3,740
Add back accretion of convertible redeemable preferred shares to redemption value	36,802	5,420
Numerator for pro forma basic and diluted net loss per share	(138,664)	(20,424)
Denominator:		
Weighted-average number of ordinary shares outstanding—basic and diluted	99,053,363	99,053,363
Add: adjustment to reflect assumed effect of automatic conversion of convertible redeemable preferred shares	85,779,361	85,779,361
Pro forma weighted average number of shares outstanding—basic and diluted	184,832,724	184,832,724
Pro forma net loss per share—basic and diluted	(0.75)	(0.11)

The unaudited pro forma balance sheets and net loss per share excluded the impacts of the Company's share-based awards that are subject to IPO conditions.

13. RELATED PARTY TRANSACTIONS

a) Related Parties

Name of related parties	Relationship
William Wei Cao	Founder, CEO and a principal shareholder of the Company
Unitex Capital Ltd.	An entity controlled by Founder

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13. RELATED PARTY TRANSACTIONS (CONTINUED)

b) The Group had the following related party transactions:

	For the years ended December 31,		
	2018 RMB	2019 RMB	US\$ (Note 2)
Rent Payment:			
William Wei Cao (a)	500	—	—
Payment for in-licensing arrangement			
Unitex Capital Ltd (b)	—	1,358	200

Note (a): For the year ended December 31, 2018, William Wei Cao paid rent expense of RMB 500 for the Company, which was reimbursed thereafter.

Note (b): For the year ended December 31, 2019, the Group paid RMB1,358 to obtain an exclusive license from Unitex Capital Ltd.

14. COMMITMENTS AND CONTINGENCIES

Operating lease commitments

Future minimum payments under non-cancelable operating leases with initial terms in excess of one year consist of the following as of December 31, 2019:

	RMB	US\$ (Note 2)
For the years ending:		
2020	10,564	1,556
2021	10,564	1,556
2022	10,407	1,533
2023	6,098	898
2024	—	—
Total	37,633	5,543

Payments under operating leases are expensed on a straight-line basis over the periods of their respective leases. The Group's lease arrangements have no renewal options, rent escalation clauses, restrictions or contingent rents and are all executed with third parties. For the years ended December 31, 2018 and 2019, total rental related expenses for all operating leases amounted to RMB3,145 and RMB11,104, respectively.

Contingencies

The Group is currently not involved in any legal or administrative proceedings that may have a material adverse impact on the Group's business, financial position or results of operations.

15. 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

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15. RESTRICTED NET ASSETS (CONTINUED)

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.

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.

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 17).

16. SUBSEQUENT EVENTS

The Group evaluated subsequent events through October 19, 2020, the date these consolidated financial statements were issued.

Beginning in January 2020, the emergence and wide spread of the novel Coronavirus ("COVID-19") has resulted in quarantines, travel restrictions, and the temporary closure of stores and facilities in China, US and elsewhere. Substantially all of the Group's operating and workforce are concentrated in China and US. Consequently, the COVID-19 outbreak could potentially delay patient's access to hospitals and the progress of clinical trials of the Group, which may adversely affect the Group's business operations, financial condition and operating results for 2020. The extent to which COVID-19 impacts the business and financial results of the Group in the longer term will depend on future developments, which are uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. The Group will continue to evaluate the impact on the results of operation, financial position and cash flows of the Group and react actively as the situation evolves.

In January 2020, Suzhou Gracell entered into a loan agreement with Bank of China, under which Suzhou Gracell borrowed an aggregate principal amount of RMB69.0 million in the form of a term loan with a term of 72 months

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16. SUBSEQUENT EVENTS (CONTINUED)

commencing from the first drawdown date. Interest on the outstanding loan balance accrues at a variable annual rate equal to the five-year loan prime rate plus 0.2%. Suzhou Gracell is required to make interest payments on the loan on a quarterly basis and payments of principal according to the agreed repayment schedule which will commence from the end of the 42nd month after the first drawdown date.

