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

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**FORM 20-F**

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(Mark One)

☐ REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR 12(g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2022.

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

☐ SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of event requiring this shell company report

For the transition period from        to

Commission file number: 001-39838

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**Gracell Biotechnologies Inc.**

(Exact name of Registrant as specified in its charter)

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N/A

(Translation of Registrant's name into English)

Cayman Islands

(Jurisdiction of incorporation or organization)

Building 12, Block B, Phase II  
Biobay Industrial Park

218 Sangtian St.

Suzhou Industrial Park, 215123

People's Republic of China

(Address of principal executive offices)

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Biobay Industrial Park

218 Sangtian St.

Suzhou Industrial Park, 215123

People's Republic of China

(Name, Telephone, Email and/or Facsimile number and Address of Company Contact Person)

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Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American depositary shares (one American depositary share representing five ordinary shares, par value US\$0.0001 per share)	GRCL	The Nasdaq Stock Market LLC (The Nasdaq Global Select Market)
Ordinary shares, par value US\$0.0001 per share*		The Nasdaq Stock Market LLC (The Nasdaq Global Select Market)

\* Not for trading, but only in connection with the listing on The Nasdaq Global Select Market of American depositary shares.

Securities registered or to be registered pursuant to Section 12(g) of the Act:

None

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**(Title of Class)**  
**Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:**  
**None**

**(Title of Class)**

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

As of December 31, 2022, 338,498,819 ordinary shares (excluding 17,865,387 ordinary shares issued to the depositary bank for bulk issuance of ADSs reserved for future issuances upon the exercise or vesting of awards granted under our share incentive plans), par value of US\$0.0001 per share, were issued and outstanding.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

☐ Yes ☒ No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

☐ Yes ☒ No

Note — Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐ 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<sup>†</sup> provided pursuant to Section 13(a) of the Exchange Act.

☐ Yes ☒ No

<sup>†</sup> 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.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

☐ Yes ☒ No

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐ Yes ☒ No

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐ Yes ☒ No

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☒ International Financial Reporting Standards as issued by the International Accounting Standards Board ☐ Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

☐ Item 17 ☐ Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

☐ Yes ☒ No

(APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PAST FIVE YEARS)

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court.

☐ Yes ☐ No

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## INTRODUCTION

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

- “ADSs” are to the American depositary shares, each of which represents five of our ordinary shares;
- “CAR” are to chimeric antigen receptor;
- “ADRs” are to the American depositary receipts that evidence the ADSs;
- “CDE” are to the Center for Drug Evaluation of the National Medical Products Administration in China;
- “China” and “PRC” are to the People’s Republic of China, excluding, for the purpose of this annual report 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;
- “CR” are to complete response, which generally means the disappearance of all signs of cancer in response to treatment, with the exact criteria varying from indication to indication;
- “CRi” are to complete response with incomplete hematologic recovery;
- “CRS” are to cytokine release syndrome, a symptom complex and an expected adverse event associated with CAR-T cell therapies and measured by Lee grading system or ASBMT grading system. Grade 1 CRS is generally associated with non-life threatening symptoms and requires symptomatic treatment only, Grade 2 or Grade 3 CRS requires moderate to more aggressive intervention, and Grade 4 or higher CRS is associated with life-threatening symptoms that require ventilation support, or death;
- “FDA” are to U.S. Food and Drug Administration;
- “Gracell,” “we,” “us,” “our company,” or “our” are to Gracell Biotechnologies Inc. and its subsidiaries and, in the context of describing our operations and consolidated financial information, also include the VIE and its subsidiary;
- “GvHD” are to graft versus host disease, where donor cells recognize the patient’s normal tissues as foreign and cause potentially lethal tissue damage;
- “HvG” are to host versus graft rejection, where a patient’s immune cells recognize infused non-HLA-matched donor cells as foreign and reject them;
- “ICANS” are to immune effector cell-associated neurotoxicity syndrome, a common adverse event and treatment-related toxicity observed after CAR-T cell therapies and measured by ASBMT grading system. Grade 1 ICANS is generally associated with low depressed level of consciousness where patients awaken spontaneously, Grade 2 or Grade 3 ICANS is generally associated with moderate depressed level of consciousness where patients still awaken to voice or tactile stimulus, and clinical seizure that resolves rapidly, and Grade 4 ICANS is generally associated more serious symptoms such as stupor, coma, prolonged seizure and deep focal motor weakness;
- “MRD” are to minimal residual disease, the small number of cancer cells in the body after cancer treatment. An MRD positive or MRD+ test result means that disease was still detected after treatment; an MRD negative or MRD- result means that no disease was detected after treatment;
- “NMPA” are to the National Medical Products Administration in China;
- “Onset” are to the first appearance of any sign or symptom of an illness;
- “ordinary shares” are to ordinary shares of our company, par value US\$0.0001 per share;

- “ORR” are to overall response rate, percentage of patients achieving a response to therapy;
- “Renminbi” and “RMB” are to the legal currency of the PRC;
- “PFS” are to progression-free survival, the length of time during and after the treatment of a disease, such as cancer, that a patient lives without the disease getting worse;
- “PR” are to partial response;
- “Preferred Shares” are to the series A, series B-1, series B-2 and series C preferred shares, par value \$0.0001 per share;
- “sCR” are to stringent complete response, a deeper response category than CR used in multiple myeloma;
- “SOC” are to standard of care;
- “TME” are to tumor microenvironment;
- “US\$,” “U.S. dollars,” “\$,” and “dollars” are to the legal currency of the United States;
- “we,” “us,” “our company” and “our” are to Gracell Biotechnologies Inc., a Cayman Islands exempted company and its subsidiaries and, in the context of describing our operations and consolidated financial information, also include its consolidated PRC affiliated entities; and
- “VGPR” are to very good partial response.

Unless otherwise noted, all translations from Renminbi to U.S. dollars and from U.S. dollars to Renminbi in this annual report were made at a rate of RMB6.8972 to US\$1.00, the exchange rate as of December 31, 2022 as 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, or at all.

## FORWARD-LOOKING INFORMATION

This annual report contains forward-looking statements that reflect our current expectations and views of future events. The forward-looking statements are contained principally in “Item 3. Key Information—D. Risk Factors,” “Item 4. Information on the Company—B. Business Overview” and “Item 5. Operating and Financial Review and Prospects.” Known and unknown risks, uncertainties and other factors, including those set forth in “Item 3. Key Information—D. 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 consistently maintain effective internal control over financial reporting;
- 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;
- 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;
- the effect of epidemics and pandemics, such as the COVID-19 pandemic, or other business disruptions on our business; and
- our anticipated use of our existing resources and the proceeds from our initial public offering.

These forward-looking statements involve various risks and uncertainties. You should read thoroughly this annual report 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. Important risks and factors that could cause our actual results to be materially different from our expectations are generally set forth in “Item 3. Key Information—D. Risk Factors,” “Item 4. Information on the Company—B. Business Overview” and “Item 5. Operating and Financial Review and Prospects” and other sections in this annual report. Moreover, we operate in an evolving environment. New risk factors and uncertainties emerge from time to time and it is not possible for our management to predict all risk factors and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. We qualify all of our forward-looking statements by these cautionary statements.

You should not rely upon forward-looking statements as predictions of future events. The forward-looking statements made in this annual report relate only to events or information as of the date on which the statements are made in this annual report. 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 annual report and the documents that we refer to in this annual report and have filed as exhibits to this annual report, completely and with the understanding that our actual future results may be materially different from what we expect.

## PART I

### Item 1. Identity of Directors, Senior Management and Advisers

Not applicable.

### Item 2. Offer Statistics and Expected Timetable

Not applicable.

### Item 3. Key Information

Investing in our securities involves a high degree of risk. Please carefully consider the risks discussed under “Item 3. Key Information—D. Risk Factors” in this annual report. We provide the following disclosure to help investors better understand our corporate structure, operations in China and the associated risks.

As used in this annual report, (i) “Shanghai Gracell Biotech” or the “VIE” refers to Gracell Biotechnologies (Shanghai) Co., Ltd.; (ii) “Gracell Bioscience” or the “WFOE” refers to Gracell Bioscience (Shanghai) Co., Ltd., our wholly-owned subsidiary incorporated in the PRC; (iii) “Gracell HK” refers to Gracell Biotechnologies (HK) Limited, our wholly-owned subsidiary incorporated in Hong Kong; (iv) “Gracell Cayman” refers to Gracell Biotechnologies Inc., our Cayman Islands holding company; and (v) “Gracell,” “we,” “us,” “our company,” or “our” refer to Gracell Biotechnologies Inc. and its subsidiaries and, in the context of describing our operations and consolidated financial information, also include the VIE and its subsidiary.

#### Our Corporate Structure and Operation in China

Gracell Biotechnologies Inc., or Gracell Cayman, is a Cayman Islands holding company that conducts a significant portion of its operations through its wholly-owned subsidiaries in the United States, Hong Kong and China, as well as a variable interest entity, or VIE, and the VIE’s subsidiary. Neither Gracell Cayman nor its subsidiaries own any equity interest or direct foreign investment in the VIE, Gracell Biotechnologies (Shanghai) Co., Ltd., or Shanghai Gracell Biotech, and the VIE’s subsidiary, Suzhou Gracell Biotechnologies Co., Ltd., or Suzhou Gracell Biotech. Instead, Gracell Cayman relies on contractual arrangements among its PRC subsidiary, the VIE and the VIE’s nominee shareholders, which allow Gracell Cayman to (i) direct the activities of the VIE that most significantly impact the VIE’s economic performance; (ii) receive substantially all of the economic benefits of the VIE and the VIE’s subsidiary; and (iii) have an exclusive option to purchase all or part of the equity interests in the VIE when and to the extent permitted by PRC law. As a result of these contractual arrangements, Gracell Cayman is considered the primary beneficiary of the VIE and the VIE’s subsidiaries for accounting purposes. Investors in the ADSs or our ordinary shares would not hold any ownership interest, directly or indirectly, in the VIE and its subsidiary in China and would merely have a contractual relationship with the operating entities in China.

For a detailed description about these contractual arrangements, see “Item 4. Information on the Company—C. Organizational Structure—Contractual Arrangements with the VIE and Its Shareholders.”

As a result, holders of the ADSs are not holding equity interest in the VIE or its subsidiary but instead are holding equity interest in Gracell Cayman, a Cayman Islands holding company whose consolidated financial results include those of the VIE and its subsidiary under U.S. GAAP. More specifically, investors in the ADSs or our ordinary shares would not hold any ownership interest, directly or indirectly, in the VIE and its subsidiary in China and would merely have a contractual relationship with the operating entities in China.



Our corporate structure is subject to risks associated with our contractual arrangements with the VIE. These contractual arrangements have not been tested in a court of law in the PRC. If the PRC government finds that these contractual arrangements do not comply with PRC laws and regulations, or if these regulations or the interpretation of existing regulations change or are interpreted differently in the future, we and the VIE could be subject to severe penalties or be forced to relinquish our interests in the operations of the VIE and its subsidiary. This would result in the VIE and its subsidiary being deconsolidated. As of December 31, 2020, 2021 and 2022, 24%, 15%, 17% of our assets were held by the VIE, respectively. An event that results in the deconsolidation of the VIE would have a material adverse effect on our operations and result in the value of the securities diminish substantially or even become worthless. There are substantial uncertainties regarding potential future actions by the PRC government that could affect the enforceability of the contractual arrangements with the VIE and consequently, significantly affect the financial performance of the VIE and our company as a whole. For a detailed description of the risks associated with our corporate structure, see “Item 3. Key Information—D. Risk Factors—Risks Related to Our Corporate Structure.”

In addition, we rely on contractual arrangements with the VIE and its shareholders for a portion of our business operations in China, and these contractual arrangements may not be as effective as direct ownership in providing us with control over the VIE. We rely on the performance by the VIE and its shareholders of their obligations under the contracts to direct the activities of the VIE that most significantly impact the VIE’s economic performance. The shareholders of the VIE may not act in the best interests of us 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 the VIE. See “Item 3. Key Information—D. Risk Factors—Risks Related to Our Corporate Structure—We rely on contractual arrangements with the VIE and its shareholders to direct the activities of the VIE that most significantly impact the VIE’s economic performance, which may not be as effective as direct ownership in providing operational control.”

We face various legal and operational risks and uncertainties related to doing business in China, including complex and evolving PRC laws and regulations. For example, we face risks associated with regulatory approvals on offshore offerings, the use of variable interest entities, anti-monopoly regulatory actions, and oversight on cybersecurity and data privacy, as well as the lack of inspection by the Public Company Accounting Oversight Board, or PCAOB, on our independent registered public accounting firm in the past, which may impact our ability to conduct certain businesses, accept foreign investments, or list on a U.S. or other foreign exchange. These risks could result in a material adverse change in our operations and the value of the ADSs, significantly limit or completely hinder our ability to offer or continue to offer securities to investors and cause such securities to significantly decline in value or become worthless, as further explained below:

- The PRC government has significant authority to regulate or intervene in the China operations of an offshore holding company, such as us, at any time. Therefore, investors in the ADSs and our business face potential uncertainty from the PRC government’s policy. The Chinese government may intervene or influence our operations at any time, or may exert more control over offerings conducted overseas and/or foreign investment in China-based issuers, which could result in a material change in our operations and/or the value of our ADSs. Any actions by the Chinese government to exert more oversight and control over offerings that are conducted overseas and/or foreign investment in China-based issuers could significantly limit or completely hinder our ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline. See “Item 3. Key Information—D. Risk Factors—Risks Related to Doing Business in China—The PRC government has significant authority to regulate or intervene in the China operations of an offshore holding company, such as us, at any time. Therefore, investors in the ADSs and our business face potential uncertainty from the PRC government’s policy”;

- We believe that our corporate structure and contractual arrangements with the VIE comply with the current applicable PRC laws and regulations. As of the date of this annual report, we believe that our PRC subsidiaries and the VIE are not required to obtain permission or approval from the Chinese Securities Regulatory Commission, or the CSRC, or the Cyberspace Administration of China, or the CAC, to operate their respective business in China or to approve our contractual arrangements with the VIE and its shareholders. However, PRC laws and regulations governing the conditions and the requirements of such approval are uncertain and the relevant government authorities have broad discretion in interpreting these laws and regulations. Accordingly, the PRC regulatory authorities may take a different view. There can be no assurance that the PRC government authorities would agree that our corporate structure or any of the above contractual arrangements comply with PRC licensing, registration or other regulatory requirements, with existing policies or with requirements or policies that may be adopted in the future. On December 28, 2021, the CAC, and several other regulatory authorities in China jointly promulgated the Cybersecurity Review Measures, which came into effect on February 15, 2022. As the Cybersecurity Review Measures was newly issued, there remain uncertainties as to how it would be interpreted and enforced, and to what extent it may affect us. See “Risk Factors—Risks Related to Doing Business in China—The approval, filing or other requirements of the CSRC, the CAC or other PRC government authorities may be required under PRC law in connection with our issuance of securities overseas.” As of the date of this annual report, we have not received any inquiry, notice, warning, or sanctions regarding our corporate structure and contractual arrangements from the CSRC, CAC or any other PRC governmental agency. If we, our subsidiaries or the VIE (i) do not receive or maintain such permissions or approvals if required, (ii) inadvertently conclude that such permissions or approvals are not required, or (iii) if applicable laws, regulations, or interpretations change and we are required to obtain such permissions or approvals in the future,, our ADSs may significantly decline in value or become worthless if we are unable to assert our contractual control rights over the economic benefits and assets of the VIE and its subsidiaries. See “Item 3. Key Information—D. Risk Factors—Risks Related to Our Corporate Structure”; and
- Recently, the PRC government initiated a series of regulatory actions and released guidelines to regulate business operations in China with little advance notice, including those related to data security or anti-monopoly concerns, which may have an impact on our ability to conduct certain business in China, accept foreign investments, or list on a U.S. or other foreign exchange. Since these statements and regulatory actions are new, it is highly uncertain how soon legislative or administrative regulation making bodies will respond and what existing or new laws or regulations or detailed implementations and interpretations will be modified or promulgated, if any, and the potential impact of such modified or new laws and regulations will have on our daily business operation, the ability to accept foreign investments and list on a U.S. or other foreign exchange. For a detailed description of risks and regulations related to doing business in China, see “Item 3. Key Information—D. Risk Factors—Risks Related to Doing Business in China.”

## The Holding Foreign Companies Accountable Act

Pursuant to the Holding Foreign Companies Accountable Act, or the HFCAA, if the SEC determines that we have filed audit reports issued by a registered public accounting firm that has not been subject to inspections by the PCAOB for two consecutive years, the SEC will prohibit our shares or the ADSs from being traded on a national securities exchange or in the over-the-counter trading market in the United States. On December 16, 2021, the PCAOB issued a report to notify the SEC of its determination that the PCAOB was unable to inspect or investigate completely registered public accounting firms headquartered in mainland China and Hong Kong, including our auditor. In May 2022, the SEC conclusively listed us as a Commission-Identified Issuer under the HFCAA following the filing of this annual report on Form 20-F for the fiscal year ended December 31, 2021. On December 15, 2022, the PCAOB issued a report that vacated its December 16, 2021 determination and removed mainland China and Hong Kong from the list of jurisdictions where it is unable to inspect or investigate completely registered public accounting firms. For this reason, we do not expect to be identified as a Commission-Identified Issuer under the HFCAA after we file this annual report on Form 20-F. Each year, the PCAOB will determine whether it can inspect and investigate completely audit firms in mainland China and Hong Kong, among other jurisdictions. If PCAOB determines in the future that it no longer has full access to inspect and investigate completely accounting firms in mainland China and Hong Kong and we continue to use an accounting firm headquartered in one of these jurisdictions to issue an audit report on our financial statements filed with the Securities and Exchange Commission, we would be identified as a Commission-Identified Issuer following the filing of the annual report on Form 20-F for the relevant fiscal year. There can be no assurance that we would not be identified as a Commission-Identified Issuer for any future fiscal year, and if we were so identified for two consecutive years, we would become subject to the prohibition on trading under the HFCAA. See “Item 3. Key Information—D. Risk Factors—Risks Related to Doing Business in China—The PCAOB had historically been unable to inspect our auditor in relation to their audit work performed for our financial statements and the inability of the PCAOB to conduct inspections of our auditor in the past has deprived our investors with the benefits of such inspections” and “Item 3. Key Information—D. Risk Factors—Related to Doing Business in China—Our ADSs may be prohibited from trading in the United States under the HFCAA in the future if the PCAOB is unable to inspect or investigate completely auditors located in China. The delisting of the ADSs, or the threat of their being delisted, may materially and adversely affect the value of your investment.”

### *Transfer of Cash Through Our Organization*

Although we consolidate the results of the VIE and its subsidiaries under U.S. GAAP, we only have access to the assets or earnings of the VIE and its subsidiaries through our contractual arrangements with the VIE and its shareholders. The cash flows that have occurred between Gracell Cayman, its subsidiaries and the VIE and its subsidiaries are summarized as follows:

	For the years ended December 31,			
	2020	2021	2022	
	RMB	RMB	RMB	US\$
		(in thousands)		
Fees paid for services to the VIE and its subsidiaries	16,906	16,226	26,415	3,830

### *Restrictions and Limitations on Transfer of Cash*

Gracell Cayman is incorporated in the Cayman Islands and its businesses in China are conducted mainly through its PRC subsidiaries and partly through the VIE and its subsidiary. While we currently do not have cash management policies and procedures on the transfer of funds within our group, we face various restrictions and limitations on foreign exchange, our ability to transfer cash between entities, across borders and to U.S. investors, and our ability to distribute earnings from our subsidiaries and/or the VIE and its subsidiaries, to Gracell Cayman and holders of the ADSs as well as the ability to settle amounts owed under the contractual arrangements with the VIE.

Uncertainties regarding the interpretation and implementation of the contractual arrangements with the VIE could limit our ability to enforce such agreements. If the PRC authorities determine that the contractual arrangements constituting part of the VIE structure do not comply with PRC regulations, or if current regulations change or are interpreted differently in the future, our ability to settle amount owed by the VIE under the VIE agreements may be seriously hindered.

Current PRC regulations permit our PRC subsidiaries, including the WFOE, to pay dividends to us only out of their accumulated profits, if any, determined in accordance with PRC accounting standards and regulations. In addition, each of our PRC subsidiaries, the VIE and its PRC subsidiaries are required to set aside at least 10% of their respective accumulated profits each year, if any, to fund certain reserve funds until the total amount set aside reaches 50% of their respective registered capital. Our PRC subsidiaries and the VIE and its subsidiaries may also allocate a portion of their after-tax profits based on PRC accounting standards to employee welfare and bonus funds at their discretion. These reserves are not distributable as cash dividends. Furthermore, if the WFOE incurs debt on its own behalf in the future, the instruments governing the debt may restrict its ability to pay dividends or make other payments to us. In addition, the PRC tax authorities may require us to adjust our taxable income under the contractual arrangements we currently have in place in a manner that would materially and adversely affect the WFOE's ability to pay dividends and other distributions to us. Any limitation on the ability of our PRC subsidiaries, including the WFOE, to distribute dividends to us or on the ability of the VIE to make payments to the WFOE may restrict our ability to satisfy our liquidity requirements. See "Item 4. Information on the Company—B. Business Overview—Regulation—PRC Regulation—Other PRC National- and Provincial-Level Laws and Regulations – Regulations Relating to Dividend Distributions."

Gracell HK may be considered a non-resident enterprise for tax purposes, so that any dividends paid by our PRC subsidiaries to Gracell HK may be regarded as China-sourced income and, as a result, may be subject to PRC withholding tax at a rate of up to 10%. If we are required under the PRC Enterprise Income Tax Law to pay income tax for any dividends we receive from PRC subsidiaries, or if Gracell HK 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 ADS holders. If the PRC tax authorities determine that Gracell Cayman is 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 and ADS holders, in each case that are non-resident enterprises. See "Item 3. Key Information—D. 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."

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 Gracell Cayman were deemed to be 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 holders may be subject to PRC tax at a rate of 20% which in the case of dividends may be withheld at source. Any such tax may reduce the returns on your investment in the ADSs or ordinary shares. See "Item 3. Key Information—D. 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."

Our offshore entities are permitted under PRC laws and regulations to provide funding to our PRC subsidiaries 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 or prevent us from using the proceeds from our offshore capital raising activities to make loans or capital contribution to our PRC subsidiaries. See "Item 3. Key Information—D. Risk Factors—Risks Relating to Our Business and Industry—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."

Additionally, the PRC government imposes controls on the convertibility of the RMB into foreign currencies and, in certain cases, the remittance of currency out of China. Under existing PRC foreign exchange regulations, payments of current account items, such as profit distributions and trade and service-related foreign exchange transactions, can be made in foreign currencies without prior approval from the State Administration of Foreign Exchange of the PRC, or the SAFE, by complying with certain procedural requirements. Dividends payments to us by Gracell HK in foreign currencies are subject to the condition that the remittance of such dividends outside of the PRC complies with certain procedures under PRC foreign exchange regulations, such as the overseas investment registrations by our shareholders or the ultimate shareholders of our corporate shareholders who are PRC residents. Approvals by or registration with appropriate government authorities is required where RMB is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of loans denominated in foreign currencies. 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 currencies to satisfy our foreign currency demands, our PRC subsidiaries, including the WFOE, may not be able to pay dividends in foreign currencies to us and our access to cash generated from its operations will be restricted. See “Item 3.D. Key Information—Risk Factors—Risks Related to Doing Business in China—Governmental control of currency conversion may affect the value of your investment.” and “Item 3.D. Key Information—Risk Factors—Risks Related to Doing Business in China—Fluctuation in exchange rates could have a negative effect on our results of operations and the value of your investment.”

### ***Taxation on Dividends or Distributions***

Gracell Cayman’s source of dividend partly comes from dividends paid by its PRC subsidiaries, including the WFOE, which in part depends on payments received from the VIE under the contractual arrangements with the VIE. None of our subsidiaries has declared or paid any dividend or distribution to us. We have never declared or paid any dividend on our ordinary shares and we have no current intention to pay dividends to shareholders or holders of ADSs. We currently intend to retain most, if not all, of our available funds and any future earnings to fund the research and development of our product candidates and the development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future.

Under the current laws of the Cayman Islands, Gracell Cayman is not subject to tax on income or capital gains. Upon payments of dividends to our shareholders, no Cayman Islands withholding tax will be imposed. For purposes of illustration, the following discussion reflects the hypothetical taxes that might be required to be paid in Mainland China and Hong Kong, assuming that: (i) we have taxable earnings in the VIE, and (ii) we determine to pay a dividend in the future:

Hypothetical pre-tax earnings in the VIE <sup>(1)</sup>	100 %
Tax on earnings at statutory rate of 25% at WFOE level	(25)%
Amount to be distributed as dividend from WFOE to Gracell HK <sup>(2)</sup>	75 %
Withholding tax at tax treaty rate of 5%	(3.75)%
Amount to be distributed as dividend at Gracell HK level and net distribution to Gracell Cayman <sup>(3)</sup>	71.25 %

Notes:

- (1) For purposes of this example, the tax calculation has been simplified. The hypothetical book pre-tax earnings amount is assumed to equal Chinese taxable income.
- (2) China’s Enterprise Income Tax Law imposes a withholding income tax of 10% on dividends distributed by a Foreign Invested Enterprise to its immediate holding company outside of Mainland China. A lower withholding income tax rate of 5% is applied if the Foreign Invested Enterprise’s immediate holding company is registered in Hong Kong or other jurisdictions that have a tax treaty arrangement with Mainland China, subject to a qualification review at the time of the distribution. There is no incremental tax at Gracell HK level for any dividend distribution to Gracell Cayman.
- (3) If a 10% withholding income tax rate is imposed, the withholding tax will be 7.5 and the amount to be distributed as dividend at Gracell HK level and net distribution to Gracell Cayman will be 67.5.

**A. [Reserved]**

***Disaggregated Financial Information Relating to the VIE***

For the years ended December 31, 2020, 2021 and 2022, the VIE and its subsidiaries accounted for a substantial portion of our financial position, results of operations and cash flows. Set forth below are the condensed consolidating schedule showing the financial position as of December 31, 2021 and 2022, the results of operations and cash flows for the years ended December 31, 2020, 2021 and 2022 for (i) Gracell Cayman, (ii) the VIE and its consolidated subsidiaries, (iii) the WFOE (which is the primary beneficiary of the VIE) and (iv) other consolidated entities, and eliminating adjustments and consolidated totals (in thousands of RMB).

We expect that the financial position, results of operations and research and development activities of the VIE and its subsidiaries will constitute a material portion of our consolidated financial information for the foreseeable future. Accordingly, we believe the risks associated with the contractual arrangement with the VIE and its shareholders, if materialized, could adversely affect our financial position, results of operations, prospects or the value of the ADSs.

**Condensed Consolidated Balance Sheets Data**

	As of December 31, 2021					
	Parent Only RMB	Other Equity Subsidiaries RMB	WFOE RMB	VIE and VIE's Subsidiary RMB	Eliminating adjustments RMB	Consolidated Totals RMB
<b>ASSETS</b>						
<b>Current assets:</b>						
Cash and cash equivalents	1,517,362	106,790	82,634	122,220	—	1,829,006
Short-term investments	—	—	—	3,615	—	3,615
Amounts due from Group companies	—	50,000	487,676	65,705	(603,381)	—
Prepayments and other current assets	26	11	11,454	40,968	—	52,459
<b>Total current assets</b>	<b>1,517,388</b>	<b>156,801</b>	<b>581,764</b>	<b>232,508</b>	<b>(603,381)</b>	<b>1,885,080</b>
Investment in subsidiaries	—	159,818	—	—	(159,818)	—
Investment in VIEs	—	—	—	—	—	—
Amounts due from Group companies-long-term	372,092	—	—	—	(372,092)	—
Property, equipment and software	—	—	62,874	60,944	—	123,818
Operating lease right-of-use assets	—	—	24,825	4,827	—	29,652
Other non-current assets	—	—	13,604	7,983	—	21,587
<b>TOTAL ASSETS</b>	<b>1,889,480</b>	<b>316,619</b>	<b>683,067</b>	<b>306,262</b>	<b>(1,135,291)</b>	<b>2,060,137</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)</b>						
<b>Current liabilities:</b>						
Amounts due to Group companies	45,587	—	71,000	486,794	(603,381)	—
Accruals and other current liabilities	6,989	5,096	21,350	35,685	—	69,120
Short-term borrowings	—	—	—	66,100	—	66,100
Operating lease liabilities, current	—	—	13,160	4,367	—	17,527
Current portion of long-term borrowings	—	—	—	2,376	—	2,376
<b>Total current liabilities</b>	<b>52,576</b>	<b>5,096</b>	<b>105,510</b>	<b>595,322</b>	<b>(603,381)</b>	<b>155,123</b>
Deficit in subsidiaries	1,069	—	—	—	(1,069)	—
Deficit in VIEs	—	—	403,639	—	(403,639)	—
Amounts due to Group companies-long-term	—	312,592	—	59,500	(372,092)	—
Operating lease liabilities, non-current	—	—	14,100	730	—	14,830
Long-term borrowings	—	—	—	54,349	—	54,349
Other non-current liabilities	8,464	—	—	—	—	8,464
<b>TOTAL LIABILITIES</b>	<b>62,109</b>	<b>317,688</b>	<b>523,249</b>	<b>709,901</b>	<b>(1,380,181)</b>	<b>232,766</b>
<b>Shareholders' equity (deficit):</b>						
Ordinary shares	223	336	820,452	6,016	(826,804)	223
Additional paid-in capital	2,902,856	787,791	80,034	67,812	(935,637)	2,902,856
Accumulated other comprehensive income	(57,936)	(321)	—	—	321	(57,936)
Accumulated deficit	(1,017,772)	(788,875)	(740,668)	(477,467)	2,007,010	(1,017,772)
<b>Total shareholders' equity (deficit)</b>	<b>1,827,371</b>	<b>(1,069)</b>	<b>159,818</b>	<b>(403,639)</b>	<b>244,890</b>	<b>1,827,371</b>
<b>TOTAL LIABILITIES, AND SHAREHOLDERS' EQUITY (DEFICIT)</b>	<b>1,889,480</b>	<b>316,619</b>	<b>683,067</b>	<b>306,262</b>	<b>(1,135,291)</b>	<b>2,060,137</b>

	As of December 31, 2022					
	Parent Only RMB	Other Equity Subsidiaries RMB	WFOE RMB	VIE and VIE's Subsidiary RMB	Eliminating Adjustments RMB	Consolidated Totals RMB
<b>ASSETS</b>						
<b>Current assets:</b>						
Cash and cash equivalents	1,198,856	81,797	63,513	110,479	—	1,454,645
Short-term investments	—	—	—	3,559	—	3,559
Amount due from Group companies	—	184,000	626,646	93,705	(904,351)	—
Prepayments and other current assets	253	266	16,357	20,675	—	37,551
<b>Total current assets</b>	<b>1,199,109</b>	<b>266,063</b>	<b>706,516</b>	<b>228,418</b>	<b>(904,351)</b>	<b>1,495,755</b>
Amount due from Group companies -long-term	435,788	—	—	—	(435,788)	—
Property, equipment and software	—	6,066	72,318	44,742	—	123,126
Operating lease right-of-use assets	—	548	13,087	7,911	—	21,546
Other non-current assets	3,137	1,394	8,572	2,746	—	15,849
<b>TOTAL ASSETS</b>	<b>1,638,034</b>	<b>274,071</b>	<b>800,493</b>	<b>283,817</b>	<b>(1,340,139)</b>	<b>1,656,276</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)</b>						
<b>Current liabilities:</b>						
Amount due to Group companies	45,177	—	183,000	676,174	(904,351)	—
Accruals and other current liabilities	7,358	16,364	20,844	41,425	—	85,991
Short-term borrowings	—	—	—	104,600	—	104,600
Operating lease liabilities, current	—	557	11,990	4,998	—	17,545
Current portion of long-term borrowings	—	—	—	7,844	—	7,844
Amount due to related parties	4,662	—	—	—	—	4,662
<b>Total current liabilities</b>	<b>57,197</b>	<b>16,921</b>	<b>215,834</b>	<b>835,041</b>	<b>(904,351)</b>	<b>220,642</b>
Deficit in subsidiaries	198,193	79,055	—	—	(277,248)	—
Deficit in VIEs	—	—	661,665	—	(661,665)	—
Amounts due to Group companies-long-term	—	376,288	—	59,500	(435,788)	—
Operating lease liabilities, non-current	—	—	2,049	4,436	—	6,485
Long-term borrowings	—	—	—	46,505	—	46,505
Other non-current liabilities	6,879	—	—	—	—	6,879
<b>TOTAL LIABILITIES</b>	<b>262,269</b>	<b>472,264</b>	<b>879,548</b>	<b>945,482</b>	<b>(2,279,052)</b>	<b>280,511</b>
<b>Shareholders' equity (deficit):</b>						
Ordinary shares	223	336	1,004,106	6,016	(1,010,458)	223
Additional paid-in capital	2,927,295	1,184,838	90,393	72,943	(1,348,174)	2,927,295
Accumulated other comprehensive income (loss)	73,528	(18,934)	—	—	18,934	73,528
Accumulated deficit	(1,625,281)	(1,364,433)	(1,173,554)	(740,624)	3,278,611	(1,625,281)
<b>Total shareholders' equity (deficit)</b>	<b>1,375,765</b>	<b>(198,193)</b>	<b>(79,055)</b>	<b>(661,665)</b>	<b>938,913</b>	<b>1,375,765</b>
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)</b>	<b>1,638,034</b>	<b>274,071</b>	<b>800,493</b>	<b>283,817</b>	<b>(1,340,139)</b>	<b>1,656,276</b>



**Condensed Consolidated Statements of Operations Data**

	For the year ended December 31, 2020					
	Parent Only RMB	Other Equity Subsidiaries RMB	WFOE RMB	VIE and VIE's Subsidiary RMB	Eliminating adjustments RMB	Consolidated Totals RMB
<b>Revenues</b>						
Other-intercompany(a)	—	—	—	16,906	(16,906)	—
<b>Total revenues</b>	—	—	—	16,906	(16,906)	—
<b>Expenses</b>						
Research and development expenses	(1,753)	(1,185)	(53,356)	(112,536)	—	(168,830)
Administrative expenses	(13,745)	(6,439)	(18,463)	(6,919)	—	(45,566)
Other - intercompany(a)	—	—	(16,906)	—	16,906	—
<b>Loss from operations</b>	<b>(15,498)</b>	<b>(7,624)</b>	<b>(88,725)</b>	<b>(102,549)</b>	<b>—</b>	<b>(214,396)</b>
Interest income(d)	2,179	—	822	554	(685)	2,870
Interest expense(d)	—	—	—	(2,840)	685	(2,155)
Other income	—	—	54	4,653	—	4,707
Foreign exchange gain (loss), net	(1,551)	—	(1,362)	(1)	—	(2,914)
Equity in losses of subsidiaries and VIE(c)	(197,030)	(189,406)	(100,195)	—	486,631	—
Others, net	—	—	—	(12)	—	(12)
<b>Loss before income taxes</b>	<b>(211,900)</b>	<b>(197,030)</b>	<b>(189,406)</b>	<b>(100,195)</b>	<b>486,631</b>	<b>(211,900)</b>
Income tax expense	—	—	—	—	—	—
<b>Net loss</b>	<b>(211,900)</b>	<b>(197,030)</b>	<b>(189,406)</b>	<b>(100,195)</b>	<b>486,631</b>	<b>(211,900)</b>
Accretion of convertible redeemable preferred shares to redemption value	(62,733)	—	—	—	—	(62,733)
<b>Net loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders</b>	<b>(274,633)</b>	<b>(197,030)</b>	<b>(189,406)</b>	<b>(100,195)</b>	<b>486,631</b>	<b>(274,633)</b>
<b>Other comprehensive income (loss)</b>						
Foreign currency translation adjustments, net of nil tax	(20,754)	(1,249)	—	—	1,249	(20,754)
<b>Total comprehensive loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders</b>	<b>(295,387)</b>	<b>(198,279)</b>	<b>(189,406)</b>	<b>(100,195)</b>	<b>487,880</b>	<b>(295,387)</b>

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	For the year ended December 31, 2021					
	Parent Only	Other Equity Subsidiaries	WFOE	VIE and VIE's Subsidiary	Eliminating adjustments	Consolidated Totals
	RMB	RMB	RMB	RMB	RMB	RMB
<b>Revenues</b>						
Licensing and collaboration revenue	—	—	—	366	—	366
Other-intercompany(a)(b)	—	—	22,958	16,226	(39,184)	—
<b>Total revenues</b>	—	—	22,958	16,592	(39,184)	366
<b>Expenses</b>						
Research and development expenses	(15,245)	(24,296)	(82,651)	(204,707)	—	(326,899)
Administrative expenses	(58,594)	(14,202)	(46,337)	(17,907)	—	(137,040)
Other - intercompany(a)(b)	—	—	(16,226)	(22,958)	39,184	—
<b>Loss from operations</b>	<b>(73,839)</b>	<b>(38,498)</b>	<b>(122,256)</b>	<b>(228,980)</b>		<b>(463,573)</b>
Interest income(d)	8,292	36	1,413	630	(1,255)	9,116
Interest expense(d)	—	—	—	(6,318)	1,255	(5,063)
Other income	—	—	45	9,075	—	9,120
Foreign exchange gain (loss), net	(55)	691	(1,933)	—	—	(1,297)
Equity in losses of subsidiaries and VIE(c)	(386,152)	(348,381)	(225,650)	—	960,183	—
Others, net	—	—	—	(57)	—	(57)
<b>Loss before income taxes</b>	<b>(451,754)</b>	<b>(386,152)</b>	<b>(348,381)</b>	<b>(225,650)</b>	<b>960,183</b>	<b>(451,754)</b>
Income tax expense	—	—	—	—	—	—
<b>Net loss</b>	<b>(451,754)</b>	<b>(386,152)</b>	<b>(348,381)</b>	<b>(225,650)</b>	<b>960,183</b>	<b>(451,754)</b>
Accretion of convertible redeemable preferred shares to redemption value	(1,989)	—	—	—	—	(1,989)
<b>Net loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders</b>	<b>(453,743)</b>	<b>(386,152)</b>	<b>(348,381)</b>	<b>(225,650)</b>	<b>960,183</b>	<b>(453,743)</b>
<b>Other comprehensive income (loss)</b>						
Foreign currency translation adjustments, net of nil tax	(34,024)	1,087	—	—	(1,087)	(34,024)
<b>Total comprehensive loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders</b>	<b>(487,767)</b>	<b>(385,065)</b>	<b>(348,381)</b>	<b>(225,650)</b>	<b>959,096</b>	<b>(487,767)</b>

	For the year ended December 31, 2022					
	Parent Only	Other Equity Subsidiaries	WFOE	VIE and VIE's Subsidiary	Eliminating Adjustments	Consolidated Totals
	RMB	RMB	RMB	RMB	RMB	RMB
Revenues						
Other-intercompany(a)(b)	—	—	16,597	26,415	(43,012)	—
Total revenues	—	—	16,597	26,415	(43,012)	—
Expenses						
Research and development expenses	(8,517)	(114,452)	(109,895)	(252,524)	—	(485,388)
Administrative expenses	(42,576)	(23,906)	(51,745)	(21,043)	—	(139,270)
Other - intercompany(a)(b)	—	—	(26,415)	(16,597)	43,012	—
Loss from operations	(51,093)	(138,358)	(171,458)	(263,749)	—	(624,658)
Interest income(d)	19,143	2,470	2,924	1,309	(1,929)	23,917
Interest expense(d)	—	—	—	(8,666)	1,929	(6,737)
Other income	—	—	81	7,920	—	8,001
Foreign exchange gain (loss), net	(1)	(6,784)	(1,384)	—	—	(8,169)
Equity in losses of subsidiaries and VIE(c)	(575,558)	(432,886)	(263,157)	—	1,271,601	—
Others, net	—	—	130	29	—	159
Loss before income taxes	(607,509)	(575,558)	(432,864)	(263,157)	1,271,601	(607,487)
Income tax expense	—	—	(22)	—	—	(22)
Net loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders	(607,509)	(575,558)	(432,886)	(263,157)	1,271,601	(607,509)
Other comprehensive income (loss)						
Foreign currency translation adjustments, net of nil tax	131,464	(18,613)	—	—	18,613	131,464
Total comprehensive loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders	(476,045)	(594,171)	(432,886)	(263,157)	1,290,214	(476,045)

### Notes to the Condensed Consolidated Statements of Operations Data

- (a) Reflects elimination of inter-company technical service fees charged by VIE to the WFOE subsidiaries. The VIE provided research and development related service to the WFOE and recognized revenue of RMB16.9 million, RMB16.2 million and RMB26.4 million in the years ended December 31, 2020, 2021 and 2022, respectively.
- (b) Reflects the elimination of the inter-company administrative expenses charged by WFOE to the VIE subsidiaries. The VIE received the business cooperation support from the WFOE and recognized the administrative expenses of nil, RMB23.0 million and RMB16.6 million in total in the years ended December 31, 2020, 2021 and 2022.
- (c) Reflects the equity in loss of subsidiaries and VIEs which is eliminated in consolidation.
- (d) Reflects the elimination of the inter-company interest income and expenses.

**Condensed Consolidated Cash Flows Data**

	For the year ended December 31, 2020					Consolidated Totals
	Parent Only	Other Equity Subsidiaries	WFOE	VIE and VIE's Subsidiary	Eliminating adjustments	
	RMB	RMB	RMB	RMB	RMB	RMB
<b>Net cash used in operating activities</b>	<b>(13,309)</b>	<b>(6,952)</b>	<b>(93,026)</b>	<b>(84,862)</b>	<b>—</b>	<b>(198,149)</b>
<b>Cash flows from investing activities:</b>						
Purchase of property, equipment and software	—	—	(25,313)	(54,087)	—	(79,400)
Investment in subsidiaries	(305,734)	(298,538)	—	—	604,272	—
Loans to Group companies and VIEs(e)(f)	(6,915)	—	(189,980)	—	196,895	—
Investments in short-term investments	—	—	—	(28,055)	—	(28,055)
Proceeds from disposal of short-term investments	—	—	—	13,514	—	13,514
<b>Net cash (used in) generated from investing activities</b>	<b>(312,649)</b>	<b>(298,538)</b>	<b>(215,293)</b>	<b>(68,628)</b>	<b>801,167</b>	<b>(93,941)</b>
<b>Cash flow from financing activities</b>						
Repayment of convertible loans	—	—	—	(138,695)	—	(138,695)
Proceeds from issuance of convertible redeemable preferred shares, net of issuance costs	795,420	—	—	—	—	795,420
Borrowings under loans from Group companies(e)(f)	—	—	—	196,895	(196,895)	—
Capital contribution from parent	—	305,734	298,538	—	(604,272)	—
Proceeds from bank borrowings	—	—	—	103,008	—	103,008
Repayments of bank borrowings	—	—	—	(122)	—	(122)
Payment of initial public offering costs	(2,645)	—	(499)	—	—	(3,144)
<b>Net cash (used in) generated from financing activities</b>	<b>792,775</b>	<b>305,734</b>	<b>298,039</b>	<b>161,086</b>	<b>(801,167)</b>	<b>756,467</b>
Effect of exchange rate on cash and cash equivalents	(19,515)	(1,249)	(1,363)	—	—	(22,127)
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>447,302</b>	<b>(1,005)</b>	<b>(11,643)</b>	<b>7,596</b>	<b>—</b>	<b>442,250</b>
Cash and cash equivalents at the beginning of year	236,263	1,453	32,189	42,153	—	312,058
<b>Cash and cash equivalents at the end of year</b>	<b>683,565</b>	<b>448</b>	<b>20,546</b>	<b>49,749</b>	<b>—</b>	<b>754,308</b>

	For the year ended December 31, 2021					
	Parent Only	Other Equity Subsidiaries	WFOE	VIE and VIE's Subsidiary	Eliminating adjustments	Consolidated Totals
	RMB	RMB	RMB	RMB	RMB	RMB
<b>Net cash (used in) generated from operating activities</b>	<b>2,039</b>	<b>(34,535)</b>	<b>(105,277)</b>	<b>(166,777)</b>	<b>—</b>	<b>(304,550)</b>
<b>Cash flows from investing activities:</b>						
Purchase of property, equipment and software	—	—	(38,886)	(17,857)	—	(56,743)
Investment in subsidiaries	(227,146)	(350,638)	—	—	577,784	—
Loans to Group companies and VIEs(e)(f)	(342,177)	(50,000)	(192,454)	—	584,631	—
Investments in short-term investments	—	—	—	(10,000)	—	(10,000)
Proceeds from disposal of short-term investments	—	—	—	25,127	—	25,127
<b>Net cash (used in) generated from investing activities</b>	<b>(569,323)</b>	<b>(400,638)</b>	<b>(231,340)</b>	<b>(2,730)</b>	<b>1,162,415</b>	<b>(41,616)</b>
<b>Cash flow from financing activities</b>						
Proceeds from initial public offering and over-allotment, net of underwriting discounts and commissions	1,448,959	—	—	—	—	1,448,959
Proceeds from exercise of options and restricted share units	1,745	—	—	—	—	1,745
Borrowings under loans from Group companies(e)(f)	—	312,592	50,000	222,039	(584,631)	—
Capital contribution from parent	—	227,146	350,638	—	(577,784)	—
Proceeds from bank borrowings	—	—	—	71,233	—	71,233
Repayments of bank borrowings	—	—	—	(51,294)	—	(51,294)
Payment of initial public offering costs	(14,458)	—	—	—	—	(14,458)
<b>Net cash (used in) generated from financing activities</b>	<b>1,436,246</b>	<b>539,738</b>	<b>400,638</b>	<b>241,978</b>	<b>(1,162,415)</b>	<b>1,456,185</b>
Effect of exchange rate on cash and cash equivalents	(35,165)	1,777	(1,933)	—	—	(35,321)
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>833,797</b>	<b>106,342</b>	<b>62,088</b>	<b>72,471</b>	<b>—</b>	<b>1,074,698</b>
Cash and cash equivalents at the beginning of year	683,565	448	20,546	49,749	—	754,308
<b>Cash and cash equivalents at the end of year</b>	<b>1,517,362</b>	<b>106,790</b>	<b>82,634</b>	<b>122,220</b>	<b>—</b>	<b>1,829,006</b>

For the Year Ended December 31, 2022						
	Parent Only	Other Equity Subsidiaries	WFOE	VIE and VIE's Subsidiary	Eliminating Adjustments	Consolidated Totals
	RMB	RMB	RMB	RMB	RMB	RMB
<b>Net cash used in operating activities</b>	<b>(16,324)</b>	<b>(123,438)</b>	<b>(132,288)</b>	<b>(210,598)</b>	<b>—</b>	<b>(482,648)</b>
<b>Cash flows from investing activities:</b>						
Purchase of property, equipment and software	—	(7,961)	(31,316)	(9,111)	—	(48,388)
Investment in subsidiaries	(385,761)	(183,654)	—	—	569,415	—
Loans to Group companies and VIEs (e)(f)	(63,696)	(134,000)	(121,788)	—	319,484	—
Investments in short-term investments	(174,966)	(70,000)	—	(16,200)	—	(261,166)
Proceeds from disposal of short-term investments	174,966	70,000	—	16,256	—	261,222
<b>Net cash used in investing activities</b>	<b>(449,457)</b>	<b>(325,615)</b>	<b>(153,104)</b>	<b>(9,055)</b>	<b>888,899</b>	<b>(48,332)</b>
<b>Cash flows from financing activities:</b>						
Proceeds from exercise of options and restricted share units	337	—	—	—	—	337
Capital contribution from parent	—	385,761	183,654	—	(569,415)	—
Borrowing under loan from Group companies (e)(f)	—	63,696	84,000	171,788	(319,484)	—
Proceeds from bank borrowings	—	—	—	104,600	—	104,600
Repayments of bank borrowings	—	—	—	(68,476)	—	(68,476)
Payment of offering costs	(3,137)	—	—	—	—	(3,137)
<b>Net cash (used in) generated from financing activities</b>	<b>(2,800)</b>	<b>449,457</b>	<b>267,654</b>	<b>207,912</b>	<b>(888,899)</b>	<b>33,324</b>
Effect of exchange rate on cash and cash equivalents	150,075	(25,397)	(1,383)	—	—	123,295
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>(318,506)</b>	<b>(24,993)</b>	<b>(19,121)</b>	<b>(11,741)</b>	<b>—</b>	<b>(374,361)</b>
Cash and cash equivalents at the beginning of year	1,517,362	106,790	82,634	122,220	—	1,829,006
<b>Cash and cash equivalents at the end of year</b>	<b>1,198,856</b>	<b>81,797</b>	<b>63,513</b>	<b>110,479</b>	<b>—</b>	<b>1,454,645</b>

#### Notes to the Condensed Consolidated Cash Flow Data

- (e) The VIE received the loans from the parent company of RMB6.9 million, RMB29.6 million and nil in total in the years ended December 31, 2020, 2021 and 2022, respectively.
- (f) The VIE received the loans from the WFOE of RMB190.0 million, RMB192.5 million and RMB171.8 million in total in the years ended December 31, 2020, 2021 and 2022, respectively.

#### B. Capitalization and Indebtedness

Not applicable.

#### C. Reasons for the Offer and Use of Proceeds

Not applicable.

#### D. Risk Factors

*Our business and our industry are subject to significant risks. You should carefully consider all of the information set forth in this annual report and in our other filings with the United States Securities and Exchange Commission, including the following risk factors, in evaluating our business. If any of the following risks actually occur, our business, financial condition, operating results, and growth prospects would likely be materially and adversely affected. This annual report also contains forward-looking statements that involve risks and uncertainties. See “Forward-Looking Information.”*

## Summary of Risk Factors

The following summary description sets forth an overview of the material risks we are exposed to in the normal course of our business activities. The summary does not purport to be complete and is qualified in its entirety by reference to the full risk factor discussion immediately following this summary description. We encourage you to read the full risk factor discussion carefully.

Our business, results of operations and financial condition could be materially and adversely affected by any of the following material risks:

### ***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 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.
- Raising additional capital may cause dilution to holders of the ADSs or other securities of our company, restrict our operations or require us to relinquish rights to our technologies or product candidates.

### ***Risks Related to the Development of Our Product Candidates***

- 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 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.
- 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.
- 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 have derived and plan to continue to derive results from investigator-initiated trials of our product candidates to expedite our global clinical development activities. Investigator-initiated trials are sponsored and conducted by principal investigators. As a result, our role and access to the clinical results and data are limited 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.

***Risks Related 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.
- 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.

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

***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.
- 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.

***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 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.

***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.
- 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.

***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 rely on contractual arrangements with the VIE and its shareholders to direct the activities of the VIE that most significantly impact the VIE's economic performance, which may not be as effective as direct ownership in providing operational control.

***Risks Related to Doing Business in China***

- The PRC government has significant authority to regulate or intervene in the China operations of an offshore holding company, such as us, at any time. Therefore, investors in the ADSs and our business face potential uncertainty from the PRC government's policy.
- The pharmaceutical industry in China is highly regulated and such regulations are subject to change which may affect approval and commercialization of our drugs.
- Changes in U.S. and international trade policies, particularly with regard to China, may adversely impact our business and operating results.
- 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.
- The approval, filing or other requirements of the CSRC, the CAC or other PRC government authorities may be required under PRC law in connection with our issuance of securities overseas.
- 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.
- The PCAOB had historically been unable to inspect our auditor in relation to their audit work performed for our financial statements and the inability of the PCAOB to conduct inspections of our auditor in the past has deprived our investors with the benefits of such inspections.
- Our ADSs may be prohibited from trading in the United States under the HFCAA in the future if the PCAOB is unable to inspect or investigate completely auditors located in China. The delisting of the ADSs, or the threat of their being delisted, may materially and adversely affect the value of your investment.
- Various proceedings and legislative and regulatory developments due to political tensions between the U.S. and China may have an adverse impact on our listing and trading in the U.S., including adverse impact on the market prices of the ADSs.
- 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, adverse impact on the trading prices of the ADSs, or possible delisting.

***Risks Related to the ADSs***

- If we fail to maintain effective internal controls over financial reporting, our ability to produce accurate financial statements on a timely basis could be impaired.
- Holders of the ADSs have fewer rights than our shareholders and must act through the depositary to exercise their rights.