In May 2020, Suzhou Gracell entered into a loan agreement with China Construction Bank, under which Suzhou Gracell borrowed an aggregate principal amount of RMB5.0 million in the form of a term loan for 12 months. Interest on the outstanding loan balance accrues at a fixed annual rate equal to the one-year loan prime rate plus 0.5%. Suzhou Gracell is required to make interest payments on the loan on a monthly basis and repay principal at the end of the loan term. In June 2020, Suzhou Gracell entered into another loan agreement with China Construction Bank, under which Suzhou Gracell borrowed additional RMB5.0 million for a term of 12 months at an interest rate equal to the one-year loan prime rate plus 0.15%. In July 2020, Suzhou Gracell entered into the third loan agreement with China Construction Bank, under which Suzhou Gracell borrowed additional RMB5.0 million for a term of 12 months at an interest rate equal to the one-year loan prime rate minus 0.2%. In September 2020, Suzhou Gracell entered into the fourth loan agreement with China Construction Bank, under which Suzhou Gracell borrowed additional RMB5.0 million for a term of 12 months at an interest rate equal to the one-year loan prime rate. Other than the interest rate, these loan agreements with China Construction Bank have substantially the same terms and conditions.

In July 2020, Suzhou Gracell entered into a loan agreement with China Merchants Bank, under which Suzhou Gracell obtained a term loan facility of RMB29.0 million for a term of 60 months commencing from June 2, 2020 and ending on June 1, 2025. During the term, Suzhou Gracell may make multiple drawdowns within the facility limit. Interest on the outstanding loan balance accrues quarterly at a variable annual rate equal to the one-year loan prime rate plus 1%. Suzhou Gracell is required to make payments of principal and interest on the loan on a semi-annual basis unless otherwise agreed by the parties.

From July 2, 2020 to September 9, 2020, after obtaining the ODI approval, the investors of Series B-1 Preferred Shares converted the warrants to preferred shares and the convertible loans to the VIE were cancelled accordingly.

In February 2020, Gracell BVI established another its wholly owned subsidiary, Gracell Biopharmaceuticals, Inc. ("Gracell US"). Further, in August 2020, the WFOE incorporated its wholly owned PRC subsidiary Gracell Biomedicine (Shanghai) Co., Ltd.

On March 6, 2020, William Wei Cao entered into an amended equity pledge agreement with the WFOE and the VIE, which contains terms substantially similar to the equity pledge agreement described in Note 1(d).

In October 2020, the Company entered into a Series C Preferred Share Subscription Agreement with certain investors that the number of Series C Preferred Shares to be issued by the Company and purchased by these investors is a maximum of 73,379,643 Series C Preferred Shares and the aggregate purchase price amounts to approximately US\$120,000,000 assuming the issuance and purchase with respect to all Series C Preferred Shares available for issuance.

17. 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 I(3), "General Notes to Financial Statements"

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17. CONDENSED FINANCIAL INFORMATION OF THE PARENT COMPANY (CONTINUED)

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, 2018 and 2019.

Balance sheets

	As of December 31,		
	2018 RMB	2019 RMB	US\$ (Note 2)
ASSETS			
Current assets:			
Cash and cash equivalents	—	236,263	34,798
Amounts due from related parties	138,695	138,695	20,427
Total current assets	138,695	374,958	55,225
Investments in subsidiaries	2,383	41,198	6,068
Amounts due from related parties	—	23,000	3,388
TOTAL ASSETS	141,078	439,156	64,681
LIABILITIES, MEZZANINE EQUITY AND SHAREHOLDERS' DEFICIT			
Current liabilities:			
Amounts due to related parties	—	44,705	6,584
Accruals and other current liabilities	—	400	59
Total current liabilities	—	45,105	6,643
Convertible loans	138,695	138,695	20,428
TOTAL LIABILITIES	138,695	183,800	27,071

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17. CONDENSED FINANCIAL INFORMATION OF THE PARENT COMPANY (CONTINUED)

	As of December 31,		
	2018	2019	US\$
	RMB	RMB	(Note 2)
LIABILITIES, MEZZANINE EQUITY AND SHAREHOLDERS' DEFICIT (CONTINUED)			
Mezzanine equity:			
Series A convertible redeemable preferred shares (US\$ 0.0001 par value; 36,567,165 and 31,343,284 shares authorized, issued and outstanding as of December 31, 2018 and 2019, respectively)	83,404	82,334	12,126
Series B-2 convertible redeemable preferred shares (US\$ 0.0001 par value; Nil and 59,327,653 shares authorized, issued and outstanding as of December 31, 2018 and 2019, respectively)	—	465,509	68,562
Total mezzanine equity	83,404	547,843	80,688
Shareholders' deficit:			
Ordinary shares	69	68	10
Accumulated other comprehensive loss	—	(3,159)	(465)
Accumulated deficit	(81,090)	(289,396)	(42,623)
Total shareholders' deficit	(81,021)	(292,487)	(43,078)
TOTAL LIABILITIES, MEZZANINE EQUITY AND SHAREHOLDERS' DEFICIT	141,078	439,156	64,681

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17. CONDENSED FINANCIAL INFORMATION OF THE PARENT COMPANY (CONTINUED)

Statements of comprehensive loss

	For the years ended December 31,		
	2018 RMB	2019 RMB	US\$ (Note 2)
Expenses			
Research and development expenses	—	(2,289)	(337)
Administrative expenses	—	(3,334)	(492)
Loss from operations	—	(5,623)	(829)
Interest income, net	—	2,904	428
Other losses	—	(21)	(3)
Share of losses of subsidiaries	(60,793)	(135,924)	(20,020)
Loss before income tax	(60,793)	(138,664)	(20,424)
Income tax expenses	—	—	—
Net loss	(60,793)	(138,664)	(20,424)
Deemed dividend to convertible redeemable preferred shareholders	—	(25,390)	(3,740)
Accretion of convertible redeemable preferred shares to redemption value	(12,199)	(36,802)	(5,420)
Net loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders	(72,992)	(200,856)	(29,584)
Other comprehensive income			
Foreign currency translation adjustments	—	(3,159)	(465)
Total comprehensive loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders	(72,992)	(204,015)	(30,049)

Statements of cash flows

	For the years ended December 31,		
	2018 RMB	2019 RMB	US\$ (Note 2)
Net cash used in operating activities	—	(5,499)	(810)
Net cash used in investing activities	—	(197,739)	(29,124)
Net cash provided by financing activities	—	439,501	64,732
Net increase in cash and cash equivalents	—	236,263	34,798
Cash and cash equivalents at the beginning of year	—	—	—
Cash and cash equivalents at the end of year	—	236,263	34,798

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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 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.

The 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 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.

We intend to enter into indemnification agreements with each of our directors and executive officers prior to completion of this offering, the form of which is filed as Exhibit 10.2 to this registration statement. Under these agreements, we may 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.

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 in reliance on Regulation S under the Securities Act or pursuant to Section 4(a)(2) of the Securities Act regarding transactions not involving a public offering. No underwriters were involved in these issuances of securities.

Securities/Purchaser	Date of Issuance	Number of Securities	Consideration
Series B-1 Preferred Shares			
Suzhou Lirui Equity Investment Center (Limited Partnership)	September 9, 2020	9,879,873	RMB63,043,000 in equivalent U.S. dollars
Suzhou Kington Capital Holdings Co., Ltd.			RMB63,043,000 in equivalent U.S. dollars
Chengdu Miaoji Medical Technology Co., Ltd.	August 25, 2020	9,879,873	U.S. dollars
	July 2, 2020	1,975,975	RMB12,608,600 in equivalent U.S. dollars
Series B-2 Preferred Shares			
King Star Med LP	February 22, 2019	7,533,670	US\$ 8,000,000
LAV Granite Limited	February 22, 2019	14,125,632	US\$15,000,000
TLS Beta Pte. Ltd.	February 22, 2019	37,668,351	US\$40,000,000

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Securities/Purchaser	Date of Issuance	Number of Securities	Consideration
Series A Preferred Shares			
Suzhou Tonghe Yucheng Investment Partnership (L.P.)	March 6, 2020	13,059,700	US\$ 1,305.97
Suzhou Tonghe Venture Investment Partnership II (L.P.)	March 6, 2020	18,283,584	US\$1,828.3584
Voyager Biosciences IV Limited	February 22, 2019	31,343,284	US\$3,134.3284
Ordinary shares			
Suzou Tonghe Venture Investment Partnership II (L.P.)	March 6, 2020	1,044,776	US\$ 104.4776
Voyager Biosciences IV Limited	February 22, 2019	1,044,776	US\$ 104.4776
Gracell Venture Holdings Limited	February 22, 2019	97,990,000	US\$ 9,799
Gracell Venture Holdings Limited	May 10, 2018	9,999	US\$ 0.9999
Sertus Nominees (Cayman) Limited	May 10, 2018	1	US\$ 0.0001
Options			
Directors, executive officers, employees and consultants of our company	Various dates	Options to purchase 7,017,599 ordinary shares	Past and future services to our company

Item 8. Exhibits and Financial Statement Schedules.

(a) Exhibits

See the Exhibit Index.

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 underwriters at the closing specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriters 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

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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.

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.