## 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 and experienced negative operating cash flows since our inception. We expect to continue to incur losses and experience negative operating cash flows 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 and experienced negative operating cash flows since we commenced operations in 2017. For each year ended December 31, 2020, 2021 and 2022, our net losses were RMB211.9 million, RMB451.8 million and RMB607.5 million (US\$88.1 million), respectively, and our net cash used in operating activities was RMB198.1 million, RMB304.6 million and RMB482.6 million (US\$70.0 million), respectively. As of December 31, 2022, we had an accumulated deficit of RMB1,625.3 million (US\$235.6 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 hematologic malignancies and solid tumors;
- 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 market price of the 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 market price of the 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, 2022, we had RMB1,458.2 million (US\$211.4 million) in cash, cash equivalents and short-term investments. We had received total net proceeds of approximately US\$220.2 million from our initial public offering in 2021 (including in connection with the underwriters' exercise of the over-allotment options in full). We believe 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 might need to raise additional capital to complete the development and commercialization of our product candidates, including but not limited to, GC012F, for the treatment of r/r MM, newly diagnosed multiple myeloma, or NDMM, and B-cell non-Hodgkin lymphoma, or B-NHL, GC502, for the treatment of B-cell malignancies, and GC007g, for the treatment of B-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.

***Raising additional capital may cause dilution to holders of the ADSs or other securities of our company, 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 the ADSs or other securities of our company.

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 the ADSs to decline.

## **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 FastTCAR-enabled autologous CAR-T product candidate, GC012F, for which we have obtained IND approvals from the FDA and National Medical Products Administration in China, or the NMPA, GC019F, for which we have obtained IND approval from the NMPA, and, our allogeneic donor-derived CAR-T product candidate, GC007g, for which we have been granted approval from the NMPA for a seamless Phase 1/2 registrational trial, all of our other 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 clinical data that are supportive of further development. Except for the IND approvals we obtained from the NMPA for GC12F in r/r MM, GC007g in B-ALL and for GC019F in B-ALL and from FDA for GC012F in r/r MM, 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 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 proprietary technology such as SMART CART™, 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 a few 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 two CAR-T cell therapy products 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 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 GC012F 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 European Medicines Agency in the European Union and the Pharmaceuticals and Medical Devices Agency 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;
- a delay in or the ability of health authorities to complete regulatory inspections of our development activities, regulatory filings or manufacturing operations, whether as a result of the COVID-19 pandemic or other reasons, or our satisfactorily complete such inspections;
- 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 liability 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 clinical-stage product candidates, including but not limited to, GC012F, for the treatment of r/r MM, NDMM and B-NHL, GC502, for the treatment of B-cell malignancies, GC007g, for the treatment of B-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 hematologic cell malignancies and solid tumors. 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 next generation product candidates or expanding into solid tumor indications, such as mesothelin-positive cancers including ovarian cancer and Claudin 18.2-positive cancers, 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;
- 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 market price of the 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 results in preclinical testing and earlier-stage clinical trials that are supportive of further development. 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 data to date in the investigator-initiated Phase 1 trials that are supportive of further development for our clinical-stage product candidates, such as GC012F, for the treatment of r/r MM, NDMM and B-NHL, GC502, for the treatment of B-cell malignancies, and GC007g, for the treatment of B-ALL, there is no assurance that we will be able to generate positive data in the subsequent clinical trials. 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 results in preclinical studies or having successfully advanced through initial investigator-initiated Phase 1 trials that are supportive of further development. 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, B cell acute lymphoblastic leukemia, or B-ALL, the indication for our clinical product candidate GC007g 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 preclinical and clinical trials for our product candidates, including both investigator-initiated trials initiated by principal investigators 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 registrational trial 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 portion that needs 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 derived and plan to continue to derive results from investigator-initiated trials of our product candidates to expedite our global clinical development activities. Investigator-initiated trials are sponsored and conducted by principal investigators. As a result, our role and access to the clinical results and data are limited 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.***

Certain of our product candidates are being studied in investigator-initiated trials. In addition, part of our strategy is to continue to explore new opportunities for cell therapy in investigator-initiated trials in China, where such trials are initiated and conducted by principal investigators 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 result, our role and access to clinical results and data are limited. We engineer, produce and provide CAR-T cells to the principal investigators at the specialized hospitals for administration in patients. The principal investigators agree to provide us results and findings generated from the investigator-initiated trials, and will only provide the underlying data points if separately requested by us and approved by them. To the extent that, after discussions with the FDA and/or the NMPA, we are permitted to rely on all or part of the initial results and the underlying data points from these studies to support our regulatory filings with the FDA and/or the NMPA, we work in close collaboration with the principal investigators to collect the data with their approval. 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 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 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 may be characterized as first line, second line or third line therapy depending on options for treatment and prior treatments received, and the NMPA and the 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 consist 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 a patient's cancer relapses, then he or she 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 t/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 an 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 GC007g is seeking to enroll patients with r/r B-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 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, cytopenia's, 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 and clinical studies as well as results and findings from the investigator-initiated trials of our product candidates conducted by principal investigators if we obtain their consent, which are based on a preliminary analysis of then-available data and are subject to change as patient enrollment and treatment continues and more patient data become available. For example, we have reported interim data from the ongoing investigator-initiated Phase 1 trials of GC012F for the treatment of r/r MM, NDMM and B-NHL, GC027 for the treatment of T-ALL, GC502, for the treatment of B-cell malignancies, and GC007g, for the treatment of B-ALL. These trials are being conducted by principal investigators at specialized hospitals in China. 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 (with necessary consent from principal investigators) 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 analysis 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 analysis 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;
- 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, and 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 have entered into a Manufacturing Services Agreement with Lonza Houston, Inc. for clinical manufacturing of our FasTCAR-enabled CAR-T cell product candidates in the U.S. We are considering establishing a manufacturing facility in the United States and may consider establishing 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 in developing new manufacturing capability, 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 one to six weeks and achieving next-day manufacturing. 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 have contracted with a third party for the manufacture of certain of our product candidates for use in clinical trials in the United States and may in the future contract with additional 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. Supply of the relevant product candidates 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 in China, and enter into manufacturing service agreement for manufacturing GC012F in support of our IND submission in the United States and conducting clinical studies. 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 one or more CAR(s). 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- 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 clinical-stage 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 market price of the 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 share incentive plans;
- 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 December 31, 2022, we had 314 full-time employees. As our development and commercialization plans and strategies to expand and develop, and 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. Wendy Li, our Chief Medical Officer, Dr. Yili Kevin Xie, our Chief Financial Officer, and Dr. Samuel Zhang, our Chief Business 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. 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. While we enter into non-competition agreements with our departed employees, there is no guarantee that these agreements will be fully complied by such departed employees. 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. On December 28, 2021, the CAC, and several other regulatory authorities in China jointly promulgated the Cybersecurity Review Measures, which came into effect on February 15, 2022. Pursuant to the Cybersecurity Review Measures, (i) where the relevant activity affects or may affect national security, a CIIO that purchases network products and services, or an internet platform operator that conducts data process activities, shall be subject to the cybersecurity review, (ii) an application for cybersecurity review shall be made by an issuer who is an internet platform operator holding personal information of more than one million users before such issuer applies to list its securities on a foreign stock exchange, and (iii) relevant governmental authorities in the PRC may initiate cybersecurity review if they determine an operator's network products or services or data processing activities affect or may affect national security. Numerous regulations, guidelines and other measures are expected to be adopted under the umbrella of the Cyber Security Law. Opinions on Strictly Cracking Down on Illegal Securities Activities which was issued on July 6, 2021 also requires improving relevant laws and regulations on data security, cross-border data flow, and confidential information management, revising the regulations on strengthening confidentiality and file management related to the issuance and listing of securities overseas. In addition, the Personal Information Protection Law promulgated by the SCNPC on August 20, 2021, which became effective on November 1, 2021, outlines the main system framework of personal information protection and processing. The Personal Information Protection Law also strengthens the punishment for those who illegally process personal information. Furthermore, the Data Security Law of the PRC was published on June 10, 2021 by the National People's Congress and came into effect on September 1, 2021. The 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. On November 14, 2021, the draft Regulations for the Administration of Cyber Data Security, or the Draft Data Security Regulations, published by the CAC for public comments requires data processors processing important data or being listed outside China shall carry out data security assessment annually by itself or through a third party data security service provider and submit assessment report to local agency of the CAC. Drafts of some of these measures have now been published, which if enacted, may require security review before transferring human health-related data out of China. Moreover, currently no detailed rules or implementation of the Cybersecurity Review Measures or the Draft Data Security Regulations have been issued by the CAC, and the PRC governmental authorities may have wide discretion in the interpretation and enforcement of these laws and regulations. It also remains uncertain whether the future regulatory changes would impose additional restrictions on companies like us. We cannot predict the impact of the Draft Data Security Regulations, if any, at this stage, and we will closely monitor and assess any development in the rulemaking process. If the enacted version of the Draft Data Security Regulations requires any clearance of cybersecurity review and other specific actions to be completed by companies like us, we face uncertainties as to whether such clearance can be timely obtained, or at all. If we are not able to comply with the cybersecurity and data privacy requirements in a timely manner, or at all, we may be subject to government enforcement actions and investigations, fines, penalties, or suspension of our non-compliant operations, among other sanctions, which could materially and adversely affect our business and results of operations. In addition, 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, the Personal Information Protection Law of the PRC, and the Biosecurity 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. China's Ministry of Science and Technology, or the MOST, issued the Draft Implementing Rules on the Administrative Regulations on Human Genetic Resources for public comment, or the HGR Draft Implementing Rules, on March 22, 2022. The MOST is soliciting public comments until April 21, 2022. The HGR Drafting Implementing Rules provides that the party that carries out the collection, reservation and provision overseas of human genetic resources in PRC should be a PRC research institution, high education school, medical institution and enterprise, and Foreign Entities, including foreign organization, individual and organ established or *de facto* controlled by them, shall not collect, reserve or provide overseas human genetic resources in PRC. In addition, the provision or access of human genetic resources to foreign organization, individual or the organ established or *de facto* controlled by them shall be filed with the MOST.



On July 7, 2022, the CAC promulgated the Outbound Data Transfer Security Assessment Measure, or the Security Assessment Measures, which took effect on September 1, 2022. Pursuant to the Security Assessment Measures, a data processor shall apply to competent authorities for security assessment prior to transferring any data abroad if the transfer involves (i) important data; (ii) personal information transferred overseas by a CIO and a data processor that has processed personal information of more than one million individuals; (iii) personal information transferred overseas by a data processor who has already provided personal information of 100,000 persons or sensitive personal information of 100,000 persons overseas since January 1 of the previous year; or (iv) other circumstances as requested by the CAC. Furthermore, on August 31, 2022, the CAC promulgated the Guidelines for filing the Outbound Data Transfer Security Assessment (Version 1), which provides that acts of outbound data transfer include (i) overseas transmission and storage by data processors of data generated during mainland China domestic operations; (ii) the access to, use, download or export of the data collected and generated by data processors and stored in mainland China by overseas institutions, organizations or individuals; and (iii) other acts as specified by the CAC.

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.

***A sustained outbreak of the COVID-19 coronavirus could adversely impact our business, including our clinical trials.***

There has been a sustained outbreak of the COVID-19 virus in China and globally. The outbreak and government measures taken in response have 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. The highly-transmissible Delta and Omicron variants of COVID-19 have caused authorities in various countries and regions to reimpose restrictions such as mask mandates, curfews and prohibitions on large gatherings. While we believe the impact of the COVID-19 on our business, operations and timelines and plans of our preclinical studies and clinical trials remains immaterial to date, we may experience further impacts in the future, 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, government-imposed lockdown, and social distancing regulations, travel restrictions, business closures or business disruptions and the effectiveness of actions taken to contain and treat the disease.

## 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.

Our development activities, regulatory filings and manufacturing operations also could be harmed or delayed by a shutdown of the U.S. government, including the FDA, or governments and regulatory authorities in other jurisdictions. As of May 2021, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals. In July 2020, the FDA noted that it is continuing to expedite oncology product development with its staff teleworking full-time. However, the FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the COVID-19 pandemic and travel restrictions FDA is unable to complete such required inspections during the review period. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections. In May 2021, certain inspections, such as foreign preapproval, surveillance, and for-cause inspections that are not deemed mission-critical, remain temporarily suspended. In April 2021, the FDA issued guidance for industry formally announcing plans to employ remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates and in May 2021, announced plans to continue progress toward resuming standard operation levels. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue a complete response letter or defer action on the application until an inspection can be completed. In July 2021, the FDA issued a Q&A to further illustrate the actions that it may take when it cannot inspect a facility due to factors including travel restrictions. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the ongoing COVID-19 pandemic and may experience delays in their regulatory activities. If the FDA or other health authorities are delayed or unable to complete required regulatory inspections of our development activities, regulatory filings or manufacturing operations, or we do not satisfactorily complete such inspections, our business could be materially harmed. 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;
- 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 labeling 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, the Trump administration, and the Biden 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 "Item 4. Information on the Company—B. Business Overview—Regulation—United States Regulation—Healthcare Reform."



For example, the Affordable Care Act, or 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. Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed repeal legislation, several 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, 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 eliminated, 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. In March 2020, the Supreme Court granted a writ of certiorari and agreed to review the judgement of the federal appeals court. On June 17, 2021, the Supreme Court held that the plaintiffs (comprised of the state of Texas, as well as numerous other states and certain individuals) did not have standing to challenge the constitutionality of the ACA’s individual mandate and, accordingly, vacated the Fifth Circuit’s decision and instructed the district court to dismiss the case. As a result, the ACA will remain in effect in its current form for the foreseeable future. However, we cannot predict what additional challenges may arise in the future, the outcome thereof, or the impact any such actions may have on our business.

In addition, other federal health reform measures have been proposed and adopted in the United States that may impact reimbursement by Medicare or other government healthcare programs. 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 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken. While the Consolidated Appropriations Act of 2021 extended the suspension through March 31, 2021, the American Rescue Plan Act of 2021 (ARPA) did not include any additional extensions, and, under the Statutory Pay-As-You-Go Act of 2010, per the analysis of the Congressional Budget Office, could trigger reductions in Medicare spending of up to four (4) percentage points. 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, which would have significantly cut payment for participating Medicare clinicians, 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. Under both APMs and MIPS, performance data collected each performance year will affect Medicare payments in later years, including potentially reducing payments. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors, or private payors may independently reduce reimbursement under their health plans.

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. For example, at the federal level, in July 2021, the Biden administration released an executive order, “Promoting Competition in the American Economy,” with multiple provisions aimed at prescription drugs. In response to President Biden’s executive order, on September 9, 2021, the U.S. Department of Health and Human Services (“HHS”) released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Implementation of the new rebate safe harbor has been delayed until January 2032. It is unclear whether OIG will ultimately withdraw or modify the rebate rule prior to the January 2023 effective date. The likelihood of implementation of, or willingness to defend, any of the other reform initiatives is uncertain. In addition, the IRA includes a provision requiring the Secretary of HHS to negotiate prices with drug companies for a small number of single-source brand-name drugs or biologics without generic or biosimilar competitors that are covered under Medicare Part D (starting in 2026) and Part B (starting in 2028). The number of drugs subject to price negotiation will be 10 Part D drugs for 2026, another 15 Part D drugs for 2027, another 15 Part D and Part B drugs for 2028, and another 20 Part D and Part B drugs for 2029 and later years. These drugs will be selected from among the 50 drugs with the highest total Medicare Part D spending and the 50 drugs with the highest total Medicare Part B spending. The law establishes an upper limit for the negotiated price for a given drug or biologic and specifies factors the Secretary of HHS is required to consider when negotiating these upper pricing limits. The IRA also imposes rebates under Medicare Part B and Medicare Part D that penalize manufacturers for price increases that outpace inflation. Further, on October 14, 2022, the Biden administration released an additional executive order directing HHS to report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. 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.

We cannot predict the likelihood, nature, or extent of health reform initiatives that may arise from future legislation or administrative action. 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. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

***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 and social impact assessment 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 and construction related procedures and filings in a timely manner, which could subject us to fines and other administrative penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of 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.

Furthermore, we are subject to numerous international, national, municipal and local environmental, health and safety laws and regulations relating to, among other matters, safe working conditions, product stewardship and environmental protection. However, environmental and social laws and regulations have tended to become increasingly stringent. There has been increased global focus on environmental and social issues and it is possible that China may potentially adopt more stringent standards or new regulations in these areas. The extent regulatory changes occur in the future, they could result in, among other things, increased costs to our company.

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, biologicals 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 “Item 4. Information on the Company—B. Business Overview—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;
- 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.

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 March 31, 2023, our patent portfolio was comprised of sixteen issued invention patents in PRC, six patent applications in PRC, fifteen model utility models in PRC, four issued invention patents in Taiwan, four patent applications in Taiwan, sixteen patent applications in PCT/CN (including three patent applications in Hong Kong, eight patent applications in the U.S., three patent applications in Israel, three patent applications in Australia, five patent applications in Europe, three patent applications in Singapore, three patent applications in South Korea, three patent applications in Japan, one patent application in Canada and three patent applications in Taiwan.) 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 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 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 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, GC502 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 market price of the 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, 2seventy bio, Inc., Allogene, Inc., Juno Therapeutics, Inc. (acquired by Celgene Corporation), Kite Pharma, Inc. (a Gilead Sciences, Inc. company), Poseida Therapeutics, Autolus Therapeutics plc, 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 willfully 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 market price of the 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, which currently may not be sufficient to protect our intellectual property in China. For example, an amendment to the PRC Patent Law, or Amendment to the PRC Patent Law, was approved in October 2020 and became effective on June 1, 2021, which introduced patent extensions to eligible innovative drug patents. The patents owned by third parties may be eligible for patent term extension, which may in turn affect our ability to commercialize our product candidates (if approved) without facing infringement risks. The precise length of any such extension by a third party is uncertain though the extended length has a maximum of five years. 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 Amendment to the PRC Patent Law introduces patent extensions to patents of new drugs that launched in the PRC, which may enable the patent owner to submit applications for a patent term extension. The precise length of any such extension is uncertain though the extended length has a maximum of five years. 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 “Item 4. Information on the Company—Business Overview—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 market price of the 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 European Patent Office, or 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, the 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 market price of the 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 prospects.***

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, and GC019F product candidates 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.

***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 operate our business in China by entering into a series of contractual arrangements by and among our wholly owned PRC subsidiary, Gracell Bioscience (Shanghai) Co., Ltd., or Gracell Bioscience or the WFOE, the VIE, Gracell Biotechnologies (Shanghai) Co., Ltd., or Shanghai Gracell Biotech and its shareholders, which enable us to (i) direct the activities of the VIE that most significantly impact the VIE's economic performance, (ii) receive substantially all of the economic benefits of the VIE and its subsidiary, and (iii) have an exclusive option to purchase all or part of the equity interests and assets in the VIE, when and to the extent permitted by PRC laws. As a result of these contractual arrangements, Gracell Cayman is considered the primary beneficiary of the VIE and the VIE's subsidiaries for accounting purposes and is able to consolidate the financial results of the VIE and VIE's subsidiary in the consolidated financial statements in accordance with U.S. GAAP. See "Item 4. Information on the Company—C. Organizational 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 the WFOE, the 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 the 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 the WFOE and the VIE;
- imposing fines, confiscating the income from the WFOE or the VIE, or imposing other requirements with which we or the VIE may not be able to comply;
- requiring us to restructure our 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 our ability to consolidate or derive economic interests from the VIE;
- restricting or prohibiting use of any of our offering proceeds 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 the 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 the VIE or our right to receive substantially all the economic benefits and residual returns from the VIE and we are not able to restructure our ownership structure and operations in a satisfactory manner, we would no longer be able to be considered the primary beneficiary of the VIE and the VIE's subsidiary for accounting purposes or consolidate the financial results of the 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 the VIE and its shareholders to direct the activities of the VIE that most significantly impact the VIE's economic performance, 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, the 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 the VIE. For example, the 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.

If we had direct ownership of the VIE, we would be able to exercise our rights as a shareholder to effect changes in the board of directors of the 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 the VIE and its shareholders of their respective obligations under the contracts to direct the activities of the VIE that most significantly impact the VIE's economic performance. The shareholders of the 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 the 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 the 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, or the 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, or 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 controlled 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," or the Negative List, which shall be promulgated by or promulgated with approval by the State Council, 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 the 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 (2021), which was promulgated on December 27, 2021 and became effective on January 1, 2022, or the 2021 Negative List. If our rights with respect to the VIE through contractual arrangements are deemed as foreign investment in the future, and any business of the 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 direct the activities of the VIE that most significantly impact the VIE's economic performance 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 and consequently affecting our ability to prepare for and seek approval and commercialization of our product candidates both in China and elsewhere.

In addition, according to the Reply to Journalist by CSRC Respondent Officers dated February 17, 2023, CSRC will consult with relevant competent authorities and complete the filings for the overseas listing company with VIE structures that satisfy the legal compliance requirements for the supporting the utilization of two different markets and resources by the enterprise. However, CSRC Regulatory Guideline No.2 of Trial Measures provides that, where an issuer with a VIE structure files with the CSRC for overseas initial public offering, or IPO, the following specific disclosures on the VIE structure must be included in its application report: (1) reasons for the set-up of the VIE structure and the specific arrangements; (2) risks associated with control, counterparty default and tax issues; and (3) risk mitigants.

***The shareholders of the 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 the VIE may have potential conflicts of interest with us. For example, Dr. William Wei Cao is one of the shareholders of the VIE. Dr. Cao is also our founder, chairman and chief executive officer. Any shareholder of the VIE may breach, or cause the VIE to breach, or refuse to renew, the existing contractual arrangements we have with any of them and the VIE, which would have a material and adverse effect on our ability to direct the activities of the VIE that most significantly impact the VIE's economic performance and receive substantially all the economic benefits from them. For example, the shareholders may be able to cause our agreements with the 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 the 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 the VIE have executed powers of attorney to appoint the WFOE to vote on their behalf and exercise voting rights as shareholders of the VIE. If we cannot resolve any conflicts of interest or disputes between us and the shareholders of the 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 the 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 the WFOE. However, we cannot assure you that these undertakings and arrangements will be complied with or effectively enforced. The shareholders of the 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 the VIE and the validity or enforceability of our contractual arrangements with its shareholders. For example, in the event that any of the shareholders of the VIE divorces his or her spouse, the spouse may claim that the equity interest of the 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 negatively affect our rights with respect to the VIE. Similarly, if any of the equity interests of the VIE is inherited by a third-party with whom the current contractual arrangements are not binding, our ability to direct the activities of the VIE that most significantly impact the VIE's economic performance and receive substantially all the economic benefits from them would be adversely affected, which could cause significant disruption to our business and operations and harm our financial condition and results of operations.

***Contractual arrangements in relation to the VIE may be subject to scrutiny by the PRC tax authorities and they may determine that we or the 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 the WFOE, the VIE and its 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 the 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 the 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 the VIE for the adjusted but unpaid taxes according to the applicable regulations. Our financial position could be materially and adversely affected if the 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 the VIE and its subsidiary that are important to our business if the VIE and its subsidiary declare bankruptcy or become subject to a dissolution or liquidation proceeding.***

As part of our contractual arrangements with the VIE, the 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 intellectual property rights. If the VIE and its subsidiary are declared 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, the 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, the 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 the 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 the 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 could be forced to relinquish our interests in the operations of the VIE and its subsidiary, and our ability to conduct our business may be negatively affected.

#### **Risks Related to Doing Business in China**

***The PRC government has significant authority to regulate or intervene in the China operations of an offshore holding company, such as us, at any time. Therefore, investors in the ADSs and our business face potential uncertainty from the PRC government's policy.***

We conduct our operations in China through our PRC subsidiaries and the VIE and its subsidiary. Our operations in China are governed by PRC laws and regulations. The PRC government's significant oversight over our business operation could result in a material adverse change in our operations and the value of our ADSs. The Chinese government may intervene or influence our operations at any time, or may exert more control over offerings conducted overseas and/or foreign investment in China-based issuers, which could result in a material change in our operations and/or the value of our ADSs. Any actions by the Chinese government to exert more oversight and control over offerings that are conducted overseas and/or foreign investment in China-based issuers could significantly limit or completely hinder our ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or become worthless.

The new, stricter regulations or interpretations of existing regulations imposed by the central or local governments may require additional expenditures and efforts on our part to ensure our compliance with such regulations or interpretations, and if relevant regulations are issued and become effective in a short notice, we may not be able to take the required actions in a timely manner without allocating significant resource.

***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 “Item 4. Information on the Company—B. Business Overview—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.

In addition, the PRC government has significant oversight and discretion over the conduct of our operations and may intervene or influence our operations as the government deems appropriate to further regulatory, political and social goals. The PRC government has recently published new policies that significantly affected certain industries such as the internet industries, and we cannot rule out the possibility that it will in the future release further regulations or policies or take regulatory actions regarding our industry that could adversely affect our business, financial condition and results of operations. Furthermore, the PRC government has recently indicated an intent to exert more oversight and control over securities offerings and other capital markets activities that are conducted overseas and foreign investment in companies like us.

***You may experience difficulties in effecting service of legal process, enforcing foreign judgments or bringing actions in China against us or our management 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. On April 2, 2022, CSRC, MoF, National Administration of State Secrets Protection, and National Archives Administration jointly issued a draft of the revision on Provisions on Strengthening Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies for public comments, or Confidentiality Provision Revision Draft, pursuant to which, a PRC domestic company that plans to, either directly or through its overseas listed entity, publicly disclose or provide to relevant entities or individuals including securities companies, securities service providers, and overseas regulators, documents and materials that contain state secrets or government work secrets, shall first obtain approval from competent authorities according to law, and file with the secrecy administrative department at the same level. Where there is ambiguity or dispute over the identification of a state secret, a request shall be submitted to the competent secrecy administrative department for determination; where there is ambiguity or dispute over the identification of a government work secret, a request shall be submitted to the competent government authority for determination. In addition, Confidentiality Provision Revision Draft also provides that overseas securities regulators and competent overseas authorities may request to investigate, including to collect evidence for investigation purpose, or inspect a domestic company that has been listed or offered securities in an overseas market or securities companies and securities service providers that undertake securities business for such domestic companies. Such investigation and inspection shall be conducted under a cross-border regulatory cooperation mechanism, and the CSRC and competent authorities of the Chinese government will provide necessary assistance pursuant to bilateral and multilateral cooperation mechanisms. Before cooperating with the investigation and inspection by, or providing documents and materials to overseas securities regulators or other competent overseas authorities, such domestic companies, securities companies and securities service providers shall report to the CSRC or other competent authorities.

***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, the former 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 the 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.

***We may rely on dividends paid by our subsidiaries for our cash needs, and any limitation on the ability of our subsidiaries to make payments to us could have a material adverse effect on our ability to conduct our business.***

As a holding company, we conduct substantially all of our business through our consolidated subsidiaries incorporated in China. We may rely on dividends paid by these PRC subsidiaries for our cash needs, including the funds necessary to pay any dividends and other cash distributions to our shareholders, to service any debt we may incur and to pay our operating expenses. The payment of dividends by entities established in China is subject to limitations. Regulations in China currently permit payment of dividends only out of accumulated profits as determined in accordance with accounting standards and regulations in China. In accordance with the Article 166, 168 of the Company Law of the PRC (Amended in 2018), each of our PRC subsidiaries is required to set aside at least 10% of its after-tax profit based on PRC accounting standards each year to its general reserves or statutory capital reserve fund until the aggregate amount of such reserves reaches 50% of its respective registered capital. A company may discontinue the contribution when the aggregate sum of the statutory surplus reserve is more than 50% of its registered capital. The statutory common reserve fund of a company shall be used to cover the losses of the company, expand the business and production of the company or be converted into additional capital. As a result, our PRC subsidiaries are restricted in their ability to transfer a portion of their net assets to us in the form of dividends. In addition, if any of our PRC subsidiaries incurs debt on its own behalf in the future, the instruments governing the debt may restrict its ability to pay dividends or make other distributions to us. Any limitations on the ability of our PRC subsidiaries to transfer funds to us could materially and adversely limit our ability to grow, make investments or acquisitions that could be beneficial to our business, pay dividends and otherwise fund and conduct our business. As of December 31, 2021, our PRC subsidiaries have not generated any after-tax profit and therefore have not set aside any capital reserve fund.

***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 the 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.

As advised by our PRC counsel, we will not be considered as 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 the 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 the 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 the ADSs or ordinary shares.

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, and our non-PRC resident shareholders may be required to file a return and being taxed under SAT Bulletin 37 and SAT Public Notice 7.

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 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 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 annual report, 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 any offering proceeds we receive 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 any offering proceeds we receive 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. As an overseas listed company, we and our PRC resident employees who have been granted stock options or other share-based incentives of ours are subject to the Stock Option Rules. 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.

***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.

***The approval, filing or other requirements of the CSRC, the CAC or other PRC government authorities may be required under PRC law in connection with our issuance of securities overseas.***

The M&A Rules purport to require offshore special purpose vehicles that are controlled by PRC companies or individuals and that have been formed for the purpose of seeking a public listing on an overseas stock exchange through acquisitions of PRC domestic companies or assets to obtain approval from the CSRC prior to publicly listing their securities on an overseas stock exchange. The interpretation and application of the regulations remain unclear. If CSRC's approval under the M&A Rules is required, it is uncertain whether it would be possible for us to obtain the approval, and any failure to obtain or delay in obtaining CSRC approval for our future issuance of securities overseas would subject us to sanctions imposed by the CSRC and other PRC regulatory agencies.

Furthermore, the recently issued Opinions on Strictly Cracking Down on Illegal Securities Activities emphasized the need to strengthen the administration over “illegal securities activities” and the supervision on overseas listings by China-based companies, and proposed to take effective measures, such as promoting the construction of relevant regulatory systems to deal with the risks and incidents faced by China-based overseas-listed companies, although such opinions did not specify the definition of “illegal securities activities.” On December 24, 2021, the CSRC published the draft Administrative Provisions of the State Council on the Overseas Issuance and Listing of Securities by Domestic Companies (Draft for Comments), or the Draft Overseas Listing Regulations, and the draft Measures for the Overseas Issuance and Listing of Securities Record-filings by Domestic Companies (Draft for Comments), or the Draft Overseas Listing Measures, for public comments. On February 17, 2023, the CSRC promulgated the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (the “Trial Measures”), which took effect on March 31, 2023. The Trial Measures clarified and emphasized several aspects, which include but are not limited to: (1) comprehensive determination of the “indirect overseas offering and listing by PRC domestic companies” in compliance with the principle of “substance over form” and particularly, an issuer will be required to go through the filing procedures under the Trial Measures if the following criteria are met at the same time: a) 50% or more of the issuer’s operating revenue, total profit, total assets or net assets as documented in its audited consolidated financial statements for the most recent accounting year is accounted for by PRC domestic companies, and b) the main parts of the issuer’s business activities are conducted in mainland China, or its main places of business are located in mainland China, or the senior managers in charge of its business operation and management are mostly Chinese citizens or domiciled in mainland China; (2) exemptions from immediate filing requirements for issuers that a) have already been listed or registered but not yet listed in foreign securities markets, including U.S. markets, prior to the effective date of the Trial Measures, whose such overseas securities offering or listing shall be completed before September 30, 2023, and b) are not required to re-perform the regulatory procedures with the relevant overseas regulatory authority or the overseas stock exchange, provided however that such issuers shall carry out filing procedures as required if they conduct refinancing or are involved in other circumstances that require filing with the CSRC; (3) a negative list of types of issuers banned from listing or offering overseas, such as (a) offering and listing is explicitly prohibited by provisions in laws, administrative regulations and relevant state rules; (b) offering and listing may endanger national security as reviewed and determined by competent authorities under the State Council in accordance with law; (c) the controlling shareholders and the actual controller of the Issuer, have committed crimes such as corruption, bribery, embezzlement, misappropriation of property or undermining the order of the socialist market economy during the latest three years; (d) the issuer is suspected of committing crimes or major violations of laws and regulations, and is under investigation according to law, and no conclusion has yet been made thereof; (e) there are material ownership disputes over equity held by the domestic company’s controlling shareholder or by other shareholders that are controlled by the controlling shareholder and/or actual controller; (4) issuers’ compliance with web security, data security, and other national security laws and regulations; (5) issuers’ filing and reporting obligations, such as obligation to file with the CSRC after it submits an application for initial public offering to overseas regulators, and obligation after offering or listing overseas to report to the CSRC material events including change of control or voluntary or forced delisting of the issuer; and (6) the CSRC’s authority to fine both issuers and their shareholders between 1 and 10 million RMB for failure to comply with the Trial Measures, including failure to comply with filing obligations or committing fraud and misrepresentation. As of the date of this annual report, we cannot predict the impact of these regulations on maintaining the listing status of our ADSs and/or other securities, or any of our future offerings of securities overseas in a foreign country.

Furthermore, on February 24, 2023, the CSRC, the Ministry of Finance, the National Administration of State Secrets Protection and the National Archives Administration jointly issued the Provisions on Strengthening Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies, or the Confidentiality and Archives Provisions, which took effective from March 31, 2023. The Confidentiality and Archives Provisions specify that during the overseas issuance of securities and listing activities of domestic enterprises, domestic enterprises and securities companies and securities service institutions that provide relevant securities services shall, by strictly abiding by the relevant laws and regulations of the PRC and the requirements therein, establish sound confidentiality and archives management systems, take necessary measures to implement confidentiality and archives management responsibilities, and shall not leak national secrets, work secrets of governmental agencies and undermine national and public interests. Work manuscripts generated in the PRC by securities companies and securities service institutions that provide relevant securities services for overseas issuance and listing of securities by domestic enterprises shall be kept in the PRC. Without the approval of relevant competent authorities, it shall not be transferred overseas. Where archives or copies need to be transferred outside of the PRC, it shall be subject to the approval procedures in accordance with relevant PRC regulations.

In addition, on December 28, 2021, the CAC, and several other regulatory authorities in China jointly promulgated the Cybersecurity Review Measures, which came into effect on February 15, 2022. Pursuant to the Cybersecurity Review Measures, (i) where the relevant activity affects or may affect national security, a CIIO that purchases network products and services, or an internet platform operator that conducts data process activities, shall be subject to the cybersecurity review, (ii) an application for cybersecurity review shall be made by an issuer who is an internet platform operator holding personal information of more than one million users before such issuer applies to list its securities on a foreign stock exchange, and (iii) relevant governmental authorities in the PRC may initiate cybersecurity review if they determine an operator's network products or services or data processing activities affect or may affect national security. As the Cybersecurity Review Measures was newly issued, there remain uncertainties as to how it would be interpreted and enforced, and to what extent it may affect us.

On July 30, 2021, State Council of the PRC promulgated Regulations on the Security Protection of Critical Information Infrastructure, effective on September 1, 2021, which stipulates the obligations and liabilities of the regulators, society and critical information infrastructure operators, or the CIIOs, in protecting the security of critical information infrastructure, or the CII. In addition, drafts of some of these measures have now been published, including the draft rules on the Measures for the Security Assessment of Personal Information and Important Data to be Transmitted Abroad, which may, upon enactment, require security review before transferring human health-related data out of China. On October 29, 2021, the CAC published the Measures on Security Assessment of Cross-border Transfer of Data (Draft for Comments), which provides that data processors are required to make self-assessment of the risks before transferring data cross-border, and are required to apply for security assessment for cross-border data transfer in any of the certain circumstances.

On December 14, 2021, CAC published the draft Regulations for the Administration of Cyber Data Security, or the Draft Data Security Regulations, for public comments which provides that a data processor who processes personal information of more than 1 million individuals shall go through the cyber security review if it intends to be listed in a foreign country, and if a data processor conducts any data processing activities that affect or may affect national security, an application for cyber security review shall also be made by such processor. And the Draft Data Security Regulations require data processors processing important data or being listed outside China shall carry out data security assessment annually by itself or through a third party data security service provider and submit assessment report to local agency of the CAC. The Draft Data Security Regulations provide a broad definition of data processing activities, including collection, storage, usage, processing, transfer, provision, publication, deletion and other activities, and the Draft Data Security Regulations also provide a broad definition of data processor as individuals and entities which autonomously determine the purpose and method during data processing activities. However, the Draft Data Security Regulations provide no further elaboration on what constitutes a situation that "affects or may affect national security" and are subject to further changes before being formally adopted and coming into effect.

On December 27, 2021, the NDRC and the MOFCOM, jointly issued the Special Administrative Measures for Entry of Foreign Investment (Negative List) (2021 Version), or the Negative List, which became effective and replaced the previous version on January 1, 2022. Pursuant to Article 6 of the Negative List, if a PRC company, which engages in any business where foreign investment is prohibited under the Negative List, or prohibited businesses, seeks to issue shares overseas and list and trade shares overseas, it must obtain the approval from competent governmental authorities. Additionally, foreign investors in such PRC company must not take part in the company's operation or management, and their shareholding ratio should be subject to regulations relating to the management of PRC securities investments by foreign investors. According to a set of Q&A published on the NDRC's official website, a NDRC official indicated that after a PRC company submits its application for overseas listing to the CSRC and where matters relating to prohibited businesses under the Negative List are implicated, the CSRC will consult the regulatory authorities having jurisdiction over the relevant industries and fields.

As of the date of this annual report, we believe that our PRC subsidiaries and the VIE are not required to obtain permission or approval from the CSRC or the CAC for us to maintain our current listing status on the Nasdaq Global Select Market. In addition, as of the date of this annual report, we have not received any inquiry, notice, warning, or sanctions regarding our corporate structure and contractual arrangements from the CSRC, CAC or any other PRC governmental agency. There is no assurance that we will be able to meet all applicable filing requirements and guidelines of the CSRC, or comply with all applicable regulations at all times under Trial Measures. Any failure to obtain or delay in obtaining such filing or completing such procedures for this listing, or a rescission of any such filing obtained by CSRC, would be subject to fine by the CSRC or other PRC regulatory authorities. If the CSRC, the CAC or other relevant PRC regulatory agencies subsequently determine that prior approval is required for any of our future offerings of securities overseas or to maintain the listing status of our ADSs, we cannot guarantee that we will be able to obtain such approval in a timely manner, or at all. The CSRC, the CAC or other PRC regulatory agencies also may take actions requiring us, or making it advisable for us, not to proceed with such offering or maintain the listing status of our ADSs. If we proceed with any of such offering or maintain the listing status of our ADSs without obtaining these regulatory agencies' approval to the extent it is required, or if we are unable to comply with any new approval requirements which might be adopted for offerings that we have completed prior to the publication of the above-referenced opinions, we may face regulatory actions or other sanctions from these regulatory agencies. These regulatory agencies may impose fines and penalties on our operations in China, limit our ability to pay dividends outside of China, limit our operating privileges in China, delay or restrict the repatriation of the proceeds from offering of securities overseas into China or take other actions that could have a material adverse effect on our business, financial condition, results of operations and prospects, as well as the trading price of the ADSs.

Furthermore, if there are any other approvals, filings and/or other administration procedures to be obtained from or completed with the CSRC, the CAC or other PRC regulatory agencies as required by any new laws and regulations for any of our future proposed offering of securities overseas or the listing of the ADSs, we cannot assure you that we can obtain the required approval or complete the required filings or other regulatory procedures in a timely manner, or at all. Any failure to obtain the relevant approvals or complete the filings and other relevant regulatory procedures may subject us to regulatory actions or other sanctions from the CSRC or other PRC regulatory agencies, which may have a material adverse effect on our business, financial condition or results of operations.

***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 PCAOB had historically been unable to inspect our auditor in relation to their audit work performed for our financial statements and the inability of the PCAOB to conduct inspections of our auditor in the past has deprived our investors with the benefits of such inspections.***

Our auditor, the independent registered public accounting firm that issues the audit report included elsewhere in this annual report, as an auditor of companies that are traded publicly in the United States and a firm registered with the PCAOB, is subject to laws in the United States pursuant to which the PCAOB conducts regular inspections to assess its compliance with the applicable professional standards. The auditor is located in mainland China, a jurisdiction where the PCAOB was historically unable to conduct inspections and investigations completely before 2022. As a result, we and investors in the ADSs were deprived of the benefits of such PCAOB inspections. The inability of the PCAOB to conduct inspections of auditors in China in the past has made it more difficult to evaluate the effectiveness of our independent registered public accounting firm’s audit procedures or quality control procedures as compared to auditors outside of China that are subject to the PCAOB inspections. On December 15, 2022, the PCAOB issued a report that vacated its December 16, 2021 determination and removed mainland China and Hong Kong from the list of jurisdictions where it is unable to inspect or investigate completely registered public accounting firms. However, if the PCAOB determines in the future that it no longer has full access to inspect and investigate completely accounting firms in mainland China and Hong Kong, and we use an accounting firm headquartered in one of these jurisdictions to issue an audit report on our financial statements filed with the Securities and Exchange Commission, we and investors in our ADSs would be deprived of the benefits of such PCAOB inspections again, which could cause investors and potential investors in the ADSs to lose confidence in our audit procedures and reported financial information and the quality of our financial statements.

***Our ADSs may be prohibited from trading in the United States under the HFCAA in the future if the PCAOB is unable to inspect or investigate completely auditors located in China. The delisting of the ADSs, or the threat of their being delisted, may materially and adversely affect the value of your investment.***

Pursuant to the HFCAA, if the SEC determines that we have filed audit reports issued by a registered public accounting firm that has not been subject to inspections by the PCAOB for two consecutive years, the SEC will prohibit our shares or ADSs from being traded on a national securities exchange or in the over-the-counter trading market in the United States.



On December 16, 2021, the PCAOB issued a report to notify the SEC of its determination that the PCAOB was unable to inspect or investigate completely registered public accounting firms headquartered in mainland China and Hong Kong and our auditor was subject to that determination. In May 2022, the SEC conclusively listed us as a Commission-Identified Issuer under the HFCAA following the filing of our annual report on Form 20-F for the fiscal year ended December 31, 2021. On December 15, 2022, the PCAOB removed mainland China and Hong Kong from the list of jurisdictions where it is unable to inspect or investigate completely registered public accounting firms. For this reason, we do not expect to be identified as a Commission-Identified Issuer under the HFCAA after we file this annual report on Form 20-F for the fiscal year ended December 31, 2022.

Each year, the PCAOB will determine whether it can inspect and investigate completely audit firms in mainland China and Hong Kong, among other jurisdictions. If the PCAOB determines in the future that it no longer has full access to inspect and investigate completely accounting firms in mainland China and Hong Kong and we use an accounting firm headquartered in one of these jurisdictions to issue an audit report on our financial statements filed with the Securities and Exchange Commission, we would be identified as a Commission-Identified Issuer following the filing of the annual report on Form 20-F for the relevant fiscal year. In accordance with the HFCAA, our securities would be prohibited from being traded on a national securities exchange or in the over-the-counter trading market in the United States if we are identified as a Commission-Identified Issuer for two consecutive years in the future. If our shares and ADSs are prohibited from trading in the United States, there is no certainty that we will be able to list on a non-U.S. exchange or that a market for our shares will develop outside of the United States. A prohibition of being able to trade in the United States would substantially impair your ability to sell or purchase our ADSs when you wish to do so, and the risk and uncertainty associated with delisting would have a negative impact on the price of our ADSs. Also, such a prohibition would significantly affect our ability to raise capital on terms acceptable to us, or at all, which would have a material adverse impact on our business, financial condition, and prospects.

***Various proceedings and legislative and regulatory developments due to political tensions between the U.S. and China may have an adverse impact on our listing and trading in the U.S., including adverse impact on the market prices of the ADSs.***

Political tensions between the United States and China have escalated due to, among other things, trade disputes, the COVID-19 outbreak, sanctions imposed by the U.S. Department of Treasury on certain officials of the Hong Kong Special Administrative Region and the central government of the PRC and the executive orders issued by the former U.S. President Donald J. Trump in August 2020 that prohibit certain transactions with certain Chinese companies and their applications. Rising political tensions could reduce levels of trade, investment, technological exchange and other economic activities between the two major economies, which would have a material adverse effect on global economic conditions and the stability of global financial markets. Any of these factors could have a material adverse effect on our business, prospects, financial condition and results of operations.

***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 2021 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 annual report, 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 in the future. For risks relating to the “negative list” in connection with the 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 may be 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 share incentive plans, which may result in significant share-based compensation expenses and you will incur immediate and substantial dilution.***

We have adopted an employee stock option plan, which was amended and restated in October 2020, for the purpose of granting share-based compensation awards to employees, directors and consultants to incentivize their performance and align their interests with ours. In addition, our shareholders and board of directors have approved a share incentive plan in December 2020 which became effective in January 2021. As of the date of this annual report, options to purchase a total of 27,324,678 ordinary shares have been granted and outstanding under our employee stock option plan. See "Item 6. Directors, Senior Management and Employees—B. Compensation." As of the date of this annual report, we incurred share-based compensation expenses relating to awards granted under our employee stock option plan. 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.



## Risks Related to the ADSs

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

We must maintain effective internal control over financial reporting in order to accurately and timely report our results of operations and financial condition. As a public company, we are subject to reporting obligations under U.S. securities laws, including the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. Section 404(a) of the Sarbanes-Oxley Act, or Section 404(a), requires that 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. In addition, once we cease to be an “emerging growth company” as such term is defined in the JOBS Act, our independent registered public accounting firm must attest to and report on the effectiveness of our internal control over financial reporting. Our management may conclude that our internal control over financial reporting is not effective. Moreover, even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm, after conducting its own independent testing, may issue an adverse report if it is not satisfied with our internal controls or the level at which our controls are documented, designed, operated or reviewed, or if it interprets the relevant requirements differently from us. The rules governing the standards that must be met for our management to assess our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act are complex and require significant documentation, testing and possible remediation. These stringent standards require that our audit committee be advised and regularly updated on management’s review of internal control over financial reporting. The presence of material weaknesses, if identified, 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. See “Item 15. Controls and Procedures” for a detailed description of management’s report on internal control over financial reporting and remediation of a material weaknesses in internal control over financial reporting reported in 2020. In order to maintain effective disclosure controls and procedures and internal controls over financial reporting, we must expend significant resources and provide significant management oversight. There can be no assurance that we will be effective in maintaining adequate internal controls.

If either we are unable to conclude that we have effective internal controls over financial reporting or, 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.

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

Holders of the 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 cancel your ADSs and 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, including those who purchase the ADSs in a secondary transaction, 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 the ADSs serves as a waiver by any holder or beneficial owner of the 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 the 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, lead to increased costs to bring a claim, limited access to information and other imbalances of resources between such holder and us, or limit such holder's ability to bring a claim in a judicial forum that such holder finds favorable. 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, 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 the 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 the 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 the ADSs will be your sole source of gains for the foreseeable future. Investors seeking cash dividends should not purchase the ADSs.

***We may have been a passive foreign investment company for 2022 and there is a significant risk that we will be a PFIC for the current and possibly future taxable years, which could result in adverse tax consequences to our U.S. shareholders.***

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 the above calculations, a non-U.S. corporation that owns, directly or indirectly, at least 25% by value of the shares of another corporation is treated as if it directly held its proportionate share of the assets of the other corporation and directly earned its proportionate share of the income of the other corporation. Passive income generally 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 estimated income, assets and market capitalization for 2022, we may have been a PFIC for 2022. While we hold a substantial amount of cash and cash equivalents our PFIC status for any taxable year will depend primarily on the average value of our goodwill. Because our market capitalization has declined substantially since our initial public offering (including in recent months), if the value of our goodwill is determined by reference to our market capitalization there is a significant risk that we will be a PFIC for our taxable year 2023, and possibly future taxable years. 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 interpretations. 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. The treatment of our goodwill as a passive or active asset will depend on the allocation of our goodwill to our business assets, which is subject to significant uncertainty. 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 the 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 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, the VIE and its nominal shareholders will be treated for purposes of the PFIC rules, and we may be or become a PFIC if the 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. Because our PFIC status is a factual determination, our U.S. counsel expresses no opinion with respect to our PFIC status for any 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 makes a valid qualified electing fund, or QEF, election. See "Item 10. Additional Information—E. Taxation—United States Federal Income Tax Consequences" for more details.

***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.

***If the ownership of our shares continues to be highly concentrated, it may prevent you and other minority shareholders from influencing significant corporate decisions and may result in conflicts of interest.***

As of April 21, 2023, Dr. William Wei Cao, including through Gracell Venture Holdings Limited, beneficially owned approximately 24.1% of our ordinary shares. As a result, Dr. Cao will exercise significant influence over all matters requiring a shareholder vote, including the election of directors; mergers, consolidations and acquisitions; the sale of all or substantially all of our assets and other decisions affecting our capital structure; the amendment of our amended and restated memorandum of association; and our winding up and dissolution. This concentration of ownership may delay, deter or prevent acts that would be favored by our other shareholders. The interests of Dr. Cao may not always coincide with our interests or the interests of our other shareholders. This concentration of ownership may also have the effect of delaying, preventing or deterring a change in control of us. Also, Dr. Cao may seek to cause us to take courses of action that, in his judgment, could enhance his investment in us, but which might involve risks to our other shareholders or adversely affect us or our other shareholders, including our public investors. As a result, the market price of our shares could decline or shareholders might not receive a premium over the then-current market price of our shares upon a change in control. In addition, this concentration of share ownership may adversely affect the trading price of our shares because investors may perceive disadvantages in owning shares in a company with significant shareholders.

***We are an “emerging growth company” and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, the 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. 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 31 (the last day of our fiscal year). Emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. Additionally, as an emerging growth company, we have elected to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As such, our financial statements may not be comparable to companies that comply with public company effective dates. We cannot predict if investors will find the ADSs less attractive because we may rely on these exemptions. If some investors find the ADSs less attractive as a result, there may be a less active trading market for the ADSs and the trading price of the ADSs may be more volatile.

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

We 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 a foreign private issuer, we are permitted to, and we have elected to, rely on exemptions from certain Nasdaq corporate governance standards applicable to U.S. issuers, including the requirement that a majority of an issuer's directors consist of independent directors. This may afford less protection to holders of our ordinary shares and ADSs.***

As a Cayman Islands company listed on the Nasdaq Global Select Market, we are subject to the Nasdaq corporate governance listing standards. For example, Rule 5605 of the Nasdaq Stock Market Rules requires listed companies to have, among other things, a majority of its board members to be independent, and to have independent director oversight of executive compensation and nomination of directors.

However, Nasdaq rules permit a foreign private issuer like us to follow the corporate governance practices of its home country. Certain corporate governance practices in the Cayman Islands, which is our home country, may differ significantly from the Nasdaq corporate governance listing standards. For example, under Cayman Islands law we are not required to have a compensation committee composed entirely of independent directors. With respect to the foregoing corporate governance requirement, we have elected to follow home country practice. See "Item 16G. Corporate governance." We may also elect to rely on home country practice to be exempted from other corporate governance requirements. As a result, our shareholders may be afforded less protection than they otherwise would enjoy under the Nasdaq corporate governance listing standards applicable to U.S. domestic issuers.



***Our articles of association designate specific courts in Cayman Islands and the United States as the exclusive forum for certain litigation that may be initiated by the holders of our ordinary shares, ADSs or other securities, which could limit their ability to obtain a favorable judicial forum for disputes with us.***

Pursuant to our articles of association, unless we consent in writing to the selection of an alternative forum, the courts of the Cayman Islands shall have exclusive jurisdiction to hear, settle and/or determine any dispute, controversy or claim (including any non-contractual dispute, controversy or claim) whether arising out of or in connection with these articles or otherwise, including any questions regarding their existence, validity, formation or termination, or the Cayman Forum Provision. The Cayman Forum Provision will not apply to any causes of action arising under the Securities Act or Exchange Act. Our articles of association further provide that unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by relevant law, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, regardless of whether such legal suit, action, or proceeding also involves parties other than us, or the Federal Forum Provision. In addition, our articles of association provide that any person or entity purchasing or otherwise acquiring any shares or other securities in us, or purchasing or otherwise acquiring ADSs issued pursuant to the deposit agreements is deemed to have notice of and consented to the Cayman Forum Provision and the Federal Forum Provision. Notwithstanding the above, holders of our ordinary shares, ADSs or other securities cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

We recognize that the Cayman Forum Provision and the Federal Forum Provision in our articles of association may impose additional litigation costs on holders of our ordinary shares, ADSs or other securities in pursuing their claims, particularly if the holders do not reside in or near the Cayman Islands or the United States. Additionally, the forum selection clauses in our amended and restated articles of association may limit the holders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit holders of our securities. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court were "facially valid" under Delaware law and the California Supreme Court made a similar ruling under the California law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on holders of our securities who assert that the provision is not enforceable or invalid.

***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 Act (as amended) of the Cayman Islands, or the Companies Act, 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 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. Since we have chosen to follow certain home country practice, our shareholders may be afforded less protection than they otherwise would enjoy under the Nasdaq corporate governance listing standards applicable to U.S. domestic issuers. See “—As a foreign private issuer, we are permitted to, and we have elected to, rely on exemptions from certain Nasdaq corporate governance standards applicable to U.S. issuers, including the requirement that a majority of an issuer’s directors consist of independent directors. This may afford less protection to holders of our ordinary shares and ADSs.”

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 Act and the laws applicable to companies incorporated in the United States and their shareholders, see “Item 10. Additional Information—B. Memorandum and Articles of Association—Differences in Corporate Law.”

***Provisions in our memorandum and articles of association 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 the ADSs may be lower as a result.***

There are provisions in our memorandum and articles of association 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 100,000,000 shares of an additional class or classes of shares, which could include preferred 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 the 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; and
- the notice of any meeting at which a resolution to remove a director shall be proposed or voted upon must contain a statement of the intention to remove that director and such notice must be served on that director not less than ten (10) calendar days before the meeting.

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 the ADSs.

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

Your ADSs are transferable on the books of the depositary. However, the depositary may close its transfer books at any time or from time to time when 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 depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary deems it advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason.



## General Risk Factors

***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.

***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.

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

The trading price of the ADSs has been volatile and has ranged from a low of US\$1.68 to a high of US\$33.7 since the ADSs started to trade on Nasdaq on January 8, 2021.

The trading price of the ADSs may continue to be 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 "Item 3. Key Information—D. Risk Factors" section and elsewhere in this annual report, 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 the ADSs on Nasdaq;
- sales of the 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, such as recent events associated with Silicon Valley Bank and the aftermath thereof;
- 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 the ADSs to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their ADSs at or above the price paid for the ADSs and may otherwise negatively affect the liquidity of the 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 the ADSs.

***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 have incurred, and expect to continue to incur significant legal, accounting and other expenses that we did not incur as a private company. 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 are 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 have been 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.

***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 the ADSs could decline.***

The trading market for the ADSs will be influenced by the research and reports that equity research analysts publish about us and our business. If research analysts do not establish and maintain adequate research coverage of our ADSs or if one or more equity research analysts downgrade the ADSs or issue other unfavorable commentary or research about us, the market price of the ADSs could decline. If one or more equity research analysts cease coverage of us or fail to publish reports on us regularly, demand for the ADSs could decrease, which in turn could cause the trading price or trading volume of the ADSs to decline.

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

The market price of the 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.

**Item 4. Information on the Company**

**A. History and Development of the Company**

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 annual report. 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 annual report. 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 wholly foreign-owned enterprise, or WFOE, in this annual report, was incorporated as a PRC subsidiary wholly owned by Gracell HK. The WFOE incorporated its wholly owned PRC subsidiaries Gracell Biomedicine (Shanghai) Co., Ltd. and Hainan Gracell Biomedicine Co., Ltd., in August 2020 and June 2021, respectively. In July 2021, Suzhou Gracell Bioscience Co., Ltd. was incorporated as a PRC subsidiary wholly owned by Gracell HK.

Neither the Company nor its subsidiaries own any equity interest or direct foreign investment in Shanghai Gracell Biotech, or the variable interest entity, or the VIE, Gracell Bioscience, and the VIE's subsidiary, Suzhou Gracell Biotechnologies Co., Ltd., or Suzhou Gracell Biotech. Instead, the Company relies on contractual arrangements among its PRC subsidiary, the VIE and the VIE's nominee shareholders, which allow the Company to (i) direct the activities of the VIE that most significantly impact the VIE's economic performance; (ii) receive substantially all of the economic benefits of the VIE and the VIE's subsidiary; and (iii) have an exclusive option to purchase all or part of the equity interests in the VIE when and to the extent permitted by PRC law. As a result of these contractual arrangements, the Company is considered the primary beneficiary of the VIE and the VIE's subsidiary for accounting purposes and is able to consolidate the financial results of the VIE and VIE's subsidiary in the consolidated financial statements in accordance with U.S. GAAP. For more details and risks related to the variable interest entity structure, please see "Item 7. Major Shareholders and Related Party Transactions—B. Related Party Transactions—Contractual Agreements with The VIE and its Shareholders" and "Item 3. Key Information—D. Risk Factors—Risks Related to Our Corporate Structure."

PRC laws and regulations impose restrictions on foreign ownership companies engaged in the development and application of human stem cell or gene diagnostic and therapeutic technologies, or the Restricted Activities. Although as of the date of this annual report, there has been no official interpretation of the scope of the Restricted Activities, and the application of this regulation remains unclear, we carry out all of our operations that may fall into the Restricted Activities through the VIE and its subsidiary. We use the WFOE to carry out preliminary research and development activities on animals, which we believe do not fall into the Restricted Activities. The research and development activities of the VIE and its subsidiary are not attributable to the WFOE.

For a description of our principal capital expenditures and divestitures for the three years ended December 31, 2022 and for those currently in progress, see Item 5. "Operating and Financial Review and Prospects."

On January 8, 2021, the ADSs representing our ordinary shares commenced trading on Nasdaq under the symbol "GRCL." We raised from our initial public offering US\$220.2 million in net proceeds after deducting underwriting commissions and discounts and the offering expenses payable by us. We entered into a sales agreement in April 2022 pursuant to which we may, but are not obligated to, sell ADSs under an at-the-market financing program, for a potential amount of up to US\$50.0 million. The program is not yet effective and we have not sold any ADSs under the program.

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 4th Floor, Harbour Place, 103 South Church Street, P.O. Box 10240, Grand Cayman, KY1-1002, Cayman Islands. Investors should submit any inquiries to the address and telephone number of our principal executive offices.

SEC maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC on [www.sec.gov](http://www.sec.gov). You can also find information on our website [www.gracellbio.com](http://www.gracellbio.com). The information contained on our website is not a part of this annual report.

## B. 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.

Despite the vast potential of CAR-T cell therapies, significant unmet medical needs remain 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. Unlike autologous therapies that derive cells from patients, 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, where a patient's immune cells recognize infused non-HLA-matched donor cells as foreign and reject them, 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 aim to develop next-generation, transformational CAR-T cell therapies to broaden the use of this potent treatment modality across a wide range of disease indications in hematological malignancies, solid tumors and beyond.

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

- **FasTCAR.** With FasTCAR, we are able to deliver younger, less exhausted T cells for autologous cell therapies with enhanced activities and next-day manufacturing versus the industry norm of one to six weeks. FasTCAR is designed to address the most pressing challenges associated with autologous therapies, such as lengthy manufacturing time, suboptimal cell 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 actively *in vivo*. In addition, FasTCAR manufactured CAR-T cells are younger, less exhausted and show enhanced proliferation, tissue migration and tumor cell clearance activities 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 one 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 capability 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, on our FasTCAR platform.

- TruUCAR.** 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. 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 expand in the patient without the need for combination treatment with immunosuppressive agents like anti-CD52 antibodies that may leave a patient at increased risk for infection. TruUCAR is designed to avoid HvG and GvHD, severe adverse events of allogeneic CAR-T cell therapies, and rapidly eliminate cancer cells. As a result, TruUCAR's 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 could potentially result in meaningful cost savings, further increasing the accessibility of cell therapies for cancer patients. We are developing our allogeneic product candidates, GC027 and GC502, as well as multiple allogeneic pipeline candidates based on our TruUCAR platform.

In addition, we have a suite of technology modules, Dual CAR and SMART CART™, that can be leveraged with FasTCAR and TruUCAR to generate CAR-T cell therapies. Dual CAR enables the CAR-T cells to target two antigens and 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. SMART CART™ is designed to strengthen the functionality of CAR-T cells to combat solid tumors, and aims to overcome TME. SMART CART™ includes signaling mechanism of inhibitory TME molecule to enhance expansion and persistence and to reduce the exhaustion of CAR T cells. We believe this design has the potential to reverse and turn immunosuppressive signals of TME into stimulatory reactions of CAR-T cells. SMART CART™ technology can be applied to many targets for the treatment of solid tumors. Additionally, with donor-derived CAR technique, we are developing an allogeneic CAR-T cell therapy program using T cells from HLA-matched donors to minimize risk of GvHD as well as HvG without gene editing.

Leveraging our pioneering platforms, technology modules, 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. Our clinical development strategy is built on the robust pre-IND investigator-initiated trial programs that we have established in partnership with top-tier hospitals in China. We engineer, produce and provide CAR-T cells to the principal investigators at those hospitals for administration in patients. The principal investigators agree to provide us results and findings generated from the investigator-initiated trials. We do not have direct access to the raw data or underlying data points from these studies. The availability of early safety and efficacy data for our pipeline candidates allows us to determine and de-risk our portfolio strategy in early stages of development. In addition, we may be able to utilize certain parts of data for future filings and submissions to regulatory agencies. There is no guarantee that this strategy will be successful or will speed up the development of our product candidates. We have generated all our product candidates internally. We believe the pre-IND IIT programs will help provide insights on product candidates that are critical to the further clinical development,




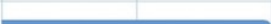

The pipeline diagram below presents our most clinically advanced product candidates that we have either submitted IND or received IND approval to commence clinical trials in China or the United States.

	PROGRAM	INDICATION	PHASE OF DEVELOPMENT			
			Preclinical	Clinical IIT <sup>1</sup>	Phase 1 - IND	Phase 2/3 <sup>2</sup>
<b>FasTCAR</b>	GC012F BCMA/CD19	R/R MM	US Ph1b/2 IND cleared	China Ph1/2 IND cleared		
	GC019F CD19	B-ALL				
<b>Donor-derived CAR</b>	GC007g CD19	B-ALL		China Ph1 study ongoing		

1. We intend to use the clinical data generated from the investigator-initiated trials in China (China IITs) in our IND filings to FDA and NMPA; however, we make no guarantee that such data will be accepted by the FDA and/or the NMPA.
2. Phase 3 may not be required if Phase 2 is registrational

R/R MM = relapsed and/or refractory multiple myeloma, B-ALL = B cell acute lymphoblastic leukemia

Additionally, we have generated a suite of product candidates that are being studied in investigator-initiated trials in China as presented in the pipeline diagram below.

	PROGRAM	INDICATION	PHASE OF DEVELOPMENT			
			Preclinical	Clinical IIT <sup>1</sup>	Phase 1 - IND	Phase 2/3 <sup>2</sup>
<b>Fast CAR</b>	GC012F BCMA/CD19	Newly Diagnosed MM				
		B-NHL				
<b>TruUCAR</b>	GC502 CD19/CD7	B-ALL				
	GC027 CD7	Adult T-ALL				
<b>SMART CAR-T</b>	GC503 Mesothelin	Solid tumors				

1. We intend to use the clinical data generated from the investigator-initiated trials in China (China IITs) in our IND filings to FDA and NMPA; however, we make no guarantee that such data will be accepted by the FDA and/or the NMPA.
2. Phase 3 may not be required if Phase 2 is registrational

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



Our clinical-staged product candidates include:

- **GC012F.** GC012F is a FasTCAR-enabled dual BCMA- and CD19-directed autologous CAR-T product candidate being studied in investigator-initiated Phase 1 trials across multiple centers in China, for two indications, MM and B-NHL. Data was presented at EHA 2022 where 29 r/r MM patients had been enrolled and treated. 90% (26/29) patients were high risk based on mSMART 3.0 criteria and patients had received a median of five prior lines of therapy. At the data cutoff of June 8, 2022, the 29 patients had been evaluated for response with a median follow-up duration of 11 months, ranging from 4.9 to 34.5 months. The response rate at different dose levels was 100% (2/2) in DL1, 80% (8/10) in DL2, and 100% (17/17) in DL3. All patients 100% (29/29) achieved minimal residual disease (MRD) negativity. 75.9% (22/29) of all patients treated achieved MRD- sCR. The safety profile of GC012F was consistent with previous findings with mostly low grade of cytokine release syndrome (CRS). 93% (27/29) of events were Grade 0-2 and 7% (2/29) of events were Grade 3. No Grade 4 or 5 CRS, and not any Grade of immune effector cell-associated neurotoxicity syndrome (ICANS) were observed. The first clinical data of our ongoing Phase 1 IIT study in China which enrolled 16 newly diagnosed, transplant-eligible, high-risk multiple myeloma (NDMM) patients was presented at ASH 2022. All patients had multiple high-risk features. As of the October 14, 2022 data cutoff date, the clinical data indicated 100% ORR and 100% MRD negativity in the 16 NDMM patients treated. 14 of 16 patients, or 87.5% of patients, achieved MRD-sCR. The median follow-up time was 8.0 months, with a range of 1.3 to 15.4 months post infusion. 12 patients, or 75%, did not experience CRS of any grade. Three patients, or 19%, experienced Grade 1 CRS and one patient, or 6%, experienced Grade 2 CRS. No Grade 3, 4 or 5 CRS was observed. No patient developed ICANS of any grade. Early results of the first-in-human phase 1 IIT in China evaluating the safety and tolerability of GC012F in B-NHL patients were presented at EHA 2022. Three patients who had received a median of two prior lines of therapy were enrolled, all of which presented with bulky disease. As of the February 22, 2022 data cutoff date, the enrolled patients had received one single infusion of GC012F at three different doses of  $3.7 \times 10^4$  cells/kg and  $2-3 \times 10^5$  cells/kg. All three patients had achieved a complete response (CR) confirmed by PET- CT at day 28 after GC012F infusion. At 3-month follow-up, both of the two assessable patients had ongoing response. No dose-limiting toxicities were observed and no ICANS were observed. CRS presented as Grade 1 in two patients and Grade 3 in one patient (duration of two days) with no Grade 4 or 5 events. We have obtained IND approval from the FDA to study GC012F in r/r MM and plan to initiate a Phase 1b/2 clinical trial in the second quarter of 2023 in the U.S. to further evaluate GC012F in r/r MM patients. Concurrently, we have obtained IND clearance from the China NMPA to study GC012F in r/r MM and plan to initiate a Phase 1/2 clinical trial in the third quarter of 2023 in China.
- **GC019F.** GC019F is a FasTCAR-enabled CD19-directed autologous CAR-T product candidate that has been studied for the treatment of adult B-ALL in an investigator-initiated Phase 1 trial across multiple centers in China. We have obtained IND approval from the NMPA to study GC019F in adult B-ALL and have initiated the Phase 1 trial for GC019F in r/r B-ALL.
- **GC502.** GC502 is a TruUCAR-enabled dual CD19- and CD7-directed, off-the-shelf allogeneic CAR-T product candidate being studied for the treatment of B-cell malignancies in an ongoing investigator-initiated Phase 1 trial in China. GC502 is manufactured using T cells from non-HLA matched healthy donors. An enhancer molecule is embedded in the basic construct of TruUCAR to enhance proliferation of TruUCAR T cells. Optimized for CD19/CD7 dual CAR functionality and in vivo durability, GC502 has demonstrated robust anti-tumor efficacy with promising potential to suppress HvG rejection in preclinical models. Early results of the first-in-human phase 1 IIT in China evaluating the safety and tolerability of GC502 in B-ALL patients were presented at EHA 2022. As of the February 2022 data cutoff date, four B-ALL patients were enrolled and treated. Three out of four patient achieved MRD- CR or CRi. Cytokine release syndrome (CRS) presented as Grade 2 and Grade 3 with no Grade 4 or 5 events. No patient developed ICANS or acute GvHD.
- **GC027.** GC027 is a TruUCAR-enabled CD7-directed allogeneic CAR-T product candidate being studied for the treatment of adult T-ALL in an investigator-initiated Phase 1 trial across multiple centers in China. As of the February 2021 data cutoff date, six adult r/r T-ALL patients were enrolled and treated on study. All six patients enrolled had relapsed from, or were refractory to, their prior line of therapy. All six evaluable patients achieved a CR or CRi, resulting in all patients obtaining a response, including five patients, or 83%, achieving MRD-CR on Day 28 after treatment. CRS was observed in all patients and was resolved with treatment. No patient developed ICANS or acute GvHD.

- **GC007g.** GC007g is a donor-derived CD19-directed allogeneic CAR-T cell therapy that is being studied for the treatment of r/r B-ALL in a Phase 2 trial, where CAR-T cells were manufactured using T cells from an HLA-matched healthy donor. We have obtained IND approval from the NMPA to study GC007g in B-ALL and were granted approval from the NMPA on December 24, 2020 for a seamless Phase 1/2 registrational trial. Following completion of the Phase 1 portion, we have announced the dosing of the first patient in October 2022, in the Phase 2 portion of the registrational Phase1/2 trial.
- **GC503.** GC503 is a SMART CART™ cell therapy candidate that targets mesothelin. It is being evaluated for the treatment of mesothelin-positive solid tumors in a China IIT.

In addition to our clinical-stage product candidates, we have a broad portfolio of earlier stage product candidates targeting various cancer indications, such as hematologic malignancies and solid tumors.

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 in China mainly through our good manufacturing practices, or GMP, compliant manufacturing facility in Suzhou and also through our Shanghai process development center for preclinical and clinical engineering runs, making us self-sufficient in the production of CAR-T cells for preclinical and clinical development as well as early stage commercialization. We established fully-closed capability in our Suzhou facility and Shanghai process development center, which are designed to produce FasTCAR product candidates while reducing contamination risks and optimizing cost-efficiency. We believe these advantages allow us to substantially reduce manufacturing costs, improve productivity and scale up our production in a cost-efficient manner. Our Shanghai process development center 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., a cell therapy company. Prior to that, Dr. Cao held research positions at Harvard Medical School and Stanford University Medical Center, as well as senior roles at Chiron (Novartis and Bayer) and Affymetrix (ThermoFisher). Our Chief Medical Officer, Dr. Wendy Li, M.D., has over 20 years of experience leading all critical aspects of clinical and medical operations at early-stage and large pharmaceutical organizations in the U.S. and China. Her expertise spans both clinical development and medical affairs, including leading early- and late-stage clinical trials for several therapeutic candidates for the treatment of hematological malignancies and solid tumors, and overseeing over 30 successful Investigational New Drug applications (INDs), New Drug Applications (NDAs) and Biologics License Applications (BLAs) that led to several multi-billion-dollar blockbuster drugs. Prior to joining Gracell, Dr. Li served as CMO of EXUMA Biotech, where she provided strategic medical and clinical leadership for the advancement of its cell therapy pipeline in the U.S. and Asia. She has also held clinical development and medical affairs leadership positions at Pfizer, Sanofi, Genentech, and Sihuan Pharmaceutical. Our Chief Financial Officer, Dr. Yili Kevin Xie, Ph.D., has over 20 years of experience in healthcare industry and 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 Humanigen Inc. (Nasdaq: HGEN). Our Chief Business Officer, Dr. Samuel Zhang has over 20 years of industry experience, covering the entire drug development spectrum, and the expertise to integrate key scientific, commercial, and clinical/regulatory perspectives to facilitate strategic business decisions including business development transactions. Dr. Zhang has a long history and broad exposure of deal making at large pharm and small biotech. Prior to joining Gracell, Dr. Zhang served as Chief Business Officer at Rockville, Maryland-based NeoImmuneTech, another publicly traded biotech company, from 2019 to 2022. While there, he defined the company's overall business strategy with his cross-functional leadership and oversaw business development including deal initiation, deal execution, and alliance management. He has also held various management positions at Novartis, Pfizer, Bristol-Myers Squibb (BMS), and Eli Lilly, responsible for product and portfolio strategies, business development, global and U.S. product launches, and global medical strategy.

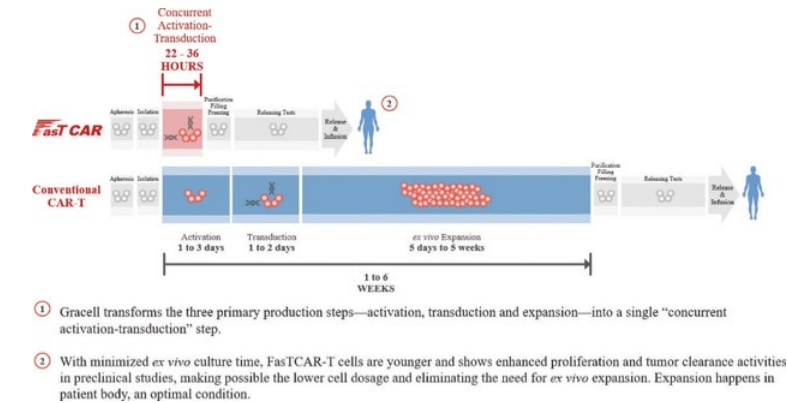
## **Our Proprietary Technologies**

With FasTCAR, we are able to deliver younger, less exhausted T cells for autologous cell therapies with enhanced activities and next-day manufacturing versus the industry norm of one 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 technology modules including Dual CAR and SMART CART™, that can be leveraged with FasTCAR and TruUCAR technology platforms to generate CAR-T cell therapies. Dual CAR enables dual tumor antigen-targeting that can potentially improve efficacy by reducing potential disease relapse possibly caused by antigen escape. With SMART CART™, we are able to reverse and turn immunosuppressive signals of tumor microenvironment, or TME, into stimulatory reactions of CAR-T cells to generate less exhausted T cells to combat solid tumors. Additionally, with donor-derived CAR technique, we are developing an allogeneic CAR-T cell therapy program using T cells from HLA-matched donors to minimize risk of GvHD as well as HvG without gene editing.

### ***FasTCAR – Our Autologous CAR-T Platform***

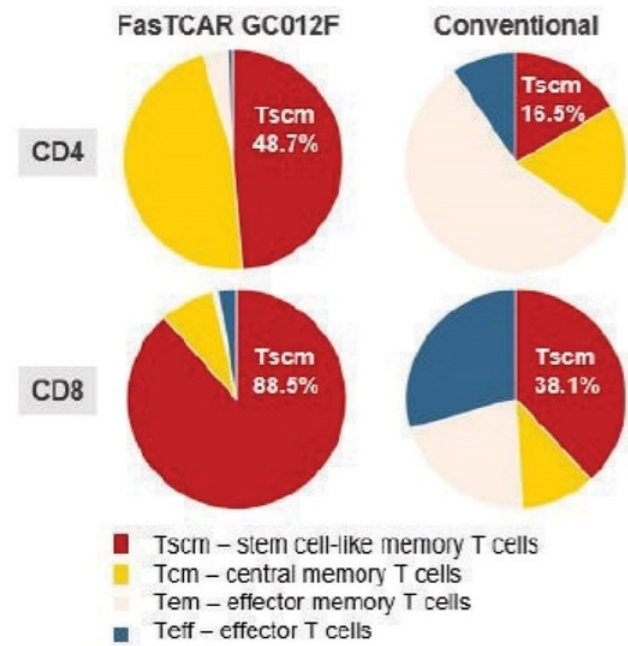
FasTCAR is our novel autologous CAR-T platform that tackles the most pressing challenges associated with autologous therapies, such as lengthy manufacturing time, suboptimal cell quality, high therapy cost and poor T cell fitness. In the conventional CAR-T manufacturing process, the first and most essential step is activating a patient's 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 one 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 active in proliferation and tumor cell 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 one to six weeks and achieving next-day manufacturing.

Comparison of FasTCAR Manufacturing Process and the Conventional Process



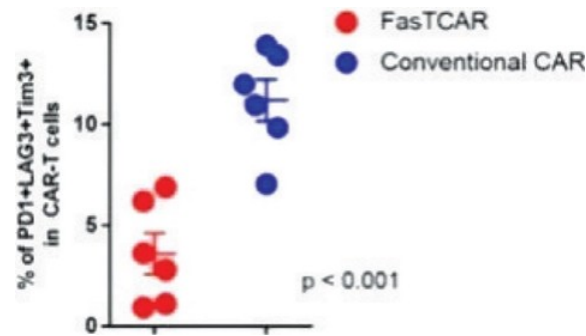
As exemplified by the preclinical studies for FasTCAR T cells targeting CD19 as well as the FasTCAR T cells targeting BCMA/CD19, FasTCAR T cells are younger, less exhausted and show enhanced proliferation, tissue migration and tumor cell clearance activities, as compared to conventional CAR-T cells, 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 BCMA/CD19-targeting 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 therapeutic effects. 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 *In Vitro*



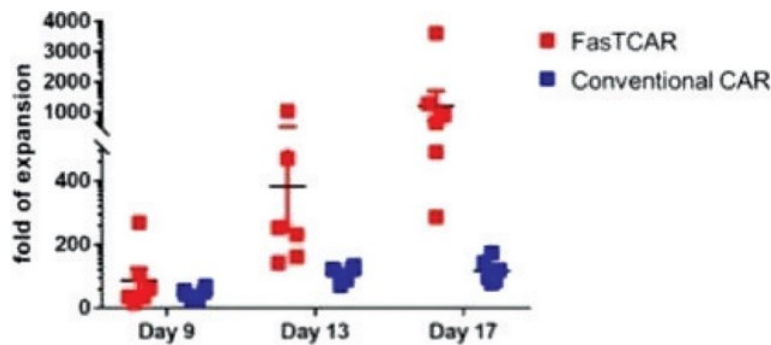
We compared T cell exhaustion of FasTCAR T cells targeting CD19 to conventional CAR-T cells targeting CD19 in a preclinical study, where the percentage of exhausted T cells was measured using common exhaustion markers, PD-1+Lag3+Tim3. T cell exhaustion is a state of T cell dysfunction due to reasons such as prolonged antigen stimulation and cancer. As depicted in the figure below, we observed that FasTCAR cells are less exhausted than conventional CAR-T cells.

**FasTCAR T Cells Are Less Exhausted than Conventional CAR-T Cells, As Measured by the Percentage of T Cell Exhaustion Markers**



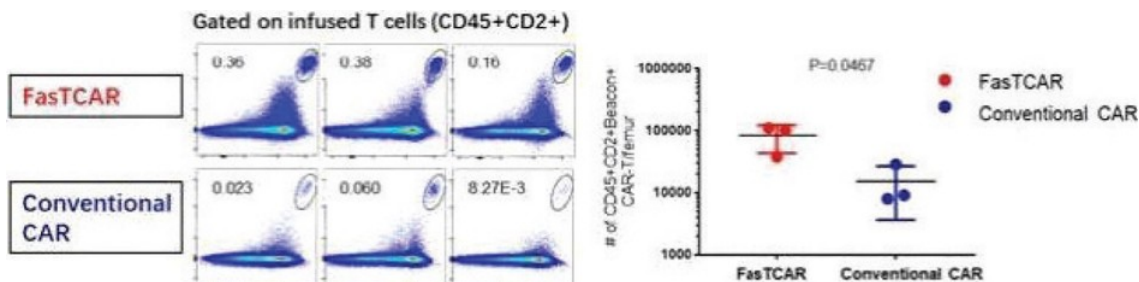
We observed that FasTCAR-T cells targeting CD19 also demonstrated more robust and enhanced proliferation activities than conventional CAR-T cells in vitro upon antigen re-stimulation, as depicted in the figure below.

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



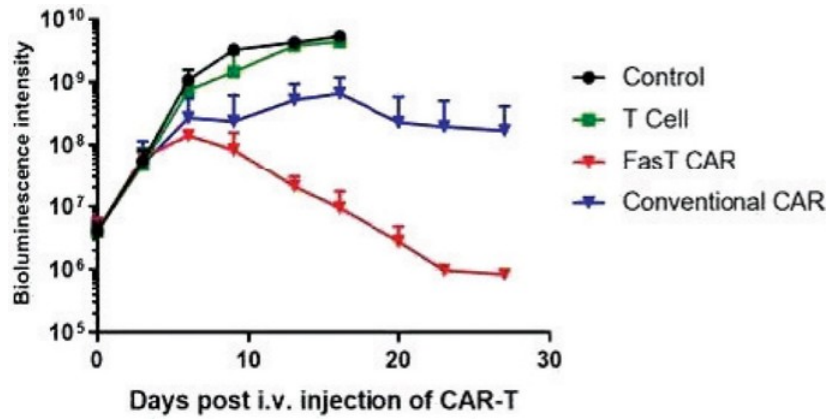
We also assessed the CAR-T cell migration to the bone marrow after infusion. As depicted in the figure below, we observed that significantly more FasTCAR T cells targeting CD19 were found in the bone marrow than conventional CAR-T cells ten days after CAR-T cell infusion.

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



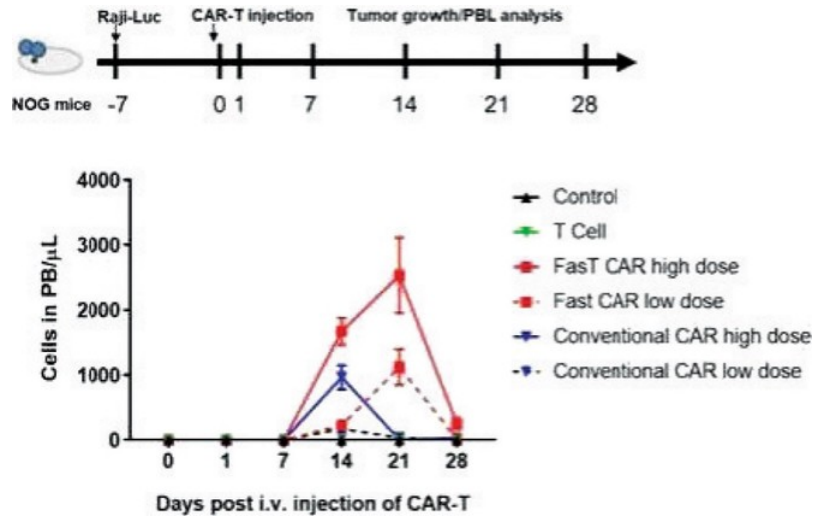
Additionally, we observed that FasTCAR T cells targeting CD19 demonstrated significantly better and more sustained anti-leukemia effects *in vivo* in a Raji xenograft mouse model, or Raji-Luc, as depicted in the figure below. Immunocompromised mice were implanted intravenously with tumor cells and the tumors were established for seven days before injection with a dose of  $5.0 \times 10^5$  total CAR-T cells. FasTCAR T cells targeting CD19 exhibited better and more sustained anti-tumor effects than conventional CAR-T cells at the same dose.

**FasTCAR T Cells Exhibit Significantly More Active and Sustained Anti-Tumor Effects 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.

**Enhanced Anti-Tumor Activities of FasTCAR T Cells Was, at Least Partly, Attributable to Increased Proliferation Activities 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 capability in our Suzhou and Shanghai facilities, which are designed to produce FasTCAR product candidates while reducing contamination risks and optimizing cost-efficiency. We believe these advantages, coupled with our ability to achieve next-day manufacturing for autologous CAR-T cells, allow us to substantially reduce manufacturing cost, improve productivity and scale up our production in a cost-efficient manner.

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 and GC019F, targeting hematologic malignancies, such as MM, B-ALL and B-NHL.

### ***TruUCAR – Our Off-the-Shelf Allogeneic CAR-T Platform***

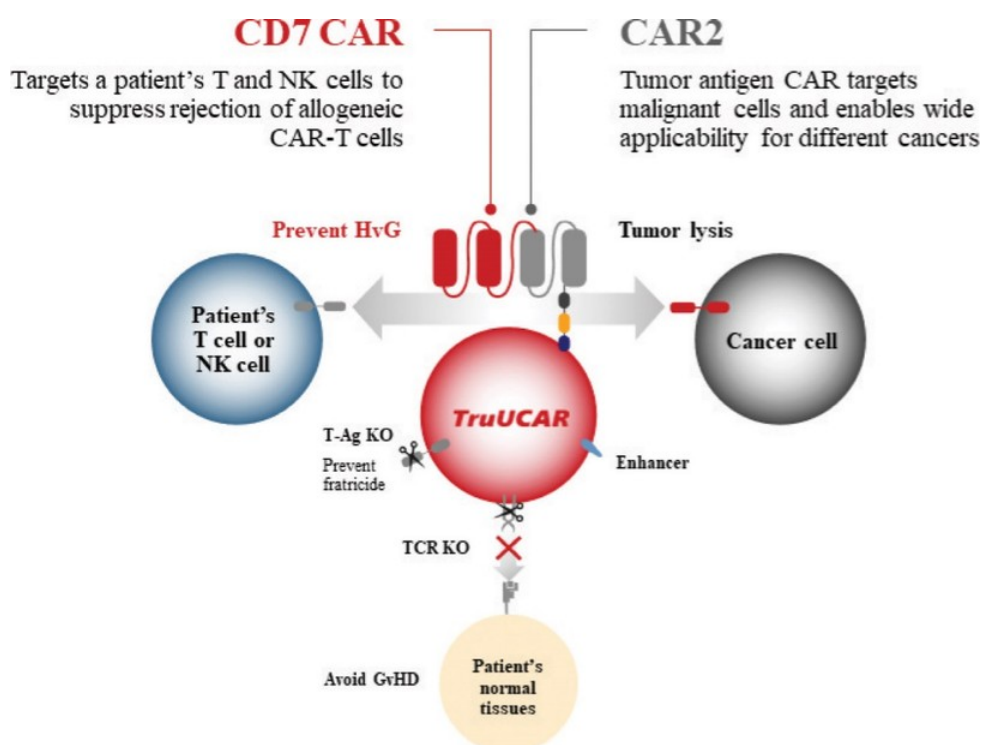
TruUCAR is our proprietary and innovative technology platform for generating high-quality allogeneic CAR-T therapies that can be administered “off-the-shelf” at lower cost. Unlike autologous CAR-T therapies, these product candidates use T cells from non-HLA-matched healthy donors, making them readily 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 cell 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.

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, preventing 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. We have also implanted our proprietary enhancer for proliferation, or EP 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 safer and more effective allogeneic CAR-T cell therapies.



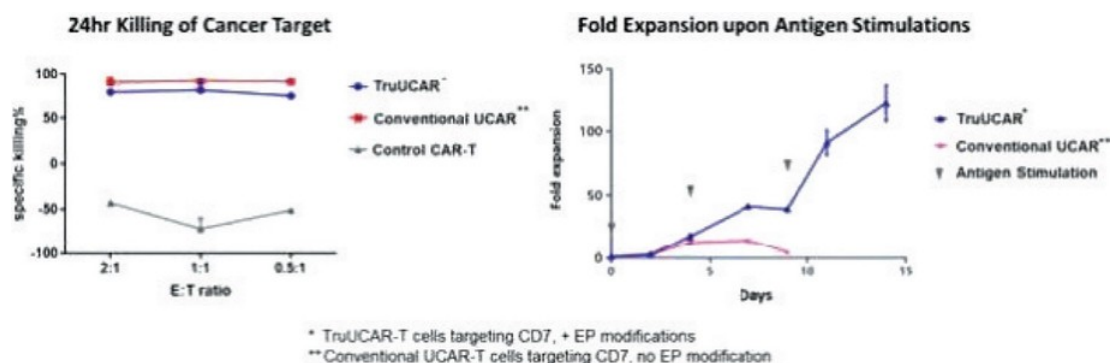
### Mechanism of Action of TruUCAR



Since TruUCAR is modular, alternative CAR constructs targeting against different antigens can be applied to TruUCAR to achieve similar 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. GC502, our dual CD19- and CD7-directed off-the-shelf allogeneic CAR-T product candidate, for example, leverages such unique dual CAR design with one CAR targeting CD7 to suppress HvG rejection and the second CAR targeting CD19. 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.

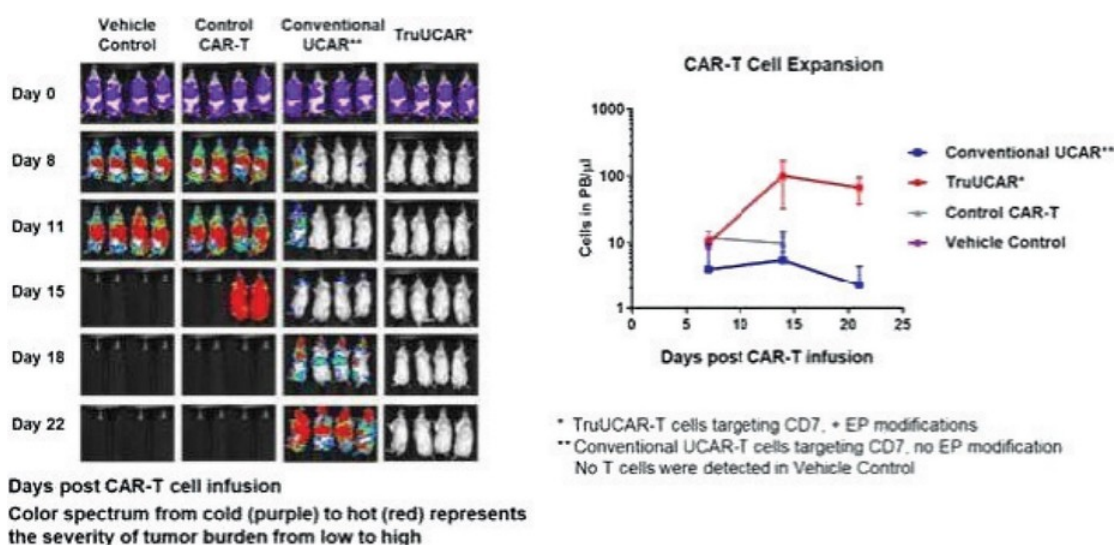
We believe that TruUCAR could potentially result in meaningful cost savings, further increasing the accessibility of CAR-T cell therapies for cancer patients. In preclinical studies that we conducted for TruUCAR T cells targeting CD7, TruUCAR T cells demonstrated comparable short-term cancer cell killing in vitro and better long-term expansion over conventional UCAR T cells targeting CD7 without EP modifications.

## TruUCAR T Cells Exhibited Comparable *In Vitro* Cancer Cell Killing and Better Expansion over Conventional UCAR T Cells



Additionally, TruUCAR T cells targeting CD7 demonstrated better engraftment and anti-leukemia effects *in vivo* compared to conventional UCAR T cells targeting CD7 in a highly malignant xenograft murine model for T-ALL. As depicted in the figures below, immunocompromised NOG mice were implanted intravenously with  $2.0 \times 10^6$  CCRF-CEM leukemia cells and leukemia were established for six days before injection with  $1.0 \times 10^6$  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 better and more sustained anti-leukemia effects than conventional UCAR T cells. TruUCAR T cells also demonstrated better *in vivo* proliferation as well as duration of expansion in the peripheral blood of treated animals, which was correlated with its robust anti-leukemia effects in mouse models.

## In Murine Xenograft Model of Human T-ALL, TruUCAR T Cells Demonstrated Better *In Vivo* Engraftment and Anti-Leukemia Effects Compared to Conventional UCAR T Cells



### Technology Enhancements

We also have a suite of proprietary technology modules, Dual CAR and SMART CART™, that can be leveraged with FastCAR and TruUCAR technology platforms to generate CAR-T product candidates.

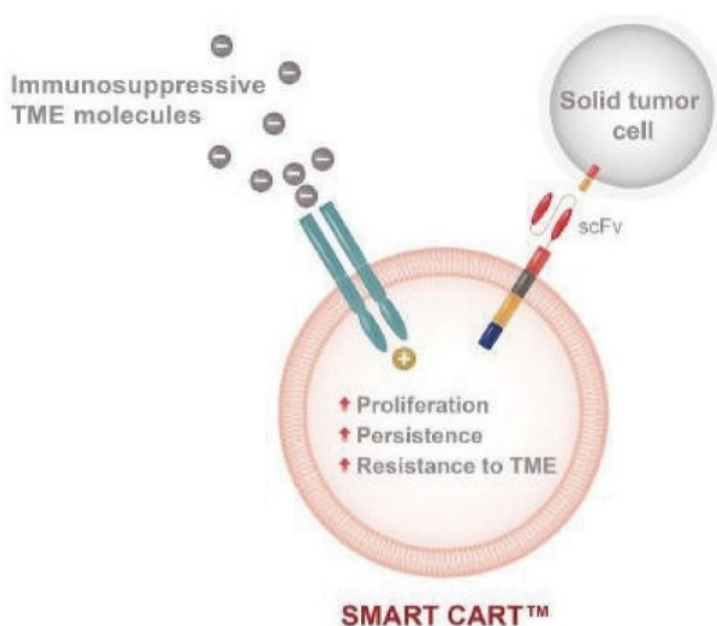
### Dual CAR

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. The final designs for our dual antigen targeting product candidates are determined through *in vivo* and *in vitro* screening. For example, our lead FasTCAR product candidate, GC012F, adopts a loop design.

### SMART CART™

SMART CART™ is designed to further strengthen the functionality of CAR-T cells and aims to overcome TME. Reversing and turning immunosuppressive signals of TME into stimulatory reactions of CAR-T cells, SMART CART™ includes altered expression of the receptor and signaling mechanism of an inhibitory TME molecule to increase proliferation and persistence, and to reduce exhaustion of CAR T cells. We can apply SMART CART™ to many targets for the treatment of solid tumors.

#### Mechanism of Action of SMART CART™



### 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 cell 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. We have obtained IND approval from then NMPA to study GC007g in B-ALL and been granted approval from the NMPA for a seamless Phase 1/2 registrational trial. Currently, the Phase 2 study is ongoing in China.

## Our Clinical Development

### *FasTCAR Autologous Product Candidates*

#### *GC012F: BCMA-CD19-directed Autologous Dual CAR-T for the Treatment of Multiple Myeloma and B Cell Non-Hodgkin's Lymphoma*

##### Overview

GC012F, our FasTCAR-enabled autologous dual CAR-T product candidate, is currently being studied in investigator-initiated Phase 1 trials across multiple centers in China, for two indications, MM and B-NHL. The goal of GC012F is to tackle MM by simultaneously targeting both malignant plasma cells expressing BCMA and early progenitor cells expressing CD19. Targeting both antigens in multiple myeloma is designed to drive fast, deep and durable responses in MM patients. This trial commenced in September 2019 and has been sponsored and conducted by principal investigators at specialized hospitals in China. From October 2019 to January 2022, 29 heavily pretreated r/r MM patients were enrolled and treated in the single-arm, open label, multicenter IIT with a single infusion of GC012F at three dose levels:  $1 \times 10^5$  cells/kg (DL1),  $2 \times 10^5$  cells/kg (DL2), and  $3 \times 10^5$  cells/kg (DL3). Data was presented at EHA 2022 where 29 r/r MM patients had been enrolled and treated. 90% (26/29) patients were high risk based on mSMART 3.0 criteria and patients had received a median of five prior lines of therapy. At the data cutoff of June 8, 2022, the 29 patients had been evaluated for response with a median follow-up duration of 11 months, ranging from 4.9 to 34.5 months. The response rate at different dose levels was 100% (2/2) in DL1, 80% (8/10) in DL2, and 100% (17/17) in DL3. All patients 100% (29/29) achieved MRD negativity. 75.9% (22/29) of all patients treated achieved MRD- sCR. The safety profile of GC012F was consistent with previous findings with mostly low grade of cytokine release syndrome (CRS). 93% (27/29) of events were Grade 0-2 and 7% (2/29) of events were Grade 3. No Grade 4 or 5 CRS, and not any Grade of ICANS were observed. The first clinical data of our ongoing Phase 1 IIT study in China which enrolled 16 newly diagnosed, transplant-eligible, high-risk multiple myeloma (NDMM) patients was presented at ASH 2022. All patients had multiple high-risk features. As of the October 14, 2022 data cutoff date, the clinical data indicated 100% ORR and 100% MRD negativity in the 16 NDMM patients treated. 14 of 16 patients, or 87.5% of patients, achieved MRD-sCR. The median follow-up time was 8.0 months, with a range of 1.3 to 15.4 months post infusion. 12 patients, or 75%, did not experience CRS of any grade. Three patients, or 19%, experienced Grade 1 CRS and one patient, or 6%, experienced Grade 2 CRS. No Grade 3, 4 or 5 CRS was observed. No patient developed ICANS of any grade. Early results of the first-in-human phase 1 IIT in China evaluating the safety and tolerability of GC012F in B-NHL patients were presented at EHA2022. Three patients who had received a median of two prior lines of therapy were enrolled, all of which presented with bulky disease. As of the February 22, 2022 data cutoff date, the enrolled patients had received one single infusion of GC012F at three different doses of  $3.7 \times 10^4$  cells/kg and  $2-3 \times 10^5$  cells/kg. All three patients had achieved a complete response (CR) confirmed by PET- CT at day 28 after GC012F infusion. At 3-month follow-up, both of the two assessable patients had ongoing response. No dose-limiting toxicities were observed and no ICANS were observed. CRS presented as Grade 1 in two patients and Grade 3 in one patient (duration of two days) with no Grade 4 or 5 events. In November 2021, GC012F received an Orphan Drug Designation from the FDA for the treatment of MM. In January and February 2023, the FDA and China NMPA cleared our IND applications for GC012F in r/r MM, respectively.

##### 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 about 35,730 expected to be diagnosed in the United States in 2023.

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 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.

### **Background on B Cell Non-Hodgkin's Lymphoma**

Non-Hodgkin's lymphoma, or NHL, is a group of blood cancers that developed from lymphocytes, most commonly derived from B cells, i.e., B-NHL. Globally, approximately 510,000 patients were diagnosed with NHL in 2018. About 80,550 patients are expected to be diagnosed with NHL in the United States in 2023.

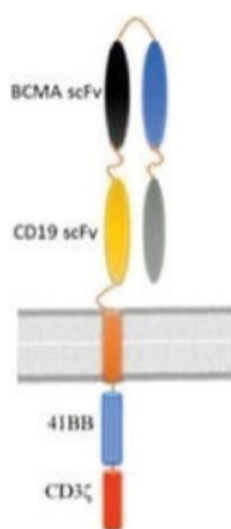
### **Dual Antigen Targeting with GC012F**

CAR-T cell therapies directed at BCMA are now well-established part of treatment in late line MM. However, CAR-T cells targeting a single antigen may not be sufficient to control disease relapse. 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, depth and duration of responses to CAR-T cell therapy for r/r MM, we designed GC012F with dual CARs targeting both BCMA and CD19.

In addition, CD19 is a well-established B-NHL target, and CAR-T cell therapy directed at CD19 has provided an encouraging modality for the management of r/r B-NHL. However, published research data also suggest that 39% to 97% of clinical NHL cell samples also express BCMA. By simultaneously targeting BCMA and CD19, GC012F is designed to improve efficacy outcome in r/r B-NHL patients.

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 CD3s intracellular domain.

### GC012F Structure



### Investigator-Initiated Phase 1 Trials and Preliminary Evidence of Clinical Benefit

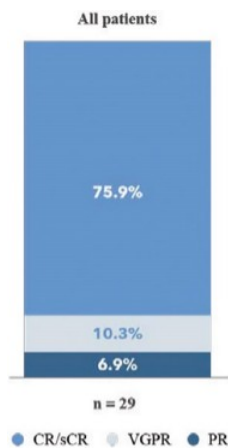
GC012F is being studied in ongoing investigator-initiated Phase 1 trials across multiple centers in China, for the treatment of two indications, MM and B-NHL. The primary endpoint of the first-in-human, single-arm, open-label studies is safety, as determined by the occurrence of treatment-related adverse events, such as CRS and ICANS. 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 ICANS which may manifest as delirium, encephalopathy, aphasia and lethargy among other symptoms. A key secondary endpoint is preliminary efficacy, as determined by clinical response, such as sCR, CR in accordance with the IMWG uniform response criteria for MM. IMWG criteria have 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.

#### *GC012F for r/r MM*

The study in r/r MM commenced in September 2019 and has been sponsored and conducted by principal investigators at specialized hospitals in China. From October 2019 to January 2022, 29 heavily pretreated r/r MM patients were enrolled and treated in the single-arm, open label, multicenter IIT with a single infusion of GC012F at three dose levels:  $1 \times 10^5$  cells/kg (DL1),  $2 \times 10^5$  cells/kg (DL2), and  $3 \times 10^5$  cells/kg (DL3). 90% (26/29) patients were high risk based on mSMART 3.0 criteria and patients had received a median of five prior lines of therapy. At the data cutoff of June 8, 2022, the 29 patients had been evaluated for response with a median follow-up duration of 11 months, ranging from 4.9 to 34.5 months.

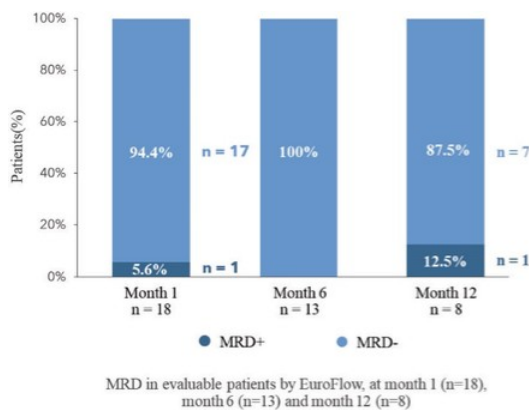
According to study protocol, all patients in this investigator-initiated Phase 1 trial were preconditioned with fludarabine and cyclophosphamide over three days. Following preconditioning, the principal investigators at this trial administered GC012F as single infusion. As of the June 8, 2022 data cutoff date, 29 patients had been enrolled and were evaluable for assessment.

Response Assessment, as of June 8, 2022



*Efficacy Results.* As of the June 8, 2022 data cutoff date, 27 of 29 patients had responded to therapy, resulting in an ORR of 93.1% of VGPR or better. Response was observed in all dosage levels with the earliest response observed on Day 28 after treatment. The response rate at different dose levels was 100% (2/2) in dose level 1, or DL1, 80% (8/10) in dose level 2, or DL2, and 100% (17/17) in dose level 3, or DL3. All 29 patients achieved MRD-. 22 of 29 patients, or 75.9% of patients, achieved MRD-sCR.

Minimal Residual Disease Assessment at Sensitivity of 10<sup>-6</sup>, as of June 8, 2022



100% of the 29 patients treated has achieved MRD-. 22 of 29 evaluable patients or 75.9%, had achieved and maintained MRD- sCR, which includes patients heavily pretreated, including by anti-CD38 agents such as daratumumab. Of the overall 29 patients, nine patients were measured by flow cytometry with a sensitivity level of 10<sup>-4</sup>, and 20 patients were measured by EuroFlow, a standardized procedure designed to measure MRD, with a sensitivity level of 10<sup>-6</sup> and at least 1.08x10<sup>7</sup> cells analyzed. At one month, six months and twelve months after treatment, 18, 13 and 8 patients, respectively, were evaluable for MRD assessment at the sensitivity of 10<sup>-6</sup>. 17 of 18 evaluable patients, or 94.4%, were MRD- at the sensitivity of 10<sup>-6</sup> at one month after treatment at the sensitivity of 10<sup>-6</sup>. All 13 evaluable patients, or 100%, were MRD- at the sensitivity of 10<sup>-6</sup> at six months after treatment. 7 of 8 evaluable patients, or 87.5%, were MRD- at the sensitivity of 10<sup>-6</sup> at twelve months after treatment.



**Safety Results.** As of the June 8, 2022 data cutoff date, 25 out of the 29 patients experienced CRS with mostly low grade. 27 patients, or 93%, experienced Grade 0-2 CRS and two patients, or 7%, experienced Grade 3 CRS. No Grade 4 or Grade 5 CRS was observed. The median time to onset, the first appearance of any symptom, of CRS was six days, with a range from two to ten days. The median duration of CRS was three days, with a range from one to eight days. CRS symptoms were managed with SOC treatment, including tocilizumab and steroids, and resolved in all cases. No patient developed ICANS of any grade. Treatment-emergent adverse events presented predominantly as cytopenias and aspartate transaminase release and were resolved with standard therapy.

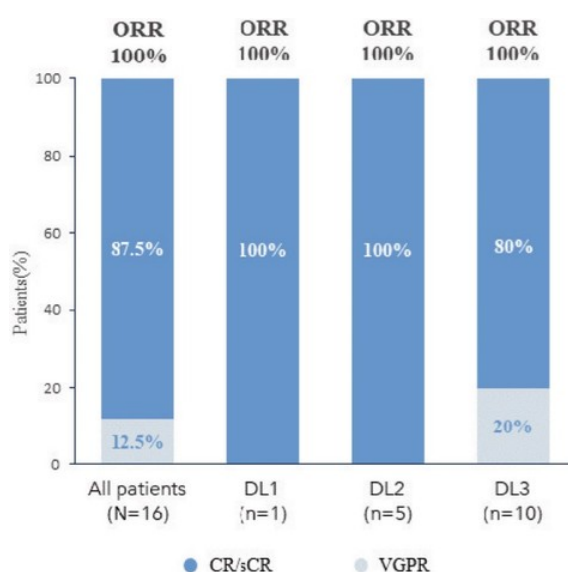
**Expansion Kinetics.** During the observation period, the CAR-T median proliferation peak was reached on Day 10 (Day 7-Day 15), and the median peak copy number was 96,438 (16,011-374,346) copies/mg DNA with long duration of persistence of up to 793 days at time of data cut off.

### **GC012F for NDMM**

The study in NDMM commenced in August 2021 and has been sponsored and conducted by principal investigators at specialized hospitals in China. From August 2021 to July 2022, 16 newly diagnosed, transplant-eligible, high-risk multiple myeloma (NDMM) patients were enrolled and treated in the single-arm, open label IIT. As of the October 14, 2022 data cutoff date, the clinical data indicated 100% ORR and 100% MRD negativity in the 16 NDMM patients treated.

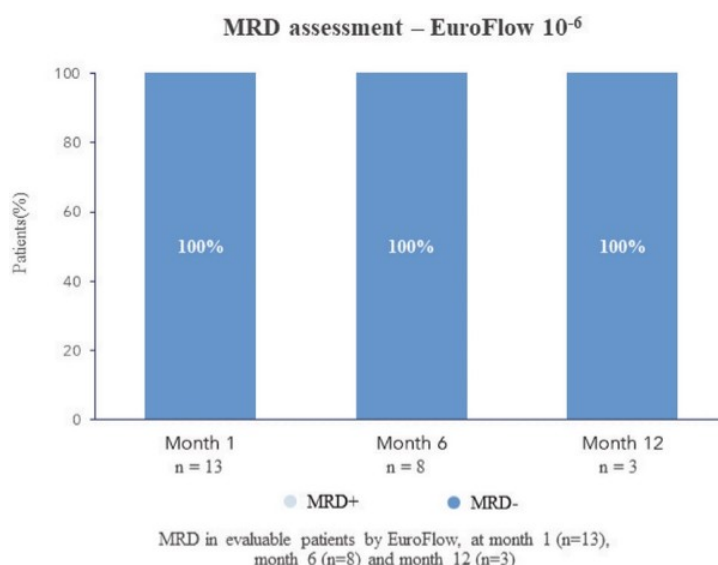
As of the October 14, 2022 data cutoff date, 16 patients had been enrolled and were evaluable for assessment. All patients had multiple high-risk features. Prior to the CAR-T infusion, 14 patients received two cycles of induction therapy of bortezomib, lenalidomide and dexamethasone (VRd), and one patient received one cycle bortezomib, epirubicin, and dexamethasone (PAD) and one cycle VRd prior to the infusion. Following preconditioning with fludarabine and cyclophosphamide, the principal investigators at this trial administered GC012F as single infusion at three dose levels:  $1 \times 10^5$  cells/kg (DL1),  $2 \times 10^5$  cells/kg (DL2), and  $3 \times 10^5$  cells/kg (DL3).

**Response Assessment, as of October 14, 2022**



**Efficacy Results.** As of the October 14, 2022 data cutoff date, 16 of 16 patients had responded to therapy, resulting in an ORR of 100.0% of VGPR or better. All 16 patients achieved MRD- at the sensitivity of  $10^{-6}$ . 14 of 16 patients, or 87.5% of patients, achieved MRD-sCR. The median follow-up time was 8.0 months, with a range of 1.3 to 15.4 months post infusion. The median duration of response (DOR) was not reached at data cut off.

### Minimal Residual Disease Assessment, as of October 14, 2022



At one month, six months and twelve months after treatment, 13, 8 and 3 patients, respectively, were evaluable for MRD assessment at sensitivity of 10<sup>-6</sup>. All 13 evaluable patients, or 100%, were MRD- at one month after treatment. All 8 evaluable patients, or 100%, were MRD- at six months after treatment. All 3 evaluable patients, or 100%, were MRD- at twelve months after treatment. All patients were measured by EuroFlow, a standardized procedure designed to measure MRD, with a sensitivity level of 10<sup>-6</sup> and at least 1.08x10<sup>7</sup> cells analyzed.

**Safety Results.** As of the October 14, 2022 data cutoff date, 12 patients, or 75%, did not experience CRS of any grade. Three patients, or 19%, experienced Grade 1 CRS and one patient, or 6%, experienced Grade 2 CRS. No Grade 3, Grade 4 or Grade 5 CRS was observed. The median time to onset, the first appearance of any symptom, of CRS was six days, with a range from six to seven days. The median duration of CRS was two days, with a range from one to four days. CRS symptoms were managed with SOC treatment, including tocilizumab and steroids, and resolved in all cases. No patient developed ICANS of any grade.

**Expansion Kinetics.** During the observation period, the CAR-T median proliferation peak was reached on Day 10 (Day 9-Day 14), and the median peak copy number was 63,086 (range: 20,097 – 331,159) copies/mg DNA.

#### **GC012F for B-NHL**

The clinical study in B-NHL has been sponsored and conducted by principal investigators at specialized hospitals in China. Three patients who had received a median of two prior lines of therapy were enrolled, all of which presented with bulky disease. As of the February 22, 2022 data cutoff date, the enrolled patients had received one single infusion of GC012F at three different doses of 3.7x10<sup>4</sup> cells/kg and 2-3x10<sup>5</sup> cells/kg. All three patients had achieved a complete response (CR) confirmed by PET- CT at day 28 after GC012F infusion. At 3-month follow-up, both of the two assessable patients had ongoing response. No dose-limiting toxicities were observed and no immune effector cell-associated neurotoxicity syndrome (ICANS) were observed. CRS presented as Grade 1 in two patients and Grade 3 in one patient (duration of two days) with no Grade 4 or 5 events.

**Efficacy Results.** As of the February 22, 2022 data cutoff date, all three patients, or 100% of assessable patients, achieved complete response at one month after treatment. At 3-month follow-up, both of the two assessable patients had ongoing response.

**Safety Results.** As of the October 14, 2022 data cutoff date, two patients, or 66.7% of the evaluable patients, experienced Grade 1 CRS and one patient, or 33.3% of the evaluable patients, experienced Grade 3 CRS (duration of two days). No Grade 4 or Grade 5 CRS was observed. No dose-limiting toxicities were observed and ICANS were observed.

## GC012F Future Clinical Plans

The investigator-initiated Phase 1 trial in r/r MM has demonstrated GC012F's potential to deliver responses in highly-pretreated late stage MM patients, including high-risk MM patients who have exhausted other therapeutic options. Based on these results generated from this trial by the principal investigators, the program was expanded into earlier lines of therapy. In November 2021, we applied and were granted Orphan Drug Designation from the FDA for the treatment of MM. In January 2023, we obtained IND approval from the FDA to study GC012F in r/r MM. We plan to initiate a Phase 1b/2 clinical trial in the second quarter of 2023 in the U.S. to further evaluate GC012F in r/r MM patients. The Phase 1b portion of the trial is designed to evaluate the safety and tolerability of GC012F in r/r MM patients, determine the recommended dose of GC012F for Phase 2 and characterize the pharmacokinetics of GC012F in r/r MM patients. The Phase 2 portion is intended to evaluate the efficacy of GC012F in r/r MM patients and further characterize the safety of GC012F. In February 2023, we have obtained IND clearance from the China NMPA to study GC012F in r/r MM and plan to initiate a Phase 1/2 clinical trial in the third quarter of 2023 in China.

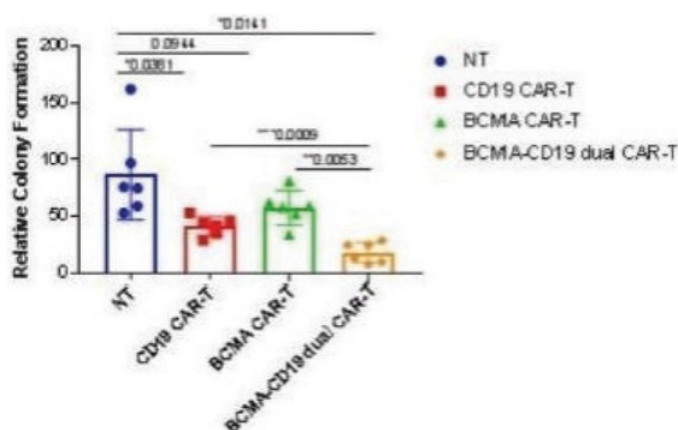
The investigator-initiated Phase 1 trial in NDMM has demonstrated GC012F's potential for substantial improvement over currently available therapies for NDMM, one of which shows sCR% of 32.9% and MRD- rate of 54.4%.

In addition, GC012F is being studied in an ongoing investigator-initiated Phase 1 trial in China for the treatment of r/r B-NHL, which is a first-in-human study evaluating a FasTCAR-enabled BCMA/CD19 dual-targeting CAR-T for B-NHL.

## Preclinical Data

As demonstrated in a preclinical study that we conducted, we observed that our GC012F, dual CAR-T cells targeting both BCMA and CD19 were more 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

#### Overview

GC019F, our FasTCAR-enabled autologous CAR-T product candidate, has been studied in a completed investigator-initiated Phase 1 trial in China, for the treatment of r/r B-ALL. This trial was sponsored and conducted by principal investigators at specialized hospitals in China. We have obtained IND approval from the NMPA to study GC019F in B-ALL. We have reduced the spending on GC019F clinical activities, as we prioritized the development of FasTCAR-enabled dual-targeting programs such as GC012F.

## **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 B-ALL includes chemotherapy, radiation therapy and stem cell transplantation. Globally, approximately 64,000 patients are diagnosed with ALL every year with over approximately 6,540 expected to be diagnosed in the United States in 2023. B-ALL accounts for 75% of ALL diagnoses in adults.

## **Completed Investigator-initiated Phase 1 Trial and GC019F Future Clinical Plans**

GC019F has been studied in a completed investigator-initiated Phase 1 trial across multiple centers in China, for the treatment of r/r B-ALL. This trial was conducted and sponsored by principal investigators at specialized hospitals in China. We have obtained IND approval from the NMPA to study GC019F in B-ALL and initiated the ongoing Phase 1 trial in r/r B-ALL.

### ***TruUCAR Off-the-Shelf Allogeneic Product Candidates***

#### ***GC502: CD19-CD7 dual-directed Allogeneic CAR-T for the Treatment of B Cell Malignancies***

### **Overview**

GC502, our TruUCAR-enabled off-the-shelf allogeneic product candidate, is being studied in an ongoing investigator-initiated Phase 1 trial in China for the treatment of adult r/r B-ALL. This trial was sponsored and is conducted by principal investigators at specialized hospitals in China.

The novel dual CAR design targeting both CD19 and CD7 allows the CD19 CAR moiety to target malignant cells, while the CD7 CAR moiety is designed to suppress HvG. GC502 is manufactured using T cells from non-HLA matched healthy donors. An enhancer molecule is embedded in the basic construct of TruUCAR to enhance proliferation of TruUCAR T cells. GC502 exemplifies the TruUCAR design that aims for optimized persistence without the need of being co-administered with additional immunosuppressive drugs.

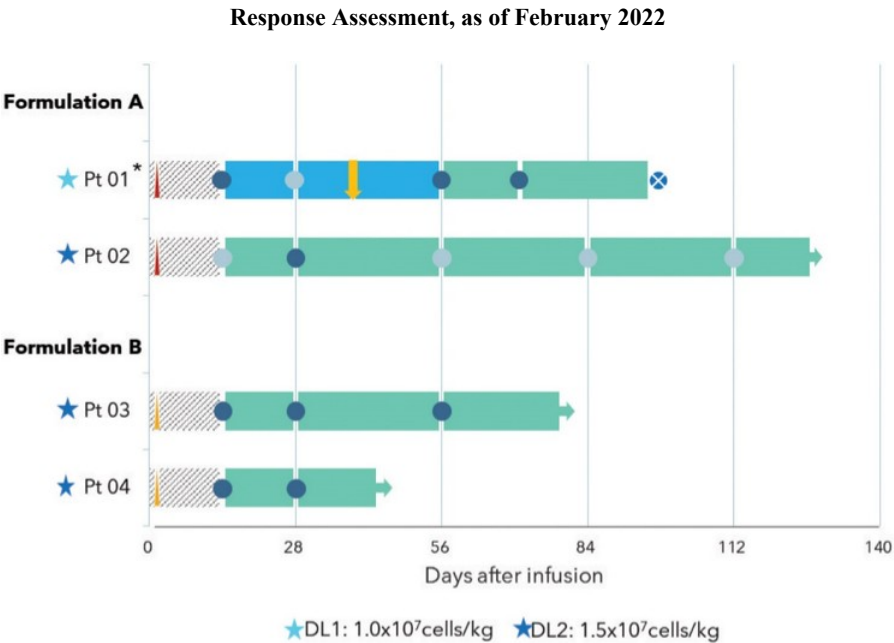
## **Ongoing Investigator-initiated Phase 1 Trial and GC502 Future Clinical Plans**

GC502 is being studied in an investigator-initiated Phase 1 trial in China, for the treatment of r/r B-ALL. The primary endpoint of this first-in-human, single-arm and open-label trial is safety. The secondary endpoint is efficacy, as determined by clinical response, such as ORR.

This trial has been sponsored and conducted by principal investigators at specialized hospital in China. Between September 2021 and January 2022, four r/r B-ALL patients were enrolled and treated in an open-label, non-randomized, prospective IIT study in China in two different dose levels and with two different formulations. Patients were heavily pretreated, and all had previously received either autologous or donor derived CD19 or CD19/CD22 targeted CAR-T therapy.

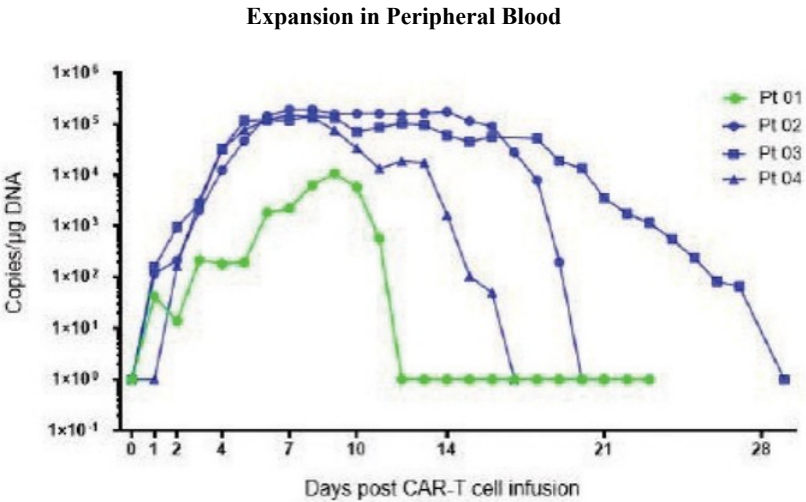
As of the February 22, 2022 data cutoff date, all four patients had received a single dose of GC502, including one patient at dose level 1 (DL1)  $1.0 \times 10^7$  cells/kg and three patients at dose level 2 (DL2)  $1.5 \times 10^7$  cells/kg. Patients received a Flu/Cy based lymphodepletion regimen prior to treatment with GC502.

**Efficacy Results.** As of the February 22, 2022 data cutoff date, three out of four patients achieved minimal residual disease negative complete response or complete response with incomplete count recovery (MRD-CR/CRi), and one patient achieved a partial response at month one and subsequently received allogeneic hematopoietic stem-cell transplantation (allo-HSCT) on day 39.



*Safety Results.* CRS presented as Grade 2 and Grade 3 with no Grade 4 or 5 events. No ICANS or aGvHD were observed.

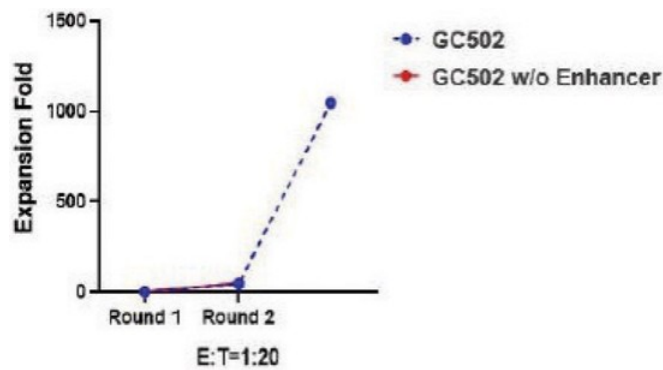
*Expansion Kinetics.* Peak expansions of GC502 in peripheral blood were observed between week 1-2 in DL 2. The patient treated in DL1 did not show adequate GC502 cellular expansion. Median peak CAR copies were 149,945 copies/ $\mu$ g DNA (range 10,849-195,400).



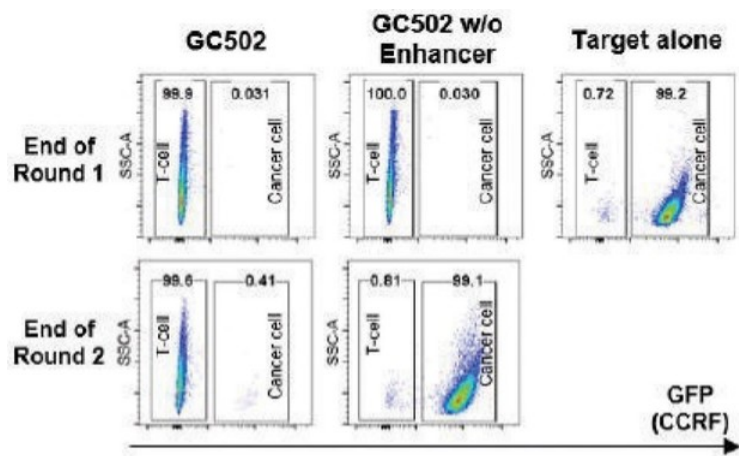
**Preclinical Data**

Preclinical results demonstrate GC502’s robust anti-tumor effects and promising potential to suppress HvG disease without the need for additional immunosuppressive therapeutics. As demonstrated in a preclinical study that we conducted, we observed that our GC502, dual CAR-T cells targeting both CD19 and CD7 with addition of an enhancer, demonstrated superior CAR-T cell expansion and cytotoxicity under repeated stimulations by either CD19+ or CD7+ target cells, as depicted in the figure below.

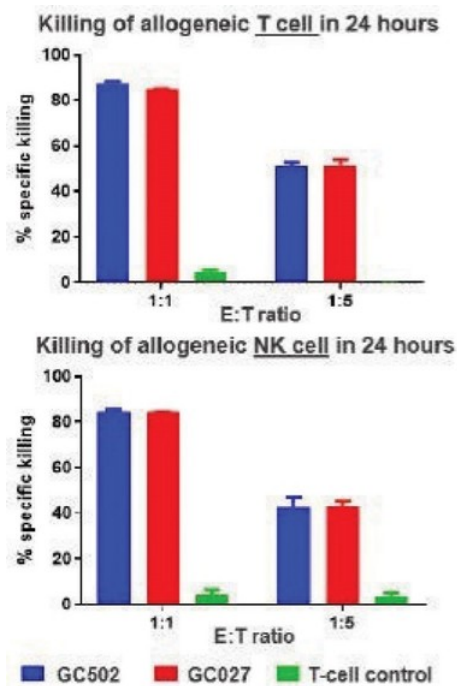
CAR-T Expansion Evaluated In a Stress Test By Serial Killing Assay with E:T at 1:20



Capacities of Target Killing Evaluated in a Stress Test By Serial Killing Assay with E:T at 1:20 and Analyzed by Flow Cytometry

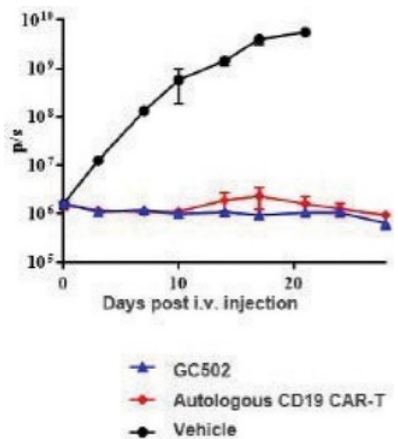


In addition, we have observed robust anti-allogeneic T and NK activities to suppress HvG, as depicted in the figure below.



In addition, GC502 has demonstrated in preclinical studies to be more effective in eliminating tumor than an autologous second generation CD19 CAR-T product candidate comprising a FMC63 scFv and a 4-1BB-CD3 $\zeta$  signaling domain, as depicted in the figure below.

**CD19 CAR Activities of GC502 and TCR Intact CD19 CAR were Compared in a Raji-based Murine Xenograft Model**



*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, has been studied in an investigator-initiated Phase 1 trial across multiple centers in China, for the treatment of adult T-ALL. This trial has been sponsored and conducted by principal investigators at specialized hospitals in China. As of the February 4, 2021 data cutoff date, six adult r/r T-ALL patients were enrolled and treated on study. All six evaluable patients achieved a CR or CRi, resulting in an ORR of 100%, including five patients, or 83%, achieving MRD- CR on Day 28 after treatment. At 6 months after treatment, three out of these five patients, or 60%, had maintained MRD- CR. After 18.5 months of follow up for the initial patients treated, one patient continued to be MRD- CR at 16.8 months. One patient maintained MRD- CR until month 9 and one patient with primary refractory disease maintained his MRD- CR status until month 7. One additional patient treated presented initially with a high tumor burden and extensive extramedullary disease. After treatment with GC027 and as confirmed by PET CT scan, all extramedullary lesions in this patient resolved and this patient achieved MRD- CR at Day 28. All CRS observed were managed with standard of care including tocilizumab. No patient developed ICANS or aGvHD.

## 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. The symptoms of T-ALL are 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 6,540 expected to be diagnosed in the United States in 2023. T-ALL accounts for approximately 25% of ALL diagnoses in adults.

## Dual Functions Single Antigen Targeting with GC027

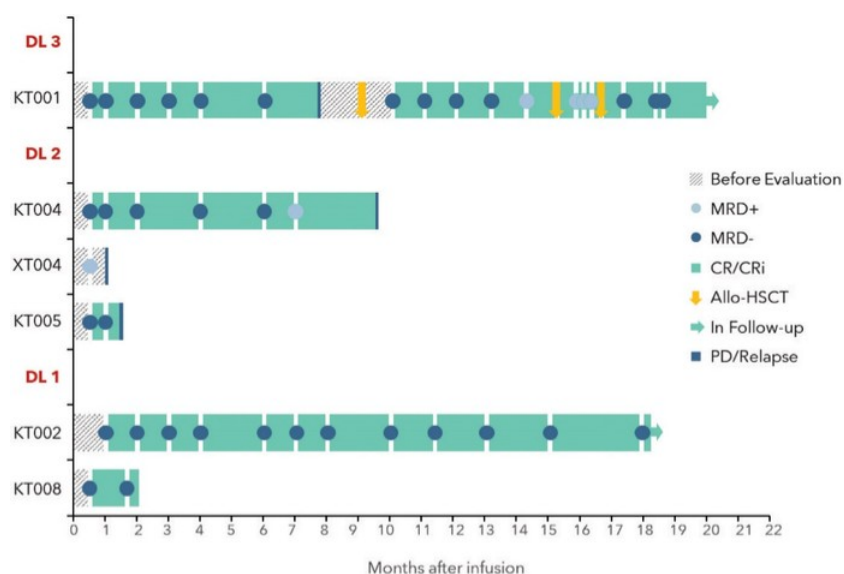
To avoid the potential for HvG, which may lead to rejection of allogeneic CAR-T cells by patients' own immune system, we have designed GC027 with a CD7-directed single CAR that carries out dual functions, targeting both the patient's own alloreactive killer T cells and NK cells as well as tumor antigen 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.

## Investigator-initiated Phase 1 Trial and Preliminary Evidence of Clinical Benefit

GC027 has been studied in an investigator-initiated Phase 1 trial 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, ICANS, GvHD and aGvHD. The secondary endpoint is efficacy, as determined by clinical response, such as ORR.

This trial has been sponsored and conducted by principal investigators at specialized hospitals in China. As of the February 4, 2021 data cutoff date, six adult r/r T-ALL patients had been enrolled, including one T-ALL patient with extensive extramedullary disease. Patients in this trial had failed a median of six prior lines of therapy. All patients enrolled had relapsed from, or were refractory to, their prior line of therapy. According to study protocol, all patients in this trial were preconditioned with a lymphodepleting regimen with a fludarabine and cyclophosphamide backbone. Following preconditioning, the principal investigators administered all patients with a single infusion of GC027, including two patients at dosage level 1, or DL1 ( $0.6 \times 10^7$  CAR+ cells/kg), three patients at dosage level 2, or DL2 ( $1.0 \times 10^7$  CAR+ cells/kg) and one patient at dosage level 3, or DL3 ( $1.5 \times 10^7$  CAR+ cells/kg). As of the February 4, 2021 data cutoff date, all six patients were evaluable for safety and efficacy assessment.

### Response, Duration of Remission and Adverse Events, as of February 2021



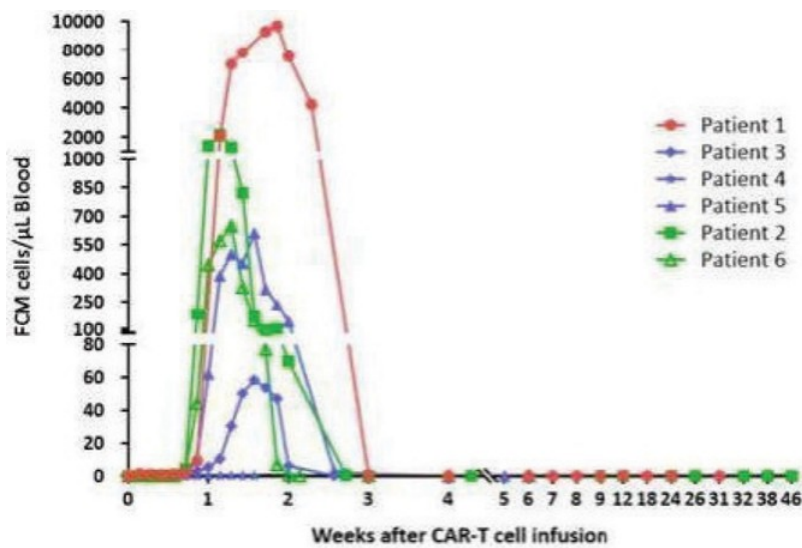
**Efficacy Results.** As of the February 4, 2021 data cutoff date, all six evaluable patients achieved a CR or CRi, representing an ORR of 100%, including five patients, or 83%, achieving MRD- CR on Day 28 after treatment. At 6 months after treatment, three out of these five patients, or 60%, had maintained MRD- CR. After 18.5 months of follow up for the initial patients treated, one patient continued to be MRD- CR at 16.8 months. One patient maintained MRD- CR until month 9 and one patient with primary refractory disease maintained his MRD- CR status until month 7. One additional patient treated presented initially with a high tumor burden and extensive extramedullary disease. After treatment with GC027 and as confirmed by PET CT scan, all extramedullary lesions in this patient resolved and this patient achieved MRD- CR at Day 28.

**Safety Results.** As of the February 4, 2021 data cutoff date, all six evaluable patients tolerated their dose levels. All six patients experienced Grade 3 or Grade 4 CRS. CRS symptoms were managed with standard of care including tocilizumab and ruxolitinib and resolved after treatment and best supportive care. No ICANS or aGvHD were observed.

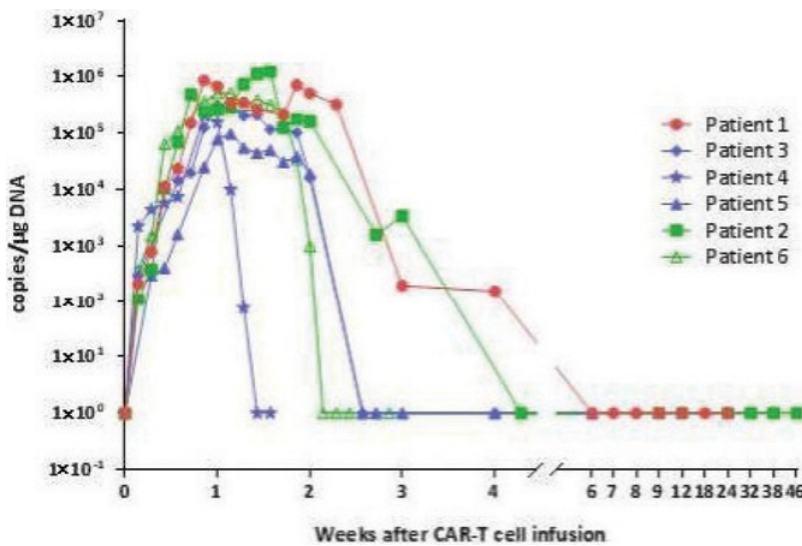
**Expansion Kinetics.** The peripheral blood of six patients enrolled as of the February 2021 data cutoff date was analyzed by flow cytometry, or FCM, a technique used to detect and measure characteristics of a population of cells or particles, and quantitative polymerase chain reaction, or qPCR, a laboratory technique of molecular biology based on the polymerase chain reaction.

Patient #	Tumor Burden	Dose Level	Peak TruUCAR cells/ul blood	Peak TruUCAR copies/ug DNA
Patient 1	38.20 %	3	9,716	872,170
Patient 3	4 %	2	69	308,303
Patient 4	80.2 %	2	0.06	205,963
Patient 5	6.7 %	2	613.44	98,460
Patient 2	45.84 %	1	2,179	1,241,762
Patient 6	6.57 %	1	648.26	525,508

Expansion Kinetics Measured by Flow Cytometry (FCM)



Expansion Kinetics Measured by qPCR



## ***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 the interim results and the relevant underlying data collected by the principal investigators as of the June 17, 2019 data cutoff date from this trial to the CDE as part of our IND application for GC007g. This trial was sponsored and conducted by principal investigators at specialized hospitals in China. As of the June 17, 2019 data cutoff date, 14 patients were enrolled and treated. 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 managed and resolved after treatment and supportive care, except for one early withdrawal due to CRS.

We obtained IND approval from the NMPA for GC007g in B-ALL, and were granted approval from the NMPA on December 24, 2020 for a seamless Phase 1/2 registrational trial. Following completion of the Phase 1 portion, we have announced the dosing of the first patient in October 2022, in the Phase 2 portion of the registrational Phase 1/2 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.

#### **Completed Investigator-Initiated Phase 1 Trial and Preliminary Evidence of Clinical Benefit**

GC007g has been studied by principal investigators 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. The secondary endpoint was efficacy, as determined by clinical response, such as ORR, CR, PFS and overall survival, or OS.

We submitted interim results as of the June 17, 2019 data cutoff date that we obtained from the principal investigators at this investigator-initiated Phase 1 trial to the CDE as part of our IND application for GC007g. This trial was sponsored and conducted by principal investigators at specialized hospitals in China. As of the June 17, 2019 data cutoff date, 14 patients had been enrolled. 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, the principal investigators administered all patients with a single infusion of GC007g including three patients at dosage level 1, or DL1 ( $1.0 \times 10^5$  CAR+ cells/kg), nine patients at dosage level 2, or DL2 ( $2.0 \times 10^6$  CAR+ cells/kg) and two patients at dosage level 3, or DL3 ( $4.2 \times 10^6$  CAR+ cells/kg). As of the June 17, 2019 data cutoff date, all 14 patients were evaluable for safety assessment and 13 patients were evaluable for efficacy assessment. One patient 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 neurotoxicity and two patients, or 14.3%, experienced acute GvHD. 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
acute GvHD	0	2 (22.2%)	0	2 (14.3%)

### GC007g Future Clinical Plans

We obtained the IND approval from the NMPA for GC007g in B-ALL, and were granted approval from the NMPA on December 24, 2020 for a seamless Phase 1/2 registrational trial. Following completion of the Phase 1 portion, we have announced the dosing of the first patient in October 2022, in the Phase 2 portion of the registrational Phase 1/2 trial.

### Preclinical Data

Data from a preclinical study of GC007g that we conducted 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 has the potential to be an effective CAR-T therapy against CD19+ B cell malignancies.

### SMART CART<sup>TM</sup> Product Candidate

#### GC503: Mesothelin-directed CAR-T for the Treatment of Mesothelin-positive Solid Tumors

### Overview

GC503, our first SMART CART<sup>TM</sup> CAR-T product candidate, is being studied in an ongoing investigator-initiated Phase 1 trial in China, for the treatment of mesothelin-positive solid tumors. We have dosed the first patient in this study in 2022.

### 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-NHL, B-ALL, T-ALL and solid tumors, 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.

Encouraged by the therapeutic potential demonstrated by GC012F and the FasTCAR platform, we are developing additional FasTCAR and dual-targeting product candidates, including:

- **GC509.** GC509 is a dual-targeting CAR-T product candidate leveraging the FasTCAR next-day manufacturing technology, for the treatment of acute myeloid leukemia (AML).

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 are currently evaluating the TruUCAR-enabled preclinical programs, including:

- **GC508.** GC508 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.

Additionally, while CAR-T therapy has been demonstrating promising efficacy for hematological malignancies, solid tumors remain a challenge for CAR-T as the immunosuppressive TME impacts T-cell activation and survival. With a construct to take advantage of the TME to combat solid tumors, SMART CART™ is designed to enhance CAR-T cell proliferation and duration of killing, and to resist exhaustion with improved persistence of CAR-T cells. We plan to advance the following SMART CART™-enabled preclinical program:

- **GC506.** GC506 is SMART CART™-enabled CAR-T therapy targeting Claudin 18.2 for the treatment of Claudin 18.2-positive solid tumors. We plan to initiate an investigator-initiated Phase 1 study in China on GC506 in 2023.

#### ***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, our clinical development strategy is built on the robust pre-IND investigator-initiated trials program that we have established in partnership with top-tier hospitals in China. This strategy is designed to expedite our global clinical development activities with the initial results in investigator-initiated Phase 1 trials utilizing safety as primary endpoint and ORR as key secondary endpoint. However, there is no guarantee that this strategy will be successful or will speed up the development of our product candidates.

#### **Our CAR-T Manufacturing Capacity and Strategy**

We have established state-of-the-art development centers and GMP facility, including over 45,500 square feet Shanghai R&D center, over 14,900 square feet Shanghai process development center, and over 66,000 square feet Suzhou GMP facility. We control our manufacturing through our GMP compliant manufacturing facility in Suzhou and process development center in Shanghai with high productivity. We have also completed a large number of engineering runs for IND preparation in our Shanghai process development center, achieving high product quality and good process robustness. We have produced hundreds of samples for our product candidates to be used with patients in the ongoing investigator-initiated and IND Phase 1 and 2 trials in China.

Our Suzhou facility and Shanghai process development center established fully-closed capability designed to produce FasTCAR product candidates while reducing contamination risks and optimizing cost-efficiency. We believe these advantages, coupled with our ability to achieve next-day manufacturing for autologous CAR-T cells, allow us to substantially reduce manufacturing cost, improve productivity and scale up our production in a cost-efficient manner. We have the capacity to support our preclinical and clinical development and early commercialization with our GMP facility and process development center in China. We have also expanded our manufacturing capabilities to the United States to enable a local supply of high-quality novel cell therapies, including through collaborations with contract development and manufacturing organizations in the U.S. See below for more details regarding our agreement with Lonza Houston, Inc. or Lonza, for clinical manufacturing of our FasTCAR-enabled CAR-T cell product candidates in the U.S.

#### ***Manufacturing Services Agreement between Lonza***

In March 2021, we entered into a Manufacturing Services Agreement with Lonza, pursuant to which Lonza agreed to use commercially reasonable efforts to diligently produce certain products intended for therapeutic use in humans in a professional and workmanlike manner, or the Lonza Agreement. Under the Lonza Agreement, the parties thereto collaborated to develop a statement of work, or SoW, setting forth the activities to be performed and the amounts and dates of our payments to Lonza. We are required to provide materials and documentation necessary for Lonza's performance of the SoW pursuant to the Lonza Agreement.

The Lonza Agreement will continue in effect for a period of five years unless terminated earlier or extended by either party. We have the right to cancel a SoW or terminate the Lonza Agreement upon prior written notice based on Lonza's repeated failure of performance as defined in detail in the Lonza Agreement. We also have the right to terminate the Lonza Agreement if we provide a written notice of termination within a specific time period in advance of the date of termination after April 1, 2022. Either party has the right to cancel a SoW or terminate the Lonza Agreement by written notice for any material breach of the Lonza Agreement by the other party if a timely cure is not provided, or upon the dissolution, termination of existence, liquidation or business failure of the other party.

## **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 developing advanced T cell therapies and other types of oncology therapies. This would include companies in the CAR-T space, including Nanjing Legend Biotech, 2seventy bio, Inc., Allogene, Inc. Juno Therapeutics, Inc. (acquired by Celgene Corporation), Kite Pharma, Inc. (acquired by Gilead Sciences, Inc.), Poseida Therapeutics, Inc., Autolus Therapeutics plc, 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 March 31, 2023, we owned one patent application in the PRC, one patent application in Hong Kong, one patent application in the U.S., one patent application in Canada, one patent application in Israel, one patent application in Australia, one patent application in Europe, one patent application in Singapore, one patent application in South Korea, one patent application in Japan and one patent application in Taiwan directed to composition-of-matter coverage, manufacture and methods of use of our FasTCAR technology platform. These patent applications also relate to the manufacture of our product candidates, GC012F and GC019F. For our TruUCAR technology platform, as of March 31, 2023, owned one patent application in the PRC, one patent application in Hong Kong, one patent application in the U.S., one patent application in Canada, one patent application in Israel, one patent application in Australia, one patent application in Europe, one patent application in Singapore, one patent application in South Korea, one patent application in Japan and one patent application in Taiwan, all of which are directed to composition-of-matter coverage, manufacture and methods of use of our TruUCAR technology platform. These patent applications are directed to composition of matter coverage and method of use of our product candidates, GC027 and GC502. For our SMART CART™ proprietary technology module, as of March 31, 2023, we owned one patent application in the PRC, which is directed to composition-of-matter coverage, manufacture and methods of use of our SMART CART™ proprietary technology module



Additionally, for our GC012F product candidate, as of March 31, 2023, we owned one patent application in the PRC, one patent application in Canada, one patent application in the U.S., one patent application in Israel, one patent application in Australia, one patent application in Europe, one patent application in Singapore, one patent application in Korea, one patent application in Japan and one patent application in Hong Kong, all of which are directed to composition-of-matter coverage, manufacture and methods of use. For our GC019F and GC007g product candidates, as of March 31, 2023, we owned one issued invention patent in the PRC directed to composition-of-matter coverage of these product candidates. We have additionally applied for patents, 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, GC502 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.

#### ***Our License Agreements with ProMab***

In November 2017, we entered into an Amended and Restated No. 1 to Exclusive License Agreement with Sublicensing Terms with ProMab Biotechnologies, Inc., or ProMab, and Unitex Capital, Ltd., or Unitex, pursuant to which Unitex agreed to transfer all its rights and obligations under its Exclusive License Agreement with ProMab dated April 19, 2017 to us, or the ProMab Agreement. Under the ProMab Agreement, we received an exclusive license to develop and commercialize certain CAR-T technology related to our GC007g, GC007F and GC019F product candidates in the field of human therapeutics in Greater China, which we refer to as the ProMab Licensed Technology. As of the date of this annual report, we have made an upfront payment of US\$0.9 million to ProMab, including a license fee and one milestone payment and are subject to up to a total of approximately US\$2.3 million additional milestone payments to ProMab under the ProMab Agreement. Pursuant to the ProMab Agreement, we are required to use reasonable commercial efforts to develop, commercialize and market the ProMab Licensed Technology with diligent research and development, testing, government approval, manufacturing, marketing and sale or lease of such technology.

ProMab has the right, at its option, upon written notice to us to terminate the ProMab Agreement or convert all exclusive licenses granted under the ProMab Agreement to nonexclusive licenses if we fail to make any payments, commit a material breach, or challenge the validity or enforceability of any patents or patent applications included within the ProMab Licensed Technologies. In addition, ProMab can convert all exclusive licenses granted under the ProMab Agreement to nonexclusive licenses if we have failed to achieve certain clinical development milestones. We have the right to terminate the ProMab Agreement upon two months' prior written notice at any time without cause, and without incurring any additional obligation, liability or penalty, or upon notice if ProMab commits a material breach under the ProMab Agreement. Upon termination of the ProMab Agreement, all rights and licenses granted to us will be terminated and we must cease to manufacture or sell the ProMab Licensed Technology. Upon termination of the ProMab Agreement for any reason other than breach by ProMab, we will permit ProMab and their future licensees to utilize, reference and otherwise have the benefit of all regulatory approvals of, or clinical trials or other studies conducted on, and all filings made with regulatory agencies with respect to, the ProMab Licensed Technology.

#### ***Our License Agreement with FutureGen***

In May 2021, we entered into an Exclusive License Agreement with FutureGen Biopharmaceutical Co., Ltd., or FutureGen, pursuant to which we received from FutureGen an exclusive, royalty-bearing license to research, develop, manufacture, commercialize, or otherwise exploit certain CLDN18.2 antibodies related technology in the field of engineered or modified immune cell therapies worldwide, which we refer to as the FutureGen Licensed Technology. Under this license agreement with FutureGen, or the FutureGen Agreement, we have the right to grant sublicenses at our sole discretion and are required to pay to FutureGen a non-refundable sublicense fee. We are also required to pay royalties to FutureGen on a product-by-product and region-by-region basis. As of the date of this annual report, we have made a non-refundable mid-six figure dollar license upfront payment to FutureGen and are subject to up to a total of approximately US\$26 million non-refundable milestone payments to FutureGen.

FutureGen has the right to terminate the FutureGen Agreement upon written notice if we commit a breach of any provision under the FutureGen Agreement where a timely cure is not provided, or if we have failed to achieve certain clinical development milestones. We have the right to terminate the FutureGen Agreement upon written notice if FutureGen commits a breach of any provision under the FutureGen Agreement where a timely cure is not provided, or if all the patents included within the FutureGen Licensed Technologies are declared non-patentable or invalid by a non-appealable decision. Upon termination of the FutureGen Agreement, we are required to immediately cease using any of the FutureGen Licensed Technologies except that we are permitted to sell any products actually in our possession on the effective date of termination.

#### ***Our License Agreement with Seagen***

In March 2023, we entered into a License Agreement with Seagen Inc., or Seagen, pursuant to which we received from Seagen (i) a worldwide license to certain patent rights that Seagen owns, which we refer to as the Seagen Licensed Patents, to conduct pre-clinical research on cell therapy products, as well as (ii) a worldwide license to conduct pre-clinical and clinical research on, and to make, have made, export, import, use, sell, offer for sale, and otherwise commercialize exploit, up to five cell therapy products that are developed by us or our affiliates and meet certain requirements, which we refer to as the Seagen Licensed Products. Under this license agreement with Seagen, or the Seagen Agreement, each license is non-exclusive and sub-licensable, subject to certain conditions. We are also required to pay to Seagen a non-refundable sub-license fee and an additional product fee for each of the third, fourth and fifth Seagen Licensed Products designated by us. As of the date of this annual report, we have made a non-refundable seven figure dollar payment of upfront fee to Seagen and are subject to up to a total of approximately US\$45 million non-refundable payments to Seagen, including a sublicense fee and additional product milestone payments.

Seagen has the right to terminate the Seagen Agreement upon written notice if we commit a material breach of the Seagen Agreement and fail to provide a timely cure. In addition, Seagen has the right to terminate the Seagen Agreement upon 60 days' written notice to us in the event that we or our affiliates take any action, including knowingly providing financial or other assistance to any third party, to challenge in a court or administrative proceeding any claim of a Seagen Licensed Patent as being invalid, unenforceable or otherwise not patentable. We have the right to terminate the Seagen Agreement upon 30 days' advanced written notice to Seagen at any time for convenience. Upon termination of the Seagen Agreement, all licenses granted to us will be terminated and we are required to promptly notify our sublicensees of such termination. The sublicensee is permitted to enter into an agreement directly with Seagen on substantially the same terms and conditions as those obligating us under the Seagen Agreement if the sublicensee is in conformity with the terms of its sublicense with us.

We have entered into and may continue to enter into additional license and/or collaboration agreements during the course of our ordinary business. 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 Amendment to the PRC Patent Law introduces patent extensions to patents of new drugs that launched in the PRC, which may enable the patent owner to submit applications for a patent term extension. The precise length of any such extension is uncertain though the extended length has a maximum of five years. For more information regarding the risks related to our intellectual property, see "Item 3. Key Information—D. 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 China, see “—Regulation—PRC Regulation—Regulatory Protections.” For more information regarding the risks related to trademarks, see “Item 3. Key Information—D. 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 “Item 3. Key Information—D. Risk Factors—Risks Related to Our Intellectual Property.”

## **Regulation**

### ***United States Regulation***

The Food and Drug Administration (FDA) and other regulatory authorities at federal, state, and local levels, 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 manufacturing, 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 Biologics License Applications (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 procedures:

- completion of preclinical laboratory tests and animal studies performed in accordance with the Code of Federal Regulations (CFR) and/or FDA’s good laboratory practices (GLP);

- 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 (IRB, equivalent to 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 and submission of a BLA to the FDA 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 current Good Manufacturing Practice (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 (GCP); 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 the first clinical trial with a product candidate in the United States, we must submit an Investigational New Drug (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 (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 calendar 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 then 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 (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 escalating doses, and, if possible, to gain early evidence on efficacy. 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 the 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 the product is manufactured, processed, packed, or held meet 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 a 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 (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 an approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Even after the approval of a product, 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 qualified 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 efficacy 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 (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; and
- product seizure or detention, or refusal of the FDA to permit the import or export of products.

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 (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 approvals. 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 eliminate, 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 Cuts and Jobs 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 inseparable 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 5<sup>th</sup> 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. In March 2020, the Supreme Court granted a writ of certiorari and agreed to review the judgement of the federal appeals court. On June 17, 2021, the Supreme Court held that the plaintiffs (comprised of the state of Texas, as well as numerous other states and certain individuals) did not have standing to challenge the constitutionality of the ACA's individual mandate and, accordingly, vacated the Fifth Circuit's decision and instructed the district court to dismiss the case. As a result, the ACA will remain in effect in its current form for the foreseeable future. However, we cannot predict what additional challenges may arise in the future, the outcome thereof, or the impact any such actions may have on our business.

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 2030 with the exception of a temporary suspension from May 1, 2020 through December 31, 2020, 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 included a \$135 billion allowance over 10 years 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 previously released a "Blueprint," or plan, to lower drug prices and reduce out of pocket costs of drugs that contained 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 (HHS) has solicited feedback on some of these measures and has implemented others under its existing authority. The FDA also released a final rule on September 24, 2020 providing guidance for states to build and submit importation plans for drugs from Canada. On November 23, 2020, a trio of industry groups sued HHS and FDA, seeking to enjoin the final rule, and a few days later, Canada passed an interim order banning the export of certain drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. HHS was sued over the rule, which was challenged as arbitrary and capricious under the Administrative Procedure Act. In response, the government agreed to delay the effective date and evaluate the rule adopted by the previous administration. In the interim, the status quo has been restored. The likelihood of implementation of any of the other Trump administration reform initiatives is uncertain, particularly in light of the transition to the Biden administration. However, the Biden administration will continue to work on healthcare access and affordability with an expectation that it will protect and build on the ACA. 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.

We expect health reform initiatives to continue. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

## ***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 related 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 (Trial) was published in 2002 by SFDA and the DRR was promulgated by the State Food and Drug Administration, or the SFDA (the predecessor of CFDA and NMPA) on February 28, 2005 and the latest amendment of DRR promulgated by the State Administration for Market Regulation, or 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.

On December 3, 2021, the CDE published the Technical Guidelines for Non-clinical Research and Evaluation of Gene Therapy Products (Trial) ("Technical Guidelines for Gene Therapy Products") and Technical Guidelines for Non-clinical Research of Gene Modified Cell Therapy Products (Trial) ("Technical Guidelines for Gene Modified Cell Therapy Products"), which became effective as of the date of promulgation. The Technical Guidelines for Gene Therapy Products provides that it is applicable to gene therapy products other than genetically modified cells therapy products, and genetically modified cells therapy products, such as CAR-T cell therapy products, shall refer to the Technical Guidelines for Gene Modified Cell Therapy Products, which was formulated according to the Technical Guidelines for the Research and Evaluation of Cell Therapy Products (Trial).



## 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 categories for therapeutic biologics, depending on marketing approval status: Category 1 is for innovative biologics that have not been approved inside or outside of China, Category 2 for improved new drugs, and Category 3 for biologics that have been marketed in China or abroad, according to Biological Project Registration Classification and Application Data Requirements published by NMPA in June 2020. 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. In order to accelerate the marketing of clinically urgent drugs with outstanding clinical value in China, the CDE promulgated the Clinical Technical Guidelines for Conditional Approval of Drugs (Trial) on November 19, 2020 which became effective on the same day. According to such guidelines, during the period of drug clinical trials, a drug may be applied for conditional approval if it meets the following conditions: (i) for the treatment of seriously life-threatening diseases with no existing effective treatment available, as well as medicines urgently needed for public health, whose clinical trials have shown efficacy and whose clinical value can be predicted; (ii) vaccines that are urgently needed in response to major public health emergencies or other vaccines that are identified as being urgently needed by the NHC, and whose benefits are assessed to outweigh the risks. The quality of clinical trial data to support conditional approval for marketing of the drugs shall comply with the requirements and standards of ICH and relevant domestic technical guidelines.

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 clinical trial 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 special channels to review and approve new drugs urgently needed for clinical use that have been approved in the US, EU and Japan within the last ten 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 CFDA, 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 relevant pharmaceutical, pharmacological and toxicological research, 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 working 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 CFDA 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. In addition, SCNPC promulgated the Biosecurity Law of PRC on October 17, 2020 and came into effect on April 15, 2021. According to Biosecurity Law of PRC, China has the rights of human genetic resources. China's Ministry of Science and Technology, or the MOST, issued the Draft Implementing Rules on the Administrative Regulations on Human Genetic Resources for public comment, or the HGR Draft Implementing Rules, on March 22, 2022. The MOST is soliciting public comments until April 21, 2022. The HGR Draft Implementing Rules provides that the party that carries out the collection, reservation and provision overseas of human genetic resources in PRC should be a PRC research institution, high education school, medical institution and enterprise, and Foreign Entities, including foreign organization, individual and organ established or de facto controlled by them, shall not collect, reserve or provide overseas human genetic resources in PRC. Such *de facto* control includes the following situations: (a) Overseas organizations or individuals directly or indirectly hold more than 50% of the shares, equity, voting rights, property shares or other similar rights and interests of the institution; (b) although the shares, equities, voting rights, property shares or other similar rights and interests of institutions directly or indirectly held by overseas organizations and individuals lower than 50%, the voting rights or other rights and interests of decision-making bodies they enjoy have the sufficient influence on the decision-making and internal management of the institution; (c) the agreement or other arrangement of the overseas organization or individual is sufficient to exert a significant influence on the decision-making, operation and management of the institution and other major matters; and (d) other circumstances identified by the MOST. The HGR Draft Implementing Rules provides that administrative approvals are applicable to the collection of human genetic resources within the territory of the PRC, such as, important genetic family, human genetic resources in specific regions, the collection activities for large-scale population studies with more than 3,000 cases.

## 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 10, 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. 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. CDE also issued a number of the guidelines for clinical trials. For example, In December 2021, CDE promulgated Technical Guidelines for the Application of Biomarkers in Clinical Research and Development of Antitumor Drugs and the Guidelines for Comprehensive Analysis of the Effectiveness of Drug Clinical Research (Trial).

### **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. Under the current regime, upon approval of the registration application, the NMPA will issue drug registration certificate to the applicant. Only when the applicant or its contracted manufacturer is equipped with relevant manufacturing capability will the NMPA issue a drug approval, 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, or the SDA, (the predecessor of the SFDA), 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 22, 2017, the CFDA published 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. On February 9, 2021, CDE issued Technical Guidelines for Clinical Trials of Immunocell Therapy Products, the guidelines provide necessary technical guidance for the overall planning, design, implementation, and data analysis of cellular immune treatment (including CAR-T) products to carry out clinical trials, to reduce certain risks of the participating subjects in clinical trials and to regulate the evaluation method of the safety and effectiveness of such treatment. On December 3, 2021, CDE promulgated Technology Guideline for Clinical Trials of long-term follow-up observation on Genetic Therapy Products (Trial), which provides that the duration of long-term follow-up should be sufficient to observe risks due to nature, exposure (biodistribution and route of administration), etc., and shall not shorter than the expected time of occurrence of delayed adverse reactions. For example, in general, gene editing products are recommended to be observed for 15 years or until data indicate that there is no longer any risk. The CDE issued the Technical Guidelines for the Clinical Risk Management Plan on Application for Marketing Approval of Chimeric Antigen Receptor T Cell (CAR-T) Therapy Products on January 29, 2022, which became effective as of the date of promulgation, to regulate and guide the drafting of the clinical risk management plans on application for marketing approval of CAR-T therapy products.

#### *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 took 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 was promulgated on June 10, 2021 by the Standing Committee of the National People's Congress, effective on September 1, 2021. The 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, which imposes data security and privacy obligations on entities and individuals carrying out data activities, and introduces a data classification and hierarchical protection system based on the importance of data in economic and social development, and the degree of harm it will cause to national security, public interests, or legitimate rights and interests of individuals or organizations when such data is tampered with, destroyed, leaked, illegally acquired or used. The Data Security Law also provides for a national security review procedure for data activities that may affect national security.

### **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*

Under the Amendment to the PRC Patent Law, 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 for innovative drugs may not be extended to more than 14 years post-marketing.

#### *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 September 25, 2002 which came into effect on December 1, 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. On December 25, 2020, the Ministry of Human Resources and Social Security of the PRC and National Healthcare Security Administration of PRC promulgated the Notice of Issuance of Drugs Catalogue for the National Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance (2020), which took effect on March 1, 2021 and simultaneously replace the current effective version of 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.

#### **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, June 23, 2020 and January 1, 2022. 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.

## **Regulations on Securities Offering and Listing Outside of the PRC**

On December 24, 2021, the CSRC published the draft Administrative Provisions of the State Council on the Overseas Issuance and Listing of Securities by Domestic Companies (Draft for Comments), or the Draft Overseas Listing Regulations, and the draft Measures for the Overseas Issuance and Listing of Securities Record-filings by Domestic Companies (Draft for Comments), or the Draft Overseas Listing Measures, for public comments. On February 17, 2023, the CSRC promulgated the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (the “Trial Measures”), which took effect on March 31, 2023. The Trial Measures clarified and emphasized several aspects, which include but are not limited to: (1) comprehensive determination of the “indirect overseas offering and listing by PRC domestic companies” in compliance with the principle of “substance over form” and particularly, an issuer will be required to go through the filing procedures under the Trial Measures if the following criteria are met at the same time: a) 50% or more of the issuer’s operating revenue, total profit, total assets or net assets as documented in its audited consolidated financial statements for the most recent accounting year is accounted for by PRC domestic companies, and b) the main parts of the issuer’s business activities are conducted in mainland China, or its main places of business are located in mainland China, or the senior managers in charge of its business operation and management are mostly Chinese citizens or domiciled in mainland China; (2) exemptions from immediate filing requirements for issuers that a) have already been listed or registered but not yet listed in foreign securities markets, including U.S. markets, prior to the effective date of the Trial Measures, whose such overseas securities offering or listing shall be completed before September 30, 2023, and b) are not required to re-perform the regulatory procedures with the relevant overseas regulatory authority or the overseas stock exchange, provided however that such issuers shall carry out filing procedures as required if they conduct refinancing or are involved in other circumstances that require filing with the CSRC; (3) a negative list of types of issuers banned from listing or offering overseas, such as (a) offering and listing is explicitly prohibited by provisions in laws, administrative regulations and relevant state rules; (b) offering and listing may endanger national security as reviewed and determined by competent authorities under the State Council in accordance with law; (c) the controlling shareholders and the actual controller of the Issuer, have committed crimes such as corruption, bribery, embezzlement, misappropriation of property or undermining the order of the socialist market economy during the latest three years; (d) the issuer is suspected of committing crimes or major violations of laws and regulations, and is under investigation according to law, and no conclusion has yet been made thereof; (e) there are material ownership disputes over equity held by the domestic company’s controlling shareholder or by other shareholders that are controlled by the controlling shareholder and/or actual controller; (4) issuers’ compliance with web security, data security, and other national security laws and regulations; (5) issuers’ filing and reporting obligations, such as obligation to file with the CSRC after it submits an application for initial public offering to overseas regulators, and obligation after offering or listing overseas to report to the CSRC material events including change of control or voluntary or forced delisting of the issuer; and (6) the CSRC’s authority to fine both issuers and their shareholders between 1 and 10 million RMB for failure to comply with the Trial Measures, including failure to comply with filing obligations or committing fraud and misrepresentation.

Furthermore, on February 24, 2023, the CSRC, the Ministry of Finance, the National Administration of State Secrets Protection and the National Archives Administration jointly issued the Provisions on Strengthening Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies, or the Confidentiality and Archives Provisions, which took effective from March 31, 2023. The Confidentiality and Archives Provisions specify that during the overseas issuance of securities and listing activities of domestic enterprises, domestic enterprises and securities companies and securities service institutions that provide relevant securities services shall, by strictly abiding by the relevant laws and regulations of the PRC and the requirements therein, establish sound confidentiality and archives management systems, take necessary measures to implement confidentiality and archives management responsibilities, and shall not leak national secrets, work secrets of governmental agencies and undermine national and public interests. Work manuscripts generated in the PRC by securities companies and securities service institutions that provide relevant securities services for overseas issuance and listing of securities by domestic enterprises shall be kept in the PRC. Without the approval of relevant competent authorities, it shall not be transferred overseas. Where archives or copies need to be transferred outside of the PRC, it shall be subject to the approval procedures in accordance with relevant PRC regulations.



### ***European Union Regulation***

In the European Union, a clinical trial application must be submitted to each country's national regulatory authority in which the clinical trial is to take place, together with an independent ethics committee, much like the FDA and IRB, respectively. It is expected, however, that the Clinical Trials Regulation 536/2014 shall start to apply during the course of 2020. This new Regulation takes direct effect in each European Union Member State and seeks to simplify and streamline the approval of clinical trials in the European Union, for example, by allowing the clinical trial sponsor to submit a single application for approval of a clinical trial across the European Union via a new European Union Portal. The new Regulation also aims to streamline and simplify the rules on safety reporting, and introduces enhanced transparency requirements such as mandatory submission of a summary of the clinical trial results to a new European Union Database.

Medicinal products can only be commercialized in the European Economic Area after a marketing authorization, or MA, has been obtained. There are two types of marketing authorizations:

- The centralized MA, which is issued by the European Commission through the Centralised Procedure, based on the opinion of the Committee for Medicinal Products for Human Use of the European Medicines Agency, or EMA, and which is valid throughout the entirety of the EEA. The Centralised Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto immune and viral diseases. The Centralised Procedure is optional for products containing an active substance not authorized in the EEA before May 20, 2004, for products that constitute a significant therapeutic, scientific or technical innovation or for which a centralized authorization would be in the interest of patients.
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralised Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

The European Union also provides opportunities for market exclusivity. For example, in the European Union, upon receiving marketing authorization, innovative medicinal products generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic or biosimilar application. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity. Products receiving orphan designation, can receive ten years of market exclusivity, during which time no similar medicinal product for the same indication may be placed on the market. An orphan product's market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the criteria for orphan drug designation are no longer met, in other words, when it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the applicant consents to a second orphan medicinal product application; or
- the applicant cannot supply sufficient quantities of the orphan medicinal product.



In the European Union, companies developing a new medicinal product must agree to a Paediatric Investigation Plan, or a PIP, with the EMA and must conduct pediatric clinical trials in accordance with that PIP, unless a deferral or waiver applies (for example, because the relevant disease or condition occurs only in adults). The MA application for the product must include the results of pediatric clinical trials conducted in accordance with the PIP, unless a waiver applies, or a deferral has been granted, in which case the pediatric clinical trials must be completed at a later date. Products that are granted a marketing authorization on the basis of the pediatric clinical trials conducted in accordance with the PIP are eligible for a six month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval) or, in the case of orphan medicinal products, a two year extension of the orphan market exclusivity. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

### **Coverage, Pricing and Reimbursement**

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost effectiveness of a particular drug candidate to currently available therapies. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross border imports from low priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

### **Advertising Regulation**

All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the European Union. Although general requirements for advertising and promotion of medicinal products are established under European Union directives, the details are governed by regulations in each European Union Member State and can differ from one country to another.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

### **Pharmacovigilance System**

The holder of a European MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, or QPPV, who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

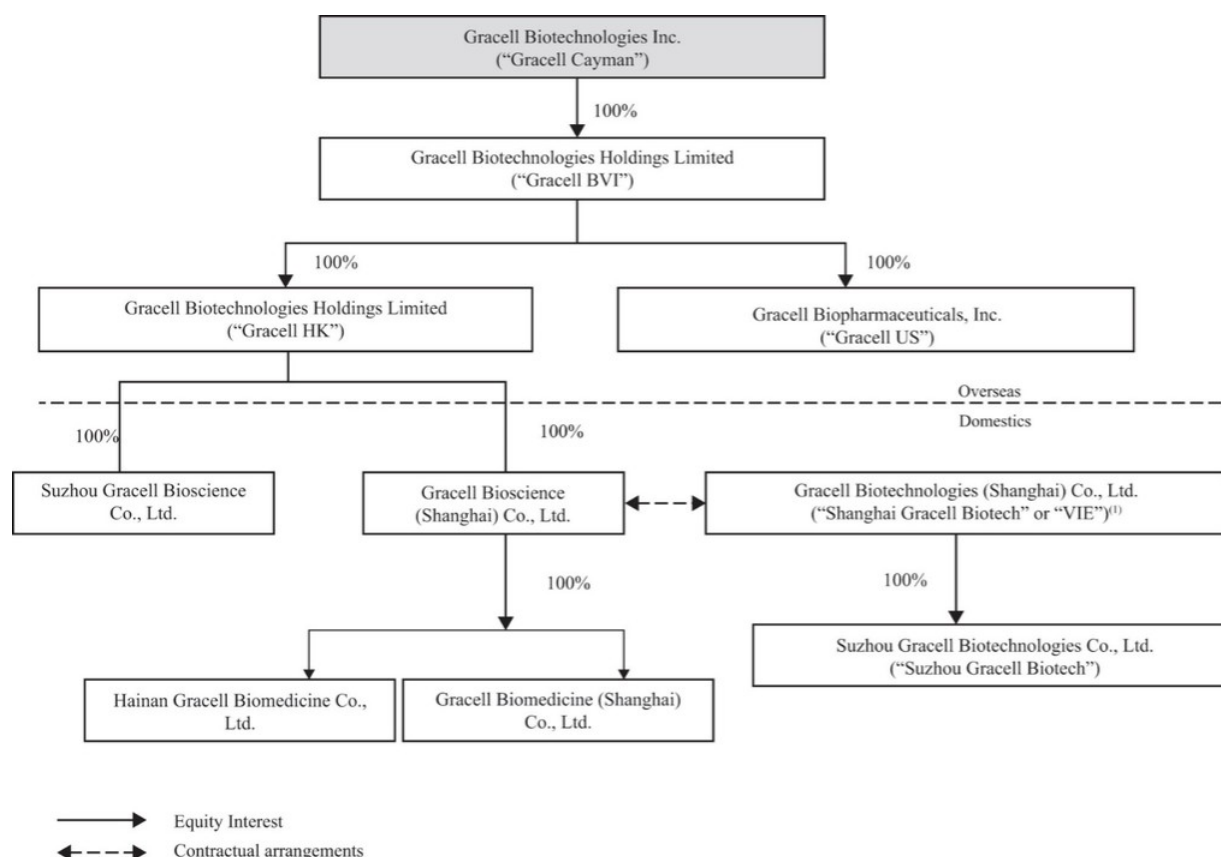
All new European MA applications must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies. RMPs and PSURs are routinely available to third parties requesting access, subject to limited redactions.

### ***Rest of World Regulation***

For other countries outside of PRC, the United States and the European Union, 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.

## C. Organizational Structure

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



Note:

- (1) Shareholders of Shanghai Gracell Biotech are Dr. William Wei Cao and Xiaomi Hua holding 99.9% and 0.1%, respectively, of the equity interest in the VIE. Dr. Cao is our Founder, Chairman of board of directors and Chief Executive Officer.

### Contractual Arrangements with the VIE and Its Shareholders

The following is a summary of the currently effective contractual arrangements by and among the WFOE, the VIE and its shareholders. These contractual arrangements enable us to (i) direct the activities of the VIE that most significantly impact the VIE's economic performance; (ii) receive substantially all of the economic benefits of the VIE and its subsidiary; and (iii) have an exclusive option to purchase all or part of the equity interests in and assets of the VIE and its subsidiary when and to the extent permitted by PRC law. As a result of these contractual arrangements, Gracell Cayman is considered the primary beneficiary of the VIE and the VIE's subsidiaries for accounting purposes and is able to consolidate the financial results of the VIE and VIE's subsidiary in the consolidated financial statements in accordance with U.S. GAAP. Investors in the ADSs or our ordinary shares would not hold any ownership interest, directly or indirectly, in the VIE and its subsidiary in China and would merely have a contractual relationship with the operating entities in China.

*Voting Rights Proxy Agreement and Power of Attorney.*

On November 10, 2020, Dr. William Wei Cao, a shareholder of the VIE, entered into an amendment to voting rights proxy agreement with the WFOE and the VIE and executed a power of attorney, superseding the voting right proxy agreement and the power of attorney he previously executed on January 3, 2019, to irrevocably authorize the WFOE to act as his attorney-in-fact to exercise all of his rights as a shareholder of the 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 the VIE, such as designation and appointment of directors, the chief executive officer and other senior management members of the 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, the WFOE may extend the term through written notification at its sole discretion.

On November 10, 2020, Xiaomi Hua, a shareholder of the VIE, entered into a voting rights proxy agreement and a power of attorney, each contains terms substantially similar to the amendment to voting rights proxy agreement and power of attorney executed by Dr. Cao respectively, as described above.

*Equity Pledge Agreements.* On November 10, 2020, Dr. Cao, a shareholder of the VIE, entered into an equity pledge supplementary agreement with the WFOE and the VIE, superseding the equity pledge agreement he previously executed on March 6, 2020, pursuant to which Dr. Cao pledges all of his equity interest in the VIE to the WFOE to guarantee the performance by Dr. Cao and the 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 the VIE's shareholders of their contractual obligations under these agreements, the WFOE, as pledgee, will have the right to dispose of the pledged equity interests in the VIE. Dr. Cao agrees that, during the term of the equity pledge agreement, he 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 the WFOE, except for the performance of the call option agreement. The equity pledge agreements will remain effective until the VIE and its shareholders discharge all of their obligations under the contractual arrangements. On November 10, 2020, Xiaomi Hua, a shareholder of the VIE, entered into an equity pledge agreement, which contains terms substantially similar to the equity pledge supplementary agreement executed by Dr. Cao, as described above. We have registered the equity pledge with the local branches of the Administration for Market Regulation in accordance with applicable PRC law.

*Spouse Consent Letter.* On November 10, 2020, the spouse of Dr. Cao, a shareholder of the VIE, unconditionally and irrevocably agreed that the equity interest in the 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 the VIE held by Dr. Cao.

***Agreements That Allow Us to Receive Economic Benefits from the VIE***

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

*Business Cooperation Agreement.* Pursuant to the business corporation agreement between the WFOE and the VIE, dated January 3, 2019, the WFOE has the exclusive right to provide to the VIE technical support, business support and related consulting services. The WFOE has exclusive right and interests in all intellectual properties arising out of or created during the performance of this agreement. The VIE agrees to pay the WFOE a monthly service fee at an amount agreed by the WFOE. The VIE has no right of early termination while the 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 the VIE***

**Call Option Agreement.** The WFOE, the VIE and Dr. Cao, a shareholder of the VIE, entered into an amendment to call option agreement on November 10, 2020, superseding the call option agreement Dr. Cao previously executed on January 3, 2019, pursuant to which he irrevocably grants the 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 his equity interests in the VIE, and such option may be exercised at the lowest price permitted by applicable PRC law. Any proceeds received by Dr. Cao from the exercise of the option shall be remitted to the WFOE or its designated party, to the extent permitted by applicable PRC law. Dr. Cao undertakes that without the WFOE's prior written consent, he shall not take any actions that may have material effects on the VIE's assets, businesses and liabilities, nor shall they appoint or replace any directors of the VIE.

On November 10, 2020, Xiaomi Hua, a shareholder of the VIE, entered into a call option agreement, which contains terms substantially similar to the amendment to call option agreement executed by Dr. Cao, as described above.

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

- the ownership structures of the VIE and the WFOE do not and will not result in any violation of PRC laws or regulations currently in effect; and
- the contractual arrangements among the WFOE, the VIE and the shareholders of the VIE governed by PRC law 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.”

**D. Property, Plants and Equipment**

Our principal research and development center is located at Building 3, 418 Guilin Road, Xuhui District, Shanghai, China with approximately 45,500 square feet of space. Our process development center is located at 12th Floor, Building 1, No. 926, Yishan Road, Xuhui District, Shanghai, China with approximately 14,900 square feet of space. Our GMP facility is located at Building 12, Block B, Phase II, Biobay Industrial Park, 218 Sangtian Street, Suzhou Industrial Park, Jiangsu Province, China with approximately 66,000 square feet of space. In March 2021, we opened our Suzhou office at Northwest 2F, GCL R&D Building, No. 28, Xinqing Road, Suzhou Industrial Park, Jiangsu Province, China with approximately over 15,000 square feet of office space. We established our Beijing branch company in February 2021 to support clinical study and the address is 17F1-A11, 1st Floor, Building 5, Courtyard 7, Liqing Road, Chaoyang District, Beijing, China. In March 2022, we expanded our Shanghai Office at 41st Floor, Building A, No. 188 Hongbaoshi Road, Changning District, Shanghai, China with approximately 24,300 square feet of office space. 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.

**Item 4A. Unresolved Staff Comments**

None.

## Item 5. Operating and Financial Review and Prospects

*You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our consolidated financial statements and the related notes included elsewhere in this annual report. This discussion contains forward-looking statements that involve risks and uncertainties about our business and operations. Our actual results and the timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those we describe under “Item 3. Key Information—D. Risk Factors” and elsewhere in this annual report.*

### A. Operating Results

#### Key Factors Affecting Our Results of Operations

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.

Since inception, we have incurred significant operating losses and experienced negative operating cash flows. Our net losses were RMB211.9 million, RMB451.8 million and RMB607.5 million (US\$88.1 million) for each year ended December 31, 2020, 2021 and 2022, respectively. Our net cash used in operating activities was RMB198.1 million, RMB304.6 million and RMB482.6 million (US\$70.0 million) for each year ended December 31, 2020, 2021 and 2022, respectively. We expect to continue to incur net losses and experience negative operating cash flows 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 product candidates, including but not limited to, GC012F for the treatment of r/r MM, NDMM and B-NHL, GC502 for the treatment of B-cell malignancies, and GC007g for the treatment of B-ALL;
- continue our ongoing and planned clinical activities for our other product candidates, including those we are developing for the treatment of B-ALL, B-NHL, AML and solid tumors;
- 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; and
- expand our operations globally.

Based upon our current operating plan, we believe 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. 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 facility, development centers, 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. For instance, affected by the recent temporary lock down in Shanghai, China, we have been experiencing disruption of operation, which might impact our patient recruitment and drug shipment for clinical trials in the area. 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;
- 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, 2021 and 2022

The following table summarizes our results of operations for the years ended December 31, 2021 and 2022:

	For the Years Ended December 31,			Year-Over-Year Change	
	2021	2022			
	RMB	RMB	US\$ (in thousands)	RMB	US\$
<b>Consolidated Statement of Operations Data:</b>					
Revenue:					
Licensing and collaboration revenue	366	—	—	(366)	(53)
<b>Operating expenses:</b>					
Research and development expenses	(326,899)	(485,388)	(70,375)	(158,489)	(22,979)
Administrative expenses	(137,040)	(139,270)	(20,192)	(2,230)	(323)
<b>Loss from operation</b>	<b>(463,573)</b>	<b>(624,658)</b>	<b>(90,567)</b>	<b>(161,085)</b>	<b>(23,355)</b>
Interest income	9,116	23,917	3,468	14,801	2,146
Interest expense	(5,063)	(6,737)	(977)	(1,674)	(243)
Other income	9,120	8,001	1,160	(1,119)	(162)
Foreign exchange loss, net	(1,297)	(8,169)	(1,184)	(6,872)	(996)
Others, net	(57)	159	23	216	31
<b>Loss before income tax</b>	<b>(451,754)</b>	<b>(607,487)</b>	<b>(88,077)</b>	<b>(155,733)</b>	<b>(22,579)</b>
Income tax expense	—	(22)	(3)	(22)	(3)
<b>Net loss</b>	<b>(451,754)</b>	<b>(607,509)</b>	<b>(88,080)</b>	<b>(155,755)</b>	<b>(22,582)</b>

## ***Operating Expenses***

### ***Research and Development Expenses***

Research and development expenses for the year ended December 31, 2022 were RMB485.4 million, compared to RMB326.9 million for the year ended December 31, 2021. This increase of RMB158.5 million was primarily due to (i) an increase of RMB36.0 million in preclinical studies and clinical trials from RMB136.8 million for the year ended December 31, 2021 to RMB172.8 million for the year ended December 31, 2022, as a result of manufacturing and other costs to support the progression of our preclinical studies and clinical trials; (ii) an increase of RMB31.2 million in payroll and other personnel expenses from RMB74.9 million for the year ended December 31, 2021 to RMB106.1 million for the year ended December 31, 2022, as a result of expanded research and development headcount; (iii) an increase of RMB11.6 million in depreciation expenses from RMB42.8 million for the year ended December 31, 2021 to RMB54.4 million for the year ended December 31, 2022, as a result of depreciation of manufacturing facilities; (iv) an increase of RMB82.3 million in professional services, from RMB26.1 million for the year ended December 31, 2021 to RMB108.4 million for the year ended December 31, 2022, as a result of various projects during the course of 2022; (v) a decrease of RMB5.1 million in share-based compensation, from RMB15.7 million for the year ended December 31, 2021 to RMB10.6 million for the year ended December 31, 2022; and (vi) an increase of RMB2.5 million in other expenses from RMB30.6 million for the year ended December 31, 2021 to RMB33.1 million for the year ended December 31, 2022.

Our key research and development projects for the years ended December 31, 2021 and 2022 were GC012F and GC007g. GC012F is our lead FasTCAR autologous CAR-T product candidate that is being studied in investigator-initiated Phase 1 trials in China for two indications, MM and B-NHL. Our research and development expenses for GC012F increased by RMB111.1 million from RMB99.5 million for the year ended December 31, 2021 to RMB210.6 million for the year ended December 31, 2022, primarily because we enrolled additional patients to the ongoing investigator-initiated Phase 1 trials to evaluate GC012F for the treatment of r/r MM, NDMM and B-NHL, and prepared and submitted IND applications in both US and China to initiate Phase 1/2 trials in r/r MM. GC007g is a donor-derived CD19-directed allogeneic CAR-T cell therapy and our most clinically advanced product candidate. Our research and development expenses for GC007g increased by RMB12.9 million from RMB72.3 million for the year ended December 31, 2021 to RMB85.2 million for the year ended December 31, 2022, as we engaged in more clinical development activities for this product candidate during the course of 2022 following the grant of approval from the NMPA on December 24, 2020 for a seamless Phase 1/2 registrational trial. We have reduced the spending on GC019F clinical activities as we prioritized the development of FasTCAR-enabled dual-targeting programs such as GC012F. Our research and development expense for other product candidates in clinical, preclinical and earlier stages increased by RMB34.5 million from RMB155.1 million for the year ended December 31, 2021 to RMB189.6 million for the year ended December 31, 2022, as we continued to invest in our overall research and development efforts.

### ***Administrative Expenses***

Administrative expenses for the year ended December 31, 2022 were RMB139.3 million (US\$20.2 million), compared to RMB137.0 million for the year ended December 31, 2021. This increase of RMB2.3 million (US\$0.3 million) was primarily due to an increase of RMB14.6 million in payroll and personnel expenses as a result of expansion of administrative functions, an increase of RMB15.3 million in professional services, an increase of RMB3.6 million in other expenses, offset by a decrease of RMB31.2 million in share-based compensation.

### ***Interest Income, Other Income and Foreign Exchange Gain***

Interest income for the year ended December 31, 2022 was RMB23.9 million (US\$3.5 million), compared to RMB9.1 million for the year ended December 31, 2021. This increase of RMB14.8 million (US\$2.1 million) was primarily attributable to the increase of interest rate. Interest expense for the year ended December 31, 2022 was RMB6.7 million (US\$1.0 million) compared to RMB5.1 million for the year ended December 31, 2021. This increase of RMB1.6 million (US\$0.2 million) was primarily attributable to the new borrowings incurred during 2022. Other income for the year ended December 31, 2022 was RMB8.0 million (US\$1.2 million), compared to RMB9.1 million for the year ended December 31, 2021. This decrease of RMB1.1 million (US\$0.2 million) was primarily due to a decrease in subsidies we received from the PRC local government in 2022.

Foreign exchange loss for the year ended December 31, 2022 was RMB8.2 million (US\$1.2 million), compared to foreign exchange loss of RMB1.3 million for the year ended December 31, 2021. This increase of RMB6.9 million (US\$1.0 million) was primarily attributable to unfavorable foreign exchange rate fluctuating (RMB versus US dollar) during the year ended December 31, 2022.

## Income Tax Expense

We incurred nil and RMB 22 thousand income tax expense for the years ended December 31, 2021 and 2022, respectively.

## Comparison of Years Ended December 31, 2020 and 2021

The following table summarizes our results of operations for the years ended December 31, 2020 and 2021:

	For the Years Ended December 31,			Year-Over-Year	
	2020	2021		Change	
	RMB	RMB	US\$ (in thousands)	RMB	US\$
<b>Consolidated Statement of Operations Data:</b>					
<b>Revenue:</b>					
Licensing and collaboration revenue	—	366	57	366	57
Operating expenses:					
Research and development expenses	(168,830)	(326,899)	(51,298)	(158,069)	(24,805)
Administrative expenses	(45,566)	(137,040)	(21,505)	(91,474)	(14,354)
<b>Loss from operation</b>	<b>(214,396)</b>	<b>(463,573)</b>	<b>(72,746)</b>	<b>(249,177)</b>	<b>(39,101)</b>
Interest income	2,870	9,116	1,430	6,246	980
Interest expense	(2,155)	(5,063)	(794)	(2,908)	(456)
Other income	4,707	9,120	1,431	4,413	693
Foreign exchange gain (loss), net	(2,914)	(1,297)	(204)	1,617	254
Others, net	(12)	(57)	(9)	(45)	(7)
<b>Loss before income tax</b>	<b>(211,900)</b>	<b>(451,754)</b>	<b>(70,892)</b>	<b>(239,854)</b>	<b>(37,638)</b>
Income tax expense	—	—	—	—	—
<b>Net loss</b>	<b>(211,900)</b>	<b>(451,754)</b>	<b>(70,892)</b>	<b>(239,854)</b>	<b>(37,638)</b>

## Operating Expenses

### Research and Development Expenses

Research and development expenses for the year ended December 31, 2021 were RMB326.9 million, compared to RMB168.8 million for the year ended December 31, 2020. This increase of RMB158.1 million was primarily due to (i) an increase of RMB60.1 million in preclinical studies and clinical trials from RMB76.7 million for the year ended December 31, 2020 to RMB136.8 million for the year ended December 31, 2021, as a result of manufacturing and other costs to support the progression of our preclinical studies and clinical trials; (ii) an increase of RMB37.3 million in payroll and other personnel expenses from RMB37.6 million for the year ended December 31, 2020 to RMB74.9 million for the year ended December 31, 2021, as a result of expanded research and development headcount; (iii) an increase of RMB21.7 million in depreciation expenses from RMB21.1 million for the year ended December 31, 2020 to RMB42.8 million for the year ended December 31, 2021, as a result of depreciation of manufacturing facilities; (iv) an increase of RMB19.3 million in professional services, from RMB6.8 million for the year ended December 31, 2020 to RMB26.1 million for the year ended December 31, 2021, as a result of various projects during the course of 2021; (v) an increase of RMB15.7 million in share-based compensation, from nil for the year ended December 31, 2020 to RMB15.7 million for the year ended December 31, 2021, as a result of completion of the Company's IPO and additional share-based awards issued; and (vi) an increase of RMB4.0 million in other expenses from RMB26.6 million for the year ended December 31, 2020 to RMB30.6 million for the year ended December 31, 2021.

Our key research and development projects for the years ended December 31, 2020 and 2021 were GC012F, GC007g, and GC019F. GC012F is our lead FasTCAR autologous CAR-T product candidate that is being studied in investigator-initiated Phase 1 trials in China for two indications, MM and B-NHL. Our research and development expenses for GC012F increased by RMB76.3 million from RMB23.2 million for the year ended December 31, 2020 to RMB99.5 million for the year ended December 31, 2021, primarily because we enrolled additional patients to the ongoing investigator-initiated Phase 1 trials. GC007g is a donor-derived CD19-directed allogeneic CAR-T cell therapy and our most clinically advanced product candidate. Our research and development expenses for GC007g increased by RMB38.0 million from RMB34.3 million for the year ended December 31, 2020 to RMB72.3 million for the year ended December 31, 2021, as we engaged in more clinical development activities for this product candidate during the course of 2021 following the grant of approval from the NMPA on December 24, 2020 for a seamless Phase 1/2 registrational trial. Our research and development expenses for GC019F, another FasTCAR autologous CAR-T product candidate, decreased by RMB11.2 million from RMB66.5 million for the year ended December 31, 2020 to RMB55.3 million for the year ended December 31, 2021, as we concluded the investigator-initiated Phase 1 trials for this product candidate in China in 2020, had initiated the Phase 1 trial for this product candidate in China but had not yet engaged in substantive clinical development for such Phase 1 trial by the end of 2021. Our research and development expense for other product candidates in clinical, preclinical and earlier stages increased by RMB54.9 million from RMB44.8 million for the year ended December 31, 2020 to RMB99.8 million for the year ended December 31, 2021, as we continued to invest in our overall research and development efforts.

#### *Administrative Expenses*

Administrative expenses for the year ended December 31, 2021 were RMB137.0 million (US\$21.5 million), compared to RMB45.6 million for the year ended December 31, 2020. This increase of RMB91.4 million (US\$14.4 million) was primarily due to an increase of RMB44.8 million (US\$7.0 million) for share-based compensation due to completion of IPO and additional share-based awards issued, an increase of RMB21.6 million (US\$3.4 million) in personnel costs attributable to the expansion of administrative functions, an increase of RMB8.9 million (US\$1.4 million) for insurance expenses, an increase of RMB6.1 million (US\$1.0 million) for rental expenses, an increase of RMB3.0 million (US\$0.5 million) for office and travel expenses, an increase of RMB1.7 million (US\$0.3 million) for professional services and an increase of RMB1.2 million (US\$0.2 million) for depreciation expenses.

#### *Interest Income, Interest Expense, Other Income and Foreign Exchange Gain*

Interest income for the year ended December 31, 2021 was RMB9.1 million (US\$1.4 million) as compared to RMB2.9 million for the year ended December 31, 2020. This increase of RMB6.2 million (US\$1.0 million) was primarily attributable to increase in bank deposit and short-term investment.

Interest expense for the year ended December 31, 2021 was RMB5.1 million (US\$0.8 million), compared to RMB2.2 million for the year ended December 31, 2020. This increase of RMB2.9 million (US\$0.5 million) was primarily attributable to the new borrowings incurred in 2021.

Other income for the year ended December 31, 2020 was RMB9.1 million (US\$1.4 million), compared to RMB4.7 million for the year ended December 31, 2019. This increase of RMB4.4 million (US\$0.7 million) was primarily due to an increase in subsidies we received from the PRC local government in 2021.

Foreign exchange loss for the year ended December 31, 2021 was RMB1.3 million (US\$0.2 million), compared to a foreign exchange loss of RMB2.9 million for the year ended December 31, 2020. This decrease in the foreign exchange loss of RMB1.6 million was primarily attributable to favorable foreign exchange rate fluctuating (RMB versus US dollar) during the year ended December 31, 2021.

#### *Income Tax Expense*

We incurred nil income tax expense for the years ended December 31, 2020 and 2021.

## B. 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. In 2022, we had received proceeds of RMB104.6 million (US\$15.2 million) from our term loan facilities with commercial banks. As of December 31, 2022, we had RMB1,458.2 million (US\$211.4 million) in cash and cash equivalents and short-term investments.

### *Cash Flows*

The following table shows a summary of our cash flow:

	For the Year Ended December 31,			
	2020	2021	2022	
	RMB	RMB	RMB	US\$
	(in thousands)			
Net cash used in operating activities	(198,149)	(304,550)	(482,648)	(69,978)
Net cash used in investing activities	(93,941)	(41,616)	(48,332)	(7,008)
Net cash generated from financing activities	756,467	1,456,185	33,324	4,832
Net (decrease)/increase in cash and cash equivalents	442,250	1,074,698	(374,361)	(54,277)
Cash and cash equivalents at the beginning of the period	312,058	754,308	1,829,006	265,181
Cash and cash equivalents at the end of the period	754,308	1,829,006	1,454,645	210,904

### *Operating Activities*

Net cash used in operating activities for the year ended December 31, 2022 was RMB482.6 million (US\$70.0 million), primarily attributable to a net loss of RMB607.5 million (US\$88.1 million), a decrease of other non-current liabilities of RMB1.6 million and a decrease of lease liabilities of RMB19.0 million, which were partially offset by an adjustment from the RMB58.8 million (US\$8.5 million) recognized in depreciation and amortization, RMB24.1 million in share-based compensation, a decrease of RMB14.1 million in prepayments and other current assets and an increase of RMB16.9 million in accrued liabilities and other liabilities.

Net cash used in operating activities for the year ended December 31, 2021 was RMB304.6 million, primarily attributable to a net loss of RMB451.8 million and an increase of RMB10.0 million in prepayments and other current assets, which were partially offset by an adjustment from the RMB44.9 million recognized in depreciation and amortization, RMB60.4 million in share-based compensation and an increase of RMB43.8 million in accrued liabilities and other liabilities.

### *Investing Activities*

Net cash used in investing activities for the year ended December 31, 2022 was RMB48.3 million (US\$7.0 million), attributable to an increase of RMB48.3 million (US\$7.0 million) in purchase of property, equipment and software and RMB261.2 million (US\$37.9 million) in short-term investments, partially offset by proceeds of RMB261.2 million (US\$37.9 million) from the disposal of short-term investments.

Net cash used in investing activities for the year ended December 31, 2021 was RMB41.6 million, attributable to an increase of RMB56.7 million in purchase of property, equipment and software and RMB10.0 million in short-term investments, partially offset by proceeds of RMB25.1 million from the disposal of short-term investments.

### *Financing Activities*

Net cash provided by financing activities in the year ended December 31, 2022 was RMB33.3 million (US\$4.8 million), attributable to proceeds of RMB0.3 million (US\$0.1 million) from the exercise of options and RSUs and proceeds of RMB104.6 million (US\$15.2 million) from bank borrowings, partially offset by RMB68.5 million (US\$9.9 million) in repayment of bank borrowings and RMB3.1 million (US\$0.5 million) in payment of ATM offering cost.

Net cash provided by financing activities in the year ended December 31, 2021 was RMB1,456.2 million, attributable to proceeds of RMB1,449 million from the issuance of ordinary shares and proceeds of RMB71.2 million from bank borrowings, partially offset by RMB51.3 million in repayment of bank borrowings and RMB14.5 million of payment of IPO costs.

### ***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 (US\$10.8 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 December 31, 2022, RMB44.3 million (US\$6.4 million) was outstanding under the loan agreement with Suzhou Industrial Park Branch of Bank of China.

#### ***Loan Agreements with China Construction Bank***

On December 30, 2022, Suzhou Gracell Biotech entered into a loan agreement with China Construction Bank, under which Suzhou Gracell Biotech borrowed additional RMB20.0 million (US\$2.9 million) for a term of 12 months at a fixed annual rate equal to the one-year loan prime rate plus 0.15%. 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 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. As of December 31, 2022, RMB20.0 million (US\$2.9 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 (US\$4.6 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 interest payments on the loan on a quarterly basis and repay principal 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 December 31, 2022, RMB10.1 million (US\$1.5 million) was outstanding under the loan agreement.

*Loan Agreement with China CITIC Bank*

On August 5, 2022, Suzhou Gracell Biotech entered into a loan agreement with China CITIC Bank, under which Suzhou Gracell Biotech obtained a term loan facility of RMB20.0 million (US\$2.9 million) for a term of 12 months. Interest on the outstanding loan balance accrues at a fixed annual rate equal to the one-year loan prime rate plus 0.15%. Under the loan agreement, 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 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 the interest of China CITIC Bank. 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 be entitled to penalties or declare all or a portion of our outstanding obligations payable to be immediately due and payable. As of December 31, 2022, RMB20.0 million (US\$2.9 million) was outstanding under the loan agreement.

*Loan Agreements with Hangzhou Bank*

In March and August 2022, Suzhou Gracell entered into two loan agreements with Hangzhou Bank. Under each agreement Suzhou Gracell borrowed a principal amount of RMB20.0 million (US\$2.9 million) and RMB15.0 million (US\$2.2 million) respectively in the form of a term loan for 12 months. The effective interest rate of these borrowings is 4.35% and 3.76% per annum, respectively. 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. Each loan agreement contains customary covenants that, among other things, require Suzhou Gracell to obtain written approval from Hangzhou 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. Each 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 December 31, 2022, RMB35.0 million (US\$5.1 million) was outstanding under these loan agreements.

*Loan Agreements with China Industrial Bank*

In March and June 2022, Suzhou Gracell entered into three loan agreements with China Industrial Bank. Under each agreement Suzhou Gracell borrowed a principal amount of RMB9.9 million (US\$1.4 million), RMB9.9 million (US\$1.4 million) and RMB9.8 million (US\$1.4 million) respectively in the form of a term loan for 12 months. The effective interest rate of these borrowing is 4.3% per annum. 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. Each loan agreement contains customary covenants that, among other things, require Suzhou Gracell to obtain written approval from Hangzhou 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. Each 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 December 31, 2022, RMB29.6 million (US\$4.3 million) was outstanding under these loan agreements.

*Contracts of Maximum Guarantee with China Industrial Bank*

On January 26, 2022, Gracell Bioscience entered into a contract of maximum guarantee with China Industrial Bank, under which Gracell Bioscience agreed to, among other things, jointly and severally assume the guarantee liability under this contract and perform the liability for repayment of debts on behalf of Suzhou Gracell Biotech under such loan agreement to be entered into between Suzhou Gracell Biotech and China Industrial Bank during December 7, 2021 and December 6, 2022. The guarantee period for Gracell Bioscience in connection with each financing by Suzhou Gracell Biotech is generally three years commencing from the expiration date of debt performance period under the financing. The maximum amount of repayment liability assumed by Gracell Bioscience is RMB29.9 million (US\$4.3 million).



On January 26, 2022, Shanghai Gracell Biotech entered into a contract of maximum guarantee with China Industrial Bank, under which Shanghai Gracell Biotech agreed to, among other things, jointly and severally assume the guarantee liability under this contract and perform the liability for repayment of debts on behalf of Suzhou Gracell Biotech under such loan agreement to be entered into between Suzhou Gracell Biotech and China Industrial Bank during December 7, 2021 and December 6, 2022. The guarantee period for Shanghai Gracell Biotech in connection with each financing by Suzhou Gracell Biotech is generally three years commencing from the expiration date of debt performance period under the financing. The maximum amount of repayment liability assumed by Shanghai Gracell Biotech is RMB29.9 million (US\$4.3 million).

#### *Contract of Maximum Guarantee with China CITIC Bank*

On June 21, 2022, Gracell Bioscience entered into a contract of maximum guarantee with China CITIC Bank, under which Gracell Bioscience agreed to, among other things, jointly assume the guarantee liability under this contract if Suzhou Gracell Biotech fails to discharge or fully discharge its debt upon the expiration of the discharge period of a single debt under such loan agreement to be entered into between Suzhou Gracell Biotech and China CITIC Bank during June 21, 2022 and June 21, 2023. The guarantee period for Gracell Bioscience is generally three years commencing from the expiration of the debt discharge period under the debt. The maximum amount of repayment liability assumed by Gracell Bioscience is RMB50.0 million (US\$7.2 million).

On June 21, 2022, Shanghai Gracell Biotech entered into a contract of maximum guarantee with China CITIC Bank, under which Shanghai Gracell Biotech agreed to, among other things, jointly assume the guarantee liability under this contract if Suzhou Gracell Biotech fails to discharge or fully discharge its debt upon the expiration of the discharge period of a single debt under such loan agreement to be entered into between Suzhou Gracell Biotech and China CITIC Bank during June 21, 2022 and June 21, 2023. The guarantee period for Shanghai Gracell Biotech is generally three years commencing from the expiration of the debt discharge period under the debt. The maximum amount of repayment liability assumed by Shanghai Gracell Biotech is RMB50.0 million (US\$7.2 million).

#### *Contracts of Maximum Guarantee with Hangzhou Bank*

On August 17, 2022, Gracell Bioscience entered into a contract of maximum guarantee with Hangzhou Bank, under which Gracell Bioscience agreed to, among other things, jointly assume the guarantee liability under this contract if Suzhou Gracell Biotech fails to discharge or fully discharge its debt upon the expiration of the discharge period of a single debt under such loan agreement to be entered into between Suzhou Gracell Biotech and Hangzhou Bank during August 17, 2022 and August 16, 2023. The guarantee period for Gracell Bioscience is generally three years commencing from the expiration of the debt discharge period under the debt. The maximum amount of repayment liability assumed by Gracell Bioscience is RMB110.0 million (US\$15.9 million).

On August 17, 2022, Shanghai Gracell Biotech entered into a contract of maximum guarantee with Hangzhou Bank, under which Shanghai Gracell Biotech agreed to, among other things, jointly assume the guarantee liability under this contract if Suzhou Gracell Biotech fails to discharge or fully discharge its debt upon the expiration of the discharge period of a single debt under such loan agreement to be entered into between Suzhou Gracell Biotech and Hangzhou Bank during August 17, 2022 and August 16, 2023. The guarantee period for Shanghai Gracell Biotech is generally three years commencing from the expiration of the debt discharge period under the debt. The maximum amount of repayment liability assumed by Shanghai Gracell Biotech is RMB110.0 million (US\$15.9 million).

#### **Funding Requirements**

Our material cash requirements as of December 31, 2022 and any subsequent interim period primarily include our operating lease obligations and our capital expenditures.

#### *Contractual Obligations*

The following table sets forth our contractual obligations and commitments as of December 31, 2022:

	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	Total
	(in RMB thousands)				
Operating Lease obligations	18,151	6,652	—	—	24,803

Our operating lease obligations related to our leases of offices, GMP facility and research centers. For the years ended December 31, 2020, 2021 and 2022, total rental related expenses for all operating leases amounted to RMB11.5 million, RMB16.3 million and RMB18.7 million (US\$2.7 million), respectively.

### *Capital Expenditure*

We incurred capital expenditure of RMB79.4 million, RMB56.7 million and RMB48.4 million (US\$7.0 million) for the years ended December 31, 2020, 2021 and 2022, respectively, primarily in connection with our expenditure for the purchase of property and equipment. These purchases primarily relate to (i) equipment used for research and production activities and (ii) renovation in Suzhou facility. We intend to fund our future capital expenditure through our existing cash balance and other financing alternatives. We expect that our capital expenditures will continue to increase to support the growth of our business.

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. In 2022, we had received proceeds of RMB104.6 million (US\$15.2 million) from our term loan facilities with commercial banks. As of December 31, 2022, we had RMB1,458.2 million (US\$211.4 million) in cash and cash equivalents and short-term investments.

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 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. 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 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.

#### **No 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 any offshore offerings 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.”

### C. Research and Development, Patents and Licenses, etc.

See “Item 4. Information on the Company—B. Business Overview—Technology,” “Item 4. Information on the Company—B. Business Overview—Intellectual Property,” and “Item 5. Operating and Financial Review and Prospects—A. Operating Results.”

### D. Trend Information

Other than as disclosed elsewhere in this annual report, we are not aware of any trends, uncertainties, demands, commitments or events for the year ended December 31, 2021 that are reasonably likely to have a material and adverse effect on our net revenues, income, profitability, liquidity or capital resources, or that would cause the disclosed financial information not necessarily to be indicative of future results of operations or financial conditions.

### E. Critical Accounting Estimates

We prepare our consolidated financial statements in accordance with U.S. GAAP, which requires our management to make estimates that affect the reported amounts of assets, liabilities and disclosures of contingent assets and liabilities at the balance sheet dates, as well as the reported amounts of revenues and expenses during the reporting periods. To the extent that there are material differences between these estimates and actual results, our financial condition or results of operations would be affected. We base our estimates on our own historical experience and other assumptions that we believe are reasonable after taking account of our circumstances and expectations for the future based on available information. We evaluate these estimates on an ongoing basis.

We consider an accounting estimate to be critical if: (1) the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made, and (2) changes in the estimate that are reasonably likely to occur from period-to-period or use of different estimates that we reasonably could have used in the current period, would have a material impact on our financial condition or results of operations. For the years ended December 31, 2020, 2021 and 2022, the Company does not have an accounting estimate that is considered critical.

## Item 6. Directors, Senior Management and Employees

### A. Directors and Senior Management

The following table sets forth certain information relating to our directors and executive officers as of the date of this annual report.

Directors and Executive Officers	Age	Position/Title
William Wei Cao, Ph.D. B.M.	64	Founder, Chairman of the Board and Chief Executive Officer
David Guowei Wang M.D., Ph.D.	61	Director
Guotong Xu M.D., Ph.D.	65	Director
Wendy Hayes	53	Director
Christophe Kin Ping Lee	54	Director
Wendy Li	64	Chief Medical Officer
Samuel Zhang	55	Chief Business Officer
Yili Kevin Xie, Ph.D.	52	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., a 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 Department of Pathology and Stanford University Medical Center Transplantation 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. Dr. Cao holds over 80 issued patents and applications for advanced cell therapies.

*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.

*Guotong Xu, M.D., Ph.D.*, has served as our director since February 2019. We have determined that Guotong Xu meets the criteria for independence set forth in Rule 10A-3 of the Exchange Act. 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. 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.

*Wendy Hayes* has served as our director since January 7, 2021. We have determined that Wendy Hayes meets the criteria for independence set forth in Rule 10A-3 of the Exchange Act. Ms. Hayes is currently an ALI Fellow at Harvard University. She has served as an independent director of Tuanche Limited (Nasdaq: TC) since November 2018, Burning Rock Biotech Limited (Nasdaq: BNR) since June 2020, iHuman Inc. (NYSE: IH) since October 2020, and SciClone Pharmaceuticals (Holdings) Limited (Hong Kong: 6600) since March 2021. Between May 2013 and September 2018, Ms. Hayes served as the Inspections Leader at the Public Company Accounting Oversight Board in the United States. Prior to that, Ms. Hayes was an audit partner at Deloitte (China). Ms. Hayes received her bachelor's degree in International Finance from University of International Business and Economics in 1991, and her executive MBA from Cheung Kong Graduate School of Business in 2012. Ms. Hayes is a certified public accountant in the United States (California) and China.

*Christophe Kin Ping Lee* has served as our director since July 2021. We have determined that Christophe Kin Ping Lee meets the criteria for independence set forth in Rule 10A-3 of the Exchange Act. Mr. Lee has over 16 years of experience in asset management. Mr. Lee is currently the chief executive officer of Lotus Asset Management Limited. From June 2019 to September 2019, Mr. Lee was a licensed representative of Zheng He Capital Management Limited for Type 4 and Type 9 regulated activities under the Securities and Futures Ordinance, or the SFO. From January 2019 to May 2019, Mr. Lee served as a responsible officer of Lotus Asset Management Limited for Type 4 and Type 9 regulated activities under the SFO. From July 2015 to July 2018, Mr. Lee was a responsible officer of MZ Asset Management Limited for Type 9 regulated activities under the SFO. From May 2014 to August 2014, Mr. Lee was a responsible officer of Fenex Capital Management Limited for Type 9 regulated activities under the SFO. Mr. Lee was a licensed representative for Type 9 regulated activities under the SFO from September 2010 to November 2011 and a responsible officer for Type 9 regulated activities under the SFO from November 2010 to March 2011 of FrontPoint Management (Hong Kong), Ltd. Mr. Lee was the chief financial officer of OrbusNeich Medical Company Ltd. from March 2012 to March 2017, and its senior advisor from March 2017 to June 2018. Mr. Lee worked in Sun Hung Kai & Co. group companies from August 2000 to August 2010 with his last position as Head of Corporate Development. Mr. Lee worked in Goldman Sachs (Asia) LLC from February 1997 to July 2000 with his last position as executive director of the Investment Management Division. Mr. Lee was appointed as a committee member of the New Business Committee of the Financial Services Development Council of Hong Kong by the Hong Kong SAR government from March 2013 to March 2019. Mr. Lee was the chairman of the Hong Kong Branch of the Alternative Investment Management Association from September 2004 to August 2012. Mr. Lee was appointed as a member of the Securities and Futures Commission Advisory Committee by the Hong Kong SAR government from June 2007 to May 2009. Mr. Lee received a Bachelor of Applied Science Degree from the University of Pennsylvania in 1991.

*Wendy Li, M.D.*, has served as our Chief Medical Officer since August 2022. Dr. Li has over 20 years of experience leading all critical aspects of clinical and medical operations at early-stage and large pharmaceutical organizations in the U.S. and China. Her expertise spans both clinical development and medical affairs, including leading early- and late-stage clinical trials for several therapeutic candidates for the treatment of hematological malignancies and solid tumors, and overseeing over 30 successful Investigational New Drug applications (INDs), New Drug Applications (NDAs) and Biologics License Applications (BLAs) that led to several multi-billion-dollar blockbuster drugs. Prior to joining us, Dr. Li served as CMO of EXUMA Biotech, where she provided strategic medical and clinical leadership for the advancement of its cell therapy pipeline in the U.S. and Asia. She has also held clinical development and medical affairs leadership positions at Pfizer, Sanofi, Genentech, and Sihuan Pharmaceutical. Dr. Li holds an M.D. from Sun Yat-Sen University of Medical Sciences.

*Yili Kevin Xie, Ph.D.*, has served as our Chief Financial Officer since July 2020. Dr. Xie has over 20 years of experience in healthcare industry and 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 Humanigen Inc. (Nasdaq: HGEN) since October 2021. 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. in Chemistry from The City University in New York, and an M.B.A. from The Wharton School, University of Pennsylvania.

*Samuel Zhang* has served as our Chief Business Officer since July 2022. Dr. Samuel Zhang has over 20 years of industry experience, covering the entire drug development spectrum, and the expertise to integrate key scientific, commercial, and clinical/regulatory perspectives to facilitate strategic business decisions including business development transactions. Dr. Zhang has a long history and broad exposure of deal making at large pharm and small biotech. Prior to joining Gracell, Dr. Zhang served as Chief Business Officer at Rockville Maryland-based NeoImmuneTech, another publicly traded biotech company, from 2019 to 2022. While there, he defined the company's overall business strategy with his cross-functional leadership and oversaw business development including deal initiation, deal execution, and alliance management. Prior to NeoImmuneTech, he was Vice President of Strategy at Merus (Nasdaq: MRUS) from 2017 to 2019. He has also held various management positions at Novartis, Pfizer, Bristol-Myers Squibb (BMS), and Eli Lilly, responsible for product and portfolio strategies, business development, global and U.S. product launches, and global medical strategy. Dr. Zhang believed in cancer immunotherapy while a graduate student at Columbia University decades ago and became professionally dedicated to Immuno-Oncology in 2009, before its success today. While at BMS, he helped bring the world's first anti-PD-1 antibody nivolumab to full development, leading to initial product approval in 2L NSCLC and approximately US\$5 billion each year in sales two years post launch. Dr. Zhang received his PhD from Columbia University and his B.S. from Peking University.



## **B. Compensation**

### **Compensation of Directors and Executive Officers**

For the year ended December 31, 2022, we paid an aggregate of approximately RMB18.0 million (US\$2.6 million) in cash and benefits to our executive officers and non-employee directors. For stock option grants to our executive officers and directors, see “—Third Amended and Restated 2017 Employee Stock Option Plan” and “—2020 Share Incentive 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, if an executive officer willfully disobeys a lawful and reasonable order of us, misconducts himself or herself, with such conduct being inconsistent with the due and faithful discharge of his or her duties, is guilty of fraud or dishonesty, or is habitually neglectful in his or her duties. We may also terminate an executive officer’s employment without cause upon three-month advance written notice.

Each executive officer has agreed to not make any disclosure of our confidential information nor to make any duplication or copy of our confidential information, and immediately upon request from us, to return to us all of our confidential information. Each executive officer may provide our confidential information in compliance with a valid court order issued by a court of competent jurisdiction, provided that such executive officer takes reasonable steps to prevent dissemination of such confidential information. The executive officers have also agreed to promptly disclose to us, in confidence (i) all proprietary information that they create during the term of their employment, and (ii) all patent applications, copyright registrations or similar rights filed or applied for by them within six months after termination of their employment.

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 the non-solicitation restrictions will survive the termination. Specifically, each executive officer has agreed not to (i) call upon, solicit, divert or take away or attempt to solicit, divert or take away any of the customers, vendors, business or patrons of us; (ii) solicit or attempt to solicit for employment or consultancy any person who is an employee of or consultant to us; or (iii) own, operate, manage, join, control, participate in the ownership, management, operation or control of, or be paid or employed by, or acquire any securities of, or otherwise become associated with or provide assistance to, as an employee, consultant, director, officer, shareholder, partner, agent, associate, principal, representative or in any other capacity, any business entity which engages in any competitive line of business in which the we are engaged.

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.

### **Third Amended and Restated 2017 Employee Stock Option Plan**

We have adopted an employee stock option plan, which was amended and restated in October 2020. As of the date of this annual report, the maximum aggregate number of ordinary shares that may be granted under our employee stock option plan is 10,216,234 ordinary shares. As of March 31, 2023, awards to purchase a total of 8,037,080 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.

*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.* The vesting schedule of each award granted under our employee stock option plan will generally be set forth in the relevant stock option award agreement.

*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.

## **2020 Share Incentive Plan**

To promote the success and enhance the value of our company, in December 2020, our shareholders and board of directors approved the 2020 Share Incentive Plan, or the 2020 Plan, which became effective in January 2021. Under the 2020 Plan, the maximum aggregate number of ordinary shares available for issuance, or the Award Pool, shall initially be 10,081,980, equal to three percent (3%) of the ordinary shares of our company outstanding immediately upon completion of our initial public offering in January 2021. The Award Pool will be increased on an annual basis on the first calendar day of each fiscal year of our company during the term of 2020 Plan commencing on January 1 of the year following the year in which this offering occurs, by the lesser of (i) an amount equal to one percent (1%) of the total number of ordinary shares of our company issued and outstanding on the last day of the immediately preceding fiscal year, and (ii) such number of ordinary shares as may be determined by our board of directors. As of February 1, 2023, 7,026,464 ordinary shares were reserved for future award grants under the 2020 Plan. As of March 31, 2023, awards to purchase a total of 9,684,190 ordinary shares have been granted and are outstanding, excluding awards that were forfeited or cancelled after the relevant grant dates. The following paragraphs summarizes the principal terms of the 2020 Plan:

*Type of Awards.* The 2020 Plan permits the awards of options, restricted shares, restricted share units or other types of awards approved by the board of directors or a committee of one or more members of the board of directors.

*Plan Administration.* Our board of directors or a committee of one or more members of the board of directors will administer the 2020 Plan. The committee or the board of directors, as applicable, will determine the participants to receive awards, the type and number of awards to be granted to each participant, and the terms and conditions of each grant.

*Award Agreement.* Awards granted under the 2020 Plan are evidenced by an award agreement that sets forth the terms, conditions and limitations for each award, which may include the term of the award, the provisions applicable in the event that the grantee's employment or service terminates, and our authority to unilaterally or bilaterally amend, modify, suspend, cancel or rescind the award.

*Eligibility.* Persons eligible to participate in the 2020 Plan include the independent directors of our company.

*Vesting Schedule.* The vesting schedule of each award granted under 2020 Plan will be set forth in the relevant award agreement.

*Exercise of Options.* The plan administrator determines the exercise price for each award, which is stated in the relevant award agreement. Options that are vested and exercisable will terminate if they are not exercised prior to the time as the plan administrator determines at the time of grant. However, the maximum exercisable term is ten years from the date of grant.

*Transfer Restrictions.* Awards may not be transferred in any manner by the participant other than in accordance with the exceptions provided in the 2020 Plan or the relevant award agreement or otherwise determined by the plan administrator, such as transfers by will or the laws of descent and distribution.

*Termination and Amendment of the 2020 Plan.* Our board of directors has the authority to terminate, amend, suspend or modify the 2020 Plan in accordance with our articles of association. However, without the prior written consent of the participant, no such action may adversely affect in any material way any award previously granted pursuant to the plan.

The following table summarizes, as of April 21, 2023, the options granted under our share incentive plans to several of our executive officers, excluding awards that were forfeited or cancelled after the relevant grant dates.

Name	Ordinary Shares & RSUs Underlying Awards	Exercise Price (US\$/Share)	Date of Grant	Date of Expiration
William Wei Cao	303,030	—	January 1, 2021	January 30, 2031
	289,020	—	February 24, 2022	February 24, 2032
	606,060	1.65	January 1, 2021	January 1, 2031
	1,000,000	1.65	January 13, 2021	January 13, 2031
	1,302,415	0.692	February 24, 2022	February 24, 2032
David Guowei Wang	—	—	—	—
Guotong Xu	*	0.30	September 1, 2017	August 31, 2027
	*	4.36	February 1, 2021	February 1, 2031
Wendy Hayes	*	—	January 8, 2021	January 8, 2031
	*	—	January 7, 2022	January 7, 2023
Christophe Kin Ping Lee	*	—	July 9, 2021	July 9, 2031
	*	—	February 24, 2022	February 24, 2032
Yili Kevin Xie	*	—	February 24, 2022	February 24, 2032
	*	1.06	July 16, 2020	July 16, 2030
	*	1.65	January 13, 2021	January 13, 2031
	*	4.64	April 13, 2021	April 13, 2031
Wendy Li	*	0.662	August 1, 2022	August 1, 2032
Samuel Zhang	*	0.814	July 18, 2022	July 18, 2032
Other grantees	7,847,730	0.30 (August 8, 2017 through November 16, 2018) 1.06 (January 18, 2019 through July 16, 2020) 1.65 (November 3, 2020 through January 13, 2021) 4.64 (March 15, 2021 through April 13, 2021) 0.4 (March 6, 2023)	From August 8, 2017	Ten years from date of award
<b>Total</b>	<b>17,721,270</b>			

\* Less than 1% of our total outstanding ordinary shares.

## **C. Board Practices**

### **Board of Directors**

Our board of directors consists of five directors. 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 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.

### **Committees of the Board of Directors**

We have established an audit committee, a compensation committee and a nominating and corporate governance committee. We have adopted a charter for each of these committees. Each committee's members and functions are described below.

#### *Audit Committee*

Our audit committee consists of Wendy Hayes, Guotong Xu and Christophe Kin Ping Lee. Wendy Hayes is the chairperson of our audit committee. We have determined that each of Wendy Hayes, Guotong Xu and Christophe Kin Ping Lee satisfies the independence requirements under Rule 5605(c)(2) of the Nasdaq Stock Market Rules and meets the criteria for independence set forth in Rule 10A-3 of the Exchange Act. We have determined that Wendy Hayes satisfies the criteria of an audit committee financial expert as set forth under the applicable rules of the SEC. The audit committee oversees our accounting and financial reporting processes and the audits of our financial statements. Our audit committee is responsible for, among other things:

- selecting the independent auditors;
- reviewing and approving the independent auditors' annual engagement letter;
- 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 pre-approving related party transactions;
- reviewing and discussing the annual audited financial statements with management and the independent auditor;
- reviewing and discussing with management and the independent auditors about all critical accounting policies and practices to be used;
- reviewing reports prepared by management and/or the independent auditors relating to significant financial reporting issues and judgments;
- reviewing earnings press releases, 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 auditors regarding all critical accounting policies and practices to be used by our company, and all other material written communications between the independent auditors 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 consists of William Wei Cao, David Guowei Wang and Wendy Hayes. William Wei Cao is the chairperson of our compensation committee. We have determined that Wendy Hayes satisfies the independence requirements under Rule 5605(a)(2) of the Nasdaq Stock Market Rules. Our compensation committee is responsible for, among other things:

- reviewing, evaluating and, if necessary, revising our overall compensation plans;
- reviewing and evaluating the performance of our directors and relevant executive officers and determining the compensation of relevant executive officers;
- reviewing and approving any severance or termination agreements to be made with any executive officers;
- reviewing our general compensation plans and other employee benefit plans, including 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 consists of William Wei Cao, Guotong Xu and Wendy Hayes. William Wei Cao is the chairperson of our nominating and corporate governance committee. We have determined that each of Wendy Hayes and Guotong Xu satisfies the independence requirements under Rule 5605(a)(2) of the Nasdaq Stock Market Rules. The nominating and corporate governance committee is 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.

## **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 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 three (3) directors, and there shall be no maximum number of directors. Our directors will be divided into three (3) classes designated as follows:

Our directors will be divided among the three classes as follows:

- Class I, which will consist of Christophe Kin Ping Lee, whose term will expire at our annual meeting of shareholders in 2024; and
- Class II, which will consist of Guotong Xu and David Guowei Wang, whose term will expire at our annual meeting of shareholders in 2025;
- Class III, which will consist of William Wei Cao and Wendy Hayes, whose term will expire at our annual meeting of shareholders in 2023.

Directors shall be assigned to each class in accordance with a resolution or resolutions adopted by the board of directors. At each succeeding annual general meeting of shareholders, directors shall be elected for a full term of three (3) years to succeed the directors of the class whose terms expire at such annual general meeting. Notwithstanding the foregoing, each director shall hold office until the expiration of his or her term, until his or her successor shall have been duly elected and qualified or until his or her earlier death, resignation or removal. 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 our 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 our amended and restated memorandum and articles of association.

Our officers are elected by and serve at the discretion of the board of directors.

## Board Diversity

The table below provides certain information regarding the diversity of our board of directors as of the date of this annual report.

**Board Diversity Matrix (as of March 31, 2023)**

<b>Country of Principal Executive Offices</b>	<b>People's Republic of China</b>			
<b>Foreign Private Issuer</b>	<b>Yes</b>			
<b>Disclosure Prohibited under Home Country Law</b>	<b>No</b>			
<b>Total Number of Directors</b>	<b>5</b>			
	<b>Female</b>	<b>Male</b>	<b>Non- Binary</b>	<b>Did Not Disclose Gender</b>
<b>Part I: Gender Identity</b>				
Directors	1	4	0	0
<b>Part II: Demographic Background</b>				
Underrepresented Individual in Home Country Jurisdiction		0		
LGBTQ+		0		
Did Not Disclose Demographic Background		0		

## D. Employees

We had a total of 202, 348, and 314 full-time employees as of December 31, 2020, 2021 and 2022, respectively. Of the 314 full-time employees as of December 31, 2022, 260 hold medical, technical or scientific credentials and qualifications, 254 were engaged in research and development activities and 60 were engaged in business development, finance, information systems, facilities, human resources or administrative support.

Most 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.

## E. Share Ownership

Except as specifically noted, the following table sets forth information with respect to the beneficial ownership of our ordinary shares as of April 21, 2023:

- 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 338,576,187 ordinary shares issued and outstanding as of April 21, 2023, excluding 24,814,479 ordinary shares issued to depositary bank as of April 21, 2023, for bulk issuance of ADSs reserved for future issuances upon the exercise or vesting of awards granted under our share incentive plans.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, we have included shares that the person has the right to acquire within 60 days, including through the exercise of any option, warrant or other right or the conversion of any other security. These shares, however, are not included in the computation of the percentage ownership of any other person.

	Ordinary Shares Beneficially Owned	
	Number	%
<b>Directors and Executive Officers**:</b>		
William Wei Cao <sup>(1)</sup>	82,243,155	24.1
David Guowei Wang	—	—
Guotong Xu	*	*
Wendy Hayes	*	*
Christophe Kin Ping Lee	*	*
Wendy Li	*	*
Yili Kevin Xie	*	*
Samuel Zhang	*	*
All Directors and Executive Officers as a Group	84,621,380	24.7
<b>Principal Shareholders:</b>		
Gracell Venture Holdings Limited <sup>(1)</sup>	79,269,010	23.4
TLS Beta Pte. Ltd. <sup>(2)</sup>	49,509,702	14.6
Entities affiliated with LAV <sup>(3)</sup>	25,406,680	7.5
Entities affiliated with OrbiMed <sup>(4)</sup>	47,488,870	14.0

\* Less than 1% of our total issued and outstanding ordinary shares.

\*\* Business address of Dr. William Wei Cao, Dr. Wendy Li, Dr. Samuel Zhang and Dr. Yili Kevin Xie is Building 12, Block B, Phase II, Biobay Industrial Park, 218 Sangtian St., Suzhou Industrial Park, Jiangsu Province, China. Dr. David Guowei Wang's business address is Unit 4706, Raffles City Shanghai Office Tower, 268 Middle Xizang Road, Huangpu District, Shanghai, China. Dr. Guotong Xu's business address is Room 102, No.18, Lane 29, Lingling Road, XuHui District, Shanghai, China. Ms. Wendy Hayes's business address is 2370 Roanoke Trail, Reno, NV 89523. Christophe Kin Ping Lee's business address is 2A, Sea Cliff Mansions, 19 Repulse Bay Road, Hong Kong.



Notes:

- (1) Represents (i) 15,853,802 ADSs directly held by Gracell Venture Holdings Limited, representing 79,269,010 ordinary shares, and (ii) 594,829 ADSs that William Wei Cao has the rights to acquire within 60 days of December 31, 2022, representing 2,974,145 ordinary shares. 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 49,509,702 ordinary shares held by TLS Beta Pte. Ltd., a company incorporated in Singapore. 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, or Temasek. Temasek is wholly owned by the Singapore Minister for Finance. Under the Singapore Minister for Finance (Incorporation) Act (Chapter 183), the Minister for Finance is a body corporate. As a commercial investment company, Temasek has its own Board of Directors and a professional management team. Temasek owns and manages its portfolio with full commercial discretion and flexibility under the guidance of its Board. The Singapore Government is not involved in Temasek's investment, divestment, or any other business or operational decisions. The principal business address of TLS Beta Pte. Ltd. is 60B Orchard Road #06-18 Tower 2, The Atrium@Orchard, Singapore 238891.
- (3) Represents (i) 10,049,125 ordinary shares (in the form of ADSs) held by LAV Biosciences Fund V, L.P., a Cayman Islands exempted limited partnership, (ii) 14,981,730 ordinary shares (in the form of ADSs) held by LAV Granite Limited, a British Virgin Island company, and (iii) 375,825 ordinary shares (in the form of ADSs) held by LAV Biosciences Fund V Sub A, L.P., a United States limited partnership, as reported on Schedule 13G filed by LAV Granite Limited, among others, on February 9, 2022. 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.
- (4) Represents 47,488,870 ordinary shares (in the form of ADSs) held by OrbiMed Advisors LLC, a Delaware corporation, OrbiMed Asia GP III, L.P., and OrbiMed Capital LLC, a Delaware corporation, on behalf of other persons who have the right to receive or the power to direct the receipt of dividends from, or proceeds from the sale of, such securities, as reported on Schedule 13D filed by OrbiMed Advisors LLC on March 29, 2023. OrbiMed Asia Partners III, L.P. ("OAP III"), a limited partnership organized under the laws of the Cayman Islands, holds 6,972,080 ADSs. OrbiMed Asia GP III, L.P. ("OAP GP III") is the general partner of OAP III, OrbiMed Advisors III Limited ("Advisors III") is the general partner of OAP GP III, and OrbiMed Advisors LLC ("OrbiMed Advisors") is the investment manager of OAP III. OrbiMed Genesis Master Fund, L.P. ("Genesis"), a limited partnership organized under the laws of the Cayman Islands, holds 305,748 ADSs. OrbiMed Genesis GP LLC ("Genesis GP") is the general partner of Genesis, and OrbiMed Advisors is the managing member of Genesis GP. OrbiMed New Horizons Master Fund, L.P. ("New Horizons"), a limited partnership organized under the laws of the Cayman Islands, holds 305,748 ADSs. OrbiMed New Horizons GP LLC ("ONH GP") is the general partner of New Horizons, and OrbiMed Advisors is the managing member of ONH GP. The Biotech Growth Trust PLC ("BIOG"), a publicly-listed investment trust organized under the laws of England, holds 813,504 ADSs, and OrbiMed Partners Master Fund Limited ("OPM"), an exempted company under the laws of Bermuda, holds 1,100,694 ADSs. OrbiMed Capital LLC ("OrbiMed Capital") is the portfolio manager of BIOG and the investment advisor of OPM. OrbiMed Advisors and OrbiMed Capital exercise the investment and voting power through management committees comprised of Carl L. Gordon, Sven H. Borho, and W. Carter Neild, each of whom disclaims beneficial ownership of the ADSs held by OAP III, Genesis, New Horizons, BIOG and OPM. The principal business address of OrbiMed Capital LLC and OrbiMed Advisors LLC is 601 Lexington Avenue, 54th Floor, New York, NY 10022.

To our knowledge, as of April 21, 2023, a total of 340,491,950 ordinary shares were held by one record holder in the United States, The Bank of New York Mellon, the depositary of our ADS program (including 24,814,479 ordinary shares issued to the depositary for bulk issuance of ADSs reserved for future issuances upon the exercise or vesting of awards granted under our share incentive plans). This number represented approximately 93.7% of the 363,390,666 total issued shares.

We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

## **Item 7. Major Shareholders and Related Party Transactions**

### **A. Major Shareholders**

See “Item 6. Directors, Senior Management and Employees—E. Share Ownership.”

### **B. Related Party Transactions**

#### **Contractual Arrangements with The VIE and Its Shareholders**

See “Item 4. Information on the Company—C. Organizational Structure.”

#### **Private Placements**

See “Description of Share Capital—History of Securities Issuances.”

#### **Transactions with Unitex Capital Ltd.**

In the year ended December 31, 2020, we paid RMB2,631 thousand (US\$381 thousand) for professional service fee to Unitex Capital Ltd, an entity controlled by Dr. William Wei Cao. In the year ended December 31, 2021, we paid RMB3,354 thousand (US\$526 thousand) for professional service fee to Unitex Capital Ltd. In the year ended December 31, 2022, we paid RMB10,885 thousand (US\$1,578 thousand) for professional service fee to Unitex Capital Ltd.

#### **Transactions with a Director and an Executive Officer**

Not applicable.

#### **Shareholders Agreement**

We entered into our second amended and restated shareholders agreement on October 20, 2020, 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, automatically terminated upon the completion of our initial public offering in January 2021.

#### ***Registration Rights***

Pursuant to our second amended and restated shareholders agreement dated October 20, 2020, 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 after the expiry of 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 (other than Form F-3 or Form S-3) 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 our 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 of such equity securities, 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) January 12, 2025, the fourth (4th) anniversary of consummation of our initial public 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.

## **Employment Agreements and Indemnification Agreements**

See “Item 6. Directors, Senior Management and Employees—B. Compensation.”

## **Share Incentive Plan**

See “Item 6. Directors, Senior Management and Employees—B. Compensation.”

## **C. Interests of Experts and Counsel**

Not applicable.

## **Item 8. Financial Information**

### **A. Consolidated Statements and Other Financial Information**

We have appended consolidated financial statements filed as part of this annual report.

### **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 “Item 3. Key Information—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 “Item 3. Key Information—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.”

### **Dividend Policy**

Our board of directors has discretion on whether to distribute dividends, subject to our amended and restated memorandum and articles of association 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. 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 “Item 4. Information on the Company—B. Business Overview—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 the 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 “Item 12. Description of Securities Other than Equity Securities—D. American Depositary Shares.” Cash dividends on our ordinary shares, if any, will be paid in U.S. dollars.

**B. Significant Changes**

Except as disclosed elsewhere in this annual report, we have not experienced any significant changes since the date of our audited consolidated financial statements included in this annual report.

**Item 9. The Offer and Listing**

**A. Offering and Listing Details**

The ADSs, each representing five of our ordinary shares, have been listed on Nasdaq since January 8, 2021. The ADSs trade under the symbol “GRCL.”

**B. Plan of Distribution**

Not applicable.

**C. Markets**

The ADSs have been listed on Nasdaq since January 8, 2021 under the symbol “GRCL.”

**D. Selling Shareholders**

Not applicable.

**E. Dilution**

Not applicable.

**F. Expenses of the Issue**

Not applicable.

**Item 10. Additional Information**

**A. Share Capital**

Not applicable.

**B. Memorandum and Articles of Association**

The following are summaries of material provisions of our current memorandum and articles of association, or Memorandum and Articles of Association, 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 and restated memorandum and 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 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 Act 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 two holders of shares being not less than an aggregate of fifty percent (50%) of all votes attaching to all shares in issue and entitled to vote.

The Companies Act only provides shareholders with limited rights to requisition a general meeting, and does not provide shareholders with any right to put any proposal before general meeting. However, the Companies Act 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 in our amended and restated memorandum and articles of association as 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;
- the ordinary shares transferred are free of any lien in favor of our company; and
- a fee of such maximum sum as The Nasdaq Global Select 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 Select Market, be suspended and our register of members 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 of members closed for more than 30 days in any year as our board may determine.

*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 Act, 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, before the issue of such shares, by our board of directors. Our company may also repurchase any of our shares on such terms and in such manner as have been approved by our board of directors or by an ordinary resolution of our shareholders. Under the Companies Act, the redemption or repurchase of any share may be paid out of our company's 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 Act 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.

*Variations of Rights of Shares.* Whenever the capital of our company is divided into different classes, the rights attached to any such 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 three-fourths 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, without the need for any approval or consent from our shareholders.

Our amended and restated memorandum of association also authorizes our board of directors, without the need for any approval or consent from our shareholders, 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 rates, 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 preferred shares without the need for any approval or consent from, or other 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 list of shareholders or our corporate records (save for our memorandum and articles of association and our register of mortgages and charges). 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 preferred shares in one or more series and to designate the price, rights, preferences, privileges and restrictions of such preferred 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 incorporated under the Companies Act. The Companies Act distinguishes between ordinary resident companies and exempted companies. Any company that is registered in the Cayman Islands but conducts business mainly outside of the Cayman Islands may apply to be registered as an exempted company. The requirements for an exempted company are essentially the same as for an ordinary company except that an exempted company:

- does not have to file an annual return of its shareholders with the Registrar of Companies;
- is not required to open its register of members for inspection;
- does not have to hold an annual general meeting;
- may issue negotiable or bearer shares or shares with no par value;
- may obtain an undertaking against the imposition of any future taxation (such undertakings are usually given for 20 years in the first instance);

- may register by way of continuation in another jurisdiction and be deregistered in the Cayman Islands;
- may register as a limited duration company; and
- may register as a segregated portfolio company.

“Limited liability” means that the liability of each shareholder is limited to the amount unpaid by the shareholder on the shares of the company (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).

### **Registered Office and Objects**

Our registered office in the Cayman Islands is located at 4th Floor, Harbour Place, 103 South Church Street, P.O. Box 10240, Grand Cayman, KY1-1002, Cayman Islands, or at such other location within the Cayman Islands as our directors may from time to time decide. The objects for which our company is established are unrestricted and we have full power and authority to carry out any object not prohibited by the Companies Act or any other law of the Cayman Islands.

### **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 Act 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 Act applicable to us and the laws applicable to companies incorporated in the United States and their shareholders.

*Mergers and Similar Arrangements.* The Companies Act 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 Act. 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 Act 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 (i) 75% in value of the members or class of members or (ii) a majority in number representing 75% in value of the creditors or class of creditors, in each case, depending on the circumstances, as are present at a meeting called for such purpose and thereafter sanctioned by the Grand Court of the Cayman Islands. 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 Act.

The Companies Act 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 have entered into indemnification agreements with our directors and executive officers 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 Act 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 Act 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 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 three-fourths 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 Act 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 amended and restated memorandum and articles of association governing the ownership threshold above which shareholder ownership must be disclosed.

See "Exhibit 2.5 — Description of Securities" attached to this form 20-F for more descriptions of our securities.

### **C. Material Contracts**

Other than in the ordinary course of business and other than those described in "Item 4. Information on the Company" or "Item 7. Major Shareholders and Related Party Transactions—B. Related Party Transactions" or elsewhere in this annual report, we have not entered into any material contract during the two years immediately preceding the date of this annual report.

### **D. Exchange Controls**

See "Item 4. Information on the Company—B. Business Overview—Regulation—Regulations Relating to Foreign Exchange."

### **E. Taxation**

*The following is a summary of Cayman Islands, People's Republic of China and United States federal income tax consequences relevant to an investment in the 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 annual report, 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 the 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, brought to, or produced before a court 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, brought to, or produced before a court of the Cayman Islands or our company holds interests in land in the Cayman Islands.

Pursuant to section 6 of the Tax Concessions Act (as amended) of the Cayman Islands, the Company may obtain an undertaking from the Governor-in-Cabinet that:

- (i) no law which is enacted in the Cayman Islands imposing any tax to be levied on profit or income or gains or appreciations shall apply to the Company or its operations; and
- (ii) no tax be levied on profits, income, gains or appreciations or which is in the nature of estate duty or inheritance tax shall be payable by the Company:
  - on or in respect of the shares, debenture, or other obligations of the Company; or
  - by way of withholding in whole or in part of any relevant payment as defined in section 6(3) of the Tax Concessions Act (as amended).

These concessions shall be for a period of 20 years from December 7, 2020.

## **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.

As advised by our PRC Counsel, our company will not be considered as a PRC resident enterprise for PRC tax purposes as (i) our company is incorporated outside of China and not controlled by a PRC enterprise or PRC enterprise group; and (ii) it does 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.

As our company is not deemed to be a PRC resident, 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. Therefore, no PRC income tax will be payable by the holders of the ADSs and ordinary shares who are not PRC resident on above situations. 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. For risks related to PRC taxes, see “Item 3. Key Information—D. 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.”



## United States Federal Income Tax Considerations

The following discussion is a summary of 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 any U.S. federal non-income tax considerations, including estate or gift tax considerations, the Medicare contribution tax on net investment income, the alternative minimum tax or the special tax accounting rules under Section 451(b) of the Code, 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;
- corporations that accumulate income to avoid U.S. federal income tax;
- 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 for U.S. federal income tax purposes;
- 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 or arrangements 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. The U.S. Treasury has expressed concerns that intermediaries in the chain of ownership between the holder of an ADS and the issuer of the security underlying the ADS may be taking actions that are inconsistent with the beneficial ownership of the underlying security. Accordingly, the creditability of foreign taxes, if any, as described below, could be affected by actions taken by intermediaries in the chain of ownership between the holders of ADSs representing our shares and our company if, as a result of such actions, the holders of ADSs representing our ordinary shares are not properly treated as beneficial owners of the underlying shares.

## **Dividends**

Subject to the discussion below under “—Passive Foreign Investment Company,” 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, would 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 depository, 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 income tax treaty with the U.S. which the Secretary of the Treasury of the U.S. determines is satisfactory for purposes of the applicable provision of the Code 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 in the United States, 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. 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 “—PRC 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,” 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 and, subject to certain exceptions, Treasury Regulations generally preclude U.S. taxpayers from claiming a foreign tax credit with respect to any non-U.S. tax imposed on gains from dispositions of shares held as capital assets unless the tax is creditable under an applicable income tax treaty. Accordingly, your ability to claim a foreign tax credit with respect to the PRC tax imposed on such sale or other taxable disposition, if any, may be significantly limited. In lieu of claiming a credit, you may be able to elect to deduct the PRC taxes in computing your taxable income, subject to applicable limitations. An election to deduct PRC taxes instead of claiming foreign tax credits applies to all foreign taxes paid or accrued in the relevant taxable year. 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 creditability or deductibility of any PRC tax on disposition gains under its particular circumstances.

#### **Passive Foreign Investment Company**

A non-U.S. corporation, such as the 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 estimated income, assets and market capitalization for 2022, we may have been a PFIC for 2022. While we hold a substantial amount of cash and cash equivalents our PFIC status for any taxable year will depend primarily on the average value of our goodwill. Because our market capitalization has declined substantially since our initial public offering (including in recent months), if the value of our goodwill is determined by reference to our market capitalization there is a significant risk that we will be a PFIC for our taxable year 2023, and possibly future taxable years. 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 interpretations. 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. The treatment of our goodwill as a passive or active asset will depend on the allocation of our goodwill to our business assets, which is subject to significant uncertainty. 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 the 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 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, the VIE and its nominal shareholders will be treated for purposes of the PFIC rules, and we may be or become a PFIC if the 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. Because our PFIC status is a factual determination, our U.S. counsel expresses no opinion with respect to our PFIC status for any 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 or a QEF election (each 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, the VIE or any of the entities in which the 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, the VIE or any of the entities in which the 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 Select Market, where the 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 a U.S. Holder makes an effective qualified electing fund election, or QEF election, the U.S. Holder will be required to include in gross income each year, whether or not we make distributions, as capital gains, such U.S. Holder’s pro rata share of our net capital gains and, as ordinary income, such U.S. Holder’s pro rata share of our earnings in excess of our net capital gains. Inclusions of net capital gains and ordinary income under a QEF election is required only for our taxable years in which we are a PFIC. An electing U.S. Holder’s basis in our ordinary shares or ADSs will be increased to reflect the amount of any taxed but undistributed income. Distributions of income that had previously been taxed will result in a corresponding reduction of basis in the ordinary shares or ADSs and generally will not be taxed again as distributions to the U.S. Holder. In addition, a U.S. Holder that makes a QEF election will be taxed on the disposition of ordinary shares or ADSs as described in “Sale or Other Disposition” above. In order to apply the QEF regime in lieu of the general PFIC rules described above a U.S. Holder generally must make the QEF election for the first taxable year that we are treated as a PFIC.

A U.S. Holder can only make a QEF election with respect to ordinary shares or ADSs in a PFIC if the Company agrees to furnish such U.S. Holder with certain information annually. If we determine that the Company is a PFIC in any taxable year, we intend to make available to U.S. Holders, upon request and in accordance with applicable procedures, a “PFIC Annual Information Statement” with respect to the Company for such taxable year. The “PFIC Annual Information Statement” may be used by U.S. Holders for purposes of complying with the reporting requirements applicable to a QEF election with respect to the Company.

U.S. Holders should note that if they make a QEF election with respect to us, they may be required to pay U.S. federal income tax with respect to their ordinary shares or ADSs for any taxable year significantly in excess of any cash distributions (which are expected to be zero) received on the ordinary shares or ADSs for such taxable year. U.S. Holders should consult their tax advisors regarding PFIC investments and making QEF elections based on their particular circumstances.

A QEF election with respect to the Company will not apply to any of our lower-tier PFICs. If we determine that any of our current subsidiaries is a lower-tier PFIC for any taxable year, we currently expect that we will provide the information necessary for U.S. Holders to make a QEF election with respect to such lower-tier PFIC upon request, but there can be no assurance that we will be able to provide such information.

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.

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 or QEF election.

**WE STRONGLY URGE YOU TO CONSULT YOUR TAX ADVISOR REGARDING THE IMPACT OF OUR PFIC STATUS ON YOUR INVESTMENT IN THE ORDINARY SHARES OR ADSs AS WELL AS THE APPLICATION OF THE PFIC RULES TO YOUR INVESTMENT IN THE ORDINARY SHARES OR ADSs.**

#### **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 generally are subject to information reporting, and may be subject to backup withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (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.

Backup withholding is not an additional tax. The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the 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. U.S. Holders should consult their tax advisors regarding the application of the United States information reporting and backup withholding rules.

#### **Information with Respect to Foreign Financial Assets**

Certain U.S. Holders who are individuals (and, under proposed regulations, certain entities) may be required to report information relating to the ordinary shares or ADSs, subject to certain exceptions (including an exception for ordinary shares or ADSs held in accounts maintained by certain U.S. financial institutions). Such U.S. Holders who fail to timely furnish the required information may be subject to a penalty. Additionally, if a U.S. Holder does not file the required information, the statute of limitations with respect to tax returns of the U.S. Holder to which the information relates may not close until three years after such information is filed. U.S. Holders should consult their tax advisers regarding their reporting obligations with respect to their ownership and disposition of the ordinary shares or ADSs.

#### **F. Dividends and Paying Agents**

Not applicable.

#### **G. Statement by Experts**

Not applicable.

#### **H. Documents on Display**

We are subject to periodic reporting and other informational requirements of the Exchange Act as applicable to foreign private issuers, and are required to file reports and other information with the SEC. Specifically, we are required to file annually an annual report on Form 20-F within four months after the end of each fiscal year, which is December 31. All information filed with the SEC can be obtained over the internet at the SEC's website at [www.sec.gov](http://www.sec.gov) or inspected and copied at the public reference facilities maintained by the SEC at 100 F Street, N.E., Washington, D.C. 20549. You can request copies of documents, upon payment of a duplicating fee, by writing to the SEC. As a foreign private issuer, we are exempt from the rules under the Exchange Act prescribing the furnishing and content of quarterly reports and proxy statements, and officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act.

We will furnish the Bank of New York Mellon, the depository of the ADSs, with our annual reports, which will include a review of operations and annual audited consolidated financial statements prepared in conformity with U.S. GAAP, and all notices of shareholders' meetings and other reports and communications that are made generally available to our shareholders. The depository will make such notices, reports and communications available to holders of ADSs and, upon our request, will mail to all record holders of ADSs the information contained in any notice of a shareholders' meeting received by the depository from us.

In accordance with Nasdaq Stock Market Rule 5250(d), we will post this annual report on Form 20-F on our website at [ir.gracellbio.com](http://ir.gracellbio.com). In addition, we will provide hardcopies of our annual report free of charge to shareholders and ADS holders upon request.

## **I. Subsidiary Information**

Not applicable.

## **J. Annual Report to Security Holders**

Not applicable.

## **Item 11. Quantitative and Qualitative Disclosures about Market Risk**

### **Foreign currency exchange risk**

Most of our revenues and expenses are denominated in Renminbi. Although our exposure to foreign exchange risks should be limited in general, 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 are traded in U.S. dollars.

The conversion of Renminbi into foreign currencies, including U.S. dollars, is based on rates set by the People's Bank of China. The Renminbi has fluctuated against the U.S. dollar, at times significantly and unpredictably. It is difficult to predict how market forces or PRC or U.S. government policy may impact the exchange rate between Renminbi and the U.S. dollar in the future.

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.

As of December 31, 2022, we had RMB-denominated cash of RMB219.9 million (US\$31.9 million). We estimate that a 10% depreciation of Renminbi against the U.S. dollar based on the foreign exchange rate on December 31, 2022 would result in a decrease of RMB22.0 million (US\$3.0 million) in our total assets as of December 31, 2022, and a 10% appreciation of Renminbi against the U.S. dollar based on the foreign exchange rate on December 31, 2022 would result in an increase of RMB22.0 million (US\$3.5 million) in our total assets as of December 31, 2022.

### **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 RMB1,458.2 million (US\$211.4 million) as of December 31, 2022. 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.

### **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 2020, 2021 and 2022 were increases of 2.5%, 0.9% and 2.0%, 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.



**Item 12. Description of Securities Other than Equity Securities**

**A. Debt Securities**

Not applicable.

**B. Warrants and Rights**

Not applicable.

**C. Other Securities**

Not applicable.

**D. American Depositary Shares**

**Fees and Charges ADS holders May Have to Pay**

An ADS holder will be required to pay the following service fees to the depositary bank and certain taxes and governmental charges (in addition to any applicable fees, expenses, taxes and other governmental charges payable on the deposited securities represented by any of the ADSs):

**Persons depositing or withdrawing Class A ordinary shares or ADS holders must pay:**

\$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)

\$0.05 (or less) per ADS

A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs

\$0.05 (or less) per ADS per calendar year

Registration or transfer fees

Expenses of the depositary

Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes

Any charges incurred by the depositary or its agents for servicing the deposited securities

**For:**

- Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property
- Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
- Any cash distribution to ADS holders
- Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders
- Depositary services
- Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares
- Cable (including SWIFT) and facsimile transmissions (when expressly provided in the deposit agreement)
- Converting foreign currency to U.S. dollars
- As necessary
- As necessary

The depositary collects its fees for delivery and surrender 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 may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

The depositary may convert currency itself or through any of its affiliates, or the custodian or we may convert currency and pay U.S. dollars to the depositary. Where the depositary converts currency itself or through any of its affiliates, the depositary acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained by it or its affiliate in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligation to act without negligence or bad faith. The methodology used to determine exchange rates used in currency conversions made by the depositary is available upon request.

#### **Fees and Other Payments Made by the Depositary to Us**

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads or commissions. For the year ended December 31, 2022, we did not receive reimbursement from the depositary for our expenses incurred in connection with the establishment and maintenance of the ADS program.

#### **Payment of Taxes**

You will be responsible for any taxes or other governmental charges payable on your ADSs or on the deposited securities represented by any of your ADSs. The depositary may refuse to register any transfer of your ADSs or allow you to withdraw the deposited securities represented by your ADSs until those taxes or other charges are paid. It may apply payments owed to you or sell deposited securities represented by your ADSs to pay any taxes owed and you will remain liable for any deficiency. If the depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes.

## **PART II**

### **Item 13. Defaults, Dividend Arrearages and Delinquencies**

None.

### **Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds**

#### **Material Modifications to the Rights of Security Holders**

None.

#### **Use of Proceeds**

The following "Use of Proceeds" information relates to the registration statement on Form F-1, as amended (File Number 333-251494) (the "F-1 Registration Statement") in relation to our initial public offering of 12,650,000 ADSs representing 63,250,000 ordinary shares, at an initial offering price of US\$19.00 per ADS. Our initial public offering closed in January 2021. Citigroup Global Markets, Inc., Jefferies LLC, Piper Sandler & Co. and Wells Fargo Securities, LLC were the representatives of the underwriters for our initial public offering. Counting in the ADSs sold upon the exercise of the over-allotment option by our underwriters, we offered and sold 12,650,000 ADSs and received a total amount of US\$220.2 million in net proceeds.

The F-1 Registration Statement was declared effective by the SEC on January 7, 2021. We received net proceeds of approximately US\$191.1 million from our initial public offering (or approximately US\$220.2 million counting in the ADSs sold upon the exercise of the over-allotment option by our underwriters) and incurred approximately US\$47.9 million in underwriting discounts and commissions and an estimated amount of approximately US\$3.3 million in other costs and expenses in connection with the offering. None of the offering expenses included any direct or indirect payments to directors or officers of our company or their associates, persons owning more than 10% or more of our equity securities or our affiliates. None of the net proceeds from the offering were paid, directly or indirectly, to any of our directors or officers or their associates, persons owning 10% or more of our equity securities or our affiliates.

For the period from January 7, 2021 to December 31, 2022, we used approximately US\$129.4 million of the net proceeds from our initial public offering for research and development, logistics management and other general corporate purposes. We intend to continue to use the proceeds from our initial public offering as disclosed in the F-1 Registration Statement.

## **Item 15. Controls and Procedures**

### **Evaluation of Disclosure Controls and Procedures**

Our management, under the supervision and with the participation of our chief executive officer and chief financial officer, carried out an evaluation of the effectiveness of our disclosure controls and procedures, which is defined in Rules 13a-15(e) of the Exchange Act, as of December 31, 2022.

Based upon that evaluation, our management, with the participation of our chief executive officer and chief financial officer, concluded that, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rule and forms and that such information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosures.

### **Management's Annual Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) under the Securities Exchange Act of 1934, as amended). Our management evaluated the effectiveness of our internal control over financial reporting based on criteria established in the framework in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management has concluded that our internal control over financial reporting was effective as of December 31, 2022.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. In addition, projections of any evaluation of effectiveness of our internal control over financial reporting to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies and procedures may deteriorate.

### **Attestation Report of Independent Registered Public Accounting Firm**

This annual report on Form 20-F does not include an attestation report of our independent registered public accounting firm because we qualified as an "emerging growth company" as defined under the JOBS Act as of December 31, 2022.

### **Changes in Internal Control Over Financial Reporting**

There were no material changes in our internal controls over financial reporting that occurred during the period covered by this annual report on Form 20-F that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Our management drives continuous improvement thereafter with all internal control related practices.

## Item 16A. Audit Committee Financial Expert

Our board of directors has determined that Ms. Wendy Hayes, an independent director (under the standards set forth in Nasdaq Stock Market Rule 5605(a)(2) and Rule 10A-3 under the Exchange Act) and member of our audit committee, is an audit committee financial expert.

## Item 16B. Code of Ethics

Our board of directors adopted a code of business conduct and ethics that applies to our directors, officers and employees in December 2020. We have posted a copy of our code of business conduct and ethics on our website at <http://irgracellbio.com/>

## Item 16C. Principal Accountant Fees and Services

The following table sets forth the aggregate fees by categories specified below in connection with certain professional services rendered by PricewaterhouseCoopers Zhong Tian LLP, our principal external auditors, for the periods indicated.

	For the Year Ended December 31,	
	2021	2022
Audit fees <sup>(1)</sup>	US\$1,018	US\$1,037
All other fees <sup>(2)</sup>	US\$23	US\$—

- (1) “Audit fees” means the aggregate fees billed in each of the fiscal years listed for professional services rendered by our principal auditors for the audit of our annual financial statements and assistance with and review of documents filed with the SEC. In 2020 and 2021, the audit refers to financial audit.
- (2) “All other fees” means the aggregate fees billed in each of the fiscal years listed for professional services rendered by our principal auditors associated with certain permitted tax services, permissible services to review and comment on internal control design over financial reporting and other advisory services.

The policy of our audit committee is to pre-approve all audit and non-audit services provided by PricewaterhouseCoopers Zhong Tian LLP, including audit services, audit-related services, tax services and other services as described above, other than those for *de minimis* services which are approved by the audit committee prior to the completion of the audit.

## Item 16D. Exemptions from the Listing Standards for Audit Committees

Not applicable.

## Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

## Item 16F. Change in Registrant’s Certifying Accountant

Not applicable.

## Item 16G. Corporate Governance

As a Cayman Islands exempted company listed on the Nasdaq Global Select Market, we are subject to the Nasdaq corporate governance listing standards. However, Nasdaq Stock Market Rules permit a foreign private issuer like us to follow the corporate governance practices of its home country. Certain corporate governance practices in the Cayman Islands, which is our home country, may differ significantly from the Nasdaq Stock Market Rules. See “Item 3. Key Information—D. Risk Factors—Risks Related to the ADSs—Since shareholder rights under Cayman Islands law differ from those under U.S. law, you may have difficulty protecting your shareholder rights.”

While we voluntarily follow most Nasdaq corporate governance rules, we may choose to take advantage exemptions afforded to us. See “Item 3. Key Information—D. Risk Factors—Risks Related to the ADSs—As a foreign private issuer, we are permitted to, and we will, rely on exemptions from certain Nasdaq corporate governance standards applicable to U.S. issuers, including the requirement that a majority of an issuer’s directors consist of independent directors. This may afford less protection to holders of our ordinary shares and ADSs.” We have elected to or intend to follow home country practice in lieu the following requirements:

- the requirement that each member of the compensation committee must be an independent director as set forth in Nasdaq Rule 5605(d)(2)(A);
- the requirement that director nomination should be made by a vote in which only independent directors participate or by a nominations committee comprised solely of independent directors as set forth in Nasdaq Rule 5605(e)(1);
- the requirement to obtain shareholder approval for certain issuances of securities, including shareholder approval of stock option plans; and
- the requirement that the board of directors shall have regularly scheduled meetings at which only independent directors are present as set forth in Nasdaq Rule 5605(b)(2).

Other than the home country practices described above, we are not aware of any significant differences between our corporate governance practices and those followed by U.S. domestic companies under Nasdaq Stock Market Rules.

**Item 16H. Mine Safety Disclosure**

Not applicable.

**Item 16I. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections**

For the immediately preceding annual financial statement period, our auditor, PricewaterhouseCoopers Zhong Tian LLP (a registered public accounting firm that the PCAOB was unable to inspect or investigate completely) issued an audit report for us.

As of the date of this annual report and to our best knowledge:

- (i) none of our shares or the shares of our consolidated foreign operating entities are owned by governmental entities in the jurisdiction in which we or such consolidated foreign operating entities are incorporated or otherwise organized;
- (ii) none of the governmental entities in the applicable foreign jurisdiction with respect to our registered public accounting firm have a controlling financial interest in us or any of our consolidated foreign operating entities;
- (iii) none of the members of our board of directors or the board of directors of our operating entities is an official of the Chinese Communist Party; and
- (iv) our or our operating entities’ articles of incorporation do not contain any charter of the Chinese Communist Party.

## PART III

### Item 17. Financial Statements

We have elected to provide financial statements pursuant to Item 18.

### Item 18. Financial Statements

The consolidated financial statements of Gracell Biotechnologies Inc., its subsidiaries and its consolidated variable interest entities are included at the end of this annual report.

### Item 19. Exhibits

Exhibit Number	Description of Document
1.1	<a href="#">Fourth Amended and Restated Memorandum and Articles of Association of the Registrant (incorporated herein by reference to Exhibit 3.2 to the registration statement on Form F-1 filed with the Securities and Exchange Commission on December 18, 2020 (File No. 333-251494))</a>
2.1	<a href="#">Registrant's Specimen American Depositary Receipt (included in Exhibit 2.3)</a>
2.2	<a href="#">Registrant's Specimen Certificate for Ordinary Shares (incorporated herein by reference to Exhibit 4.2 to the registration statement on Form F-1 filed with the Securities and Exchange Commission on December 18, 2020 (File No. 333-251494))</a>
2.3	<a href="#">Deposit Agreement, among the Registrant, the depositary and holder and beneficial owners of the American Depositary Receipts issued thereunder, dated January 7, 2021 (incorporated herein by reference to Exhibit 4.3 to the registration statement on Form S-8 filed with the Securities and Exchange Commission on February 25, 2021 (File No. 333-253486))</a>
2.4	<a href="#">Second Amended and Restated Shareholders Agreement, dated as of October 20, 2020, among the Registrant and other parties thereto (incorporated herein by reference to Exhibit 4.4 to the registration statement on Form F-1 filed with the Securities and Exchange Commission on December 18, 2020 (File No. 333-251494))</a>
2.5	<a href="#">Description of Securities (incorporated herein by reference to Exhibit 2.5 of the annual report on Form 20-F filed with the Securities and Exchange Commission on April 23, 2021 (File No. 001-39838))</a>
4.1	<a href="#">Third Amended and Restated 2017 Employee Stock Option Plan (incorporated herein by reference to Exhibit 10.1 to the registration statement on Form F-1 filed with the Securities and Exchange Commission on December 18, 2020 (File No. 333-251494))</a>
4.2	<a href="#">2020 Share Incentive Plan (incorporated herein by reference to Exhibit 10.2 to the registration statement on Form F-1 filed with the Securities and Exchange Commission on December 18, 2020 (File No. 333-251494))</a>
4.3	<a href="#">Form of Indemnification Agreement between the Registrant and its directors and executive officers (incorporated herein by reference to Exhibit 10.3 to the registration statement on Form F-1 filed with the Securities and Exchange Commission on December 18, 2020 (File No. 333-251494))</a>
4.4	<a href="#">Form of Director Agreement between the Registrant and a director of the Registrant (incorporated herein by reference to Exhibit 10.4 to the registration statement on Form F-1 filed with the Securities and Exchange Commission on December 18, 2020 (File No. 333-251494))</a>

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- 4.5 [Form of Employment Agreement between the Registrant and its executive officer \(incorporated herein by reference to Exhibit 10.5 to the registration statement on Form F-1 filed with the Securities and Exchange Commission on December 18, 2020 \(File No. 333-251494\)\)](#)
- 4.6 [Spouse Consent Letter from the spouse of a shareholder of Shanghai Gracell Biotech, dated November 10, 2020 \(incorporated herein by reference to Exhibit 10.6 to the registration statement on Form F-1 filed with the Securities and Exchange Commission on December 18, 2020 \(File No. 333-251494\)\)](#)
- 4.7 [Technical Consultation and Service Agreement between Gracell Bioscience and Shanghai Gracell Biotech dated January 3, 2019 \(incorporated herein by reference to Exhibit 10.7 to the registration statement on Form F-1 filed with the Securities and Exchange Commission on December 18, 2020 \(File No. 333-251494\)\)](#)
- 4.8 [Business Cooperation Agreement between Gracell Bioscience and Shanghai Gracell Biotech dated January 3, 2019 \(incorporated herein by reference to Exhibit 10.8 to the registration statement on Form F-1 filed with the Securities and Exchange Commission on December 18, 2020 \(File No. 333-251494\)\)](#)
- 4.9 [Amendment to Voting Rights Proxy Agreement and Power of Attorney among Shanghai Gracell Biotech, Gracell Bioscience and Dr. William Wei Cao dated November 10, 2020 \(incorporated herein by reference to Exhibit 10.9 to the registration statement on Form F-1 filed with the Securities and Exchange Commission on December 18, 2020 \(File No. 333-251494\)\)](#)
- 4.10 [Voting Rights Proxy Agreement and Power of Attorney among Shanghai Gracell Biotech, Gracell Bioscience and Xiaomi Hua dated November 10, 2020 \(incorporated herein by reference to Exhibit 10.10 to the registration statement on Form F-1 filed with the Securities and Exchange Commission on December 18, 2020 \(File No. 333-251494\)\)](#)
- 4.11 [Equity Pledge Supplementary Agreement among Gracell Bioscience, Shanghai Gracell Biotech and Dr. William Wei Cao dated November 10, 2020 \(incorporated herein by reference to Exhibit 10.11 to the registration statement on Form F-1 filed with the Securities and Exchange Commission on December 18, 2020 \(File No. 333-251494\)\)](#)
- 4.12 [Equity Pledge Agreement among Gracell Bioscience, Shanghai Gracell Biotech and Xiaomi Hua dated November 10, 2020 \(incorporated herein by reference to Exhibit 10.12 to the registration statement on Form F-1 filed with the Securities and Exchange Commission on December 18, 2020 \(File No. 333-251494\)\)](#)
- 4.13 [Amendment to Call Option Agreement among Gracell Bioscience, Shanghai Gracell Biotech and Dr. William Wei Cao dated November 10, 2020 \(incorporated herein by reference to Exhibit 10.13 to the registration statement on Form F-1 filed with the Securities and Exchange Commission on December 18, 2020 \(File No. 333-251494\)\)](#)
- 4.14 [Call Option Agreement among Gracell Bioscience, Shanghai Gracell Biotech and Xiaomi Hua dated November 10, 2020 \(incorporated herein by reference to Exhibit 10.14 to the registration statement on Form F-1 filed with the Securities and Exchange Commission on December 18, 2020 \(File No. 333-251494\)\)](#)
- 4.15<sup>Ü</sup> [Exclusive License Agreement between Unitex Capital, Ltd and Promab Biotechnologies, Inc. dated April 19, 2017 \(incorporated herein by reference to Exhibit 10.21 to the registration statement on Form F-1 filed with the Securities and Exchange Commission on December 18, 2020 \(File No. 333-251494\)\)](#)
- 4.16<sup>Ü</sup> [Amended and Restated No. 1 to Exclusive License Agreement with Sublicensing Terms among Shanghai Gracell Biotech, Unitex Capital, Ltd and Promab Biotechnologies, Inc. dated November 29, 2017 \(incorporated herein by reference to Exhibit 10.22 to the registration statement on Form F-1 filed with the Securities and Exchange Commission on December 18, 2020 \(File No. 333-251494\)\)](#)
- 4.17<sup>Ü</sup> [Exclusive License Agreement between FutureGen Biopharmaceutical Co., Ltd. and Gracell Biotechnologies \(HK\) Limited, dated May 11, 2021 \(incorporated herein by reference to Exhibit 4.17 of the annual report on Form 20-F filed with the Securities and Exchange Commission on April 22, 2022 \(File No. 001-39838\)\)](#)



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4.18 <sup>Ü</sup>	<a href="#"><u>Manufacturing Services Agreement between Lonza Houston, Inc., Suzhou Gracell Biotechnologies Co., Ltd., and Gracell Biopharmaceuticals, Inc., dated March 31, 2021 (incorporated herein by reference to Exhibit 4.18 of the annual report on Form 20-F filed with the Securities and Exchange Commission on April 22, 2022 (File No. 001-39838)).</u></a>
4.19	<a href="#"><u>Sales Agreement, dated as of April 28, 2022, by and among Gracell Biotechnologies, Inc., Cantor Fitzgerald &amp; Co. and BTIG, LLC (incorporated herein by reference to Exhibit 1.2 to the registration statement on Form F-3 filed with the Securities and Exchange Commission on June 17, 2022 (File No. 333-264545)).</u></a>
4.20 <sup>^</sup>	<a href="#"><u>License Agreement between Seagen Inc. and Gracell Biotechnologies, Inc., dated March 8, 2023.</u></a>
8.1*	<a href="#"><u>List of significant subsidiaries and consolidated affiliated entity of the Registrant</u></a>
11.1	<a href="#"><u>Code of Business Conduct and Ethics of the Registrant (incorporated herein by reference to Exhibit 99.1 to the registration statement on Form F-1 filed with the Securities and Exchange Commission on December 18, 2020 (File No. 333-251494)).</u></a>
12.1*	<a href="#"><u>Certification by Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u></a>
12.2*	<a href="#"><u>Certification by Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u></a>
13.1**	<a href="#"><u>Certification by Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u></a>
13.2**	<a href="#"><u>Certification by Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u></a>
15.1*	<a href="#"><u>Consent of PricewaterhouseCoopers Zhong Tian LLP, an independent Registered Public Accounting Firm</u></a>
15.2*	<a href="#"><u>Consent of Harney Westwood &amp; Riegels</u></a>
15.3*	<a href="#"><u>Consent of AllBright Law Offices</u></a>
15.4**	<a href="#"><u>Submission under Item 161(a) of Form 20-F in relation to the Holding Foreign Companies Accountable Act</u></a>
101.INS*	Inline XBRL Instance Document — the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File — the cover page XBRL tags are embedded within the Exhibit 101 Inline XBRL document set

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\* Filed with this Annual Report on Form 20-F.

\*\* Furnished with this Annual Report on Form 20-F.

Ü Pursuant to Item 601(b)(10)(iv) of Regulation S-K promulgated by the Securities and Exchange Commission, certain portions of this exhibit have been redacted because they are both not material and the type that the Company treats as private or confidential.

**SIGNATURES**

The registrant hereby certifies that it meets all of the requirements for filing its annual report on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Date: April 25, 2023

**Gracell Biotechnologies Inc.**

By: /s/ William Wei Cao

Name: William Wei Cao

Title: Chairman of the Board of Directors and Chief  
Executive Officer

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, 2022 and 2021, and the related consolidated statements of comprehensive loss, of changes in shareholders’ equity (deficit) and of cash flows for each of the three years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022 in conformity with accounting principles generally accepted in the United States of America.

### ***Change in Accounting Principle***

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2021.

### ***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. 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

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  
April 25, 2023

We have served as the Company’s auditor since 2020.

**GRACELL BIOTECHNOLOGIES INC.**

**CONSOLIDATED BALANCE SHEETS AS OF DECEMBER 31, 2021 AND 2022**

(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Notes	As of December 31,		
		2021	2022	
		RMB	RMB	US\$ (Note 2)
<b>ASSETS</b>				
<b>Current assets:</b>				
Cash and cash equivalents		1,829,006	1,454,645	210,904
Short-term investments		3,615	3,559	516
Prepayments and other current assets	3	52,459	37,551	5,443
<b>Total current assets</b>		<b>1,885,080</b>	<b>1,495,755</b>	<b>216,863</b>
Property, equipment and software, net	4	123,818	123,126	17,852
Operating lease right-of-use assets	5	29,652	21,546	3,124
Other non-current assets	6	21,587	15,849	2,298
<b>TOTAL ASSETS</b>		<b>2,060,137</b>	<b>1,656,276</b>	<b>240,137</b>
<b>LIABILITIES, AND SHAREHOLDERS' EQUITY</b>				
<b>Current liabilities:</b>				
Accruals and other current liabilities (including accruals and other current liabilities of the consolidated VIEs without recourse to the Company of RMB35,685 and RMB41,425 as of December 31, 2021 and 2022, respectively)	7	69,120	85,991	12,467
Short-term borrowings (including short-term borrowings of the consolidated VIEs without recourse to the Company of RMB66,100 and RMB104,600 as of December 31, 2021 and 2022, respectively)	8	66,100	104,600	15,166
Operating lease liabilities, current (including operating lease liabilities, current of the consolidated VIEs without recourse to the Company of RMB4,367 and RMB4,998 as of December 31, 2021 and 2022, respectively)	5	17,527	17,545	2,544
Amounts due to a related party		—	4,662	676
Current portion of long-term borrowings (including current portion of long-term borrowings of the consolidated VIEs without recourse to the Company of RMB2,376 and RMB7,844 as of December 31, 2021 and 2022, respectively)	8	2,376	7,844	1,137
<b>Total current liabilities</b>		<b>155,123</b>	<b>220,642</b>	<b>31,990</b>
Operating lease liabilities, non-current (including operating lease liabilities, non-current of the consolidated VIEs without recourse to the Company of RMB730 and RMB4,436 as of December 31, 2021 and 2022, respectively)	5	14,830	6,485	940
Long-term borrowings (including long-term borrowings of the consolidated VIEs without recourse to the Company of RMB54,349 and RMB46,505 as of December 31, 2021 and 2022, respectively)	8	54,349	46,505	6,743
Other non-current liabilities		8,464	6,879	997
<b>TOTAL LIABILITIES</b>		<b>232,766</b>	<b>280,511</b>	<b>40,670</b>
<b>Commitments and contingencies</b>	15			
<b>Shareholders' equity:</b>				
Ordinary shares (par value of US\$0.0001 per share; 500,000,000 and 500,000,000 shares authorized; 337,969,926 and 338,498,819 shares issued and outstanding as of December 31, 2021 and 2022, respectively)	9	223	223	32
Additional paid-in capital		2,902,856	2,927,295	424,418
Accumulated other comprehensive (loss) income		(57,936)	73,528	10,661
Accumulated deficit		(1,017,772)	(1,625,281)	(235,644)
<b>Total shareholders' equity</b>		<b>1,827,371</b>	<b>1,375,765</b>	<b>199,467</b>
<b>TOTAL LIABILITIES, AND SHAREHOLDERS' EQUITY</b>		<b>2,060,137</b>	<b>1,656,276</b>	<b>240,137</b>

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, 2020, 2021 AND 2022**

(All amounts in thousands, except for share and per share data, unless otherwise noted)

		For the years ended December 31,			
	Notes	2020 RMB	2021 RMB	2022 RMB	US\$ (Note 2)
<b>Revenues</b>					
Licensing and collaboration revenue		—	366	—	—
<b>Expenses</b>					
Research and development expenses		(168,830)	(326,899)	(485,388)	(70,375)
Administrative expenses		(45,566)	(137,040)	(139,270)	(20,192)
<b>Loss from operations</b>		<b>(214,396)</b>	<b>(463,573)</b>	<b>(624,658)</b>	<b>(90,567)</b>
Interest income		2,870	9,116	23,917	3,468
Interest expense		(2,155)	(5,063)	(6,737)	(977)
Other income		4,707	9,120	8,001	1,160
Foreign exchange loss, net		(2,914)	(1,297)	(8,169)	(1,184)
Others, net		(12)	(57)	159	23
<b>Loss before income tax</b>		<b>(211,900)</b>	<b>(451,754)</b>	<b>(607,487)</b>	<b>(88,077)</b>
Income tax expense	12	—	—	(22)	(3)
<b>Net loss</b>		<b>(211,900)</b>	<b>(451,754)</b>	<b>(607,509)</b>	<b>(88,080)</b>
Accretion of convertible redeemable preferred shares to redemption value	10	(62,733)	(1,989)	—	—
<b>Net loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders</b>		<b>(274,633)</b>	<b>(453,743)</b>	<b>(607,509)</b>	<b>(88,080)</b>
<b>Other comprehensive (loss) income</b>					
Foreign currency translation adjustments, net of nil tax		(20,753)	(34,024)	131,464	19,060
<b>Total comprehensive loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders</b>		<b>(295,386)</b>	<b>(487,767)</b>	<b>(476,045)</b>	<b>(69,020)</b>
<b>Weighted average number of ordinary shares used in per share calculation:</b>					
—Basic	13	99,044,776	328,866,599	338,342,051	338,342,051
—Diluted	13	99,044,776	328,866,599	338,342,051	338,342,051
<b>Net loss per share attributable to Gracell Biotechnologies Inc.'s ordinary shareholders</b>					
—Basic	13	(2.77)	(1.38)	(1.80)	(0.26)
—Diluted	13	(2.77)	(1.38)	(1.80)	(0.26)

The accompanying notes are an integral part of these consolidated financial statements.

GRACELL BIOTECHNOLOGIES INC.

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY (DEFICIT)

FOR THE YEARS ENDED DECEMBER 31, 2020, 2021 AND 2022

(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Ordinary shares					
	Number of Shares	Amount RMB	Additional paid-in capital RMB	Accumulated other comprehensive income (loss) RMB	Accumulated deficit RMB	Total shareholders' equity/(deficit) RMB
<b>Balance as of January 1, 2020</b>	<b>99,044,776</b>	<b>68</b>	<b>—</b>	<b>(3,159)</b>	<b>(289,396)</b>	<b>(292,487)</b>
Net loss	—	—	—	—	(211,900)	(211,900)
Accretions of convertible redeemable preferred shares to redemption value	—	—	—	—	(62,733)	(62,733)
Foreign currency translation adjustment	—	—	—	(20,753)	—	(20,753)
<b>Balance as of December 31, 2020</b>	<b>99,044,776</b>	<b>68</b>	<b>—</b>	<b>(23,912)</b>	<b>(564,029)</b>	<b>(587,873)</b>
Net loss	—	—	—	—	(451,754)	(451,754)
Accretions of convertible redeemable preferred shares to redemption value	—	—	—	—	(1,989)	(1,989)
Share-based compensation	—	—	60,384	—	—	60,384
Conversion of preferred shares to ordinary shares upon the completion of initial public offering ("IPO")	173,771,220	113	1,409,412	—	—	1,409,525
Issuance of ordinary shares upon IPO and over-allotment, net of issuance cost	63,250,000	41	1,431,316	—	—	1,431,357
Exercise of options and registration of restricted share units	1,903,930	1	1,744	—	—	1,745
Foreign currency translation adjustment	—	—	—	(34,024)	—	(34,024)
<b>Balance as of December 31, 2021</b>	<b>337,969,926</b>	<b>223</b>	<b>2,902,856</b>	<b>(57,936)</b>	<b>(1,017,772)</b>	<b>1,827,371</b>
Net loss	—	—	—	—	(607,509)	(607,509)
Share-based compensation	—	—	24,102	—	—	24,102
Exercise of options and registration of restricted share units	528,893	—	337	—	—	337
Foreign currency translation adjustment	—	—	—	131,464	—	131,464
<b>Balance as of December 31, 2022</b>	<b>338,498,819</b>	<b>223</b>	<b>2,927,295</b>	<b>73,528</b>	<b>(1,625,281)</b>	<b>1,375,765</b>

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, 2020, 2021 AND 2022**

(All amounts in thousands, except for share and per share data, unless otherwise noted)

	For the years ended December 31,			
	2020	2021	2022	
	RMB	RMB	RMB	US\$ (Note 2)
<b>Cash flows from operating activities:</b>				
Net loss	(211,900)	(451,754)	(607,509)	(88,080)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation of property, equipment and software	21,589	44,870	58,766	8,520
Share-based compensation	—	60,384	24,102	3,494
Amortization of right-of use assets and interest of lease liabilities	—	15,397	18,742	2,717
Foreign exchange (gain) loss, net	2,914	1,297	8,169	1,184
Changes in operating assets and liabilities:				
Prepayments and other current assets	(18,295)	(10,040)	14,096	2,044
Amounts due to related parties	—	—	4,662	676
Accrued liabilities and other current liabilities	7,543	43,760	16,871	2,446
Other non-current assets	—	(1,619)	—	—
Lease liabilities	—	(15,309)	(18,963)	(2,749)
Other non-current liabilities	—	8,464	(1,584)	(230)
<b>Net cash used in operating activities</b>	<b>(198,149)</b>	<b>(304,550)</b>	<b>(482,648)</b>	<b>(69,978)</b>
<b>Cash flows from investing activities:</b>				
Purchase of property, equipment and software	(79,400)	(56,743)	(48,388)	(7,016)
Investments in short-term investments	(28,055)	(10,000)	(261,166)	(37,866)
Proceeds from disposal of short-term investments	13,514	25,127	261,222	37,874
<b>Net cash used in investing activities</b>	<b>(93,941)</b>	<b>(41,616)</b>	<b>(48,332)</b>	<b>(7,008)</b>
<b>Cash flows from financing activities:</b>				
Proceeds from initial public offering and over-allotment, net of underwriting commissions	—	1,448,959	—	—
Proceeds from exercise of options and registration of restricted share units	—	1,745	337	49
Repayment of convertible loans	(138,695)	—	—	—
Proceeds from issuance of convertible redeemable preferred shares, net of issuance costs	795,420	—	—	—
Proceeds from bank borrowings	103,008	71,233	104,600	15,166
Repayments of bank borrowings	(122)	(51,294)	(68,476)	(9,928)
Payment of initial public offering costs	(3,144)	(14,458)	—	—
Payment of offering costs	—	—	(3,137)	(455)
<b>Net cash generated from financing activities</b>	<b>756,467</b>	<b>1,456,185</b>	<b>33,324</b>	<b>4,832</b>
Effect of exchange rate on cash and cash equivalents	(22,127)	(35,321)	123,295	17,877
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>442,250</b>	<b>1,074,698</b>	<b>(374,361)</b>	<b>(54,277)</b>
Cash and cash equivalents at the beginning of year	312,058	754,308	1,829,006	265,181
<b>Cash and cash equivalents at the end of year</b>	<b>754,308</b>	<b>1,829,006</b>	<b>1,454,645</b>	<b>210,904</b>
<b>Supplemental cashflow disclosures:</b>				
Interest paid	2,155	5,063	6,737	977
<b>Non-cash activities:</b>				
Accretion of convertible redeemable preferred shares to redemption value	62,733	1,989	—	—
Payables for deferred initial public offering cost	14,924	—	—	—

The accompanying notes are an integral part of these consolidated financial statements.

# GRACELL BIOTECHNOLOGIES INC.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(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 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, 2022, the Company’s principal subsidiaries are as follows:

	<b>Date of incorporation</b>	<b>Place of incorporation</b>	<b>Percentage of legal ownership by the Company</b>	<b>Principal activities</b>
<b>Subsidiaries</b>				
Gracell Biotechnologies Holdings Limited (“Gracell BVI”)	May 22, 2018	British Virgin Islands	100 %	Investment holding
Gracell Biotechnologies (HK) Limited (“Gracell HK”)	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
Gracell Biopharmaceuticals, Inc.	February 11, 2020	The United States of America	100 %	Research and development of innovative medicines
Gracell Biomedicine (Shanghai) Co., Ltd.	August 19, 2020	The PRC	100 %	Research and development of innovative medicines
Hainan Gracell Biomedicine Co., Ltd.	June 25, 2021	The PRC	100 %	Research and development of innovative medicines
Suzhou Gracell Bioscience Co., Ltd.	July 12, 2021	The PRC	100 %	Research and development of innovative medicines
<b>VIE</b>				
Gracell Biotechnologies (Shanghai) Co., Ltd.	May 22, 2017	The PRC	—	Research and development of innovative medicines
<b>VIE’s subsidiary</b>				
Suzhou Gracell Biotechnologies Co., Ltd. (“Suzhou Gracell”)	April 23, 2018	The PRC	—	Research and development of innovative medicines

On January 12, 2021, the Company completed its Initial Public Offering and became listed on the Nasdaq Global Selected Market (see Note 9 for details).

**GRACELL BIOTECHNOLOGIES INC.**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**(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 William Wei Cao (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**

The Group operates certain of its businesses in the PRC through the VIE, whose equity interests are ultimately held by the Founder and other shareholders of the Group through the VIE’s nominee shareholder.

Neither the Company nor its subsidiaries own any equity interest or direct foreign investment in the VIE, Gracell Biotechnologies (Shanghai) Co., Ltd., or Shanghai Gracell Biotech, and the VIE’s subsidiary, Suzhou Gracell Biotechnologies Co., Ltd., or Suzhou Gracell Biotech. Instead, the Company relies on contractual arrangements among its PRC subsidiary, the VIE and the VIE’s nominee shareholders, which allow the Company to (i) direct the activities of the VIE that most significantly impact the VIE’s economic performance; (ii) receive substantially all of the economic benefits of the VIE and the VIE’s subsidiary; and (iii) have an exclusive option to purchase all or part of the equity interests in the VIE when and to the extent permitted by PRC law. As a result of these contractual arrangements, the Company is considered the primary beneficiary of the VIE and the VIE’s subsidiary for accounting purposes and is able to consolidate the financial results of the VIE and VIE’s subsidiary in the consolidated financial statements in accordance with U.S. GAAP. 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.

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 the 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 VIE and exercise other voting rights the shareholders are entitled to.

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.

**GRACELL BIOTECHNOLOGIES INC.**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**(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)**

*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 distribute 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 VIE engages the WFOE as its exclusive consultant and provider of fund, human, technology and intellectual properties services 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, the VIE agrees to pay an annual service fee to the WFOE and such fee is determined by the WFOE based on its services provided including various factors such as the 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 the 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 the WFOE, the 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 the WFOE. In exchange, the VIE agrees to pay a monthly service fee to the WFOE based on the services provided including various factors such as WFOE's incurred technology support and consulting services fees, performance data and the 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 the WFOE, the shareholders of the VIE have to pledge all of their equity interests in the VIE to the 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, business cooperation agreement and voting rights proxy agreement. If the VIE and/or its shareholders breach their contractual obligations under those agreements, the WFOE, as pledgee, will be entitled to certain rights, including the right to sell the pledged equity interests. The shareholders of the 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, the 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.

GRACELL BIOTECHNOLOGIES INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(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)

*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 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, 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 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;

**GRACELL BIOTECHNOLOGIES INC.**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**(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)*

- 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 the VIE under U.S. GAAP;
- restricting or prohibiting the Group's use of the proceeds of the public 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.

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 the ultimate primary beneficiary of 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.

GRACELL BIOTECHNOLOGIES INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(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)*

The following financial information of the Group's VIE and the VIE's subsidiary as of December 31, 2021 and 2022 and for each of the three years in the period ended December 31, 2022 is included in the accompanying consolidated financial statements of the Group as follows:

	As of December 31,		
	2021 RMB	2022 RMB	US\$ (Note 2)
<b>ASSETS</b>			
<b>Current assets:</b>			
Cash and cash equivalents	122,220	110,479	16,018
Short-term investments	3,615	3,559	516
Amounts due from related parties	65,705	93,705	13,586
Prepayments and other current assets	40,968	20,675	2,998
<b>Total current assets</b>	<b>232,508</b>	<b>228,418</b>	<b>33,118</b>
Property, equipment and software	60,944	44,742	6,487
Operating lease, right-of-use assets	4,827	7,911	1,147
Other non-current assets	7,983	2,746	398
<b>TOTAL ASSETS</b>	<b>306,262</b>	<b>283,817</b>	<b>41,150</b>
<b>LIABILITIES</b>			
<b>Current liabilities:</b>			
Amounts due to related parties	486,794	676,174	98,036
Accruals and other current liabilities	35,685	41,425	6,006
Short-term borrowings	66,100	104,600	15,166
Operating lease liabilities, current	4,367	4,998	725
Current portion of long-term borrowings	2,376	7,844	1,137
<b>Total current liabilities</b>	<b>595,322</b>	<b>835,041</b>	<b>121,070</b>
Amounts due to related parties	59,500	59,500	8,627
Long-term borrowings	54,349	46,505	6,742
Operating lease liabilities, non-current	730	4,436	643
<b>TOTAL LIABILITIES</b>	<b>709,901</b>	<b>945,482</b>	<b>137,082</b>

	For the years ended December 31,			
	2020 RMB	2021 RMB	2022 RMB	US\$ (Note 2)
<b>Total revenue from related parties</b>	<b>16,906</b>	<b>16,226</b>	<b>26,415</b>	<b>3,830</b>
<b>Net loss</b>	<b>(100,195)</b>	<b>(225,650)</b>	<b>(263,157)</b>	<b>(38,154)</b>

	For the years ended December 31,			
	2020 RMB	2021 RMB	2022 RMB	US\$ (Note 2)
<b>Net cash used in operating activities</b>	<b>(84,862)</b>	<b>(166,777)</b>	<b>(210,598)</b>	<b>(30,534)</b>
<b>Net cash used in investing activities</b>	<b>(68,628)</b>	<b>(2,730)</b>	<b>(9,055)</b>	<b>(1,313)</b>
<b>Net cash generated from financing activities</b>	<b>161,086</b>	<b>241,978</b>	<b>207,912</b>	<b>30,144</b>



**GRACELL BIOTECHNOLOGIES INC.**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**(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)*

The VIE provided research and development related service to the WFOE and recognized revenue of RMB16.9 million, RMB16.2 million and RMB26.4million in the years ended December 31, 2020, 2021 and 2022, respectively.

The VIE received business cooperation support from the WFOE and recognized administrative expenses of nil, RMB23.0 million and RMB16.6 million in total in the year ended December 31, 2020, 2021 and 2022, respectively.

The VIE received loans from the Company of RMB6.9 million, RMB29.6 million and nil in total in the years ended December 31, 2020 and 2021 and 2022, respectively.

The VIE received loans from the WFOE of RMB190.0 million, RMB192.5 million and RMB171.8 million in total in the years ended December 31, 2020, 2021 and 2022, respectively.

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 Company's ability to consolidate 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.

GRACELL BIOTECHNOLOGIES INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(All amounts in thousands, except for share and per share data, unless otherwise noted)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

*Principles of Consolidation (Continued)*

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; (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, British Virgin Islands, United States of America and Hong Kong, the RMB is the functional currency of the Company’s PRC subsidiaries.

Transactions denominated in currencies other than in the functional currency are translated into the functional currency using the exchange rates prevailing at the transaction dates. Monetary assets and liabilities denominated in foreign currencies are translated into functional currency using the applicable exchange rates at the balance sheet date. Non-monetary items that are measured in terms of historical cost in foreign currency are re-measured using the exchange rates at the dates of the initial transactions. Exchange gains or losses arising from foreign currency transactions are included in the consolidated statements of comprehensive loss.

The consolidated financial statements of the Group are translated from the functional currency to the reporting currency, RMB. Assets and liabilities of the subsidiaries are translated into RMB using the exchange rate in effect at each balance sheet date. Income and expenses are translated at the average exchange rates prevailing 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’ equity and consolidated statements of cash flows from RMB into US\$ as of and for the year ended December 31, 2022 are solely for the convenience of the readers and were calculated at the rate of US\$1.00=RMB6.8972, representing the noon buying rate in The City of New York for cable transfers of RMB as certified for customs purposes by the Federal Reserve Bank of New York on December 31, 2022. 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, 2022, or at any other rate. The US\$ convenience translation is not required under U.S. GAAP.

**GRACELL BIOTECHNOLOGIES INC.****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)****(All amounts in thousands, except for share and per share data, unless otherwise noted)****2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)*****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.

The Group does not have any non-financial assets or liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis. The carrying amounts of cash and cash equivalent, short-term investments, other current assets, accrued liabilities and other current liabilities and short-term borrowings approximate their fair values because of their generally short maturities.

***Property, equipment and software***

Property, equipment and software are stated at cost less accumulated depreciation and amortization. Depreciation and amortization is computed using the straight-line method over the estimated useful lives of the assets as follows:

Category	Estimated Useful Life
Machinery and laboratory equipment	5-10 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.

**GRACELL BIOTECHNOLOGIES INC.****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)****(All amounts in thousands, except for share and per share data, unless otherwise noted)****2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)*****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, 2020, 2021 and 2022.

***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, 2022, 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, 2022 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, 2020, 2021 and 2022, no specific subsidies were received by the Group. Other subsidies of RMB 4,707, RMB 9,120 and RMB8,001 for the years ended December 31, 2020, 2021 and 2022 respectively are recognized as other income upon receipt as further performance by the Group is not required.

GRACELL BIOTECHNOLOGIES INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(All amounts in thousands, except for share and per share data, unless otherwise noted)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

*Leases*

The Group adopted ASC 842, Leases, on January 1, 2021.

Leases are classified at the inception date as either a finance lease or an operating lease. Leases that transfer substantially all of the benefits and risks incidental to the ownership of assets are accounted for as finance leases as if there was an acquisition of an asset and incurrence of an obligation at the inception of the lease. All other leases are accounted for as operating leases. The Group had no finance leases for the years ended December 31, 2021 and 2022.

Under ASC 842, at the commencement date, a lessee should recognize a financing liability equal to the present value of future lease payments and a right to use ("ROU") asset. The expense recognition is consistent with the expense recognition under the existing lease guidance, 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.

The Group, as an emerging growth company, elected to early adopt the standard for annual reporting period beginning January 1, 2021, utilizing the modified retrospective transition method. The Group has recorded lease assets and liabilities of approximately RMB 24.5 million on its consolidated balance sheet on January 1, 2021, with no material impact to its consolidated statements of comprehensive loss and consolidated statements of cash flows.

After the initial adoption of ASC 842 on January 1, 2021, lease liability is measured at the present value of future base rent over the remaining lease terms discounted at 5%, which represents the incremental borrowing rate on January 1, 2021 for a 72 months loan term in China. ROU asset is measured as the initially recognized ROU asset less the difference between (a) cumulative straight-line expense recognized after January 1, 2021 and (b) cumulative accretion of the lease liability under the effective interest rate method after January 1, 2021.

As of December 31, 2021 and 2022, the Company had operating lease ROU assets of RMB 29.7 million and RMB 21.5 million respectively, and operating lease liabilities of RMB 32.4 million and RMB 24.0 million respectively.

*Comprehensive income (loss)*

Comprehensive income (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 income (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.

GRACELL BIOTECHNOLOGIES INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(All amounts in thousands, except for share and per share data, unless otherwise noted)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

*Income taxes (Continued)*

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.

*Share-based compensation*

The Company grants share-based awards 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-based award 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 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.

**GRACELL BIOTECHNOLOGIES INC.****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)****(All amounts in thousands, except for share and per share data, unless otherwise noted)****2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)*****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***

Full time employees of the Group in the PRC participate in a government mandated defined contribution plan, pursuant to which certain pension benefits, medical care, employee housing fund and other welfare benefits are provided to the employees. Chinese labor regulations require that the PRC subsidiaries and the VIE of the Group make contributions to the government for these benefits based on certain percentages of the employees' salaries, up to a maximum amount specified by the local government. The Group has no legal obligation for the benefits beyond the contributions made. The total amounts of such employee benefit expenses, which were expensed as incurred, were approximately RMB 4.29 million, RMB 15.74 million and RMB 20.59 million for the years ended December 31, 2020, 2021 and 2022, respectively.

***Concentration of risks******Concentration of credit risk***

As of December 31, 2021 and 2022, the aggregate amount of cash and cash equivalents and short-term investments of RMB 1,822,364 and RMB 1,403,024 respectively, were held at major financial institutions located in the mainland of China, and RMB 10,257 and RMB 55,180, respectively, were deposited with major financial institutions located outside the mainland of China. 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.



**GRACELL BIOTECHNOLOGIES INC.****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)****(All amounts in thousands, except for share and per share data, unless otherwise noted)****2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)*****Concentration of risks (continued)******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 depreciation of approximately 2.5% and appreciation of 9.2% in the years ended December 31, 2021 and 2022, 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***

The Group qualifies as an "emerging growth company", or EGC, pursuant to the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. As an EGC, the Group does not need to comply with any new or revised financial accounting standards until such date that a private company is otherwise required to comply with such new or revised accounting standards. The Group adopts the following standards based on extended transition period provided to private companies or early adopts as necessary as permitted by the respective standards.

***New and amended standards adopted by the Group***

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 for annual periods beginning after December 15, 2021. Certain amendments in this update should be applied retrospectively or modified retrospectively, all other amendments should be applied prospectively. The Group has adopted ASU 2019-12 and the impact of this adoption was assessed to be not material.

***New and amended standards not yet adopted by the Group***

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.

**GRACELL BIOTECHNOLOGIES INC.**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

(All amounts in thousands, except for share and per share data, unless otherwise noted)

**3. PREPAYMENTS AND OTHER CURRENT ASSETS**

Prepayments and other current assets consist of the following:

	As of December 31,		
	2021 RMB	2022 RMB	US\$ (Note 2)
Deductible value-added tax input	40,690	26,330	3,817
Prepayments for CRO and other services	4,614	5,296	768
Deposits	4,083	3,355	486
Deferred expenses	531	408	59
Prepayment for raw materials	2,335	1,448	210
Others	206	714	103
	<u>52,459</u>	<u>37,551</u>	<u>5,443</u>

**4. PROPERTY, EQUIPMENT AND SOFTWARE**

Property, equipment and software consist of the following:

	As of December 31,		
	2021 RMB	2022 RMB	US\$ (Note 2)
Machinery and laboratory equipment	100,693	138,049	20,015
Leasehold improvements	85,177	101,048	14,651
Computer Software	2,809	10,417	1,510
Construction in Progress	5,149	283	41
Others	4,785	6,890	999
Total property, equipment and software	198,613	256,687	37,216
Less: accumulated depreciation and amortization	(74,795)	(133,561)	(19,364)
Property, equipment and software, net	<u>123,818</u>	<u>123,126</u>	<u>17,852</u>

Depreciation and amortization expenses recognized for the years ended December 31, 2020, 2021 and 2022 were RMB 21,589, RMB 44,870 and RMB 58,766, respectively.

**5. LEASES**

As of December 31, 2022, the Company has operating leases recorded on its balance sheet for certain office spaces and facilities that expire on various dates through 2025. The Group does not plan to cancel the existing lease agreements for its existing facilities prior to their respective expiration dates. When determining the lease term, the Group includes options to extend or terminate the lease when it is reasonably certain that it will exercise that option, if any. All of the Group's leases qualify as operating leases.

Information related to operating leases as of December 31, 2021 and 2022 is as follows.

	As of December 31,		
	2021 RMB	2022 RMB	US\$ (Note 2)
<b>Assets</b>			
Operating lease right-of-use assets	29,652	21,546	3,124
<b>Liabilities</b>			
Operating lease liabilities, current	17,527	17,545	2,544
Operating lease liabilities, non-current	14,830	6,485	940
	<u>32,357</u>	<u>24,030</u>	<u>3,484</u>

**GRACELL BIOTECHNOLOGIES INC.**
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

(All amounts in thousands, except for share and per share data, unless otherwise noted)

**5. LEASES (CONTINUED)**

Future minimum payments under non-cancelable operating leases with initial terms in excess of one year consist of the following as of December 31, 2022:

	RMB	US\$ (Note 2)
For the years ending:		
2023	18,151	2,632
2024	5,029	729
2025	1,623	235
2026	—	—
2027 and thereafter	—	—
Total undiscounted lease payments	24,803	3,596
Less: imputed interest	(773)	(112)
Total lease liabilities	24,030	3,484

For the years ended December 31, 2021 and 2022, total operating lease expense amounted to RMB16,338 and RMB18,742 respectively.

The below table summarizes lease costs and other information for the year ended December 31, 2022:

	As of December 31, 2022	
	RMB	US\$ (Note 2)
<b>Lease costs</b>		
Operating lease cost	18,742	2,717
Short-term lease cost	1,580	229
Total lease cost	20,322	2,946
<b>Other information</b>		
Cash paid for amounts included in the measurement of lease liabilities	18,963	2,749
Right-of-use assets obtained in exchange for new operating lease liabilities	9,345	1,355
Weighted-average remaining lease term	1.13 years	1.13 years
Weighted-average discount rate	5.0 %	5.0 %

For the year ended December 31, 2022, the Company did not have variable lease cost or sublease income.

**GRACELL BIOTECHNOLOGIES INC.**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

(All amounts in thousands, except for share and per share data, unless otherwise noted)

**6. OTHER NON-CURRENT ASSETS**

Other non-current assets consist of the following:

	<b>As of December 31,</b>		
	<b>2021</b>	<b>2022</b>	
	<b>RMB</b>	<b>RMB</b>	<b>US\$</b>
			<b>(Note 2)</b>
Prepayment for property, equipment and software	19,968	10,282	1,491
Long-term deposit	1,619	2,430	352
Others	—	3,137	455
	<u>21,587</u>	<u>15,849</u>	<u>2,298</u>

**7. ACCRUALS AND OTHER CURRENT LIABILITIES**

Accruals and other current liabilities consist of the following:

	<b>As of December 31,</b>		
	<b>2021</b>	<b>2022</b>	
	<b>RMB</b>	<b>RMB</b>	<b>US\$</b>
			<b>(Note 2)</b>
Accrued external research and development related expenses	36,389	47,073	6,825
Salary and welfare payables	20,909	20,622	2,990
Professional service fees	5,161	10,252	1,486
Deferred income for reimbursement of the expenses related to the establishment of the ADS facility	2,902	2,902	421
Others	3,759	5,142	745
	<u>69,120</u>	<u>85,991</u>	<u>12,467</u>

**8. BORROWINGS**

	<b>As of December 31,</b>		
	<b>2021</b>	<b>2022</b>	
	<b>RMB</b>	<b>RMB</b>	<b>US\$</b>
			<b>(Note 2)</b>
<b>Current</b>			
Short-term borrowings:			
Bank loans	66,100	104,600	15,166
Current portion of long-term borrowings	2,376	7,844	1,137
Total current borrowings	<u>68,476</u>	<u>112,444</u>	<u>16,303</u>
<b>Non-Current</b>			
Long-term borrowings:			
Bank loans	54,349	46,505	6,743
Total non-current borrowings	<u>54,349</u>	<u>46,505</u>	<u>6,743</u>
Total borrowings	<u>122,825</u>	<u>158,949</u>	<u>23,046</u>

**GRACELL BIOTECHNOLOGIES INC.****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

(All amounts in thousands, except for share and per share data, unless otherwise noted)

**8. BORROWINGS (CONTINUED)*****Short-term borrowings***

In June, July, August, November and December 2021, Suzhou Gracell entered into five loan agreements with China Construction Bank, under which Suzhou Gracell borrowed RMB6.1 million, RMB5.0 million, RMB5.0 million, RMB5.0 million, RMB5.0 million, respectively, for a term of 12 months at a fixed annual rate equal to the one-year loan prime rate plus 0.45%. These loans were paid back to the bank during 2022.

In December 2022, Suzhou Gracell entered into a loan agreement with China Construction Bank, under which Suzhou Gracell borrowed RMB20 million for a term of 12 months. The effective interest rate of this borrowing is 3.8% per annum.

Other than the interest rate, these loan agreements with China Construction Bank have substantially the same terms and conditions. The effective interest rate of these borrowing is 3.65% to 4.35% per annum.

In March 2021, Suzhou Gracell entered into a loan agreement with China CITIC Bank. Under the agreement Suzhou Gracell borrowed a principal amount of RMB10.0 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 0.15%. Suzhou Gracell is required to make interest payments on the loan on a monthly basis and repay the principal at the end of the loan term. This loan was paid back to the bank during 2022.

In August 2022, Suzhou Gracell entered into a loan agreement with China CITIC Bank. Under the agreement Suzhou Gracell borrowed a principal amount of RMB20.0 million in the form of a term loan for 12 months. The effective interest rate of this borrowing is 3.8% per annum. Suzhou Gracell is required to make interest payments on the loan on a monthly basis and repay the principal at the end of the loan term.

In March and June 2022, Suzhou Gracell entered into three loan agreements with China Industrial Bank Co., Ltd., under which Suzhou Gracell borrowed principal amounts of RMB9.9 million, RMB9.9 million and RMB9.8 million in the form of three term loans for 12 months. The effective interest rate of these borrowings is 4.30% per annum. Suzhou Gracell is required to make interest payments on the loans on a monthly basis and repay the principal at the end of the loan term.

In October and November 2021, Suzhou Gracell entered into two loan agreements with Hangzhou Bank. Under the agreements, Suzhou Gracell borrowed principal amounts of RMB10.0 million and RMB20.0 million in the form of two term loans for 12 months. The effective interest rate of these borrowings is 4.35% per annum. Suzhou Gracell is required to make interest payments on the loan on a monthly basis and repay the principal at the end of the loan term. These loans were paid back to the bank during 2022.

In March and August 2022, Suzhou Gracell entered into two loan agreements with Hangzhou Bank. Under the agreements, Suzhou Gracell borrowed principal amounts of RMB20.0 million and RMB15.0 million in the form of two term loans for 12 months. The effective interest rate of these borrowings is 4.35% and 3.76% per annum respectively. Suzhou Gracell is required to make interest payments on the loan on a monthly basis and repay the principal at the end of the loan term.

***Long-term borrowings***

In January 2020, Suzhou Gracell entered into a loan agreement with Bank of China, under which Suzhou Gracell obtained a term loan facility of RMB69.0 million for 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%. Suzhou Gracell is required to make interest payments on the loan on a semi-annual 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. Suzhou Gracell borrowed an aggregate principal amount of RMB44.28 million within the facility limit as of December 31, 2022. The effective interest rate of these borrowings is 4.85% to 5.00% per annum.

**GRACELL BIOTECHNOLOGIES INC.****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)****(All amounts in thousands, except for share and per share data, unless otherwise noted)****8. BORROWINGS (CONTINUED)*****Long-term borrowings (continued)***

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. Suzhou Gracell borrowed an aggregate principal amount of RMB13.87 million within the facility limit and repaid RMB3.80 million as of December 31, 2022. The effective interest rate of these borrowings is 4.85% per annum.

**9. ORDINARY SHARES**

As of December 31, 2019 and 2020, 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. On March 6, 2020, 1,044,776 ordinary shares of the Company was transferred from Tonghe II to OrbiMed Asia Partners III, L.P., King Star Med LP, LAV Granite Limited, LAV Biosciences Fund V, L.P., Victory Treasure Limited and OrbiMed Asia Partners III, L.P. On October 14, 2020, William Cao Wei transferred 5,910,000 ordinary shares of the Company to Michelia Figo Holding Limited with an aggregate consideration of US\$1.00 per share.

On January 12, 2021, the Company completed its IPO. At the closing of its IPO, the Company issued 11,000,000 American depositary shares (“ADSs”) at public offering price of US\$19.00 per ADS. The number of ADSs issued at closing included the exercise in full of the underwriters’ option to purchase 1,650,000 additional ADSs from the Company. The aggregate gross proceeds from the IPO were approximately US\$240 million, before deducting underwriting discounts and commissions and estimated offering expenses payable by the Company. Each ADS represents 5 ordinary shares of the Company. Upon the completion of the IPO, the Company’s then outstanding 31,343,284 Series A Preferred Shares, 21,735,721 Series B-1 Preferred Shares, 59,327,653 Series B-2 Preferred Shares and 61,364,562 Series C Preferred Shares were converted into 31,343,284, 21,735,721, 59,327,653 and 61,364,562 ordinary shares, respectively.

As of December 31, 2022, 338,498,819 shares of ordinary shares were issued and outstanding.

**GRACELL BIOTECHNOLOGIES INC.**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

(All amounts in thousands, except for share and per share data, unless otherwise noted)

**10. CONVERTIBLE REDEEMABLE PREFERRED SHARES**

On January 12, 2021, the Company completed its IPO. Upon the completion of the IPO, the Company's then outstanding 31,343,284 Series A Preferred Shares, 21,735,721 Series B-1 Preferred Shares, 59,327,653 Series B-2 Preferred Shares and 61,364,562 Series C Preferred Shares were converted into 31,343,284, 21,735,721, 59,327,653 and 61,364,562 ordinary shares, respectively.

The Company's Preferred Shares activities for the periods presented are summarized below:

<b>Mezzanine equity</b>	<b>Series A RMB</b>	<b>Series B-1 RMB</b>	<b>Series B-2 RMB</b>	<b>Series C RMB</b>	<b>Total RMB</b>
Balance as of December 31, 2019	82,334	—	465,509	—	547,843
Issuance of Series B 1 Preferred Shares	—	138,695	—	—	138,695
Issuance of Series C Preferred Shares	—	—	—	658,265	658,265
Accretion of Series A Preferred Shares to redemption value	28,134	—	—	—	28,134
Accretion of Series B-1 Preferred Shares to redemption value	—	3,786	—	—	3,786
Accretion of Series B-2 Preferred Shares to redemption value	—	—	30,290	—	30,290
Accretion of Series C Preferred Shares to redemption value	—	—	—	523	523
Balance as of December 31, 2020	110,468	142,481	495,799	658,788	1,407,536
Accretion of Series A Preferred Shares to redemption value	867	—	—	—	867
Accretion of Series B-1 Preferred Shares to redemption value	—	302	—	—	302
Accretion of Series B-2 Preferred Shares to redemption value	—	—	733	—	733
Accretion of Series C Preferred Shares to redemption value	—	—	—	87	87
Conversion of preferred shares to ordinary shares upon the IPO	(111,335)	(142,783)	(496,532)	(658,875)	(1,409,525)
<b>Balance as of December 31, 2021</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>

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.

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.



**GRACELL BIOTECHNOLOGIES INC.**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**(All amounts in thousands, except for share and per share data, unless otherwise noted)**

**10. CONVERTIBLE REDEEMABLE PREFERRED SHARES (CONTINUED)**

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. 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.

During the period from July 2, 2020 to September 9, 2020, the Company issued 21,735,721 Series B-1 Preferred Shares upon conversion of convertible loan and exercise of the warrants.

On October 20, 2020, the Company issued 61,364,562 shares of Series C convertible redeemable preferred shares ("Series C Preferred Shares") to certain investors at US\$ 1.635331 per share for total consideration of US\$100,351.

The key features of the Series A, Series B and Series C 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 C Preferred Shares shall be entitled to receive a per share amount equal to 100% of the issue price of Series C Preferred Shares, respectively, plus all declared but unpaid dividends and minus all paid dividends.
- (ii) 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 and minus all paid dividends.
- (iii) 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 and minus all paid 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 of underwriting discounts and registration expenses) that reflects the minimum market capitalization and other conditions set forth in the Company's articles).

**GRACELL BIOTECHNOLOGIES INC.**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**(All amounts in thousands, except for share and per share data, unless otherwise noted)**

**10. CONVERTIBLE REDEEMABLE PREFERRED SHARES (CONTINUED)**

*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 October 20, 2020;
- (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 October 20, 2020 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 C Preferred Share, 100% of the original issue price on each preferred share, plus all declared but unpaid dividends on such Series C Preferred Share accrued as of the redemption payment date; and
- (ii) 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
- (iii) in respect of each Series A Preferred Share, 150% of the issue price of Series B-2 Preferred Share on each Series A Preferred, 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.

## GRACELL BIOTECHNOLOGIES INC.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(All amounts in thousands, except for share and per share data, unless otherwise noted)

**10. CONVERTIBLE REDEEMABLE PREFERRED SHARES (CONTINUED)***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 not achieving a Qualified Public Offering or a deemed liquidation event before October 20, 2025 ("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 incurred issuance cost with amount of RMB13,386 (US\$2,000) for the issuance of Series C Preferred Shares. 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 36,802, RMB 62,733 and RMB 1,989 for the years ended December 31, 2019, 2020 and 2021.

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. Upon the cancellation of convertible loans and exercise of the warrants, the convertible loans were debit with a corresponding entry to credit the issued preferred shares.

*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 modification rather than extinguishment as the fair values of these Preferred Shares immediately after the amendment 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 change in fair value of Series A Preferred Shares immediately before and after the modification was RMB625. The decrease in fair value of the ordinary shares is RMB625, in substance, a transfer of wealth from the ordinary shareholders to the Series A preferred shareholders.

On March 6, 2020, the redemption price of Series A Preferred Shares was amended. Before modification, the redemption price of each share of Series A Preferred Shares equals to 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 from August 8, 2017 to the redemption payment date minus all paid dividends on such Series A Preferred Share. The amendment is accounted for as a modification rather than extinguishment as the fair values of these Preferred Shares immediately after the amendment 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 change in fair value of Series A Preferred Shares immediately before and after the modification was RMB9,055. The decrease in fair value of the ordinary shares is RMB9,055, in substance, a transfer of wealth from the ordinary shareholders to the Series A preferred shareholders.

**GRACELL BIOTECHNOLOGIES INC.****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)****(All amounts in thousands, except for share and per share data, unless otherwise noted)****10. CONVERTIBLE REDEEMABLE PREFERRED SHARES (CONTINUED)***Modification of Preferred Shares (Continued)*

On October 20, 2020, the Target QIPO Date was extended from February 22, 2024 to October 20, 2025 upon issuance of Series C Preferred Shares. The amendment is accounted for as a modification rather than extinguishment as the fair values of these Preferred Shares immediately after the amendment 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 change in fair value of Series A, Series B-1 and Series B-2 Preferred Shares immediately before and after the modification was RMB1,284, RMB82 and RMB394, respectively. The increase in fair value of the ordinary shares is RMB1,760, in substance, a transfer of wealth from the preferred shareholders to the ordinary shareholders, respectively.

**11. SHARE-BASED COMPENSATION***(a) Employee Stock Option Plan*

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. In July 2020, the Company adopted the Second Amended and Restated Employee Stock Option Plan (“the Second Global Plan”) and increased the maximum number of shares issuable to 7,388,060. In October 2020, the Company adopted the Third Amended and Restated Employee Stock Option Plan (“the Third Global Plan”) and increased the maximum number of shares issuable to 10,216,234. The terms of the Second Global Plan and the Third Global Plan are substantially the same other than the maximum aggregate number of shares the Company may issue under the respective plan.

Share options granted will be exercisable upon the Company completes a listing and the grantee renders service to the Company in accordance with a stipulated service. Grantees are generally subject to a four-year vesting schedule, under which the shares vest in four equal instalments over the four years. The share option, to the extent then vested, shall become exercisable only upon the earlier of (i) a listing, or (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 grantee shall be forfeited at the time the grantee terminates his service with the Group. After the Company completes a listing, vested options not exercised by a grantee 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 (“Option Period”). If a listing is not achieved, a share option will lapse automatically upon the expiry of the Option Period.

In December 2020, the Company adopted 2020 Share Incentive Plan (the “2020 Plan”), which will become effective immediately prior to the completion of the Company’s IPO. Under the 2020 Plan, the maximum aggregate number of ordinary shares available for issuance shall initially be three percent (3%) of the ordinary shares of the Company outstanding immediately upon completion of the Company’s IPO. Subsequently, the maximum aggregate number of ordinary shares available for issuance will be increased on an annual basis on the first calendar day of the fiscal year to be the lesser of a number determined by the board of directors or one percent (1%) of the total issued and outstanding ordinary shares on the last day of the immediately preceding fiscal year. The 2020 Plan is governed by the Company’s board of directors or a designated committee and permits various types of awards to be granted to eligible persons under specific terms and vesting schedule evidenced by an award agreement.

**GRACELL BIOTECHNOLOGIES INC.**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

(All amounts in thousands, except for share and per share data, unless otherwise noted)

**11. SHARE-BASED COMPENSATION (CONTINUED)**

*(a) Employee Stock Option Plan (Continued)*

The following table sets forth the share options activities for the years ended December 31, 2020, 2021 and 2022:

	Number of Options	Weighted- Average Exercise Price US\$ per option	Weighted- Average Grant Date Fair Value 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, 2020	2,757,124	0.55	0.28	1.93	8.67	7,728
Granted	5,198,298	1.65	0.56	3.92	—	—
Forfeited	(545,823)	0.71	0.37	2.56	—	—
Outstanding at January 1, 2021	7,409,599	1.32	0.47	3.28	8.89	112,024
Granted	6,503,323	1.82	1.74	11.22	—	—
Forfeited	(280,222)	1.47	0.95	6.31	—	—
Exercised	(530,110)	0.51	0.28	1.89	—	—
Outstanding at January 1, 2022	13,102,590	1.60	1.10	7.21	8.86	12,335
Granted	4,314,826	0.69	0.38	2.52	—	—
Forfeited	(1,384,672)	1.45	1.14	7.52	—	—
Exercised	(164,815)	0.30	0.22	1.47	—	—
Expired	(705,383)	1.20	0.84	5.66	—	—
Outstanding at December 31, 2022	15,162,546	1.39	0.91	5.98	8.14	1,290
Vested and expected to vest at December 31, 2022	15,162,546	1.39	0.91	5.98	8.14	1,290
Exercisable at December 31, 2022	6,555,655	1.06	0.79	5.24	7.68	1,290

**GRACELL BIOTECHNOLOGIES INC.**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

(All amounts in thousands, except for share and per share data, unless otherwise noted)

**11. SHARE-BASED COMPENSATION (CONTINUED)**

*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 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, 2020	For the year ended December 31, 2021	For the year ended December 31, 2022
Risk-free interest rate	1.6%-2.1%	1.1%-1.8%	1.8%-3.7%
Dividend yield	0%	0%	0%
Expected volatility range	54.9%-58.1%	52.2%-56.4%	55.6%-57.0%
Exercise multiple	2.20-2.80	2.20-2.80	2.20-2.80
Contractual life	10 years	10 years	10 years

Since the exercisability was dependent upon the listing, and it was not probable that this performance condition could be achieved until a listing, no share-based compensation expense was recorded for the year ended December 31, 2020. The Group has recognized RMB36,004 and RMB21,747 share-based compensation expenses relating to options vested for the year ended December 31, 2021 and 2022.

Share-based compensation expenses related to options were included in:

	2021 RMB	As of December 31, 2022 RMB	US\$ (Note 2)
Research and development expenses	15,670	10,581	1,534
Administrative expenses	20,334	11,166	1,619
Total	36,004	21,747	3,153

*(b) Restricted Shares Units*

During the year ended December 31, 2021 and 2022, the Company granted 1,494,650 and 479,741 restricted shares units (“RSUs”) to employees, directors and consultants under the 2020 Plan, respectively.

The Company measured the fair value of the RSUs based on the Company’s stock price on the date of the award grant. As of December 31, 2022, 1,737,902 RSUs were vested, the Company recognized the share-based compensation expense of RMB 24,380 and RMB2,355 for the year ended December 31, 2021 and 2022.

Share-based compensation expenses related to RSUs were included in:

	2021 RMB	As of December 31, 2022 RMB	US\$ (Note 2)
Research and development expenses	4,052	644	93
Administrative expenses	20,328	1,711	248
Total	24,380	2,355	341

**GRACELL BIOTECHNOLOGIES INC.**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**(All amounts in thousands, except for share and per share data, unless otherwise noted)**

**12. 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 research and development ("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, 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 BVI is not subject to tax on income or capital gains. In addition, upon payments of dividends by Gracell BVI to its shareholders, no British Virgin Islands withholding tax is imposed.

*United States*

Gracell Biopharmaceuticals, Inc. is incorporated in U.S. and is subject to U.S. federal corporate income tax at a rate of 21%. Gracell Biopharmaceuticals, Inc. is also subject to state income tax in California of 8.84%. Dividends payable by an U.S. entity, to non-U.S. resident enterprises shall be subject to 30% withholding tax, unless the respective non-U.S. resident enterprise's jurisdiction of incorporation has a tax treaty or arrangements with U.S. that provides for a reduced withholding tax rate or an exemption from withholding tax.

*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 three years ended December 31, 2022, 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.



GRACELL BIOTECHNOLOGIES INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(All amounts in thousands, except for share and per share data, unless otherwise noted)

12. INCOME TAX EXPENSE (CONTINUED)

*Hong Kong (Continued)*

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,			
	2020 RMB	2021 RMB	2022 RMB	US\$ (Note 2)
Loss before income tax	(211,900)	(451,754)	(607,487)	(88,077)
Income tax computed at respective applicable tax rate	(48,607)	(94,531)	(138,079)	(20,020)
Research and development super-deduction	(22,121)	(44,646)	(65,299)	(9,467)
Non-deductible expenses	100	193	142	21
Changes in valuation allowance	70,628	138,984	203,258	29,469
Income tax expense	—	—	22	3

*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, 2021 and 2022 are as follows:

	For the years ended December 31,		
	2021 RMB	2022 RMB	US\$ (Note 2)
<b>Deferred tax assets:</b>			
Net operating loss carry forward	274,502	441,456	64,005
Capitalized research and development expenses	—	21,630	3,136
Accrued expenses	—	10,482	1,520
Capitalized Inventory	4,361	5,624	816
Depreciation and amortization of property, equipment and software	2,075	2,430	352
Others	1,843	4,417	640
<b>Gross deferred tax assets</b>	282,781	486,039	70,469
Less: valuation allowance	(282,781)	(486,039)	(70,469)
<b>Total deferred tax assets, net</b>	—	—	—

Movement of the valuation allowance is as follows:

	For the years ended December 31,			
	2020 RMB	2021 RMB	2022 RMB	US\$ (Note 2)
<b>Balance as of January 1</b>	73,169	143,797	282,781	40,999
Addition	70,628	138,984	203,258	29,470
<b>Balance as of December 31</b>	143,797	282,781	486,039	70,469

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.

**GRACELL BIOTECHNOLOGIES INC.**
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

(All amounts in thousands, except for share and per share data, unless otherwise noted)

**12. INCOME TAX EXPENSE (CONTINUED)**
*Deferred tax assets (Continued)*

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, 2021 and 2022.

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, 2021 and 2022, the Group did not have any significant unrecognized uncertain tax positions.

**13. NET LOSS PER SHARE**

Basic and diluted net loss per share for the years ended December 31, 2020, 2021 and 2022 are calculated as follows:

	For the years ended December 31,			
	2020 RMB	2021 RMB	2022 RMB	US\$ (Note 2)
Numerator:				
Net loss attributable to Gracell Biotechnologies Inc.'s shareholders	(211,900)	(451,754)	(607,509)	(88,080)
Accretion of convertible redeemable preferred shares to redemption value	(62,733)	(1,989)	—	—
Net loss attributable to Gracell Biotechnologies Inc.'s ordinary shareholders	(274,633)	(453,743)	(607,509)	(88,080)
Denominator:				
Weighted-average number of ordinary shares outstanding—basic and diluted	99,044,776	328,866,599	338,342,051	338,342,051
Net loss per share attributable to Gracell Biotechnologies Inc.'s ordinary shareholders—basic and diluted	(2.77)	(1.38)	(1.80)	(0.26)

For the year ended December 31, 2020, 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 year ended December 31, 2020, the Company also has certain share options, which cannot be exercised until the Company completes IPO, 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,		
	2020 shares	2021 shares	2022 shares
Convertible redeemable preferred shares	110,230,842	—	—
Share options and RSUs	—	930,498	2,851,075

## GRACELL BIOTECHNOLOGIES INC.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

(All amounts in thousands, except for share and per share data, unless otherwise noted)

## 14. 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 the Founder

## b) The Group had the following related party transactions:

	For the years ended December 31,			
	2020 RMB	2021 RMB	2022 RMB	US\$ (Note 2)
<b>Payment for professional service fee</b>				
Unitex Capital Ltd (a)	2,631	3,354	10,885	1,578

Note (a): For the years ended December 31, 2020, 2021 and 2022, the Group incurred professional service fees to Unitex Capital Ltd, in the amount of RMB2,631, RMB 3,354 and RMB10,885 respectively.

## 15. COMMITMENTS AND CONTINGENCIES

## 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.

## 16. RESTRICTED NET ASSETS

The Group's ability to pay dividends may depend on the Group receiving distributions of funds from its PRC subsidiaries. Relevant PRC statutory laws and regulations permit payments of dividends by the Group's PRC subsidiaries 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 subsidiaries.

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 subsidiaries were 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 subsidiaries are 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.

**GRACELL BIOTECHNOLOGIES INC.**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**(All amounts in thousands, except for share and per share data, unless otherwise noted)**

**16. RESTRICTED NET ASSETS (CONTINUED)**

As of December 31, 2022, the total restricted net assets of the Company's subsidiaries and the VIE incorporated in the PRC and subjected to restriction amounted to approximately RMB 91,626.

Rules 12-04(a) and 4-08(e)(3) of Regulation S-X require condensed financial information as to the financial position, cash flows and results of operations of a parent company to be presented for the same periods for which the audited consolidated financial statements have been presented when the restricted net assets of the consolidated subsidiaries together exceed 25% of consolidated net assets as of the end of the most recently completed fiscal year. The Group performed a test on the restricted net assets of consolidated subsidiaries in accordance S-X Rule 4-08 (e)(3) and concluded that the restricted net assets of the consolidated subsidiaries did not exceed 25% of the consolidated net assets as of December 31, 2022. Therefore, it was not applicable for the Group to present the condensed financial information of the parent company.

**17. SUBSEQUENT EVENTS**

The Group evaluated subsequent events through April 25, 2023, the date these consolidated financial statements were issued.

In March 2023, the Group entered into a License Agreement with Seagen Inc., or Seagen, pursuant to which the Group received from Seagen a worldwide license to certain patent rights that Seagen owns. Under this license agreement with Seagen, each license is non-exclusive and sublicensable, subject to certain conditions. As of the date these consolidated financial statements were issued, the Group has made a nonrefundable seven figure US dollar payment of upfront fee to Seagen and are subject up to a total of approximately US\$45 million of nonrefundable payments to Seagen.

Certain confidential information contained in this document, marked by [\*\*\*], has been omitted because such information is both not material and is the type that Gracell Biotechnologies Inc. customarily and actually treats that as private or confidential.

## LICENSE AGREEMENT

This License Agreement (this “Agreement”), entered into by and between Seagen Inc., a Delaware corporation with offices at 21823 30th Drive SE, Bothell, WA 98021 (“Seagen”), and Gracell Biotechnologies Inc., a Cayman Island company with offices at 4th Floor, Harbour Place, 103 South Church Street, P.O. Box 10240, Grand Cayman, KY1-1002, George Town, Cayman Islands (“Gracell”) (each of Seagen and Gracell may be referred to herein, individually, as a “Party” or, together, as the “Parties”), is effective as of March 8, 2023 (the “Effective Date”).

## BACKGROUND

- A. Seagen owns patent rights claiming the composition and use of certain [\*\*\*]; and
- B. Gracell wishes to obtain a non-exclusive license to such patent rights, and Seagen is willing to grant such a license to Gracell, all on the terms and conditions set forth in this Agreement below.

**NOW, THEREFORE**, in consideration of the covenants and promises contained in this Agreement, and intending to be legally bound, the Parties agree as follows:

## Article 1 DEFINITIONS; INTERPRETATION

- 1.1 “Action” means any suit, claim, action or proceeding.
- 1.2 “Affiliate” means, as to any Person, any other Person that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, such Person. As used in this definition, “control” (including, with its correlative meanings, “controlled by” and “under common control with”) means the possession, directly or indirectly, of the power to direct or cause the direction of management or policies of a Person, whether through the ownership of voting interests, by contract or otherwise.
- 1.3 “Business Day” means each day that is not a Saturday, Sunday or other day on which commercial banks in Seattle, Washington or Shanghai, China are authorized or obligated by Law or executive order to close.
- 1.4 “Cell Therapy Product” means any product developed or labeled for the prevention, treatment, cure, or mitigation of any health condition in humans, which product comprises a population of autologous, allogeneic, or xenogeneic cells that have been propagated, expanded, selected, pharmacologically treated, or otherwise altered in biological characteristics.
- 1.5 “Confidential Information” has the meaning given in Section 5.1.
- 1.6 “Designation Notice” has the meaning given in Section 1.11.

1.7 “Governmental Authority” means any U.S. or non-U.S. multinational, national, regional, federal, state, provincial, municipal or local governmental, legislative, judicial, administrative or regulatory or self-regulatory authority, agency, commission, body or court or arbitrator and any of their respective subdivisions, agencies, instrumentalities, authorities or tribunals.

1.8 “Gracell Core Technology” means (a) Gracell’s proprietary autologous CAR-T platform known as of the Effective Date as FastCAR™, (b) Gracell’s proprietary CAR-T platform known as of the Effective Date as TruUCAR™, (c) Gracell’s proprietary enhanced CAR-T technology module known as of the Effective Date as SMART CART™, and (d) any and all other proprietary CAR-T platform technologies of Gracell or any of its Affiliates existing as of the Effective Date or arising at any time on or prior to December 31, 2029.

1.9 “Law” means any statute, law, ordinance, requirement, decree, regulatory rule, code or order of a Governmental Authority.

1.10 “Licensed Patents” means [\*\*\*]. The Licensed Patents existing as of the Effective Date are listed in Appendix A hereto.

1.11 “Licensed Product” means up to five (5) Cell Therapy Products developed by Gracell or any its Affiliates (itself or in collaboration with Third Parties); provided that each such Cell Therapy Product must incorporate Gracell Core Technology as a component, and Gracell or its Affiliates must have been more than incidentally involved in the research and development thereof; [\*\*\*].

1.12 “Losses” means, collectively, any and all damages, losses, liabilities, claims, judgments, penalties, costs and expenses (including reasonable attorneys’ fees and litigation expenses).

1.13 “MAA” (Marketing Approval Application) means, with respect to a product, (a) a Biologics License Application filed with the FDA, as provided for in 42 U.S.C. § 262 and 21

C.F.R. Part 601 (a “BLA”), for such product or (b) a similar application or submission with the applicable Governmental Authority to obtain the approvals, licenses, registrations, clearances, or authorizations necessary for the use, marketing, importation, selling, offer for sale and other commercialization of such product in a jurisdiction.

1.14 “Person” means any individual, corporation, partnership, limited liability company, joint venture, trust, business association, organization, Governmental Authority or other entity.

1.15 “Phase 2 Trial” means a human clinical trial of a product (or portion thereof, in the case of a Phase 1/2 human clinical trial), the principal purpose of which is a determination of safety and efficacy in the target patient population, or a similar clinical study prescribed by the applicable regulatory authority, pursuant to Law or otherwise, including the trials referred to in 21 C.F.R. §312.21(b), as amended.

1.16 “Prosecution” means preparation, filing, prosecution, issuance and maintenance of any patent rights, including substitutions, continuations, divisionals, extensions, re-examinations, reissues, and controlling supplemental examination, appeals, interferences, derivation proceedings, oppositions, all other proceedings before the United States Patent and Trademark Office (including the Patent Trial and Appeal Board) and foreign patent offices, and any judicial or other appeals of the foregoing.

1.17 “Representatives” means, with respect to a Party, its Affiliates and its and their respective directors, officers, employees, personnel, contractors, agents and representatives (including attorneys and accountants), and the respective successors and assigns of any of the foregoing. In the case of Gracell, “Representatives” includes Sublicensees and their respective directors, officers, employees, personnel, contractors, agents and representatives, and the respective successors and assigns of any of the foregoing.

1.18 “Sublicense” means an agreement pursuant to which Gracell grants, licenses, permits or otherwise transfers to a Third Party any right (including an option or other right to obtain a license or otherwise acquire the right) to conduct pre-clinical or clinical research on, make, have made, export, import, use, sell, offer for sale, and otherwise commercially exploit any Licensed Product; provided that (a) any agreement pursuant to which Gracell grants a Third Party such option or other right shall only be considered a Sublicense (and shall be deemed to have been executed)



upon the exercise of such option or other right by such Third Party and (b) an agreement pursuant to which Gracell assigns this Agreement in accordance with Section 9.1 shall not be a Sublicense. For clarity, strictly fee-for-service arrangements where Gracell or its Affiliate engages a Third Party to perform services on its or their behalf, including consulting, research, development (including clinical development), manufacturing, logistics, distribution or other services, and grants such Third Party rights under the Licensed Patents solely for such purposes (and not for any other purpose), are not Sublicenses.

1.19 “Sublicensee” means any Third Party to which Gracell has granted a permitted Sublicense.

1.20 “Substitution Notice” has the meaning given in Section 1.11.

1.21 “Term” has the meaning given in Section 8.1.

1.22 “Territory” means worldwide.

1.23 “Third Party” means any Person other than Gracell or Seagen or their respective Affiliates.

1.24 Interpretation. The captions and headings to this Agreement are for convenience only and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless specified to the contrary, references to Articles, Sections or the Appendix mean the particular Articles, Sections or the Appendix to this Agreement and references to this Agreement include the Appendix hereto. Unless context otherwise clearly requires, whenever used in this Agreement: (a) the words “include” or “including” shall be construed as incorporating, also, “but not limited to” or “without limitation;” (b) references to a Party includes its permitted assignees and/or the respective successors in title to substantially the whole of its undertakings hereunder; (c) the word “notice” means notice in writing (whether or not specifically stated) and includes notices, consents, approvals and other communications contemplated under this Agreement; (d) the words “hereof,” “herein,” “hereby” and derivative or similar words refer to this Agreement; (e) the word “or” shall be construed as the inclusive meaning identified with the phrase “and/or;” (f) words of any gender include the other gender; (g) words using the singular or plural number also include the plural or singular number, respectively; (h) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement law, rule or regulation thereof; and (i) all currency amounts referred to in this Agreement are in U.S. Dollars. The Parties agree that the terms and conditions of this Agreement are the result of negotiations between the Parties and that this Agreement shall not be construed in favor of or against either Party by reason of the extent to which such Party participated in its preparation.

## Article 2 LICENSE GRANT

### 2.1 License Grants to Gracell.

2.1.1 Subject to the terms and conditions of this Agreement, Seagen hereby grants to Gracell:

(a) commencing upon the Effective Date and ending on December 31, 2029, a non-exclusive, non-transferable (except in accordance with Section 9.1) license (without the right to sublicense) under the Licensed Patents to conduct pre-clinical research on Cell Therapy Products throughout the Territory (the “Research License”); and

(b) during the Term, a non-exclusive, perpetual and irrevocable (subject only to Section 8.2), non-transferable (except in accordance with Section 9.1) license (sublicensable in accordance with Section 2.1.2) under the Licensed Patents to conduct pre-clinical and clinical research on, and to make, have made, export, import, use, sell, offer for sale, and otherwise commercially exploit, Licensed Products throughout the Territory (the “Commercial License” and together with the Research License, the “Licenses”).

2.1.2 The Commercial License includes the limited right to grant and authorize sublicenses; provided that (a) each Sublicense (i) is in writing, (ii) contains terms and conditions sufficient to enable Gracell and Gracell’s Sublicensees to comply with this Agreement, and (iii) grants to the applicable Sublicensee a (sub)license under other material patent, data or market exclusivity rights owned or controlled by Gracell or its Affiliates pertaining to the applicable Licensed Product(s) and the Gracell Core Technology, and (b) Gracell shall remain primarily and fully responsible for compliance by all Sublicensees with the terms and conditions of this Agreement applicable to Gracell. Within twenty (20) Business Days of Gracell or its Affiliate executing any Sublicense, Gracell shall provide Seagen an accurate summary thereof (without any economic terms), certifying that the Sublicense complies with the requirements of (a) and (b) and providing a copy of the applicable provisions of the Sublicense imparting such compliance (which copy, for clarity, may be redacted of provisions not imparting such compliance).

2.1.3 During the Term, Gracell and its Affiliates will not (and will not authorize any third party to) sell, offer for sale, or otherwise commercially exploit any products Covered by a Licensed Patent other than the Licensed Products. For purposes of this Section 2.1.3, “Covered” means, with respect to a Licensed Patent and a compound, product, other composition of matter, technology, process, or method, that, in the absence a license to, such Licensed Patent, the practice or exploitation of such compound, product, other composition of matter, technology, process, or method, would infringe such Licensed Patent. For clarity if Gracell disputes that a product is Covered by a Licensed Patent in accordance with Section 8.2.1, then the foregoing shall not apply to such product until such dispute has been finally resolved in accordance therewith against Gracell; however in such case the cure period shall be extended to six (6) months to provide for a period for winddown of the activities with respect to such product.

2.2 Affiliates and Third Party Service Providers. Gracell may have Affiliates and Third Party service providers perform activities on its behalf. Gracell shall require that any such Affiliates and

Third Party service providers comply with all terms and conditions of this Agreement applicable to Gracell. All acts or omissions by any such Affiliate or Third Party service provider shall be considered acts or omissions of Gracell, which is, and shall be, liable for them.

2.3 Retained Rights. Except for the Licenses, no right, title, or interest of any nature whatsoever is granted, whether by implication, estoppel, reliance, or otherwise, by either Party to the other Party and all rights not so granted are reserved by the owner thereof.

### **Article 3** **CONSIDERATION; PAYMENTS**

3.1 License Payment. In consideration of the Licenses and other obligations of Seagen hereunder, Gracell shall pay Seagen the following amounts:

3.1.1 \$[\*\*\*] within [\*\*\*] ("Upfront Fee");

3.1.2 \$[\*\*\*] (the "Sublicense Fee") upon [\*\*\*] (the "Sublicense Fee Milestone");

3.1.3 \$[\*\*\*] for each of the third, fourth and fifth Licensed Products (each, an "Additional Product Fee") designated as such by Gracell pursuant to Section 1.11 (excluding, for clarity, [\*\*\*] and the second Licensed Product designated as such by Gracell pursuant to Section 1.11), in each case [\*\*\*] (each, an "Additional Product Fee Milestone"); and

3.1.4 Gracell shall provide to Seagen by [\*\*\*] of each year a high-level written report summarizing the progress of the research and development activities performed by Gracell, its Affiliates and, to the extent available to Gracell or any of its Affiliates with the right to disclose, Sublicensees during the preceding calendar year with respect to each Licensed Product (each an "Annual Progress Report"); provided that no Annual Progress Report shall be required with respect to [\*\*\*], the second Licensed Product designated by Gracell, and any Licensed Product for which the Additional Product Fee has been paid. In addition, Gracell shall notify Seagen within [\*\*\*] Business Days of the achievement of the applicable event which would trigger the payment of the Sublicense Fee or any Additional Product Fee.

3.2 Payments. All amounts (including the Sublicense Fee and any Additional Product Fees), to be paid to Seagen hereunder shall be non-refundable and non-creditable and paid in U.S. Dollars by wire transfer of immediately available funds to a bank and account designated in writing by Seagen at least [\*\*\*] Business Days in advance of date such payment is payable.

Any payment that is not paid on or before the date such payment is due under this Agreement, after the expiration of a [\*\*\*] Business Day grace period, shall bear interest at an

annual rate equal to [\*\*\*].

3.3 Taxes. Each Party shall be responsible for the payment of all taxes that it is obligated to pay under applicable Law. Neither Party is or shall be responsible for, or shall incur any liability on account of, any such taxes of the other Party. Notwithstanding the above, to the extent that any applicable Law requires Gracell to withhold any taxes on any amounts payable by Gracell to Seagen under this Agreement, Gracell will withhold and pay such taxes to the appropriate tax authority. Upon Seagen's request, Gracell will promptly provide Seagen with copies of receipts from the competent tax authorities as evidence of payment of such taxes.

In addition, if, solely as a result of any action by either Party (or its assignee pursuant to Section 9.1 of this Agreement), including assignment or transfer of this Agreement, change in the residence of such Party for tax purposes, change in the entity making such payment, or failure on the part of such Party to comply with applicable Laws or filing or record retention requirements (each, a "**Tax Action**"), the amount of any tax (including tax withholdings, value added tax or any other tax) is increased, then the Party responsible for such Tax Action shall bear such additional taxes.

3.4 Transfer Restrictions. If, by applicable Laws in any country in the Territory, conversion into U.S. Dollars or transfer of funds of a convertible currency to the U.S. becomes materially restricted, forbidden or substantially delayed, then Gracell will promptly notify Seagen and, thereafter, any amounts accrued under Section 3.1 will be paid to Seagen in such country in local currency by deposit to an escrow account in a local bank designated by Seagen and to the credit of Seagen, unless the Parties otherwise agree. Any amounts paid by deposit to such escrow account in accordance with this Section 3.4 will be deemed paid as of the date of deposit to such escrow account for purposes of Section 3.2.

#### **Article 4** **PATENT MATTERS**

4.1 Prosecution. As between the Parties, Seagen shall have the sole right to control the Prosecution of the Licensed Patents, including choice of counsel, at Seagen's sole expense. Seagen shall notify Gracell of the issuance subsequent to the Effective Date of any Licensed Patents.

#### 4.2 Enforcement of the Licensed Patents.

4.2.1 If either Party believes, discovers, receives notice of, or otherwise reasonably suspects that a Licensed Patent is being infringed by a Third Party, such Party shall notify the other Party of such belief in writing.

4.2.2 Seagen (or its designee) shall have the sole right, but not the obligation, to bring, control, and settle an Action against an infringer of any Licensed Patent or defend any declaratory judgment Action with respect thereto, in either case, at Seagen's sole expense.

## Article 5 CONFIDENTIALITY

5.1 Confidentiality; Exceptions. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, during the Term and for [\*\*\*] years thereafter, the receiving Party shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement any confidential and proprietary information and materials furnished to it by the other Party pursuant to this Agreement (collectively, "Confidential Information"). For clarity, Confidential Information of a Party shall (a) include information disclosed by such Party or its designee that (i) is marked as "Confidential," "Proprietary" or with similar designation at the time of disclosure or (ii) by its nature should reasonably be considered Confidential Information by the recipient and (b) exclude information unrelated to the subject matter of this Agreement. The terms and conditions of this Agreement shall be the Confidential Information of both Parties. If Confidential Information is disclosed by the disclosing Party or its Affiliates other than in written or electronic form, then the receiving Party's obligations of confidentiality and non-use shall only apply if the Confidential Information is indicated upon disclosure as being confidential and is then summarized electronically or otherwise in writing and provided to the receiving Party within thirty (30) days after initial disclosure. Notwithstanding the foregoing, Confidential Information (other than the terms and conditions of this Agreement) shall not include any information to the extent that it can be established by written documentation by the receiving Party that such Confidential Information:

5.1.1 was already rightfully known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure;

5.1.2 was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

5.1.3 became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

5.1.4 was independently developed by the receiving Party (without reference to or use of Confidential Information of the other Party) as demonstrated by documented evidence prepared contemporaneously with such independent development; or

5.1.5 was disclosed to the receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the disclosing Party not to disclose such Confidential Information to others.

5.2 Authorized Disclosure. Except as expressly provided otherwise in this Agreement, each Party may use and disclose Confidential Information of the other Party solely as follows: (a) under appropriate confidentiality provisions substantially equivalent to those in this Agreement in connection with the performance of its obligations or as reasonably necessary or useful in the exercise of its rights under this Agreement, (b) in connection with seeking financing, discussions regarding potential mergers, acquisitions and similar corporate transactions, and discussions with actual or potential collaborators, licensees or Sublicensees, as applicable, in each case under

appropriate confidentiality provisions or professional standards of confidentiality substantially equivalent to those of this Agreement (but of duration customary for agreements for such purpose); (c) to the extent such disclosure is to a Governmental Authority (including a regulatory authority) as reasonably necessary to prosecute or defend litigation in accordance with this Agreement, comply with applicable governmental regulations with respect to performance under this Agreement, or otherwise comply with applicable Law or the rules of any securities exchange or automated quotation system applicable to such Party, provided, however, that if a Party is required by applicable Law or the rules of any securities exchange or automated quotation system applicable to such Party to make any such disclosure of the other Party's Confidential Information, it shall (if permitted) provide reasonable advance notice to the other Party of such disclosure requirement and shall use its reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed; or (d) to its Representatives on a need to know basis, in each case under appropriate confidentiality provisions or professional standards of confidentiality substantially equivalent to those of this Agreement.

5.3 **Publicity.** Neither Party shall issue any press release with respect to this Agreement or its terms except with the prior written approval of the other Party.

5.4 **Prior NDA.** This Agreement supersedes the Non-Disclosure Agreement between Seagen and Gracell dated September 14, 2022 (the "**Prior NDA**") with respect to information disclosed thereunder. All information disclosed or provided by Seagen to Gracell under the Prior NDA shall be deemed Confidential Information of Seagen (subject to the exceptions set forth in Sections 5.1.1 - 5.1.5, inclusive); and all information disclosed by Gracell to Seagen under the Prior NDA shall be deemed Confidential Information of Seagen (subject to the exceptions set forth in Sections 5.1.1 - 5.1.5, inclusive).

5.5 **Publications.** Gracell shall have the sole right to publish and to make scientific presentations with respect to the research, development, manufacture or commercialization of Licensed Products. At and only upon Seagen's written request, Gracell will (and will require its Affiliates and Sublicensees to) acknowledge the contribution of Seagen, in accordance with scientific customs, in all publications, communications, and written or oral public disclosures relating to the Licensed Products.

## **Article 6**

### **INDEMNIFICATION AND INSURANCE**

6.1 **Indemnification by Gracell.** Gracell shall defend, indemnify, and hold Seagen and its Representatives (each, a "**Seagen Indemnitee**") harmless from and against Losses resulting from any Action brought by a Third Party (collectively, "**Claims**") to the extent that such Claims arise out of, are based on, or relate to (a) the research, development, use, manufacture, commercialization, importation, sale, distribution or other exploitation of any Licensed Product by or under authority of Gracell or any of its Affiliates or Sublicensees, including where a Licensed Product causes or is alleged to have caused bodily injury, including death, to any person or physical injury to or destruction of any tangible property; (b) a material breach of any of Gracell's representations or warranties, or obligations under the Agreement, including the failure of Gracell or any of its Affiliates or Sublicensees or any of their respective Representatives to comply with any Laws; or (c) any willful misconduct or negligent act or omission of Gracell or any of its

Representatives in connection with this Agreement. The foregoing indemnity obligation shall be reduced to the extent that any Loss arises from, is based on, or relates to a matter for which Seagen is obligated to provide indemnification pursuant to Section 6.2.

6.2 Indemnification by Seagen. Seagen shall defend, indemnify, and hold Gracell and its Representatives (each, a “Gracell Indemnatee”) harmless from and against Losses resulting from any Claims to the extent that such Claims arise out of, are based on, or relate to (a) a material breach of any of Seagen’s representations or warranties, or obligations under the Agreement, including the failure of Seagen or any of its Affiliates or any of their Representatives to comply with any Laws; or (b) any willful misconduct or negligent act or omission of Seagen or any of its Representatives in connection with this Agreement. The foregoing indemnity obligation shall be reduced to the extent that any Loss arises from, is based on, or relates to a matter for which Gracell is obligated to provide indemnification pursuant to Section 6.1.

6.3 Indemnification Procedures. The Party seeking indemnification hereunder shall give written notice to the other Party promptly after learning of such Claim. The Party seeking indemnification shall provide the indemnifying Party with reasonable assistance, at the indemnifying Party’s expense, in connection with the defense of the Claim for which indemnity is being sought. The Party seeking indemnification may participate in and monitor such defense with counsel of its own choosing at its sole expense; provided, however, that the indemnifying Party shall have the right to assume and conduct the defense of the Claim with counsel of its choice. The indemnifying Party shall not settle any Claim without the prior written consent of the Party seeking indemnification, not to be unreasonably withheld, unless the settlement involves only the payment of money by the indemnifying Party for which the Party seeking indemnification has no responsibility whatsoever.

6.4 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING ANYTHING TO THE CONTRARY, NOTHING IN THIS SECTION 6.4 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY UNDER SECTION 6.1 OR 6.2, OR DAMAGES AVAILABLE FOR A PARTY’S BREACH OF ITS CONFIDENTIALITY OBLIGATIONS IN ARTICLE 5.

6.5 Insurance. Gracell shall procure and maintain insurance, continuing throughout the Term of this Agreement and for a period of [\*\*\*] years thereafter, including product liability insurance, adequate to cover its obligations hereunder and consistent with normal business practices of prudent companies similarly situated at all times during which any Licensed Product is being clinically tested in human subjects or commercially distributed or sold by Gracell. It is understood that such insurance shall not be construed to create a limit of Gracell’s indemnification obligations under this Article 6 and that the maintenance of such insurance shall not be construed to relieve Gracell of its other obligations under this Agreement. Gracell shall provide Seagen with written evidence of such insurance upon request. Gracell shall provide Seagen with written notice at least thirty (30) days prior to the cancellation, non-renewal or material change in such insurance.



**Article 7**  
**REPRESENTATIONS, WARRANTIES, DISCLAIMERS**

7.1 Representations and Warranties of the Parties. Each Party represents and warrants to the other Party that as of the Effective Date:

7.1.1 it is duly organized, validly existing and in good standing as a corporation or other entity as represented herein under the Laws of its jurisdiction of incorporation, organization or chartering;

7.1.2 it has the full right, power and authority to enter into this Agreement and to perform its obligations hereunder;

7.1.3 the execution of this Agreement by its representative whose signature is set forth at the end hereof has been duly authorized by all necessary organizational action of such Party; and

7.1.4 when executed and delivered by such Party, this Agreement shall constitute the legal, valid and binding obligation of that Party, enforceable against that Party in accordance with its terms.

7.2 Seagen's Representations and Warranties. Seagen hereby represents, warrants and covenants to Gracell as of the Effective Date:

7.2.1 it is the record owner of all patents and patent applications within the Licensed Patents listed in Appendix A;

7.2.2 immediately prior to giving effect to the provisions of Section 2.1, Seagen owns the entire right, title and interest in the Licensed Patents free and clear of all liens, claims, security interests or other encumbrances of any kind (including any prior license grants) that would conflict with the Licenses granted to Gracell hereunder;

7.2.3 it has the right, power and authority to grant the Licenses and the grant thereof does not (a) conflict with, violate or result in a breach by Seagen of any Law or any provision of any agreement to which Seagen or its Affiliate is a party, (b) require the consent, approval or authorization of any Third Party.

7.3 Gracell's Covenant. Gracell and its Affiliates and Sublicensees shall carry out all obligations under this Agreement in compliance with all applicable Laws.

7.4 Disclaimers. EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 7, (A) NO REPRESENTATION OR WARRANTY WHATSOEVER IS MADE OR GIVEN BY OR ON BEHALF OF EITHER PARTY; AND (B) ALL OTHER REPRESENTATIONS AND WARRANTIES WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE ARE HEREBY EXPRESSLY EXCLUDED, INCLUDING ANY REPRESENTATIONS AND WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT.

**Article 8**  
**TERM AND TERMINATION**

8.1 Term. The term of this Agreement shall commence on the Effective Date and shall continue until the earlier of (a) termination of this Agreement in accordance with Section 8.2 and (b) the expiration of the last payment obligation hereunder (the "Term"). Notwithstanding the foregoing, the Licenses shall become fully-paid and irrevocable (i) with respect to the first ([\*\*]) and second Licensed Products (including in the case of the second Licensed Product, any substituted Licensed Product), upon the full payment of both the Upfront Fee and Sublicense Fee; and (ii) with respect to each of the third, fourth, and fifth Licensed Product (including in the case of each such Licensed Product, any substituted Licensed Product), upon the full payment of the Additional Product Fee therefor.

8.2 Termination. This Agreement may be terminated as follows:

8.2.1 Termination for Breach. If Seagen believes that Gracell is in material breach of this Agreement, then Seagen may deliver notice to Gracell of such material breach (specifying the nature of the breach in reasonable detail and referencing this Section 8.2.1). If Gracell fails to cure such material breach within ninety (90) days after the receipt of such notice (or thirty (30) days with respect to any failure to pay amounts due hereunder), then Seagen shall be permitted to terminate this Agreement by written notice given within ninety (90) days after the end of such cure period and effective upon delivery; provided that if such material breach is not reasonably subject to cure within the ninety (90)-day period from the date of such notice, then Gracell shall have an additional ninety (90) days to effect such cure if it is undertaking diligent efforts to cure such breach and shall have provided a written plan intended to cure such breach to Seagen within such additional period; provided, further, that if Gracell in good faith disputes such breach by written notice to Seagen the applicable cure period, then Seagen shall not have the right to terminate this Agreement pursuant to this Section 8.2.1 unless and until it has been determined that this Agreement was materially breached and Gracell fails to comply with its obligations hereunder within ninety (90) days after such determination (or thirty (30) days if such breach is a failure to pay amounts owed).

8.2.2 Termination for Convenience. Gracell shall have the right to terminate this Agreement at any time for convenience by giving thirty (30) days' advanced written notice to Seagen.

8.2.3 Termination for Patent Challenge. In the event that Gracell or any of its Affiliates takes any action, including knowingly providing financial or other assistance to any Third Party, to challenge in a court or administrative proceeding any claim of a Licensed Patent as being invalid, unenforceable or otherwise not patentable, Seagen shall have the right to terminate this Agreement upon sixty (60) days' written notice to Gracell; provided that Seagen shall not have the right to terminate this Agreement if Gracell or its Affiliate (a) withdraws or terminates (or causes to be withdrawn or terminated) such proceeding during such sixty (60)-day period, (b) is required to participate in such proceeding pursuant to a subpoena or court order, or (c) challenges the Licensed Patent in defense of claims raised by or on behalf of Seagen or its Affiliate against Gracell or its Affiliate. If any Sublicensee takes any such action to challenge a Licensed Patent in a court or administrative proceeding, then Gracell shall use diligent efforts to terminate such Sublicensee's

Sublicense in accordance with its terms, unless such Sublicensee (i) withdraws or terminates (or causes to be withdrawn or terminated) such proceeding within sixty (60) days' written notice from Seagen to Gracell, (ii) is required to participate in such proceeding pursuant to a subpoena or court order, or (iii) challenges such Licensed Patent in defense of claims raised by or on behalf of Seagen or its Affiliate against such Sublicensee. For clarity, a challenge for purposes of this Section 8.2.3 shall not be deemed to include (y) ordinary course patent prosecution or maintenance activities, or (z) participation in any proceeding that is initiated by a patent office.

8.3 Effect of Termination. Any termination of this Agreement shall be without prejudice to any other right or remedy to which a Party may be entitled. Termination of this Agreement shall have the following effects:

8.3.1 the Licenses shall terminate;

8.3.2 each Party shall promptly return to the other Party or destroy (and upon the other Party's written request certify such destruction to the other Party) all Confidential Information of the other Party; and

8.3.3 Termination of this Agreement shall not relieve the Parties of any obligation accruing prior to the effective date of such termination (including, with respect to Gracell, any payments that become due pursuant to Section 3.1). Any termination of this Agreement shall be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement prior to termination, including the obligation to pay for any amounts that accrued prior to the effective date of such termination.

8.4 Effect on Sublicenses. Upon termination of this Agreement, for any reason, Gracell shall promptly notify its Sublicensees of such termination. If a Sublicensee is in conformity with the terms of its Sublicense (as confirmed by Gracell in writing), such Sublicensee shall have the right by written notice, within ninety (90) days of termination, to enter into an agreement directly with Seagen on substantially the same terms and conditions as those obligating Gracell as it was bound to Seagen under this Agreement, for a license of the same scope as the Commercial License; provided that (a) the Sublicensee (alone or together with Gracell, its Affiliates and/or other Sublicensees) cures any uncured payment breach of Gracell and (b) in no event shall Seagen be obligated in any manner that it was not to Gracell hereunder. If the Sublicensee does not request to enter into such an agreement within ninety (90) days after the effective date of termination of this Agreement, the Sublicense and all rights granted thereunder shall terminate.

8.5 Survival. The following provisions of this Agreement, and the defined terms and provisions used or referenced therein, shall survive termination of this Agreement: Article 1, Article 6 (with respect to Section 6.5, for the period specified therein), Article 9, Sections 2.3, 5.1 (for the period specified therein), 5.2-5.5, 7.4, 8.3, 8.4 and 8.5.

## **Article 9 MISCELLANEOUS**

9.1 Assignment. This Agreement shall not be assignable by either Party to any Third Party without the written consent of the other Party and any such attempted assignment shall be void.

Notwithstanding the foregoing, either Party may assign this Agreement, without the written consent of the other Party, (a) to an Affiliate of such Party (in whole or in part) or (b) to a Third Party which acquires all or substantially all of the stock, business or assets of such Party to which this Agreement relates (whether by merger, reorganization, acquisition, sale, operation of law or otherwise). The terms and conditions of this Agreement shall be binding on and inure to the benefit of the respective successors and permitted assigns of the Parties. Except as expressly provided in this Section 9.1, any attempted assignment or transfer of this Agreement shall be null and void.

9.2 Notices. All notices and other communications hereunder shall be in writing and shall be deemed duly delivered (i) three (3) Business Days after being sent by registered or certified mail, return receipt requested, postage prepaid, or (ii) one (1) Business Day after being sent for next Business Day delivery, fees prepaid, via a reputable nationwide overnight courier service, in each case to the intended recipient as set forth below:

<u>Gracell</u> : Gracell Biotechnologies Inc. 4th Floor, Harbour Place, 103 South Church Street P.O. Box 10240 Grand Cayman, KY1-1002, George Town, Cayman Islands  Attention: CEO	<u>Seagen</u> : Seagen Inc. 21823 30 <sup>th</sup> Drive SE Bothell, WA 98021 United States  Attention: General Counsel
<u>With copy to</u> :  Wilson Sonsini Goodrich & Rosati 650 Page Mill Road Palo Alto, CA 94304 Attention: [***] ([***)	

Either Party may send notices or other communications hereunder using any other means (including personal delivery, messenger service, or ordinary mail), but no such notice or other communication shall be deemed to have been duly given unless and until it is given as set forth in the first sentence above. Either Party may change the addresses to which notices and other communications hereunder are to be delivered by giving the other Party notice in the manner herein set forth.

9.3 Governing Law. This Agreement and all Actions arising from or relating to this Agreement shall be governed by and construed and enforced in accordance with the internal laws of the State of New York without reference to conflict of law principles that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

9.4 Arbitration. Any dispute arising out of or in connection with this Agreement shall be referred to and finally resolved by binding arbitration in San Francisco, California, USA administered by the International Chamber of Commerce (“**ICC**”) (or any successor entity thereto) pursuant to its arbitration rules and procedures then in effect (the “**Rules**”) then in force. The

number of arbitrators will be one, and the language to be used in such arbitration will be English. The decision of the arbitrator will be deemed final and binding upon each of the Parties, and the prevailing Party will be entitled to enter and enforce the decision of the arbitrator in any court of competent jurisdiction. Notwithstanding the foregoing, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any patent rights shall be submitted to a court of competent jurisdiction in the country in which such patent rights were granted or arose. Nothing in this Section 9.4 will preclude either Party from seeking equitable, interim or provisional relief from a court of competent jurisdiction, including a preliminary injunction, either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding. Notwithstanding the foregoing, any dispute with respect to the scope, enforceability, or validity of any Licensed Patent shall be exclusively subject the laws and jurisdiction of the applicable courts or administrative bodies in the jurisdiction in which such Licensed Patent is issued or pending.

9.5 Severability. If any term or other provision of this Agreement is determined by a court of competent jurisdiction to be invalid, illegal or incapable of being enforced, all other terms and provisions of this Agreement shall nevertheless remain in full force and effect. Upon such determination that any term or other provision is invalid, illegal or incapable of being enforced, the Parties shall negotiate in good faith to modify this Agreement so as to effect the original intent of the Parties as closely as possible in a mutually acceptable manner.

9.6 No Waiver. No waiver by either Party of any breach of any covenant, agreement, representation or warranty hereunder shall be deemed a waiver of any preceding or succeeding breach of the same. The exercise of any right granted to either Party herein shall not operate as a waiver of any default or breach on the part of the other Party. Each and all of the several rights and remedies of either Party under this Agreement shall be construed as cumulative and no one right as exclusive of the others.

9.7 Amendments. No change, modification, alteration, amendment or agreement to discharge in whole or in part, or waiver of, any of the terms and conditions of this Agreement, shall be binding upon either Party, unless the same shall be made by a written instrument signed and executed by the authorized representative of each Party.

9.8 Entire Agreement; No Third Party Beneficiaries. This Agreement (a) constitutes the entire agreement between the Parties and supersedes all other prior agreements and understandings, both written and oral, between the Parties with respect to the subject matter hereof, including any proposal which preceded its drafting and the Prior NDA, and (b) is not intended to confer upon any Person other than the Parties any rights or remedies, except as set forth in Article 6.

9.9 Independent Contractors. For the purpose of this Agreement, each Party shall be, and shall be deemed to be, an independent contractor and not an agent, partner, joint venturer or employee of the other Party. Neither Party shall have authority to make any statement, representation or commitment of any kind, or to take any action on behalf of the other Party, except as may be explicitly authorized in writing by such other Party.

9.10 Counterparts. This Agreement may be executed in counterparts. Each such counterpart, when so executed and delivered, shall be deemed to be an original, and all such counterparts, taken

together, shall constitute one and the same instrument even if both Parties have not executed the same counterpart. Digital or electronic signatures complying with the U.S. Federal ESIGN ACT of 2000 shall be deemed to be original signatures.

*[The remainder of this page left blank intentionally; signature page follows]*

**IN WITNESS WHEREOF**, each Party has duly executed this Agreement by its duly authorized representative effective as of the Effective Date.

GRACELL BIOTECHNOLOGIES INC.

SEAGEN INC.

By: /s/ William Cao

By: /s/ David Epstein

Name: William Cao

Name: David Epstein

Title: CEO

Title: CEO



**Appendix A**  
**LICENSED PATENTS**

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**Significant Subsidiaries, Consolidated Entity and Subsidiary of Consolidated Affiliated Entity of the Registrant**

<b>Subsidiary</b>	<b>Place of Incorporation</b>
Gracell Biotechnologies Holdings Limited	British Virgin Islands
Gracell Biotechnologies (HK) Limited	Hong Kong
Gracell Biopharmaceuticals, Inc.	United States
Gracell Bioscience (Shanghai) Co., Ltd.	People's Republic of China
Suzhou Gracell Bioscience Co., Ltd.	People's Republic of China
Gracell Biomedicine (Shanghai) Co., Ltd.	People's Republic of China
Hainan Gracell Biomedicine Co., Ltd.	People's Republic of China
<b>Consolidated Variable Interest Entity</b>	<b>Place of Incorporation</b>
Gracell Biotechnologies (Shanghai) Co., Ltd.	People's Republic of China
<b>Consolidated Variable Interest Entity</b>	<b>Place of Incorporation</b>
Suzhou Gracell Biotechnologies Co., Ltd.	People's Republic of China

**Certification by the Principal Executive Officer  
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, William Wei Cao, certify that:

1. I have reviewed this annual report on Form 20-F of Gracell Biotechnologies Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: April 25, 2023

By: /s/ William Wei Cao

Name: William Wei Cao

Title: Chief Executive Officer

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**Certification by the Principal Financial Officer  
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Yili Kevin Xie, certify that:

1. I have reviewed this annual report on Form 20-F of Gracell Biotechnologies Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: April 25, 2023

By: /s/ Yili Kevin Xie

Name: Yili Kevin Xie

Title: Chief Financial Officer

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**Certification by the Principal Executive Officer  
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Annual Report of Gracell Biotechnologies Inc. (the “Company”) on Form 20-F for the fiscal year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, William Wei Cao, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 25, 2023

By: /s/ William Wei Cao

Name: William Wei Cao

Title: Chief Executive Officer

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**Certification by the Principal Financial Officer  
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Annual Report of Gracell Biotechnologies Inc (the “Company”) on Form 20-F for the fiscal year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Yili Kevin Xie, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 25, 2023

By: /s/ Yili Kevin Xie  
Name: Yili Kevin Xie  
Title: Chief Financial Officer

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## CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (File No. 333-253486 and File No. 333-269505) and Form F-3 (No. 333-264545) of Gracell Biotechnologies Inc. of our report dated April 25, 2023 relating to the financial statements, which appears in this Form 20-F.

/s/ PricewaterhouseCoopers Zhong Tian LLP  
Shanghai, the People's Republic of China  
April 25, 2023

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Date: April 25, 2023

**Gracell Biotechnologies Inc.**  
Building 12, Block B, Phase II  
Biobay Industrial Park  
218 Sangtian St.  
Suzhou Industrial Park, 215123  
People's Republic of China

Dear Sir or Madam:

Gracell Biotechnologies Inc. (the Company)

We are attorneys-at-law qualified to practise in the Cayman Islands and have been asked to provide this consent to you with regard to the laws of the Cayman Islands in relation to the Company's Annual Report on Form 20-F for the year ended 31 December 2022 (the **Annual Report**), which will be filed with the Securities and Exchange Commission (the SEC) in the month of April 2023.

We hereby consent to the reference to our firm and the summary of our opinion under the heading "Item 10. Additional Information—E. Taxation— Cayman Islands Taxation" in the Annual Report, and further consent to the incorporation by reference of the summary of our opinion under these headings into the registration statements on Form S-8 (File No. 333-253486 and File No.333-269505) and Form F-3 (No. 333-264545) of Gracell Biotechnologies Inc. We also consent to the filing of this consent letter with the SEC as an exhibit to the Annual Report.

In giving such consent, we do not thereby admit that we come within the category of persons whose consent is required under Section 7 of the Securities Act of 1933, or under the Securities Exchange Act of 1934, in each case, as amended, or the regulations promulgated thereunder.

Yours Sincerely,

/s/ Harney Westwood & Riegels

Harney Westwood & Riegels

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Date: April 25, 2023

**Gracell Biotechnologies Inc.**  
Building 12, Block B, Phase II  
Biobay Industrial Park  
218 Sangtian St.  
Suzhou Industrial Park, 215123  
People's Republic of China

Dear Sir/Madam:

We hereby consent to the reference to our firm and the summary of our opinion under the headings “Item 3. Key Information,” “Item 3. Key Information—D. Risk Factors—Risks Related to Our Corporate Structure,” “Item 4. Information on the Company—C. Organizational Structure,” “Item 4. Information on the Company—B. Business Overview—Regulations” and “Item 10. Additional Information—E. Taxation—PRC Taxation” in Gracell Biotechnologies Inc.’s Annual Report on Form 20-F for the year ended December 31, 2022 (the “Annual Report”), which will be filed with the Securities and Exchange Commission (the “SEC”) in the month of April 2023, and further consent to the incorporation by reference of summary of our opinion under these headings into the registration statements on Form S-8 (File No. 333-253486 and File No. 333-269505) and Form F-3 (No. 333-264545) of Gracell Biotechnologies Inc. We also consent to the filing of this consent letter with the SEC as an exhibit to the Annual Report.

In giving such consent, we do not thereby admit that we come within the category of persons whose consent is required under Section 7 of the Securities Act of 1933, or under the Securities Exchange Act of 1934, in each case, as amended, or the regulations promulgated thereunder.

Yours Sincerely,  
/s/ AllBright Law Offices  
\_\_\_\_\_  
AllBright Law Offices

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**VIA EDGAR**

April 25, 2023

U.S. Securities and Exchange Commission  
Division of Corporation Finance  
Office of Finance  
100 F Street, N.E.  
Washington, D.C. 20549

Re: *Gracell Biotechnologies Inc.*  
*Supplemental Submission pursuant to Item 16I(a) of Form 20-F*

Dear Madam/Sir:

This letter is being submitted to the U.S. Securities and Exchange Commission (the “**Commission**”) pursuant to the requirements set forth under Item 16I(a) of Form 20-F, which requires a registrant identified by the Commission pursuant to the Holding Foreign Companies Accountable Act (the “**HFCAA**”) to submit to the Commission on a supplemental basis documentation that establishes that the registrant is not owned or controlled by a governmental entity in the foreign jurisdiction.

On May 26, 2022, the Commission conclusively identified Gracell Biotechnologies Inc. (the “**Company**”) as a Commission-Identified Issuer pursuant to the HFCAA because (i) the audit report included in the Company’s Annual Report on Form 20-F for the fiscal year ended December 31, 2021 was issued by PricewaterhouseCoopers Zhong Tian LLP, a registered public accounting firm retained by the Company and headquartered in mainland China, and (ii) on December 16, 2021, the Public Company Accounting Oversight Board (the “**PCAOB**”) determined that it is unable to inspect or investigate completely registered public accounting firms located in mainland China because of a position taken by authorities in mainland China, which determination was subsequently vacated by the PCAOB on December 15, 2022.

Based on an examination of the Company’s register of members in the Cayman Islands and publicly available documents such as beneficial ownership reports on Schedule 13D or Schedule 13G filed with the Commission with respect to the Company’s securities, and to the Company’s best knowledge, no shareholder beneficially owned 5% or more of the Company’s total outstanding shares and voting power as of April 21, 2023, except for Dr. William Wei Cao, TLS Beta Pte. Ltd., entities affiliated with LAV Granite Limited (collectively, the “**LAV Entities**”) and entities affiliated with OrbiMed Advisors LLC (collectively, the “**OrbiMed Entities**”), as described in detail below.

- Dr. William Wei Cao is the Company’s founder, chairman and chief executive officer. Dr. Cao beneficially owned 82,243,155 ordinary shares of the Company as of April 21, 2023, representing approximately 24.1% of the Company’s total outstanding shares and voting power.
- TLS Beta Pte. Ltd. is a company incorporated in Singapore. Based on the Schedule 13G filed by TLS Beta Pte. Ltd., among others, on January 7, 2021, TLS Beta Pte. Ltd. beneficially owned 49,509,702 ordinary shares of the Company as of December 31, 2022, representing approximately 14.6% of the Company’s total outstanding shares and voting power.

Gracell Biotechnologies Inc. Building 12, Block B, Phase II, Biobay Industrial Park, 218 Sangtian St., Suzhou Industrial Park, 215123,  
People’s  
Republic of China  
t: + 86 512-6262-6701 gracellbio.com

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- Based on the Schedule 13G filed by the LAV Entities on February 9, 2022, the LAV Entities beneficially owned 25,406,680 ordinary shares of the Company as of December 31, 2022, representing approximately 7.5% of the Company's total outstanding shares and voting power.
- Based on the Schedule 13D filed by the OrbiMed Entities on March 29, 2023, the OrbiMed Entities beneficially owned 47,488,870 ordinary shares of the Company as of March 29, 2023, representing approximately 14.0% of the Company's total outstanding shares and voting power.

In addition, the Company is not aware of any governmental entity in mainland China that is in possession of the power, direct or indirect, to direct or cause the direction of the management and policies of the Company, whether through the ownership of voting securities, by contract, or otherwise.

Given the above, the Company respectfully advises the Commission that the Company is not owned or controlled by a governmental entity in mainland China.

The above calculation of percentage ownership and voting power is based on (i) the total number of 338,576,187 ordinary shares of the Company issued and outstanding as of April 21, 2023, excluding 24,814,479 ordinary shares issued to depositary bank as of April 21, 2023, for bulk issuance of American Depositary Shares reserved for future issuances upon the exercise or vesting of awards granted under the Company's share incentive plans, (ii) the assumption that Dr. Cao's beneficial ownership in the Company remains unchanged since April 21, 2023, (iii) the assumption that TLS Beta Pte. Ltd.'s beneficial ownership in the Company remains unchanged since December 31, 2022, (iv) the assumption that the LAV Entities' beneficial ownership in the Company remains unchanged since December 31, 2022, and (v) the assumption that the OrbiMed Entities' beneficial ownership in the Company remains unchanged since March 29, 2022. For more information relating to share ownership in the Company, please refer to "Item 6. Directors, Senior Management and Employees—E. Share Ownership" of the Company's Annual Report on Form 20-F for the fiscal year ended December 31, 2022, which was filed with the Commission on April 25, 2023.

\* \* \* \*

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Should any member of the Staff have any questions or comments regarding the Company's submission set forth above, please do not hesitate to contact our outside legal counsel, Will H. Cai at (852) 3758-1210 or Jie Zhang at (852) 3758-1231.

Sincerely,

Gracell Biotechnologies Inc.

/s/ William Wei Cao

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William Wei Cao, Chief Executive Officer

cc: Yili Kevin Xie, Chief Financial Officer, Gracell Biotechnologies Inc.  
Will H. Cai, Esq., Partner, Cooley LLP  
Jie Zhang, Esq., Partner, Cooley LLP

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