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description of Document</u>
1.1*	Form of Underwriting Agreement
3.1*	Second Amended and Restated Memorandum and Articles of Association of the Registrant, as currently in effect
3.2*	Form of Third Amended and Restated Memorandum and Articles of Association of the Registrant, as effective upon the completion 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*	Deposit Agreement, dated as of _____, 2020, among the Registrant, the depositary and holder of the American Depositary Receipts
4.4*	Amended and Restated Shareholders' Agreement, dated as of _____, 2020, among the Registrant, the holders of the Registrant's ordinary and preferred shares and certain parties thereto
5.1*	Opinion of Harney Westwood & Riegels regarding the validity of the ordinary shares being registered
8.1*	Opinion of Harney Westwood & Riegels regarding certain Cayman Islands tax matters (included in Exhibit 5.1)
10.1*	Amended and Restated 2017 Employee Stock Option Plan
10.2*	Form of Indemnification Agreement between the Registrant and each its executive officers and directors
10.3*	Form of Employment Agreement between the Registrant and an executive officer of the Registrant
10.4*	Voting Rights Proxy Agreement and Power of Attorney among Gracell Biotech, Gracell Bioscience, and shareholders of Gracell Biotech dated January 3, 2019
10.5*	Equity Pledge Agreement among Gracell Bioscience and shareholders of Gracell Biotech dated January 3, 2019
10.6*	Spouse Consent Letter from the spouse of a shareholder of Gracell Biotech dated January 3, 2019
10.7*	Technical Consultation and Service Agreement between Gracell Bioscience and Gracell Biotech dated January 3, 2019
10.8*	Business Cooperation Agreement between Gracell Bioscience and Gracell Biotech dated January 3, 2019
10.9*	Call Option Agreement among Gracell Bioscience, Gracell Biotech and shareholders of Gracell Biotech dated January 3, 2019
10.10*	Voting Rights Proxy Agreement and Power of Attorney among Gracell Biotech, Gracell Bioscience and Dr. William Wei Cao dated December 20, 2019
10.11*	Equity Pledge Agreement among Gracell Bioscience, Gracell Biotech and Dr. William Wei Cao dated March 6, 2020
10.12*	Call Option Agreement among Gracell Bioscience, Gracell Biotech and Dr. William Wei Cao dated December 20, 2019
10.13*	Series A and Ordinary Share Subscription Agreement by and among the Registrant and other parties thereto dated January 3, 2019
10.14*	Share Subscription and Framework Agreement by and among the Registrant and other parties thereto dated January 3, 2019
21.1*	Principal subsidiaries of the Registrant
23.1*	Consent of PricewaterhouseCoopers Zhong Tian LLP, Independent Registered Public Accounting Firm

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<u>Exhibit Number</u>	<u>Description of Document</u>
23.2*	Consent of Harney Westwood & Riegels (included in Exhibit 5.1)
23.3*	Consent of AllBright Law Offices (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 AllBright Law Offices regarding certain PRC law matters

* 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 Suzhou, China, on _____, 2020.

Gracell Biotechnologies Inc.

By: _____
Name:
Title:

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints William Wei Cao and Yili Kevin Xie and each of them, his or her true and lawful agent, proxy and attorney-in-fact, with full power of substitution and resubstitution, for and in his or her name, place and stead, in any and all capacities, to (i) act on, sign and file with the Securities and Exchange Commission any and all amendments (including post-effective amendments) to this Registration Statement together with all schedules and exhibits thereto and any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, together with all schedules and exhibits thereto, (ii) act on, sign and file such certificates, instruments, agreements and other documents as may be necessary or appropriate in connection therewith, (iii) act on and file any supplement to any prospectus included in this Registration Statement or any such amendment or any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and (iv) take any and all actions which may be necessary or appropriate to be done, as fully for all intents and purposes as he or she might or could do in person, hereby approving, ratifying and confirming all that such agent, proxy and attorney-in-fact or any of his or her substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Amendment No. 1 to the 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>
_____ William Wei Cao	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	, 2020
_____ Yili Kevin Xie	Chief Financial Officer (Principal Financial and Accounting Officer)	, 2020
_____ Jieyu Zou	Director	, 2020
_____ Ye Shen	Director	, 2020
_____ Guotong Xu	Director	, 2020
_____ David Guowei Wang	Director	, 2020

SIGNATURE OF AUTHORIZED U.S. REPRESENTATIVE OF THE REGISTRANT

Pursuant to the requirements of the Securities Act of 1933, as amended, the undersigned, the duly authorized representative in the United States of Gracell Biotechnologies Inc., has signed this registration statement on Form F-1 in New York, on _____, 2020.

Authorized U.S. Representative
[Name]

By: _____
Name:
Title: