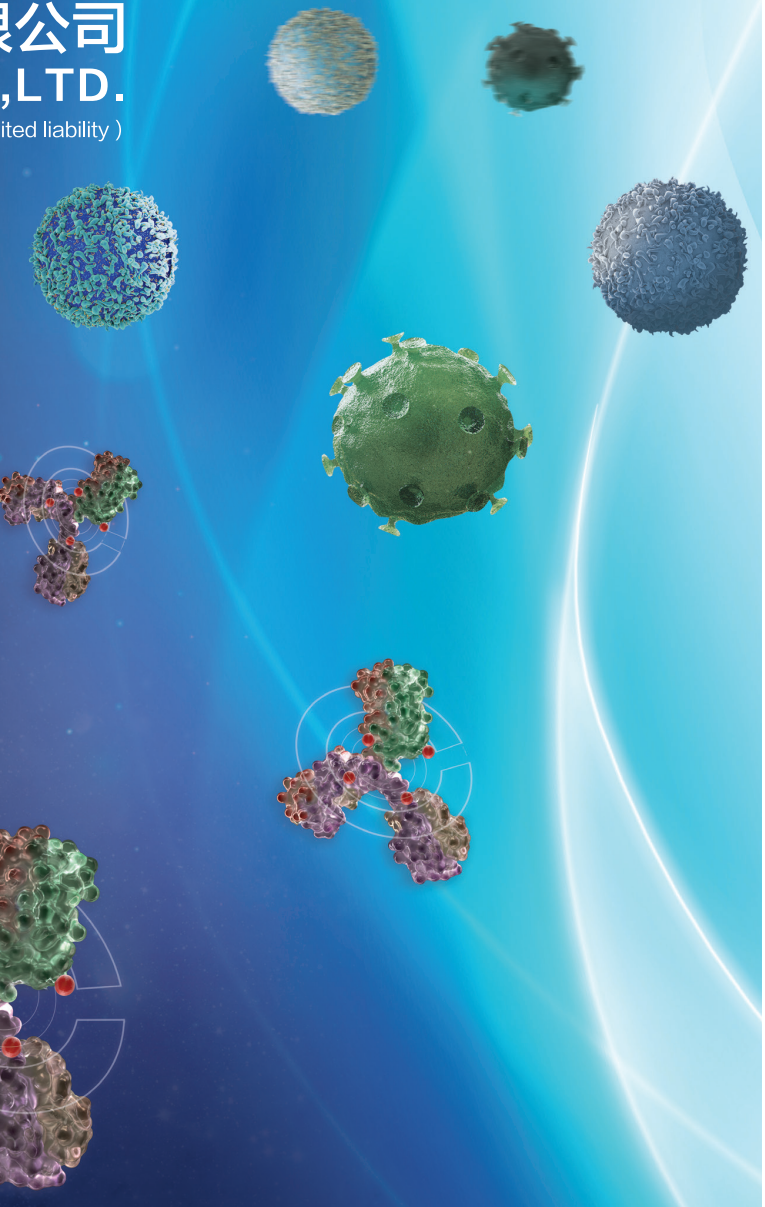
乐普生物
LEPU BIOPHARMA

# 樂普生物科技股份有限公司
# LEPU BIOPHARMA CO.,LTD.

(incorporated in the People's Republic of China with limited liability)

Stock Code: 2157



# GLOBAL OFFERING

Joint Sponsors, Joint Global Coordinators and Joint Bookrunners (in alphabetical order)

CICC 中金公司　　Morgan Stanley

Joint Bookrunners

海通國際 HAITONG　华泰国际 HUATAI INTERNATIONAL　中國銀河國際 CHINA GALAXY INTERNATIONAL　華盛証券 Valuable Capital Limited

Shanghai Miracogen Inc.- Ex. 2032, Page 000001
IPR2025-00685 (CSPC Megalith Biopharmaceutical Co., LTD. v. Shanghai Miracogen Inc.)

# IMPORTANT

*If you are in any doubt about any of the contents of this prospectus, you should seek independent professional advice.*

# LEPU BIOPHARMA CO., LTD.
# 樂普生物科技股份有限公司

*(A joint stock company incorporated in the People's Republic of China with limited liability)*

## GLOBAL OFFERING

| | | |
|---|---|---|
| **Total Number of Offer Shares under the Global Offering** | **:** | **126,876,000 H Shares (subject to the Over-allotment Option)** |
| **Number of Hong Kong Offer Shares** | **:** | **12,688,000 H Shares (subject to adjustment)** |
| **Number of International Offer Shares** | **:** | **114,188,000 H Shares (subject to the Over-allotment Option and adjustment)** |
| **Offer Price** | **:** | **Not more than HK$7.38 per H Share, plus brokerage of 1.0%, SFC transaction levy of 0.0027%, Stock Exchange trading fee of 0.005% and FRC transaction levy of 0.00015% (payable in full on application in Hong Kong dollars and subject to refund)** |
| **Nominal value** | **:** | **RMB1.00 per H Share** |
| **Stock code** | **:** | **2157** |

**Joint Sponsors, Joint Global Coordinators and Joint Bookrunners**

*(in alphabetical order)*

CICC 中金公司 Morgan Stanley

**Joint Bookrunners**

海通國際 HAITONG 华泰国际 HUATAI INTERNATIONAL 中國銀河國際 CHINA GALAXY INTERNATIONAL 華盛証券 Valuable Capital Limited

Hong Kong Exchanges and Clearing Limited, The Stock Exchange of Hong Kong Limited and Hong Kong Securities Clearing Company Limited take no responsibility for the contents of this prospectus, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this prospectus. A copy of this prospectus, having attached thereto the documents specified in "Documents Delivered to the Registrar of Companies in Hong Kong and on Display" in Appendix IX to this prospectus, has been registered by the Registrar of Companies in Hong Kong as required by section 342C of the Companies (Winding Up and Miscellaneous Provisions) Ordinance. The Securities and Futures Commission of Hong Kong and the Registrar of Companies in Hong Kong take no responsibility for the contents of this prospectus or any other documents referred to above.

The Offer Price is expected to be determined by agreement between the Joint Global Coordinators, on behalf of the Underwriters, and our Company on or before Tuesday, February 15, 2022 or such later time as may be agreed between the parties, but in any event, no later than Tuesday, February 22, 2022. If, for any reason, the Joint Global Coordinators, on behalf of the Underwriters, and our Company are unable to reach an agreement on the Offer Price by Tuesday, February 22, 2022, the Global Offering will not proceed and will lapse immediately. The Offer Price will be not more than HK$7.38 per Share and is expected to be not less than HK$6.87 per Share, unless otherwise announced. Investors applying for the Hong Kong Offer Shares must pay, on application, the maximum offer price of HK$7.38 for each Offer Share together with brokerage of 1.0%, SFC transaction levy of 0.0027%, Stock Exchange trading fee of 0.005% and FRC transaction levy of 0.00015% subject to refund if the Offer Price is lower than HK$7.38. The Joint Global Coordinators, on behalf of the Underwriters, may, with the consent of our Company, reduce the number of Offer Shares being offered under the Global Offering and/or the indicative Offer Price range below that stated in this prospectus at any time prior to the morning of the last day for lodging applications under the Public Offering. In such a case, notices of such reduction will be published in the South China Morning Post (in English) and the Hong Kong Economic Times (in Chinese) and on the websites of the Stock Exchange at **www.hkexnews.hk** and the Company at **http://www.lepubiopharma.com** as soon as practicable but in any event not later than the morning of the last day for lodging applications under the Hong Kong Public Offering.

We are incorporated, and most of our businesses are operated, in the PRC. Potential investors should be aware of the differences in legal, economic and financial systems between the PRC and Hong Kong and that there are different risk factors relating to investments in PRC-incorporated businesses. Potential investors should also be aware that the regulatory framework in the PRC is different from the regulatory framework in Hong Kong and should take into consideration the different market nature of the H Shares. Such differences and risk factors are set out in the sections headed "Risk Factors," "Appendix VI – Summary of Principal Legal and Regulatory Provisions" and "Appendix VII – Summary of the Articles of Association."

Prior to making an investment decision, prospective investors should carefully consider all of the information set out in this prospectus, in particular, the risk factors set out in the section headed "Risk Factors."

Pursuant to the termination provisions contained in the Hong Kong Underwriting Agreement in respect of the Offer Shares, the Joint Global Coordinators, on behalf of the Hong Kong Underwriters, have the right in certain circumstances, in their absolute discretion, to terminate the obligations of the Hong Kong Underwriters pursuant to the Hong Kong Underwriting Agreement at any time prior to 8:00 a.m. on the Listing Date. Further details of the terms of the termination provisions are set out in the section headed "Underwriting – Grounds for Termination". It is important that you refer to that section for further details.

The Offer Shares have not been and will not be registered under the U.S. Securities Act or any offered and sold state securities law in the United States and may not be offered, sold, pledged or otherwise transferred within the United States, except that the Offer Shares may be offered and sold (a) in the United States solely to Qualified Institutional Buyers in reliance on Rule 144A or another exemption from, or in a transaction not subject to, the registration requirements of the U.S. Securities Act or (b) outside the United States in offshore transactions in reliance on Regulation S.

**ATTENTION**

We have adopted a fully electronic application process for the Hong Kong Public Offering. We will not provide printed copies of this prospectus or printed copies of any application forms to the public in relation to the Hong Kong Public Offering.

This prospectus is available at the website of the Stock Exchange (**www.hkexnews.hk** ) and our Company **http://www.lepubiopharma.com**. If you require a printed copy of this prospectus, you may download and print from the website addresses above.

February 10, 2022

# IMPORTANT

## IMPORTANT NOTICE TO INVESTORS: FULLY ELECTRONIC APPLICATION PROCESS

**We have adopted a fully electronic application process for the Hong Kong Public Offering. We will not provide printed copies of this prospectus or printed copies of any application forms to the public in relation to the Hong Kong Public Offering.**

**This prospectus is available at the website of the Hong Kong Stock Exchange at www.hkexnews.hk under the "*HKEXnews* > *New Listings* > *New Listing Information*" section, and our website at https://www.lepubiopharma.com. If you require a printed copy of this prospectus, you may download and print from the website addresses above.**

To apply for the Hong Kong Offer Shares, you may:

(1) apply online through the **White Form eIPO** service at **www.eipo.com.hk**; or

(2) apply through **CCASS EIPO** service to electronically cause HKSCC Nominees to apply on your behalf, including by:

  (i) instructing your **broker** or **custodian** who is a CCASS Clearing Participant or a CCASS Custodian Participant to give **electronic application instructions** via CCASS terminals to apply for the Hong Kong Offer Shares on your behalf; or

  (ii) (if you are an existing **CCASS Investor Participant**) giving **electronic application instructions** through the CCASS Internet System (**https://ip.ccass.com**) or through the CCASS Phone System by calling +852 2979 7888 (using the procedures in HKSCC's "An Operating Guide for Investor Participants" in effect from time to time). HKSCC can also input **electronic application instructions** for CCASS Investor Participants through HKSCC's Customer Service Centre at 1/F, One & Two Exchange Square, 8 Connaught Place, Central, Hong Kong by completing an input request.

If you have any question about the application for the Hong Kong Offer Shares, you may call the enquiry hotline of our H Share Registrar and **White Form eIPO** Service Provider, Computershare Hong Kong Investor Services Limited, both at +852 2862 8629 on the following dates:

**Thursday, February 10, 2022 – 9:00 a.m. to 9:00 p.m.**
**Friday, February 11, 2022 – 9:00 a.m. to 9:00 p.m.**
**Monday, February 14, 2022 – 9:00 a.m. to 9:00 p.m.**
**Tuesday, February 15, 2022 – 9:00 a.m. to 12:00 noon**

# IMPORTANT

We will not provide any physical channels to accept any application for the Hong Kong Offer Shares by the public. The contents of the electronic version of this prospectus are identical to the printed document as registered with the Registrar of Companies in Hong Kong pursuant to Section 342C of the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

If you are an **intermediary**, **broker** or **agent**, please remind your customers, clients or principals, as applicable, that this prospectus is available online at the website addresses above.

Please refer to "How to Apply for Hong Kong Offer Shares" for further details on the procedures through which you can apply for the Hong Kong Offer Shares electronically.

Your application through the **White Form eIPO** service or by giving **electronic application instructions** to HKSCC must be for a minimum of 1,000 Hong Kong Offer Shares and in one of the numbers set out in the table. You are required to pay the amount next to the number you select.

**Lepu Biopharma Co., Ltd. (Stock Code: 2157)**

**(HK$7.38 per Hong Kong Offer Share)**

**NUMBER OF HONG KONG OFFER SHARES THAT MAY BE APPLIED FOR AND PAYMENTS**

| No. of Hong Kong Offer Shares applied for | Amount payable on application *HK$* | No. of Hong Kong Offer Shares applied for | Amount payable on application *HK$* | No. of Hong Kong Offer Shares applied for | Amount payable on application *HK$* | No. of Hong Kong Offer Shares applied for | Amount payable on application *HK$* |
|---|---|---|---|---|---|---|---|
| 1,000 | 7,454.38 | 15,000 | 111,815.70 | 80,000 | 596,350.35 | 900,000 | 6,708,941.39 |
| 2,000 | 14,908.76 | 20,000 | 149,087.59 | 90,000 | 670,894.14 | 1,000,000 | 7,454,379.33 |
| 3,000 | 22,363.14 | 25,000 | 186,359.49 | 100,000 | 745,437.94 | 1,500,000 | 11,181,569.00 |
| 4,000 | 29,817.52 | 30,000 | 223,631.38 | 200,000 | 1,490,875.86 | 2,000,000 | 14,908,758.66 |
| 5,000 | 37,271.91 | 35,000 | 260,903.28 | 300,000 | 2,236,313.80 | 2,500,000 | 18,635,948.33 |
| 6,000 | 44,726.28 | 40,000 | 298,175.17 | 400,000 | 2,981,751.73 | 3,000,000 | 22,363,137.99 |
| 7,000 | 52,180.65 | 45,000 | 335,447.08 | 500,000 | 3,727,189.67 | 4,000,000 | 29,817,517.32 |
| 8,000 | 59,635.03 | 50,000 | 372,718.96 | 600,000 | 4,472,627.60 | 5,000,000 | 37,271,896.65 |
| 9,000 | 67,089.41 | 60,000 | 447,262.76 | 700,000 | 5,218,065.53 | 6,000,000 | 44,726,275.98 |
| 10,000 | 74,543.79 | 70,000 | 521,806.55 | 800,000 | 5,963,503.47 | 6,344,000(1) | 47,290,582.48 |

(1) Maximum number of Hong Kong Offer Shares you may apply for.

No application for any other number of the Hong Kong Offer Shares will be considered and any such application is liable to be rejected.

# EXPECTED TIMETABLE[1]

*If there is any change in the following expected timetable of the Hong Kong Public Offering, we will issue an announcement in Hong Kong to be published on the websites of the Stock Exchange at* ***www.hkexnews.hk*** *and our Company at* ***http://www.lepubiopharma.com****.*

Hong Kong Public Offering commences ..... 9:00 a.m. on Thursday, February 10, 2022

Latest time to complete electronic applications under **White Form eIPO** service through the designated website **www.eipo.com.hk**[2] ..... 11:30 a.m. on Tuesday, February 15, 2022

Application lists open[3] ..... 11:45 a.m. on Tuesday, February 15, 2022

Latest time for (a) completing payment of **White Form eIPO** applications by effecting internet banking transfer(s) or PPS payment transfer(s) and (b) giving **electronic application instructions** to HKSCC[4] ..... 12:00 noon on Tuesday, February 15, 2022

If you are instructing your **broker** or **custodian** who is a CCASS Clearing Participant or a CCASS Custodian Participant to give **electronic application instructions** via CCASS terminals to apply for the Hong Kong Offer Shares on your behalf, you are advised to contact your **broker** or **custodian** for the latest time for giving such instructions which may be different from the latest time as stated above.

Application lists close[3] ..... 12:00 noon on Tuesday, February 15, 2022

Expected Price Determination Date[5] ..... Tuesday, February 15, 2022

Announcement of Offer Price, the level of applications in the Hong Kong Public Offering; the indication of level of interest in the International Offering; and the basis of allocation of the Hong Kong Offer Shares to be published on our website at **http://www.lepubiopharma.com**[6] and the website of the Stock Exchange at **www.hkexnews.hk** on or before ..... Tuesday, February 22, 2022



Shanghai Miracogen Inc.- Ex. 2032, Page 000005

The results of allocations in the Hong Kong Public Offering (with successful applicants' identification document numbers, where appropriate) to be available through a variety of channels, including:

- in the announcement to be posted on our website and the website of the Stock Exchange at **http://www.lepubiopharma.com** and **www.hkexnews.hk**, respectively . . . . . Tuesday, February 22, 2022

- from the designated results of allocations website at **www.iporesults.com.hk** (alternatively: English **https://www.eipo.com.hk/en/Allotment**; Chinese **https://www.eipo.com.hk/zh-hk/Allotment**) with a "search by ID" function from . . . . . 8:00 a.m. on Tuesday, February 22, 2022 to 12:00 midnight on Monday, February 28, 2022

- from the allocation results telephone enquiry by calling +852 2862 8555 between 9:00 a.m. and 6:00 p.m. on . . . . . Tuesday, February 22, 2022, Wednesday, February 23, 2022, Thursday, February 24, 2022 and Friday, February 25, 2022

H Share certificates in respect of wholly or partially successful applications to be dispatched/collected or deposited into CCASS on or before[7] [9] . . . . . Tuesday, February 22, 2022

**White Form** e-Refund payment instructions/refund checks in respect of wholly or partially successful applications if the final Offer Price is less than the maximum Offer Price per Offer Share initially paid on application (if applicable) or wholly or partially unsuccessful applications to be dispatched/collected on or before[8] [9] . . . Tuesday, February 22, 2022

Dealings in H Shares on the Hong Kong Stock Exchange expected to commence at 9:00 a.m. on . . . . . Wednesday, February 23, 2022



Shanghai Miracogen Inc.- Ex. 2032, Page 000006

*Notes:*

(1) All dates and times refer to Hong Kong local dates and times, except as otherwise stated. Details of the structure of the Global Offering, including conditions of the Hong Kong Public Offering, are set forth in the section headed "Structure of the Global Offering" in this prospectus.

(2) If you have already submitted your application through the designated website at **www.eipo.com.hk** and obtained an application reference number from the designated website prior to 11:30 a.m., you will be permitted to continue the application process (by completing payment of application monies) until 12:00 noon on the last day for submitting applications, when the application lists close. You will not be permitted to submit your application through the designated website at **www.eipo.com.hk** after 11:30 a.m. on the last day for submitting applications.

(3) If there is/are a tropical cyclone warning signal number 8 or above, or a "black" rainstorm warning and/or Extreme Conditions in force in Hong Kong at any time between 9:00 a.m. and 12:00 noon on Tuesday, February 15, 2022, the application lists will not open or close on that day. Please refer to the paragraph headed "How to Apply for Hong Kong Offer Shares – 10. Effect of Bad Weather on the Opening and Closing of the Application Lists" in this prospectus.

(4) Applicants who apply for the Hong Kong Offer Shares by giving **electronic application instructions** to HKSCC should refer to the paragraph headed "How to Apply for Hong Kong Offer Shares – 6. Applying through CCASS EIPO Service" in this prospectus.

(5) The Price Determination Date is expected to be on or about Tuesday, February 15, 2022, and in any event, not later than Tuesday, February 22, 2022. If, for any reason, the Offer Price is not agreed between the Joint Global Coordinators (for themselves and on behalf of the Underwriters) and us on or before Tuesday, February 22, 2022, the Global Offering will not proceed and will lapse.

(6) None of the website or any of the information contained on the website forms part of this prospectus.

(7) The H Share certificates will only become valid certificates of title provided that the Global Offering has become unconditional in all respects and neither of the Hong Kong Underwriting Agreement nor the International Underwriting Agreement is terminated in accordance with its respective terms prior to 8:00 a.m. on the Listing Date. The Listing Date is expected to be on or about Wednesday, February 23, 2022. Investors who trade the H Shares on the basis of publicly available allocation details prior to the receipt of H Share certificates or prior to the H Share certificates becoming valid certificates of title do so entirely at their own risk.

(8) e-Refund payment instructions/refund checks will be issued in respect of wholly or partially unsuccessful applications, and also in respect of wholly or partially successful applications if the Offer Price is less than the price payable on application. Part of the applicant's Hong Kong identity card number or passport number, or, if the application is made by joint applicants, part of the Hong Kong identity card number or passport number of the first-named applicant, provided by the applicant(s) may be printed on the refund check, if any. Such data would also be transferred to a third party for refund purposes. Banks may require verification of an applicant's Hong Kong identity card number or passport number before encashment of the refund check. Inaccurate completion of an applicant's Hong Kong identity card number or passport number may invalidate or delay encashment of the refund check.

(9) Applicants who have applied on **White Form eIPO** for 1,000,000 or more Hong Kong Offer Shares may collect any refund checks (where applicable) and/or H Share certificates in person from our H Share Registrar, Computershare Hong Kong Investor Services Limited, at Shops 1712-1716, 17th Floor, Hopewell Centre, 183 Queen's Road East, Wan Chai, Hong Kong from 9:00 a.m. to 1:00 p.m. on Tuesday, February 22, 2022 or such other date as notified by us as the date of dispatch/collection of H Share certificates/e-refund payment instructions/refund checks. Applicants being individuals who are eligible for personal collection may not authorize any other person to collect on their behalf. Individuals must produce evidence of identity acceptable to our H Share Registrar at the time of collection.

Applicants who have applied for Hong Kong Offer Shares through CCASS EIPO service should refer to the section headed "How to Apply for Hong Kong Offer Shares – 14. Despatch/Collection of Share Certificates and Refund Monies – Personal Collection – If you apply through CCASS EIPO service" in this prospectus for details.



Shanghai Miracogen Inc.- Ex. 2032, Page 000007

Applicants who have applied through the **White Form eIPO** service and paid their applications monies through single bank accounts may have refund monies (if any) dispatched to the bank account in the form of e-Refund payment instructions. Applicants who have applied through the **White Form eIPO** service and paid their application monies through multiple bank accounts may have refund monies (if any) dispatched to the address as specified in their application instructions in the form of refund checks by ordinary post at their own risk.

H Share certificates and/or refund checks for applicants who have applied for less than 1,000,000 Hong Kong Offer Shares and any uncollected H Share certificates and/or refund checks will be dispatched by ordinary post, at the applicants' risk, to the addresses specified in the relevant applications.

Further information is set out in the sections headed "How to Apply for Hong Kong Offer Shares – 13. Refund of Application Monies" and "How to Apply for Hong Kong Offer Shares – 14. Despatch/Collection of Share Certificates and Refund Monies".

The above expected timetable is a summary only. For details of the structure of the Global Offering, including its conditions, and the procedures for applications for Hong Kong Offer Shares, please refer to the sections headed "Structure of the Global Offering" and "How to Apply for Hong Kong Offer Shares" in this prospectus, respectively.

If the Global Offering does not become unconditional or is terminated in accordance with its terms, the Global Offering will not proceed. In such a case, the Company will publish an announcement as soon as practicable thereafter.



Shanghai Miracogen Inc.- Ex. 2032, Page 000008

# CONTENTS

**IMPORTANT NOTICE TO INVESTORS**

*This prospectus is issued by the Company solely in connection with the Hong Kong Public Offering and does not constitute an offer to sell or a solicitation of an offer to buy any security other than the Hong Kong Offer Shares offered by this prospectus pursuant to the Hong Kong Public Offering. This prospectus may not be used for the purposes of, and does not constitute, an offer or invitation in any other jurisdiction or in any other circumstances. No action has been taken to permit a public offering of the Offer Shares or the distribution of this prospectus in any jurisdiction other than Hong Kong.*

*You should rely only on the information contained in this prospectus and the Application Forms to make your investment decision. Our Company has not authorized anyone to provide you with information that is different from what is contained in this prospectus. Any information or representation not made in this prospectus must not be relied on by you as having been authorized by our Company, the Joint Sponsors, Joint Global Coordinators and Joint Bookrunners, the Joint Lead Managers, any of the Underwriters, any of their respective directors, officers, representatives or advisors or any other person involved in the Global Offering.*


*Page*

**EXPECTED TIMETABLE** . . . . . i

**CONTENTS** . . . . . v

**SUMMARY** . . . . . 1

**DEFINITIONS** . . . . . 43

**GLOSSARY OF TECHNICAL TERMS** . . . . . 60

**FORWARD-LOOKING STATEMENTS** . . . . . 72

**RISK FACTORS** . . . . . 74

**WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES AND EXEMPTION FROM STRICT COMPLIANCE WITH THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE** . . . . . 144

**INFORMATION ABOUT THIS PROSPECTUS AND THE GLOBAL OFFERING** . . . . . 154

**DIRECTORS AND PARTIES INVOLVED IN THE GLOBAL OFFERING** . . . . . 160

**CORPORATE INFORMATION** . . . . . 167





Shanghai Miracogen Inc.- Ex. 2032, Page 000009

# CONTENTS


| | | |
|---|---|---|
| **INDUSTRY OVERVIEW** | | 170 |
| **REGULATORY OVERVIEW** | | 211 |
| **HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE** | | 233 |
| **BUSINESS** | | 263 |
| **CONNECTED TRANSACTIONS** | | 440 |
| **DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT** | | 450 |
| **RELATIONSHIP WITH CONTROLLING SHAREHOLDER** | | 471 |
| **SUBSTANTIAL SHAREHOLDERS** | | 476 |
| **SHARE CAPITAL** | | 480 |
| **FINANCIAL INFORMATION** | | 490 |
| **FUTURE PLANS AND USE OF PROCEEDS** | | 540 |
| **CORNERSTONE INVESTORS** | | 544 |
| **UNDERWRITING** | | 550 |
| **STRUCTURE OF THE GLOBAL OFFERING** | | 563 |
| **HOW TO APPLY FOR HONG KONG OFFER SHARES** | | 575 |
| **APPENDIX I** | **ACCOUNTANT'S REPORT** | I-1 |
| **APPENDIX II** | **UNAUDITED PRO FORMA FINANCIAL INFORMATION** | II-1 |
| **APPENDIX III** | **LOSS ESTIMATE** | III-1 |
| **APPENDIX IV** | **PROPERTY VALUATION REPORT** | IV-1 |
| **APPENDIX V** | **TAXATION AND FOREIGN EXCHANGE** | V-1 |
| **APPENDIX VI** | **SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS** | VI-1 |
| **APPENDIX VII** | **SUMMARY OF THE ARTICLES OF ASSOCIATION** | VII-1 |
| **APPENDIX VIII** | **STATUTORY AND GENERAL INFORMATION** | VIII-1 |
| **APPENDIX IX** | **DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES IN HONG KONG AND ON DISPLAY** | IX-1 |




Shanghai Miracogen Inc.- Ex. 2032, Page 000010

*This summary aims to give you an overview of the information contained in this prospectus. As it is a summary, it does not contain all the information that may be important to you. You should read the whole prospectus before you decide to invest in the Offer Shares. There are risks associated with any investment. Some of the particular risks in investing in the Offer Shares are set out in the section headed "Risk Factors" in this prospectus. You should read that section carefully in full before you decide to invest in the Offer Shares.*

## OVERVIEW

Incorporated on January 19, 2018, we are a biopharmaceutical company focusing on oncology therapeutics, seeking to list on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules on the basis that we are unable to meet the requirements under Rule 8.05 (1), (2) or (3) of the Listing Rules. Our pipeline has been designed with a range of oncology products. As of the Latest Practicable Date, we had (i) eight clinical-stage drug candidates, including four Core Products acquired through acquisitions of all equity interests or controlling stake in the relevant subsidiaries, with three of them subject to in-license arrangements and one of them co-developed through a joint venture, (ii) three pre-clinical drug candidates, and (iii) three clinical-stage combination therapies of the candidates in our pipeline. Among the eight clinical-stage drug candidates, five are in targeted therapy and three are in immunotherapy, with two of the three being immune checkpoint drugs and one being oncolytic virus drug. As of the Latest Practicable Date, we had initiated 28 clinical trials, among which three had entered registration trial phase and two were ongoing in the U.S.

**WE MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP OR MARKET OUR CORE PRODUCTS, INCLUDING MRG003, MRG002, HX008 AND LP002.**

The following chart summarizes the development status of our clinical-stage and pre-clinical drug candidates:



Shanghai Miracogen Inc.- Ex. 2032, Page 000011

Shanghai Miracogen Inc.- Ex. 2032, Page 000012

*Notes:*

* Denotes our core product candidates

** Denotes registration trials

1 MRG003 received IND approval from the NMPA in August 2017, which includes Phase Ia, Ib clinical study protocol and subsequent Phase II and Phase III study draft protocols. We acquired MRG003 at the Phase Ia stage and completed MRG003 Phase Ia trial in January 2020 and MRG003 Phase Ib trial in March 2021. As advised by our PRC Legal Advisor and taking into account the industry practice as advised by Frost & Sullivan, the MRG003 Phase Ia trial was a complete clinical trial with its main purpose aligning with the overall purpose of a conventional phase I trial, and the completion of the MRG003 Phase Ia trial is thus equivalent to the completion of a conventional Phase I trial. The MRG003 Phase II trials had been duly registered with the NMPA per the relevant regulatory requirements without any objection from the NMPA to our clinical development plans with respect to the regulatory review or approval process of MRG003. We have obtained all necessary approvals from the NMPA to proceed with the MRG003 Phase II trials. As of the Latest Practicable Date, we were conducting Phase II clinical trials of MRG003 in recurrent or metastatic advanced HNSCC, NPC, advanced NSCLC and BTC in China and expect to initiate Phase Ia/Ib clinical trials in recurrent or metastatic advanced HNSCC in the U.S.

2 MRG002 received IND approval from the NMPA in May 2018, which includes Phase Ia, Ib clinical study protocol and subsequent Phase II and Phase III study draft protocols. We acquired MRG002 when it obtained IND approval and completed MRG002 Phase Ia trial in August 2020. As advised by our PRC Legal Advisor and taking into account the industry practice as advised by Frost & Sullivan, the MRG002 Phase Ia trial was a complete clinical trial with its main purpose aligning with the overall purpose of a conventional phase I trial, and the completion of the MRG002 Phase Ia trial is thus equivalent to the completion of a conventional Phase I trial. Additionally, as part of the application to the NMPA for the combination program of MRG002 with HX008, the results of the MRG002 Phase Ia trial have been submitted to the NMPA for assessment. In January 2021, the NMPA confirmed in writing that, based on the pre-clinical and clinical data submitted to the NMPA (including the results of the MRG002 Phase Ia trial and the HX008 Phase Ia trial), we have provided support to proceed with phase I/II trial for the combination program of MRG002 with HX008. The MRG002 Phase II trials had been duly registered with the NMPA per the relevant regulatory requirements without any objection from the NMPA to our clinical development plans with respect to the regulatory review or approval process of MRG002. We have obtained all necessary approvals from the NMPA to proceed with the MRG002 Phase II trials. As of the Latest Practicable Date, we had initiated Phase II clinical trials of MRG002 in HER2 low-expressing and over-expressing breast cancer, UC (urothelial cancer) and HER2 over-expressing BTC. For HER2 over-expressing breast cancer, we had completed patient enrollment and were in the follow-up period, and had obtained approval from the NMPA of registration trial as of the Latest Practicable Date. In addition, we had initiated a Phase I/II clinical trial of MRG002 in gastric cancer in the U.S. and China as of the Latest Practicable Date.

3 HX008 received IND approval from the NMPA in August 2017, which includes Phase Ia, Ib clinical study protocol and subsequent Phase II and Phase III study draft protocols. We obtained HX008 at the Phase Ia stage and its Phase Ia trial was completed with MTD and RP2D determined per the clinical trial protocol in May 2018 and the final CSR issued in May 2020. As advised by our PRC Legal Advisor and taking into account the industry practice as advised by Frost & Sullivan, the HX008 Phase Ia trial was a complete clinical trial with its main purpose aligning with the overall purpose of a conventional phase I trial, and the completion of the HX008 Phase Ia trial is thus equivalent to the completion of a conventional Phase I trial. We filed an NDA of HX008 with the NMPA in melanoma in June 2021. We submitted pre-NDA meeting application of HX008 in MSI-H/dMMR solid tumors in July 2021, filed an NDA of HX008 with the NMPA in MSI-H/dMMR solid tumors in October 2021 and was granted priority review. According to our PRC Legal Advisor, we have obtained all necessary approvals from the NMPA to, proceed with the HX008 Phase II registration trials. As of the Latest Practicable Date, we had completed patient enrollment and were in the follow-up period for Phase Ib clinical trial of HX008 in advanced solid tumor and for Phase II clinical trials in NSCLC, TNBC (triple-negative breast cancer), gastric cancer and HCC. We were also conducting a Phase II clinical trial in NMIBC and a Phase III clinical trial in the second-line gastric cancer. We plan to initiate the Phase III clinical trials of HX008 in melanoma and in MSI-H/dMMR solid tumors after obtaining the respective approvals.

4 LP002 received IND approval from the NMPA in August 2018, which includes Phase Ia, Ib clinical study protocol and subsequent Phase II and Phase III study draft protocols. We obtained LP002 at its pre-clinical stage and completed LP002 Phase Ia trial in April 2019. As advised by our PRC Legal Advisor and taking into account the industry practice as advised by Frost & Sullivan, the LP002 Phase Ia trial was a complete clinical trial with its main purpose aligning with the overall purpose of a conventional Phase I trial, and thus is equivalent to the completion of a conventional Phase I trial. The data from the LP002 Phase Ia trial on its own has been accepted by the NMPA as sufficient to proceed with the LP002 Phase II trial. The LP002 Phase II trial for ES-SCLC indication had been duly registered with the NMPA pursuant to the relevant regulatory requirements without any objection from the NMPA to our clinical development plans with respect to its regulatory review or approval process. We have obtained all necessary approvals from the NMPA to proceed with LP002 Phase II trials. As of the Latest Practicable Date, we were in the process of a cohort expansion trial in advanced digestive system cancer and had completed patient enrollment and entered the follow-up period for Phase II clinical trial in ES-SCLC (extensive stage small-cell lung cancer).

5 Miracogen Shanghai acquired the co-ownership of the TF-targeted mAb and the joint right to develop ADCs based on the TF-targeted mAb from Fudan University and SIMMCAS. See "Business – Collaboration, Licensing and Transfer Arrangements – Collaboration with Fudan University and SIMMCAS." We received the IND clearance of MRG004A from the FDA in February 2021 to initiate Phase I/II clinical trials in patients with TF-positive advanced or metastatic solid tumors and we received IND approval of MRG004A from the NMPA in August 2021.



Shanghai Miracogen Inc.- Ex. 2032, Page 000013

6 CMG901 is co-developed by Keymed and us through KYM, a joint venture owned by us and Keymed's affiliate, iBridge, in which we owned 30.0% equity interest as of the Latest Practicable Date. See "Business – Collaboration, Licensing and Transfer Arrangements – Collaboration with Keymed and iBridge." KYM was enrolling patients for a Phase I clinical trial of CMG901 in advanced gastric cancer and pancreatic cancer in China as of the Latest Practicable Date and submitted an IND application to the FDA in February 2021 for a Phase I clinical trial in advanced unresectable or metastatic G/GEJ carcinoma.

7 We in-licensed the rights to develop, manufacture and commercialize CG0070 in Mainland China, Hong Kong and Macau from CG Oncology. See "Business – Collaboration, Licensing and Transfer Arrangements – Collaboration with CG Oncology." CG Oncology had completed a Phase II clinical trial (BOND II) of CG0070 in BCG-unresponsive NMIBC in the U.S., and we obtained IND approval for CG0070 from the NMPA in November 2021.

8 OH2 is an oncolytic virus developed by Wuhan Binhui. As of the Latest Practicable Date, we had initiated a Phase I clinical trial for LP002 in combination with OH2 for the treatment of advanced solid tumors. See "Business – Combination Therapies within Our Pipeline."

9 The status below refers to the clinical development progress of the relevant drug candidates and combination therapies in China except as otherwise specified.

10 According to the Technical Guidelines for the Communication of Clinical Aspects of Single-arm Trials to Support Pre-marketing License Applications for Marketed Antineoplastic Drugs (《單臂試驗支持上市的抗腫瘤藥上市許可申請前臨床方面溝通交流技術指導原則》) issued by the NMPA, we must conduct Phase III clinical trials for HX008. We plan to initiate the Phase III clinical trials for HX008 in melanoma and in MSI-H/dMMR solid tumors after obtaining the respective approvals.



Shanghai Miracogen Inc.- Ex. 2032, Page 000014

**Our Business Model**

We have built a pipeline of drug candidates focusing on oncology therapeutics in several indications. The majority of our pipeline products were obtained through acquisitions of subsidiaries, in-licensing and joint venture. We relied on our research and development team to carry out the subsequent clinical trials and research and development activities.

We obtained global rights to the ADC drug candidates of MRG003, MRG002 and MRG001 in our pipeline by acquiring the controlling equity interest in Miracogen Shanghai in July 2018, and developed our ADC drug candidate MRG004A in house. We are also collaborating with Keymed and its affiliate, iBridge HK Holding Limited ("iBridge"), in the development of CMG901.

- ***MRG003***: We acquired MRG003 at the Phase Ia stage. Since our acquisition of Miracogen Shanghai in July 2018, we completed MRG003 Phase Ia trial in January 2020 and MRG003 Phase Ib trial in March 2021; we also initiated Phase II clinical trials of MRG003 in various indications. As of the Latest Practicable Date, we were conducting Phase II clinical trials of MRG003 in recurrent or metastatic advanced HNSCC (head and neck squamous cell carcinoma), NPC (nasopharyngeal cancer), advanced NSCLC (non-small cell lung cancer) and BTC (biliary tract cancer) in China, and expect to initiate Phase Ia/Ib clinical trials in recurrent or metastatic advanced HNSCC in the U.S.

- ***MRG002***: We acquired MRG002 when it obtained IND approval. Since our acquisition of Miracogen Shanghai in July 2018, we completed MRG002 Phase Ia trial in August 2020. As of the Latest Practicable Date, we had initiated Phase II clinical trials of MRG002 in HER2 low-expressing and over-expressing breast cancer, UC (urothelial cancer) and HER2 over-expressing BTC. For HER2 over-expressing breast cancer, we had completed patient enrollment and were in the follow-up period, and had obtained approval from the NMPA of registration trial as of the Latest Practicable Date. In addition, we were conducting a Phase I/II clinical trial of MRG002 in gastric cancer in the U.S. and China as of the Latest Practicable Date.

We obtained our anti PD-1 antibody candidate, HX008, and our anti PD-L1 antibody candidate, LP002, by acquiring the controlling equity interest in Taizhou Hanzhong Biotechnology Co., Ltd. ("Taizhou Hanzhong") and Taizhou Houde Aoke Technology Co., Ltd. ("Taizhou Aoke"), respectively.

- ***HX008***: We obtained HX008 at Phase Ia stage. Since our acquisition of Taizhou Hanzhong from Ningbo Houde Yimin in June 2018 and from HanX pursuant to the equity purchase agreement entered in September 2019, the HX008 Phase Ia trial was completed with MTD and RP2D determined per the clinical trial protocol in May 2018 and final CSR issued in May 2020; its main purpose aligned with the overall purpose of a conventional phase I trial as advised by our PRC Legal Advisor and



Shanghai Miracogen Inc.- Ex. 2032, Page 000015

taking into account the industry practice as advised by Frost & Sullivan. As of the Latest Practicable Date, we had completed patient enrollment and were in the follow-up period for Phase Ib clinical trial of HX008 in advanced solid tumor and for Phase II clinical trial in NSCLC, in gastric cancer, TNBC (triple-negative breast cancer) and HCC. We also initiated Phase II clinical trials in NMIBC and registration trials in melanoma and MSI-H/dMMR (high levels of microsatellite instability/deficient mismatch repair) solid tumors. The HX008 Phase II Melanoma Registration trial was completed with its clinical study objective achieved as per the clinical trial protocol in January 2021. We are also in the process of a Phase III clinical trial in the second-line gastric cancer. We filed an NDA of HX008 with the NMPA in melanoma in June 2021. We submitted pre-NDA meeting application of HX008 in MSI-H/dMMR solid tumors in July 2021, filed an NDA of HX008 with the NMPA in MSI-H/dMMR solid tumors and was granted priority review in October 2021.

- ***LP002***: We obtained LP002 at pre-clinical stage. Since our acquisition of Taizhou Aoke from Ningbo Houde Yimin in June 2018, we completed LP002 Phase Ia clinical trial in April 2019. As of Latest Practicable Date, we were in the process of a cohort expansion trial in advanced digestive system cancer and had completed patient enrollment and entered the follow-up period for Phase II clinical trial in ES-SCLC (extensive stage small-cell lung cancer).

We in-licensed our oncolytic virus product CG0070 from a third-party business partner CG Oncology, Inc. ("CG Oncology") in March 2019 with the rights to develop, manufacture and commercialize it in Mainland China, Hong Kong and Macau.

We have the global rights to develop and commercialize our clinical-stage and pre-clinical drug candidates and the drug candidate we co-developed through a joint venture apart from CG0070 for which we were granted the right to develop, manufacture and commercialize in Mainland China, Hong Kong and Macau.

Our major pipeline assets consist of four Core Products, namely, MRG003, MRG002, HX008 and LP002, and three key clinical-stage drug candidates:

➢ *ADC drug candidates (Core products)*

- ***MRG003 (Core Product)***: MRG003 is an EGFR-targeted ADC in Phase II clinical trials in China. We expect to initiate clinical trials in recurrent or metastatic advanced HNSCC in the U.S. and expand MRG003 indications based on the clinical data obtained, further expanding the overall addressable market with the aim of achieving international commercialization with MRG003.



Shanghai Miracogen Inc.- Ex. 2032, Page 000016

Please refer to the following comparison of the efficacy of MRG003 with other globally marketed EGFR-ADC.

| Drug Name | Indications (Clinical trial stage, as applicable) | ORR | DCR | CR | PR | SD |
|---|---|---|---|---|---|---|
| Cetuximab Sarotalocan Sodium | Head and Neck Cancer | 43.4% | N/A | 13.3% | 30.0% | 36.7% |
| MRG003 | >2L HNSCC (Phase Ib) | 40.0% | 100.0% | N/A | N/A | N/A |
| | >2L NPC (Phase Ib) | 44.4% | 88.8% | N/A | N/A | N/A |

Abbreviations: ORR = objective response rate; DCR = disease control rate; CR = complete response; PR = partial response; SD = stable disease

*Source: PMDA, Literature Review, Frost & Sullivan*

*Note:*

1. N/A refers to data not available.

2. No head-to-head comparison was conducted between drugs. Clinical trials of a drug cannot be directly compared to the clinical trials of another drug and may not be representative of the overall data.

- ***MRG002 (Core Product)***: MRG002 is an HER2-targeted ADC, innovatively designed to utilize a high affinity anti-HER2 mAb that is sugar-modified trastuzumab, a clinically-validated payload MMAE and a cleavable vc linker. As of the Latest Practicable Date, we had initiated Phase II clinical trials of MRG002 in HER2 low-expressing and over-expressing breast cancer, UC (urothelial cancer) and HER2 over-expressing BTC. For HER2 over-expressing breast cancer, we had completed patient enrollment and were in the follow-up period, and had obtained approval from the NMPA of registration trial as of the Latest Practicable Date.



Shanghai Miracogen Inc.- Ex. 2032, Page 000017

Please refer to the following comparison of the efficacy of MRG002 with other globally marketed HER2-ADC.

| Drug Name | Indications (Clinical trial stage, as applicable) | ORR | DCR | CR | PR | SD | DOR (months) | PFS (months) | OS (months) |
|---|---|---|---|---|---|---|---|---|---|
| Trastuzumab deruxtecan-nxki | HER2-positive breast cancer | 60.9% | 97.3% | 6.0% | 54.9% | 36.4% | 14.8 | 16.4 | 24.6 |
| Adotrastuzumab emtansine | HER2-positive breast cancer | 43.6% | N/A | N/A | N/A | N/A | 12.6 | 9.6 | 30.9 |
| Disitamab Vedotin | Locally advanced or metastatic gastric cancer and gastroesophageal junction adenocarcinoma | 24.4% | N/A | N/A | N/A | N/A | N/A | 4.1 | 7.6 |
| MRG002 | HER2-positive advanced solid tumors (Phase Ia) | 45.5% | 81.8% | 0.0% | 45.5% | 36.4% | N/A | N/A | N/A |
| | HER2-positive advanced solid tumors (Phase Ib) | 53.2% | 93.6% | 0.0% | 53.2% | 40.4% | N/A | N/A | N/A |

Abbreviations: ORR = objective response rate; DCR = disease control rate; CR = complete response; PR = partial response; SD = stable disease; DOR = duration of objective response; PFS = progression-free survival; OS = overall survival

*Source: FDA, CDE, Literature Review, Frost & Sullivan*

*Notes:*

1. N/A refers to data not available.

2. No head-to-head comparison was conducted between drugs. Clinical trials of a drug cannot be directly compared to the clinical trials of another drug and may not be representative of the overall data.



Shanghai Miracogen Inc.- Ex. 2032, Page 000018

➢ *Anti-PD-1/anti-PD-L1 drug candidates*

- ***HX008 (Core Product)***: HX008 is a humanized antagonist mAb (monoclonal antibody, an antibody generated by identical cells that are all clones of the same parent cell) to human PD-1. As of the Latest Practicable Date, we had completed patient enrollment and were in the follow-up period for Phase Ib clinical trial of HX008 in advanced solid tumor and Phase II clinical trial in NSCLC, TNBC (triple-negative breast cancer), gastric cancer and HCC, and were conducting Phase II clinical trial in NMIBC and Phase III clinical trial in second-line gastric cancer. We have completed the registration trials in melanoma and MSI-H/dMMR solid tumors.

  Please refer to the following comparison of the efficacy of HX008 with other marketed PD-1 mAbs with the same indications.

| Drug name | Indications (Clinical trial stage, as applicable) | ORR | DCR | CR | PR | SD | DOR (months) | PFS (months) | OS (months) |
|---|---|---|---|---|---|---|---|---|---|
| HX008 | MSI-H/dMMR solid tumors (Phase II) | 46.0% | 70.0% | N/A | N/A | N/A | N/A | N/A | N/A |
| Pembrolizumab | MSI-H/dMMR solid tumors | 39.6% | N/A | 7.4% | 32.2% | N/A | NR | N/A | N/A |
| Nivolumab | MSI-H/dMMR CRC | 32.0% | N/A | 9.0% | 23.0% | N/A | N/A | N/A | N/A |
| HX008 | Melanoma (Phase II) | 18.5% | 44.5% | N/A | N/A | N/A | N/A | 2.9 | N/A |
| Pembrolizumab | Melanoma | 16.7% | 38.2% | 1.0% | 15.7% | 21.6% | 8.4 | 2.8 | 12.1 |
| Toripalimab | Melanoma | 17.3% | 57.5% | 0.8% | 16.5% | 40.2% | NR | 3.6 | 22.2 |
| HX008 | First-line advanced gastric cancer (Phase II) | 60.0% | 77.1% | 2.9% | 57.1% | N/A | 12.7 | 9.2 | 12.9 |
| | Second-line advanced gastric cancer (Phase II) | 27.6% | 60.3% | N/A | N/A | 32.8% | 12.8 | 4.2 | 12.1 |
| Pembrolizumab | Gastric cancer | 48.6% | N/A | N/A | N/A | N/A | N/A | 6.9 | 12.5 |
| Nivolumab | Gastric cancer | 58.0% | N/A | 10.0% | 48.0% | 28.0% | 8.5 | 7.7 | 13.8 |
| HX008 | Advanced solid tumor (Phase Ia) | 16.7% | 36.7% | 0.0% | 16.7% | 20.0% | N/A | N/A | N/A |

Abbreviations: ORR = objective response rate; DCR = disease control rate; CR = complete response; PR = partial response; SD = stable disease; DOR = duration of objective response; PFS = progression-free survival; OS = overall survival; NR = not reached;

*Source: FDA, CDE, Literature Review, Frost & Sullivan*

*Notes:*

1. N/A refers to data not available.

2. No head-to-head comparison was conducted between drugs. Clinical trials of a drug cannot be directly compared to the clinical trials of another drug and may not be representative of the overall data.



Shanghai Miracogen Inc.- Ex. 2032, Page 000019

- ***LP002 (Core Product)***: LP002 is a humanized mAb against PD-L1. As of the Latest Practicable Date, we were in the process of a cohort expansion trial in advanced digestive system cancer and had completed patient enrollment and entered the follow-up period for the Phase II clinical trial in ES-SCLC (extensive stage small-cell lung cancer).

  Please refer to the following comparison of the efficacy of LP002 with other China marketed PD-L1 mAbs.

| Drug name | Indications (Clinical trial stage, as applicable) | ORR | DCR | CR | PR | SD | DOR (months) | PFS (months) | OS (months) |
|---|---|---|---|---|---|---|---|---|---|
| Atezolizumab | SCLC | 60.0% | N/A | 2.0% | 58.0% | N/A | 4.2 | 5.2 | 12.3 |
| | HCC | 29.8% | N/A | 7.7% | 22.1% | 44.2% | 18.1 | 6.8 | 19.2 |
| Durvalumab | NSCLC | 28.4% | N/A | 1.4% | 27.1% | 52.6% | N/A | 16.8 | N/A |
| LP002 | Advanced solid tumor (Phase Ia) | 15.2% | 51.5% | N/A | N/A | N/A | N/A | N/A | N/A |

Abbreviations: ORR = objective response rate; DCR = disease control rate; CR = complete response; PR = partial response; SD = stable disease; DOR = duration of objective response; PFS = progression-free survival; OS = overall survival

*Source: FDA, CDE, Literature Review, Frost & Sullivan*

*Note:*

1. N/A refers to data not available.

2. No head-to-head comparison was conducted between drugs. Clinical trials of a drug cannot be directly compared to the clinical trials of another drug and may not be representative of the overall data.

➢ *Other ADC drug candidates*

- ***MRG001***: MRG001 is a clinically advanced CD20-targeted ADC to address medical needs of B-cell NHL patients with primary drug resistance to rituximab and B-cell NHL patients with acquired drug resistance to the combination therapy of rituximab and standard chemotherapies. We have completed the Phase Ia dose escalation study of MRG001 in China which has shown encouraging safety and efficacy results. As of the Latest Practicable Date, we were conducting the subsequent dose expansion study of MRG001 in China.



Shanghai Miracogen Inc.- Ex. 2032, Page 000020

- ***MRG004A***: MRG004A is a novel TF-targeted site-specifically conjugated ADC. We received the IND clearance of MRG004A from the FDA in February 2021 for a Phase I/II clinical trial in the U.S. We received IND approval of MRG004A from the NMPA in August 2021.

➢ *Oncolytic virus drug candidate*

- ***CG0070***: CG0070 was an oncolytic adenovirus for the treatment of bladder cancer in clinical-stage development. We in-licensed CG0070 from CG Oncology and were granted the rights to develop, manufacture and commercialize it in Mainland China, Hong Kong and Macau. We obtained IND approval from the NMPA for CG0070 in November 2021.

See "Business – Overview."

Since our inception, we have established a platform across drug discovery, clinical development and CMC and GMP-compliant manufacturing, and are building dedicated sales and marketing forces.

We are committed to fulfilling current medical needs. We continuously invest in our research and development infrastructure and talent pool. Our research and development system is underpinned by three core technology platforms: (i) a clinically-validated ADC platform with advanced conjugation and CMC technologies; (ii) an antibody discovery platform with multispecific antibody construction and discovery capabilities and a $10^{11}$-scale antibody library; and (iii) an advanced process and analytical development platform.

We keep abreast of the latest trends and technology breakthroughs in the development of innovative biopharmaceuticals globally. We have a dedicated clinical development team in China to fulfill our clinical development strategy with high efficiency and quality. We are building a research and development center in Houston, Texas, U.S., aiming to focus on the translational medical research and clinical development of innovative drugs in the international markets.

Our visionary management team has extensive industry experience, with a proven track record of bringing novel therapies from early-stage discovery through clinical development to commercialization. Our founder and chairman of the Board of Directors, Dr. Pu Zhongjie, has accumulated rich industry resources and commercialization experience for decades, from which our commercialization efforts will benefit. Our Co-CEO, Dr. Hu Chaohong, founded Miracogen Shanghai and led the clinical development of three innovative ADC candidates in China. Dr. Hu previously served as a department director at ID Biomedical Corporation, GlaxoSmithKline plc and Seagen Inc., where she participated in the development of Adcetris, the second approved ADC product globally. Our Global CMO, Dr. Frederick Herman Hausheer, is an internationally recognized expert in commercial oncology drug global development and translational science and medicine, with nearly 30 years of experience in commercial and academic settings and is certified in internal medicine by the American Board of Internal



Shanghai Miracogen Inc.- Ex. 2032, Page 000021

Medicine. Dr. Hausheer was previously the global chief medical officer of WuXi AppTec, Inc. and was previously a faculty member of The Johns Hopkins Oncology Center in Medical Oncology. Our chief technology officer, Dr. Qin Minmin, has over 20 years of experience in CMC development and commercial manufacturing. Dr. Qin has previously served as a senior director of Five Prime Therapeutics and BioMarin Pharmaceutical Inc. and led the development, technology transfer, process characterization, process validation and technology support for commercial manufacturing of Aldurazyme and Naglazyme, which are used to treat mucopolysaccharidosis.

## MARKET OPPORTUNITY AND COMPETITION

The biopharmaceutical industry is characterized by rapid market growth, fierce competition and a strong emphasis on proprietary drugs. While we believe that our research and development capabilities enable us to establish a favorable position in the industry, we encounter competition from international and domestic biopharmaceutical companies, specialty pharmaceutical and biotechnology companies of various sizes, academic institutions and research institutions. The major oncology therapy options available in the market include surgery, chemotherapy, radiotherapy, targeted therapy and immuno-therapy. Any drug candidates we successfully develop and commercialize, including our Core Products targeting receptors such as EGFR and HER2, will compete with existing drugs or any new drugs that target receptors and focus on largely the same cancer indications that may become available in the future. There are also challenges to successful commercialization of our Core Product candidates. These challenges may render the clinical development in respect of each Core Product unsuccessful. Our ability to successfully commercialize any approved drug candidates will also depend, in part, on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers and other organizations.

### EGFR-targeted ADC Drug

Major indications of EGFR-targeted ADCs include HNC, NPC and NSCLC.

The existing size and growth of the HNC, NPC and NSCLC markets demonstrates significant market opportunities. According to Frost & Sullivan, the size of the global HNC market was US$3.9 billion in 2020 and is expected to reach US$6.0 billion by 2025 and US$8.7 billion by 2030, respectively; the size of the China HNC market was RMB3.0 billion in 2020 and is expected to reach RMB7.4 billion by 2025 and RMB13.0 billion by 2030, respectively. The EGFR-positive rate among HNSCC is approximately 86.5%. The second line progression percentage is 95.9% in HNSCC in China. The size of the global NPC market was US$0.4 billion in 2020 and is expected to reach US$0.6 billion by 2025 and US$0.8 billion by 2030, respectively; the size of the China NPC market was RMB0.6 billion in 2020 and is expected to reach RMB1.6 billion by 2025 and RMB2.8 billion by 2030, respectively. The EGFR positive rate for NPC is approximately 82.7%. The second line progression percentage is 88.8% in NPC in China. The size of the global NSCLC market was US$52.8 billion in 2020 and is expected to reach US$108.5 billion and US$172.8 billion by 2025 and 2030,



Shanghai Miracogen Inc.- Ex. 2032, Page 000022

respectively; the size of the China NSCLC market was RMB42.3 billion in 2020 and is expected to reach RMB111.7 billion and RMB177.5 billion by 2025 and 2030, respectively. The EGFR positive rate for NSCLC is approximately 60.0%. The second line progression percentage is 91.2% in NSCLC in China.

Our EGFR-targeted ADC drug, however, faces competition from other targeted therapy drugs and candidates in China and worldwide which target the same indications, such as Akalux (Rakuten Medical Inc.), M1231 (EMD Serono Research and Development Institute, Inc.) and EGFR(V)-EDV-Dox (Engeneic Pty Limited), when commercialized. See "Industry Overview – The ADC Market – EGFR-Targeted ADC Drug Market."

**HER2-targeted ADC Drug**

Major indications of HER2-targeted ADCs include breast cancer, gastric cancer and urothelial carcinoma.

In China, the size of breast cancer market was RMB50.7 billion in 2020 and is expected to reach RMB81.8 billion and RMB124.6 billion by 2025 and 2030, respectively, according to Frost & Sullivan. The HER2 positive rate for breast cancer is approximately 25.4%. The second line progression percentage is 94.3% in breast cancer in China. According to the same source, the size of global gastric cancer market was US$14.4 billion in 2020 and is expected to reach US$24.2 billion and US$36.4 billion by 2025 and 2030, respectively; the market size of gastric cancer in China was RMB28.0 billion in 2020 and is expected to reach RMB51.4 billion and RMB83.2 billion by 2025 and 2030, respectively. The HER2 positive rate for gastric cancer is approximately 23.7%. The second line progression percentage is 94.6% in gastric cancer in China. Urothelial carcinoma accounts for about 90% of all bladder cancers. Bladder cancer is the most common malignant tumor of the urinary system, accounting for the highest incidence of urogenital tumors in China. The number of new cases of bladder cancer in China was 85.7 thousand in 2020 and is expected to reach 101.1 thousand and 117.6 thousand in 2025 and 2030, respectively, representing a CAGR of 3.4% from 2020 to 2025 and a CAGR of 3.1% from 2025 to 2030. The HER2 positive rate for bladder cancer is approximately 36.0%. The second line progression percentage is 81.5% in bladder cancer in China.

Our HER2-targeted ADC drug, however, faces competition from other targeted therapy drugs and candidates in China and worldwide which target the same indications, such as Enhertu (Astra-Zeneca), Kadcyla Genetech (Roche), Disitamab Vedotin (RemeGen Co., Ltd), when commercialized. See "Industry Overview – The ADC Market – HER2-targeted ADC Drug Market."



Shanghai Miracogen Inc.- Ex. 2032, Page 000023

**PD-1 and PD-L1 mAbs**

Major indications of PD-1/PD-L1 therapies include melanoma, MSI-H/dMMR solid tumors, gastric cancer, NSCLC, triple-negative breast cancer and SCLC (small-cell lung cancer).

According to Frost & Sullivan, the size of the China melanoma market was RMB1.4 billion in 2020 and is expected to reach RMB2.1 billion by 2025 and RMB2.8 billion by 2030, respectively. The size of the China MSI-H/dMMR solid tumors market was RMB1,000.7 million in 2020 and is expected to reach RMB3,671.1 million and RMB4,864.5 million by 2025 and 2030, respectively. The size of global gastric cancer market was US$14.4 billion in 2020 and is expected to reach US$24.2 billion and US$36.4 billion by 2025 and 2030; and the market size of gastric cancer in China was RMB28.0 billion in 2020 and is expected to reach RMB51.4 billion and RMB83.2 billion by 2025 and 2030, respectively. The size of the global NSCLC market was US$52.8 billion in 2020 and is expected to reach US$108.5 billion and US$172.8 billion by 2025 and 2030, respectively; and the size of the China NSCLC market was RMB42.3 billion in 2020 and is expected to reach RMB111.7 billion and RMB177.5 billion by 2025 and 2030, respectively. Triple-negative breast cancer accounts for 15% of the breast cancer incidences. In China, the size of breast cancer market was RMB50.7 billion in 2020 and is expected to reach RMB81.8 billion and RMB124.6 billion by 2025 and 2030, respectively.

According to Frost & Sullivan, SCLC accounts for about 15% of all lung cancers and is more aggressive than NSCLC. The number of new cases of small-cell lung cancer in China was 138.6 thousand in 2020 and is expected to increase to 162.4 thousand and 186.6 thousand in 2025 and 2030, respectively.

According to Frost & Sullivan, with respect to our Core Product MRG003, as of the Latest Practicable Date, there were no marketed product of EGFR-targeted ADC in China and five pipeline candidates for the EGFR-targeted ADC drugs worldwide. With respect to our Core Product MRG002, as of the Latest Practicable Date, there were three marketed HER2-targeted ADC drugs and eleven pipeline candidates for HER2-targeted ADC drugs, which are in the Phase II clinical trial or more advanced in China and worldwide. With respect to our Core Product HX008, as of the Latest Practicable Date, there were ten marketed PD-1 mAb drugs approved by the FDA and NMPA and ten late-stage or NDA pipeline candidates for PD-1 therapies in China. With respect to our Core Product LP002, as of the Latest Practicable Date, there were five marketed PD-L1 mAb drugs approved by the FDA and NMPA and nine pipeline candidates for PD-L1 therapies, which were in the Phase II clinical trial or more advanced in China.

According to Frost & Sullivan, with respect to our MRG001, as of the Latest Practicable Date, there were no marketed products of CD20-targeted ADC worldwide and two pipeline candidates for CD20-targeted ADC drugs in China. With respect to our MRG004A, as of the Latest Practicable Date, there was one marketed product of TF-targeted ADC worldwide and two pipeline candidates for TF-targeted ADC drugs in China and worldwide. With respect to our CG0070, as of the Latest Practicable Date, there were two pipeline candidates for oncolytic virus therapies in the bladder cancer globally.



Shanghai Miracogen Inc.- Ex. 2032, Page 000024

See "Industry Overview."

Any drug candidates we successfully develop and commercialize, including our Core Products, will compete with existing drugs or any new drugs that may become available in the future. We have been developing our commercialization capabilities by recruiting sales and marketing personnel and formulating our commercialization strategy. We have established long-term relationships with top hospitals, KOLs and doctors. We expect to market our products with a customized marketing focus for each product depending on its indication and market coverage. See "Business – Commercialization – Our Commercialization Strategy."

**CD20-targeted ADC Drug**

Major indications of CD20-targeted ADCs include DLBCL and FL.

According to Frost & Sullivan, DLBCL and FL are two subtypes of NHL, accounting for 41.0% and 6.1% of NHL, respectively. NHL accounts for approximately 90% of lymphoma with varieties of subtypes. The market size of lymphoma in China reached US$12.0 billion in 2020 and is expected to reach US$37.9 billion and US$62.5 billion in 2025 and 2030, respectively.

**TF-targeted ADC Drug**

Major indications of TF-targeted ADCs include cervical cancer, ovarian cancer and pancreatic cancer.

According to Frost & Sullivan, the number of new cases of cervical cancer globally was 604.1 thousand in 2020 and is expected to increase to 665.8 thousand and 727.5 thousand in 2025 and 2030, respectively; the number of new cases of cervical cancer in China was 118.5 thousand in 2020 and is expected to increase to 123.3 thousand and 125.9 thousand in 2025 and 2030, respectively, representing a CAGR of 0.8% from 2020 to 2025 and 0.4% from 2025 to 2030, respectively. The number of new cases of ovarian cancer globally was 314.0 thousand in 2020 and is expected to increase to 344.3 thousand and 374.2 thousand in 2025 and 2030, respectively; the number of new cases of ovarian cancer in China was 55.3 thousand in 2020 and is expected to increase to 59.5 thousand and 62.7 thousand in 2025 and 2030, respectively, representing a CAGR of 1.5% from 2020 to 2025 and 1.1% from 2025 to 2030, respectively. The number of new cases of pancreatic cancer globally was 495.8 thousand in 2020, and is expected to reach 564.9 thousand and 640.5 thousand in 2025 and 2030, respectively; the number of new cases of pancreatic cancer in China was 112.0 thousand in 2020, and is expected to reach 133.1 thousand and 155.8 thousand in 2025 and 2030, respectively, representing a CAGR of 3.5% from 2020 to 2025 and a CAGR of 3.2% from 2025 to 2030.



Shanghai Miracogen Inc.- Ex. 2032, Page 000025

**Oncolytic Virus Therapies**

One of the major indications of oncolytic viruses is bladder cancer. As discussed above, there are significant market opportunities for the treatment of bladder cancer considering its prevalence.

## OUR STRENGTHS

- Product pipeline with clinical efficacy and commercialization synergies
- Discovery and development capabilities
- Manufacturing facilities
- Seasoned and visionary management team and strong shareholder support

See "Business – Our Strengths."

## OUR STRATEGIES

- Expedite immune checkpoint inhibitor therapy development for marketing approval and commercialization
- Advance the clinical development of our drug candidates and combination therapies
- Create a pipeline for novel therapies, design and develop innovative products and build advanced technology platforms
- Capture international opportunities for our products and technologies
- Expand GMP-compliant manufacturing facilities to increase capacity and enhance product quality
- Further enhance our management and research and development teams with global vision and strong execution capabilities

See "Business – Our Strategies."

## SUMMARY OF KEY FINANCIAL INFORMATION

The following sets forth summary financial data from our consolidated financial information for the Track Record Period, extracted from the Accountant's Report set out in Appendix I to this Prospectus. These summary financial data should be read together with our consolidated financial statements included in the Accountant's Report in Appendix I to this Prospectus, including the accompanying notes, as well as the section headed "Financial Information."



Shanghai Miracogen Inc.- Ex. 2032, Page 000026

**Selected Results of Operation Data**

We have not generated any revenue from product sales. We were not profitable and incurred operating losses during the Track Record Period. In 2019, 2020 and the eight months ended August 31, 2021, we had operating losses of RMB454.7 million, RMB520.4 million and RMB662.2 million, respectively. Substantially all of our operating losses resulted from research and development expenses, administrative expenses and fair value changes on financial assets and liabilities through profit or loss.

The following table sets out selected data of our consolidated statements of comprehensive loss for the periods indicated:

| | Year ended December 31, | | Eight months ended August 31, | |
|---|---|---|---|---|
| | **2019** | **2020** | **2020** | **2021** |
| | *RMB'000* | *RMB'000* | *RMB'000 (Unaudited)* | *RMB'000* |
| Other income | 5,553 | 7,964 | 2,656 | 4,601 |
| Other expenses | (892) | (1,915) | (1,380) | (707) |
| Administrative expenses | (191,551) | (93,757) | (49,727) | (108,328) |
| Research and development expenses | (229,197) | (354,427) | (196,273) | (509,483) |
| Fair value changes on financial assets and liabilities through profit and loss | (38,312) | (77,991) | (117,497) | (47,434) |
| Other (losses)/gains, net | (256) | (225) | (420) | (831) |
| **Operating loss** | **(454,655)** | **(520,351)** | **(362,641)** | **(662,182)** |
| Finance income | 397 | 5,306 | 1,019 | 3,267 |
| Finance costs | (52,559) | (86,319) | (85,144) | (3,027) |
| Finance (costs)/income, net | (52,162) | (81,013) | (84,125) | 240 |
| Share of (loss)/profit of investments accounted for using the equity method | (8,675) | (12,084) | (5,390) | (6,293) |
| **Loss before income tax** | **(515,492)** | **(613,448)** | **(452,156)** | **(668,235)** |
| Income tax expense | – | – | – | – |
| **Loss for the year** | **(515,492)** | **(613,448)** | **(452,156)** | **(668,235)** |
| **Loss attributable to:** | | | | |
| Owners of the Company | (447,036) | (581,849) | (427,971) | (656,392) |
| Non-controlling interests | (68,456) | (31,599) | (24,185) | (11,843) |



Shanghai Miracogen Inc.- Ex. 2032, Page 000027

Our net loss increased by 19.0% from RMB515.5 million in 2019 to RMB613.4 million in 2020, and increased from RMB452.2 million in the eight months ended August 31, 2020 to RMB668.2 million in the eight months ended August 31, 2021, primarily due to the increase in research and development expenses. Our research and development expenses increased by 54.6% from RMB229.2 million in 2019 to RMB354.4 million in 2020, and increased significantly from RMB196.3 million in the eight months ended August 31, 2020 to RMB509.5 million in the eight months ended August 31, 2021, primarily due to increases in clinical trial expenses, pre-clinical study costs and employee benefit expenses in relation to our research and development staff. Such increases were in line with our continuous research and development efforts to support our steadily advancing and expanding pipeline of drug candidates.

Our administrative expenses decreased by 51.0% from RMB191.6 million in 2019 to RMB93.8 million in 2020, primarily because we recorded one-off share-based payment expenses related to the Controlling Shareholder Loans of RMB143.7 million in 2019, representing the difference between the issuance price of the Controlling Shareholder Loans of RMB450.0 million and the fair value of equity on issuance date, while we did not have such expense in 2020. See "– Discussion of Certain Key Balance Sheet Items – Current Assets and Liabilities – Financial Instruments with Preferred Rights at Amortized Cost." Such decrease was partially offset by (i) an increase in wages, salaries and bonuses in relation to our administrative staff as we engaged more administrative staff to satisfy our daily operation need; and (ii) an increase in depreciation and amortization expenses, which was in line with the increases in our right-of-use assets and property, plant and equipment. Our administrative expenses increased significantly from RMB49.7 million in the eight months ended August 31, 2020 to RMB108.3 million in the eight months ended August 31, 2021, primarily due to (i) an increase in the employee benefit expenses in relation to our administrative staff, especially the share-based payment expenses in relation to our ESOP, see Note 8 of Appendix I to this prospectus; and (ii) an increase in the professional services fees, primarily in relation to the Listing.

See "Financial Information – Description of Major Components of Our Results of Operations."



Shanghai Miracogen Inc.- Ex. 2032, Page 000028

**Selected Consolidated Balance Sheet Data**

The following table sets out selected data from our consolidated balance sheet as of the dates indicated:

| | As of December 31, | | As of August 31, |
|---|---|---|---|
| | **2019** | **2020** | **2021** |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| **Assets** | | | |
| **Non-current assets** | | | |
| Property, plant and equipment | 331,110 | 606,371 | 725,819 |
| Right-of-use assets | 130,721 | 163,666 | 149,600 |
| Intangible assets | 517,333 | 497,922 | 479,662 |
| Investments accounted for using the equity method | 169,878 | 160,294 | 154,002 |
| Other receivables, prepayments and deposits | 154,700 | 152,009 | 147,148 |
| **Total non-current assets** | 1,303,742 | 1,580,262 | 1,656,231 |
| **Current assets** | | | |
| Inventories | 8,082 | 19,569 | 24,164 |
| Other receivables, prepayments and deposits | 24,912 | 70,256 | 82,713 |
| Financial assets at fair value through profit or loss | – | 330,657 | 132,724 |
| Cash and cash equivalents | 188,545 | 402,867 | 261,194 |
| Term deposits with initial terms of over three months | – | 20,000 | 50,000 |
| **Total current assets** | 221,539 | 843,349 | 550,795 |
| **Total assets** | **1,525,281** | **2,423,611** | **2,207,026** |
| **Liabilities** | | | |
| **Non-current liabilities** | | | |
| Borrowings | 118,266 | 147,266 | 168,064 |
| Lease liabilities | 48,251 | 33,534 | 23,259 |
| Deferred government grants | 12,000 | 12,000 | 12,000 |
| Deferred tax liabilities | 37,687 | 37,687 | 37,687 |
| Financial liabilities at fair value through profit or loss | 279,081 | 309,181 | 357,339 |
| Other payables and accruals | – | – | 150,000 |
| **Total non-current liabilities** | 495,285 | 539,668 | 748,349 |



Shanghai Miracogen Inc.- Ex. 2032, Page 000029

| | As of December 31, | | As of August 31, |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| **Current liabilities** | | | |
| Borrowings | – | – | 30,000 |
| Trade payables | 31,684 | 42,448 | 84,560 |
| Other payables and accruals | 378,278 | 321,307 | 147,927 |
| Lease liabilities | 27,565 | 18,466 | 16,188 |
| Convertible loans | 380,620 | – | – |
| Financial instruments with preferred rights at amortised cost | 397,489 | – | – |
| **Total current liabilities** | 1,215,636 | 382,221 | 278,675 |
| **Total liabilities** | **1,710,921** | **921,889** | **1,027,024** |
| **Net current (liabilities)/assets** | **(994,097)** | **461,128** | **272,120** |
| **Equity** | | | |
| **Equity attributable to owners of the Company** | | | |
| Paid-in capital/Share capital | 1,000,000 | 1,492,693 | 1,531,670 |
| Treasury stock | (347,454) | – | – |
| Reserves | (462,631) | 612,260 | 919,773 |
| Accumulated losses | (542,415) | (631,442) | (1,287,834) |
| | (352,500) | 1,473,511 | 1,163,609 |
| **Non-controlling interests** | 166,860 | 28,211 | 16,393 |
| **Total equity** | **(185,640)** | **1,501,722** | **1,180,002** |
| **Total equity and liabilities** | **1,525,281** | **2,423,611** | **2,207,026** |

We had net current liabilities of RMB994.1 million as of December 31, 2019 and net current assets of RMB461.1 million as of December 31, 2020, mainly because (i) our total current assets increased significantly from RMB221.5 million as of December 31, 2019 to RMB843.3 million as of December 31, 2020, primarily due to increases in financial assets at fair value through profit or loss as well as cash and cash equivalents; and (ii) our total current liabilities decreased by 68.6% from RMB1,215.6 million as of December 31, 2019 to RMB382.2 million as of December 31, 2020, primarily due to the decreases in convertible loans as well as financial instruments with preferred rights at amortized cost. Our net current assets decreased by 41.0% from RMB461.1 million as of December 31, 2020 to RMB272.1 million as of August 31, 2021, primarily because of a decrease in our cash and cash equivalents, partially offset by a decrease in other payables and accruals. Our net current assets of RMB272.1 million as of August 31, 2021 changed to net current liabilities of RMB234.9



Shanghai Miracogen Inc.- Ex. 2032, Page 000030

million as of December 31, 2021, primarily due to the increase in other payables and accruals according to the repayment schedule of consideration payable for non-controlling interest transaction, as well as the increase in our trade payables resulting from our research and development activities during such period.

We had net liabilities of RMB185.6 million as of December 31, 2019 and net assets of RMB1,501.7 million as of December 31, 2020, mainly due to (i) an increase in total current assets of RMB621.8 million, as a result of increases in financial assets at fair value through profit or loss, as well as cash and cash equivalent and an increase in total non-current assets of RMB276.5 million, mainly representing an increase in property, plant and equipment; and (ii) a decrease in total current liabilities of RMB833.4 million, primarily due to decreases in convertible loans as well as financial instruments with preferred rights at amortized cost. Our net assets remained relatively stable as of December 31, 2020 and August 31, 2021, being RMB1,501.7 million and RMB1,180.0 million, respectively. We had net liabilities of RMB185.6 million as of December 31, 2019 and net assets of RMB1,501.7 million as of December 31, 2020, mainly reflecting changes in equity comprising (i) issuance of equity interests to series B investors of RMB1,291.0 million; (ii) derecognition of financial instruments with preferred rights at amortized cost recognized in 2019 of approximately RMB450.0 million; (iii) conversion of convertible loans of RMB427.3 million; (iv) capital contribution from Lepu Medical Technology (Beijing) Co., Ltd. of RMB90.0 million; and (v) loss for the year in 2020 of RMB613.5 million. Our net assets remained relatively stable as of December 31, 2020 and August 31, 2021, being RMB1,501.7 million and RMB1,180.0 million, respectively, mainly reflecting changes in equity comprising (i) issuance of shares to series C investors of RMB260.7 million; and (ii) loss for the period in the eight months ended August 31, 2021 of RMB668.2 million. See Consolidated Statements of Changes in Equity of Appendix I to this prospectus.

See "Financial Information – Discussion of Certain Key Balance Sheet Items."

**Selected Consolidated Cash Flow Statements Data**

The following table sets out our selected data from our consolidated statements of cash flows for the periods indicated:

| | Year ended December 31, | | Eight months ended August 31, | |
|---|---|---|---|---|
| | **2019** | **2020** | **2020** | **2021** |
| | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* |
| Operating cash flows before movements in working capital | (225,352) | (359,011) | (189,909) | (469,527) |
| Change in working capital | (9,038) | (68,908) | (22,642) | 47,604 |
| Interest received | 396 | 5,230 | 1,019 | 3,601 |



Shanghai Miracogen Inc.- Ex. 2032, Page 000031

| | Year ended December 31, | | Eight months ended August 31, | |
|---|---|---|---|---|
| | 2019 | 2020 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* |
| Net cash used in operating activities | (233,994) | (422,689) | (211,532) | (418,322) |
| Net cash used in investing activities | (415,318) | (749,669) | (763,807) | (13,519) |
| Net cash generated from financing activities | 770,394 | 1,386,679 | 1,398,812 | 291,140 |
| Interest paid | (571) | (7,433) | (4,222) | (3,127) |
| Net increase/(decrease) in cash and cash equivalents | 121,082 | 214,321 | 423,473 | (140,701) |
| Cash and cash equivalents at the beginning of the year/period | 67,462 | 188,545 | 188,545 | 402,867 |
| Effects of exchange rate changes on cash and cash equivalents | 1 | 1 | – | (972) |
| Cash and cash equivalents at the end of the year | 188,545 | 402,867 | 612,018 | 261,194 |

Since the commencement of our business operation, we have incurred negative cash flows from our operations. Substantially all of our operating outflows have resulted from our cash used in our operations. Net cash used in operating activities primarily comprises our loss before tax for the period adjusted by (i) non-operating items and non-cash items; and (ii) changes in working capital. We expect to improve our net operating cash outflows position through our improved research and development capabilities as we continuously invest in our research and development platforms and engage experienced members on our research and development team, which helps reduce our needs for third-party research and development services, see "Business – Research and Development;" we also expect to improve such position through revenue to be generated from sales of our drug products in the event of successful commercialization through dedicated sales and marketing forces and internationally via partnerships.

In the eight months ended August 31, 2021, our net cash used in operating activities was RMB418.3 million, which was primarily attributable to our loss before income tax of RMB668.2 million, as adjusted by (i) the add back of non-operating items and non-cash items, primarily comprising share-based payments of RMB85.8 million and change in fair value of


Shanghai Miracogen Inc.- Ex. 2032, Page 000032

financial liabilities at fair value through profit or loss of RMB48.2 million; and (ii) changes in working capital, primarily including an increase in other receivables, prepayments and deposits of RMB4.8 million, partially offset by an increase in trade payables, other payables and accruals of RMB57.0 million.

In 2020, our net cash used in operating activities was RMB422.7 million, which was primarily attributable to our loss before income tax of RMB613.4 million, as adjusted by (i) the add back of non-operating items and non-cash items, primarily comprising change in fair value of financial liabilities at fair value through profit or loss of RMB78.6 million, net finance costs of RMB79.9 million, amortization of intangible assets of RMB28.6 million, depreciation of property, plant and equipment and right-of-use assets of RMB55.6 million; and (ii) changes in working capital, primarily including an increase in other receivables and prepayments of RMB76.1 million, partially offset by an increase in trade payables, other payables and accruals of RMB18.7 million.

In 2019, our net cash used in operating activities was RMB234.0 million, which was primarily attributable to our loss before income tax of RMB515.5 million, as adjusted by (i) the add back of non-operating items and non-cash items, primarily comprising amortization of intangible assets of RMB26.8 million, change in fair value of financial liabilities at fair value through profit or loss of RMB38.3 million and net finance costs of RMB51.9 million; and (ii) changes in working capital, which primarily comprised an increase in other receivables and prepayments of RMB46.4 million, partially offset by an increase in trade payables, other payables and accruals of RMB33.4 million.

See "Financial Information – Liquidity and Capital Resources – Cash Flow."

While we had net operating cash outflows and net losses during the Track Record Period, we believe our liquidity requirements will be satisfied by using funds from a combination of our cash and cash equivalents, unutilized loan facilities, net proceeds from the Global Offering and other funds raised from the capital markets from time to time. As of August 31, 2021, we had cash and cash equivalents of RMB261.2 million and unutilized banking facilities of RMB351.9 million. Other than the bank borrowings that we have obtained or may obtain, we currently do not have any plans for material external debt financing. Taking into account the above, together with the estimated net proceeds from the Global Offering, our Directors are of the view that we have sufficient working capital to cover at least 125% of our costs, including research and development expenses, administrative expenses, finance costs and other expenses for at least the next 12 months from the date of this prospectus.

Our cash burn rate refers to the average monthly aggregate amount of (i) net cash used in operating activities, including research and development expenses; (ii) purchase amount of property, plant and equipment; (iii) payment of lease liabilities; (iv) purchase amount of intangible assets; and (v) payment of interests. Assuming that the average cash burn rate going forward will be similar to the cash burn rate level for the 20 months ended August 31, 2021, which is primarily based on the level of the average monthly burn rate in the 20 months ended August 31, 2021 and the prospective burn rate based on the average monthly net cash used in



Shanghai Miracogen Inc.- Ex. 2032, Page 000033

operating activities and capital expenditure in 2021 and 2022, and excluding financial assets at fair value through profit or loss, our cash balance (including cash and cash equivalents and term deposits with initial terms of three months) will be able to maintain our financial viability for 4.9 months or, if we also take into account the estimated net proceeds (based on the low-end of the indicative offer price) from the Global Offering, 14.7 months. We expect to raise our next round of financing (not taking into account bank loans we may take out in the ordinary course of business) no earlier than September 2022. Our Directors and our management team will continue to monitor our working capital, cash flows, and our business development progress.

**Key Financial Ratios**

The following table sets out our key financial ratios as of the dates indicated:

| | As of December 31, | | As of August 31, |
|---|---|---|---|
| | **2019** | **2020** | **2021** |
| Current ratio[(1)] | 18.2% | 220.6% | 197.6% |
| Quick ratio[(2)] | 17.6% | 215.5% | 189.0% |

*Notes:*

(1) Represents current assets divided by current liabilities as of the same date.

(2) Represents current assets less inventories and divided by current liabilities as of the same date.

See "Financial Information."

## LOSS ESTIMATE FOR THE YEAR ENDED DECEMBER 31, 2021

On the basis set out in Appendix III to this prospectus, and in the absence of unforeseen circumstances, we estimate that our unaudited consolidated loss attributable to the owners of the Company are as follows:

| | |
|---|---|
| **Estimated consolidated loss attributable to owners of the Company for the year ended December 31, 2021** | **Not more than RMB1,023 million (approximately HK$1,250 million)** *(Note)* |

*Note:* For the purpose of this estimated consolidated loss attributable to owners of the Company, the amounts stated in Renminbi are converted into Hong Kong dollars at a rate of HK$1.00 to RMB0.81824. No representation is made that Renminbi amounts have been, could have been or may be converted to Hong Kong dollars, or vice versa, at that rate.



Shanghai Miracogen Inc.- Ex. 2032, Page 000034

## INTELLECTUAL PROPERTY

Our success depends in part on our ability to obtain and maintain proprietary intellectual property protection for our drug candidates and technologies; it also depends in part on our ability to defend and enforce our patents, preserve the confidentiality of our trade secrets, and operate without infringing, misappropriating or otherwise violating intellectual property rights of other parties. To this end, we have set up our own intellectual property department housing experienced and trained professionals, who would conduct intellectual property-related due diligence on our potential in-licensing or acquisition target product portfolio, such as assessing the validity and scope of protection of the intellectual property rights obtained, and any risk of potential infringement upon other intellectual property rights. We also hire external patent firms to assist us in intellectual property rights work, including work in relation to prosecution or defense of our intellectual property rights. We have a portfolio of patents to protect our drug candidates and technologies. As of the Latest Practicable Date, we had (i) 11 issued patents in China, 20 in the U.S., nine in Japan, seven in the European Union and one in each of South Korea, Australia, Chile, India, Colombia, Indonesia, New Zealand and Israel, and (ii) 74 pending patent applications, consisting of 15 in Mainland China and 59 in overseas jurisdictions such as the U.S., Japan, South Korea, Australia, Israel, India and the European Union, spanning across mAb structure, targeted epitope, CMC, usage, biopharmaceutical formulation and indications. With respect to our Core Products, we had six issued patents and five pending patent applications in China, as well as 18 issued patents and 27 pending patent applications in overseas jurisdictions as of the Latest Practicable Date. See "Business – Intellectual Property Rights." As of the Latest Practicable Date, our Directors confirm that we were not involved in any proceedings in respect of, and we had not received notice of any claims of infringements of any third-party intellectual property that are threatened or pending. For certain risks relating to our intellectual property rights, see "Risk Factors – Risks Relating to Our Intellectual Property Rights."

## COLLABORATION, LICENSING AND TRANSFER ARRANGEMENTS

### Collaboration with JMT

On March 2, 2015, Miracogen Shanghai entered into a patent licensing agreement (the "JMT Agreement") with Shanghai JMT-Bio, Inc. ("JMT") with respect to the development, manufacturing and commercialization of ADCs in China under the licensed patent related to human anti-EGFR antibodies (the "Licensed Patent").

**Nature of the rights**: Under the JMT Agreement, JMT granted to Miracogen Shanghai an exclusive, royalty-bearing, non-sublicensable license under the Licensed Patent to develop, manufacture and commercialize ADCs against the target covered by the Licensed Patent. The exclusivity period lasts throughout the contract term. JMT retains the right to use the Licensed Patent for the development, manufacturing and commercialization of antibody drugs or drugs other than ADCs.


Shanghai Miracogen Inc.- Ex. 2032, Page 000035

**Related drug candidate**: The Licensed Patent was subsequently used in the development of MRG003 (Core Product).

For intellectual-property-related disputes with third parties, JMT is responsible for prosecution and defense.

See "Business – Collaboration, Licensing and Transfer Arrangements – Collaboration with JMT."

**Arrangements among us, HanX and Akeso**

Our subsidiary, Taizhou Hanzhong, entered into an agreement with HanX and Akeso regarding the transfer of HX008 in August 2018. Pursuant to the agreement, HanX transferred its rights jointly held with Akeso in HX008 to Taizhou Hanzhong with nil consideration. Akeso, as the co-developer, agreed to waive its global rights and is not entitled to any other right to disallow or restrict our use of HX008-related patent or technology. Akeso is entitled to a mid single-digit percentage of global sales revenue once HX008 is commercialized until the expiry of the patents. Through such arrangement, we obtained HX008 at Phase Ia stage.

**Patent Arrangements:** As HanX transferred its rights jointly held with Akeso in HX008 to Taizhou Hanzhong in 2018 and Akeso agreed to waive its global rights, Taizhou Hanzhong became the new co-applicant replacing HanX for patents directed to HX008, and shall own the global rights to manufacture, develop and commercialize HX008.

**Termination:** Both parties may terminate the agreement in the event of force majeure and development failure.

**Dispute Resolution:** Parties agree to first try to resolve any dispute through negotiation and mediation, failing which the dispute shall be resolved through legal proceedings before competent local courts in the PRC.

**Related drug candidate:** HX008 (Core Product).

For intellectual-property-related disputes with third parties, HanX is responsible for prosecution and defense. We have the right to independently prosecute upon approval from HanX, or the right to join HanX in such prosecution.

We separately entered into a technology development agreement with HanX from February 2019 to March 2021. The services originally covered included various technology service support in purchases of raw materials, CMC manufacturing, testing, and process optimization and preparation of regulatory filings, for an aggregate amount of up to RMB87.6 million (excluding tax, or RMB92.9 million including tax, representing payments to HanX for the coordination services rendered thereunder and payments through HanX to third-party CROs and CDMOs) depending on the actual services rendered, payable in eight installments. Despite the original service scope, the actual services rendered by HanX were primarily coordination services.



Shanghai Miracogen Inc.- Ex. 2032, Page 000036

As we required HanX to provide only a small part of the services originally covered under the technology development agreement prior to its expiration in March 2021 with only a few milestones achieved, we have agreed with HanX to pay a total of RMB25.0 million (representing payments to HanX for the coordination services rendered and the payments made through HanX to third-party CROs and CDMOs). HanX also agreed that we do not need to pay the remaining RMB67.9 million (including tax) as we have no further payment obligations for services HanX did not provide. The payment of RMB25.0 million was completely settled before July 31, 2021. Any potential dispute relating to this technology development agreement shall be referred to arbitration and settled by Beijing Arbitration Commission. We did not have any dispute with HanX as of the Latest Practicable Date.

See "Business – Collaboration, Licensing and Transfer Arrangements – Arrangements among us, HanX and Akeso."

**Collaboration with I-Mab Shanghai and Hangzhou HealSun**

On April 26, 2017, Ningbo Houde Yimin Information Technology Co., Ltd. ("Ningbo Houde Yimin") entered into a technology transfer agreement with I-Mab Biopharma Co., Ltd. ("I-Mab Shanghai"), a third-party biopharmaceutical company focusing on novel biologics, and Hangzhou HealSun Biopharma Co., Ltd. ("Hangzhou HealSun"), a biopharmaceutical company focusing on therapeutic antibody development, with respect to the development of an anti-PD-L1 mAb drug (the "Yimin Transfer Agreement"). Hangzhou HealSun is the collaborator with I-Mab Shanghai to develop the anti-PD-L1 mAb drug pursuant to the Yimin Transfer Agreement, and they agreed to transfer the cell line for the anti-PD-L1 mAb expression, and exclusively license to Ningbo Houde Yimin certain intellectual property rights for the development, manufacturing and commercialization of the anti-PD-L1 mAb drug globally. The exclusivity period lasts throughout the contract term.

On June 22, 2018, Ningbo Houde Yimin entered into a technology transfer agreement with Taizhou Aoke, under which Ningbo Houde Yimin transferred (i) its rights and obligations under the Yimin Transfer Agreement, (ii) the rights over its subsequent development of the anti-PD-L1 mAb drugs since the Yimin Transfer Agreement, and (iii) its rights and obligations under certain CMC development cooperation arrangements to Taizhou Aoke (the "Aoke Transfer Agreement"). An aggregate consideration of RMB112 million was agreed between Ningbo Houde Yimin and Taizhou Aoke.

On April 21, 2021, Ningbo Houde Yimin, I-Mab Shanghai, Hangzhou HealSun and Taizhou Aoke entered into an amendment and restatement to the technology transfer and license agreement to amend, ratify and confirm the rights and obligations under the aforementioned agreements (together with the Yimin Transfer Agreement and the Aoke Transfer Agreement, the "I-Mab Agreements").



Shanghai Miracogen Inc.- Ex. 2032, Page 000037

**Nature of the rights and obligations**:

(i) Patent arrangements: Under the I-Mab Agreements, I-Mab Shanghai granted Taizhou Aoke an exclusive, royalty-bearing and sublicensable license to use such existing rights under certain patents and know-how of I-Mab Shanghai for the development of an anti-PD-L1 antibody and the product thereof globally. I-Mab Shanghai is entitled to a preemptive right to repurchase such rights from Taizhou Aoke if the latter seeks to sell or otherwise transfer any of such rights. Taizhou Aoke is entitled to any and all intellectual property rights generated from the research and development activities under the I-Mab Agreements, either developed by itself or by other parties. Any intellectual property rights developed by Taizhou Aoke based on the existing results and intellectual property rights of I-Mab Shanghai and Hangzhou HealSun shall belong to Taizhou Aoke. Hangzhou HealSun does not hold any material intellectual property rights generated from the research and development activities under the I-Mab Agreements.

(ii) R&D arrangements: I-Mab Shanghai and Hangzhou HealSun agreed to assist Taizhou Aoke in the development of the anti-PD-L1 antibody and the product thereof in research and development activities, with the aim to obtain the IND approval from the NMPA which shall be held in the name of Taizhou Aoke.

**Related drug candidate**: The relevant intellectual property rights under the I-Mab Agreements were subsequently used in the development of LP002 (Core Product).

For intellectual-property-related disputes with third parties, I-Mab Shanghai is responsible for prosecution and defense. I-Mab Shanghai has priority in prosecution and we have the right to prosecute if I-Mab Shanghai decides not to proceed.

See "Business – Collaboration, Licensing and Transfer Arrangements – Collaboration with I-Mab Shanghai and Hangzhou HealSun."

Our industry consultant, Frost & Sullivan, is of the view that the arrangements under the collaboration, licensing and transfer agreements described above are in line with the industry norm.

**Collaboration with CG Oncology**

In March 2019, we entered into a development and license agreement (the "CG Licensing Agreement") with CG Oncology for CG Oncology's CG0070 recombinant adenovirus. Under the CG Licensing Agreement, CG Oncology granted us and our affiliates an exclusive, royalty-bearing, non-transferable license under licensed patents and licensed know-how, to develop, manufacture and commercialize CG0070 recombinant adenovirus and/or n-Dodecyl-beta-Maltoside to treat and/or prevent cancer in Mainland China, Hong Kong and Macau. The exclusivity period lasts throughout the contract term. We shall use commercially reasonable efforts to develop CG0070 recombinant adenovirus and/or n-Dodecyl-beta-Maltoside in


Shanghai Miracogen Inc.- Ex. 2032, Page 000038

Mainland China, Hong Kong and Macau at our sole expense, and to commercialize CG0070 recombinant adenovirus and/or n-Dodecyl-beta-Maltoside product in Mainland China, Hong Kong and Macau after receipt of marketing authorization approval. CG Oncology retains the right to manufacture, commercialize and develop CG0070 recombinant adenovirus and/or n-Dodecyl-beta-Maltoside to treat and/or prevent cancer in jurisdictions other than Mainland China, Hong Kong and Macau.

**Related drug candidate**: CG0070.

For intellectual-property-related disputes with third parties, we are responsible for prosecution and defense, and CG Oncology can join us in such prosecution.

See "Business – Collaboration, Licensing and Transfer Arrangements – Collaboration with CG Oncology."

**Collaboration with SYNAFFIX**

On April 9, 2019, Miracogen Shanghai entered into a commercial license and option agreement (the "Synaffix Licensing Agreement") with Synaffix B.V. ("Synaffix") with respect to the development, manufacturing and commercialization of ADC globally under GlycoConnect™ and HydraSpace™ (collectively, the "Licensed Technology"). The Licensed Technology was applied on MRG004A.

**Nature of the rights**: Under the Synaffix Licensing Agreement, Synaffix granted to Miracogen Shanghai:

i. a non-exclusive, transferable, royalty-bearing, sublicensable license under the Licensed Technology to develop, manufacture and commercialize ADCs against human TF, a target with a UniProtKB/Swiss-Prot number of P13726 selected by Miracogen Shanghai (the "Initial Target");

ii. an option to obtain a non-exclusive, transferable, royalty-bearing, sublicensable license under the Licensed Technology to develop, manufacture and commercialize ADCs against another target chosen by the Miracogen Shanghai (the "Second Target") has been exercised in December 2019.

**Sublicensing**: Miracogen Shanghai shall have the right to grant sublicenses to third parties pursuant to a written sublicense agreement.

**Related drug candidate**: The Licensed Technology was subsequently used in the development of MRG004A.

For intellectual-property-related disputes with third parties, Synaffix is responsible for prosecution and defense.



Shanghai Miracogen Inc.- Ex. 2032, Page 000039

See "Business – Collaboration, Licensing and Transfer Arrangements – Collaboration with SYNAFFIX."

**Collaboration with Keymed and iBridge**

On October 30, 2017, Miracogen Shanghai, a then subsidiary of Miracogen HK, entered into a patent licensing framework agreement with a third-party biotechnology company, Keymed (the "Framework Agreement"). The Framework Agreement was renewed and supplemented on March 3, 2020 pursuant to a supplemental agreement and further supplemented on December 22, 2020 pursuant to another supplemental agreement. As supplemented, (i) Miracogen Shanghai and Keymed agreed to jointly develop and commercialize CMG901 through a joint venture, KYM; (ii) the Framework Agreement is effective until March 2030 and may be renewed by the parties based on arms' length negotiation; (iii) all clinical data and results shall belong to the joint venture to be established; and (iv) any intellectual property rights directed to CMG901 shall be jointly owned by both parties with Miracogen Shanghai holding 30% and Keymed holding 70%.

In July 2018, we acquired 63.01% equity interest in Miracogen Shanghai from Miracogen HK. See "History, Development and Corporate Structure – Our Key Subsidiaries and Major Shareholding Changes – Miracogen Shanghai."

Miracogen HK entered into a joint venture, KYM, with iBridge, an affiliate of Keymed, in February 2020. Miracogen HK held 30% equity interest in KYM by then. Miracogen HK later agreed to transfer its joint venture interest to us at a nominal value, as we shall assume the rights and obligations under the Framework Agreement through Miracogen Shanghai since our acquisition of the latter's controlling interest. In May 2020, we acquired the remaining 36.99% of the equity interest in Miracogen Shanghai from Miracogen HK, making Miracogen Shanghai our wholly owned subsidiary.

On December 31, 2020, Innocube entered into a stock purchase agreement with Miracogen HK to acquire the 30% equity interest held by Miracogen HK in KYM for a nominal consideration of US$100. The transaction was completed on February 2, 2021.

On January 11, 2021, Innocube, our wholly owned subsidiary, entered into a joint venture agreement (the "Joint Venture Agreement") and a stockholders' agreement with, among others, iBridge, for a joint venture, KYM, to develop and commercialize CMG901. On the same date, iBridge and Innocube each entered into a license agreement (collectively, the "License Agreements") and a services agreement (collectively, the "Services Agreements") for the licensing and services arrangement in connection with CMG901. Under these agreements, KYM shall be responsible for the global development, manufacturing and commercialization of pharmaceutical products based on CMG901 at KYM's own cost and expense. These agreements specify the rights and obligations of the parties to the collaboration under the Framework Agreement.


Shanghai Miracogen Inc.- Ex. 2032, Page 000040

**Obligations of the parties**: Under the Joint Venture Agreement, Innocube and iBridge agreed (i) to make a capital contribution to KYM of US$30,000 and US$70,000, respectively; (ii) to assign and transfer to KYM their respective rights, title and interest in a patent application covering CMG901; and (iii) to transfer all Miracogen Shanghai and its affiliates' interest in the know-how relating to the manufacturing of CMG901 to KYM.

Under the License Agreements, Innocube and iBridge each granted KYM an exclusive, royalty free and sub-licensable license under the patents and know-how that are related to the antibody drug conjugate containing vcMMAE (valine-citrulline monomethyl auristatin E, a potent tubulin binder with a half maximal inhibitory concentration in the subnanomolar range), and the anti-CLDN18.2 antibody, respectively, for the development, manufacturing and commercialization of CMG901 and retained the rights to use the licensed patents, patent applications and know-how covering CMG901 in order to perform its obligations under the relevant agreements. The exclusivity period lasts throughout the contract term.

Under the Services Agreements, iBridge agreed to supply CMG901 antibody and provide research and development, regulatory and operational services to KYM, and Innocube agreed to provide KYM with CMC services for the development of CMG901.

**Nature of the rights**: Under the Joint Venture Agreement, Innocube and iBridge own 30.0% and 70.0%, respectively, equity interests in KYM. The business management and operations of KYM will be controlled and supervised by its board of directors, consisting of three members, with two designated by iBridge and one by Innocube. KYM will fund its operation by the paid-in capital, operating cash flow and additional financing through bank facilities, shareholder loans and/or additional capital contributions if necessary. Innocube and iBridge are entitled to distributable profits of KYM in proportion to the respective equity ownership in KYM.

Under the Services Agreements, KYM shall pay Innocube for the services performed in an amount equal to the service costs plus a prescribed markup.

**Related drug candidate**: CMG901.

For intellectual-property-related disputes with third parties, iBridge is responsible for prosecution and defense. iBridge has the priority in prosecution and other parties have the right to prosecute without prejudicing iBridge's interest.

See "Business – Collaboration, Licensing and Transfer Arrangements – Collaboration with Keymed and iBridge."



Shanghai Miracogen Inc.- Ex. 2032, Page 000041

**Collaboration with Fudan University and SIMMCAS**

On June 4, 2018, Miracogen Shanghai entered into a technology development agreement (the "Fudan SIMMCAS Agreement") with Fudan University and the Shanghai Institute of Materia Medica, Chinese Academy of Sciences ("SIMMCAS"), with respect to the development of a new ADC, TF-ADC.

**Nature of the rights and obligations**: Under the Fudan SIMMCAS Agreement, Fudan University and the SIMMCAS granted Miracogen Shanghai an exclusive right to use the technology, patent and know-how developed by Fudan University and the SIMMCAS related to TF-ADC (the "TF-ADC Technology") to develop, manufacture and commercialize TF-ADC in China. The exclusivity period lasts throughout the contract term. In relation to the overseas development, Miracogen Shanghai is obligated to file and maintain relevant patent applications overseas, apply for the necessary approvals for pre-clinical studies and conduct clinical studies overseas. The profit for overseas development will be distributed among the parties based on their respective contribution upon mutual agreement.

**Related drug candidate**: MRG004A.

For intellectual-property-related disputes with third parties, all parties have the right to prosecute and defend. Fudan University and the SIMMCAS can delegate the responsibilities to Miracogen Shanghai, but all parties shall defray the expenses and costs equally.

See "Business – Collaboration, Licensing and Transfer Arrangements – Collaboration with Fudan University and SIMMCAS."

**RESEARCH AND DEVELOPMENT**

We are committed to developing innovative biopharmaceutical drugs in targeted therapy, represented by our ADC candidates, and immuno-oncology therapy, represented by our anti-PD-1/anti-PD-L1 antibody candidates. See "Business – Clinical-Stage Drug Candidates" and "Business – Pre-clinical Drug Candidates." We are also dedicated to the development of combination therapies, which we believe to be a significant improvement in terms of efficacy as compared to monotherapies due to the synergies from the combination of targeted therapy and immuno-oncology therapy. See "Business – Combination Therapies within Our Pipeline." We incurred research and development expenses of RMB229.2 million, RMB354.4 million and RMB509.5 million in 2019, 2020 and the eight months ended August 31, 2021, respectively, of which RMB168.9 million, RMB233.8 million and RMB315.5 million are attributable to our Core Products in 2019, 2020 and the eight months ended August 31, 2021, respectively.

See "Business – Research and Development."



Shanghai Miracogen Inc.- Ex. 2032, Page 000042

## MANUFACTURING AND QUALITY CONTROL

Since our inception, we have been building GMP-compliant manufacturing facilities. As our late-stage drug candidates approach the commercialization stage, we are preparing for commercial-scale manufacturing that can produce high-quality biologics in large scale.

As of the Latest Practicable Date, all of our products remained in the research and development stage, and our manufacturing activities are mainly conducted in support of our clinical trials. We commenced the operation of a 2,000L GMP-compliant antibody production line at our Beijing manufacturing plant in 2019 in support of clinical trials for our antibody products, for which we have received a drug manufacturing license from Beijing Municipal Medical Products Administration. In addition, we are building a production line for oncolytic virus in Beijing with a designed capacity of 200L at our Beijing manufacturing plant, as well as a biologics manufacturing plant in Shanghai Biotech Park with laboratories and manufacturing facilities. The Shanghai Biotech Park production line has a designed capacity of 12,000L initially, and one production line with capacity of 6,000L is under construction.

We have adopted a series of internal procedures and protocols including standard operating procedures for quality management of manufacturing process, product release and stability testing, storage and shipment to achieve compliant and standardized production quality control. We also have standard process procedures in place to ensure that the finished products meet the process requirements for registration.

See "Business – Manufacturing and Quality Control."

## COMMERCIALIZATION

Any drug candidates we successfully develop and commercialize, including our Core Products, will compete with existing drugs or any new drugs that may become available in the future. We have been developing our commercialization capabilities by recruiting sales and marketing personnel and formulating our commercialization strategy. We plan to establish our commercialization team comprising 50 to 100 members to engage in the academic promotion, marketing and commercialization of our pipeline products by the first quarter of 2022 and dispatch approximately five to ten members of the commercialization team to each province, depending on the local market size. Specifically, our team will include medical directors and medical science liaisons, who will be responsible for KOL engagement, medical education, medical conference management, investigator-initiated study support, and advocacy group engagement. We will also build an in-house commercialization team in collaboration with our strategic partners. We have established long-term relationships with top hospitals, KOLs and doctors. Our commercialization team team will help them understand the MOA, clinical data and features of our products which could assist them in finding appropriate patients. We expect to market our products with a customized marketing focus for each product depending on its indication and market coverage.



Shanghai Miracogen Inc.- Ex. 2032, Page 000043

We may seek inclusion of some of our products into NRDL and other reimbursement programs. Such inclusion is determined by relevant government authorities and is beyond our control. According to Frost & Sullivan, since the establishment of the National Healthcare Security Administration in 2018, there have been four NRDL negotiations aiming to lower drug prices. During the negotiations, if the drug prices offered by the enterprises can match the cost price precalculated by the National Healthcare Security Administration based on the NRDL payment guidelines, the drugs can be included under the NRDL. The cost prices are determined by the National Healthcare Security Administration following two steps: (i) there will be evaluations of the drugs by the expert committee comprising over 100 experts and presentations and submissions of supportive evidence for the clinical values of the drugs and pricing models from the enterprises; and (ii) the final NRDL cost price will be calculated based on all the information collected in the previous step. In addition, availability of adequate coverage and reimbursement under the NRDL will affect the sales price and volume of our products. According to Frost & Sullivan, in 2019, 2020 and 2021, drugs newly included in the NRDL had average price discounts of 60.7%, 50.6% and 61.7% respectively. Frost & Sullivan also advised more specific examples: the price of Disitamab vedotin (RC48), an HER-2 ADC product developed by RemeGen Co., Ltd., dropped by 71.85% in 2021 after its inclusion in the NRDL in 2019. The price of Sintilimab developed by Innovent Biologics, Inc. dropped by 63.7% after its inclusion in the NRDL in 2019, while its sales revenue increased from RMB320.0 million in 2019 to RMB2,488.9 million in 2020, representing an increase of 677.8%. The price of Tislelizumab developed by BeiGene, Ltd. dropped by 80.0% after its inclusion in the NRDL in 2020, while its sales revenue increased from US$49.9 million in the three months ended September 30, 2020 to US$77.0 million in the same period in 2021, representing an increase of 54.0%. If we fail to have our products included into NRDL after commercialization, our revenue will be more dependent on patients' ability to pay. We may need to seek alternatives such as commercial insurance coverage of our drugs, and need to expand our sales channels and explore new collaboration patterns, such as distribution partnership, with various sales channel partners, to enhance our commercialization capability, especially on customer reach. We may also seek to create operational synergies by enriching and introducing our portfolio of drug candidates.

For certain risks related to our commercialization strategy, see "Risk Factors – Risks Relating to the Commercialization of our Drug Candidates."

**SUPPLIERS**

Our suppliers are primarily reputable CROs (contract research organizations), SMOs (site management organizations), CDMOs (contract development and manufacturing organizations) and hospitals in China with whom we collaborate on pre-clinical and clinical studies in China and overseas, and from whom we procure raw materials and equipment to support the manufacturing of our drug products. We select our suppliers by taking into account a number of factors, including their qualifications, industry reputation, cost competitiveness and compliance with relevant laws and regulations. We did not experience any material difficulty in engaging CDMOs for the procurement of clinical materials during the Track Record Period. In line with the industry norm, we engage third-party contractors to manage, conduct and


Shanghai Miracogen Inc.- Ex. 2032, Page 000044

support our pre-clinical studies and clinical trials in China and the U.S. We expect to engage third-party CDMOs to manufacture certain of our products after they are commercialized. HX008, the drug candidate we expect to be first commercialized, will be initially manufactured by CDMOs upon marketing approval and later transferred to our own manufacturing facility in Shanghai upon approval by relevant regulatory authority. We expect to manufacture ADC products at CDMOs upon their commercial launch. During the Track Record Period, purchases from our five largest suppliers in each year/period of 2019, 2020 and the eight months ended August 31, 2021 amounted to RMB213.3 million, RMB284.8 million and RMB198.1 million, respectively, representing 43.4%, 46.2% and 38.7%, respectively, of our total purchase cost for the same year/period. During the Track Record Period, our largest supplier accounted for 25.5%, 25.0% and 15.2%, respectively, of our total purchase cost in the same year/period. Save for Lepu Pharmaceutical Co. Ltd., CG Oncology and HanX, none of our Directors, their respective associates nor any shareholder who, to the knowledge of our Directors, owned more than 5% of our issued share capital as of the Latest Practicable Date, has any interest in any of our five largest suppliers in each year/period during the Track Record Period.

See "Business – Suppliers."

## RISK FACTORS

We are a biopharmaceutical company seeking to list on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules. There are unique challenges, risks and uncertainties associated with investing in companies such as ours, including the following:

(i) Our business and financial prospects depend substantially on the success of our clinical-stage and pre-clinical-stage drug candidates. If we are unable to successfully complete clinical development, obtain regulatory approvals or achieve commercialization for our drug candidates, or if we experience significant delays or cost overruns in doing any of the foregoing, our business and competitive position could be materially and adversely affected;

(ii) Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and we may encounter unexpected difficulties executing our clinical trials. Results of earlier studies and trials may not be predictive of future trial result;

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

(iv) Our drug candidates may cause AEs (adverse events) or have other properties that could delay or affect the granting of regulatory approvals, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval;



Shanghai Miracogen Inc.- Ex. 2032, Page 000045

(v) We have incurred net losses during the Track Record Period and anticipate that we will continue to incur net losses for the foreseeable future; and

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

See "Risk Factors."

## DIVIDEND

No dividend was paid or declared by our Company or other entities comprising our Group during the Track Record Period.

We currently expect to retain all future earnings for use in operation and expansion of our business, and do not have any dividend policy to declare or pay any dividends in the foreseeable future. Any future declarations and payments of dividends will be at the absolute discretion of our Directors and will depend on our actual and expected results of operations, cash flow and financial position, general business conditions and business strategies, expected working capital requirements and future expansion plans, legal, regulatory and other contractual restrictions, and other factors which our Directors consider relevant. No dividend shall be declared or payable except out of our profits and reserves lawfully available for distribution. As confirmed by our PRC Legal Advisor, according to relevant PRC laws, any future net profit that we make will have to be first applied to make up for our historically accumulated losses, after which we will be obliged to allocate 10% of our net profit to our statutory common reserve fund until such fund has reached more than 50% of our registered capital. We will therefore only be able to declare dividends after (i) all our historically accumulated losses have been made up for; and (ii) we have allocated sufficient net profit to our statutory common reserve fund as described above.

## GLOBAL OFFERING STATISTICS

The statistics in the following table are based on the assumptions that the Global Offering has been completed and 126,876,000 Shares are issued pursuant to the Global Offering.

| | **Based on an Offer Price of HK$6.87 per Share** | **Based on an Offer Price of HK$7.38 per Share** |
|---|---|---|
| Market capitalization of our Shares[(1)] | HK$11,394 million | HK$12,240 million |
| Unaudited pro forma adjusted consolidated net tangible assets per Share[(2)] | HK$0.99 | HK$1.03 |



Shanghai Miracogen Inc.- Ex. 2032, Page 000046

*Notes:*

(1) The calculation of market capitalization is based on 1,658,545,838 Shares expected to be in issue immediately upon completion of the Global Offering, assuming the Over-allotment Option is not exercised.

(2) The pro forma adjusted consolidated net tangible assets of the Group attributable to owners of the Company per Share is calculated after making the adjustments referred to in "Financial Information – Unaudited Pro Forma Statement of Adjusted Net Tangible Assets" and on the 1,658,545,838 Shares expected to be in issue immediately after completion of the Global Offering.

## OUR CONTROLLING SHAREHOLDER

As of the Latest Practicable Date, Dr. Pu Zhongjie owned (through Beijing Houde Yimin, Ningbo Houde Yimin and Lepu Medical) approximately 43.0% of our total issued share capital. Lepu Medical, a company listed on the Shenzhen Stock Exchange (stock code: 300003), is a medical device and pharmaceutical company dedicated to the development, manufacturing and sales of cardiovascular products. Immediately following the completion of the Global Offering, Dr. Pu Zhongjie will own (through Beijing Houde Yimin Investment Management Co., Ltd. ("Beijing Houde Yimin"), Ningbo Houde Yimin and Lepu Medical) approximately 39.7% of our total issued share capital (assuming the Over-allotment Option is not exercised) or approximately 39.3% of our total issued share capital (assuming the Over-allotment Option is exercised in full). Dr. Pu is our Controlling Shareholder as of the Latest Practicable Date and will remain as our Controlling Shareholder upon the Listing. Our Directors are of the view that Dr. Pu is not interested in a business, apart from our business, which competes or is likely to compete, either directly or indirectly, with our business under Rule 8.10 of the Listing Rules as of the Latest Practicable Date. See "Relationship with Controlling Shareholder."

## PRE-IPO INVESTMENTS

We have completed the Pre-IPO Investments raising approximately RMB2,002.12 million mainly by way of increase and subscription of registered capital in 2020 and 2021. Our Pre-IPO Investors include funds focusing on investment in companies and assets in the healthcare sector such as Vivo Capital Fund IX, L.P. ("Vivo Capital"), Shenzhen Shiyu Capital Management Co., Ltd. ("Shenzhen Shiyu") and SDIC Unity Capital Investment Fund (Limited Partnership) ("SDIC Unity Capital"). Among the Pre-IPO Investors, Shenzhen Shiyu, SDIC Unity Capital and Ping An Group are sophisticated investors. The shareholding interests held by Shenzhen Shiyu through Suzhou Danqing and Jiaxing Danqing, SDIC Unity Capital, and Ping An Group through Tianjin Pingan and Haihui Quanxing in our Company are approximately 4.93%, 1.59% and 2.76%, respectively, immediately following completion of the Global Offering (assuming the Over-Allotment Option is not exercised). Shares held by the Pre-IPO Investors are subject to a lock-up period of 12 months after the date of Listing on the Stock Exchange. For details, please refer to the paragraph headed "History, Development and Corporate Structure – Pre-IPO Investments".



Shanghai Miracogen Inc.- Ex. 2032, Page 000047

According to the PRC Company Law, all of the Shares in issue as of the date of this Prospectus, representing 92.35% of our total issued Shares upon Listing (assuming the Over-allotment Option is not exercised), will be subject to a lock-up period of one year from the Listing Date. Further, the Offer Shares to be purchased by the Cornerstone Investors will also be subject to a lock-up period of six months from the Listing Date. These may significantly affect the liquidity and trading volume of our Shares in the short term following the Global Offering. For details, please refer to the paragraph headed "Risk Factors – Risks relating to the Global Offering – There has been no prior public market for our Shares, and their liquidity and market price may be volatile."

**FUTURE PLANS AND USE OF PROCEEDS**

We estimate that we will receive the net proceeds of approximately HK$804.2 million from the Global Offering after deducting the underwriting fees and other estimated expenses in connection with the Global Offering, assuming no Over-allotment Option is exercised and assuming an Offer Price of HK$7.13 per Offer Share, being the mid-point of the indicative Offer Price range of HK$6.87 to HK$7.38 per Offer Share in this prospectus.

We intend to use the net proceeds we will receive from the Global Offering for the following purposes and in the amounts set out below, subject to changes in light of our evolving business needs and changing market condition:

(a) Approximately HK$551.0 million (representing 68.5% of the net proceeds) will be allocated to fund our Core Products, and specifically:

- approximately HK$185.0 million (representing 23.0% of the net proceeds) is expected to be used for MRG003.
- approximately HK$177.0 million (representing 22.0% of the net proceeds) is expected to be used for MRG002.
- approximately HK$130.0 million (representing 16.2% of the net proceeds) is expected to be used for HX008.
- approximately HK$10.0 million (representing 1.2% of the net proceeds) is expected to fund the clinical development and preparation for registration filings of LP002, including the ongoing and planned clinical trials.
- approximately HK$49.0 million (representing 6.1% of the net proceeds) is expected to be used to fund the planned clinical development and other development activities of the combination therapies of HX008 and LP002 with our other products including MRG003, MRG002 and CG0070.


Shanghai Miracogen Inc.- Ex. 2032, Page 000048

(b) Approximately HK$51.0 million (representing 6.3% of the net proceeds) will be allocated to fund our other key clinical-stage drug candidates and our key pre-clinical drug candidates.

(c) Approximately HK$127.0 million (representing 15.8% of the net proceeds) is expected to be allocated to acquire potential technologies and assets and expand our pipeline of drug candidates, including discovery of new drug candidates and business development activities and to fulfill our continuous payment obligation under our acquisition of HX008 from HanX.

(d) Approximately HK$75.2 million (representing 9.4% of the net proceeds) is expected to be allocated for general corporate purposes.

See "Future Plans and Use of Proceeds."

**LISTING EXPENSE**

Listing expenses represent professional fees, underwriting commissions and other fees incurred in connection with the Global Offering. We expect to incur listing expenses of approximately RMB82.2 million (HK$100.4 million), comprising (i) underwriting fees of RMB29.6 million (HK$36.2 million); and (ii) non-underwriting-related expenses of RMB52.5 million (HK$64.2 million), including (a) the fees paid and payable to the legal advisors and the Reporting Accountants of RMB24.6 million (HK$30.1 million), and the Joint Sponsors' fees, the fees paid and payable to the internal control consultant, Frost & Sullivan as the industry consultant, the Property Valuer and the Independent Valuer of RMB8.3 million (HK$10.1 million); and (b) other fees and expenses of RMB19.6 million (HK$24.0 million), assuming the Over-allotment Option is not exercised and based on the Offer Price of HK$7.13 per Offer Share, being the mid-point of the Offer Price range), approximately RMB49.1 million (HK$60.0 million) of which is expected to be charged to our consolidated statements of profit or loss, and approximately RMB33.1 million (HK$40.4 million) of which is expected to be capitalized and will be deducted from equity upon the completion of the Global Offering. The listing expenses are expected to represent approximately 11.10% of the gross proceeds of the Global Offering, assuming an Offer Price of HK$7.13 per Offer Share (being the mid-point of the indicative Offer Price range) and that the Over-allotment Option is not exercised. The listing expenses above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

**PROPERTY VALUATION**

The Property Valuation Report from AVISTA Valuation Advisory Limited ("AVISTA"), an independent property valuer, set out in Appendix IV to this prospectus, sets out details of our selective property interests as of December 31, 2021. AVISTA is of the opinion that the total market value of our selective property interests as of December 31, 2021 was RMB698.7 million. See Appendix IV to this prospectus.



Shanghai Miracogen Inc.- Ex. 2032, Page 000049

## RECENT DEVELOPMENT

### Employee Share Ownership Plan

On December 7, 2020, 151 eligible employees were granted shares of the Company pursuant to the Employee Share Ownership Plan. Subsequently in April 2021, as a reward for certain senior management members' service, we have entered into supplemental agreements with certain senior management members to modify key terms under the original Employee Share Ownership Plan. As a result, the restriction of service conditions of 11,262,500 shares granted on December 7, 2020 were canceled and the period of continuous service of 3,000,000 shares has been shortened. Expense related to vesting of restricted share aforementioned amounted to approximately RMB45,202,000 were recognized immediately upon modification. See "5. Employee Share Ownership Plan" in Appendix VIII and Note 27 of Appendix I to this Prospectus.

### Impact of the COVID-19 Outbreak

The outbreak of COVID-19 has caused illness in, and killed, many people in and outside China, caused temporary suspension of production and shortage of labor and raw materials in affected regions, and disrupted local and international travel and economy. The exacerbation, continuance or reoccurrence of COVID-19 has already caused, and may continue to cause, an adverse and prolonged impact on the economy and social conditions in the PRC and other affected countries.

Our Directors confirmed that the COVID-19 outbreak did not have any material adverse impact on our business operations and financial performance as of the Latest Practicable Date, primarily because: (i) there had been no material disruption of our ongoing clinical or pre-clinical trials; and (ii) we had not encountered any material supply chain disruption. See "Financial Information – No Material Adverse Change."

Although the COVID-19 outbreak has caused a three-month delay in process performance qualification in a CDMO we engaged in Wuhan, a three-month delay in patient enrollment, and follow-up for clinical studies due to the temporary closure of hospitals from January 2020 to April 2020, the COVID-19 outbreak had not caused any early termination of our clinical trials or necessitated any removal of any patients enrolled in our clinical trials during the Track Record Period and up to the Latest Practicable Date. We had resumed full and normal operations since April 2020. The COVID-19 outbreak did not have any material adverse impact on our financial performance. However, we cannot foresee when the COVID-19 outbreak will become completely under control or whether COVID-19 will have a material and adverse impact on our business going forward. See "Risk Factors – Risks Relating to Our Operations – We may be subject to disasters, health epidemics such as COVID-19, acts of war, terrorism, business disruptions and other force majeure events, which may have a material adverse effect on our business, financial condition and results of operations." We are continually monitoring the COVID-19 situation as well as various regulatory and administrative measures adopted by local governments to prevent and control the outbreak. We will continue to monitor and evaluate any impact of the COVID-19 outbreak on us and adjust our precautionary measures according to the latest developments of the outbreak.



Shanghai Miracogen Inc.- Ex. 2032, Page 000050

**Expected Net Loss Increase**

We expect that our net loss will increase significantly in 2021, primarily because we expect to incur increasing research and development expenses and administrative expenses as we advance the development of our pipeline, expand clinical development programs, continue to engage CROs and CDMOs to support our pre-clinical studies and clinical trials, and have granted shares of our Company pursuant to the Employee Share Ownership Plan. See "Appendix III – Loss Estimate."

**Impact of the Draft Guiding Principles for Clinical Research and Development of Anti-tumor Drugs Oriented by Clinical Value issued by the CDE on July 2, 2021**

The Draft Guiding Principles for Clinical Research and Development of Anti-tumor Drugs Oriented by Clinical Value (《以臨床價值為導向的抗腫瘤藥物臨床研發指導原則》 or the "Draft Rule") issued by the CDE on July 2, 2021 is a normative document, which is currently at a stage of seeking public comments and has not yet officially taken effect. According to our PRC Legal Advisor, the aim of the Draft Rule is to promote the patient-oriented research and development concept throughout the clinical trial design both of which should focus on the demand of patients. For example, with respect to clinical development, especially for early-stage clinical trial design and key clinical trial design, the Draft Rule encourages (i) the use of scientific tools such as establishing models to guide drug development, and (ii) the use of efficient clinical trial design, setting decision-making metrics and carrying out necessary interim analysis to reduce the invalid exposure of patients, protect the curative effect and interests of patients while improving the efficiency of research and development. The Draft Rule also emphasizes that attention should be paid to the representativeness of the patient population and the development of drugs for special patient populations so as to meet the demand for drugs by different types of populations in a safe manner to the maximum extent in clinical practice. The Draft Rule sets the aim of emphasizing the principle of "driven by clinical value and centered on the need of patients" and that drug innovation should not be limited to a "me-too" approach, where biotechnology and pharmaceutical companies merely imitate competitors' products. As a biopharmaceutical company with global drug development capabilities, as well as an experienced development team dedicated to innovation, we believe we are well positioned in the following aspects to take advantage of the measures and provisions in the Draft Rule: (i) we have designed a pipeline of 14 drug candidates while conducting development and research activities, which is an approach that is in line with the goal of the Draft Rule; (ii) we have explored combination therapies leveraging our innovation-driven discovery platform; and (iii) we have an experienced research and development team led by seasoned and visionary industry executives, with our senior members having on average 20 years of experience on the research and development of oncology drug products. With our focus on innovative drug products and our good track record of adhering to the laws and regulations relevant to our business, we believe we are well positioned to comply with the Draft Rule to be adopted by the CDE in the future and our dedication will help enable us to capture the favorable provisions in the Draft Rule. As of the Latest Practicable Date, the Draft Rule did not have a significant adverse impact on our research and development progress as we have obtained confirmation from CDE with


Shanghai Miracogen Inc.- Ex. 2032, Page 000051

respect to all of our registrational trials and NDA candidates, and we will obtain confirmation from the CDE before commencing the registration trials of our other pipeline candidates. Therefore, we do not expect the official issuance of the Draft Rule to have any material negative impact on our business in the future. We will continue to monitor and evaluate any impact of the Draft Rule on us. See "Risk Factors – Risks Relating to Our Doing Business in the PRC – The Biopharmaceutical Industry in the PRC is Highly Regulated and Such Regulations are Subject to Change, which may affect approvals and commercialization of our drug candidates."

**Disposal of Hangzhou Xiyuan Biotechnology Co., Ltd.**

Hangzhou Xiyuan Biotechnology Co., Ltd. (杭州熙源生物技術有限公司) was originally a minority investment held as to 30% by our Company. On October 9, 2021, an equity transfer agreement was entered into among Lepu Shanghai, Xiyuan Anjian Medical (Shanghai) Co., Ltd. 熙源安健醫藥(上海)有限公司) and Hangzhou Xiyuan Biotechnology Co., Ltd., pursuant to which Xiyuan Anjian Medical (Shanghai) Co., Ltd. agreed to acquire 30% of the equity interest in Hangzhou Xiyuan Biotechnology Co., Ltd. from Lepu Shanghai at the cash consideration of RMB10 million. Upon the completion of such disposal, Hangzhou Xiyuan Biotechnology Co., Ltd. will cease to be an associate held by our Company.

**No Material Adverse Change**

Our Directors confirm that up to the date of this Prospectus, save as disclosed in this Prospectus, there has been no material adverse change in our financial, operational or trading positions or prospects since August 31, 2021, being the end of the period reported on as set out in the Accountant's Report included in Appendix I to this Prospectus.



Shanghai Miracogen Inc.- Ex. 2032, Page 000052

*In this prospectus, unless the context otherwise requires, the following expressions have the following meanings.*

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| "Accountant's Report" | accountant's report for the years ended December 31, 2019, 2020 and the eight months ended August 31, 2021 in Appendix I to this prospectus |
| "Actual Controller" | the individual or entity that can control a company by way of investment, contract or other arrangements according to the Listing Rules of the Growth Enterprise Market (《創業板股票上市規則》) published by Shenzhen Stock Exchange where Lepu Medical is listed |
| "Akeso" | Zhongshan Kangfang Biopharma Co., Ltd. (中山康方生物醫藥有限公司) |
| "Articles of Association" or "Articles" | the articles of association of our Company, as amended, which shall become effective on the Listing Date, a summary of which is set out in Appendix VII to this prospectus |
| "associate(s)" | has the meaning ascribed to it under the Listing Rules |
| "Audit Committee" | the audit committee of our Company |
| "Authorized Representative(s)" | the authorized representative(s) of our Company |
| "AVISTA" | AVISTA Valuation Advisory Limited, the independent property valuer commissioned by us to conduct property valuation on the properties of our Group |
| "Beijing Houde Yimin" | Beijing Houde Yimin Investment Management Co., Ltd. (北京厚德義民投資管理有限公司), a limited liability company incorporated in the PRC on August 17, 2009 |
| "Board" or "Board of Directors" | the board of Directors of our Company |
| "Board Committee(s)" | the board committees of our Company, namely the Audit Committee, the Remuneration and Appraisal Committee, the Nomination Committee and the Strategy Committee |



Shanghai Miracogen Inc.- Ex. 2032, Page 000053

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| "Business day" or "business day" | a day on which banks in Hong Kong are generally open for normal banking business to the public and which is not a Saturday, Sunday or public holiday in Hong Kong |
| "BVI" | the British Virgin Islands |
| "CCASS" | the Central Clearing and Settlement System established and operated by HKSCC |
| "CCASS Clearing Participant" | a person admitted to participate in CCASS as a direct clearing participant or general clearing participant |
| "CCASS Custodian Participant" | a person admitted to participate in CCASS as a custodian participant |
| "CCASS EIPO" | the application for the Hong Kong Offer Shares to be issued in the name of HKSCC Nominees and deposited directly into CCASS to be credited to your or a designated CCASS Clearing Participant's stock account through causing HKSCC Nominees to apply on your behalf, including by (a) instructing your broker or custodian who is a CCASS Clearing Participant or a CCASS Custodian Participant to give electronic application instructions via CCASS terminals to apply for the Hong Kong Offer Shares on your behalf, or (b) (if you are an existing CCASS Investor Participant) giving electronic application instructions through the CCASS Internet System (https://ip.ccass.com) or through the CCASS Phone System (following the procedures contained in HKSCC's "An Operating Guide for Investor Participants" in effect from time to time). HKSCC can also input electronic application instructions for CCASS Investor Participants through HKSCC's Customer Service Centre by completing an input request form |
| "CCASS Investor Participant" | a person admitted to participate in CCASS as an investor participant who may be an individual, joint individuals or a corporation |
| "CCASS Participant" | a CCASS Clearing Participant, a CCASS Custodian Participant or a CCASS Investor Participant |
| "CDE" | Center for Drug Evaluation (藥品審評中心) of the NMPA |



Shanghai Miracogen Inc.- Ex. 2032, Page 000054

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| "CG Oncology" | CG Oncology, Inc. (previously known as Cold Genesys, Inc.), a clinical-stage immuno-oncology company headquartered in the U.S., of which Lepu Medical holds approximately 7.73% equity interest through Lepu Holdings Limited, a company wholly owned by Lepu Medical, and Ms. Pu Jue (蒲珏) serves as a director |
| "China," "Mainland China" or "PRC" | the People's Republic of China, excluding, for the purpose of this prospectus, Hong Kong, Macau and Taiwan |
| "China Reform" | China Reform Guangzhou Investment Fund (Limited Partnership) (國新央企運營(廣州)投資基金(有限合夥)), one of our Pre-IPO Investors, the details of which are set out in the section headed "History, Development and Corporate Structure" |
| "CNIPA" | China National Intellectual Property Administration (國家知識產權局) |
| "Companies (Winding up and Miscellaneous Provisions) Ordinance" | the Companies (Winding up and Miscellaneous Provisions) Ordinance (Chapter 32 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time |
| "Companies Ordinance" | the Companies Ordinance (Chapter 622 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time |
| "Company" or "our Company" | Lepu Biopharma Co., Ltd. (樂普生物科技股份有限公司) (including our predecessor, Lepu Biopharma Co., Ltd. (樂普生物科技有限公司)) |
| "Company Law" or "PRC Company Law" | the Company Law of the People's Republic of China (中華人民共和國), as amended, supplemented or otherwise modified from time to time |
| "Compliance Advisor" | has the meaning ascribed to it under the Listing Rules |
| "connected person(s)" | has the meaning ascribed to it under the Listing Rules |


Shanghai Miracogen Inc.- Ex. 2032, Page 000055

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| "Controlling Shareholder" | has the meaning ascribed to it under the Listing Rules and, unless the context requires otherwise, refers to Dr. Pu Zhongjie, for further details of whom, please refer to the section headed "Relationship with Controlling Shareholder" in this prospectus |
| "Conversion" | the conversion of our Company into a joint stock company as described in the section headed "History, Development and Corporate Structure" in this prospectus |
| "Core Product(s)" | has the meaning ascribed to it in Chapter 18A of the Listing Rules and in this context, refers to our Core Products including MRG003, MRG002, HX008 and LP002 |
| "CSDC" | China Securities Depository and Clearing Corporation Limited |
| "CSDC (Hong Kong)" | China Securities Depository and Clearing (Hong Kong) Company Limited |
| "CSRC" | China Securities Regulatory Commission (中國證券監督管理委員會) |
| "CtM Bio" | CtM Bio Co., Ltd. (樂普創一生物科技(上海)有限公司), a limited liability company incorporated in the PRC on March 26, 2020, and our non-wholly owned subsidiary |
| "Directors" | the directors of our Company |
| "Domestic Share(s)" | ordinary shares in the share capital of our Company, with a nominal value of RMB1.00 each, which are subscribed for and paid up in Renminbi |
| "Dr. Pu" or "Dr. Pu Zhongjie" | Dr. Pu Zhongjie (蒲忠傑), the Controlling Shareholder of our Company |
| "EIT Law" | the Enterprise Income Tax Law of the People's Republic of China (中華人民共和國企業所得税法), as amended, supplemented or otherwise modified from time to time |
| "Employee Share Ownership Plan" or "ESOP" | the employee share ownership plan established by our Company in December 2020 |



Shanghai Miracogen Inc.- Ex. 2032, Page 000056

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| "Extreme Condition(s)" | extreme condition(s) including but not limited to serious disruption of public transport services, extensive flooding, major landslides and large-scale power outage caused by a super typhoon according to the revised "Code of Practice in Times of Typhoons and Rainstorms" issued by the Labour Department of the government of Hong Kong in June 2019, as announced by the government of Hong Kong |
| "FRC" | the Financial Reporting Council of Hong Kong |
| "Global Offering" | the Hong Kong Public Offering and the International Offering |
| "Green Application Form(s)" | the application form(s) to be completed by the White Form eIPO Service Provider, Computershare Hong Kong Investor Services Limited |
| "Group", "our Group", "the Group", "we", "us", or "our" | our Company and its subsidiaries from time to time |
| "H Share(s)" | overseas listed foreign invested ordinary share(s) in the ordinary share capital of our Company, with a nominal value of RMB1.00 each, which are to be subscribed for and traded in Hong Kong dollars and for which an application has been made for the granting of listing and permission to deal in on the Stock Exchange |
| "H Share Registrar" | Computershare Hong Kong Investor Services Limited |
| "Haihui Quanxing" | Shenzhen Haihui Quanxing Investment Consultation Limited Partnership (Limited Partnership) (深圳市海匯全興投資諮詢合夥企業(有限合夥)), one of our Pre-IPO Investors, the details of which are set out in the section headed "History, Development and Corporate Structure" |
| "Haitong Capital" | Haitong Innovation Securities Investment Co., Ltd. (海通創新證券投資有限公司), one of our Pre-IPO Investors, the details of which are set out in the section headed "History, Development and Corporate Structure" |
| "Hangzhou HealSun" | Hangzhou HealSun Biopharma Co., Ltd. (杭州皓陽生物技術有限公司), a limited liability company incorporated in the PRC on November 19, 2015 |


Shanghai Miracogen Inc.- Ex. 2032, Page 000057

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| "HanX" | Hangzhou HanX Biomedical Co., Ltd. (杭州翰思生物醫藥有限公司), a limited liability company incorporated in the PRC on August 3, 2016, which is a biopharmaceutical company principally engaged in biological products, biotechnology, medical technology development and consulting, and held by Mr. Zhang Faming, the director of Miracogen Shanghai as to 53.75% and four Independent Third Parties as to 46.25% in aggregate with each Independent Third Party holding no more than 20% of the equity interest of HanX |
| "HK$" or "Hong Kong dollars" or "HK dollars" | Hong Kong dollars, the lawful currency of Hong Kong |
| "HKSCC" | Hong Kong Securities Clearing Company Limited, a wholly-owned subsidiary of Hong Kong Exchange and Clearing Limited |
| "HKSCC Nominees" | HKSCC Nominees Limited, a wholly owned subsidiary of HKSCC |
| "Hong Kong" or "HK" | the Hong Kong Special Administrative Region of the PRC |
| "Hong Kong Offer Shares" | the H Shares offered pursuant to the Hong Kong Public Offering |
| "Hong Kong Public Offering" | the offer of the Hong Kong Offer Shares for subscription by the public in Hong Kong at the Public Offer Price on the terms and conditions described in this prospectus |
| "Hong Kong Stock Exchange" or "Stock Exchange" | The Stock Exchange of Hong Kong Limited |
| "Hong Kong Underwriters" | the underwriters of the Hong Kong Public Offering listed in the section headed "Underwriting – Hong Kong Underwriters" in this document |
| "Hong Kong Underwriting Agreement" | the underwriting agreement dated Wednesday, February 9, 2022, relating to the Hong Kong Public Offering and entered into by, our Company, the Controlling Shareholder, the Joint Sponsors, Joint Global Coordinators and the Hong Kong Underwriters, as further described in section headed "Underwriting" in this prospectus |



Shanghai Miracogen Inc.- Ex. 2032, Page 000058

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| "iBridge" | iBridge HK Holding Limited |
| "IFRS" | International Financial Reporting Standards, which include standards, amendments and interpretations issued by the International Accounting Standards Board |
| "Independent Third Party(ies)" | person(s) or company(ies) and their respective ultimate beneficial owner(s), who/which, to the best of our Directors' knowledge, information and belief, having made all reasonable enquiries, is/are not connected with our Company |
| "International Offer Shares" | the H Shares offered pursuant to the International Offering together with, where relevant, any additional H Shares which may be issued by us pursuant to the exercise of the Over-allotment Option |
| "International Offering" | the conditional placing by the International Underwriters of the International Offer Shares at the Offer Price outside the United States in offshore transactions in reliance on Regulation S, and to persons within the United States who are QIBs in reliance on Rule 144A or another available exemption from the registration requirements of the U.S. Securities Act, as further described in the section headed "Structure of the Global Offering" in this prospectus |
| "International Underwriters" | the group of underwriters, led by the Joint Global Coordinators, that expects to enter into the International Underwriting Agreement to underwrite the International Offering |
| "International Underwriting Agreement" | the international underwriting agreement relating to the International Offering, which is expected to be entered into by, among others, the Joint Global Coordinators, the International Underwriters and us on or about the Price Determination Date |
| "I-Mab Shanghai" | I-Mab Biopharma Co., Ltd. (天境生物科技(上海)有限公司), a limited liability company incorporated in the PRC on August 24, 2016, as the case may be, its affiliated entities |



Shanghai Miracogen Inc.- Ex. 2032, Page 000059

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| "Jiaxing Danqing" | Jiaxing Danqing Investment Partnership (Limited Partnership) (嘉興丹青投資合夥企業(有限合夥)), one of our Pre-IPO Investors, the details of which are set out in the section headed "History, Development and Corporate Structure" |
| "JMT" | Shanghai JMT-Bio, Inc. (上海津曼特生物科技有限公司), a limited liability company incorporated in the PRC on June 5, 2012 |
| "Joint Bookrunners" | the joint bookrunners as named in the section headed "Directors and Parties Involved in the Global Offering" of this prospectus |
| "Joint Global Coordinators" | the joint global coordinators as named in the section headed "Directors and Parties Involved in the Global Offering" of this prospectus |
| "Joint Lead Managers" | the joint lead managers as named in the section headed "Directors and Parties Involved in the Global Offering" of this prospectus |
| "Joint Sponsors" | China International Capital Corporation Hong Kong Securities Limited and Morgan Stanley Asia Limited (in alphabetical order) |
| "Kaiyuan Guochuang" | Suzhou Industrial Park Guochuang Kaiyuan II Investment Center (Limited Partnership) (蘇州工業園區國創開元二期投資中心(有限合夥)), one of our Pre-IPO Investors, the details of which are set out in the section headed "History, Development and Corporate Structure" |
| "Keymed" | Keymed Bioscience (Chengdu) Co., Ltd. (康諾亞生物醫藥科技(成都)有限公司), a limited liability company incorporated in the PRC on September 1, 2016, which is a third-party biotechnology company focusing on the in-house discovery and development of innovative biological therapies in the autoimmune and oncology therapeutic areas |


Shanghai Miracogen Inc.- Ex. 2032, Page 000060

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| "Kington Capital" | Kington Capital No. 1 Equity Investment Partnership (Limited Partnership) (蘇州翼樸一號股權投資合夥企業(有限合夥)), one of our Pre-IPO Investors, the details of which are set out in the section headed "History, Development and Corporate Structure" |
| "KYM" | KYM Biosciences Inc., a Delaware corporation |
| "Latest Practicable Date" | February 1, 2022, being the latest practicable date prior to the date of this prospectus for the purpose of ascertaining certain information contained in this prospectus |
| "Lepu Beijing" | Lepu (Beijing) Biopharma Co., Ltd. (樂普(北京)生物科技有限公司), a limited liability company incorporated in the PRC on July 30, 2018, and our wholly owned subsidiary |
| "Lepu Hangjia" | Lepu Hangjia (Shanghai) Venture Capital Co., Ltd. (樂普航嘉(上海)創業孵化器管理有限公司), a limited liability company incorporated in the PRC on July 4, 2018, and our wholly owned subsidiary |
| "Lepu Medical" | Lepu Medical Technology (Beijing) Co., Ltd. (樂普(北京)醫療器械股份有限公司), a joint stock company incorporated in the PRC on June 11, 1999 and listed on the Shenzhen Stock Exchange (stock code: 300003), and the promoter of our Company |
| "Lepu Medical Group" | Lepu Medical and its subsidiaries |
| "Lepu Shanghai" | Shanghai Lepu Biopharma Investment Co., Ltd. (上海樂普生物投資有限公司), a limited liability company incorporated in the PRC on May 30, 2018, and our wholly owned subsidiary |
| "Linzhi Lecheng" | Linzhi Lecheng Medical Industry Development Co., Ltd. (林芝樂成醫療產業發展有限公司), one of our Pre-IPO Investors, the details of which are set out in the section headed "History, Development and Corporate Structure" |
| "Listing" | the listing we are seeking on the Hong Kong Stock Exchange under Chapter 18A of the Listing Rules |


Shanghai Miracogen Inc.- Ex. 2032, Page 000061

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| "Listing Committee" | the Listing Committee of the Hong Kong Stock Exchange |
| "Listing Date" | the date, expected to be on or about Wednesday, February 23, 2022 on which the Shares are listed on the Main Board of the Hong Kong Stock Exchange and from which dealings in the Shares are permitted to commence on the Main Board of the Hong Kong Stock Exchange |
| "Listing Rules" | the Rules Governing the Listing of Securities on the Stock Exchange, as amended or supplemented from time to time |
| "Main Board" | the stock market (excluding the option market) operated by the Hong Kong Stock Exchange which is independent from and operated in parallel with the Growth Enterprise Market of the Hong Kong Stock Exchange |
| "Mandatory Provisions" | the Mandatory Provisions for Articles of Association of Companies to be Listed Overseas (到境外上市公司章程必備條款), as amended, supplemented or otherwise modified from time to time, for inclusion in the Articles of Association of companies incorporated in the PRC to be listed overseas (including Hong Kong), which were promulgated by the former Securities Commission of the State Council (國務院證券委員會) and the former State Commission for Restructuring the Economic Systems (國家經濟體制改革委員會) on August 27, 1994 |
| "Minxin Qiyuan" | Qingdao Minxin Qiyuan Investment Center (Limited Partnership) (青島民芯啟元投資中心(有限合夥)), one of our Pre-IPO Investors, the details of which are set out in the section headed "History, Development and Corporate Structure" |
| "Miracogen HK" | Miracogen Limited, a limited liability company established under the laws of Hong Kong and a special purpose investment vehicle wholly-owned by Miracogen Inc., which in turn is a company wholly-owned by Dr. Hu Chaohong, our executive Director and co-chief executive officer of our Company |



Shanghai Miracogen Inc.- Ex. 2032, Page 000062

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| "Miracogen Shanghai" | Shanghai Miracogen Inc. (上海美雅珂生物技術有限責任公司), a limited liability company incorporated in the PRC on January 27, 2014, and our wholly owned subsidiary |
| "MOF" | Ministry of Finance of the PRC (中華人民共和國財政部) |
| "MOFCOM" | Ministry of Commerce of the PRC (中華人民共和國商務部) |
| "Nasdaq" | Nasdaq Global Select Market |
| "Negative List" | the Special Administrative Measures for Access of Foreign Investment (Negative List) (2020 Edition), most recently jointly promulgated by the MOFCOM and the NDRC on June 23, 2020 and which became effective on July 23, 2020, as amended, supplemented or otherwise modified from time to time |
| "Ningbo Houde Yimin" | Ningbo Houde Yimin Information Technology Co., Ltd. (寧波厚德義民信息科技有限公司), a limited liability company incorporated in the PRC on March 29, 2017, and the promoter of our Company |
| "NMPA" | the National Medical Products Administration of the PRC (國家藥品監督管理局) |
| "Nomination Committee" | the nomination committee of our Company |
| "Offer Price" | the final price per Offer Share in Hong Kong dollars (exclusive of brokerage fee of 1%, SFC transaction levy of 0.0027%, Hong Kong Stock Exchange trading fee of 0.005% and FRC transaction levy of 0.00015%) of not more than HK$7.38 and expected to be not less than HK$6.87, at which Hong Kong Offer Shares are to be subscribed, to be determined in the manner further described in the paragraphs headed "Structure of the Global Offering" in this prospectus |
| "Offer Share(s)" | the Hong Kong Offer Shares and the International Offer Shares, being ordinary shares of the Company, together with, where relevant, any additional ordinary shares which we may issue pursuant to the exercise of the Over-allotment Option |


Shanghai Miracogen Inc.- Ex. 2032, Page 000063

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| "Over-allotment Option" | the option we expect to grant to the International Underwriters, exercisable by the Joint Global Coordinators (for themselves and on behalf of the International Underwriters) under the International Underwriting Agreement, which may require us to allot and issue up to an aggregate of 19,031,000 additional Offer Shares at the Offer Price to cover over-allocations in the International Offering, if any |
| "PRC Company Law" | the Company Law of the PRC (《中華人民共和國公司法》), enacted by the Standing Committee of the Eighth National People's Congress on December 29, 1993 and effective on July 1, 1994, and subsequently amended on December 25, 1999, August 28, 2004, October 27, 2005, December 28, 2013 and October 26, 2018, as amended, supplemented or otherwise modified from time to time |
| "PRC GAAP" | generally accepted accounting principles of the PRC |
| "PRC Legal Advisor" | Zhong Lun Law Firm, our legal advisor as to the laws of the PRC |
| "Pre-IPO Investments" | the pre-IPO investments in our Company undertaken by the Pre-IPO Investors, details of which are set out in the section headed "History, Development and Corporate Structure" |
| "Pre-IPO Investors" | Series A Investors other than Lepu Medical, Series B Investors, Series C Investors and Miracogen HK |
| "Price Determination Agreement" | the agreement to be entered into by the Joint Global Coordinators (for themselves and on behalf of the Underwriters) and us on the Price Determination Date to record and fix the pricing of the Offer Shares |
| "Price Determination Date" | the date, expected to be on or about Tuesday, February 15, 2022, on which the Offer Price will be determined, or such later time as the Joint Global Coordinators (for themselves and on behalf of the Underwriters) and we may agree, but in any event, not later than Tuesday, February 22, 2022 |
| "prospectus" | this prospectus being issued in connection with the Hong Kong Public Offering |



Shanghai Miracogen Inc.- Ex. 2032, Page 000064

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| "province" | each being a province or, where the context requires, a provincial-level autonomous region or municipality under the direct supervision of the central government of the PRC |
| "Qualified Institutional Buyers" or "QIBs" | qualified institutional buyers within the meaning of Rule 144A under the U.S. Securities Act |
| "Regulation S" | Regulation S under the U.S. Securities Act |
| "Remuneration and Appraisal Committee" | the remuneration and appraisal committee of our Company |
| "RMB" or "Renminbi" | Renminbi, the lawful currency of the PRC |
| "Ronghui Sunshine" | Beijing Ronghui Sunshine Xinxing Industry Investment Management Center (Limited Partnership) (北京融匯陽光新興產業投資管理中心(有限合夥)), one of our Pre-IPO Investors, the details of which are set out in the section headed "History, Development and Corporate Structure" |
| "Rule 144A" | Rule 144A under the U.S. Securities Act |
| "SAFE" | State Administration of Foreign Exchange of the PRC (中華人民共和國國家外匯管理局), the PRC governmental agency responsible for matters relating to foreign exchange administration, including local branches, when applicable |
| "SAIC" | State Administration of Industry and Commerce of the PRC (中華人民共和國國家工商行政管理總局) |
| "SAT" | State Taxation Administration of the PRC (中華人民共和國國家税務總局) |
| "SDIC Unity Capital" | SDIC Unity Capital Investment Fund (Limited Partnership) (國投創合國家新興產業創業投資引導基金(有限合夥)), one of our Pre-IPO Investors, the details of which are set out in the section headed "History, Development and Corporate Structure" |
| "Seagen Inc." | a global biotechnology company, previously known as Seattle Genetics Inc. |



Shanghai Miracogen Inc.- Ex. 2032, Page 000065

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| "Securities Law" or "PRC Securities Law" | the Securities Law of the PRC (中華人民共和國證券法), as amended, supplemented or otherwise modified from time to time |
| "Series A Investors" | Suzhou Danqing, Jiaxing Danqing, Suzhou Private Capital Investment, Kaiyuan Guochuang, Kington Capital, Suzhou Suzi, Suzhou Xinrui, Linzhi Lecheng and Lepu Medical |
| "Series B Investors" | Tianjin Pingan, Haihui Quanxing, Haitong Capital, Sunshine Insurance, Ronghui Sunshine, China Reform, Xinye Guangzhou, SDIC Unity Capital, Minxin Qiyuan, Mr. Wang Xinglin (王興林), Mr. Guo Tongjun (郭同軍), Mr. Wang Lei (王磊), Mr. Wei Zhanjiang (魏戰江), Ms. Zhang Xia (張霞), Ms. Wang Yong (王泳), Ms. Chen Juan (陳娟) and Mr. Lin Yi (林儀) |
| "Series C Investors" | Vivo Capital and SHC |
| "SFC" | the Securities and Futures Commission of Hong Kong |
| "Shanghai Chunrui" | Shanghai Chunrui Zongheng Technology Limited Partnership (Limited Partnership) (上海純瑞縱橫科技合夥企業(有限合夥)), a limited partnership incorporated in the PRC on December 12, 2019, and the promoter of our Company |
| "Shanghai Lvyuan" | Lvyuan (Shanghai) Technology Co., Ltd. (律元(上海)科技有限公司), a limited liability company incorporated in the PRC on April 11, 2019, and the promoter of our Company |
| "Shanghai Stock Exchange" | the Shanghai Stock Exchange (上海證券交易所) |
| "Share(s)" | ordinary shares in the capital of our Company with a nominal value of RMB1.00 each, comprising Domestic Share(s), Unlisted Foreign Share(s) and H Share(s) |
| "Shareholder(s)" | holder(s) of the Share(s) |


Shanghai Miracogen Inc.- Ex. 2032, Page 000066

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| "SHC" | Shanghai Healthcare Capital Partnership (Limited Partnership) (上海生物醫藥產業股權投資基金合夥企業(有限合夥)), one of our Pre-IPO Investors, the details of which are set out in the section headed "History, Development and Corporate Structure" |
| "Shenzhen Shiyu" | Shenzhen Shiyu Capital Management Co., Ltd. (深圳市拾玉投資管理有限公司) |
| "Shenzhen Stock Exchange" | the Shenzhen Stock Exchange (深圳證券交易所) |
| "SIMMCAS" | Shanghai Institute of Materia Medica, Chinese Academy of Sciences (中國科學院上海藥物研究所), a research institution for drug discovery in PRC |
| "Special Regulations" | the Special Regulations of the State Council on the Overseas Offering and Listing of Shares by Joint Stock Limited Companies (國務院關於股份有限公司境外募集股份及上市的特別規定) |
| "Stabilizing Manager" | China International Capital Corporation Hong Kong Securities Limited |
| "Strategy Committee" | the strategy committee of our Company |
| "subsidiaries" | has the meaning ascribed to it in section 15 of the Companies Ordinance |
| "substantial shareholder(s)" | has the meaning ascribed to it under the Listing Rules |
| "Sunshine Insurance" | Sunshine Life Insurance Company Limited (陽光人壽保險股份有限公司), one of our Pre-IPO Investors, the details of which are set out in the section headed "History, Development and Corporate Structure" |
| "Supervisor(s)" | member(s) of our Supervisory Committee |
| "Supervisory Committee" | the supervisory committee of our Company |
| "Suzhou Danqing" | Suzhou Danqing II Innovation Pharmaceutical Industry Investment Partnership (Limited Partnership) (蘇州丹青二期創新醫藥產業投資合夥企業(有限合夥)), one of our Pre-IPO Investors, the details of which are set out in the section headed "History, Development and Corporate Structure" |



Shanghai Miracogen Inc.- Ex. 2032, Page 000067

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| "Suzhou Private Capital Investment" | Suzhou Private Capital Investment Holdings Co., Ltd. (蘇州民營資本投資控股有限公司) |
| "Suzhou Suzi" | Suzhou Suzi Investment Limited Partnership (蘇州蘇梓投資合夥企業(有限合夥)), one of our Pre-IPO Investors, the details of which are set out in the section headed "History, Development and Corporate Structure" |
| "Suzhou Xinrui" | Suzhou Xinrui Qiyuan Investment Center (Limited Partnership) (蘇州新銳啟源投資中心(有限合夥)), one of our Pre-IPO Investors, the details of which are set out in the section headed "History, Development and Corporate Structure" |
| "Synaffix" | Synaffix B.V, a biotechnology company headquartered in the Netherlands |
| "Taizhou Aoke" | Taizhou Houde Aoke Technology Co., Ltd. (泰州厚德奧科科技有限公司), a limited liability company incorporated in the PRC on March 23, 2018, and our non-wholly owned subsidiary |
| "Taizhou Hanzhong" | Taizhou Hanzhong Biotechnology Co., Ltd. (泰州翰中生物醫藥有限公司), a limited liability company incorporated in the PRC on November 25, 2016, and our non-wholly owned subsidiary |
| "Takeovers Code" | the Codes on Takeovers and Mergers and Share Buy-backs issued by the SFC, as amended, supplemented or otherwise modified from time to time |
| "Tianjin Pingan" | Tianjin Pingan Consumption Technology Investment Limited Partnership (Limited Partnership) (天津市平安消費科技投資合夥企業(有限合夥)), one of our Pre-IPO Investors, the details of which are set out in the section headed "History, Development and Corporate Structure" |
| "Track Record Period" | the years ended December 31, 2019 and 2020 and the eight months ended August 31, 2021 |
| "Underwriters" | the Hong Kong Underwriters and the International Underwriters |



Shanghai Miracogen Inc.- Ex. 2032, Page 000068

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| "Underwriting Agreements" | the Hong Kong Underwriting Agreement and the International Underwriting Agreement |
| "Unlisted Foreign Share(s)" | unlisted ordinary share(s) of RMB1.00 each in the share capital of our Company held by Miracogen HK and Vivo Capital before the Listing |
| "US$", "USD" or "U.S. dollars" | United States dollars, the lawful currency of the United States |
| "U.S." or "United States" | the United States of America, its territories and possessions, any State of the United States, and the District of Columbia |
| "U.S. Securities Act" | The United States Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder |
| "Vivo Capital" | Vivo Capital Fund IX, L.P., one of our Pre-IPO Investors, the details of which are set out in the section headed "History, Development and Corporate Structure" |
| "White Form eIPO" | the application for Hong Kong Offer Shares to be issued in the applicant's own name by submitting applications online through the designated website of the White Form eIPO Service Provider, **www.eipo.com.hk** |
| "White Form eIPO Service Provider" | Computershare Hong Kong Investor Services Limited |
| "Wuhan Binhui" | Wuhan Binhui Biological Technology Co., Ltd. (武漢濱會生物科技股份有限公司), a limited liability company incorporated in the PRC on November 19, 2010, which is a biological technology company rendering services in connection with integrated oncology programs |
| "Xinye Guangzhou" | Xinye (Guangzhou) Equity Investment Limited Partnership (Limited Partnership) (新業(廣州)股權投資合夥企業(有限合夥)), one of our Pre-IPO Investors, the details of which are set out in the section headed "History, Development and Corporate Structure" |
| "%" | per cent |



Shanghai Miracogen Inc.- Ex. 2032, Page 000069

*This glossary contains explanations of certain technical terms used in this prospectus in connection with our Company and our business. Such terminology and meanings may not correspond to standard industry meanings or usages of those terms.*

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| "ADC" | antibody drug conjugate, a class of biopharmaceutical drugs that combine monoclonal antibodies specific to surface antigens present on particular tumor cells with highly potent antitumor small molecule agents linked via a chemical linker |
| "ADCC" | antibody-dependent cell-mediated cytotoxicity |
| "AE" | adverse event, which may be mild, moderate, or severe, any untoward medical occurrences in a patient administered a drug or other pharmaceutical product during clinical trials and which do not necessarily have a causal relationship with the treatment |
| "ALK" | anaplastic lymphoma kinase, a gene on 2p23 that encodes an orphan receptor with tyrosine kinase activity belonging to the insulin receptor superfamily, which plays an important role in brain development |
| "antagonist" | a type of drug or ligand that blocks or decreases a biological response by binding to and blocking a receptor without activating it |
| "AR" | adverse reaction, any unexpected or dangerous reaction to a drug |
| "Asn297" | a sugar part of IgG, which plays an important role in the antibody properties such as antibody stability, effector functions, solubility, pharmacokinetics, and immunogenicity |
| "ATF" | alternating tangential flow filtration, a lower shear technology for cell retention with perfusion cultures |
| "B-cell" | a type of white blood cell that differs from other types of lymphocytes by expressing B-cell receptors on its surface, and responsible for producing antibodies |
| "B-NHL" | B-cell non-Hodgkin's lymphoma |



Shanghai Miracogen Inc.- Ex. 2032, Page 000070

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| "B7-1" | B-lymphocyte activation antigen, which provides regulatory signals for T lymphocytes as a consequence of binding to the CD28 and CTLA4 ligands of T cells |
| "Bacillus Calmette-Guerin" or "BCG" | a type of bacteria that causes a reaction in a patient's immune system that can destroy cancer cells located in the lining of the bladder. It is also widely used as a vaccine against tuberculosis |
| "BC" | breast cancer |
| "BLA" | biologics license application |
| "BOR" | best overall response |
| "BRAF" | a gene found on chromosome 7q34, involved in many cellular processes, including cell proliferation, differentiation, and transcriptional regulation |
| "BT-474" | a human breast cancer cell line |
| "BTC" | biliary tract cancer |
| "C-met/cMET" | cellular-mesenchymal epithelial transition, a cellular process during which epithelial cells acquire mesenchymal phenotypes and behaviour following the downregulation of epithelial features |
| "CAGR" | compound annual growth rate |
| "CAR-T" | chimeric antigen receptor T-cell, which is a T cell that has been genetically engineered to produce an artificial T-cell receptor for use in immunotherapy |
| "CD16a" | a receptor expressed on NK cells that facilitates antibody dependent cellular cytotoxicity (ADCC) by binding to the Fc portion of various antibodies |
| "CD20" | a B-lymphocyte antigen that is expressed on the surface of B cells, starting at the pre-B cell stage and also on mature B cells in the bone marrow and in the periphery |


Shanghai Miracogen Inc.- Ex. 2032, Page 000071

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| "CDMO" | contract development and manufacturing organization, a pharmaceutical company that develops and manufactures drugs for other pharmaceutical companies on a contractual basis |
| "CDX model" | cell-line derived xenograft models, which involves implanting in vitro cultured human cell lines into immunodeficient mice to determine efficacy of oncology therapeutic candidate |
| "cGMP" | current good manufacturing practice, a system that stipulates minimum requirements for the methods, facilities, and controls used in manufacturing, processing and packing of a drug product to make sure that a product is safe for use, and that it has the ingredients and strength it claims to have |
| "chemotherapy" | a category of cancer treatment that uses one or more anti-cancer small molecule chemical agents as part of its standardized regimen |
| "CI" | confidence interval |
| "CIS" | bladder carcinoma in situ |
| "CLDN18.2" | Claudin 18.2, a highly specific tissue junction protein for gastric tissue |
| "CMC" | chemistry, manufacturing, and controls processes in the development, licensure, manufacturing, and ongoing marketing of pharmaceutical products |
| "CMO" | contract manufacturing organization, a company that serves other companies in the pharmaceutical industry on a contract basis to provide comprehensive services from drug development through drug manufacturing |
| "cohort" | a group of patients as part of a clinical study who share a common characteristic or experience within a defined period and who are monitored over time |
| "combination therapy" | a treatment modality that combines two or more therapeutic agents |


Shanghai Miracogen Inc.- Ex. 2032, Page 000072

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| "CR" | complete response, the disappearance of all signs of cancer in response to treatment |
| "CRC" | colorectal cancer |
| "CRO" | contract research organization, a pharmaceutical company that conducts research for other pharmaceutical companies on a contractual basis |
| "CTLA-4" | cytotoxic T lymphocyte-associated antigen-4, an essential receptor involved in the negative regulation of T cell activation |
| "cytotoxic" | toxic to living cells |
| "DAR" | drug-to-antibody ratio, the average number of drugs conjugated to the antibodies |
| "DCR" | disease control rate, the total proportion of patients who demonstrate a response to treatment, equal to the sum of complete responses (CR), partial responses (PR) and stable disease (SD) |
| "DDM" | Dodecyl-beta-D-maltoside |
| "DLBCL" | diffuse large B-cell lymphoma |
| "DLT" | dose-limiting toxicity, side effects of a drug or other treatment that are serious enough to prevent an increase in dose of that treatment in clinical trial |
| "DOR" | duration of response |
| "DTP pharmacy" | direct-to-patient pharmacy which directly sell and distribute prescription pharmaceutical products to patients |
| "efficacy evaluable patient" | a patient who is enrolled in a clinical trial and completes at least one efficacy assessment |
| "EGFR" | epidermal growth factor receptor |
| "ESCC" | esophageal squamous cell carcinoma |


Shanghai Miracogen Inc.- Ex. 2032, Page 000073

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| "ES-SCLC" | extensive stage small-cell lung cancer |
| "Fc" | fragment crystallisable region, which is the tail region of an antibody that interacts with cell surface receptors called Fc receptors and some proteins of the complement system |
| "FDA" | Food and Drug Administration of the United States |
| "first-line" or "1L" | with respect to any disease, the first line therapy, which is the treatment regimen or regimens that are generally accepted by the medical establishment for initial treatment. It is also called primary treatment or therapy |
| "FISH" | fluorescence in situ hybridization, a test that maps the genetic material in human cells, including specific genes or portions of genes |
| "FL" | follicular lymphoma |
| "GBD" | global burden of disease, a project aiming to comprehensively assess regional and global mortality and disability from major diseases, injuries, and risk factors |
| "GC" | gastric cancer |
| "GEJ" | gastroesophageal junction |
| "GM-CSF" | granulocyte-macrophage colony-stimulating factor, a potent cytokine produced by viral vector |
| "GMP" | a system for ensuring that products are consistently produced and controlled according to quality standards, which is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. It is also the practice required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture and sale of pharmaceutical products |
| "H1975" | a human non-small cell lung carcinoma |
| "HCC" | hepatocellular carcinoma, a common form of liver cancer |



Shanghai Miracogen Inc.- Ex. 2032, Page 000074

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| "HER2" | human epidermal growth factor receptor 2 |
| "HER2-expressing" | HER2 status of tumor cells identified with a test score of IHC 1+ or above |
| "HER2-low-expressing" | HER2 status of tumor cells identified with a test score of IHC 1+ or IHC 2+ plus FISH (or ISH)- |
| "HER2-negative" | HER2 status of tumor cells identified with a test score of IHC 0 |
| "HER2-positive" or "HER2-over-expressing" | HER2 status of tumor cells identified with a test score of either IHC 3+ or IHC 2+/FISH (or ISH)+ (IHC 2+ plus FISH (or ISH)+) |
| "HNC" | head and neck cancer |
| "HNSCC" | head and neck squamous cell carcinoma |
| "IARC" | the International Agency for Research on Cancer |
| "IC50" | half maximal inhibitory concentration |
| "IgC" | immunoglobulin constant |
| "IgG" | human immunoglobulin G, the most common antibody type found in blood circulation that plays an important role in antibody-based immunity against invading pathogens |
| "IgV" | immunoglobulin variable |
| "IHC" | immunohistochemistry, the most common application of immunostaining. It involves the process of selectively identifying antigens in cells of a tissue section by exploiting the principle of antibodies binding specifically to antigens in biological tissues |
| "ILD" | Interstitial lung disease |
| "*in vitro*" | Latin for "within the glass", studies using components of an organism that have been isolated from their usual biological surroundings, such as microorganisms, cells or biological molecules |



Shanghai Miracogen Inc.- Ex. 2032, Page 000075

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| "*in vivo*" | Latin for "within the living", studies in vivo are those in which the effects of various biological or chemical substances are tested on whole, living organisms including animals, humans and plants, as opposed to a partial or dead organism, or those done in vitro |
| "IND" | investigational new drug or investigational new drug application, also known as clinical trial application in China or the U.S. |
| "KRAS" | kirsten rat sarcoma viral oncogene, one of the most frequently mutated genes associated with pancreatic cancer |
| "LYM" | Lymphocyte count |
| "mAb" | monoclonal antibody, an antibody generated by identical cells that are all clones of the same parent cell |
| "MC38" | an immuno-oncology model with significant utility in drug development |
| "MDR" | multi-drug resistant |
| "metastatic" | in reference to any disease, including cancer, disease producing organisms or of malignant or cancerous cells transferred to other parts of the body by way of the blood or lymphatic vessels or membranous surfaces |
| "MMAE" | monomethyl auristatin E, a potent tubulin binder with a half maximal inhibitory concentration (IC50) in the subnanomolar range |
| "MSI-H/dMMR" | high levels of microsatellite instability/deficient mismatch repair |
| "MTD" | maximum tolerated dose, the highest dose of a drug or treatment that does not cause unacceptable side effects |
| "MZL" | marginal zone lymphoma |
| "NDA" | new drug application |
| "NHL" | non-Hodgkin's lymphoma |



Shanghai Miracogen Inc.- Ex. 2032, Page 000076

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| "NK cell" | natural killer cell, a kind of cells that play important roles in immunity against viruses and in the immune surveillance of tumors |
| "NMIBC" | non-muscle invasive bladder cancer |
| "NPC" | nasopharyngeal cancer |
| "NRDL" | National Reimbursement Drug List |
| "NSCLC" | non-small cell lung cancer |
| "NTRK" | a class of oncogenes associated with a wide range of pediatric and adult solid tumors |
| "ORR" | objective response rate, which is equal to the sum of CR and PR |
| "OS" | overall survival |
| "PAR2" | protease activated receptor 2, a protein that in humans is encoded by the F2RL1 gene |
| "PARs" | protease activated receptors, a family of G-protein-coupled receptors (GPCRs) that are irreversibly activated by proteolytic cleavage of the N terminus |
| "PCT" | the Patent Cooperation Treaty, which assists applicants in seeking patent protection internationally for their inventions, helps patent offices with their patent granting decisions, and facilitates public access to a wealth of technical information relating to those inventions |
| "PD" | progressive disease, refers to a at least 20% increase in the size of a tumor or in the extent of cancer in the body in response to treatment, according to RECIST |
| "PD-1" | programmed cell death protein 1, an immune checkpoint receptor expressed on T cells, B cells and macrophages |
| "PD-L1" | PD-1 ligand 1, which is a protein on the surface of a normal cell or a cancer cell that binds to its receptor, PD-1, on the surface of the T cell that causes the T cell to turn off its ability to kill the cancer cell |



Shanghai Miracogen Inc.- Ex. 2032, Page 000077

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| "PDX model" | patient derived xenograft model, a model of cancer where the tissue or cells from a patient's tumor are implanted into an immunodeficient or humanized mouse to evaluate the natural growth of cancer, its monitoring, and corresponding treatment for the original patient |
| "PFS" | progression-free survival, the length of time during and after the treatment of a disease, such as cancer, that a patient lives with the disease but it does not get worse |
| "Phase I clinical trials" | study in which a drug is introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion, and if possible, to gain an early indication of its effectiveness |
| "Phase II clinical trials" | study in which a drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases, and to determine dosage tolerance and optimal dosage |
| "Phase III clinical trials" | study in which a drug is administered to an expanded patient population generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to provide adequate information for the labeling of the product |
| "PK" | a measurement of how fast and how completely the drug is absorbed into animal or human body, and the distribution, metabolism, and excretion of drugs in animal or human body |
| "placebo" | any dummy medical treatment administered to the control group in a controlled clinical trial in order that the specific and non-specific effects of the experimental treatment can be distinguished |
| "PMBL" | primary mediastinal large B-cell lymphoma |



Shanghai Miracogen Inc.- Ex. 2032, Page 000078

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| "PR" | partial response, refers to an at least 30% but below 100% decrease in the size of a tumor or in the extent of cancer in the body in response to treatment, according to RECIST |
| "pre-clinical studies" | studies or programs testing a drug on non-human subjects, to gather efficacy, toxicity, pharmacokinetic and safety information and to decide whether the drug is ready for clinical trials |
| "R-CHOP" | a systemic treatment, which means that it spreads through the body |
| "RB" | retinoblastoma |
| "RECIST" | Response Evaluation Criteria in Solid Tumors, a set of published rules that define when tumors in cancer patients improve ("respond"), stay the same ("stabilize"), or worsen ("progress") during treatment. The criteria were published in February 2000 by an international collaboration including the European Organisation for Research and Treatment of Cancer (EORTC), National Cancer Institute of the United States, and the National Cancer Institute of Canada Clinical Trials Group. Now the majority of clinical trials evaluating cancer treatments for objective response in solid tumors use RECIST. These criteria were developed and published in February 2000, and subsequently updated in 2009 |
| "registration trial" | a clinical trial or study intended to provide evidence for a drug marketing approval |
| "RP2D" | recommended Phase II dose |
| "RTK" | receptor tyrosine kinase |
| "SAE" | serious AE, any medical occurrence in human drug trials that at any dose: results in death; is life-threatening; requires inpatient hospitalization or causes prolongation of existing hospitalization; results in persistent or significant disability/incapacity; may have caused a congenital anomaly/birth defect, or requires intervention to prevent permanent impairment or damage |



Shanghai Miracogen Inc.- Ex. 2032, Page 000079

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| "SCLC" | small-cell lung cancer |
| "SD" | stable disease. In oncology, it refers to cancer that is neither decreasing at least 30% nor increasing at least 20% in the size of a tumor or in the extent of cancer in the body in response to treatment, according to RECIST |
| "second-line" or "2L" | with respect to any disease, the therapy or therapies that are tried when the first-line treatments do not work adequately |
| "SKBR-3" | a human breast cancer cell line |
| "SMO" | site management organization, an organization that provides clinical trial related services to medical device companies having adequate infrastructure and staff to meet the requirements of the clinical trial protocol |
| "solid tumors" | an abnormal mass of tissue that usually does not contain cysts or liquid areas. Solid tumors may be benign (not cancer), or malignant (cancer). Different types of solid tumors are named for the type of cells that form them |
| "standard of care" | treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals |
| "T cell" | a lymphocyte of a type produced or processed by the thymus gland and actively participating in the immune response, which plays a central role in cell-mediated immunity. T cells can be distinguished from other lymphocytes, such as B cells and NK cells, by the presence of a T cell receptor on the cell surface |
| "TCM" | traditional Chinese medicine |
| "TGFBRII" | TGF-β receptor II |
| "tissue factor" or "TF" | a protein encoded by the F3 gene, present in subendothelial tissue and leukocytes. Many cancer cells express high level of TF |



Shanghai Miracogen Inc.- Ex. 2032, Page 000080

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| "TKIs" | tyrosine kinase inhibitors, a class of small molecule that inhibit or block the activity of tyrosine kinase enzymes |
| "TNBC" | triple-negative breast cancer |
| "TRAE" | a treatment related AE, which is adverse events present after medical treatment |
| "UC" | urothelial cancer |
| "USPTO" | United States Patent and Trademark Office |
| "vc linker" | valine-citrulline linker, which is adequately stable in blood circulation and cleaved effectively by the lysosomal cathepsin enzyme after the ADC is internalized and enters lysosome |
| "VEGF" | vascular endothelial growth factor, a critical factor that controls the growth and permeability of blood vessels |
| "VEGFR" | a set of three homologous transmembrane receptor tyrosine kinases that bind VEGF |
| "vp" | virion particle |


Shanghai Miracogen Inc.- Ex. 2032, Page 000081

This prospectus includes forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including, without limitation, those regarding our future financial position, our strategy, plans, objectives, goals, targets and future developments in the markets where we participate or are seeking to participate, and any statements preceded by, followed by or that include the words "believe," "expect," "estimate," "predict," "aim," "intend," "will," "may," "plan," "consider," "anticipate," "seek," "should," "could," "would," "continue," or similar expressions or the negative thereof, are forward-looking statements. These forward-looking statements involve known and unknown risks, uncertainties and other factors, some of which are beyond our control, which may cause our actual results, performance or achievements, or industry results, to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These forward-looking statements are based on numerous assumptions regarding our present and future business strategies and the environment in which we will operate in the future. Important factors that could cause our actual performance or achievements to differ materially from those in the forward-looking statements include, among other things, the following:

- general political and economic conditions, including those related to the PRC;
- our ability to successfully implement our business plans and strategies;
- future developments, trends and conditions in the industry and markets in which we operate or into which we intend to expand;
- our business operations and prospects;
- our capital expenditure plans;
- the actions and developments of our competitors;
- our financial condition and performance;
- capital market developments;
- our dividend policy;
- any changes in the laws, rules and regulations of the central and local governments in the PRC and other relevant jurisdictions and the rules, regulations and policies of the relevant governmental authorities relating to all aspects of our business and our business plans;
- various business opportunities that we may pursue; and


Shanghai Miracogen Inc.- Ex. 2032, Page 000082

- changes or volatility in interest rates, foreign exchange rates, equity prices or other rates or prices, including those pertaining to the PRC and Hong Kong and the industry and markets in which we operate.

Additional factors that could cause actual performance or achievements to differ materially include, but are not limited to, those discussed in "Risk Factors" and elsewhere in this prospectus. We caution you not to place undue reliance on these forward-looking statements, which reflect our management's view only as of the date of this prospectus. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. In light of these risks, uncertainties and assumptions, the forward-looking events discussed in this prospectus might not occur. All forward-looking statements contained in this prospectus are qualified by reference to the cautionary statements set out in this section.


Shanghai Miracogen Inc.- Ex. 2032, Page 000083

*An investment in our Shares involves significant risks. You should carefully consider all of the information in this prospectus, including the risks and uncertainties described below, before making an investment in our Shares. The following is a description of what we consider to be our material risks. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations and prospects. In any such case, the market price of our Shares could decline, and you may lose all or part of your investment. In particular, we are a biotechnology company seeking to list on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules. There are unique challenges, risks and uncertainties associated with investing in companies such as ours, which may cause you to lose all or part of your investment.*

*These factors are contingencies that may or may not occur, and we are not in a position to express a view on the likelihood of any such contingency occurring. The information given is as of the Latest Practicable Date unless otherwise stated, will not be updated after the date hereof, and is subject to the cautionary statements in the section headed "Forward-looking Statements" in this prospectus.*

## RISKS RELATING TO THE RESEARCH AND DEVELOPMENT OF OUR DRUG CANDIDATES

***Our business and financial prospects depend substantially on the success of our clinical-stage and pre-clinical-stage drug candidates. If we are unable to successfully complete clinical development, obtain regulatory approvals or achieve commercialization for our drug candidates, or if we experience significant delays or cost overruns in doing any of the foregoing, our business and competitive position could be materially and adversely affected.***

Our revenue and profitability are substantially dependent on our ability to complete the development of our drug candidates, obtain requisite regulatory approvals and successfully manufacture and commercialize our drug candidates. We have invested a significant portion of our efforts and financial resources in the development of our existing drug candidates, and we expect to incur substantial and increasing expenditures for the development and commercialization of our drug candidates in the future.

The success of our drug candidates will depend on a number of factors, including:

- favorable safety and efficacy data from our pre-clinical studies and clinical trials;
- sufficient resources to acquire or discover additional drug candidates and successful identification of potential drug candidates based on our research or business development methodology or search criteria and process;
- successful enrollment of patients in, and completion of, clinical trials as well as completion of pre-clinical studies;



Shanghai Miracogen Inc.- Ex. 2032, Page 000084

- sufficient supplies of drug products that are either used in combination or in comparison with our drug candidates in clinical trials;
- the performance by CROs or other third parties we engage to conduct clinical trials and their compliance with our protocols and applicable laws without damaging or compromising integrity of the resulting data;
- the capabilities and competence of our collaborators;
- receipt of regulatory approvals;
- strong commercial manufacturing capabilities;
- successful launch of commercial sales of our drug candidates, if and when approved;
- the obtaining and maintenance of favorable reimbursement from third-party payers for drugs, if and when approved;
- competition with other drug candidates and drugs;
- the obtaining, maintenance and enforcement of patents, trademarks, trade secrets and other intellectual property protections and regulatory exclusivity for our drug candidates;
- successful defense against any claims brought by third parties that we have infringed, misappropriated or otherwise violated any intellectual property of any such third party; and
- the continued acceptable safety profile of our drug candidates following regulatory approval.

Some of our drug candidates represent a novel approach to therapeutic needs compared with more commonly used medical methods, and therefore carry inherent development risks that could result in delays and cost overruns in clinical development, regulatory approvals or commercialization. Any modification to the protocols related to the demonstration of safety or efficacy of our drug candidates may delay the clinical program, regulatory approvals or commercialization, and we may be required to supplement, modify, or withdraw and refile our applications for regulatory approvals. In addition, potential patients and their doctors may be inclined to use conventional standard-of-care treatments rather than any novel approach. Given the novelty of our drug candidates, a substantial amount of education and training may need to be provided to patients and medical personnel. This may have a material adverse effect on revenues generated from our drug candidates, which in turn may materially and adversely affect our competitive position, business, financial condition and results of operations.


Shanghai Miracogen Inc.- Ex. 2032, Page 000085

As of the Latest Practicable Date, all of our existing drug candidates were in various phases of pre-clinical and clinical development, and we plan to file the NDA applications for several drug candidates with the FDA or NMPA in the next two years. If we do not achieve one or more of the aforementioned factors in a timely manner or at all, we could experience significant delays or difficulties in obtaining approvals for and commercializing our drug candidates, which would have a material adverse effect on our business, financial condition and results of operations.

***Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and we may encounter unexpected difficulties executing our clinical trials. Results of earlier studies and trials may not be predictive of future trial results.***

Clinical trials are capital-intensive and may demand years of effort to complete, while their outcomes are inherently uncertain and may not be favorable. We may encounter unexpected difficulties while executing our clinical trials, such as delays in regulatory approvals, complexities of analytical testing technology, shortages of material supplies and outbreaks of epidemics, which may result in changes to our current clinical development plans. See "– Risks Relating to Our Operations – We may be subject to disasters, health epidemics such as COVID-19, acts of war, terrorism, business disruptions and other force majeure events, which may have a material adverse effect on our business, financial condition and results of operations." Failure can occur at any time or stage during the clinical trial process, which would result in a material and adverse effect on our business, financial condition and results of operations.

The results of pre-clinical studies and early clinical trials may not be predictive of the success of later-phase clinical trials, and favorable initial or interim results of a clinical trial do not necessarily indicate the success of final results. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to a lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. It is common that various aspects of the development programs, such as manufacturing and formulation, are altered along the entire research and development stage in an effort to optimize processes and results, and there can be no assurance that such alterations would help achieve the intended objectives.

There may be significant variability in safety or efficacy results among different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in size and demographics of the enrolled patients (such as genetic differences and patient adherence to the dosage regimen) and the dropout rate among enrolled patients in clinical trials. Differences in the number of clinical trial sites and countries involved may also lead to variability between earlier and later-phase clinical trials. Therefore, the results of planned clinical trials or other future clinical trials could be significantly different and other than as predicted, which could result in delays in the completion of clinical trials, regulatory approvals and commencement of commercialization of our drug candidates.



Shanghai Miracogen Inc.- Ex. 2032, Page 000086

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

ADCs are considered as emerging and relatively novel therapies for cancer treatment. Their mechanisms of action have yet to be thoroughly understood, and AEs or side effects have been observed in pre-clinical and clinical studies and reported by medical practitioners in connection with their usage in patients with cancers.

Before obtaining regulatory approvals for the commercialization of our drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. If the results of clinical trials of our drug candidates are not positive or only modestly positive for proposed indications, or if they raise safety concerns, any or some of the following would occur:

- regulatory approvals for our drug candidates would be delayed or denied;
- we may be required to conduct additional clinical trials or other testing of our drug candidates beyond our current development plan;
- we may be required to add labeling statements, such as a "boxed" warning or a contraindication;
- we may be required to create a medication guide outlining the risks of the side effects for distribution to patients;
- we may be required to implement a risk evaluation and mitigation strategy program, including medication guides, doctor communication plans and other risk management tools with restricted distribution methods and patient registries;
- we may not be able to obtain regulatory approvals for all the proposed indications as intended;
- we may be subject to restrictions on how the drug is distributed or used;
- we may be sued or held liable for injury caused to individuals exposed to or taking our drug candidates;
- we may be unable to obtain reimbursement for use of the drug; and
- conditional regulatory approval of our drug candidates may require us to conduct confirmatory studies to verify the predicted clinical benefit and additional safety studies. The results from such studies may not support the clinical benefit, which would result in the approval being withdrawn.



Shanghai Miracogen Inc.- Ex. 2032, Page 000087

Having expended a significant amount of capital to progress our drug candidates, if such drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results in future clinical trials, we would not be able to realize any revenue on such drug candidates if they then or ultimately fail to receive regulatory approvals due to unsatisfactory clinical trial results, thereby materially and adversely affecting our business, financial condition, results of operations and prospects.

***If we encounter difficulties in enrolling patients for our clinical trials, our clinical development activities could be delayed or otherwise materially and adversely affected.***

The successful and timely completion of clinical trials in accordance with their protocols depends, among others, on our ability to enroll a sufficient number of patients who opt to participate and remain in the clinical trials until the end of the trial. We may experience difficulties in patient enrollment for our clinical trials for a variety of reasons, including:

- the selection, contracting and performance of third-party suppliers;
- the design of the trial;
- the size and demographics of the patient population;
- the size of the study population required for analysis of the trial's primary endpoints;
- the patient eligibility criteria defined in the protocol;
- our ability to obtain and maintain patient consents;
- patients' and clinicians' perceptions of the potential advantages and side effects of the drug candidate being studied compared with other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- the availability of approved therapies that are similar in mechanism to our drug candidates;
- the outbreak of epidemics or pandemics, such as COVID-19. See "– We may be subject to disasters, health epidemics such as COVID-19, acts of war, terrorism, business disruptions and other force majeure events, which may have a material adverse effect on our business, financial condition and results of operations;"
- the proximity of patients to trial sites; and
- the selection of quality clinical trial sites and investigators with the appropriate competencies and experience.


Shanghai Miracogen Inc.- Ex. 2032, Page 000088

In addition, our clinical trials may compete with other clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead choose to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct certain clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients available for our clinical trials at such clinical trial sites. Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of our planned clinical trials, thereby hindering the completion of these trials and adversely affecting our ability to advance the development of our drug candidates.

***We may be unable to identify, discover, develop or in-license new drug candidates, or to identify additional therapeutic opportunities for our drug candidates, to expand or maintain our product pipeline.***

Although we mainly focus on the continued clinical testing, potential approvals and commercialization of our existing product candidates, the success of our business depends in part upon our ability to discover, identify, in-license, develop or commercialize additional product candidates. There can be no assurance that we will be successful in identifying potential drug candidates. Although we have developed technology platforms such as an ADC technology platform, an antibody discovery platform and an advanced process and analytical development platform, which we believe enable us to design, evaluate and select optimal candidates and continue to expand our pipeline, there can be no assurance that we will be successful in identifying, discovering, developing or in-licensing potential drug candidates in the future. Drug candidates that we identify may be shown to have side effects or other characteristics that make them unmarketable or unlikely to receive regulatory approvals. Some drug candidates are technically challenging to develop and manufacture, such as our ADCs. We have also pursued collaboration with third parties in the discovery and development of potential drug candidates. However, there can be no assurance that such collaboration will be able to deliver the expected results.

Research programs to pursue the development of our drug candidates for additional indications and to identify new drug candidates and drug targets require substantial technical, financial and human resources. Our research programs may show promising results in identifying potential indications and/or drug candidates at an initial stage yet fail to yield favorable results for clinical development.

We may fail to discover, identify or in-license new drug candidates for clinical development and commercialization for a number of reasons, including the following:

- the research methodology used may not be effective in identifying potential indications or new drug candidates;



Shanghai Miracogen Inc.- Ex. 2032, Page 000089

- there may be a lack of transferability of experimental results obtained in the laboratory testing in cells or from animals into clinical treatment and safety outcomes in human subjects, including unexpected toxicities in humans;

- potential drug candidates may be shown to have adverse effects or other characteristics that indicate they are unlikely to achieve the safety and efficacy desired; or

- we may need to invest greater resources in identifying additional therapeutic opportunities for our drug candidates or developing suitable potential drug candidates, which would limit our ability to diversify and expand our drug portfolio.

In addition, we may not be able to secure our business objectives for lack of control over our joint ventures. In particular, based on the Joint Venture Agreement as mentioned in "Business – Collaboration, Licensing And Transfer Arrangements – Collaboration with Keymed and iBridge," we own 30% equity interest in KYM, which does not provide us with the unilateral ability to control KYM's business actions which require shareholders or directors' approval. Although we participate in the management, we may not be able to control its daily operation. As a result, we may not be able to pass certain important board resolutions, and our joint venture partner may be unable or unwilling to perform its obligations under the Joint Venture Agreement and may take actions contrary to our requests, instructions, or our business objectives in KYM.

Therefore, we may not be able to identify new drug candidates or additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs. We may invest efforts and resources in potential drug candidates or other potential programs that ultimately prove to be unsuccessful. Any of the foregoing events will have a material adverse effect on our business, results of operations and prospects.

## RISKS RELATING TO REGULATORY APPROVALS AND GOVERNMENT REGULATIONS

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

The development and commercialization of drug candidates are heavily regulated in various jurisdictions. While we focus on expanding our business in the PRC, we also strive to pursue opportunities in the U.S. and other jurisdictions. Under the strict regulations of the biopharmaceutical industry, regulatory authorities in various jurisdictions employ fairly similar regulatory strategies which cover the development, approval, manufacturing, marketing, sales


Shanghai Miracogen Inc.- Ex. 2032, Page 000090

and distribution of products, including operations related to data and genetic information processing. However, certain regulatory regimes impose onerous compliance burdens upon companies that expect to expand into the relevant jurisdictions.

The process of obtaining regulatory approvals and maintaining compliance with applicable laws and regulations requires considerable expenditure of time and financial resources. Failure to comply with the applicable laws and regulations at any time or stage before or after approvals may lead to administrative penalties or judicial sanctions upon an applicant. Such penalties and sanctions include, among others, refusal to approve pending applications, withdrawal of an approval, revocation of a license, a hold on clinical trials, voluntary or mandatory recalls of products, the seizure of products, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, and disgorgement of profits. Any of the foregoing events could materially adversely affect our business, financial condition, results of operations and prospects.

***The regulatory approval processes of the NMPA, the FDA and other comparable regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are unable to obtain without undue delay any regulatory approvals for our drug candidates in our targeted markets, our business may be subject to actual or perceived harm.***

We are subject to risks associated with obtaining regulatory approvals. Difficulties and failures in doing so may expose us to various harms, either actual or perceived. Granting, and the time in granting, regulatory approvals by the NMPA, the FDA and other comparable regulatory authorities involve various factors, including regulatory officials' discretion. It generally takes several years to obtain regulatory approvals following the commencement of pre-clinical studies and clinical trials. In addition, regulations, approval policies and requirements for clinical data may change during the clinical development process of a drug candidate and may vary among jurisdictions. There can be no assurance that we will be able to obtain regulatory approvals for our existing drug candidates or any drug candidates we may discover, identify, in-license or develop in the future.

We may fail to receive the regulatory approvals from the NMPA, the FDA or other comparable regulatory authorities for our drug candidates due to a number of reasons, including:

- disagreement in the design or implementation of our clinical trials;
- failure to demonstrate that a drug candidate is safe and effective for its proposed indication;
- failure of our clinical trial results to meet the level of statistical and medical significance required for approvals;
- failure of our clinical trial process to pass GCP inspections;


Shanghai Miracogen Inc.- Ex. 2032, Page 000091

- failure to demonstrate that a drug candidate's efficiency and other benefits outweigh its safety risks;

- disagreement with our interpretation of data from pre-clinical studies or clinical trials;

- insufficient or suboptimal data collected from the clinical trials of our drug candidates to support the NDA, or other submissions or regulatory approvals;

- changes in regulations, testing requirements, or approval policies that render our pre-clinical and clinical data insufficient for approval;

- failure of our drug candidates to pass cGMP inspections during the regulatory review process or across the production cycle of our drug;

- failure of our clinical sites to pass audits carried out by the NMPA, the FDA or other comparable regulatory authorities, resulting in a potential invalidation of our research data;

- findings by the NMPA, the FDA or other comparable regulatory authorities of deficiencies related to our manufacturing processes or the manufacturing facilities of third-party manufacturers from whom we procure clinical and commercial supplies; and

- failure of our clinical trial process to keep abreast with any scientific or technological advancements required by regulations or approval policies.

The NMPA, the FDA or other comparable regulatory authorities may require more information to support approval, including additional pre-clinical, clinical or CMC data, which may result in delay in regulatory approval and commercialization plans or denial of regulatory approval. In the case where an approval is issued, regulatory authorities may approve fewer indications, including undesired indications, of our drug candidates than the indications we applied for, or grant approvals contingent on the performance of post-marketing clinical trials.

Failure to obtain regulatory approvals in a timely manner, or at all, or failure to obtain regulatory approvals with an ideal scope of indications could have a negative impact on the commercial prospects of our drug candidates, and may cause reputational damage.


Shanghai Miracogen Inc.- Ex. 2032, Page 000092

***We may seek approvals from the NMPA, the FDA or other comparable regulatory authorities for an expedited review process for our drug candidates or for the use of data from registrational trials through accelerated development pathways, failure to obtain which may have a material adverse effect on our business, financial condition, results of operations and prospects.***

The NMPA, the FDA and the comparable regulatory authorities in other jurisdictions may allow the use of data from a registrational trial and/or have implemented expedited review programs for drug candidates, among others, which are innovative drug applications, or which treat a serious or life-threatening condition and provide meaningful therapeutic benefit over available therapies upon a determination that the drug candidate demonstrates an effect on a surrogate endpoint or intermediate clinical endpoint which is reasonably likely to predict clinical benefit. For example, a drug candidate might receive an innovative drug designation from the NMPA if such drug or drug candidate has a novel molecular structure and formulation composition, possesses a novel mechanism of action, and improved pharmacological properties involving improved safety, large therapeutic index and window, or superior efficacy that may result in a significant improvement in the clinical outcomes for patients, and has not been marketed anywhere in the world; the FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity, or mortality.

There can be no assurance that the regulatory authorities will consider our existing or future candidates as innovative drug applications or agree with our surrogate endpoints or intermediate clinical endpoints, or that we will decide to pursue or submit any additional NDAs for accelerated approvals or any other form of expedited development, review or approvals. Similarly, there can be no assurance that, after receiving feedback from the regulatory authorities, we will continue to pursue or apply for accelerated approvals or any other form of expedited development, review or approvals, even if we initially decide to do so. Furthermore, for any submission of an application for accelerated approvals or application under another expedited regulatory designation, there can be no assurance that such submission or application will be accepted for filing, or that any expedited development, review or approvals will be granted on a timely basis, or at all.

Any failure to obtain accelerated approvals or any other form of expedited development, review or approvals for our drug candidates would result in a longer period of time prior to the commercialization of such drug candidate, an increase in the development expenses for such drug candidate and an adverse impact on our competitive position in the market.

In addition, if we obtain accelerated approvals of a drug candidate based on a surrogate endpoint, we will likely be required to conduct a post-approval clinical outcome trial to confirm the clinical benefit of the drug candidate. If the post-approval trial is not successful, we may not be able to continue marketing the drug for the relevant indication.



Shanghai Miracogen Inc.- Ex. 2032, Page 000093

***Our drug candidates may cause AEs or have other properties that could delay or affect the granting of regulatory approvals, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval.***

AEs caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or cease clinical trials and may result in a more restrictive label, delay in or denial of regulatory approval by the NMPA, the FDA or other comparable regulatory authorities, or a significant change in our clinical protocol or our development plan. Our trial results could reveal a high level of severity or prevalence of certain AEs. In such an event, our trials could be suspended or terminated and the NMPA, the FDA or other comparable regulatory authorities could deny approvals of, or order us to cease further development of, our drug candidates for any or all targeted indications. AEs related to our drug candidates may affect patient recruitment or the ability of enrolled patients to complete the trial and could result in potential liability claims. Any of these occurrences may significantly harm our reputation, business, financial condition, results of operations and prospects.

Additionally, if side effects caused by any of our drug candidates after they receive regulatory approvals have been identified, it may lead to severe negative consequences, including the following:

- we may need to suspend marketing of the drug candidate;
- regulatory authorities may withdraw their approvals of or revoke the licenses for the drug candidate;
- regulatory authorities may require additional warnings on the label;
- regulatory authorities may require us to implement a risk evaluation and mitigation strategy program, or restrict distribution of our drugs or otherwise impose burdensome implementation requirements on us;
- we may be required to conduct specific post-marketing studies; and
- we could be subject to litigation and held liable for harm caused to patients, and our reputation may suffer.

Any of the foregoing events could prevent us from achieving or maintaining market acceptance of any drug candidate that is approved and could materially and adversely affect our business, financial condition, results of operations and prospects. Moreover, combination therapy, such as using our drug candidates together with third-party agents, may involve unique AEs that could be exacerbated compared with AEs from monotherapies.


Shanghai Miracogen Inc.- Ex. 2032, Page 000094

***After we receive regulatory approvals for our drug candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expenses and penalties for noncompliance.***

If any of our drug candidates receives regulatory approvals in the future, it will be subject to ongoing and additional regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including the requirements of regulatory authorities in the PRC and other jurisdictions.

Our drug candidates that have received regulatory approvals may be subject to conditions of approval or limitations on the approved indicated uses for which the drug may be marketed, or may be required to perform post-marketing testing or continuously monitor the safety and efficacy of the drug candidate, which could adversely affect the drug's commercial potential. The NMPA, FDA or other comparable regulatory authorities may also require a risk evaluation and mitigation strategy program as a condition of approval of our drug candidates or following approval. If the NMPA, FDA or other comparable regulatory authorities approve our drug candidates, we will have to comply with requirements, including submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs, for any clinical trials that we conduct post approval.

We are required to maintain and renew various approvals, licenses, permits and certificates from relevant authorities to operate our business pursuant to relevant laws and regulations. Any failure to maintain or renew any approvals, licenses, permits and certificates necessary for our operations may result in enforcement actions thereunder, including orders issued by the relevant regulatory authorities to take remedial actions, suspend our operations or bear fines and penalties which could materially and adversely affect our business, financial condition and results of operations. Furthermore, if the interpretation or implementation of existing laws and regulations changes or new regulations come into effect, we may be required to obtain any additional approvals, permits, licenses or certificates and there can be no assurance that we will be able to do so. Our failure to obtain the additional approvals, permits, licenses or certificates may restrict the conduct of our business, increase our costs, and in turn, adversely affect our results of operations and prospects.

In addition, after a drug is approved by the NMPA, FDA or a comparable regulatory authority for marketing, there may be a subsequent discovery of problems with respect to our drug products which have not been identified previously, including problems with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements. Such problems may result in, among others:

- restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market, or voluntary or mandatory drug recalls;

- fines, warning letters or holds on our clinical trials;



Shanghai Miracogen Inc.- Ex. 2032, Page 000095

- refusal by the NMPA, FDA or comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us;
- suspension or revocation of existing drug license approvals;
- refusal by the NMPA, FDA or comparable regulatory authorities to accept any of our other IND approvals or BLAs;
- drug seizure or detention, or refusal to permit the import or export of drugs; and
- injunctions or the imposition of civil, administrative or criminal penalties.

The NMPA, FDA and comparable regulatory authorities strictly regulate the marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for their approved indications and for use in accordance with the provisions of the approved label. The NMPA, FDA and other comparable regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. If we are not able to maintain regulatory compliance, we may lose the regulatory approvals that we have already obtained and may not achieve or sustain profitability, which in turn could have a material adverse effect on our business, financial condition, results of operations and prospects.

***We are subject to stringent privacy laws, information security policies and contractual obligations related to data privacy and security, and we may be exposed to risks relating to our management of the medical data of patients enrolled in our clinical trials and other personal or sensitive information.***

We routinely receive, collect, generate, store, process, transmit and maintain medical data treatment records and other personal details of patients enrolled in our clinical trials, along with other personal or sensitive information. As such, we are subject to the relevant local, national and international data protection and privacy laws, directives regulations and standards that apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data in the various jurisdictions in which we operate and conduct our clinical trials, as well as contractual obligations. These data protection and privacy law regimes continue to evolve and may result in strengthened public scrutiny, elevated levels of enforcement and sanctions and increased costs of compliance. Compliance with applicable laws, regulations, standards and obligations relating to data privacy, security and transfers may cause us to incur substantial operational costs or require us to change our data processing processes. Noncompliance with such laws or regulations could result in enforcement action against us, including fines, imprisonment of our management personnel, public censure, claims for damages by customers and other 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.


Shanghai Miracogen Inc.- Ex. 2032, Page 000096

Such data protection and privacy laws and regulations generally require clinical trial sponsors and operators and their respective personnel to protect the privacy of their enrolled patients and prohibit unauthorized disclosure of personal information. If such institutions or personnel divulge patients' private or medical records without their consent, they will be held liable for damage caused thereby. We have taken measures to maintain the confidentiality of the medical records and personal data we collect on patients enrolled in our clinical trials. However, such measures may not be always effective. For example, our information technology systems could be breached through hacking activities, and personal information could be leaked due to theft or misuse of personal information arising from misconduct or negligence. In addition, our clinical trials frequently involve professionals from third-party institutions who are working on-site with our staff and enrolled patients. There can be no assurance that such persons will always comply with our data privacy measures. Furthermore, any change in such laws and regulations could affect our ability to use medical data and subject us to liability for the use of such data, which would be otherwise permissible prior to the new legislation becoming effective. Any failure to protect patients' medical records and personal data could have a material adverse effect on our business, financial condition and results of operations.

We may not be able to quickly or effectively respond to regulatory, legislative and other developments, and these changes may in turn impair our ability to offer our existing or planned drug candidates or increase our operational costs. In addition, if our practices are not consistent, or deemed as not consistent, with legal and regulatory requirements, we may become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, loss of export privileges and severe criminal or civil sanctions. Any of the foregoing events could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

***We may be directly or indirectly subject to applicable anti-kickback, false claims laws, doctor payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in the PRC, the U.S. and other jurisdictions, which could, in the event of noncompliance, expose us to administrative sanctions, criminal sanctions, civil penalties, contractual damages, reputational damage and diminished profits and future earnings.***

Healthcare providers, doctors and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. If we obtain the NMPA or the FDA approvals for any of our drug candidates and begin commercializing those drugs in the PRC or in the U.S., our operations may be subject to various PRC and U.S. federal and state fraud and abuse laws, including the PRC Anti-Unfair Competition Law (反不當競爭法), PRC Criminal Law (刑法), the Federal Anti-Kickback Statute and the Federal False Claims Act, and doctor payment transparency laws and regulations which primarily include the Affordable Care Act (《平價醫療法案》) and the Physician Payments Sunshine Act (《醫師酬勞陽光法案》). These laws may impact, among others, our proposed sales, marketing and education programs.


Shanghai Miracogen Inc.- Ex. 2032, Page 000097

In addition, we are subject to similar healthcare laws in other jurisdictions, some of which may be broader in scope than others and may apply to healthcare services reimbursed by any source, which may include not only governmental payers, but also private insurers. There are ambiguities as to what is required to comply with any of these requirements, and if we fail to comply with any such requirement, we could be subject to penalties.

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines, exclusion or suspension from federal and state healthcare programs and being debarred from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the Federal False Claims Act as well as under the false claims laws of several states.

Neither the PRC government nor the PRC courts have provided definitive guidance on the applicability of fraud and abuse laws to our business. Law enforcement authorities are increasingly focusing on enforcing these laws, and some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties are in compliance with applicable healthcare laws and regulations will involve substantial costs. Regulatory authorities could conclude that our business practices may not comply with current or future fraud, abuse or other healthcare laws or regulations. If any such actions are instituted against us, and if we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in governmental healthcare programs, contractual damages, reputational damage, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and have a material adverse effect on our business and results of operations.

***We are subject to registration, review and other requirements of the regulatory authorities for cross-border sales or licensing of technology as well as operations related to genetics and data safety.***

China imposes controls on the import and export of technology and software products. Under the Regulations on Administration of Imports and Exports of Technologies (技術進出口管理條例) promulgated by the State Council, which were amended in November 2020, technology import and export is defined to include, among others, the transfer or licensing of patents and know-how, and the provision of services related to technology. Depending on the nature of the relevant technology, the import and export of technology require either approvals by or registration with the relevant PRC governmental authorities. The Measures for the Administration of Registration of Technology Import and Export Contracts (技術進出口合同登記管理辦法), issued by the MOFCOM in February 2009, specify registration requirements related to the import and export of technology.

We have entered into and may enter into agreements with CROs in the U.S. and Europe for their technical support to assist us with the development of individual drug candidates, which may be deemed to constitute the import of technology under the regulations. As a result,


Shanghai Miracogen Inc.- Ex. 2032, Page 000098

such transfers are required to be registered with applicable PRC governmental authorities. Although there are no explicit penalties set forth in these regulations for lack of such registration, failure to register an agreement where such registration is required may result in restrictions concerning foreign exchange, banking and taxation matters relating to such agreements. We have not registered our technology transfer agreements, and so far have not encountered any problems with respect to foreign exchange, banking or taxation matters relating to our technology transfer agreements, nor have we received any notice from any governmental authority requiring us to complete registration of the technology transfer agreements. We are also subject to regulatory supervision over genetics and data-related operations. To carry out clinical trials, as a foreign-invested enterprise, we are required to obtain approval from the Office of Human Genetic Resources Management under the Ministry of Science and Technology (科學技術部人類遺傳資源管理辦公室) who will conduct genetics and data safety review. There can be no assurance that we will be able to obtain such approval in a timely manner, or at all. In addition, we may also be subject to similar requirements of overseas regulatory authorities.

## RISKS RELATING TO MANUFACTURING OF OUR DRUG CANDIDATES

***We are exposed to various supply chain risks as we depend on a stable, adequate and quality supply of raw materials, technical services, equipment and infrastructure construction services, and any price increases or interruptions of such supply may have a material adverse effect on our business.***

Our business operations are exposed to various supply chain risks. During the Track Record Period, we relied on third parties to supply technical, construction and other services, materials and equipment. We expect to continue to rely on third parties to supply such services, materials and equipment for the research, development, manufacturing and commercialization of our drug candidates. See "Business – Procurement and Supply."

Currently, the services, materials and equipment are supplied by multiple source suppliers. We have agreements for the supply of services, materials and equipment with suppliers that we believe have sufficient capacity to meet our demands. However, if supplies are interrupted, we may not be able to find alternative supplies in a timely and commercially reasonable manner, or at all. Any disruption in production or the inability of our suppliers to produce adequate quantities to meet our needs could impair our operations and the research and development of our drug candidates. Moreover, we require a stable supply of materials for our drug candidates in the course of our research and development activities, and such needs are expected to increase significantly once we enter commercial production of drugs upon receipt of marketing approvals. However, there can be no assurance that current suppliers have the capacity to meet our demand. Any delay in receiving such materials in the quantities and of the quality that we need could delay the completion of our clinical studies, regulatory approvals of our drug candidates or our ability to timely meet market demand for our commercialized


Shanghai Miracogen Inc.- Ex. 2032, Page 000099

products, as applicable. Our suppliers may not be able to cater to our growing demands or may reduce or cease their supply of materials to us at any time. We are also exposed to the possibility of price increases, which we may not be able to pass on to customers and may, in turn, lower our profitability.

Our suppliers may also fail to maintain adequate quality of the services, materials and equipment we need. Although we implement quality inspection on the materials, there can be no assurance that we will be able to identify all of the quality issues. Suboptimal or even deficient supplies of services, materials and equipment may hinder the research and development of our drug candidates, subject us to product liability claims or otherwise have a material adverse effect on our operations.

In addition, there can be no assurance that these third parties will be able to maintain and renew all licenses, permits and approvals necessary for their operations or comply with all applicable laws and regulations. Failure to do so by them may lead to interruption in their business operations, which, in turn, may result in shortage of the services, materials and equipment supplied to us, and cause delays in clinical trials and regulatory filings, or the recall of our products. The noncompliance of these third parties may also subject us to potential product liability claims, cause us to fail to comply with the continuing regulatory requirements, and incur significant costs to rectify such incidents of noncompliance, which may have a material and adverse effect on our business, financial condition and results of operation.

***If we are unable to meet the increasing demand for our existing drug candidates and future drug products by ensuring that we have adequate manufacturing capacity, or if we are unable to successfully manage our anticipated growth or to precisely anticipate market demand, our business and financial condition would be materially and adversely affected.***

Manufacturers of biological drug products often encounter difficulties in production, particularly in scaling up or out, validating the production process and assuring the high reliability of the manufacturing process. If our manufacturing facilities encounter unanticipated delays and expenses as a result of any of these difficulties, or if construction, regulatory evaluation and/or approvals of our new manufacturing facilities are delayed, we may not be able to manufacture sufficient quantities of our drug candidates, which would limit our development and commercialization activities.

In anticipation of the commercialization of our drug candidates and market demand of our drug candidates, if approved, we aim to significantly expand our manufacturing capacity. However, the timing and success of our capacity expansion are subject to significant uncertainty. Moreover, such plans are capital-intensive considerable upfront investment and regulatory approvals, and there can be no assurance that we will be able to timely obtain such financing, if at all.


Shanghai Miracogen Inc.- Ex. 2032, Page 000100

Given the size of our new manufacturing facilities, we may not be able to fully utilize them immediately or within a reasonable period of time after we commence operation. During the construction and ramp-up period, there may be significant changes in the biopharmaceutical industry, including, among others, market demand, product and supply pricing, and customer preferences. Any adverse trends in these respects could result in operational inefficiency and excess capacity in our manufacturing facilities. We may also experience various unfavorable events in the course of developing our new manufacturing facilities, such as:

- unforeseen delays due to construction, land use rights or regulatory issues, which could result in loss of business opportunities;

- construction cost overruns, which may require diverting resources and management's attention from other projects; and

- difficulty in finding sufficient numbers of trained and qualified staff.

The success of our business expansion also depends on our ability to advance drug candidates through the development, regulatory approval and commercialization stages. Any delay, suspension or termination in such respects would harm our ability to generate satisfactory returns on our investment in manufacturing expansion, if at all, which in turn could have a material adverse effect on our business, financial condition, results of operations and prospects.

***We have no experience in manufacturing therapeutic biologics on a large commercial scale and our business could be materially and adversely affected if we encounter problems in manufacturing our future drug products.***

As of the Latest Practicable Date, all of our products were in the research and development stage, and we mainly produce drugs that are used for clinical trials. See "Business – Manufacturing and Quality Control – Our Manufacturing Facilities." We have limited experience in managing the manufacturing process. The manufacture of biopharmaceutical products is complex, in part due to strict regulatory requirements. If we are unable to identify an appropriate production site or a suitable partner to develop the manufacturing infrastructure, or fail to do so in a timely manner, it may lead to significant delays in the manufacturing of our drug candidates after we have obtained regulatory and marketing approvals. Investments in constructing or leasing new biologics manufacturing facilities which are in compliance with GMP regulations may result in significant cost for us and in turn would have a material adverse effect on our commercialization plans. We may also fail to attract and retain personnel with the requisite skills and experience for drug manufacturing.

In addition, problems may arise during the manufacturing process for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials, delays in the construction of new manufacturing facilities or expansion of any future manufacturing facilities, changes in manufacturing production sites or


Shanghai Miracogen Inc.- Ex. 2032, Page 000101

limits to manufacturing capacity due to regulatory requirements, changes in the types of products produced, physical limitations that could inhibit continuous supply, and the occurrence of natural disasters. If problems arise during the production process of certain future products, a batch or even several related batches of such product may have to be discarded and cause production delays, cost increases, lost revenue and damage to customer relationships and our reputation. If problems have not been discovered before the relevant products are released to the market, we may incur additional costs in connection with product recalls and product liability.

***Changes in U.S. and international trade policies, particularly with regard to China, may cause significant disruptions to our drug candidate manufacturing and other operations.***

The U.S. government has made statements and taken certain actions that may lead to potential changes to U.S. and international trade policies towards China. In January 2020, the "Phase One" agreement was signed between the U.S. and China on trade matters and went into effect on February 14, 2020, under which China agreed to expand purchases of certain U.S. goods and services by a combined US$200 billion over 2020 and 2021 from 2017 levels. However, it remains unclear what additional actions, if any, will be taken by the U.S. or other governments with respect to international trade agreements, the imposition of tariffs on goods imported into the U.S., tax policy related to international commerce, or other trade matters. It is unknown whether new tariffs or 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 import or export of raw materials and directly disrupt our drug development and the manufacture of our drug candidates. Such unfavorable policies may also negatively impact the hiring of scientists and other research and development personnel, the demand for our drug products or the competitive position of our drug products, or prevent us from selling our drug products in certain countries. If any new tariffs, policies, 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 recent U.S.-China trade tensions, such changes could have an adverse effect on our business, financial condition, results of operations and prospects.

## RISKS RELATING TO COMMERCIALIZATION OF OUR DRUG CANDIDATES

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

Even if our drug candidates receive regulatory approvals, they may nonetheless fail to achieve satisfactory market acceptance by doctors, patients, third-party payers, hospitals or others in the medical community. Doctors and patients may prefer other drugs or drug candidates to ours. If our drug candidates do not achieve an adequate level of acceptance, the commercialization of such drug candidates may become less successful or profitable than we had expected.



Shanghai Miracogen Inc.- Ex. 2032, Page 000102

The degree of market acceptance of our drug candidates, if and when they are approved for commercial sale, will depend on a number of factors, such as:

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

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


Shanghai Miracogen Inc.- Ex. 2032, Page 000103

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

The biopharmaceutical industry in which we operate is highly competitive and rapidly changing. While our principal focus is to develop drug candidates with the potential to become novel or highly differentiated drugs, we face competition with respect to our current drug candidates and will face competition with respect to any drug candidates that we may seek to develop or commercialize in the future. Large multinational pharmaceutical companies, well-established biopharmaceutical companies, specialty pharmaceutical companies, universities and other research institutions have commercialized, are in the process of commercialization, or are pursuing the development of drugs for the treatment of cancers or other indications for which we are developing our drug candidates. For example, in recent years an increasing number of biotechnology companies have joined the competition in the research and development of PD-1/PD-L1 mAb, with large pharmaceutical companies leading the competition and small biotechnology companies making frequent breakthroughs. Some of these competitive drugs and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. See "Business – Our Drug Candidates." Potential competitors further include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Even if successfully developed and subsequently approved by the NMPA, the FDA or other comparable regulatory authorities, our drug candidates may still face competition in various aspects, including safety and efficacy, the timing and scope of the regulatory approvals, the availability and cost of supply, sales and marketing capabilities, price and patent status. Many of our competitors have substantially greater financial, technical and other resources, such as more advanced commercial infrastructure, more drug candidates in late-stage clinical development, more seasoned research and development staff and well-established marketing and manufacturing teams than us. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Additional mergers and acquisitions in the biopharmaceutical industry may result in even more resources being concentrated in our competitors. Our competitors may succeed in developing competing drugs and obtaining regulatory approvals before us or achieve better acceptance in the markets in which we operate or have established a competitive position. For example, the NMPA has recently accelerated marketing approvals of drugs for diseases with high medical needs and the NMPA may review and approve drugs that have gained regulatory marketing approvals in the U.S., the EU or Japan in the past ten years without requiring further clinical trials in the PRC. This may lead to potential increased competition from drugs that have already obtained approvals in other jurisdictions.



Shanghai Miracogen Inc.- Ex. 2032, Page 000104

Competition may further intensify as a result of advances in the commercial applicability of technologies and availability of capital for investment in the industry. Our competitors may succeed in developing, acquiring, or licensing on an exclusive basis, products that are more effective with a lower cost than our drug candidates, or achieve earlier patent protection, regulatory approvals, product commercialization and market penetration than we do. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability or safety in order to overcome price competition and to be commercially successful. Furthermore, disruptive technologies and medical breakthroughs may further intensify the competition and render our drug candidates obsolete or noncompetitive. Technologies developed by our competitors may render our potential drug candidates uneconomical or obsolete, and we may not be successful in marketing our drug candidates against competitors.

***We have limited experience in launching and marketing drug candidates. If we are unable to effectively build and manage our sales network or benefit from the sales networks of third-party collaborators, we may be unable to generate any revenue.***

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

If we are unable or decide not to establish internal sales, marketing and commercial distribution capabilities, we will likely pursue collaborative arrangements with third parties regarding the sales and marketing of our drugs. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or, if we are able to do so, that such arrangements will provide sufficient and effective sales support. Any revenue we receive will depend on the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our drug candidates ourselves. We will also face competition in the search for third parties to assist us with the sales and marketing efforts of our drug candidates.

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


Shanghai Miracogen Inc.- Ex. 2032, Page 000105

***Even if we are able to commercialize any approved drug candidates, reimbursement may be limited or not immediately available in the PRC or other countries for our drug candidates, and we may be subject to unfavorable pricing regulations, which may affect our profitability.***

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. Some countries require approvals of the sale price of a drug before marketing. In many countries, the pricing review period commences after marketing or licensing approvals are granted. In some markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approvals are granted. As a result, we might obtain regulatory approvals for a drug in a particular country, but then be subject to price regulations that delay our commercial launch of the drug and negatively impact the revenues we are able to generate from the sale of the drug in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if our drug candidates obtain regulatory approvals.

The successful commercialization of our drugs also depends on the extent to which reimbursement for these drugs and related treatments will be available from relevant health administrative authorities, private health insurers and other organizations. Government authorities and third-party payers, such as private health insurers and healthcare organizations, decide which medications they will pay for and stipulate reimbursement levels. With the trend of cost containment in the global healthcare industry, government authorities and third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. There are an increasing number of third-party payers requiring companies to provide them with predetermined discounts from list prices and challenging the prices charged for medical products. There can be no assurance as to whether or to what extent reimbursement will be available for any drug we commercialize. Reimbursement may impact the demand for, or the price of, any drug for which we obtain regulatory approvals. Obtaining reimbursement for our drugs may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a doctor. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidate that we have developed.

There may be significant delays in obtaining reimbursement for approved drug candidates, and coverage may be more limited than the indications and purposes for which the drug candidates are approved by the NMPA, the FDA or other comparable regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may be subject to change. Payment rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for drugs with lower cost that have been covered in reimbursement policies, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by governmental healthcare programs or private payers and by any future lift or relaxation of laws and regulations that presently restrict imports of drugs from countries where they may be sold at lower prices than in the jurisdictions in



Shanghai Miracogen Inc.- Ex. 2032, Page 000106

which we operate or have a presence. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payers for any future approved drug candidates and any new drugs that we develop could have a material adverse effect on our business, financial condition, results of operations and prospects.

***If safety, efficacy, or other issues arise with any medical product that is used in combination with our drug candidates, we may be unable to market such drug candidate or may experience significant regulatory delays or supply shortages, which could have a material adverse effect on our business.***

We plan to develop certain of our drug candidates for use as combination therapies. Combination therapy development carries a higher risk of failure compared to single agent development due to greater risk of combined drug toxicity as well as lower efficacy due to drug-drug interactions as well as toxicity limitations on efficacy. The development risks of failure are even higher if both agents are investigational. There are additional regulatory requirements for combination development to ensure patient safety during development, including the requirement for separate combination IND review and the trial designs which are also more complex and require close monitoring. If the NMPA, the FDA or another comparable regulatory agency revokes its approval of any therapy we use in combination with our drug candidates, we will not be able to market our drug candidates in combination. If safety or efficacy issues arise with these or other therapies that we seek to combine with our drug candidates in the future, we may experience significant regulatory delays, and we may be required to redesign or terminate the relevant clinical trials. In addition, if manufacturing or other issues result in a supply shortage of any component of our combination drug candidates, we may not be able to complete clinical development of our drug candidates on our current timeline, or at all.

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

Our drug candidates may be administered in combination with drugs of other pharmaceutical companies as one regimen. We may also use third-party drugs in our development and clinical trials as controls for our studies. As a result, both the results of our clinical trials and the sales of our drugs may be affected by the availability of these third-party drugs. We generally have no influence over the availability and pricing of such drugs. If other pharmaceutical companies discontinue these combination drugs, or if these drugs become prohibitively expensive, regimens that use these combination drugs may no longer be prescribed, and we may not be able to introduce or find an alternative drug to be used in combination with our drugs in a timely manner and on commercially reasonable terms, or at all. As a result, demand for our drugs may be lowered, which would in turn materially and adversely affect our business, financial condition, results of operations and prospects.



Shanghai Miracogen Inc.- Ex. 2032, Page 000107

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

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

Certain drug products distributed or sold may be manufactured without proper licenses or approvals or be fraudulently mislabeled with respect to their contents or manufacturers. These products are generally referred to as counterfeit pharmaceutical products. Relevant governmental authorities may be unable to timely prevent counterfeit pharmaceutical products imitating our products. As counterfeit pharmaceutical products in many cases resemble the authentic pharmaceutical products, yet are generally sold at lower prices, any counterfeiting of our products could reduce the demand for our future approved drug candidates.

Counterfeit pharmaceutical products are unlikely to meet our or our collaborators' rigorous manufacturing and testing standards, and may even cause health damage to patients. Our reputation and business could suffer harm as a result of counterfeit pharmaceutical products.

## RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

***We have incurred net losses during the Track Record Period and anticipate that we will continue to incur net losses for the foreseeable future.***

Investment in the development of biopharmaceutical products is highly speculative as it requires substantial upfront capital expenditures and involves significant risks that a drug candidate may fail to demonstrate efficacy or safety to gain regulatory or marketing approvals or become commercially viable. During the Track Record Period, we had financed our operating activities primarily through capital contributions from our shareholders, private



Shanghai Miracogen Inc.- Ex. 2032, Page 000108

equity financing and bank borrowings. While we have other sources of income including government grants, investment income on financial assets and rental income, we had not generated any revenue from commercialization of our drug products during the Track Record Period, and had incurred, and will continue to incur, significant research and development expenses and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred net losses in each period since our inception. In 2019, 2020 and the eight months ended August 31, 2021, our operating losses were RMB454.7 million, RMB520.4 million and RMB662.2 million, respectively. Substantially all of our net losses resulted from costs incurred in connection with our research and development expenses and administrative expenses, as well as fair value changes on financial assets and liabilities through profit or loss.

We expect to continue to incur net losses for the foreseeable future, and also expect that these operating losses will increase as we may carry out certain activities relating to our development, including the following:

- conducting pre-clinical and clinical trials of our drug candidates;
- manufacturing clinical trial materials through CMOs and CDMOs in and outside China;
- seeking regulatory approvals for our drug candidates;
- commercializing our drug candidates for which we have obtained marketing approvals;
- hiring additional clinical, operational, financial, quality control and scientific personnel;
- establishing a commercialization team for any future drug products that have obtained regulatory approvals;
- seeking to identify additional drug candidates;
- obtaining, maintaining, expanding and protecting our intellectual property portfolio;
- enforcing and defending any intellectual property-related claims; and
- acquiring or in-licensing other drug candidates, intellectual property and technologies.

Typically, it takes many years to develop one new drug from the time of its discovery to the time when it becomes available for treating patients. During the process, we may encounter unforeseen expenses, difficulties, complications, delays and other unknown events that may have an adverse effect on our business, financial condition and results of operations. The size



Shanghai Miracogen Inc.- Ex. 2032, Page 000109

of our future operating losses will depend partially on the rate of the future growth of our expenses, our ability to generate revenues and the timing and amount of milestone payments and other payments that we receive from, or pay to, third parties. If any of our drug candidates fails during clinical trials or does not obtain regulatory approval, or, even if approved, fails to achieve market acceptance, our business may not become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods thereafter. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our working capital and shareholders' equity.

***We have incurred and expect to continue to incur significant share-based payments in connection with equity grants to our key management, directors and employees.***

Our share-based payments include: (i) share-based payment expenses related to Controlling Shareholder Loans, representing the difference between the issuance price of Controlling Shareholder Loans and the fair value of equity on its issuance date; and (ii) share-based payment expenses under our ESOP launched on December 7, 2020. See "Financial Information – Critical Accounting Policies – Share-based Payments."

To incentivize and maintain our key management, directors and employees, we have granted and expect to continue to grant employee share ownership plans in the form of restricted shares. On December 7, 2020, 151 eligible employees were granted shares of the Company pursuant to the Employee Share Ownership Plan. Subsequently in April 2021, as a reward for certain senior management members' service, we have entered into supplemental agreements with certain senior management members. The granting of such plan would increase our share-based payment expenses and thus may adversely affect our financial performance. In 2019, 2020 and the eight months ended August 31, 2021, we had share-based payment expenses of RMB143.7 million, RMB5.2 million and RMB85.8 million, respectively. See Note 27 of Appendix I to this prospectus.

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

During the Track Record Period, our operations have consumed a substantial amount of cash. Net cash used in operating activities was RMB234.0 million, RMB422.7 million and RMB418.3 million for 2019, 2020 and the eight months ended August 31, 2021, respectively.

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



Shanghai Miracogen Inc.- Ex. 2032, Page 000110

In addition, if we obtain regulatory approvals for any of our drug candidates, we expect to incur significant commercialization expenses relating to product manufacturing, marketing, sales and distribution and post-approval commitments to continue monitoring the efficacy and safety data of our future products on the market. We may also incur expenses as we create additional infrastructure to support our operations as a public company.

We currently have no drug approved for commercial sale and have not generated any revenue from drug sales. We have incurred operating losses in each year since inception. We expect that we may continue to experience net cash outflows from our operating activities for the foreseeable future. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations through public or private equity offerings, debt financing or other sources. Adequate additional funding may not be available to us on commercially reasonable terms, or at all. If we are unable to raise sufficient capital in a timely manner or on commercially reasonable terms, we could be forced to delay, reduce or terminate our research and development projects or any future commercialization efforts, which could have a material adverse effect on our business, financial condition and results of operations.

***We recorded net liabilities and net current liabilities as of December 31, 2019.***

We recorded net liabilities of RMB185.6 million as of December 31, 2019. Our net liabilities position as of December 31, 2019 was primarily because we had financial instruments with preferred rights at amortized cost of RMB397.5 million, convertible loans of RMB380.6 million, other payables and accruals of RMB378.3 million and financial liabilities at fair value through profit or loss of RMB279.1 million.

In addition, we recorded net current liabilities of RMB994.1 million as of December 31, 2019. The major components of our current liabilities during the Track Record Period were other payables and accruals representing primarily payables for acquisitions. A net current liabilities position can expose us to the risk of shortfalls in liquidity. This in turn would require us to seek adequate financing from sources such as external debt, which may not be available on commercially reasonable terms, or at all. If we are unable to maintain adequate working capital or obtain sufficient equity or debt financing to meet our capital needs, we may be unable to continue our operations according to our plans and be forced to scale back our operations, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

***We have indebtedness and may incur additional indebtedness in the future, which may materially and adversely affect our financial condition and results of operations.***

We maintained certain borrowings to finance our operations during the Track Record Period. We had bank borrowings of RMB118.3 million as of December 31, 2019, RMB147.3 million as of December 31, 2020, RMB198.1 million as of August 31, 2021 and RMB292.9 million as of December 31, 2021, being the indebtedness date for the purpose of the indebtedness statement. See "Financial Information – Indebtedness – Borrowings." We may incur additional indebtedness in the future, and may not be able to generate sufficient cash to satisfy our existing and future debt obligations.



Shanghai Miracogen Inc.- Ex. 2032, Page 000111

Our indebtedness could have a material adverse effect on us by, among others, increasing our vulnerability to adverse developments in general economic or industry conditions, such as significant increases in interest rates, and limiting our flexibility in making changes in our business and operations. Our borrowings may subject us to certain restrictive covenants which may restrict or otherwise adversely affect our operations. These covenants may restrict our ability to, among others, incur additional debt, provide loans or guarantees, provide security and quasi-security, incur liens, dispose of material assets through sale, lease or other methods, pay dividends or distributions on certain of our subsidiaries' capital stock, repay or transfer certain indebtedness, reduce registered capital, make investments and acquisitions, establish joint ventures, conduct mergers, consolidation and other change-of-control transactions, and file for bankruptcy or dissolution. In addition, some of the loans may have restrictive covenants linked to our financial performance, such as maintaining a prescribed maximum debt-to-asset ratio or minimum profitability levels during the term of the loans.

Moreover, our borrowings were secured against certain of our land use right and construction-in-progress. See Note 28 of Appendix I to this prospectus and "Financial Information – Indebtedness – Borrowings." In the event that we default on payment obligations of the secured indebtedness or are unable to comply with the restrictions and covenants imposed by the loan agreements in our future debt obligations, banks could terminate their commitments to us, accelerate the payments and declare all amounts borrowed due and payable, enforce the security or terminate the loan agreements. If any of the foregoing events occurs, there can be no assurance that our assets and cash flow will be sufficient to repay all of our debts as they become due, or that we will be able to obtain alternative financing on commercially reasonable terms. Furthermore, if the banks enforce any security over our assets, our business, financial condition, results of operations and prospects would be materially and adversely affected.

***We have significant amount of intangible assets. Amortisation or potential impairment of goodwill may adversely affect our results of operations and financial condition.***

Our intangible assets primarily represent goodwill and intellectual properties. Our intangible assets remained relatively stable, being RMB517.3 million as of December 31, 2019 and RMB497.9 million as of December 31, 2020 and RMB479.7 million as of August 31, 2021. Intangible assets that have an indefinite useful life such as goodwill are not subject to amortisation and are tested annually for impairment, or more frequently if events or changes in circumstances indicate that they might be impaired. As of August 31, 2021, our goodwill amounted to RMB52.6 million, primarily due to our acquisition of Miracogen Shanghai in 2018. We have conducted impairment reviews on our goodwill as of December 31, 2019 and 2020, and no impairment was made as of such dates. We may recognize goodwill impairment in the future, as required under further similar reviews. Goodwill arising from acquisitions represents the excess of the sum of the consideration transferred, the amount of any non-controlling interest in the acquiree and the acquisition date fair value of the acquirer's previously held equity interest in the acquiree, if any, over the net amount of the identifiable assets acquired and the liabilities assumed at acquisition date. Goodwill impairment reviews are undertaken annually, or more frequently if events or changes in circumstances indicate a


Shanghai Miracogen Inc.- Ex. 2032, Page 000112

potential impairment. Determining whether goodwill is impaired requires us to estimate the recoverable amounts of the cash-generating unit to which we have allocated goodwill, which is the higher of fair value less costs of disposal and value in use. This recoverable amount calculation requires us to estimate the future cash flows expected to arise from the cash-generating unit and a suitable discount rate to calculate the present value. Where the book value of the cash-generating unit exceeds its recoverable amounts, an impairment loss may arise. See Note 16 to the Accountant's Report in Appendix I to this prospectus.

Other assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognised for the amount by which the asset's carrying amount exceeds its recoverable amount. Any failure to generate business performance or financial results commensurate with our intangible assets estimates may adversely affect the recoverability of such intangible assets, and, in turn, result in impairment losses. There are inherent uncertainties related to the assessment of the recoverability of relevant intangible assets. In making such assessment, we rely on certain key assumptions including industry and market conditions which are beyond our control. See Notes 2, 4 and 16 to the Accountant's Report in Appendix I to this prospectus. While we did not recognize impairment loss for intangible assets during the Track Record Period, there can be no assurance that there will be no such charges in the future. In addition, certain of our intangible assets are with a definite useful life and hence subject to amortization. As we carry a substantial balance of intangible assets, any significant impairment losses on, or amortization of, our intangible assets could have a material adverse effect on our business, financial condition and results of operations.

***Potential acquisition or strategic partnership in which we engage in may entail various risks.***

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail various risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of additional equity securities and hence the dilution of our existing shareholders;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel, or failure to otherwise achieve intended synergies in the combined operations;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;


Shanghai Miracogen Inc.- Ex. 2032, Page 000113

- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;

- risks and uncertainties associated with the assimilation of operations, corporate culture and personnel of the acquired business;

- risks associated with the acquisition of intangible assets which are subject to amortization and impairment assessment;

- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and its existing drugs or drug candidates and regulatory approvals;

- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs; and

- changes in accounting principles relating to the recognition and measurement of our investments that may have a significant impact on our financial results.

Moreover, we may not be able to locate suitable opportunities for acquisition and strategic partnerships, which may limit our ability to grow or obtain access to technology or products that may be important to the development of our business.

***The results of our equity investment in associates are subject to uncertainties, and we may be subject to liquidity risk associated therewith.***

We have equity investment in four associates, Wuhan Binhui, Hangzhou HealSun, Hangzhou Xiyuan Biotechnology Co., Ltd. and KYM. We incurred share of the loss of investments accounted for using the equity method of RMB8.7 million in 2019 and RMB12.1 million in 2020, and share of the profit of investments accounted for using the equity method of RMB6.3 million in the eight months ended August 31, 2021, representing our loss or profit of investments in associates. See "Financial Information – Description of Major Components of Our Results of Operations – Share of Loss of Investments Accounted for Using the Equity Method" and Note 17 to the Accountant's Report in Appendix I to this prospectus. The performance of such associates are subject to the soundness of their business management and market conditions, among others, which are beyond our control. We may therefore continue to record share of the losses from such investments and be subject to liquidity risk if such associates are not profitable, which may adversely affect our financial condition.

In addition, our investment in associates is subject to liquidity risk. Our investments in associates are not as liquid as other investment products as there is no cash flow until dividends are received even if our associates reported profits under the equity accounting. Furthermore, our ability to promptly sell one or more of our interests in the associates in response to changing economic, financial and investment conditions is limited. The market is affected by


Shanghai Miracogen Inc.- Ex. 2032, Page 000114

various factors, such as general economic conditions, availability of financing, interest rates and supply and demand, many of which are beyond our control. We cannot predict whether we will be able to sell any of our interests in the associates for the price or on the terms set by us, or whether any price or other terms offered by a prospective purchaser would be acceptable to us. We also cannot predict the length of time needed to find a purchaser and to complete the relevant transaction. Therefore, the illiquid nature of our investment in associates may significantly limit our ability to respond to adverse changes in the performance of our associates.

***Fair value changes on financial assets are subject to uncertainties and may affect our financial position and results of operations.***

Fair value estimation is made based on certain judgments, estimates and assumptions which are subject to various inherent uncertainties. The fair value change on financial assets may significantly affect our financial position and results of operations. Our financial assets at fair value through profit or loss represents our structured deposits. We did not have financial assets at fair value through profit or loss as of December 31, 2019, while we had financial assets at fair value through profit or loss of RMB330.7 million as of December 31, 2020, all representing our structured deposits. Our financial assets at fair value through profit or loss decreased by 59.9% from RMB330.7 million as of December 31, 2020 to RMB132.7 million as of August 31, 2021, primarily due to the redemption of structured deposits at maturity in the eight months ended August 31, 2021. See "Financial Information – Discussion of Certain Key Balance Sheet Items – Current Assets and Liabilities – Financial Assets at Fair Value through Profit or Loss."

Factors beyond our control can significantly influence and cause adverse changes to the estimates we use and thereby affect the fair value of such assets. These factors include, but are not limited to, general economic conditions, changes in market interest rates and the stability of the capital markets. Any of these factors, as well as others, could cause our estimates to vary from actual results. In addition, when determining whether an impairment of a financial asset is other than temporary, the process usually requires complex and subjective judgments. All of these could materially and adversely affect our financial condition and results of operations.

***Fair value changes on financial liabilities are subject to uncertainties and may affect our financial position and results of operations.***

During the Track Record Period, we had net fair value losses on financial liabilities through profit or loss of RMB38.3 million in 2019 and RMB78.6 million in 2020 and RMB48.2 million in the eight months ended August 31, 2021, due to the increases in the valuation of our variable consideration payable for our acquisition of 40% equity interests of Taizhou Hanzhong from the non-controlling shareholder and the convertible loans we issued. See Notes 31 and 34 of Appendix I to this prospectus.



Shanghai Miracogen Inc.- Ex. 2032, Page 000115

We evaluate the fair value of the variable consideration periodically using the discounted cash flow method under which key assumptions like the compound net revenue growth rate and the pre-tax discount rate were adopted to determine the fair value of the variable consideration. The convertible loans issued by us exhibit the characteristics of an embedded derivative, and we have designated the entire instruments as a financial liability at fair value through profit or loss. The fair value of the convertible loans in which no quoted prices in an active market exist is established by using valuation techniques such as back-solve method and discounted cash flow method. Key assumptions, such as the discount rate, were based on our management's best estimates. Management's estimates and assumptions are reviewed periodically and adjusted if necessary. However, such estimates and assumptions may not be accurate and may be subject to changes. Such changes in the fair value will be recognized in the statements of comprehensive loss, which may lead to fluctuations of our financial performance and may adversely affect our financial position and results of operations. See Note 4.3 of Appendix I to this prospectus.

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

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

***We have a limited operating history and have limited experience in manufacturing and sales and marketing of drugs, which may make it difficult to evaluate our current business and predict our future performance.***

We are a development-stage biopharmaceutical company with a relatively short operating history. Our operations to date have focused on the pre-clinical studies and clinical trials of drug candidates in the therapeutic areas of cancers. However, we have not yet successfully advanced any drug candidates from research and development to commercial sale and have not generated any revenue from product sales. We also have limited experience in commercial-scale manufacturing and sales and marketing of drugs. For these reasons, particularly in light of the rapidly evolving biopharmaceutical industry, it may be difficult to evaluate our current business and reliably predict our future performance. We may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. If we do not address these risks and difficulties successfully, our business will suffer.


Shanghai Miracogen Inc.- Ex. 2032, Page 000116

***Fluctuations in exchange rates of the Renminbi could result in foreign currency exchange losses.***

The change in the value of the RMB against the Hong Kong dollar, the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in the PRC's political and economic conditions and China's foreign exchange policies. Substantially all of our costs are denominated in RMB and most of our financial assets are also denominated in RMB. However, our proceeds from the Global Offering will be denominated in Hong Kong dollars. Any significant change in the exchange rates of the Hong Kong dollar against the RMB may materially and adversely affect the value of, and any dividends payable on, our Shares in Hong Kong dollars.

***Our property valuation is based on certain assumptions which, by their nature, are subjective and uncertain and may materially differ from actual results.***

Valuations of our selective property interests as of December 31, 2021 prepared by AVISTA, an independent property valuer, are set forth in the Property Valuation Report set out as Appendix IV to this prospectus. The valuations are made based on assumptions which, by their nature, are subjective and uncertain and may differ from actual results. In addition, unforeseeable changes in general and local economic conditions or other factors beyond our control may affect the value of our properties. As a result, the valuation of our selective property interests may differ materially from the price we could receive in an actual sale of the properties in the market and should not be taken as their actual realizable value or an estimation of their realizable value.

## RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

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

Our commercial success depends, to a certain extent, on our ability to protect our proprietary technology and drug candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights, including patent rights. See "Business – Intellectual Property Rights." We seek to protect the drug candidates and technology that we consider commercially important by filing patent applications in the PRC, the U.S. and other countries or regions, relying on a combination of trade secrets and regulatory protection methods. This process is expensive and time-consuming, and we or our licensors may not be able to file and prosecute all necessary or desirable patent applications in all jurisdictions in a timely manner. It is also possible that we or our licensors will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, we or our licensors may fail to timely identify third-party infringement of our intellectual property rights and take necessary actions to defend and enforce our rights, or at all.



Shanghai Miracogen Inc.- Ex. 2032, Page 000117

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been frequently litigated. The issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not be granted with approvals which effectively prevent third parties from commercializing competitive technologies and biosimilar drug candidates. The patent examination process may require us or our licensors to narrow the scope of the claims of our or our licensors' pending and future patent applications, which may limit the scope of patent protection that could be obtained. There can be no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent application from being granted with a patent.

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

Our competitors may be able to circumvent our patent issuance by developing similar or alternative technologies or drug candidates in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in any jurisdictions. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and drug candidates, or limit the duration of the patent protection of our technology and drug candidates. In addition, certain of our technologies and know-how are not protected with patents or rely on patents that have entered the public domain. See "Business – Research and Development – Antibody Discovery Platform" and "Business – Research and Development – Advanced Process and Analytical Development Platform." We may therefore be unable to prevent competitors from using the same or similar technologies and know-how in their research and development.


Shanghai Miracogen Inc.- Ex. 2032, Page 000118

Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection. For example, after March 2013, under the Leahy-Smith America Invents Act ("Leahy-Smith Act"), the U.S. transitioned to a first-to-file system in which, assuming that the other statutory 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. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases are not published at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

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

Filing and prosecuting patent applications and defending patents covering our drug candidates in all countries across the world could be prohibitively expensive. Competitors may use our and our licensors' technologies in jurisdictions in which we have not obtained patent protection to develop their own drug candidates and may export otherwise infringing drug candidates to territories, including the PRC, where we and our licensors have patent protection, given that the levels of law enforcement vary across jurisdictions. These drug candidates may compete with our drug candidates, and our and our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The laws of some jurisdictions, including the PRC, do not protect intellectual property rights to the same extent as the laws or rules and regulations in the U.S. and Europe, and many companies have encountered significant difficulties in registering, protecting and defending such rights in the relevant jurisdictions, including China. For example, we may not be able to register our exclusive licenses for our in-licensed products in China. While this does not impact our contractual rights under our licensing agreements, we may experience difficulties enforcing our exclusive rights against third parties if our licensors were to breach the licensing agreements and license such parties to use those products in China. Furthermore, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing drug candidates in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and our patent applications at risk of not issuing as patents, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our


Shanghai Miracogen Inc.- Ex. 2032, Page 000119

intellectual property rights in our expected significant markets, there can be no assurance that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may expect to market our drug candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have a material adverse effect on our ability to successfully commercialize our drug candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we are, 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.

***Even if we are able to obtain patent protection for our drug candidates, the term of such protection, if any, is limited, and third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us after the expiration of our patent rights, if any, and it would have a material adverse effect on our ability to successfully commercialize any product or technology.***

Although various adjustments and extensions may be available, the term of a patent, and the protection it affords, is limited. For example, the expiration of a patent is generally 20 years for invention in the PRC and generally 20 years from the earliest date of filing of the first non-provisional patent application to which the patent claims priority in the U.S. The patents for the marketed ADCs in China and the U.S. expired or are expected to expire between 2020 and 2040 and the patents for the marketed products for the PD-1/PD-L1 therapies in China and the U.S. are expected to expire between 2033 and 2038. On the other hand, with respect to our Core Products, for example, for MRG003, the two issued Chinese patents are expected to expire in February 2036 and October 2032, respectively, and the issued U.S. patent is expected to expire in September 2036. For MRG002, the patents that may be issued from the currently pending patent application is expected to expire in June 2038. For HX008, the issued Chinese patents are expected to expire in April 2036 and January 2037, respectively, the issued U.S. patent is expected to expire in January 2037, and the issued Japan patent is expected to expire in October 2036. For LP002, the patents are expected to expire within the period from 2036 to 2037. See "Business – Intellectual Property Rights." Even if we successfully obtain patent protection for an approved drug candidate, it may face competition from generic or biosimilar ADCs or products for PD-1/PD-L1 therapies once the relevant patent has expired. Manufacturers of generic or biosimilar drugs may challenge the scope, validity or enforceability of our patents in court or before a patent office; thus, we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. The issued patents and pending patent applications, if



Shanghai Miracogen Inc.- Ex. 2032, Page 000120

issued, for our drug candidates are expected to expire on various dates. Upon the expiration of our issued patents or patents that may be issued from our pending patent applications, we will not be able to assert such patent rights against potential competitors, which may have an adverse effect on our business, financial condition, results of operations and prospects.

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 owned and licensed patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing events could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

***Our owned and in-licensed patents and other intellectual property may be subject to further priority disputes or to inventorship disputes and similar proceedings. If we or our licensors are unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, or to modify or cease the development, manufacture and commercialization of one or more of the drug candidates we may develop, which could have a material adverse effect on our business, financial condition and results of operations.***

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents or other intellectual property as an inventor or co-inventor. If we or our licensors are unsuccessful in any interference proceedings or other priority or validity disputes (including any patent oppositions) to which we or they are subject, we may lose valuable intellectual property rights through the loss of one or more patents owned or licensed or our owned or licensed patent claims may be narrowed, invalidated, or held unenforceable. In addition, if we or our licensors are unsuccessful in any inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights, such as the exclusive ownership of, or exclusive right to use, our owned or in-licensed patents. If we or our licensors are unsuccessful in any interference proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all or may be nonexclusive. If we are unable to obtain and maintain such licenses, we may need to modify or cease the development, manufacture, and commercialization of one or more of our drug candidates. Any of our licensors may also grant licenses to others in breach of its exclusive license granted to us, enabling others to engage in the development, manufacture and commercialization of competing drug candidates, which may have a material adverse effect on the commercial prospect of our drug candidates. The loss


Shanghai Miracogen Inc.- Ex. 2032, Page 000121

of exclusivity or the narrowing of our owned and licensed patent claims could limit our ability to stop others from using or commercializing similar or identical drug products. Any of the foregoing events could result in a material adverse effect on our business, financial condition, results of operations and prospects. Even if we are successful in an interference proceeding or other similar priority or inventorship disputes, it could result in substantial costs and be a distraction to our management and other employees.

We may also engage third-party contractors, including CROs, to assist us with the research and development of our drug candidates. There can be no assurance that such contractors will not transfer the drug candidates to other third parties without our permission. Such unauthorized transfer may also result in the loss or restriction of our intellectual property rights and therefore limit our ability to develop, manufacture and commercialize the drug candidates.

***Claims that our drug candidates or the sale or use of our future products infringe, misappropriate or otherwise violate the patents or other intellectual property rights of third parties could result in substantial legal costs. Intellectual property litigations may lead to unfavorable publicity which may harm our reputation and cause the market price of our Shares to decline, and any unfavorable outcome of such litigation could limit our research and development activities and/or our ability to commercialize our drug candidates.***

There can be no assurance that our drug candidates or the sale or use of our future products do not and will not in the future infringe, misappropriate or otherwise violate third-party patents or other intellectual property rights. Third parties might allege that we are infringing their patent rights or that we have misappropriated their trade secrets, or that we are otherwise violating their intellectual property rights, whether with respect to the manner in which we have conducted our research, or with respect to the use or manufacture of the compounds we have developed or are developing. Litigations relating to patents and other intellectual property rights in the biopharmaceutical industry are common, including patent infringement lawsuits. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. Some claimants may have substantially greater resources than us and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. Third parties might resort to litigation against us or other parties we have agreed to indemnify, which litigation could be based on either existing intellectual property or intellectual property that arises in the future.

It is also possible that we failed to identify, or may in the future fail to identify, relevant patents or patent applications held by third parties that cover our drug candidates. Publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent, or the first to file patent applications on, our drug candidates or for their uses, or that our drug candidates will not infringe patents that are currently issued or that are issued in the future. In the event that a third party has also filed a patent application covering one of our drug candidates or a similar



Shanghai Miracogen Inc.- Ex. 2032, Page 000122

invention, our patent application may be regarded as a competing application and may not be approved in the end. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our products or their use.

Moreover, we had eight clinical-stage drug candidates, including four Core Products acquired through acquisitions of all equity interests or controlling stake in the relevant subsidiaries, with three of them subject to in-licensing arrangements. Disputes may arise between us and our licensors over intellectual property rights of our in-licensed Core Products. In addition, for certain of our drug candidates subject to in-license or acquisition arrangements, the responsibility for prosecution and defense lies with the counterparty. See "Business – Collaboration, Licensing and Transfer Arrangements." Nevertheless, such counterparties may choose not to proceed with the prosecution of the intellectual property rights relevant to our drug candidates or defense in event of intellectual property right disputes, and hence, preventing us from timely prosecuting for or defending the underlying intellectual property rights, impairing our ability to maintain our licensing arrangements on commercially acceptable terms, and further affecting our ability to successfully develop and commercialize the relevant drug candidates.

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



Shanghai Miracogen Inc.- Ex. 2032, Page 000123

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

During the course of any intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements, or the announcement of the litigation, as negative, the perceived value of our drug candidates, future drugs, programs or intellectual property could be diminished. Accordingly, the market price of our Shares may decline. Such announcements could also harm our reputation or the market for our drug candidates, which could have a material adverse effect on our business. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to conduct our clinical trials, in-license required technology, or enter into strategic partnerships that would help us bring our drug candidates to market.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications are due to be paid to the CNIPA, the USPTO and other patent agencies in other jurisdictions in several stages over the lifetime of a patent. The CNIPA, the USPTO and other governmental patent agencies also require compliance with a number of procedural, documentary, and other similar provisions during the patent application process. We rely on our outside counsel and other professionals to help us comply, and are dependent on our licensors to take the necessary action to comply, with these requirements with respect to our licensed intellectual property. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment, loss of priority or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include the failure to respond to official actions within prescribed time limits, nonpayment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors or other third parties might be able to enter the market, which would have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.


Shanghai Miracogen Inc.- Ex. 2032, Page 000124

***Changes in patent laws of the PRC, the U.S. or other jurisdictions could reduce the value of patents in general, thereby impairing our ability to protect our drug candidates and future drugs.***

Our success depends on obtaining, maintaining, enforcing and defending intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves technological and legal complexity and obtaining and enforcing pharmaceutical and biopharmaceutical patents is costly, time-consuming and inherently uncertain. Changes in either the patent laws or their interpretation in the PRC, the U.S. or other jurisdictions may increase the uncertainties and costs surrounding the prosecution of our patents, diminish our ability to protect our inventions, obtain, maintain, defend, and enforce our intellectual property rights and, more generally, affect the value of our intellectual property or narrow the scope of our patent rights.

In the PRC, intellectual property laws are constantly evolving, with efforts being made to improve intellectual property protection. For example, the new PRC Patent Law (專利法) was amended on October 17, 2020 and became effective on June 1, 2021. The new PRC Patent Law will introduce patent extensions to eligible innovative drug patents, and the patents owned by third parties may be extended, which may in turn affect our ability to commercialize our drug products. The new PRC Patent Law may enable the patent owners to apply for a patent term extension. The compensation period shall not exceed five years, and the total validity period of patent rights for a new drug shall not exceed 14 years after the new drug is approved for marketing. If we are required to delay commercialization for an extended period of time, technological advances may develop and new products may be launched, which may in turn render our products noncompetitive. There can be no assurance that any other changes to PRC intellectual property laws would not have an adverse effect on our intellectual property protection.

Recently enacted U.S. laws have changed the procedures through which patents may be obtained and by which the validity of patents may be challenged. For example, the Leahy-Smith Act, includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, enable 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. Assuming that other requirements for patentability are met, prior to March 2013, in the U.S., the first to invent the claimed invention was entitled to the patent, while outside the U.S., the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith Act, the U.S. transitioned to a first-to-file system in which, assuming that the other statutory 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. See "– Risks Relating to Our Intellectual Property Rights – If we are unable to obtain and maintain patent and other intellectual property protection for our drug candidates, or if the scope of such intellectual property rights obtained


Shanghai Miracogen Inc.- Ex. 2032, Page 000125

is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and our ability to successfully commercialize any product or technology may be adversely affected." As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications in the U.S. and the enforcement or defense of our issued patents, each of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Recent U.S. Supreme Court rulings have also changed the law surrounding patent eligibility, narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained, if any. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. There could be similar changes in the laws of foreign jurisdictions that may impact the value of our patent rights or our other intellectual property rights, all of which could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future, as well as on our competitive position, business, financial condition, results of operations and prospects.

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

In addition to our issued patents and pending patent applications, we rely on a combination of copyrights, trade secrets and confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drug candidates. We seek to protect our copyrights, trade secrets and confidential information, in part, by entering into copyright agreements and confidentiality agreements with parties that have access to trade secrets or confidential information, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties that have access to them. However, we may not be able to prevent the unauthorized disclosure or use of our copyrights, trade secrets and confidential information by the parties to these agreements. Monitoring unauthorized use and disclosure is difficult and we do not know whether the steps we have taken to protect our proprietary rights will be effective. Any of the foregoing parties may breach or violate the terms of their agreements with us and may disclose our proprietary information or otherwise infringe our rights, and we may not be able to obtain adequate remedies for any such breach or violation. We could lose our trade secrets and third parties could use our trade secrets to compete with our drug candidates and technology. Additionally, there can be no assurance that we have entered into all necessary agreements with each party



Shanghai Miracogen Inc.- Ex. 2032, Page 000126

that may have or has had access to our trade secrets or proprietary technology and processes. Enforcing a claim that a party infringed our copyrights or illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

Many of our employees, including our senior management, may have been previously employed at other pharmaceutical or biopharmaceutical 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 others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer or, in the case of consultants and advisors, other companies for which they currently work. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying damages, we may lose valuable intellectual property rights or be required to obtain licenses to such intellectual property rights, which may not be available on commercially reasonable terms, or at all. An inability to incorporate such intellectual property rights would harm our business and may prevent us from successfully commercializing our drug candidates. In addition, we may lose personnel as a result of such claims and any such litigation or the threat thereof may have an adverse effect on our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our drug candidates and technology, which would have a material adverse effect on our business, financial condition, results of operations and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees.

Moreover, while we typically require our employees, consultants and contractors who are engaged in the development of intellectual property to execute agreements assigning the ownership of intellectual property to us, we may be unsuccessful in executing such an agreement with any other party who in fact develops intellectual property that we believe we have the ownership of. Furthermore, even when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, each of which may result in claims by or against us related to the ownership of such intellectual property to determine the ownership of what we regard as our intellectual property. In addition, individuals executing agreements with us may have pre-existing or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual. If we fail in prosecuting or defending any such claims, in addition to paying damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending any of the foregoing claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.



Shanghai Miracogen Inc.- Ex. 2032, Page 000127

In addition, we may in the future be subject to claims by former employees, consultants or other third parties asserting an ownership right in our owned or licensed patents or patent applications as well as other intellectual properties. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate, patent or copyright claims being narrowed, invalidated or held unenforceable which could limit our ability to stop others from using or commercializing similar drug candidates or technology without payment to us or could limit the duration of protection covering our drug candidates and technology. Such challenges may also result in our inability to develop, manufacture or commercialize our drug candidates without infringing third-party rights. In addition, if the breadth or strength of protection provided by our owned or licensed patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates. Any of the foregoing events could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

***If our trademarks and trade names are not adequately protected, we may not be able to build brand recognition in our markets of interest which may have an adverse effect on our business.***

We currently own issued trademark registrations and have trademark applications pending, any of which may be the subject of a governmental or third-party objection, which could prevent the registration or maintenance of the same.

There can be no assurance that any currently pending trademark applications or any trademark applications we may file in the future will be approved. During trademark registration proceedings, we may receive rejections and, although we are given an opportunity to respond to those rejections, may be unable to overcome such rejections. In addition, in proceedings before the USPTO and in proceedings before comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks and our trademarks may not survive such proceedings. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and, as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, or engaging in conduct that constitutes unfair competition, defamation or other violation of our rights, it may have a material adverse effect on our business.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential



Shanghai Miracogen Inc.- Ex. 2032, Page 000128

trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. 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. Any of the foregoing events could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

During the Track Record Period, we in-licensed certain drug candidates, including CG0070 from CG Oncology and MRG004A from Fudan University and SIMMCAS. See "Business – Clinical-Stage Drug Candidates." We may in the future enter into license agreements with third parties providing us with rights to various third-party intellectual property, including rights in patents, patent applications and copyrights. These license agreements may impose diligence, development or commercialization timelines and milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under future license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any drug or drug candidate that is covered by the licenses provided for under these agreements or we may face claims for damages or other penalties under these agreements. Such an occurrence could diminish the value of these products and our business. Termination of the licenses provided for under these agreements or the reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under such agreements to important intellectual property or technology or our rights to develop and commercialize our drug candidates. In addition, such an event may cause us to experience significant delays in the development and commercialization of our drug candidates or incur liability for damages. If any such license is terminated, our competitors or other third parties could have the freedom to seek regulatory approvals of, and to market, products and technologies identical or competitive to ours and we may be required to cease our development and commercialization of certain drug candidates.

In addition, we may need to obtain additional licenses from licensors and others to advance our research or allow commercialization of drug candidates we may develop. In connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties, including our competitors, to receive licenses to a portion of the intellectual property that is subject to our existing licenses and to compete with our drug candidates and technology. It is possible that we may be unable to obtain any additional


Shanghai Miracogen Inc.- Ex. 2032, Page 000129

licenses at a reasonable cost or on reasonable terms, if at all. We may therefore be required to expend significant time and resources to redesign our drug candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected drug candidates, which could harm our business, financial condition, results of operations and prospects significantly.

Disputes may arise regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other issues related to interpretation;
- our or our licensors' obligation to obtain, maintain and defend intellectual property and to enforce intellectual property rights against third parties;
- the extent to which our technology, drug candidates and processes infringe, misappropriate or otherwise violate intellectual property of the licensor that is not subject to the license agreement;
- the sublicensing of patent and other intellectual property rights under our license agreements;
- our diligence, financial or other obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology from third parties are, and any such future license agreements are likely to be, complex, and certain provisions in such agreements may be susceptible to several 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 diligence, 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 or any other dispute described above related to our license agreements prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected drug candidates. Any of the foregoing events could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.


Shanghai Miracogen Inc.- Ex. 2032, Page 000130

***Intellectual property rights do not necessarily protect us from all potential threats.***

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

- others may be able to make products that are similar to any drug candidates we may develop or utilize similar technology that are not covered by the claims of the patents or copyrights that we own or license now or in the future;

- we, our licensors or current or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;

- we, our licensors or current or future collaborators might not have been the first to file patent applications covering certain of our, or their, inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our owned or licensed intellectual property rights;

- it is possible that our pending owned or licensed patent applications or those that we may own or license in the future will not lead to issued patents;

- issued patents that we hold rights to may not provide us with a competitive advantage, or may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;

- our competitors or other third parties might conduct research and development activities in jurisdictions 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 validity and scope of any claims relating to copyrights or other intellectual property may involve complex legal and factual questions and analyses and, as a result, the outcome may be highly uncertain;

- we may not develop additional proprietary technologies that are patentable;

- the patents of others may harm our business; and

- we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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



Shanghai Miracogen Inc.- Ex. 2032, Page 000131

## RISKS RELATING TO OUR RELIANCE ON THIRD PARTIES

***We work with various third parties to develop our drug candidates and may have limited control over them. If these third parties fail to duly perform their contractual obligations or meet expected timelines, we may be unable to obtain regulatory approvals for, or commercialize, our drug candidates, and our business, financial condition and results of operations could be materially and adversely affected.***

We have worked with and may continue to work with third-party CROs including SMOs, to monitor and manage data for our ongoing pre-clinical and clinical programs. We work with these parties to execute our pre-clinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocols, legal and regulatory requirements and scientific standards, and our collaboration with the CROs does not relieve us of our regulatory responsibilities. We, our CROs for our clinical programs and our clinical investigators are required to comply with GCPs, which are regulations and guidelines enforced by the NMPA, the FDA and other comparable regulatory authorities for all of our drugs in clinical development. If we or any of our CROs or clinical investigators fail to comply with the applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the NMPA, the FDA or other comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our registration trials must be conducted with products produced under cGMP regulations. Any failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminates, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and nonclinical programs. If CROs fail to duly perform their contractual obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they or our clinical investigators obtain is compromised due to failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approvals for, or successfully commercialize, our drug candidates.

Switching or adding additional CROs involves additional cost and delays, which can materially influence our ability to meet our desired clinical development timelines. Any of the foregoing events may cause cost increases, restrict our revenue generation ability and have a material adverse effect on our business and prospects.

Our future revenues are dependent on our ability to work effectively with collaborators to develop our drug candidates, including to obtain regulatory approvals. Our arrangements with collaborators will be critical to the successful commercialization of our drug candidates and future products. We rely on collaborators in various respects, including to undertake research and development programs and conduct clinical trials, manage or assist with the



Shanghai Miracogen Inc.- Ex. 2032, Page 000132

regulatory filings and approval process, and to assist with our commercialization efforts. We do not control our collaborators, and therefore there can be no assurance that these third parties will adequately and timely perform all of their obligations under their agreements with us. If they fail to complete the remaining studies successfully, or at all, it could delay or adversely affect the obtaining of regulatory approvals. There can be no assurance of the satisfactory performance of any of our collaborators, and if any of our collaborators breach or terminate their agreements with us, we may not be able to successfully commercialize the licensed product which could materially and adversely affect our business, financial condition, cash flows and results of operations. In addition, we will rely on third parties to perform certain specification tests on our drug candidates prior to delivery to patients. If these tests are not appropriately carried out and test data are not reliable, patients could be put at risk of serious harm and regulatory authorities could place significant restrictions on us until deficiencies are remedied.

More generally, supply chain risks associated with the foregoing third-party service providers and our other suppliers may have a material adverse effect on our business, financial conditions, results of operations and prospects. See "– Risks Relating to Manufacturing of Our Drug Candidates – We are exposed to various supply chain risks as we depend on a stable, adequate and quality supply of raw materials, technical services, equipment and infrastructure construction services, and any price increases or interruptions of such supply may have a material adverse effect on our business."

***We have entered into collaborations with our partners and may form or seek additional collaborations or strategic alliances or enter into additional licensing arrangements in the future. We may not realize any or all benefits of such alliances or licensing arrangements, and disputes may arise between us and our current or future collaboration partners.***

We have in the past formed, and may in the future seek and form, strategic alliances, joint ventures or other collaborations, including entering into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop. See "Business – Collaboration, Licensing and Transfer Arrangements." Any of these relationships may require us to incur nonrecurring and other charges, increase our near-and long-term expenditures, issue securities that dilute our existing shareholders, or disrupt our management and business.

Our strategic collaboration with partners involves various risks, including that we may not achieve the revenue and cost synergies expected from the transaction. These synergies are inherently uncertain, and are subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and beyond our control. Also, the synergies from our collaboration with partners may be offset by other costs incurred in the collaboration, increases in other expenses, operating losses or problems in the business unrelated to our collaboration. As a result, there can be no assurance that expected synergies will be achieved in due course, or at all.



Shanghai Miracogen Inc.- Ex. 2032, Page 000133

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

Disputes may arise between us and our current or future collaboration partners. Such disputes may cause delays in or termination of the research, development or commercialization of our drug candidates, or may result in costly litigation or arbitration that diverts management's attention and resources.

Global markets are an important component of our growth strategy. We have retained rights for the development and commercialization of certain of our drug candidates globally. If we fail to obtain licenses or enter into collaboration arrangements with third parties in other markets, or if any third-party collaborator is not successful, our revenue-generating growth potential will be adversely affected.

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

- efforts to enter into collaboration or licensing arrangements with third parties in connection with our international sales, marketing and distribution efforts may increase our expenses or divert our management's attention from the acquisition or development of drug candidates;

- difficulty of effective enforcement of contractual provisions in local jurisdictions;

- third parties obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our drug candidates;

- difficulty of ensuring that third-party partners do not infringe, misappropriate, or otherwise violate the patent, trade secret, or other intellectual property rights of others;

- unexpected changes in or imposition of trade restrictions, such as tariffs, sanctions or other trade controls, and similar regulatory requirements;

- economic weakness, including inflation;


Shanghai Miracogen Inc.- Ex. 2032, Page 000134

- compliance with tax, employment, immigration and labor laws for employees traveling abroad;

- the effects of applicable foreign tax structures and potentially adverse tax consequences;

- currency fluctuations, which could result in increased operating expenses and reduced revenue;

- workforce uncertainty and labor unrest;

- failure of our employees and contracted third parties to comply with the U.S. Department of the Treasury's Office of Foreign Assets Control rules and regulations, the U.S. Foreign Corrupt Practices Act of 1977, as amended ("**FCPA**") and other applicable laws and regulations; and

- business interruptions resulting from geopolitical actions, including war and acts of terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

***We may rely on third parties to manufacture a portion of our drug candidates for clinical development and commercial sales. Our business could be harmed if those third parties fail to deliver sufficient quantities of product or fail to do so at acceptable quality levels or prices.***

We currently engage third-party CDMOs and CMOs to manufacture certain drug candidates used for some of our clinical trials, which is not expected to be a major undertaking in addition to owning and operating our in-house manufacturing facilities. As of the Latest Practicable Date, anti-PD-1 drugs for clinical trials and the antibodies, cytotoxic small molecules, and linker parts in ADC products were supplied by third-party CDMOs. We also engage third-party CMOs to manufacture clinical materials used for some of our clinical trials.

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

- we may be unable to identify manufacturers on acceptable terms, or at all because the number of potential manufacturers is limited and the NMPA, the FDA or other comparable regulatory authorities must evaluate and/or approve any manufacturers as part of their regulatory oversight of our drug candidates;

- our third-party manufacturers might be unable to timely manufacture our drug candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;


Shanghai Miracogen Inc.- Ex. 2032, Page 000135

- manufacturers are subject to ongoing periodic unannounced inspection and other government regulations by the NMPA, the FDA or other comparable regulatory authorities to ensure strict compliance with GMP. We do not have control over third-party manufacturers' compliance with these regulations and requirements;

- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our drug candidates;

- manufacturers may not properly obtain, protect, maintain, defend or enforce our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;

- manufacturers may infringe, misappropriate, or otherwise violate the patent, trade secret, or other intellectual property rights of third parties;

- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects; and

- our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters.

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

***Our rights to develop and commercialize our drug candidates are subject to the terms and conditions of licenses and sublicenses granted to us by third parties.***

We rely on licenses and sublicenses to certain patent rights and other intellectual property from third parties that are important or necessary for the development of our drug candidates. Our licensors and sublicensors may also provide us with clinical data required for NDA filings in our licensed or sublicensed territories pursuant to these licenses, among other methods of support. However, the licenses may not provide exclusive rights to use such intellectual property in all relevant fields of use and in all territories in which we may expect to develop or commercialize our drug products and the underlying patents may fail to provide the intended exclusivity. As a result, we may not be able to prevent competitors from developing and commercializing competitive drug products in the markets that we expect to address. In addition, our licenses may not include rights to all intellectual property relevant to our drug candidates, and therefore we may need to obtain additional licenses from our existing licensors, which may not be available on an exclusive basis, commercially reasonable terms, or at all, or expend significant time and resources to redesign our drug candidates or the methods for


Shanghai Miracogen Inc.- Ex. 2032, Page 000136

manufacturing them, all of which may not be feasible on a technical or commercial basis. Moreover, we do not own the underlying intellectual property related to these drug candidates, and our rights are continuously subject to the terms of the underlying agreements. If our licensors breach our license agreements, we may not be able to enforce such agreements or obtain sufficient or adequate remedies. If these in-licenses are terminated, competitors may develop, seek regulatory approval of, and market, products identical to ours.

Our license agreements may not grant us the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering our drugs. Moreover, we have not had, and do not have, primary control over these activities for certain of our patents or patent applications and other intellectual property rights that we jointly own with certain of our licensors and sublicensors. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our current or future licensing or collaboration partners fail to prosecute, maintain (including by failing to pay the relevant fees), enforce and defend patents licensed to us that are material to our business, the exclusivity associated with the relevant drug candidate may be reduced or eliminated, and our ability to prevent competitors from developing or commercializing biosimilar drugs could be adversely affected. Even if we have the right to control patent prosecution and maintenance of patents and patent applications licensed to us, we may still be adversely affected or prejudiced by actions or inactions of our sublicensees, our licensors, the inventors, third-party collaborators and each of their respective counsel that took place either before or after the date upon which we assumed that control.

In addition, our licensors may have relied on third-party consultants or collaborators or on funds, resources or expertise from third parties such that our licensors are not the sole and exclusive owners of the patents we in-license. If other third parties have ownership rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market biosimilar products and technologies. In addition, if our licensors have not obtained adequate rights and licenses from these third parties, we may need to obtain additional rights from these third parties or we could be prevented from developing and commercializing the relevant drug candidates or encounter direct competition. This could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

Over time, we may seek additional rights to intellectual property from our licensors and, in connection with the related negotiations, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including enabling third parties to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Any of the foregoing events could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.



Shanghai Miracogen Inc.- Ex. 2032, Page 000137

## RISKS RELATING TO OUR OPERATIONS

***The loss of any key members of our senior management team or our inability to attract, retain and motivate highly qualified management, clinical and scientific personnel could delay or prevent the successful development of our drug candidates and result in a material and adverse effect on our business and results of operations.***

Our success depends, in part, on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, as well as other key clinical and scientific personnel, and other employees and consultants. The loss of the services of any of these individuals could delay or prevent the successful development of our drug candidates and our business operations would be impaired.

Although we have not historically experienced difficulties in attracting and retaining qualified employees, we may experience such problems in the future. Competition for qualified employees in the biopharmaceutical industry is intense and the pool of qualified candidates is limited. We may not be able to retain the services of, or attract and retain, experienced management or key clinical and scientific personnel in the future. The departure of one or more of our management or key clinical and scientific personnel, regardless of whether or not they join a competitor or form a competing company, may subject us to risks relating to replacing them in a timely manner, or at all, which may disrupt our drug development progress and have a material and adverse effect on our business and results of operations. In addition, we will need to hire additional employees as we expand our commercialization team. We may not be able to attract and retain qualified employees on commercially reasonable terms, or at all.

***We are subject to the risks of doing business in multiple jurisdictions.***

As we operate in the PRC, the U.S. and other countries, our business is subject to risks associated with doing business in multiple jurisdictions. Our business and financial results in the future could be adversely affected due to a variety of factors, including:

- changes in a specific country's or region's political and cultural climate or economic condition;
- unexpected changes in laws and regulatory requirements in relevant jurisdictions;
- efforts to develop an international sales, marketing and distribution organization may increase our expenses, divert our management's attention from the acquisition or development of drug candidates or cause us to forgo profitable licensing opportunities in these geographies;
- the occurrence of economic stagnation or downturn in certain jurisdictions, including those caused by inflation or political instability;



Shanghai Miracogen Inc.- Ex. 2032, Page 000138

- the burden of complying with a variety of foreign laws, including difficulties in enforcement of contractual provisions;
- inadequate intellectual property protection in certain jurisdictions;
- enforcement of anti-corruption and anti-bribery laws;
- trade-protection measures, import or export licensing requirements and fines, penalties or suspension or revocation of export privileges;
- delays resulting from difficulty in obtaining export licenses, tariffs and other barriers and restrictions, potentially longer payment cycles, greater difficulty in accounts receivable collection and potentially adverse tax treatment;
- the effects of applicable local tax regimes and potentially adverse tax consequences; and
- significant adverse changes in local currency exchange rates.

We may pursue partnerships with entities in foreign countries and regions, in particular in the U.S. In the event that China or the countries from which we import raw materials impose import tariffs, trade restrictions or other trade barriers affecting the importation of such components or raw materials, we may not be able to obtain a stable supply of necessary components or raw materials at competitive prices, and our business and operations may be materially and adversely affected. We may also sell our products to certain foreign countries in the future. Our business is therefore subject to constantly changing international economic, regulatory, social and political conditions, and local conditions in foreign countries and regions. It is notable that the U.S. government has recently made significant changes in its trade policy and has taken certain actions that may materially impact international trade, such as announcing import tariffs, which have led to other countries, including China and members of the EU, imposing tariffs against the U.S. in response. See "– Risks Relating to Manufacturing of Our Drug Candidates – Changes in U.S. and international trade policies, particularly with regard to China, may cause significant disruptions to our drug candidate manufacturing and other operations." These trade disputes may escalate and may result in certain types of goods, such as advanced research and development equipment and materials, becoming significantly more expensive to procure from overseas suppliers or even illegal to export. Furthermore, there can be no assurance that our existing or potential service providers or collaboration partners will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships between China and the relevant foreign countries or regions. Tensions and political concerns between China and the relevant foreign countries or regions may therefore adversely affect our business, financial condition, results of operations and prospects.


Shanghai Miracogen Inc.- Ex. 2032, Page 000139

In addition, we are subject to general geopolitical risks in foreign countries where we operate, such as political and economic instability and changes in diplomatic and trade relationships. The occurrence of any one or more of these risks of doing business internationally, individually or in the aggregate, could materially and adversely affect our business and results of operations.

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

We are subject to the anti-bribery laws of various jurisdictions. As our business has expanded, we may be subject to an increasing range of applicable anti-bribery laws. Our procedures and controls to monitor anti-bribery compliance may fail to protect us from reckless or criminal acts committed by our employees or agents. If we, due to either our own deliberate or inadvertent acts or those of others, fail to comply with applicable anti-bribery laws, such as the FCPA, or if any of the doctors or other providers or entities we do business with are found to be not in compliance with applicable laws, our reputation could be damaged and we may face civil, administrative or criminal penalties or incur significant expenses, which could have a material adverse effect on our business, including our financial condition, results of operations and prospects.

***Product and professional liability claims or lawsuits against us could result in expensive and time-consuming litigation, payment of substantial damages and increases in our insurance rates.***

We are exposed to risks relating to product and professional liability as a result of clinical testing and any future commercialization of our drug candidates in and outside China. For example, we may be sued if our drug candidates cause, or are perceived to cause, injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing or design, a failure to warn of the inherent dangers in the drugs, negligence, strict liability or a breach of warranties. Claims could also be asserted under applicable consumer protection laws. If we cannot successfully defend ourselves against, or obtain indemnification from our collaborators for, product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Defending ourselves would require significant expenditures and management resources. Regardless of the merits or eventual outcome, liability claims may result in a decrease in demand for our drug candidates, reputational damage, withdrawal of clinical trial participants and inability to continue clinical trials, initiation of investigations by regulators, costs to defend the related litigation, a diversion of management's time and our resources, substantial monetary awards to trial participants or patients, product recalls, withdrawals, restrictive labeling and marketing or promotional restrictions.

It is possible that our liabilities could exceed our insurance coverage or that our insurance will not cover all situations in which a claim against us could be made. We may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be


Shanghai Miracogen Inc.- Ex. 2032, Page 000140

adequate to satisfy any liability that may arise. If a product liability claim or a series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations may be impaired. Should any of the foregoing events occur, our business, financial condition and results of operations would be materially and adversely affected.

***If we use hazardous materials in a manner that causes injury, we could be liable for damages.***

We are subject to laws and regulations governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials. Our operation involves the use of hazardous materials, including chemicals, and may produce hazardous waste products. We cannot eliminate the risks of contamination or personal injury from these materials.

We do not maintain work injury insurance for injuries to our employees resulting from the use of hazardous materials. We also do not maintain insurance for environmental liability claims that may be asserted against us in connection with our storage or disposal of hazardous materials. In the event of contamination or personal injury resulting from our use of hazardous materials or our or third parties' disposal of hazardous materials, we could be held liable for any resulting damages. We may also incur significant costs associated with civil, administrative or criminal fines and penalties.

We may incur substantial costs in order to comply with current or future laws and regulations on the use of hazardous materials. These current or future laws and regulations may impose restrictions on our research, development or production activities. Failure to comply with these laws and regulations may also result in substantial fines, penalties or other sanctions.

***We may be subject to intellectual property infringement claims, which may be expensive to defend and may disrupt our business and operations.***

We cannot be certain that our operations or any aspects of our business do not or will not infringe upon or otherwise violate patents, copyrights or other intellectual property rights held by third parties. We may therefore be subject to legal proceedings and claims relating to the intellectual property rights of others. We cannot assure you that holders of intellectual property rights purportedly relating to some aspect of our business, if any such holders exist, would not seek to enforce such rights against us. Further, the application and interpretation of China's patent laws and the procedures and standards for granting patents in China are still evolving and are uncertain, and we cannot assure you that PRC courts or regulatory authorities would agree with our analysis. If we are found to have violated the intellectual property rights of others, we may be subject to liability for our infringement activities or may be prohibited from using such intellectual property, and we may incur licensing fees or be forced to develop alternatives of our own. In addition, we may incur significant expenses, and may be forced to divert management's time and other resources from our business and operations to defend against these third-party infringement claims, regardless of their merits. Successful infringement or licensing claims made against us may result in significant monetary liabilities and may have a material adverse effect on our business, results of operations and reputation.



Shanghai Miracogen Inc.- Ex. 2032, Page 000141

***We may be subject to disasters, health epidemics such as COVID-19, acts of war, terrorism, business disruptions and other force majeure events, which may have a material adverse effect on our business, financial condition and results of operations.***

Natural disasters, acts of war, terrorism or other force majeure events beyond our control may adversely affect the economy, infrastructure and livelihood of the people in the regions where we conduct our business. Our operations, and those of our third-party research institution collaborators, suppliers and other contractors and consultants, may be under the threat of natural disasters such as floods, earthquakes, sandstorms, snowstorms, fire or drought, the outbreak of a widespread health epidemic, such as swine flu, avian influenza, severe acute respiratory syndrome, or SARS, Ebola, Zika, COVID-19, force majeure events, such as power, water or fuel shortages, failures, malfunction and breakdown of information management systems, unexpected maintenance or technical problems, or potential wars or terrorist attacks.

The occurrence of a disaster or a prolonged outbreak of an epidemic illness or other adverse public health developments in the PRC or elsewhere in the world could materially disrupt our business and operations. For example, the outbreak of COVID-19 has caused illness in, and killed, many people in and outside China, caused temporary suspension of production and shortage of labor and raw materials in affected regions, and disrupted local and international travel and economy. The exacerbation, continuance or reoccurrence of COVID-19 has already caused, and may continue to cause, an adverse and prolonged impact on the economy and social conditions in the PRC and other affected countries. The existing clinical trials and the commencement of new clinical trials could be substantially delayed or prevented by any delay or failure in patient recruitment or enrollment in our or our collaborators' trials as a result of the outbreak of COVID-19. These factors could cause delay of clinical trials, regulatory submissions, and required approvals of our drug candidates, and could cause us to incur additional costs. If our employees or employees of our suppliers and other business partners are suspected of being infected with an epidemic disease, our operations may be disrupted because we or our business partners must quarantine some or all of the affected employees or disinfect relevant facilities. If we are not able to effectively develop and commercialize our drug candidates as a result of protracted clinical trials of enrolled patients, elevated public health safety measures, or failure to recruit and conduct patient follow-up, we may not be able to generate revenue from sales of our drug candidates as planned.

Serious natural disasters may result in loss of lives, injury, destruction of assets and disruption of our business and operations. We partially rely on our third-party research institution collaborators for conducting research and development of our drug candidates, and they may be affected by government shutdowns or funding withdrawals. The occurrence of any of the foregoing events could seriously harm our operations and financial condition and could increase our costs and expenses. We also partially rely on third-party manufacturers to produce and process supplies of our drugs and drug candidates. Our ability to obtain supplies of our drugs and drug candidates could be disrupted if the operations of these suppliers are affected by disasters, epidemics, business interruptions and other force majeure events. Damage or extended periods of interruption to our corporate, development, research or manufacturing facilities due to fire, disaster, epidemics, power loss, communications failure, unauthorized



Shanghai Miracogen Inc.- Ex. 2032, Page 000142

entry or other events could cause us to cease or delay development or commercialization of some or all of our drug candidates. Our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption. Acts of war or terrorism may also injure our employees, cause loss of lives, disrupt our business network and destroy our markets. Any of the foregoing events and other events beyond our control could have an adverse effect on the overall business sentiment and environment, cause uncertainties in the regions where we conduct business, cause our business to suffer in ways that we cannot predict and materially and adversely impact our business, financial condition and results of operations.

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

We maintain insurance policies that are required under PRC laws and regulations as well as based on our assessment of our operational needs and industry practice. See "Business – Insurance." We have elected not to maintain certain types of insurance, such as business interruption insurance or manufacturing facilities insurance. Our insurance coverage may be insufficient to cover any claims that we may have. Any liability or damage to, or caused by, our manufacturing facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources and may adversely affect our drug development and overall operations.

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

We may be exposed to fraud, bribery or other misconduct committed by our employees, principal investigators, consultants and commercial partners that could subject us to financial losses and sanctions imposed by governmental authorities, which may adversely affect our reputation. During the Track Record Period, we were not aware of any instances of fraud, bribery, or other misconduct involving employees and other third parties that had any material and adverse impact on our business and results of operations.

However, there can be no assurance that there will not be any such instances in future. Although we consider our internal control policies and procedures to be adequate, we may be unable to prevent, detect or deter all such instances of misconduct. Any such instances of misconduct committed against our interests, including undetected past acts and future acts, may have a material adverse effect on our business and results of operations.



Shanghai Miracogen Inc.- Ex. 2032, Page 000143

***We are subject to risks associated with leasing properties.***

We lease our some of our offices, laboratories, manufacturing facilities and storage space in the PRC. The lessors of the leased properties may not have valid title or have the legal rights to such leased properties or may not have complied with all the necessary procedures. In addition, as our leases expire, we may fail to negotiate renewals, either on commercially acceptable terms, or at all, which could require us to close such offices or manufacturing facilities. Our inability to enter into new leases or renew existing leases on terms acceptable to us could materially and adversely affect our business, results of operations or financial condition.

Pursuant to PRC law, the lease agreements must be filed with the local branch of the Ministry of Housing and Urban-Rural Development. The filing of such leases will require the cooperation of the lessors. Any failure to register lease agreements as required under PRC law will not affect the validity and enforceability of the lease agreements, but may subject us to a fine for non-registration which may range from RMB1,000 to RMB10,000 for each non-registration agreement, which may negatively affect our ability to operate our business covered under those leases.

## RISKS RELATING TO OUR DOING BUSINESS IN THE PRC

***We have historically received government grants and subsidies for our research and development activities and enjoyed preferential tax treatment during the Track Record Period. Expiration of, or changes to, these incentives or policies, or our failure to satisfy any condition for these incentives, would have an adverse effect on our results of operations.***

We have historically benefited from government grants primarily as incentives for our research and development activities. We recorded government grants of RMB2.5 million, RMB0.8 million and RMB0.1 million in 2019, 2020 and the eight months ended August 31, 2021, respectively. These government grants were generally in support of our research and development activities. Our government grants may vary from period to period, going forward, and our business and results of operations may be affected as a result. During the Track Record Period, we enjoyed preferential tax treatment. For example, Miracogen Shanghai, one of our subsidiaries, benefits from a preferential tax rate of 15% as it is qualified as a High and New Technology Enterprise under the relevant PRC laws and regulations on November 18, 2020. Our eligibility to receive these financial incentives in the future depends on our ability to maintain the relevant qualifications. The incentives are subject to the discretion of the central government or relevant local government authorities, which could determine to reduce the amount of, or cease to provide, the grants or incentives at any time, generally with prospective effect. In addition, the policies according to which we historically received government grants may be lifted or withdrawn by the relevant government authorities at their sole discretion. There can be no assurance that we will continue to receive such government grants or receive a similar level of government grants, or at all, in the future. The discontinuation or reduction of financial incentives currently available to us could have a material adverse effect on our business, financial condition and results of operations.


Shanghai Miracogen Inc.- Ex. 2032, Page 000144

***The biopharmaceutical industry in the PRC is highly regulated and such regulations are subject to change, which may affect approvals and commercialization of our drug candidates.***

Our research operations and manufacturing facilities are mainly conducted or located in the PRC. The biopharmaceutical industry in the PRC is subject to comprehensive government regulation and supervision, encompassing the research and development, trials, approval, registration, manufacturing, packaging, licensing and marketing of new drugs and various other aspects of the operation of pharmaceutical companies. Any violation of the relevant laws, rules and regulations may subject us to disputes, administrative sanctions, criminal sanctions and other legal proceedings. See "Regulatory Overview." In recent years, the regulatory framework in the PRC regarding the biopharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. For example, CDE issued the Draft Guiding Principles for Clinical Research and Development of Anti-tumor Drugs Oriented by Clinical Value (the "Draft Rule") on July 2, 2021. 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 the PRC and reduce the current benefits we believe are available to us from developing and manufacturing drugs in the PRC. PRC authorities have become increasingly vigilant in enforcing laws in the biopharmaceutical 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 the PRC. We believe our strategy and approach are consistent with the PRC government's policies, but there can be no assurance that our strategy and approach will remain consistent therewith.

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

Substantially all of our operations are conducted in the PRC through our PRC subsidiaries, and are governed by PRC laws, rules and regulations. Our PRC subsidiaries are subject to laws, rules and regulations applicable to foreign investment in the PRC. The PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions may be cited for reference but have limited precedential value.

In 1979, the PRC government began to promulgate a comprehensive system of laws, rules 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 the PRC. However, China has not developed a fully integrated legal system, and recently enacted laws, rules and regulations may not sufficiently cover all aspects of economic activities in the PRC or may be subject to significant degrees of interpretation by PRC regulatory agencies. In particular, because these laws, rules and regulations are relatively new and often give the relevant regulator significant discretion in how to enforce them, and because of the limited number of published decisions and the nonbinding nature of such decisions, the interpretation and enforcement of these laws, rules and regulations involve uncertainties and can be inconsistent and unpredictable. In addition, the PRC legal system is



Shanghai Miracogen Inc.- Ex. 2032, Page 000145

based, in part, on government policies and internal rules, some of which are not published on a timely basis, or at all, and which may have a retroactive effect. As a result, we may not be aware of our violation of these policies and rules until after the occurrence of the violation.

Specifically, the NMPA's recent reform of the drug-approval system may face implementation challenges. The timing and full impact of such reforms are uncertain and could prevent us from commercializing our drug candidates in a timely manner.

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

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

Due to our extensive operations in the PRC, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in the PRC. China's economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. While the PRC economy has experienced significant growth over the past 40 years, growth has been uneven across different regions and among various economic sectors of China. The PRC government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall PRC economy, but may have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are currently applicable to us. In addition, in the past, the PRC government implemented certain measures, including interest rate increases, to control the pace of economic growth. These measures may cause decreased economic activity in the PRC, which may adversely affect our business and results of operations. More generally, if the business environment in the PRC deteriorates from the perspective of domestic or international investment, our business in the PRC may also be adversely affected.

***We may be restricted from transferring our scientific data abroad.***

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (科學數據管理辦法) (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 the PRC must seek



Shanghai Miracogen Inc.- Ex. 2032, Page 000146

governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded, at least in part, by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. Given that the term "state secret" is not clearly defined, there can be no assurance that we can always obtain relevant approvals for sending scientific data including the results of our pre-clinical studies or clinical trials conducted within the PRC abroad or to our foreign partners in the PRC. If we are unable to obtain 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, financial condition, results of operations and prospects. If the relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to fines and other administrative penalties imposed by those government authorities.

***Gains on the sales of H Shares and dividends on the H Shares may be subject to PRC income taxes.***

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

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

For non-resident individual holders, gains realized through the transfer of properties are normally subject to PRC individual income tax at a rate of 20%. However, according to the Circular of the Ministry of Finance and the State Administration of Taxation on Issues Concerning Individual Income Tax Policies (財政部、國家税務總局關於個人所得税若干政策問題的通知), income received by individual foreigners from dividends and bonuses of a foreign-invested enterprise are exempt from individual income tax for the time being. According to the Circular Declaring that Individual Income Tax Continues to Be Exempted over Individual Income from Transfer of Shares issued by the MOF and the SAT (關於個人轉讓股票所得繼續暫免徵收個人所得税的通知) effective as of March 30, 1998, income from individuals' transfer of stocks of listed companies continued to be temporarily exempted from



Shanghai Miracogen Inc.- Ex. 2032, Page 000147

individual income tax. On February 3, 2013, the State Council approved and promulgated the Notice of Suggestions to Deepen the Reform of System of Income Distribution (國務院批轉發展改革委等部門關於深化收入分配制度改革若干意見的通知). On February 8, 2013, the General Office of the State Council promulgated the Circular Concerning Allocation of Key Works to Deepen the Reform of System of Income Distribution (國務院辦公廳關於深化收入分配制度改革重點工作分工的通知). According to these two documents, the PRC government is planning to cancel foreign individuals' tax exemption for dividends obtained from foreign-invested enterprises, and the Ministry of Finance and the State Administration of Taxation should be responsible for making and implementing details of such plan. However, relevant implementation rules or regulations have not been promulgated by the Ministry of Finance and the State Administration of Taxation.

Considering these uncertainties, non-resident holders of our Shares should be aware that they may be obligated to pay PRC income tax on the dividends and gains realized through sales or transfers of the H shares.

***Governmental control of currency conversion, and restrictions on the remittance of Renminbi into and out of China, may adversely affect the value of your investment.***

The Renminbi is not currently a freely convertible currency, as the PRC government imposes controls on the convertibility of Renminbi into foreign currencies and, in certain cases, the remittance of currency out of China. A substantial majority of our future revenue is expected to be denominated in Renminbi and we will need to convert Renminbi into foreign currencies for the payment of dividends, if any, to holders of our Shares. Shortages in the availability of foreign currency may restrict our ability to remit sufficient foreign currency to pay dividends or other payments, or otherwise satisfy our foreign currency-denominated obligations.

Under China's current foreign exchange control system, foreign exchange transactions under the current account conducted by us, including the payment of dividends, do not require advance approvals from SAFE, but we are required to present relevant documentary evidence of such transactions and conduct such transactions at designated foreign exchange banks within the PRC that have the licenses to carry out foreign exchange business. Approvals from appropriate government authorities are required where Renminbi 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. Since 2015, in response to China's declining foreign currency reserves, the PRC government has placed increasingly stringent restrictions on the convertibility of Renminbi into foreign currencies. If the foreign exchange control system prevents us from obtaining sufficient foreign currencies to satisfy our foreign currency demands, we may not be able to pay dividends in foreign currencies to our Shareholders. Further, there can be no assurance that new regulations will not be promulgated in the future that would have the effect of further restricting the remittance of Renminbi into or out of China.



Shanghai Miracogen Inc.- Ex. 2032, Page 000148

***You may experience difficulties in effecting service of legal process, enforcing foreign judgments or bringing original actions in the PRC against us or our management named in the documents based on Hong Kong or other foreign laws.***

We are incorporated under the laws of the PRC, and substantially all of our assets are located in the PRC. In addition, a majority of our Directors, Supervisors and senior management personnel reside within the PRC, and substantially all of their assets are located within the PRC. As a result, it may not be possible for investors to effect service of process upon us or our Directors, Supervisors and senior management personnel in the PRC. PRC has not entered into treaties or arrangements providing for the recognition and enforcement of judgments made by courts of most other jurisdictions.

In July 2006, the Supreme People's Court of the PRC and the government of the Hong Kong Special Administrative Region entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements between Parties Concerned (關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排) (the "**Arrangement**"). Under the Arrangement, where any designated PRC court or any designated Hong Kong court has made an enforceable final judgment requiring payment of money in a civil or commercial case under a choice of court agreement in writing, any party concerned may apply to the relevant PRC court or Hong Kong court for recognition and enforcement of the judgment. A choice of court agreement in writing is defined as any agreement in writing entered into between parties after the effective date of the Arrangement in which a Hong Kong court or a court in Mainland China is expressly selected as the court having sole jurisdiction for the dispute. Therefore, it is not possible to enforce a judgment rendered by a Hong Kong court in the PRC if the parties in dispute have not agreed to enter into a choice of court agreement in writing. Although the Arrangement became effective in August 2008, the outcome and effectiveness of any action brought under the Arrangement remain uncertain. As a result, it may be difficult or impossible for investors to effect service of process against certain of our assets or Directors in the PRC in order to seek recognition and enforcement of foreign judgments in the PRC.

## RISKS RELATING TO THE GLOBAL OFFERING

***There has been no prior public market for our Shares, and their liquidity and market price may be volatile.***

No public market currently exists for our Shares. The initial Offer Price for our Shares to the public will be the result of negotiations between our Company and the Joint Global Coordinators (for themselves and on behalf of the Underwriters) and the Offer Price may differ significantly from the market price of the Shares following the Global Offering. We have applied for listing of and permission to deal in our Offer Shares on the Stock Exchange. A listing on the Stock Exchange, however, does not guarantee that an active and liquid trading market for the Shares will develop, or if it does develop, that it will be sustained following the Global Offering, or that the market price of the Shares will not decline following the Global


Shanghai Miracogen Inc.- Ex. 2032, Page 000149

Offering. In particular, according to the PRC Company Law, all of the Shares in issue as of the date of this Prospectus, representing 92.35% of our total issued Shares upon Listing (assuming the Over-allotment Option is not exercised), will be subject to a lock-up period of one year from the Listing Date. Further, the Offer Shares to be purchased by the Cornerstone Investors will also be subject to a lock-up period of six months from the Listing Date. These may significantly affect the liquidity and trading volume of our Shares in the short term following the Global Offering.

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

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

***There will be a gap of several days between pricing and trading of our Shares, and the price of our Shares when trading begins could be lower than the offer price.***

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

***Future sales or perceived sales of our Shares in the public market by major Shareholders following the Global Offering could materially adversely affect the price of our Shares.***

Prior to the Global Offering, there has not been a public market for our Shares. Future sales or perceived sales by our existing Shareholders of our Shares after the Global Offering could result in a significant decrease in the prevailing market price of our Shares. Only a limited number of the Shares currently outstanding will be available for sale or issuance



Shanghai Miracogen Inc.- Ex. 2032, Page 000150

immediately after the Global Offering due to contractual and regulatory restrictions on disposal and new issuance. Nevertheless, after these restrictions lapse or if they are waived, future sales of significant amounts of our Shares in the public market or the perception that these sales may occur could significantly decrease the prevailing market price of our Shares and our ability to raise equity capital in the future.

In addition, our unlisted shares may be converted into H shares subject to regulatory approvals and compliance with relevant regulatory requirements. Any conversion of our unlisted shares will increase the number of H shares available on the market and may affect the trading price of our Shares.

***Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.***

We may seek additional funding through a combination of equity offerings, debt financings, collaborations and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our Shares. Issuance of additional Shares, or the possibility of such issuance, may cause dilution to our shareholders if we issue additional Shares at a price which is lower than the net tangible asset value per Share prior to the issuance of such additional Shares, and may cause the market price of our Shares to decline. In addition, the incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In the event that we enter into collaborations or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party on unfavorable terms our rights to technologies or drug candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms.

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

We currently expect to retain all future earnings for use in operation and expansion of our business, and do not have any dividend policy to declare or pay any dividends in the foreseeable future. Any future declarations and payments of dividends will be at the absolute discretion of our Directors and will depend on our actual and expected results of operations, cash flow and financial position, general business conditions and business strategies, expected working capital requirements and future expansion plans, legal, regulatory and other contractual restrictions, and other factors which our Directors consider relevant. No dividend shall be declared or payable except out of our profits and reserves lawfully available for distribution. As confirmed by our PRC Legal Advisor, according to the PRC laws, any future



Shanghai Miracogen Inc.- Ex. 2032, Page 000151

net profit that we make will have to be first applied to make up for our historically accumulated losses, after which we will be obliged to allocate 10% of our net profit to our statutory common reserve fund until such fund has reached more than 50% of our registered capital. We will therefore only be able to declare dividends after: (i) all our historically accumulated losses have been made up for; and (ii) we have allocated sufficient net profit to our statutory common reserve fund as described above. As a result, there can be no assurance whether, when and in what form we will pay dividends in the future. Subject to any of the above constraints, we may not be able to pay dividends in accordance with our dividend policy. See "Financial Information – Dividend."

***We have significant discretion as to how we will use the net proceeds of the Global Offering, and you may not necessarily agree with how we use them.***

Our management may spend the net proceeds from the Global Offering in ways you may not agree with or that do not yield a favorable return to our shareholders. We plan to use the net proceeds from the Global Offering to conduct clinical trials in China and the U.S. on our most promising drug candidates and to expand our sales and marketing staff in preparation for the approval and commercialization of those drug candidates. See "Future Plans and Use of Proceeds." However, our management will have discretion as to the actual application of our net proceeds. You are entrusting your funds to our management, whose judgment you must depend on, for the specific uses we will make of the net proceeds from this Global Offering.

***Certain facts, forecasts and statistics obtained from official government sources in this prospectus relating to the pharmaceutical markets may not be fully reliable.***

Certain facts, forecasts and statistics in this prospectus relating to the pharmaceutical markets in and outside China are obtained from official government publications that have not been independently verified by us, the Joint Global Coordinators, the Joint Sponsors, the Joint Lead Managers, the Joint Bookrunners and the Underwriters, any of their respective directors, employees, agents or advisors, or any other person or party involved in the Global Offering, and no representation is given as to its accuracy. However, we cannot guarantee the quality or reliability of these sources. Neither we, the Joint Sponsors, the Underwriters nor our or their respective affiliates or advisers have verified the facts, forecasts and statistics nor ascertained the underlying economic assumptions relied upon in those facts, forecasts and statistics obtained from these sources. Moreover, these facts, forecasts and statistics involve risk and uncertainties and are subject to change based on various factors and should not be unduly relied upon.



Shanghai Miracogen Inc.- Ex. 2032, Page 000152

***Forward-looking statements contained in this prospectus are subject to risks and uncertainties.***

This prospectus contains certain statements and information that are forward-looking and uses forward-looking terminology such as "believe," "expect," "estimate," "predict," "aim," "intend," "will," "may," "plan," "consider," "anticipate," "seek," "should," "could," "would," "continue," and other similar expressions. You are cautioned that reliance on any forward-looking statement involves risks and uncertainties and that any or all of those assumptions could prove to be inaccurate and, as a result, the forward-looking statements based on those assumptions could also be incorrect. In light of these and other risks and uncertainties, the inclusion of forward-looking statements in this prospectus should not be regarded as representations or warranties by us that our plans and objectives will be achieved and these forward-looking statements should be considered in light of various important factors, including those set forth in this section. Subject to the requirements of the Listing Rules, we do not intend publicly to update or otherwise revise the forward-looking statements in this prospectus, whether as a result of new information, future events, or otherwise. Accordingly, you should not place undue reliance on any forward-looking information. All forward-looking statements in this prospectus are qualified by reference to this cautionary statement.

***You should read the entire prospectus carefully, and we strongly caution you not to place any reliance on any information contained in press articles or other media regarding us or the Global Offering.***

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



Shanghai Miracogen Inc.- Ex. 2032, Page 000153

In preparation for the Listing, the Company has sought the following waivers and exemption from strict compliance with the relevant provisions of the Listing Rules and exemption from strict compliance with the Companies (Winding Up and Miscellaneous Provisions) Ordinance:

## WAIVER IN RESPECT OF MANAGEMENT PRESENCE IN HONG KONG

Pursuant to Rule 8.12 and 19A.15 of the Listing Rules, the Company must have sufficient management presence in Hong Kong, which normally means that at least two executive directors must be ordinarily resident in Hong Kong.

The Company do not have, and do not contemplate in the foreseeable future that the Company will have sufficient management presence in Hong Kong for satisfying the requirement under Rule 8.12 and 19A.15 of the Listing Rules. Given that (i) the Company's management, business operations and assets are principally based outside Hong Kong; (ii) the Company's headquarters and senior management are primarily based outside Hong Kong, and (iii) the Directors consider that the appointment of executive Directors who will be ordinarily resident in Hong Kong would not be beneficial to, or appropriate for, the Company and therefore would not be in the best interests of the Company and the Shareholders as a whole.

Accordingly, the Company has applied to the Stock Exchange for, and the Stock Exchange has granted us, a waiver from strict compliance with Rule 8.12 and 19A.15 of the Listing Rules. The Company will ensure that there are adequate and efficient arrangements to achieve regular and effective communication between us and the Stock Exchange as well as compliance with the Listing Rules by way of the following arrangements:

1. **Authorized representatives**: The Company has appointed Dr. Pu Zhongjie, our Company's executive Director, and Ms. Lai Siu Kuen, one of the joint company secretaries of the Company, as the authorized representatives ("**Authorized Representatives**") for the purpose of Rule 3.05 and 19A.07 of the Listing Rules. The Authorized Representatives will act as our principal channel of communication with the Stock Exchange and would be readily contactable by phone, facsimile and/or email to deal promptly with enquiries from the Stock Exchange and will also be available to meet with the Stock Exchange to discuss any matter within a reasonable period of time upon request of the Stock Exchange. Although Dr. Pu reside in the PRC, he possesses valid travel documents and is able to renew such travel documents when they expire in order to visit Hong Kong. Ms. Lai ordinarily resides in Hong Kong. Accordingly, the Authorized Representatives will be able to meet with the relevant members of the Stock Exchange to discuss any matters in relation to the Company within a reasonable period of time. See the section headed "Directors, Supervisors and Senior Management" in this Prospectus for more information about the Authorized Representatives.


Shanghai Miracogen Inc.- Ex. 2032, Page 000154

2. **Directors**: The Company will implement a policy to provide the up-to-date contact details of each Director (such as office phone numbers, mobile phone numbers, fax numbers, and email addresses) to the Authorised Representatives and to the Stock Exchange. This will ensure that the Authorised Representatives and the Stock Exchange will have the means to contact any of the Directors promptly as and when required, including when the Directors are travelling. To the best of our Company's knowledge and information, each Director who is not ordinarily resident in Hong Kong possesses or can apply for valid travel documents to visit Hong Kong and can meet with the Stock Exchange within a reasonable period when required by the Stock Exchange.

3. **Compliance advisor**: The Company has appointed Maxa Capital Limited as our compliance advisor (the "**Compliance Advisor**") in compliance with Rule 3A.19 of the Listing Rules.

   The Compliance Advisor will, among other things and in addition to the Authorized Representatives and our Directors, act as an additional channel of communication of our Company with the Stock Exchange provide us with professional advice on continuing obligations under the Listing Rules and during the period from the Listing Date to the date on which the Company complies with Rule 13.46 of the Listing Rules in respect of its financial results for the first full financial year immediately after the Listing. The Compliance Advisor will also provide advice to us when consulted by us in compliance with Rule 3A.23 of the Listing Rules. The Compliance Advisor will be available to answer enquiries from the Stock Exchange and will act as the principal channel of communication with the Stock Exchange when the Authorized Representatives and Directors are not available. In turn, they will provide to the Compliance Advisor such information and assistance as the Compliance Advisor may need or may reasonably request in connection with the performance of the Compliance Advisor's duties. The company has provided the Stock Exchange with the names, mobile phone numbers, office phone numbers, fax numbers and email addresses of at least two of our Compliance Advisor's officers who will act as the Compliance Advisor's contact persons between the Stock Exchange and the Company pursuant to Rule 19A.06(4) of the Listing Rules.

4. **Joint Company secretaries**: The Company has appointed Ms. Li Yunyi (李昀軼) and Ms. Lai Siu Kuen (黎少娟) as our joint company secretaries. Ms. Li and Ms. Lai will maintain constant contact with our Directors and senior management team members through various means.


Shanghai Miracogen Inc.- Ex. 2032, Page 000155

Meetings between the Stock Exchange and the Directors could be arranged through the Authorized Representatives, our Directors, our Compliance Advisor and/or the joint company secretaries within a reasonable time. The Company will also ensure that there are adequate and efficient means of communication among our Company, the Authorized Representatives, our Directors and other officers, the joint company secretaries and our Compliance Advisor. The Company will inform the Stock Exchange as soon as practicable in respect of any change in the Authorized Representatives, our Directors, our Compliance Advisor and/or the joint company secretaries in accordance with the Listing Rules.

## WAIVER IN RESPECT OF JOINT COMPANY SECRETARIES

Pursuant to Rules 3.28 and 8.17 of the Listing Rules, the company secretary must be an individual who, by virtue of their academic or professional qualifications or relevant experience, is, in the opinion of the Stock Exchange, capable of discharging the functions of a company secretary.

Pursuant to Note 1 to Rule 3.28 of the Listing Rules, the Stock Exchange considers the following academic or professional qualifications to be acceptable:

(a) a Member of The Hong Kong Institute of Chartered Secretaries;

(b) a solicitor or barrister (as defined in the Legal Practitioners Ordinance); and

(c) a certified public accountant (as defined in the Professional Accountants Ordinance.

Pursuant to Note 2 to Rule 3.28 of the Listing Rules, in assessing "relevant experience", the Stock Exchange will consider the individual's:

(a) length of employment with the issuer and other issuers and the roles they played;

(b) familiarity with the Listing Rules and other relevant law and regulations including the Securities and Futures Ordinance, Companies Ordinance, Companies (Winding Up and Miscellaneous Provisions) Ordinance, and the Takeovers Code;

(c) relevant training taken and/or to be taken in addition to the minimum requirement under Rule 3.29 of the Listing Rules; and

(d) professional qualifications in other jurisdictions.



Shanghai Miracogen Inc.- Ex. 2032, Page 000156

The Company appointed Ms. Li Yunyi (李昀軼) and Ms. Lai Siu Kuen (黎少娟) as joint company secretaries of the Company on April 18, 2021. See the section headed "Directors, Supervisors and Senior Management" for further information regarding the qualifications of Ms. Li and Ms. Lai.

Ms. Lai is an associate of The Hong Kong Institute of Chartered Secretaries and Administrators and The Institute of Chartered Secretaries and Administrators and therefore meets the qualification requirements under Note 1 to Rule 3.28 of the Listing Rules and is in compliance with Rule 8.17 of the Listing Rules.

Accordingly, although Ms. Li Yunyi (李昀軼) does not possess the formal qualifications required of a company secretary under Rule 3.28 of the Listing Rules and may not be able to solely satisfy the requirements of the Listing Rules, Ms. Li Yunyi (李昀軼) has substantial experience in handling board, corporate management and administrative matters relating to our Company. Based on the above reasons, our Company applied for a waiver from strict compliance with the requirements under Rules 3.28 and 8.17 of the Listing Rules such that Ms. Li Yunyi (李昀軼) may be appointed as a joint company secretary of the Company on the basis of the proposed arrangements below:

1. Ms. Lai acts as one of our joint company secretaries and provides assistance to Ms. Li Yunyi (李昀軼) for an initial period of three years from the Listing Date to enable Ms. Li Yunyi (李昀軼) to acquire the "relevant experience" under Note 2 to Rule 3.28 of the Listing Rules so as to fully comply with the requirements set forth under Rules 3.28 and 8.17 of the Listing Rules.

2. Ms. Lai will communicate regularly with Ms. Li Yunyi (李昀軼) on matters relating to corporate governance, the Listing Rules and any other laws and regulations which are relevant to the Company and its affairs. Ms. Lai will work closely with, and provide assistance to, Ms. Li Yunyi (李昀軼) in the discharge of her duties as a company secretary, including organizing the Company's Board meetings and Shareholders' general meetings. Furthermore, both Ms. Li and Ms. Lai will seek and have access to advice from the Company's Compliance Advisor and Hong Kong legal and other professional advisors as and when required.

3. Ms. Li Yunyi (李昀軼) will comply with the annual professional training requirement under Rule 3.29 of the Listing Rules and will enhance her knowledge of the Listing Rules during the three-year period from the Listing Date. Our Company will further ensure that Ms. Li Yunyi (李昀軼) has access to the relevant training and support that would enhance her understanding of the Listing Rules and the duties of a company secretary of an issuer listed on the Stock Exchange. In addition, Ms. Li will endeavor to attend relevant trainings and familiarize herself with the Listing Rules and duties required for a company secretary of a PRC issuer whose shares are listed on the Stock Exchange.



Shanghai Miracogen Inc.- Ex. 2032, Page 000157

4. Before the end of three-year period, the Company will evaluate Ms. Li's experience in order to determine if she has acquired the qualifications required under Rules 3.28 of the Listing Rules, and whether ongoing assistance should be arranged.

5. Ms. Lai has been appointed as one of our joint company secretaries for a term of three years, and such waiver will be revoked immediately if there are material breaches of the Rules 3.28 and 8.17 of the Listing Rules by our Company.

Accordingly, our Company has applied to the Stock Exchange for, and the Stock Exchange has granted us, a three-year waiver from strict compliance with Rule 3.28 and 8.17 of the Listing Rules. Such waiver will be revoked immediately if and when Ms. Lai ceases to provide the proposed assistance to Ms. Li or if there are material breaches of the Listing Rules by us. Our Company will liaise with the Stock Exchange to assess whether Ms. Li has acquired the relevant experience under Rule 3.28 of the Listing Rules before the end of the initial three-year period.

## WAIVERS IN RESPECT OF NON-EXEMPT CONTINUING CONNECTED TRANSACTIONS

The Company has entered into and is expected to continue certain transactions after Listing that will constitute non-exempt continuing connected transactions of our Company under the Listing Rules upon the Listing.

Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange has granted, waivers in relation to certain continuing connected transactions between us and certain connected persons under Chapter 14A of the Listing Rules. For further details in this respect, please refer to the section headed "Connected Transactions" in this prospectus for further information.

## WAIVER IN RELATION TO RULE 4.04(1) OF THE LISTING RULES AND EXEMPTION FROM STRICT COMPLIANCE WITH THE REQUIREMENTS UNDER SECTION 342(1) (B), PARAGRAPH 27 OF PART I AND PARAGRAPH 31 OF PART II OF THE THIRD SCHEDULE TO THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

Pursuant to section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance, a prospectus shall state the matters and set out the reports specified in the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

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



Shanghai Miracogen Inc.- Ex. 2032, Page 000158

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

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

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

We are a Biotech Company as defined under Chapter 18A of the Listing Rules and are seeking a listing under Chapter 18A of the Listing Rules. Pursuant to Rule 18A.06 of the Listing Rules, an eligible biotech company must comply with Rule 4.04 as modified so that references to "three financial years" or "three years" in that rule shall instead reference to "two financial years" or "two years", as the case may be.

Paragraph 4.4(i) of the Guidance Letter HKEX-GL25-11 issued by the Stock Exchange provides that where an applicant issues its listing document within two months after the latest year end, a Rule 4.04(1) waiver would be subject to the following conditions: (i) the applicant must list on the Stock Exchange within three months after the latest year end; (ii) the applicant must obtain a certificate of exemption from the SFC on compliance with the requirements under the Companies (Winding Up and Miscellaneous Provisions) Ordinance; (iii) a profit estimate for the latest financial year (which must comply with Rules 11.17 to 11.19 of the Listing Rules) must be included in the listing document or the applicant must provide justification why a profit estimate cannot be included in the listing document; and (iv) there must be a directors' statement in the listing document that there is no material adverse change to its financial and trading positions or prospect with specific reference to the trading results from the end of the stub period to the latest financial year end.



Shanghai Miracogen Inc.- Ex. 2032, Page 000159

An application has been made to the Stock Exchange for a waiver from strict compliance with Rule 4.04(1) of the Listing Rules not to include in this prospectus the results of our Company in respect of the financial year immediately preceding the issue of this prospectus, and such waiver has been granted by the Stock Exchange on the conditions that:

(a) this prospectus will be issued on or before February 10, 2022 and the H Shares of our Company will be listed on the Stock Exchange on or before March 31, 2022;

(b) our Company has obtained a certificate of exemption from the SFC on strict compliance with the requirements under section 342(1)(b) of, and paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to, the Companies (Winding Up and Miscellaneous Provisions) Ordinance;

(c) this prospectus contains a loss estimate for the year ended December 31, 2021 (in compliance with Rules 11.17 to 11.19 of the Listing Rules); and

(d) this prospectus contains the statement of our Directors that there is no material and adverse change to the financial and trading positions or prospects of our Company with specific reference to the trading results from August 31, 2021 to December 31, 2021.

Accordingly, an application has been made to the SFC for, and SFC has granted, a certificate of exemption from strict compliance with the requirements under section 342(1)(b) of, and paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to, the Companies (Winding Up and Miscellaneous Provisions) Ordinance, on the conditions that (i) the particulars of the exemption be set forth in this prospectus; and (ii) this prospectus will be issued on or before February 10, 2022 and the H Shares of our Company will be listed on the Stock Exchange on or before March 31, 2022.

The applications to the Stock Exchange for a waiver from strict compliance with Rule 4.04(1) of the Listing Rules and to the SFC for a certificate of exemption from strict compliance with the requirements under section 342(1)(b) of, and paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to, the Companies (Winding Up and Miscellaneous Provisions) Ordinance were made on the grounds, among others, that strict compliance with the above requirements would be unduly burdensome and the exemption would not prejudice the interests of the investing public, as:

(a) there would not be sufficient time for our Company and our reporting accountant to finalize the audited financial statements for the year ended December 31, 2021 for inclusion in this prospectus. If the financial information for the year ended December 31, 2021 is required to be audited, our Company and our reporting accountant would have to carry out substantial work to prepare, update and finalize the Accountant's Report and this prospectus, and the relevant sections of this prospectus will need to be updated to cover such additional period;



Shanghai Miracogen Inc.- Ex. 2032, Page 000160

(b) our Company is primarily engaged in the research and development, application and commercialization of biotech products, and falls within the scope of Biotech Company as defined under Chapter 18A of the Listing Rules;

(c) the Accountant's Report for each of the two financial years ended December 31, 2019 and 2020 and the eight months ended August 31, 2021 has been prepared and is set out in Appendix I to this document in compliance with Rule 18A.06 of the Listing Rules;

(d) notwithstanding that the financial results set out in this document are only for the two financial years ended December 31, 2019 and 2020 and the eight months ended August 31, 2021, other information required to be disclosed under the Listing Rules and the Companies (Winding Up and Miscellaneous Provisions) Ordinance has been adequately disclosed in the document; and

(e) given that our Company is only required to disclose its financial results for two financial years under Chapter 18A of the Listing Rules and preparation of the financial results for the year ended December 31, 2018 would require additional work to be performed by our Company and our reporting accountant, it will be unduly burdensome for our Company to strictly comply with the relevant requirements under section 342(1)(b) of, and paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to, the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

Our Directors are of the view that, up to the date of this prospectus, there has been no material adverse change to the financial and trading positions or prospects since August 31, 2021 (being the date of the latest audited statement of financial position in the Accountant's Report set out in Appendix I to this prospectus) to the date of this prospectus and there has been no event which would materially affect the information shown in the Accountant's Report as set out in Appendix I to this prospectus, the loss estimate for the year ended December 31, 2021 as set out in Appendix III to this prospectus and the section headed "Financial Information" in this prospectus and other parts of this prospectus. Based on the due diligence work performed by the Joint Sponsors so far, nothing material has come to the attention of the Joint Sponsors for them to cast doubt on the views of the Directors expressed above.

Our Company is of the view that the Accountant's Report covering the two financial years ended December 31, 2019 and 2020 and the eight months ended August 31, 2021, the loss estimate for the year ended December 31, 2021 (in compliance with Rules 11.17 to 11.19 of the Listing Rules), together with other disclosure in this document, already provides potential investors with adequate and reasonably up-to-date information in the circumstances to form a view on the track record of our Company; and our Directors confirm that all information which is necessary to enable an investor to make an informed assessment of the business, assets and liabilities, financial position, management and prospects of our Company has been included in this document. Therefore, the exemption would not prejudice the interest of the investing public.



Shanghai Miracogen Inc.- Ex. 2032, Page 000161

## CORNERSTONE PLACING BY EXISTING SHAREHOLDER AND CORE CONNECTED PERSON

Rule 9.09(b) of the Listing Rules provides that there must be no dealing in the securities for which listing is sought by any core connected person of an issuer (except as permitted by Rule 7.11 of the Listing Rules) from 4 clear business days before the expected hearing date until listing is granted.

Rule 10.03 of the Listing Rules provides that a director of the issuer and his/her close associates may only subscribe for or purchase any securities for which listing is sought if no securities are offered to them on a preferential basis and no preferential treatment is given to them in the allocation of the securities, and the minimum prescribed percentage of public shareholders required by Rule 8.08(1) of the Listing Rules is achieved.

Rule 10.04 of the Listing Rules provides that a person who is an existing shareholder of the issuer may only subscribe for or purchase securities for which listing is sought if no securities will be offered to them on a preferential basis and no preferential treatment will be given to them in the allocation of securities.

Paragraph 5(2) of Appendix 6 to the Listing Rules provides, inter alia, that without the prior written consent of the Stock Exchange, no allocations will be permitted to directors or existing shareholders of the applicant or their close associates, whether in their own names or through nominees, unless any actual or perceived preferential treatment arising from their ability to influence the applicant during the allocation process can be addressed.

Our Company has applied for a waiver from strict compliance with the requirements:

(i) under Rule 10.04 of, and a consent under paragraph 5(2) of Appendix 6 to, the Listing Rules, to allow Vivo Capital (an existing Shareholders of our Company); and

(ii) under Rules 9.09 and 10.03 of, and a consent under paragraph 5(2) of Appendix 6 to, the Listing Rules, to allow King Star Med LP (a close associate of Mr. Lin Xianghong, our non-executive Director),

to subscribe for Shares in the Global Offering (the aforementioned cornerstone investors, the "**Participating Investors**"), subscribing as cornerstone investors.



Shanghai Miracogen Inc.- Ex. 2032, Page 000162

The Stock Exchange has granted the requested waivers and consents subject to the conditions that:

(A) we will comply with the public float requirements of Rule 8.08(1) and 18A.07 of the Listing Rules;

(B) the Offer Shares to be subscribed by and allocated to the Participating Investors under the Global Offering will be at the same Offer Price and in respect of Participating Investors subscribing by way of cornerstone investment, on substantially the same terms as other cornerstone investors (including being subject to a six-month lock up arrangement following Listing) and each Participating Investor shall pay for the relevant Offer Shares before dealings commence on the Listing Date;

(C) no preferential treatment has been, nor will be, given to the Participating Investors by virtue of their relationship with the Company in any allocation in the placing tranche, other than the preferential treatment of assured entitlement under the cornerstone investment (in respect of Participating Investors subscribing as cornerstone investors) which follows the principles set out in the Guidance Letter HKEX-GL51-13, that, save as disclosed in the section headed "Cornerstone Investors" in this Prospectus, the cornerstone investment agreements of the Participating Investors do not contain any material terms which are more favorable to them than those in other cornerstone investment agreements; and

(D) details of the subscription of the Offer Shares by the Participating Investors in the Global Offering as cornerstone investors will be disclosed in this prospectus and the allotment results announcement of our Company. For further information about the cornerstone investments of the Participating Investors, please refer to the section headed "Cornerstone Investors" in this prospectus.


Shanghai Miracogen Inc.- Ex. 2032, Page 000163

## DIRECTORS' RESPONSIBILITY FOR THE CONTENTS OF THIS PROSPECTUS

This prospectus, for which our Directors, including any proposed Director who is named as such in this Prospectus, collectively and individually accept full responsibility, includes particulars given in compliance with the Companies (Winding Up and Miscellaneous Provisions) Ordinance, the Securities and Futures (Stock Market Listing) Rules (Cap 571V of the Laws of Hong Kong) and the Listing Rules for the purpose of giving information to the public with regard to us. Our Directors, having made all reasonable enquiries, confirm that, to the best of their knowledge and belief, the information contained in this prospectus is accurate and complete in all material respects and not misleading or deceptive, and there are no other matters the omission of which would make any statement in this prospectus misleading or deceptive.

## APPROVAL OF THE CSRC

We have submitted an application to the CSRC to apply for listing of the H Shares on the Stock Exchange and for the Global Offering and we obtained the letter of acceptance from the CSRC on April 25, 2021.

The CSRC issued an approval letter on June 24, 2021 for the submission of the application to list our H Shares on the Hong Kong Stock Exchange and for the Global Offering. In granting such approval, the CSRC accepts no responsibility for our financial soundness, nor for the accuracy of any of the statements made or opinions expressed in this prospectus. No other approvals are required to be obtained for the listing of the H Shares on the Stock Exchange.

## THE HONG KONG PUBLIC OFFERING AND THIS PROSPECTUS

This prospectus is published solely in connection with the Hong Kong Public Offering, which forms part of the Global Offering. The Global Offering comprises the Hong Kong Public Offering of initially 12,688,000 Offer Shares and the International Offering of initially 114,188,000 Offer Shares (subject to, in each case, reallocation on the basis referred to under the section headed "Structure of the Global Offering" in this prospectus and, in case of the International Offering, to any exercise of the Over-allotment Option).

The listing of our H Shares on the Stock Exchange is sponsored by the Joint Sponsors and the Global Offering is managed by the Joint Global Coordinators. The Hong Kong Public Offering is fully underwritten by the Hong Kong Underwriters pursuant to the Hong Kong Underwriting Agreement, subject to us and the Joint Global Coordinators (for themselves and on behalf of the Hong Kong Underwriters) agreeing on the Offer Price. The International Offering is expected to be fully underwritten by the International Underwriters under the terms of the International Underwriting Agreement relating to the International Offering which is expected to be entered into on or around Tuesday, February 15, 2022. If, for any reason, the Offer Price is not agreed among us and the Joint Global Coordinators (for themselves and on behalf of the Underwriters) on or before Tuesday, February 22, 2022, the Global Offering will not proceed and will lapse. Further information regarding the Underwriters and the Underwriting Agreements are set out in the section headed "Underwriting" in this prospectus.



Shanghai Miracogen Inc.- Ex. 2032, Page 000164

The Hong Kong Offer Shares are offered solely on the basis of the information contained and representations made in this prospectus and on the terms and subject to the conditions set out herein and therein. No person is authorized to give any information in connection with the Global Offering or to make any representation not contained in this prospectus, and any information or representation not contained herein and therein must not be relied upon as having been authorized by our Company, the Joint Sponsors, the Joint Global Coordinators, the Joint Bookrunners, the Joint Lead Managers, the Underwriters, any of their respective directors, officers, employees, partners, agents, employees or advisors or any other party involved in the Global Offering.

Neither the delivery of this prospectus nor any subscription or acquisition made under it shall, under any circumstances, constitute a representation that there has been no change or development reasonably likely to involve a change in our affairs since the date of this prospectus or imply that the information contained in this prospectus is correct as of any date subsequent to the date of this prospectus.

Further information regarding the structure of the Global Offering, including its conditions, are set out in the section headed "Structure of the Global Offering", and the procedures for applying for our Hong Kong Offer Shares are set out in the section headed "How to Apply for Hong Kong Offer Shares" in this prospectus.

## RESTRICTIONS ON OFFER AND SALE OF THE OFFER SHARES

Each person acquiring the H Shares under the Hong Kong Public Offering will be required to, or be deemed by his/her acquisition of the Hong Kong Offer Shares to, confirm that he/she is aware of the restrictions on offers and sales of the H Shares described in this prospectus.

No action has been taken to permit a public offering of the H Shares in any jurisdiction other than Hong Kong, and no action has been taken to permit the distribution of this prospectus in any jurisdiction other than Hong Kong. Accordingly, without limitation to the following, this prospectus may not be used for the purpose of, and does not constitute, an offer or invitation in any jurisdiction or in any circumstances in which such an offer or invitation is not authorized or to any person to whom it is unlawful to make such an offer or invitation. The distribution of this prospectus and the offering and sales of the Offer Shares in other jurisdictions are subject to restrictions and may not be made except as permitted under the applicable securities laws of such jurisdictions pursuant to registration with or authorization by the relevant securities regulatory authorities or an exemption therefrom. In particular, the H Shares have not been publicly offered or sold, directly or indirectly, in the PRC or the United States.


Shanghai Miracogen Inc.- Ex. 2032, Page 000165

## APPLICATION FOR LISTING OF THE H SHARES ON THE STOCK EXCHANGE

We have applied to the Stock Exchange for the granting of the listing of, and permission to deal in, the H Shares to be issued by us pursuant to the Global Offering (including any H Shares which may be issued pursuant to the exercise of the Over-allotment Option) and the H Shares to be converted from the Domestic Shares and the Unlisted Foreign Shares.

Dealings in the H Shares on the Stock Exchange are expected to commence on Wednesday, February 23, 2022. Save as disclosed in this prospectus, no part of our Shares or loan capital is listed or dealt in on any other stock exchange and no such listing or permission to list is being or proposed to be sought on any other stock exchange as of the date of this prospectus. All the Offer Shares will be registered on the Hong Kong register of members of the Company in order to enable them to be traded on the Stock Exchange.

Under section 44B(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance, any allotment made in respect of any application will be invalid if the listing of, and permission to deal in, our H Shares on the Stock Exchange pursuant to this prospectus has been refused before the expiration of three weeks from the date of the closing of the application lists, or such longer period (not exceeding six weeks) as may, within the said three weeks, be notified to the Company by or on behalf of the Stock Exchange.

## PROFESSIONAL TAX ADVICE RECOMMENDED

Potential investors in the Global Offering are recommended to consult their professional advisors as to the taxation implications of subscribing for, purchasing, holding or disposal of, and/or dealing in the H Shares or exercising rights attached to them. None of us, the Joint Sponsors, the Joint Global Coordinators, the Joint Bookrunners, the Joint Lead Managers, the Underwriters, any of their respective directors, officers, employees, partners, agents, advisors or representatives or any other person or party involved in the Global Offering accepts responsibility for any tax effects on, or liabilities of, any person resulting from the subscription, purchasing, holding, disposition of, or dealing in, the H Shares or exercising any rights attached to them.

## OVER-ALLOTMENT OPTION AND STABILIZATION

Details of the arrangements relating to the Over-allotment Option and stabilization are set out under the sections headed "Underwriting" and "Structure of the Global Offering" in this prospectus.



Shanghai Miracogen Inc.- Ex. 2032, Page 000166

## H SHARES WILL BE ELIGIBLE FOR ADMISSION INTO CCASS

Subject to the granting of the listing of, and permission to deal in, the H Shares on the Stock Exchange and compliance with the stock admission requirements of HKSCC, the H Shares will be accepted as eligible securities by HKSCC for deposit, clearance and settlement in CCASS with effect from the date of commencement of dealings in the H Shares on the Stock Exchange or on any other date as determined by HKSCC. Settlement of transactions between participants of the Stock Exchange is required to take place in CCASS on the second settlement day after any trading day. All activities under CCASS are subject to the General Rules of CCASS and CCASS Operational Procedures in effect from time to time.

All necessary arrangements have been made enabling the H Shares to be admitted into CCASS. Investors should seek the advice of their stockbrokers or other professional advisors for details of the settlement arrangements as such arrangements may affect their rights and interests.

## REGISTRATION OF SUBSCRIPTION, PURCHASE AND TRANSFER OF H SHARES

We have instructed the H Share Registrar, and the H Share Registrar has agreed, not to register the subscription, purchase or transfer of any H Shares in the name of any particular holder unless the holder delivers a signed form to the H Share Registrar in respect of those H Shares bearing statements to the effect that the holder:

(1) agrees with us and each of our Shareholders, and we agree with each Shareholder, to observe and comply with the PRC Company Law, the Companies Ordinance, the Companies (Winding Up and Miscellaneous Provisions) Ordinance, the Special Regulations and our Articles of Association;

(2) agrees with us, each of our Shareholders, Directors, Supervisors, managers and officers, and we, acting for ourselves and for each of our Directors, Supervisors, managers and officers agree with each Shareholder, to refer all differences and claims arising from our Articles of Association or any rights or obligations conferred or imposed by the PRC Company Law or other relevant laws and administrative regulations concerning our affairs to arbitration in accordance with our Articles of Association, and any reference to arbitration shall be deemed to authorize the arbitration tribunal to conduct hearings in open session and to publish its award, which shall be final and conclusive;

(3) agrees with us and each of our Shareholders that our H Shares are freely transferable by the holders thereof; and

(4) authorizes us to enter into a contract on his or her behalf with each of our Directors, Supervisors, managers and officers whereby such Directors, Supervisors, managers and officers undertake to observe and comply with their obligations to our Shareholders as stipulated in our Articles of Association. Persons applying for or purchasing H Shares under the Global Offering are deemed, by their making an application or purchase, to have represented that they are not close associates (as such term is defined in the Listing Rules) of any of the Directors of our Company or any existing Shareholders of our Company or a nominee of any of the foregoing.



Shanghai Miracogen Inc.- Ex. 2032, Page 000167

## PROCEDURES FOR APPLICATION FOR HONG KONG OFFER SHARES

The procedures for applying for Hong Kong Offer Shares are set out in the section headed "How to Apply for the Hong Kong Offer Shares" in this prospectus.

## H SHARE REGISTER AND STAMP DUTY

All of the Offer Shares will be registered on the H Share register of members of our Company maintained by our H Share Registrar, Computershare Hong Kong Investor Services Limited, in Hong Kong. Our register of members will also be maintained by us at our legal address in the PRC.

Dealings in the H Shares registered on the H Share register of members of our Company in Hong Kong will be subject to Hong Kong stamp duty. The stamp duty is charged to each of the seller and purchaser at the ad valorem rate of 0.13% of the consideration for, or (if greater) the value of, the H Shares transferred. In other words, a total of 0.26% is currently payable on a typical sale and purchase transaction of the H Shares. In addition, a fixed duty of HK$5 is charged on each instrument of transfer (if required).

Unless determined otherwise by our Company, dividends payable in respect of our H Shares will be paid to the Shareholders listed on the H Share register of our Company in Hong Kong, by ordinary post, at the Shareholders' risk, to the registered address of each Shareholder of our Company.

## STRUCTURE OF THE GLOBAL OFFERING

Details of the structure of the Global Offering, including its conditions, are set out in the section headed "Structure of the Global Offering" in this prospectus.

## EXCHANGE RATE CONVERSION

Solely for your convenience, this prospectus contains translations among certain amounts denominated in Renminbi, Hong Kong dollars and U.S. dollars. No representation is made that the amounts denominated in one currency could actually be converted into the amounts denominated in another currency at the rates indicated or at all. Unless indicated otherwise, (i) the translations between Renminbi and U.S. dollars were made at the rate of RMB6.37460 to US$1.00, being the PBOC rate prevailing on January 28, 2022, (ii) the translations between Hong Kong dollars and Renminbi were made at the rate of RMB0.81824 to HK$1.00, being the PBOC rate prevailing on January 28, 2022; and (iii) the translations between U.S. dollars and Hong Kong dollars were made at the rate of HK$7.79300 (H10 weekly statistical release of the Federal Reserve Board of the U.S. on January 28, 2022) to US$1.00. Any discrepancies in any table between totals and sums of amounts listed therein are due to rounding.



Shanghai Miracogen Inc.- Ex. 2032, Page 000168

## LANGUAGE

If there is any inconsistency between this prospectus and the Chinese translation of this prospectus, this prospectus shall prevail. However, the English names of the PRC nationals, entities, departments, facilities, certificates, titles, laws, regulations and the like are translations of their Chinese names and are included for identification purposes only. If there is any inconsistency, the Chinese name prevails.

## ROUNDING AND OTHERS

Certain amounts and percentage figures included in this prospectus have been subject to rounding adjustments, or have been rounded to one or two decimal places. Any discrepancies in any table, chart or elsewhere between totals and sums of amounts listed therein are due to rounding.

Unless otherwise specified, all references to any shareholdings in our Company following the completion of the Global Offering assume that the Over-allotment Option is not exercised.



Shanghai Miracogen Inc.- Ex. 2032, Page 000169

*For further information on our Directors and Supervisors, please refer to the section headed "Directors, Supervisors and Senior Management" of this prospectus.*

**DIRECTORS**

| Name | Address | Nationality |
|---|---|---|
| **Executive Director** | | |
| Dr. Pu Zhongjie (蒲忠傑) | No. 401, Gate 3, 3rd Floor<br>No. 9 Courtyard<br>Anningzhuang West Road<br>Haidian District<br>Beijing<br>PRC | Chinese |
| Dr. Sui Ziye (隋滋野) | Room 101, Unit 3<br>Building 8<br>Jinyu Lanwan<br>No. 35 Zhenxing Road<br>Changping District<br>Beijing<br>PRC | Chinese |
| Dr. Hu Chaohong (胡朝紅) | 21109 50th Dr. SE, Bothell<br>WA 98021<br>USA | American |
| **Non-Executive Directors** | | |
| Ms. Pu Jue (蒲珏) | No. 401, Gate 3, 3rd Floor<br>No. 9 Courtyard<br>Anningzhuang West Road<br>Haidian District<br>Beijing<br>PRC | American |
| Mr. Yang Hongbing (楊紅冰) | Building 15, 4th district<br>Lilai Garden<br>Shunyi District<br>Beijing<br>PRC | Chinese |
| Mr. Lin Xianghong (林向紅) | Room 301, Building 16<br>Sudu Garden<br>Suzhou Industrial Park<br>Suzhou City<br>Jiangsu Province<br>PRC | Chinese |



Shanghai Miracogen Inc.- Ex. 2032, Page 000170

**Independent non-executive Directors**

| | | |
|---|---|---|
| Mr. Zhou Demin (周德敏) | No.5, 10/F, Building 26<br>No. 38 Xueyuan Road<br>Haidian District, Beijing<br>PRC | Chinese |
| Mr. Yang Haifeng (楊海峰) | Flat A, 18/F, Tower 3A<br>Cullinan West II<br>28 Sham Mong Road<br>Sham Shui Po, Kowloon<br>Hong Kong | Chinese |
| Mr. Fengmao Hua (華風茂) | 55A Tower 2, The Legend<br>23 Tai Hang Drive<br>Tai Hang<br>Hong Kong | Chinese (Hong Kong) |

**Supervisors**

| | | |
|---|---|---|
| Mr. Xu Yang (徐揚) | 2-7-602, Zhuxi Garden<br>Yayun Legacy Homes<br>Xindian Road<br>Chaoyang District<br>Beijing<br>PRC | Chinese |
| Mr. Yang Ming (楊明) | Room 2101, 21/F, Unit 5<br>Building 12, Yard 38<br>Longshui Road<br>Changping District<br>Beijing<br>PRC | Chinese |
| Mr. Wang Jiwei (王倚緯) | Room 202, Unit 5<br>No.19 Tuoranjiayuan<br>Changping District<br>Beijing<br>PRC | Chinese |



Shanghai Miracogen Inc.- Ex. 2032, Page 000171

## PARTIES INVOLVED IN THE GLOBAL OFFERING

| | |
|---|---|
| **Joint Sponsors** | **China International Capital Corporation Hong Kong Securities Limited**<br>29/F, One International Finance Centre<br>1 Harbour View Street<br>Central<br>Hong Kong<br>*(in alphabetical order)*<br><br>**Morgan Stanley Asia Limited**<br>46th Floor, International Commerce Centre<br>1 Austin Road West<br>Kowloon<br>Hong Kong<br>*(in alphabetical order)* |
| **Joint Global Coordinators** | **China International Capital Corporation Hong Kong Securities Limited**<br>29/F, One International Finance Centre<br>1 Harbour View Street<br>Central<br>Hong Kong<br>*(in alphabetical order)*<br><br>**Morgan Stanley Asia Limited**<br>46th Floor, International Commerce Centre<br>1 Austin Road West<br>Kowloon<br>Hong Kong<br>*(in alphabetical order)* |
| **Joint Bookrunners** | **China International Capital Corporation Hong Kong Securities Limited**<br>29/F, One International Finance Centre<br>1 Harbour View Street<br>Central<br>Hong Kong<br>*(in alphabetical order)* |



Shanghai Miracogen Inc.- Ex. 2032, Page 000172

**Morgan Stanley Asia Limited**
(in relation to the Hong Kong Public Offering only)
46th Floor, International Commerce Centre
1 Austin Road West
Kowloon
Hong Kong
*(in alphabetical order)*

**Morgan Stanley & Co. International plc**
(in relation to the International Offering only)
25 Cabot Square, Canary Wharf
London E14 4QA
United Kingdom
*(in alphabetical order)*

**Haitong International Securities Company Limited**
22/F, Li Po Chun Chambers
189 Des Voeux Road Central
Hong Kong

**Huatai Financial Holdings (Hong Kong) Limited**
62nd Floor, The Center
99 Queens' Road Central
Hong Kong

**China Galaxy International Securities (Hong Kong) Co., Limited**
20/F, Wing On Centre
111 Connaught Road Central
Hong Kong

**Valuable Capital Limited**
Room 3601, 36/F, China Merchants Tower
Shun Tak Centre
168-200 Connaught Road Central
Hong Kong


Shanghai Miracogen Inc.- Ex. 2032, Page 000173

**Joint Lead Managers**

**China International Capital Corporation Hong Kong Securities Limited**
29/F, One International Finance Centre
1 Harbour View Street
Central
Hong Kong
*(in alphabetical order)*

**Morgan Stanley Asia Limited**
(in relation to the Hong Kong Public Offering only)
46th Floor, International Commerce Centre
1 Austin Road West
Kowloon
Hong Kong
*(in alphabetical order)*

**Morgan Stanley & Co. International plc**
(in relation to the International Offering only)
25 Cabot Square, Canary Wharf
London E14 4QA
United Kingdom
*(in alphabetical order)*

**Haitong International Securities Company Limited**
22/F, Li Po Chun Chambers
189 Des Voeux Road Central
Hong Kong

**Huatai Financial Holdings (Hong Kong) Limited**
62nd Floor, The Center
99 Queens' Road Central
Hong Kong

**China Galaxy International Securities (Hong Kong) Co., Limited**
20/F, Wing On Centre
111 Connaught Road Central
Hong Kong

**Valuable Capital Limited**
Room 3601, 36/F, China Merchants Tower
Shun Tak Centre
168-200 Connaught Road Central
Hong Kong

**Tiger Brokers (HK) Global Limited**
(in relation to the International Offering only)
18th Floor, Central 88
88-98 Des Voeux Road Central
Hong Kong


Shanghai Miracogen Inc.- Ex. 2032, Page 000174

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| **Independent Auditor and Reporting Accountant** | **PricewaterhouseCoopers**<br>*Certified Public Accountants and Registered Public Interest Entity Auditor*<br>22/F, Prince's Building<br>Central, Hong Kong |
| **Legal Advisors to the Company** | *As to Hong Kong and U.S. laws:*<br>**Clifford Chance**<br>27/F, Jardine House<br>One Connaught Place<br>Central<br>Hong Kong<br><br>*As to PRC law:*<br>**Zhong Lun Law Firm**<br>23-31/F, South Tower of CP Center<br>20 Jin He East Avenue<br>Chaoyang District<br>Beijing<br>PRC |
| **Legal Advisors to the Joint Sponsors and the Underwriters** | *As to Hong Kong and U.S. laws:*<br>**Herbert Smith Freehills**<br>23/F, Gloucester Tower<br>15 Queen's Road Central<br>Hong Kong<br><br>*As to PRC law:*<br>**Haiwen & Partners**<br>20/F, Fortune Financial Center<br>5 Dong San Huan Central Road<br>Chaoyang District, Beijing<br>PRC |
| **Industry Consultant** | **Frost & Sullivan (Beijing) Inc. Shanghai Branch Co.**<br>2504, Wheelock Square<br>1717 Nanjing West Road<br>Shanghai<br>PRC |



Shanghai Miracogen Inc.- Ex. 2032, Page 000175

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| **Property Valuer** | **AVISTA Valuation Advisory Limited**<br>23rd Floor, Siu On Centre<br>No. 188 Lockhart Road<br>Wan Chai<br>Hong Kong |
| **Compliance Advisor** | **Maxa Capital Limited**<br>Unit 1908 Harbour Center<br>25 Harbour Road<br>Wanchai<br>Hong Kong |
| **Receiving Banks** | **CMB Wing Lung Bank Limited**<br>45 Des Voeux Road Central<br>Hong Kong |
| | **Bank of China (Hong Kong) Limited**<br>1 Garden Road<br>Hong Kong |


Shanghai Miracogen Inc.- Ex. 2032, Page 000176

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|---|---|
| **Registered Office** | Room C280, Building 1<br>No. 1628, Su Zhao Road<br>Minhang District, Shanghai<br>PRC |
| **Head Office and Principal Place of Business in the PRC** | 2nd Floor, Building 41<br>Lane 518, Xinzhuan Road<br>Songjiang District, Shanghai<br>PRC |
| **Principal Place of Business in Hong Kong** | Level 54, Hopewell Centre<br>183 Queen's Road East<br>Wanchai<br>Hong Kong |
| **Company's Website** | **http://www.lepubiopharma.com**<br>*(information on this website does not form part of this prospectus)* |
| **Joint Company Secretaries** | **Ms. Li Yunyi (李昀轶)**<br>No. 22, Beiwa Xili<br>Haidian District, Beijing<br>PRC<br><br>**Ms. Lai Siu Kuen (黎少娟)** *(FCIS, FCS)*<br>Level 54, Hopewell Centre<br>183 Queen's Road East<br>Hong Kong |
| **Authorized Representatives** | **Dr. Pu Zhongjie (蒲忠傑)**<br>No. 401, Gate 3<br>3rd Floor, No. 9 Courtyard<br>Anningzhuang West Road<br>Haidian District, Beijing<br>PRC<br><br>**Ms. Lai Siu Kuen (黎少娟)**<br>Level 54, Hopewell Centre<br>183 Queen's Road East<br>Hong Kong |
| **Audit Committee** | Mr. Fengmao Hua (華風茂) *(Chairman)*<br>Mr. Yang Haifeng (楊海峰)<br>Ms. Pu Jue (蒲珏) |



Shanghai Miracogen Inc.- Ex. 2032, Page 000177

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| **Remuneration and Appraisal Committee** | Mr. Yang Haifeng (楊海峰) *(Chairman)*<br>Mr. Fengmao Hua (華風茂)<br>Dr. Pu Zhongjie (蒲忠傑) |
| **Nomination Committee** | Mr. Zhou Demin (周德敏) *(Chairman)*<br>Mr. Yang Haifeng (楊海峰)<br>Dr. Pu Zhongjie (蒲忠傑) |
| **Strategy Committee** | Dr. Pu Zhongjie (蒲忠傑) *(Chairman)*<br>Dr. Sui Ziye (隋滋野)<br>Mr. Zhou Demin (周德敏) |
| **H Share Registrar** | **Computershare Hong Kong Investor Services Limited**<br>Shops 1712-1716, 17th Floor<br>Hopewell Centre<br>183 Queen's Road East<br>Wan Chai<br>Hong Kong |
| **Principal Bank(s)** | **Industrial and Commercial Bank of China Shanghai Xinzhuang Industrial District Sub-branch**<br>No. 3800 Jindu Road<br>Minhang District<br>Shanghai<br>China<br><br>**Agricultural Bank of China Shanghai Branch Minhang Sub-branch**<br>No. 68 South Shuiqing Road<br>Minhang District<br>Shanghai<br>China<br><br>**China Merchants Bank Shanghai Minhang Sub-branch**<br>No. 365, Xinsong Road<br>Minhang District<br>Shanghai<br>China |



Shanghai Miracogen Inc.- Ex. 2032, Page 000178

**Shanghai Pudong Development Bank**
**Shanghai Branch Hongkou Sub-branch**
No. 731, Quyang Road
Hongkou District
Shanghai
China

**Industrial Bank Co.,Ltd. Shanghai**
**Changning Sub-branch**
No. 6, Lane 800, Huashan Road
Changning District
Shanghai
China


Shanghai Miracogen Inc.- Ex. 2032, Page 000179

*The information and statistics set out in this section and other sections of this Prospectus have been extracted from various official government publications, available sources from public market research and other sources from independent suppliers, and from the independent report (the "**Frost & Sullivan Report**") prepared by Frost & Sullivan. We engaged Frost & Sullivan to prepare the Frost & Sullivan Report, an independent industry report, in connection with the Global Offering. The information from official government sources has not been independently verified by us, the Joint Global Coordinators, the Joint Sponsors, the Joint Lead Managers, the Joint Bookrunners and the Underwriters, any of their respective directors, employees, agents or advisors, or any other person or party involved in the Global Offering, and no representation is given as to its accuracy. Accordingly, the information from official government sources contained herein may not be accurate and should not be unduly relied upon.*

## GLOBAL AND CHINA BIOLOGICS MARKET

Biologics, pharmaceutical products manufactured using biological methods and sources, are designed to replicate the activities of natural substances such as enzymes, antibodies or hormones. The major types of biologics include antibodies, fusion proteins, ADCs, recombinant proteins, vaccines, gene therapies and cell therapies. Biologics such as ADCs have significant clinical and market potential.

The global and China biologics markets experienced rapid growth in the recent years and are expected to grow significantly in the near future. Driven by increasing market demand, the market size of biologics in China was RMB312.0 billion in 2019, and is expected to reach RMB712.5 billion and RMB1,302.9 billion in 2024 and 2030, respectively, representing a CAGR of 18.0% from 2019 to 2024 and a CAGR of 10.6% from 2024 to 2030. The market size of biologics globally was US$286.4 billion in 2019, and is expected to reach US$456.7 billion and US$768.0 billion in 2024 and 2030, respectively, representing a CAGR of 9.8% from 2019 to 2024 and a CAGR of 9.0% from 2024 to 2030.

The PRC government promulgated a number of regulations and policies to support the development of China's biologics market. Notably, in October 2017, the *Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices* (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》) was promulgated by the General Office of the CPC Central Committee and the General Office of the State Council and aimed at improving the regulatory regime for the biologics industry and encouraging technological innovation for new drugs. Also, as a result of these favorable policies, the NMPA accelerated the review and approval process for innovative drugs. See "Regulatory Overview."


Shanghai Miracogen Inc.- Ex. 2032, Page 000180

## THE ONCOLOGY DRUG MARKET

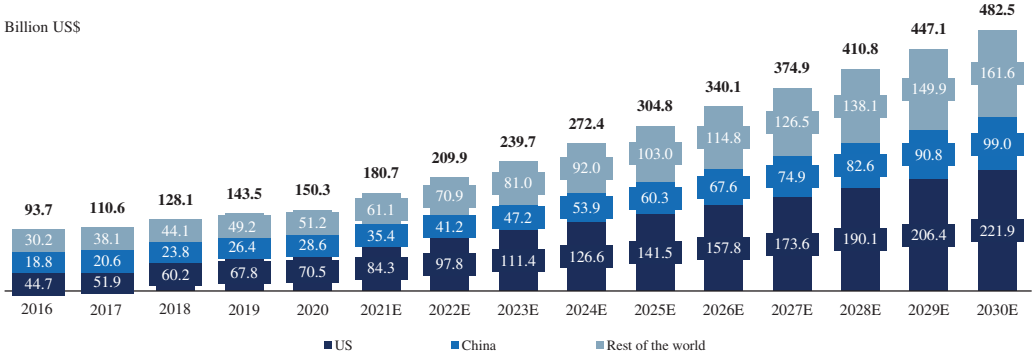
Cancer is a broad group of diseases in which cells divide and grow uncontrollably. Cancer types are usually classified as either hematological malignancies or solid tumors. It is one of the leading causes of mortality worldwide. The overall five-year survival rate of cancer patients in China was 40.5%. In comparison, the overall five-year survival rate of cancer patients in the U.S. was 67.1%. In 2020, the top five most common cancer types in China were lung cancer, stomach cancer, colorectal cancer, liver cancer and thyroid cancer, respectively, while the top five most common cancer types in the U.S. were breast cancer, lung cancer, prostate cancer, colorectal cancer and skin cancer, respectively.

New cancer cases, both worldwide and in China, have been constantly increasing. Globally, the number of new cancer cases was 19.3 million in 2020, and is expected to reach 21.6 million and 24.0 million in 2025 and 2030, respectively, representing a CAGR of 2.4% from 2020 to 2025 and a CAGR of 2.1% from 2025 to 2030. In China, the number of new cancer cases was 4.6 million in 2020, and is expected to reach 5.2 million and 5.8 million in 2025 and 2030, respectively, representing a CAGR of 2.6% from 2020 to 2025 and a CAGR of 2.3% from 2025 to 2030.

Significantly outpacing the growth rate of new cancer cases, the global oncology drug market and the oncology drug markets in China and the U.S. have demonstrated robust growth and are expected to continue the high growth rate in the near future. The size of the global oncology drug market was US$150.3 billion in 2020, and is expected to reach US$304.8 billion and US$482.5 billion in 2025 and 2030, respectively, representing a CAGR of 15.2% from 2020 to 2025 and a CAGR of 9.6% from 2025 to 2030. The size of the oncology market in China was US$28.6 billion in 2020, and is expected to reach US$60.3 billion and US$99.0 billion in 2025 and 2030, respectively, representing a CAGR of 16.1% from 2020 to 2025 and a CAGR of 10.4% from 2025 to 2030. The size of the oncology market in the U.S. was US$70.5 billion in 2020, and is expected to reach US$141.5 billion and US$221.9 billion in 2025 and 2030, respectively, representing a CAGR of 15.0% from 2020 to 2025 and a CAGR of 9.4% from 2025 to 2030.

**Breakdown of Oncology Drug Market by Region, 2016-2030E**

| Period | CAGR | | | |
|---|---|---|---|---|
| | U.S. | China | Rest of the world | Global |
| 2016 -2020 | 12.1% | 11.1% | 14.1% | 12.5% |
| 2020 -2025E | 15.0% | 16.1% | 15.0% | 15.2% |
| 2025E -2030E | 9.4% | 10.4% | 9.4% | 9.6% |




*Source: Annual Reports of Listed Pharmaceutical Companies, NMPA, CDE, NRDL, Frost & Sullivan*



Shanghai Miracogen Inc.- Ex. 2032, Page 000181

In 2019, the global oncology drug market was dominated by targeted therapy drugs which, in terms of sales revenue, accounted for 62.7% of the total global oncology drug market, while chemotherapy drugs and immunotherapy drugs accounted for 17.1% and 20.3% of the market, respectively. In 2030, the global oncology drug market is expected to be dominated by targeted therapy drugs and immunotherapy drugs which, in terms of sales revenue, are expected to account for 49.5% and 44.0% of the global oncology drug market, respectively, while chemotherapy drugs are expected to account for the remaining 6.6% of the global oncology drug market.

In 2019, China's oncology drug market was dominated by chemotherapy drugs which, in terms of sales revenue, accounted for 72.6% of China's oncology drug market, while targeted therapy and immunotherapy drugs accounted for 23.4% and 4.0% of the market, respectively. In 2030, targeted therapy drugs are expected to take 54.0% of China's oncology drug market, in terms of sales revenue, while immunotherapy drugs and chemotherapy drugs are expected to account for 35.7% and 10.3% of China's oncology market, respectively.

The oncology market in China is primarily driven by the following factors:

- **Large and growing cancer patient population**: China has the world's highest annual cancer incidence, which has increased steadily in the past five years from 4.0 million in 2015 to 4.4 million in 2019, and is projected to reach 5.7 million in 2030. The top five cancer types in terms of incidence are lung cancer, colorectal cancer, stomach cancer, liver cancer and breast cancer. The top five cancer types in terms of mortality are lung cancer, stomach cancer, liver cancer, esophageal cancer and colorectal cancer. The increases in the number of cancer cases and deaths in China are expected to lead to an overall expansion of the oncology drug market in China.

- **The increase of per capita disposable income**: The per capita disposable income of the Chinese population is expected to continue to grow in the near future, which is expected to increase patients' affordability for more expensive treatments.

- **The support of relevant policies**: In recent years, regulation and policy environment in China have been encouraging to innovative drugs. For example, priority review and the marketing authorization holder system (上市許可持有人制度) have greatly promoted the research and development of China's oncology drug industry and led to more advanced research on technology and clinical applications of oncology drugs.

The major oncology therapy options available in the market are surgery, chemotherapy, radiotherapy, targeted therapy and immuno-therapy.


Shanghai Miracogen Inc.- Ex. 2032, Page 000182

## THE ADC MARKET

ADCs are complex molecules each composed of an antibody linked to a biologically active cytotoxic agent. By combining the specific targeting ability of antibodies with cytotoxic drugs, ADCs allow sensitive discrimination between healthy and diseased tissues. ADC represents a novel therapeutic approach in oncology which functions by selectively delivering potent chemotherapy cytotoxins directly to tumor cells, with the goal of maximizing therapeutic activity in tumor cells while minimizing toxicity to healthy cells. An ADC consists of three components:

(i) a mAb that selectively targets a distinct antigen preferentially expressed on tumor cells or other cells in the tumor microenvironment;

(ii) a cytotoxic chemotherapy payload, usually consists of a microtubule inhibitor such as MMAE or DM1, or a DNA-damaging agent, that kills the target cell; and

(iii) a linker that joins the two, which is designed to be stable in circulation and capable of releasing the payload inside the target cell.

As of the Latest Practicable Date, the FDA had approved 12 ADC drugs in the U.S. and the NMPA had approved three ADC drugs in China. The table below illustrates the indications, treatment line, approval status, reimbursement status and patent expiration date of marketed ADCs in China and the U.S. as of the Latest Practicable Date:



Shanghai Miracogen Inc.- Ex. 2032, Page 000183

## Marketed ADCs in China and the U.S.

| Drugs | Company | Target | Indication | Treatment Line | FDA Approval | NMPA Approval | NRDL Status | Patent Expiration Date |
|---|---|---|---|---|---|---|---|---|
| **Zynlonta** (loncastuximab tesirine-lpyl, Lonca) | ADC Therapeutics | CD19 | • relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low grade lymphoma, and high-grade B-cell lymphoma. | ≥2L | 2021.04 | N.A. | – | N.A. |
| **Blenrep** (Belantamab mafodotin) | GSK, Seattle Genetics | BCMA | • Relapsed or refractory **multiple myeloma** who have received at least 4 prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent. | ≥2L | 2020.08 | N.A. | – | 2040 |
| **Trodelvy** (Sacituzumab govitecan-hziy) | Immuno-medics | Trop-2 | • **Metastatic triple-negative breast cancer** | ≥1L | 2020.04 | N.A. | – | 2023 |
| **Enhertu**® (Trastuzumab deruxtecan-nxki) | Astra-Zeneca | HER-2 | • For the treatment of adult patients with unresectable or metastatic **HER2-positive breast cancer** who have received two or more prior anti-HER2-based regimens in the metastatic setting. | ≥2L | 2019.12 | N.A. | – | 2033 |
| **Padcev**® (Enfortumab vedotin-ejfv) | Astellas | Nectin-4 | • For the treatment of adult patients with locally advanced or metastatic **urothelial cancer** who have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor, and a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting. | ≥2L | 2019.12 | N.A. | – | 2031 |
| **Polivy**® (Polatuzumab vedotin-piiq) | Genentech (Roche) | CD79b | • In combination with bendamustine and a rituximab product for the treatment of adult patients with relapsed or refractory **diffuse large B-cell lymphoma**, not otherwise specified, after at least two prior therapies. | ≥2L | 2019.06 | N.A. | – | 2028 |



Shanghai Miracogen Inc.- Ex. 2032, Page 000184

| Drugs | Company | Target | Indication | Treatment Line | FDA Approval | NMPA Approval | NRDL Status | Patent Expiration Date |
|---|---|---|---|---|---|---|---|---|
| **Lumoxiti®** (Moxetumomab pasudotox-tdfk) | Astra-Zeneca | CD22 | • For the treatment of adult patients with relapsed or refractory **hairy cell leukemia (HCL)** who received at least two prior systemic therapies, including treatment with a purine nucleoside analog (PNA). | ≥2L | 2018.09 | N.A. | – | 2030 |
| **Mylotarg®** (Gemtuzumab ozogamicin) | Wyeth (Pfizer) | CD33 | • For treatment of newly-diagnosed CD33-positive **acute myeloid leukemia (AML)** in adults.<br>• For treatment of relapsed or refractory CD33-positive AML in adults and in pediatric patients 2 years and older. | ≥1L | 2017.09 | N.A. | – | 2022 |
| **Besponsa®** (Inotuzumab ozogamicin) | Wyeth (Pfizer) | CD22 | • For the treatment of adults with relapsed or refractory **B-cell precursor acute lymphoblastic leukemia (ALL)**. | ≥1L | 2017.08 | N.A. | – | 2032 |
| **Kadcyla®** (Adotrastuzumab emtansine) | Genentech (Roche) | HER-2 | • For the treatment of patients with **HER2-positive, metastatic breast cancer** who previously received trastuzumab and a taxane, separately or in combination.<br>• As the adjuvant treatment of patients with HER2-positive early breast cancer who have residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment. | ≥2L | 2013.02 | 2020.01 | No | 2023 |



Shanghai Miracogen Inc.- Ex. 2032, Page 000185

| Drugs | Company | Target | Indication | Treatment Line | FDA Approval | NMPA Approval | NRDL Status | Patent Expiration Date |
|---|---|---|---|---|---|---|---|---|
| **Adcetris®** (Brentuximab vedotin) | Seattle Genetics | CD30 | • For the treatment of previously untreated Stage III or IV **classical Hodgkin lymphoma (cHL)**, in combination with doxorubicin, vinblastine, and dacarbazine.<br>• Previously untreated **systemic anaplastic large cell lymphoma (sALCL)** or other CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified, in combination with cyclophosphamide, doxorubicin, and prednisone. | ≥1L | 2011.08 | 2020.05 | No | 2020 |
| | | | • Classical Hodgkin lymphoma (cHL) at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation (auto-HSCT) consolidation.<br>• Classical Hodgkin lymphoma (cHL) after failure of auto-HSCT or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not auto-HSCT candidates.<br>• Systemic anaplastic large cell lymphoma (sALCL) after failure of at least one prior multi-agent chemotherapy regimen. Primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF) who have received prior systemic therapy. | ≥2L | | | | |
| **Aidixi** (Disitamab Vedotin) | RemeGen Co., Ltd | HER-2 | • locally advanced or metastatic gastric cancer (including gastroesophageal junction adenocarcinoma) who have received at least 2 types of systemic chemotherapy.<br>• locally advanced or metastatic urothelial carcinoma who have previously received platinum based chemotherapy and HER2 overexpression, i.e. immunohistochemical results of 2 + or 3 +. | ≥2L | N.A. | 2021.06 | 2021.11 | N.A. |
| **TIVDAK** (Tisotumab vedotin-tftv) | Seagen Inc./Genmab | TF | • recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. | ≥2L | 2021.09 | N.A. | – | N.A. |

*Source: NMPA, FDA, Frost & Sullivan*



Shanghai Miracogen Inc.- Ex. 2032, Page 000186

Traditional oncology therapies such as antibody drugs and chemotherapies each have their respective limitations. The safety and efficacy profile of antibody drugs are interfered by problems such as batch differences, background signal interference and side effects. On the other hand, traditional chemotherapies demonstrate high level of off-target toxicity and may lead to increased risk of infection, hair loss and nausea, as they are unable to distinguish healthy cells from tumor cells. In comparison, ADCs possess unique targeting capabilities and have shown encouraging clinical trial results, making them a promising treatment option for cancer patients. ADCs combine the major advantages of antibody therapy, chemotherapy and small molecule inhibitor therapies, and demonstrate the following advantages in comparison with traditional oncology therapies:

- **Specificity**: The antibody part of an ADC enables accurate targeting at cancer cells directly, with greater precision and selectivity than traditional chemotherapies, providing higher efficacy.

- **Enhanced therapeutic window and efficacy**: The chemical drug payload part of an ADC provides sufficient cytotoxicity to destroy cancer cells. Since ADCs can target cancer cells with greater precision and selectivity, ADC drugs can be given to patients at a higher dosage level that would otherwise be intolerable in traditional chemotherapies. Such sufficiency in cytotoxicity to tumor cells further enhances the efficacy of ADCs.

- **Reduced drug resistance**: Optimized ADC combination of mAbs and payloads may help to reduce, or even potentially eliminate, the drug resistance problems of targeted drugs such as EGFR-TKIs, or its own drug resistance problems, by modifying some of the ADC components, including changing cytotoxic payload of the ADCs to toxins that are poor efflux substrates, modifying the linker to increase hydrophilicity, and modifying the linker-cytotoxic structure.

- **Synergistic effect**: ADCs benefit from the synergy of the powerful cytotoxicity of small molecule drugs and the high targeting ability of monoclonal antibodies. After the administration of ADC drugs, the antibody part specifically binds to the target cells. After being endocytosed by tumor cells, ADCs enter the lysosome for degradation, and the small molecule cytotoxic drugs are released in the cell in sufficient quantities to kill the tumor cells.

- **Large addressable patient population**: By exploring more cancer specific antibodies and novel chemical drugs with greater cytotoxicity, novel ADCs can be developed and applied to different types of cancer and to patients who respond poorly to current treatment measures. More cancer indications may be included in the ADC portfolio.

The global markets of ADC drugs have demonstrated robust growth, and both the global and China ADC drug markets are expected to maintain high growth rates in the near future. The size of the global ADC drug market was US$2.8 billion in 2019, and is expected to reach



Shanghai Miracogen Inc.- Ex. 2032, Page 000187

US$10.4 billion and US$20.7 billion in 2024 and 2030, respectively, representing a CAGR of 30.6% from 2019 to 2024 and a CAGR of 12.0% from 2024 to 2030. The ADC market in China did not emerge until 2020, and is expected to reach a size of RMB7.4 billion and RMB29.2 billion in 2024 and 2030, respectively, representing a CAGR of 25.8% from 2024 to 2030.

Besides the general drivers to the oncology drug market, the ADC therapy market in China is primarily driven by the following factors:

- **Growing pipeline of ADC drugs**: The pipeline of ADC drugs is growing due to the superior therapeutic effect of marketed ADC products. As of the Latest Practicable Date, the FDA had approved 12 ADC drugs in the U.S. and the NMPA had approved three ADC drugs in China. In addition, in China there are over 20 ADCs currently under clinical development, and seven of them are in or beyond the phase III clinical stage. The wide application of ADC drugs in different cancer types, combined with an improved patient affordability and public health awareness, will sustain the further growth of ADC market.

- **Continuous technological advancement**: Development of ADC drugs involves certain major technology challenges, including linker stability in blood circulation, nature of the linker and delivery mechanism, antigen binding, payload release and potency and conjugation sites. Extensive efforts have been made to improve all these components to enhance ADCs' targetability, safety profile and therapeutic efficacy against solid tumors and hematological cancers. The development of novel and advanced ADC drugs represents a breakthrough of technological advancement, with increased therapeutic window, improved stability, improved pharmacokinetics, slower deconjugation, higher potency, higher DAR values and improved overall hydrophilicity, in comparison with ADC drugs of the previous generations. The continuous technological advancement will further drive the growth of the ADC therapies market.

- **Broad therapeutic areas**: Current therapeutic areas and indications of available ADCs encompass a wide range of solid tumors and hematological cancers. Meanwhile, ADC drugs may potentially be applied to other therapeutic areas like infectious disease, autoimmune disease and cardiovascular diseases.

**EGFR-targeted ADC Drug Market**

EGFR signaling pathways play a key role in the regulation of cell proliferation, survival and differentiation. There are many signal transduction pathways that EGFR can mediate. EGFR is expressed in many organs and its high expression is implicated in various cancers, such as head and neck cancer, nasopharyngeal cancer and NSCLC. The commercial value of ADC therapies for EGFR-expressing cancers is well-recognized by the market.


Shanghai Miracogen Inc.- Ex. 2032, Page 000188

Examples of major indications of EGFR-targeted ADCs include head and neck cancer, nasopharyngeal cancer and NSCLC:

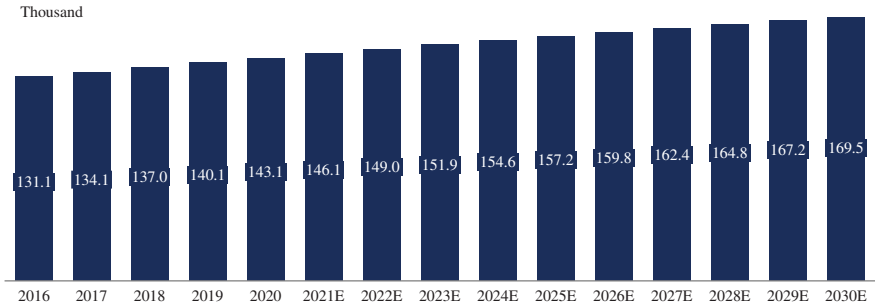
- **Head and neck cancer**:

  Head and neck cancer is a group of cancers that develops in the mouth, nose, throat, larynx, sinuses or salivary glands. Squamous cell carcinoma is a type of cancer with pathological changes in squamous cells. HNSCC occurs in the mucous membranes of the mouth, nose, and throat and accounts for more than 90% of head and neck cancer. The EGFR-positive rate of HNSCC is approximately 86.5%. The second line progression percentage is 95.9% in HNSCC in China.

  The existing size and growth of the head and neck cancer market demonstrates significant market opportunities. The size of the global head and neck cancer market was US$3.9 billion in 2020 and is expected to reach US$6.0 billion by 2025 and US$8.7 billion by 2030, respectively, representing a CAGR of 9.0% from 2020 to 2025 and a CAGR of 7.9% from 2025 to 2030, respectively. The size of the China head and neck cancer market was RMB3.0 billion in 2020 and is expected to reach RMB7.4 billion by 2025 and RMB13.0 billion by 2030, respectively, representing a CAGR of 19.8% from 2020 to 2025 and a CAGR of 12.3% from 2025 to 2030, respectively. The five-year survival rate of head and neck cancer in China and the U.S. was 66.6% and 60.6%, respectively. The number of new cases of head and neck cancer globally was 931.9 thousand in 2020, and is expected to reach 1,035.6 thousand and 1,138.6 thousand in 2025 and 2030, respectively, representing a CAGR of 2.1% from 2020 to 2025 and a CAGR of 1.9% from 2025 to 2030. The number of new cases of head and neck cancer in China was 143.1 thousand in 2020, and is expected to reach 157.2 thousand and 169.5 thousand in 2025 and 2030, respectively, representing a CAGR of 1.9% from 2020 to 2025 and a CAGR of 1.5% from 2025 to 2030.

**Incidence of Head and Neck Cancer in China, 2016-2030E**

| Period | CAGR |
|---|---|
| 2016-2020 | 2.2% |
| 2020-2025E | 1.9% |
| 2025E-2030E | 1.5% |




*Source: NCCR, Frost & Sullivan*



Shanghai Miracogen Inc.- Ex. 2032, Page 000189

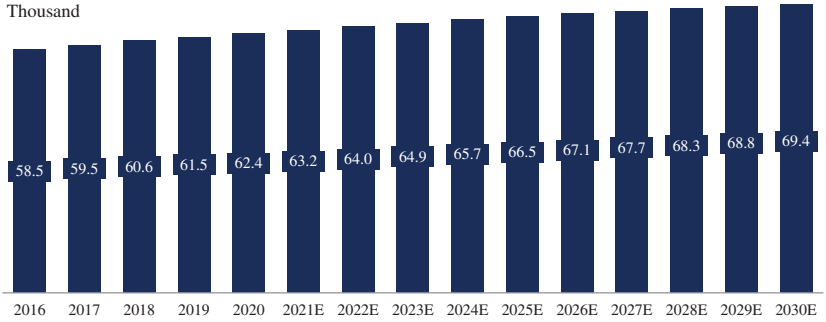
- **Nasopharyngeal cancer**:

Nasopharyngeal cancer is a type of throat cancer of the head and neck cancer group. Nasopharyngeal cancer is a disease in which cancer cells form in the tissues of the nasopharynx. Symptoms of nasopharyngeal cancer include trouble in breathing, speaking, or hearing. Nasopharyngeal cancer most commonly starts in the squamous cells that line the nasopharynx. The EGFR-positive rate of nasopharyngeal cancer is approximately 82.7%. The second line progression percentage is 88.8% in NPC in China.

The size and growth of the nasopharyngeal cancer market demonstrates significant market opportunities. The size of the global nasopharyngeal cancer market was US$0.4 billion in 2020 and is expected to reach US$0.6 billion by 2025 and US$0.8 billion by 2030, respectively, representing a CAGR of 9.1% from 2020 to 2025 and a CAGR of 8.6% from 2025 to 2030, respectively. The size of the China nasopharyngeal cancer market was RMB0.6 billion in 2020 and is expected to reach RMB1.6 billion by 2025 and RMB2.8 billion by 2030, respectively, representing a CAGR of 19.5% from 2020 to 2025 and a CAGR of 12.6% from 2025 to 2030, respectively. The five-year survival rate of nasopharyngeal cancer in China and the U.S. was 45.5% and 61.3%, respectively. The number of new cases of nasopharyngeal cancer globally was 133.4 thousand in 2020 and is expected to reach 146.9 thousand and 159.9 thousand in 2025 and 2030, respectively, representing a CAGR of 2.0% from 2020 to 2025 and a CAGR of 1.7% from 2025 to 2030. The number of new cases of nasopharyngeal cancer in China was 62.4 thousand in 2020 and is expected to reach 66.5 thousand and 69.4 thousand in 2025 and 2030, respectively, representing a CAGR of 1.3% from 2020 to 2025 and a CAGR of 0.9% from 2025 to 2030.

**Incidence of NPC in China, 2016-2030E**

| Period | CAGR |
|---|---|
| 2016-2020 | 1.6% |
| 2020-2025E | 1.3% |
| 2025E-2030E | 0.9% |




*Source: NCCR, Frost & Sullivan*



Shanghai Miracogen Inc.- Ex. 2032, Page 000190

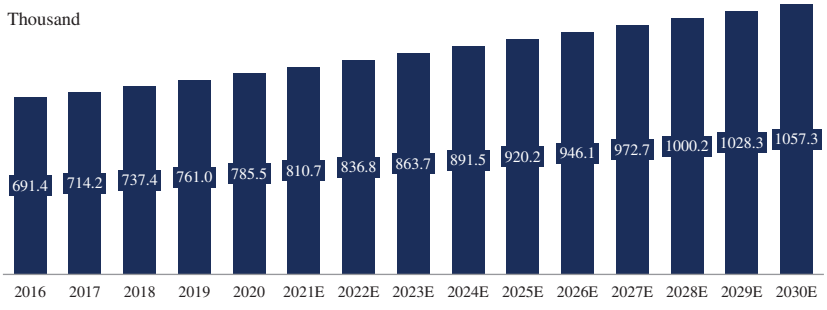
- **NSCLC**:

NSCLC is any type of epithelial lung cancer other than SCLC. The most common types of NSCLC are squamous cell carcinoma, large cell carcinoma and adenocarcinoma. All types can occur in unusual histologic variants and developed as mixed cell-type combinations. Symptoms of advanced NSCLC cases include bone pain, headache, weakness and vomiting. The EGFR-positive rate of NSCLC is approximately 60.0%. The second line progression percentage is 91.2% in NSCLC in China.

The size of the global NSCLC market was US$52.8 billion in 2020 and is expected to reach US$108.5 billion and US$172.8 billion by 2025 and 2030, respectively, representing a CAGR of 15.5% from 2020 to 2025 and a CAGR of 9.7% from 2025 to 2030. The size of the China NSCLC market was RMB42.3 billion in 2020 and is expected to reach RMB111.7 billion and RMB177.5 billion by 2025 and 2030, respectively, representing a CAGR of 21.4% from 2020 to 2025 and a CAGR of 9.7% from 2025 to 2030. The five-year survival rate of lung cancer in China and the U.S. was 19.7% and 19.4%, respectively. The number of new cases of NSCLC globally was 1,875.8 thousand in 2020 and is expected to reach 2,141.4 thousand and 2,420.7 thousand in 2025 and 2030, respectively, representing a CAGR of 2.7% from 2020 to 2025 and a CAGR of 2.5% from 2025 to 2030. The number of new cases of NSCLC in China was 785.5 thousand in 2020 and is expected to reach 920.2 thousand and 1,057.3 thousand in 2025 and 2030, respectively, representing a CAGR of 3.2% from 2020 to 2025 and a CAGR of 2.8% from 2025 to 2030.

**Incidence of NSCLC in China, 2016-2030E**

| Period | CAGR |
|---|---|
| 2016-2020 | 3.2% |
| 2020-2025E | 3.2% |
| 2025E-2030E | 2.8% |




*Source: NCCR, Frost & Sullivan*



Shanghai Miracogen Inc.- Ex. 2032, Page 000191

As of the Latest Practicable Date, there were no marketed products of EGFR-targeted ADC in China. The following table illustrates the competitive landscape of EGFR-targeted ADC drugs in China and worldwide:

**Marketed EGFR-targeted ADC Drugs Worldwide**

| Generic name | Product Name | Company | Indication | Locations | PMDA Approval Date | Price (million JYP) | Annual cost (million JYP) | Patent Expiration Date | 2020 Revenue (US$ Million) |
|---|---|---|---|---|---|---|---|---|---|
| Cetuximab Sarotalocan Sodium | Akalux | Rakuten Medical Inc. | unresectable locally recurrent head and neck cancer | Japan | Sep. 2020 | 250mg: 1.5 | 24.0 | August, 2036 | N.A. |

*Source: PMDA, Frost & Sullivan*

**Pipeline Candidates for EGFR-targeted ADC Drugs in China and Worldwide**

| Product Candidate | Company | Therapeutic Strategy | Location | Clinical Phase | First Posted Time | Indications |
|---|---|---|---|---|---|---|
| MRG003 | The Group | Mono | China | II | Sept. 2020 | Advanced NSCLC, HNSCC, NPC, BTC, GC |
| M1231 | EMD Serono Research & Development Institute, Inc. | Mono | US, Canada | I | Jan. 2021 | Metastatic solid tumors<br>Metastatic NSCLC, ESCC |
| EGFR(V)-EDV-Dox | Engeneic Pty Limited | Mono | US | I | May 2016 | Glioblastoma Astrocytoma, Grade IV |
| ZV0203 | Hisun Pharmaceutical | Mono | China | I | Nov. 2021 | HER2 expressing advanced solid tumor |
| BL-B01D1 | Sichuan Baili Pharmaceutical | Mono | China | I | Jan. 2022 | Locally advanced or metastatic urinary system tumors and other solid tumors, Locally advanced or metastatic gastrointestinal tumors and other solid tumors |

*Source: PMDA, Frost & Sullivan*



Shanghai Miracogen Inc.- Ex. 2032, Page 000192

**HER2-targeted ADC Drug Market**

The HER family of transmembrane tyrosine kinase receptors includes HER1, HER2, HER3 and HER4. HER2 is a ligand-orphan receptor expressed in many human tumors. The humanized mAb has antitumor activity against HER2-overexpressing human breast tumor cells and induces HER2 receptor downmodulation and, as a result, inhibits critical signaling pathways and blocks cell cycle progression by inducing the formation of p27/Cdk2 complexes. The small molecule TKIs that compete with ATP (adenosine triphosphate) for binding at the HER-2 catalytic kinase domain block HER2 signaling.

Examples of major indications of HER2-targeted ADCs include breast cancer, gastric cancer and urothelial carcinoma:

- **Breast cancer**:

  Breast cancer is the most common cancer type in women, and its annual incidence increases continuously. Developing from the breast tissue, breast cancer may present as lumps in the breast, change in breast shape, dimpling of the skin, fluid secreted from the nipple, inverted nipple, or red or scaly patches of skin. The HER2 positive rate for breast cancer is approximately 25.4%. The second line progression percentage is 94.3% in breast cancer in China, indicating significant market opportunities.

  There are significant market opportunities for the treatment of breast cancer in China. In China, the size of breast cancer market was RMB50.7 billion in 2020 and is expected to reach RMB81.8 billion and RMB124.6 billion by 2025 and 2030, respectively, representing a CAGR of 10.0% from 2020 to 2025 and a CAGR of 8.8% from 2025 to 2030, respectively. The five-year survival rate of breast cancer in China was 82.0%, and the number of new cases of breast cancer in China was 331.6 thousand in 2020 and is expected to reach 355.6 thousand and 372.4 thousand in 2025 and 2030, respectively, representing a CAGR of 1.4% from 2020 to 2025 and a CAGR of 0.9% from 2025 to 2030.

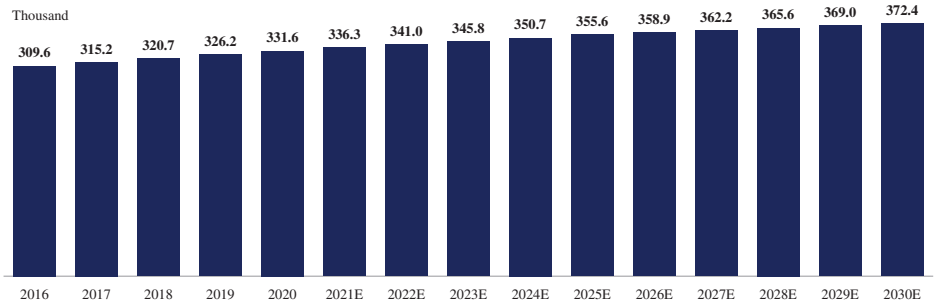
  T-DM1, launched by Roche, is the first HER2-targeted ADC that combines the anti-tumor activity of trastuzumab with the microtubule disrupting agent DM1. In 2019, the global sales revenue of T-DM1 was US$1,402 million, indicating the strong market potential of HER2-targeted ADC.



Shanghai Miracogen Inc.- Ex. 2032, Page 000193

**Incidence of Breast Cancer in China, 2016-2030E**

| Period | CAGR |
|---|---|
| 2016-2020 | 1.7% |
| 2020-2025E | 1.4% |
| 2025E-2030E | 0.9% |




*Source: NCCR, Frost & Sullivan*

- **Gastric cancer**:

Gastric cancer is a type of cancer developing from the lining of the stomach. The cancer may spread from the stomach to other parts of the body, particularly the liver, lungs, bones, lining of the abdomen and lymph nodes. Gastric cancer typically develops in stages over years. Early symptoms may include heartburn, upper abdominal pain, nausea and loss of appetite. 23.7% of all gastric cancer incidences are HER2-positive. The second line progression percentage is 94.6% in gastric cancer in China.

| | 2020 | 2025E | 2030E | CAGR 2020-2025E | CAGR 2025E-2030E |
|---|---|---|---|---|---|
| Global Gastric Cancer Market Size (Billion USD) | 14.4 | 24.2 | 36.4 | 11.0% | 8.5% |
| China Gastric Cancer Market Size (Billion RMB) | 28.0 | 51.4 | 83.2 | 12.8% | 10.2% |

| | 2020 | 2025E | 2030E | CAGR 2020-2025E | CAGR 2025E-2030E |
|---|---|---|---|---|---|
| Incidence of Gastric Cancer Globally (Thousand) | 1,089.1 | 1,255.6 | 1,435.3 | 2.9% | 2.7% |
| Incidence of Gastric Cancer in China (Thousand) | 469.6 | 545.6 | 622.4 | 3.0% | 2.7% |

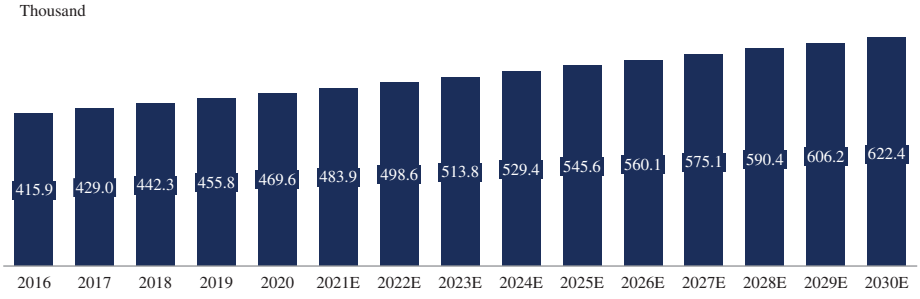
*Source: NCCR, IARC, Frost & Sullivan*



Shanghai Miracogen Inc.- Ex. 2032, Page 000194

**Incidence of Gastric Cancer in China, 2016-2030E**

| Period | CAGR |
|---|---|
| 2016-2020 | 3.1% |
| 2020-2025E | 3.0% |
| 2025E-2030E | 2.7% |



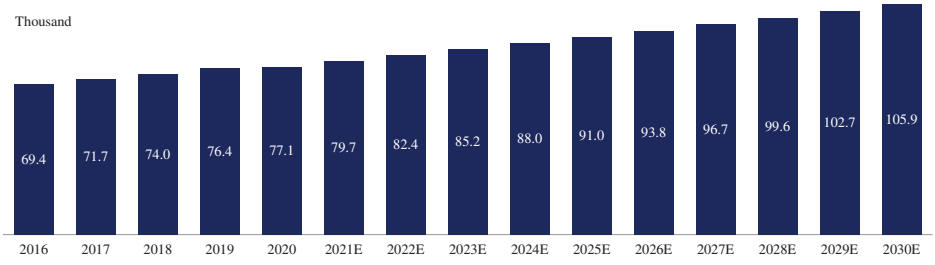

*Source: NCCR, Frost & Sullivan*

- **Urothelial Carcinoma**:

Urothelial carcinoma accounts for about 90% of all bladder cancers. It also accounts for 10% to 15% of kidney cancers diagnosed in adults. It begins in the urothelial cells found in the urinary tract. The number of new cases of urothelial carcinoma in China was 77.1 thousand in 2020, and is expected to reach 91.0 thousand and 105.9 thousand in 2025 and 2030, respectively, representing a CAGR of 3.4% from 2020 to 2025 and a CAGR of 3.1% from 2025 to 2030. HER2-positive rate of urothelial cancer is approximately 36.0%. The second line progression percentage is 81.5% in urothelial cancer in China.

**Incidence of Urothelial Cancer in China, 2016-2030E**

| Period | CAGR |
|---|---|
| 2016-2020 | 2.7% |
| 2020-2025E | 3.4% |
| 2025E-2030E | 3.1% |




*Source: NCCR, Frost & Sullivan*



Shanghai Miracogen Inc.- Ex. 2032, Page 000195

The following tables illustrate the competitive landscape of HER2-targeted ADC drugs in China and worldwide:

**Marketed HER2-targeted ADC Drugs in China and Worldwide**

| Generic name | Product Name | Company | Indications | Location | FDA/ NMPA Approval Date | Price (US$) | Annual cost (US$ thousand)[4] | Patent Expiration Date | NRDL Status | 2020 Revenue (USD Million) |
|---|---|---|---|---|---|---|---|---|---|---|
| Trastuzumab deruxtecan-nxki | Enhertu | Astra-Zeneca | See Note (1) below | US, EU, Japan | Dec. 2019/ N.A. | 2,442.45 | $134.5 | 2033 | N.A. | 383 |
| Adotrastuzumab emtansine | Kadcyla | Genentech (Roche) | See Note (2) below | US, China, EU, Japan | Feb. 2013/ Jan. 2020 | 100mg: 3,451.0; 160mg: 5,515.9 | $126.7 | 2023 | No | 1,745 |
| Disitamab Vedotin | Aidixi | RemeGen Co., Ltd | See Note (3) below | China | N.A./ Jun. 2021 | 60mg: RMB3,800.0 | RMB266.8 thousand | 2034 | 2021.11 | 0 |

*Notes:*

(1) For the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting.

(2) For the treatment of patients with HER2-positive, metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination; as the adjuvant treatment of patients with HER2-positive early breast cancer who have residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment.

(3) locally advanced or metastatic gastric cancer (including gastroesophageal junction adenocarcinoma) who have received at least 2 types of systemic chemotherapy; locally advanced or metastatic urothelial carcinoma who have previously received platinum based chemotherapy and HER2 overexpression, i.e. immunohistochemical results of 2 + or 3 +.

(4) The annual cost refers to the annual cost after considering the patient assistance program, assuming that the patient weighs 65kg and the annual medication time is 52 weeks.

*Source: NMPA, FDA, Frost & Sullivan*



Shanghai Miracogen Inc.- Ex. 2032, Page 000196

**Pipeline Candidates for HER2-targeted ADC Drugs in China and Worldwide (Phase II or later/NDA)**

| Drug Name | Indications | Therapeutic Strategy | Sponsors | Phase | Location | First Posted Date |
|---|---|---|---|---|---|---|
| ARX 788 | Breast/Gastric neoplasms<br>Solid tumors<br>HER2 positive metastatic breast cancer<br>HER2-positive breast cancer<br>HER2-positive advanced gastric cancer and adenocarcinoma of the gastroesophageal junction<br>HER2-positive advanced gastric cancer<br>HER2-positive advanced solid tumor | Mono | Ambrx,inc.; Zhejiang Medicine Co., Ltd | III | US, Australia, China | 8/21/17 |
| SYD985 | Unresectable locally advanced or metastatic HER2-positive breast cancer<br>Recurrent, advanced or metastatic endometrial cancer<br>HER2-expressing locally advanced or metastatic solid tumors | Mono/combo (with Niraparib) | Byondis B.V. | III | MRCT (US, Belgium, Denmark, France, Italy, Netherlands, Singapore, Spain, Sweden, UK) | 8/25/17 |
| DS-8201a | Unresectable and/or metastatic breast cancer with low expression of HER2<br>Advanced/metastatic HER2-low, hormone receptor (HR) positive breast cancer after receiving endocrine therapy for metastatic disease<br>Gastric cancer and adenocarcinoma of the gastroesophageal junction<br>HER2 positive patients with residual invasive breast cancer after neoadjuvant therapy<br>HER2 mutated, unresectable, locally advanced, or metastatic NSCLC<br>HER2 mutated, advanced NSCLC | Mono or combo | Daiichi Sankyo, Inc | III | China | 9/9/19 |



Shanghai Miracogen Inc.- Ex. 2032, Page 000197

| Drug Name | Indications | Therapeutic Strategy | Sponsors | Phase | Location | First Posted Date |
|---|---|---|---|---|---|---|
| TAA013 | HER2(+) locally advanced/metastatic breast cancer | Mono | TOT Biopharm Co., Ltd | III | China | 6/3/20 |
| MRG002 | Her2-positive advanced solid tumors<br>Locally advanced or metastatic gastric/gastroesophageal junction (GEJ) cancer<br>Advanced/metastatic breast cancer<br>Locally advanced/metastatic urothelial carcinoma<br>Advanced/metastatic biliary tract cancer<br>HER2-positive/HER2-low Locally Advanced or Metastatic Gastric/ Gastroesophageal Junction Cancer<br>HER2-mutated Unresectable/ Metastatic NSCLC<br>HER2-positive advanced solid tumors<br>Locally advanced or metastatic biliary adenocarcinoma<br>Locally advanced or metastatic urothelial carcinoma<br>HER2 low expression locally advanced or metastatic breast cancer<br>HER2-positive, unresectable locally advanced or metastatic breast cancer<br>Unresectable/metastatic NSCLC<br>Locally advanced or metastatic gastric/gastroesophageal junction (GEJ) cancer | Mono | Shanghai Miracogen Inc. | II | US, China | 10/11/18 |
| DX126-262 | HER2-positive advanced breast cancer and/or gastric cancer<br>HER2 positive unresectable locally advanced or recurrent metastatic breast cancer | Mono | Hangzhou DAC Biotech | II | China | 6/21/19 |



Shanghai Miracogen Inc.- Ex. 2032, Page 000198

| Drug Name | Indications | Therapeutic Strategy | Sponsors | Phase | Location | First Posted Date |
|---|---|---|---|---|---|---|
| FS-1502 | Solid tumor<br>NSCLC<br>HER2-positive advanced breast cancer and/or advanced malignant solid tumors | Mono | Shanghai Fosun Pharmaceutical | II | China | 1/18/22 |
| DP303c | HER2-positive advanced solid tumors<br>Advanced Ovarian Cancer<br>Advanced/metastatic Gastric Cancer<br>HER2 positive advanced solid tumor<br>HER2 expressing advanced ovarian cancer<br>Unresectable locally advanced, recurrent or metastatic gastric cancer | Mono | CSPC ZhongQi Pharmaceutical | II | China | 10/29/19 |
| A166 | Relapsed/refractory cancers expressing HER2 antigen or having amplified HER2 gene<br>HER2 expressing locally advanced/metastatic solid tumor<br>Urothelial Carcinoma<br>Non-small cell lung cancer<br>Breast cancer<br>HER2 positive CRC<br>HER2 positive locally advanced or metastatic gastric cancer or gastroesophageal junction adenocarcinoma | Mono | Klus Pharma, Kelun-Biotech | II | US, China | 7/26/18 |
| BDC-1001 | HER2 positive solid tumors | Mono and Combo | Bolt Biotherapeutics, Inc. | I/II | Korea, United States | 2/20/2020 |



Shanghai Miracogen Inc.- Ex. 2032, Page 000199

| Drug Name | Indications | Therapeutic Strategy | Sponsors | Phase | Location | First Posted Date |
|---|---|---|---|---|---|---|
| SHR-A1811 | HER2-expressing advanced gastric or gastroesophageal junction adenocarcinoma and colorectal cancer<br>Advanced non-small cell lung cancer with HER2 expression, amplification, or mutation<br>HER2 expressing or mutated advanced malignant solid tumor<br>HER2-expressing advanced gastric or gastroesophageal junction adenocarcinoma and colorectal cancer<br>HER2 expressing or mutated advanced malignant solid tumor<br>Advanced non-small cell lung cancer | Mono | Jiangsu HengRui Medicine Co., Ltd | I/II | MRCT (Australia, China, Korea, Taiwan) | 6/24/20 |

*Source: CDE, Clinicaltrials.gov, Frost & Sullivan*

**CD20-targeted ADC Drug Market**

ADC-CD20 is formed by CD20 mAbs conjugated with highly cytotoxic payload through a cathepsin-B-cleavable vc dipeptide linkage. Conjugation of CD20 mAbs with the payload can keep the initial effector functional activities of CD20 mAbs such as binding affinity, CDC and ADCC. In addition, the conjugation of the payload can significantly improve the cytotoxicity of CD20 against CD20-positive cells but not against CD20-negative cells. ADC-CD20 is modulated from the CD20-positive cell surface and then enters the lysosomes by receptor-mediated endocytosis, undergoes proteolytic degradation and releases active payload to induce apoptotic cell death through a caspase-3-like protease-dependent pathway.


Shanghai Miracogen Inc.- Ex. 2032, Page 000200

Examples of major indications of CD20-targeted ADCs include DLBCL and FL:

- **Lymphoma**:

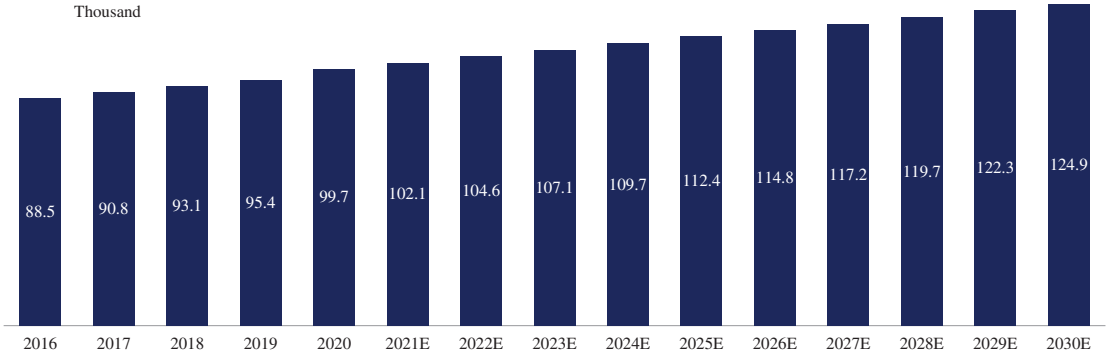
  The two main categories of lymphomas are HL and NHL, and NHL accounts for around 90% of lymphoma with varieties of subtypes. NHL subtypes are categorized by the characteristics of the lymphoma cells, including their appearance, the presence of proteins on the surface of the cells and their genetic features. DLBCL and FL are two subtypes of NHL, accounting for 41.0% and 6.1% of NHL, respectively.

  The market size of lymphoma in China reached US$12.0 billion in 2020 and is expected to reach US$37.9 billion and US$62.5 billion in 2025 and 2030, respectively, with the CAGR of 25.9% from 2020 to 2025 and 10.5% from 2025 to 2030, respectively. The five-year survival rate of lymphoma in China was 37.2%. The number of new cases of lymphoma in China was 99.7 thousand in 2020 and is expected to reach 112.4 thousand and 124.9 thousand in 2025 and 2030, respectively, representing a CAGR of 2.4% from 2020 to 2025 and a CAGR of 2.1% from 2025 to 2030.

  Rituximab is a chimeric monoclonal antibody targeted against CD20 developed by Roche, usually used as first-line or second-line treatment for NHL, CLL, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis. In 2019, the global sales revenue of MabThera/Rituxan was US$6.54 billion.

**Incidence of Lymphoma in China, 2016-2030**

| Period | CAGR |
|---|---|
| 2016-2020 | 3.0% |
| 2020-2025E | 2.4% |
| 2025E-2030E | 2.1% |




*Source: NCCR, Frost & Sullivan*



Shanghai Miracogen Inc.- Ex. 2032, Page 000201

As of the Latest Practicable Date, there were no marketed products of CD20-targeted ADC worldwide. The following table illustrates the competitive landscape of CD20-targeted ADC drugs in China:

**Pipeline Candidates for CD20-targeted ADC Drugs in China**

| Product Candidate | Company | Therapeutic Strategy | Location | Clinical Phase | First Posted Time | Indications |
|---|---|---|---|---|---|---|
| MRG001 | The Group | Mono | China | Phase I | May 2019 | NHL |
| TRS005 | Teruisi Pharmaceutical | Mono | China | Phase I | Nov. 2018 | Relapsed/refractory CD20-positive B-cell non Hodgkin's lymphoma |

*Source: CDE, Clinicaltrials.gov, Frost & Sullivan*

**TF-targeted ADC Drug Market**

Tissue factor ("**TF**") triggers the extrinsic blood coagulation cascade and is highly expressed in various types of cancer, especially pancreatic cancer, malignant glioma and gastric cancer. Under physiologic conditions, TF is expressed by fibroblasts, pericytes, and smooth muscle cells in the subendothelial vessel wall. In these cells, the majority of TF is localized in intracellular pools and remains sequestered from circulating factor VII until vascular integrity is disrupted or until TF expression is induced.

Examples of major indications of TF-targeted ADCs include cervical cancer, ovarian cancer and pancreatic cancer:

- **Cervical cancer**:

  Cervical cancer develops in a woman's cervix. Almost all cervical cancer cases are linked to infection with high-risk human papillomaviruses (HPV), an extremely common virus transmitted through sexual contact. Worldwide, cervical cancer is both the fourth most common type of cancer and the fourth most common cause of death from cancer in women. The TF positive rate of cervical cancer is approximately 94.2%.

  The number of new cases of cervical cancer globally was 604.1 thousand in 2020 and is expected to increase to 665.8 thousand and 727.5 thousand in 2025 and 2030, respectively, representing a CAGR of 2.0% from 2020 to 2025 and 1.8% from 2025 to 2030, respectively. The number of new cases of cervical cancer in China was 118.5 thousand in 2020 and is expected to increase to 123.3 thousand and 125.9 thousand in 2025 and 2030, respectively, representing a CAGR of 0.8% from 2020 to 2025 and 0.4% from 2025 to 2030, respectively.


Shanghai Miracogen Inc.- Ex. 2032, Page 000202

- **Ovarian cancer**:

  Ovarian cancer is one of the most common malignant tumors in female genital organs, and its incidence is only lower to cervical cancer and endometrial cancer. The TF positive rate of ovarian cancer is approximately 55.5%.

  The number of new cases of ovarian cancer globally was 314.0 thousand in 2020 and is expected to increase to 344.3 thousand and 374.2 thousand in 2025 and 2030, respectively, representing a CAGR of 1.9% from 2020 to 2025 and 1.7% from 2025 to 2030, respectively. The number of new cases of ovarian cancer in China was 55.3 thousand in 2020 and is expected to increase to 59.5 thousand and 62.7 thousand in 2025 and 2030, respectively, representing a CAGR of 1.5% from 2020 to 2025 and 1.1% from 2025 to 2030, respectively. 70% of patients with ovarian cancer are in advanced stage when they are first diagnosed, and the five-year survival rate of ovarian cancer is less than 30%.

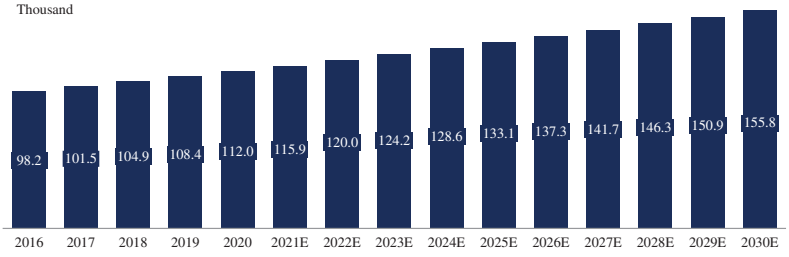
- **Pancreatic cancer**:

  Pancreatic cancer is caused by the abnormal and uncontrolled growth of cells in the pancreas, a large gland which is a part of the digestive system. The TF positive rate of pancreatic cancer is approximately 88%.

  The number of new cases of pancreatic cancer globally was 495.8 thousand in 2020, and is expected to reach 564.9 thousand and 640.5 thousand in 2025 and 2030, respectively, representing a CAGR of 2.6% from 2020 to 2025 and a CAGR of 2.5% from 2025 to 2030. The number of new cases of pancreatic cancer in China was 112.0 thousand in 2020, and is expected to reach 133.1 thousand and 155.8 thousand in 2025 and 2030, respectively, representing a CAGR of 3.5% from 2020 to 2025 and a CAGR of 3.2% from 2025 to 2030.

**Incidence of Pancreatic Cancer in China, 2016-2030E**

| Period | CAGR |
|---|---|
| 2016-2020 | 3.3% |
| 2020-2025E | 3.5% |
| 2025E-2030E | 3.2% |




*Source: NCCR, Frost & Sullivan*



Shanghai Miracogen Inc.- Ex. 2032, Page 000203

As of the Latest Practicable Date, there was one marketed products of TF-targeted ADC worldwide. The following table illustrates the competitive landscape of TF-targeted ADCs in China and worldwide:

**Globally Marketed TF-targeted ADCs**

| Generic name | Product Name | Company | Indications | Location | FDA Approval Date | Price (USD) | Annual cost (thousand USD) | Patent Expiration Date | 2020 Revenue (US$ Million) |
|---|---|---|---|---|---|---|---|---|---|
| Tisotumab vedotin-tftv | TIVDAK | Seagen Inc./ Genmab | recurrent or metastatic cervical cancer with disease progression on or after chemotherapy | US | Sep. 2021 | 40mg: $5,885 | 114.8 | NA | N.A. |

**Pipeline Candidates for TF-targeted ADCs Worldwide**

| Drug Name | Indications | Therapeutic Strategy | Sponsors | Phase | Location | First Posted Date |
|---|---|---|---|---|---|---|
| MRG004A | Solid Tumor | Mono | Lepu Biopharma | I/II | US/China | 2021/4 |
| XB002 | Locally advanced or metastatic solid tumors | Mono | Exelixis | I | US | 2021/7/4 |

*Source: CDE, Clinicaltrials.gov, Frost & Sullivan*

### Claudin18.2-targeted ADC Drug Market

Claudin18.2 is typically buried in gastric mucosa, largely inaccessible to mAbs in normal tissues. It is malignant carcinogenesis that leads to disruptions in tight junctions, exposing Claudin18.2 epitopes on the surface of tumor cells to be specifically targeted. As a result, Claudin18.2 endows targeting therapy with specificity. Claudin18.2 has highly restricted expression pattern in normal tissues, with frequent ectopic activation in a diversity of cancer types. It was expressed in many cancer types, in particularly in primary gastric cancers and its metastases. Frequently ectopic activation of Claudin18.2 was also found in pancreatic, esophageal, ovarian, and lung tumors.



Shanghai Miracogen Inc.- Ex. 2032, Page 000204

Examples of major indications of Claudin18.2-targeted ADCs include gastric cancer and pancreatic cancer:

- **Gastric cancer**:

  Gastric cancer develops in the lining of the stomach. The cancer may spread from the stomach to other parts of the body, particularly the liver, lungs, bones, lining of the abdomen and lymph nodes. For the general market size and new cases of gastric cancer, see "– the ADC Market – HER2-targeted ADC Drug Market – Gastric cancer." Claudin18.2-positive rate of gastric cancer is approximately 60.0%, indicating significant market opportunities for Claudin18.2-targeted ADC drugs.

- **Pancreatic cancer**:

  Pancreatic cancer is caused by the abnormal and uncontrolled growth of cells in the pancreas, a large gland which is a part of the digestive system. The Claudin18.2-positive rate of pancreatic cancer is approximately 55.0%.

  See "– the ADC market – TF-targeted ADC Drug Market – Pancreatic cancer."

As of the Latest Practicable Date, there were no marketed products of Claudin18.2-targeted ADC worldwide. The following table illustrates the competitive landscape of Claudin18.2-targeted ADCs in China and worldwide:

**Pipeline Candidates for Claudin18.2-targeted ADCs Worldwide**

| Drug Name | Indications | Therapeutic Strategy | Sponsors | Phase | Location | First Posted Date |
|---|---|---|---|---|---|---|
| CMG901 | Advanced solid tumor, no curative standard therapy exists | Mono | Chengdu KeyMed Biosciences/Lepu Biopharma | I | China | 2020/12/9 |
| | G/GEJ cancer | | | IND | US | 2021/02 |
| LM-302 | Advanced Solid Tumor | Mono or Combo | LaNova Medicines Ltd, Lixin Pharmaceutical | I/II | Australia, China | 2021/8/12 |
| RC-118 | Advanced unresectable/metastatic solid tumors | Mono | RemeGen Co., Ltd. | I | Australia | 2021/6/4 |
| SYSA-1801 | Advanced malignant solid tumor | Mono | CSPC Pharmaceutical Group | I | China | 2021/8/18 |
| SHR-A-1904 | Advanced Solid Tumors, | Mono | Shanghai Hengrui Pharmaceutical | I | China | 2021/5/7 |
| | Advanced Pancreatic Cancer | | | I | China | 2021/6/16 |

*Source: CDE, Clinicaltrials.gov, Frost & Sullivan*



Shanghai Miracogen Inc.- Ex. 2032, Page 000205

## THE IMMUNO-ONCOLOGY THERAPY MARKET

### Overview of the Immuno-Oncology Therapy Market

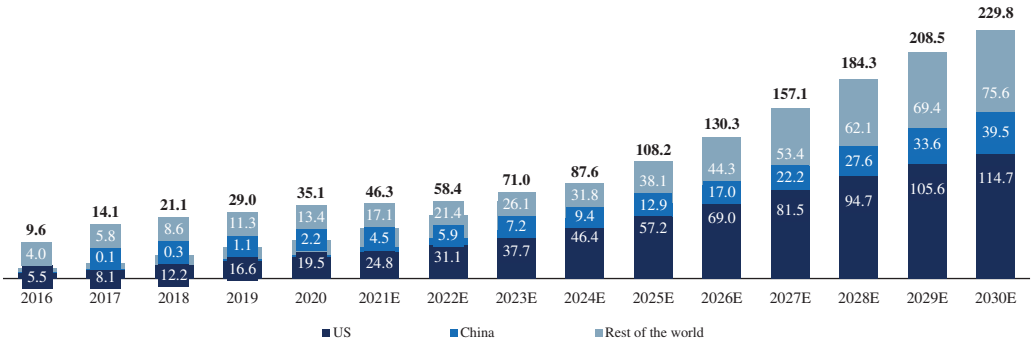
Immuno-oncology therapy represents a new paradigm of oncology treatment. Immuno-oncology therapy is designed to stimulate the patient's own immune system to generate or augment an antitumor immune response to control or eradicate tumor cells. Over the last few years, immuno-oncology therapy has revolutionized cancer care. Due to its ability to provide durable remissions while being generally well-tolerated in certain patients with advanced cancers, the discovery and development of immuno-oncology therapy in recent years mark a milestone in cancer treatment.

Major types of immuno-oncology therapy include cellular immunotherapies, checkpoint inhibitors such as the PD-1 and PD-L1 inhibitors, therapeutic cancer vaccines, cytokines, and other immunotherapy products such as oncolytic virus therapies.

Driven by increasing demand, the market size of immune-oncology therapy is expected to experience significant growth. The market size of immune-oncology therapy in China was US$2.2 billion in 2020, and is expected to reach US$12.9 billion and US$39.5 billion in 2025 and 2030, respectively, representing a CAGR of 43.0% from 2020 to 2025 and a CAGR of 25.1% from 2025 to 2030. The market size of immune-oncology therapy in the U.S. was US$19.5 billion in 2020, and is expected to reach US$57.2 billion and US$114.7 billion in 2025 and 2030, respectively, representing a CAGR of 24.0% from 2020 to 2025 and a CAGR of 14.9% from 2025 to 2030. The market size of immune-oncology therapy globally was US$35.1 billion in 2020, and is expected to reach US$108.2 billion and US$229.8 billion in 2025 and 2030, respectively, representing a CAGR of 25.3% from 2020 to 2025 and a CAGR of 16.3% from 2025 to 2030.

**Breakdown of Immuno-Oncology Therapies Market by Region, 2016-2030E**

| Period | CAGR | | | |
|---|---|---|---|---|
| | U.S. | China | Rest of the world | Global |
| 2016-2020 | 37.4% | 105.2% | 35.3% | 38.3% |
| 2020-2025E | 24.0% | 43.0% | 23.2% | 25.3% |
| 2025E-2030E | 14.9% | 25.1% | 14.7% | 16.3% |




*Source: Annual Reports of Listed Pharmaceutical Companies, NMPA, CDE, NRDL, Frost & Sullivan*



Shanghai Miracogen Inc.- Ex. 2032, Page 000206

## Overview of the Oncolytic Virus Therapies Market

Oncolytic viruses are viruses that preferentially infects and kills cancer cells. Oncolytic viruses achieve anti-tumor responses through the following steps:

- **Identifying and infecting target tumor cells**: The key proteins involved in the oncolytic viruses' identification and infection of the target are genetically modified, enabling oncolytic viruses to specifically infect the tumor cells without infecting normal ones, and replicate only in tumor cells.

- **Viral oncolysis of tumor cells**: After the oncolytic viruses successfully infect tumor cells, the viruses replicate in large quantities and finally lead to the oncolysis of tumor cells. The progeny viruses are released after oncolysis and continue to infect adjacent tumor cells.

- **Induction of systemic anti-tumor immunity**: After the death of the oncolytic tumor cells, such tumor cells release tumor-associated antigens which can lead to innate and adaptive immune responses against tumor cells, and mediate tumor regression at distant tumor sites that are not exposed to the oncolytic viruses.

One example of major indications of oncolytic viruses is the bladder cancer:

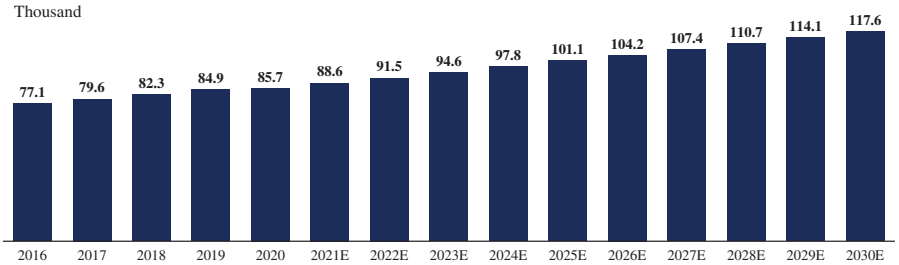
- **Bladder cancer**:

  Bladder cancer develops from the tissues of the urinary bladder, in which cells grow abnormally and have the potential to spread to other parts of the body.

  Bladder cancer is the most common malignant tumor of the urinary system, accounting for the highest incidence of urogenital tumors in China. In addition, its five-year survival rate in China was 72.9%, indicating significant market opportunities. The incidence of bladder cancer in China is constantly growing and is expected to steadily increase in the future. The number of new cases of bladder cancer in China was 85.7 thousand in 2020 and is expected to reach 101.1 thousand and 117.6 thousand in 2025 and 2030, respectively, representing a CAGR of 3.4% from 2020 to 2025 and a CAGR of 3.1% from 2025 to 2030.

**Incidence of Bladder Cancer in China, 2016-2030E**

| Period | CAGR |
|---|---|
| 2016-2020 | 2.7% |
| 2020-2025E | 3.4% |
| 2025E-2030E | 3.1% |




*Source: NCCR, Frost & Sullivan*



Shanghai Miracogen Inc.- Ex. 2032, Page 000207

In China, the market size of oncolytic virus therapies has been constantly growing, and is expected to further expand in the near future. The market size of oncolytic virus therapies in China was RMB0.02 billion in 2020, and is expected to reach RMB7.2 billion and RMB35.5 billion in 2025 and 2030, respectively, representing a CAGR of 213.4% from 2020 to 2025 and a CAGR of 37.6% from 2025 to 2030.

Besides the general drivers to the oncology drug market, the oncolytic virus therapy market in China is primarily driven by the following factor:

- **Genetic engineering technology advancement**: With the development in genetic engineering technologies, oncolytic virus can be modified by genetic engineering or attenuated virus, and can be selectively replicated in tumor cells, with little influence on normal tissues and little adverse reactions, thus improving the safety and reliability of oncolytic virus therapies.

In the near future, the oncolytic virus therapy market is expected to demonstrate the following trends:

- **A wider range of indications**: Currently, the indications of oncolytic virus therapies on the market are relatively limited. Due to the promising prospects of oncolytic virus therapies, China's major pharmaceutical companies are also expanding their product lines in oncolytic virus therapies, covering indications such as cervical cancer, bladder cancer, liver cancer and ovarian cancer. As the mechanism of oncolytic virus becomes better understood, the indications of oncolytic virus therapies are expected to gradually expand in the near future.

- **Combined therapy with other anti-tumor drugs**: Due to the limited efficacy of using oncolytic virus monotherapies, combined treatments with other therapies, such as chemotherapy, radiation therapy and small molecules therapy, may lead to improved efficacy. For example, the combination of oncolytic virus therapy with T cell therapy can assist the proliferation and movement of T cells in the local tumor microenvironment to achieve better efficacy.

- **More solutions to drug resistance**: Traditional oncolytic virus treatments may trigger strong immune response and lead to drug resistance. As pharmaceutical companies deepen their understanding of factors and targets that cause drug tolerance, oncolytic virus therapies can be used with relevant inhibitors to reduce drug resistance problems and achieve better efficacy.


Shanghai Miracogen Inc.- Ex. 2032, Page 000208

The following table illustrates the competitive landscape of pipeline candidates for oncolytic virus therapies in bladder cancer worldwide:

**Global Pipeline Candidates for Oncolytic Virus Therapies in Bladder Cancer**

| Generic Name | Company | Treatment | Indication(s) | Location | Clinical Phase | First Posted Date |
|---|---|---|---|---|---|---|
| CG0070 | Cg Oncology Inc. | • Intravesical injection | Non Muscular Invasive Bladder Cancer | US | Phase III | 2020/06/30 |
| | | • Combo with pembrolizumab<br>• Intravesical injection | Urinary Bladder Neoplasms | US | Phase II | 2020/05/13 |
| PF-07263689 | Pfizer Inc. | • Mono or combo with sasanlimab | Renal Cell Cancer;<br>Melanoma;<br>Non-Small-Cell Lung Cancer;<br>Hepatocellular Cancer;<br>Bladder Cancer;<br>Sarcoma;<br>Head and Neck Cancer;<br>Colorectal Cancer;<br>Ovarian Cancer;<br>Squamous Cell Carcinoma | NA | Phase I | 2021/9/29 |

*Source: Clinicaltrials.gov, Frost & Sullivan*

## Overview of the PD-1 and PD-L1 mAbs Market

Immune checkpoint inhibitors are one of the major types of immune-oncology therapies used today. Immune checkpoint inhibitors in the form of mAbs against the validated targets, including PD-1 and PD-L1, are among the major immune-oncology therapies.



Shanghai Miracogen Inc.- Ex. 2032, Page 000209

*The PD-1/PD-L1 mAbs Market*

PD-1 and its ligand PD-L1 perform an important role in tumor progression and survival by enabling tumor cells to escape tumor neutralizing immune surveillance in the tumor microenvironment. As compared to traditional oncology therapies, PD-1 and PD-L1 therapies demonstrate the following advantages:

- **Fewer side effects**: As targeted therapeutic approaches, PD-1/PD-L1 therapies demonstrate fewer side effects. For example, in the treatment of advanced NSCLC, PD-1/PD-L1 therapies show fewer grade 3 or higher adverse events compared to other chemotherapy medications, such as docetaxel.

- **Variety of indications**: PD-1/PD-L1 therapies display strong anti-tumor activities in multiple types of cancers, such as melanoma, NSCLC, and solid tumor. Therefore, PD-1/PD-L1 therapies have the potential to be applicable to a wide variety of indications.

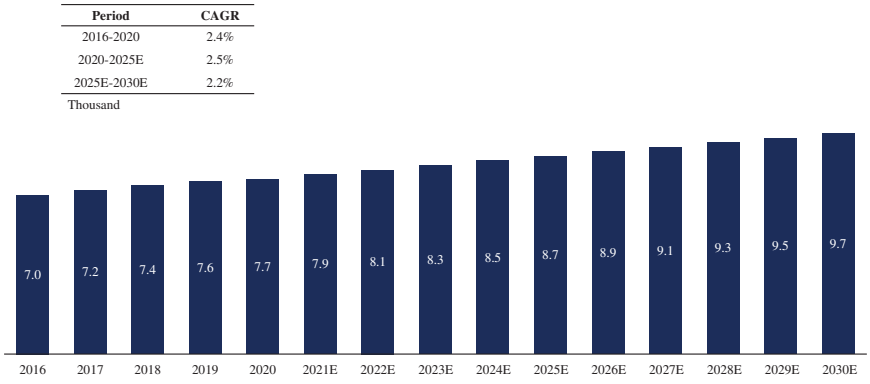
Examples of major indications of PD-1/PD-L1 therapies include melanoma, MSI-H/dMMR solid tumors, gastric cancer, NSCLC, triple-negative breast cancer and SCLC:

- **Melanoma**:

  Melanoma is the most serious type of skin cancer and it can also form in eyes and inside the body, such as in the nose or throat. It develops in melanocytes, the cells that produce the pigment melanin that colors the skin, hair and eyes. Symptoms of melanoma are often new spots or moles on the skin which change in size, shape and color. The current diagnosis of melanoma is generally based on clinical manifestation, physical exam and biopsy.

  The incidence of melanoma in China has been increasing, and is expected to expand in the near future. The size of the China melanoma market was RMB1.4 billion in 2020 and is expected to reach RMB2.1 billion by 2025 and RMB2.8 billion by 2030, respectively, representing a CAGR of 9.4% from 2020 to 2025 and a CAGR of 5.7% from 2025 to 2030, respectively. The number of new cases of melanoma in China was 7.7 thousand in 2020, and is expected to reach 8.7 thousand and 9.7 thousand in 2025 and 2030, respectively, representing a CAGR of 2.5% from 2020 to 2025 and a CAGR of 2.2% from 2025 to 2030.

**Incidence of Melanoma in China, 2016-2030E**




*Source: NCCR, Frost & Sullivan*



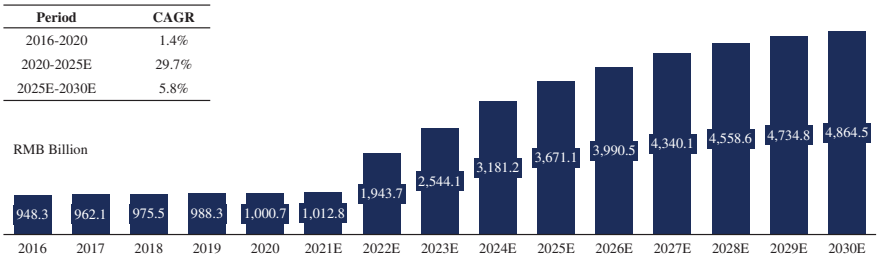
Shanghai Miracogen Inc.- Ex. 2032, Page 000210

- **MSI-H/dMMR solid tumors**:

MSI-H/dMMR solid tumors are solid tumors with high levels of microsatellite instability and/or deficient mispatch repair. MSI-H/dMMR can occur when a cell is unable to repair mistakes made during the division process.

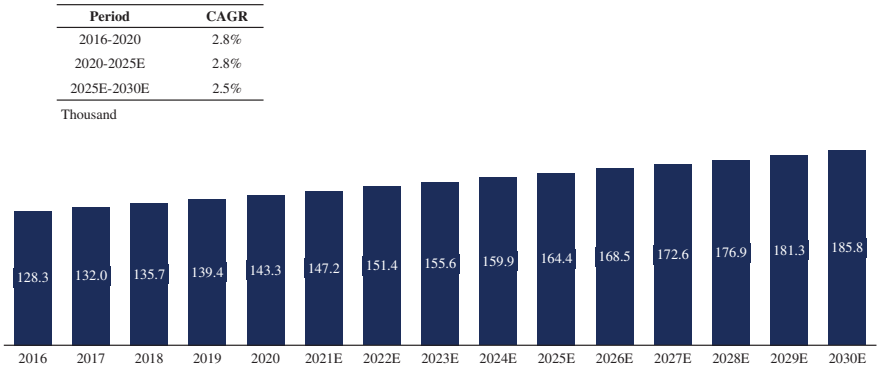
The size of the China MSI-H/dMMR solid tumors market was RMB1,000.7 million in 2020 and is expected to reach RMB3,671.1 million and RMB4,864.5 million by 2025 and 2030, respectively, representing a CAGR of 29.7% from 2020 to 2025 and a CAGR of 5.8% from 2025 to 2030, respectively. The incidence of MSI-H/dMMR solid tumors in China has been constantly increasing, and is expected to continue to increase in the near future. The number of new cases of MSI-H/dMMR solid tumors in China was 143.3 thousand in 2020, and is expected to reach 164.4 thousand and 185.8 thousand in 2025 and 2030, respectively, representing a CAGR of 2.8% from 2020 to 2025 and a CAGR of 2.5% from 2025 to 2030.

**Historical and Forecasting China MSI-H/dMMR Solid Tumors Drug Market, 2016-2030E**




*Source: NCCE, Literature Review, Frost & Sullivan*

**Incidence of MSI-H/dMMR Solid Tumors in China, 2016-2030E**




*Source: NCCR, Literature Review, Frost & Sullivan*



Shanghai Miracogen Inc.- Ex. 2032, Page 000211

- **Gastric cancer**:

  See "– the ADC Market – HER2-targeted ADC Drug Market – Gastric cancer."

- **NSCLC**:

  See "– the ADC Market – EGFR-targeted ADC Drug Market – NSCLC."

- **Triple-negative breast cancer**:

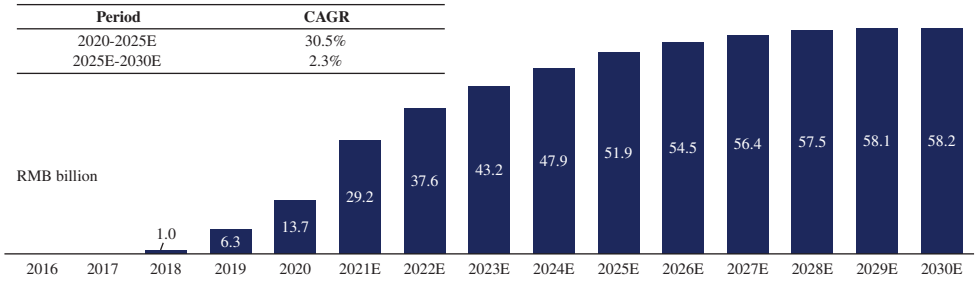
  Triple-negative breast cancer accounts for 15% of the breast cancer incidences. See "– the ADC Market – HER2-targeted ADC Drug Market – Breast Cancer."

- **SCLC**:

  Small-cell lung cancer (SCLC), accounts for about 15% of all lung cancers and is more aggressive than NSCLC. The number of new cases of small-cell lung cancer in China was 138.6 thousand in 2020 and is expected to increase to 162.4 thousand and 186.6 thousand in 2025 and 2030, respectively, representing a CAGR of 3.2% from 2020 to 2025 and 2.8% from 2025 to 2030, respectively.

In China, the market size of PD-1/PD-L1 therapies has been constantly growing, and is expected to further expand in the near future. The market size of PD-1/PD-L1 therapies in China was RMB13.7 billion in 2020, and is expected to reach RMB51.9 billion and RMB58.2 billion in 2025 and 2030, respectively, representing a CAGR of 30.5% from 2020 to 2025 and a CAGR of 2.3% from 2025 to 2030. The market size of PD-1/PD-L1 therapies globally was USD28.6 billion in 2020, and is expected to reach USD62.6 billion in 2025, representing a CAGR of 17.0% from 2020 to 2025. Due to the emergence of other innovative immuno-oncology therapies such as ADCs, bispecific antibodies and oncolytic virus therapies, the size of global PD-1/PD-L1 market is expected to stay relatively stable between 2025 and 2030.

**China PD-1/PD-L1 mAbs Market Size, 2016-2030E**




*Source: Annual Reports of Listed Pharmaceutical Companies, NMPA, CDE, NRDL, Frost & Sullivan*



Shanghai Miracogen Inc.- Ex. 2032, Page 000212

The PD-1/PD-L1 therapy market in China is primarily driven by the following factors:

- **Favorable policies**: In less than three years since June 2018, eight PD-1/PD-L1 mAb products have been approved for marketing in China. Favorable drug review policy and medical insurance policy are expected to continue to sustain the expansion of China's PD-1/PD-L1 mAb market.

- **Clinical needs and indication expansion potential**: The range of indications covered by PD-1/PD-L1 mAb in China is not as broad as that in more developed markets such as the United States. Many cancer patients in China have not used PD-1/PD-L1 mAb drugs, presenting significant market opportunities.

- **Better safety and efficacy profile**: The development of PD-1/PD-L1 mAb drug combination therapy is expected to provide better safety and efficacy profile, and lead to increased application of PD-1/PD-L1 mAb drugs.

- **Fast development of pharmaceutical companies**: In recent years, more and more biotechnology companies have joined the competition in the research and development of PD-1/PD-L1 mAb, with large pharmaceutical companies leading the competition and small biotechnology companies making breakthroughs rapidly. Such competition is expected to facilitate technology development and market expansion.

In the near future, the PD-1/PD-L1 therapy market is expected to demonstrate the following trends:

- **Development of drug administration routine**: With increased five-year survival rate of cancer patients in China, cancer is becoming a chronic disease. An increasing number of cancer patients need chronic disease management to effectively control the growth of tumor. Since many patients can live with tumors in a long life cycle, a single intravenous injection method is not enough to meet their needs. Drug administration in cancer treatment in the future is expected to shift forwards the combined application of multiple injection methods, and doctors should choose appropriate injection methods for patients according to their specific conditions.

- **Expansion of indications**: As of the Latest Practicable Date, the FDA and NMPA have approved seven and ten PD-1/PD-L1 mAb drugs, respectively, covering over 20 and 9 indications, respectively. In the future, the research and development of PD-1/PD-L1 mAb will continue to focus on expanding the range of indications and meeting the medical needs of a larger patient population.

- **Combination therapy**: In recent years, the clinical development strategy of PD-1/PD-L1 mAb has gradually shifted from monotherapy to combination therapy. A number of experimental results show that the combination therapy demonstrates significantly improved efficacy.

- **Precision treatment to improve the efficacy of monotherapy** : To improve the efficacy of PD-1/PD-L1 monotherapy, pharmaceutical companies are increasingly exploring markers that can appropriately predict the therapeutic effect, and accurately selecting the patient population that can maximize the benefit from monotherapy.



Shanghai Miracogen Inc.- Ex. 2032, Page 000213

The following tables illustrate the competitive landscape of marketed products for the PD-1/PD-L1 therapies in the U.S.:

**FDA Approved PD-1**

| Company | Drugs | Product | FDA Approval Time | NMPA Approval Time | FDA Approved Indications | Injection Methods | 2020 Global Revenue (US$ million) |
|---|---|---|---|---|---|---|---|
| MSD | Pembrolizumab | Keytruda | Sep-14 | July-18 | Melanoma, NSCLC, SCLC, HNSCC, Classical HL, PMBL, Urothelial Carcinoma, MSI-H/dMMR, GC, Esophageal cancer, Cervical carcinoma, HCC, Merkel Cell Carcinoma, Renal Cell Carcinoma, Endometrial carcinoma, TMB-H Solid Tumor, Cutaneous squamous cell carcinoma, TNBC | Intravenous | 14,380.0 |
| BMS | Nivolumab | Opdivo | Dec-14 | June-18 | Melanoma, NSCLC, SCLC, MPM, Renal Cell Carcinoma, Classical HL, HNSCC, Urothelial Carcinoma, MSI- H/dMMR, CRC, HCC, ESCC | Intravenous | 6,992.0 |
| Regeneron | Cemiplimab | Libtayo | Sep-18 | N/A | Cutaneous Squamous cell carcinoma | Intravenous | 270.7 |
| GSK | Dostarlimab-gxly | Jemperli | April-21 | N/A | dMMR endometrial cancer, dMMR recurrent or advanced solid tumor | Intravenous | NA |

**FDA Approved PD-L1**

| Company | Drugs | Product | FDA Approval Time | NMPA Approval Time | FDA Approved Indications | Injection Methods | 2020 Global Revenue (US$ million) |
|---|---|---|---|---|---|---|---|
| Roche/ Genentech | Atezolizumab | Tecentriq | May-16 | Feb-20 | Urothelial Carcinoma, NSCLC, TNBC, SCLC, HCC, Melanoma | Intravenous | 2,965.0 |
| Merck | Avelumab | Bavencio | March-17 | N/A | Merkel Cell Carcinoma, Urothelial Carcinoma, Renal Cell Carcinoma | Intravenous | 180.4 |
| AZ | Durvalumab | Imfinzi | May-17 | Dec-19 | Urothelial Carcinoma, NSCLC, SCLC | Intravenous | 2,042.0 |

*Source: FDA, Company Annual Report, Frost & Sullivan analysis*



Shanghai Miracogen Inc.- Ex. 2032, Page 000214

The following table illustrates the competitive landscape of marketed products for the PD-1/PD-L1 therapies in China:

## China Approved PD-1

| INN | Trade Name | Company | Approval Date | Indications | Price (RMB) | Dosage | Injection Methods | 2020 Revenue (US$ million) | NRDL Status | Annual Cost after PAP or NRDL (Thousand RMB) | Half-life Period | Patent Expiration Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Nivolumab | Opdivo | BMS | Jun-2018 | NSCLC, squamous cell carcinoma of the head and neck, adenocarcinoma of the stomach or gastroesophageal junction, pleural mesothelioma | 100mg: 9,250RMB; 40mg: 4,587RMB | 3mg/kg every 2 weeks | Intravenous | 6,992.0 (Global) | NO | 108.2[1] | 26.7 days | 2037-04-10 |
| Pembrolizumab | Keytruda | MSD | Jul-2018 | Melanoma, NSCLC, esophageal squamous cell carcinoma, head and neck squamous cell carcinoma, colorectal cancer | 100mg: 17,918RMB | 2mg/kg every 3 weeks | Intravenous | 14,380.0 (Global) | NO | 93.2[2] | 25 days | 2036-02-22 |
| Toripalimab | Tuoyi 拓益 | Junshi (君實生物) | Dec-2018 | Melanoma, nasopharyngeal carcinoma, urothelial carcinoma | 80mg: 906RMB | 3mg/kg every 2 weeks | Intravenous | 160.5 | Class B | 57.4 | 12.6 days | 2033-06-26 |
| Sintilimab | Daboshu 達伯舒 | Innovent (信達生物) | Dec-2018 | classical Hodgkin lymphoma, NSCLC, HCC | 100mg: 2,843RMB | 200mg every 3 weeks | Intravenous | 359.7 | Class B | 102[3] | 19.6 days | 2036-08-09 |
| Camrelizumab | Airuika 艾瑞卡 | Hengrui (江蘇恒瑞) | May-2019 | classical Hodgkin lymphoma, HCC, NSCLC, Esophageal squamous cell carcinoma | 200mg: 2,928RMB | 200mg every 2 weeks | Intravenous | 480.0 | Class B | 76.1 | 5.5 days | 2034-11-14 |
| Tislelizumab | Baizean 百澤安 | Beigene (百濟神州) | Dec-2019 | classical Hodgkin lymphoma, urothelial carcinoma, HCC, NSCLC | 100mg: 2,180RMB | 200mg every 3 weeks | Intravenous | 165.6 | Class B | 74.1 | 26 days | 2033-09-13 |
| Penpulimab | Annike 安尼可 | Chia Tai Tianqing (正大天晴)/ Akeso Biopharma (康方生物) | Aug-2021 | Recurrent or refractory classical Hodgkin's lymphoma | NA | 200mg every 2 weeks | Intravenous | NA | NO | NA | NA | NA |
| Zimberelimab | Yutuo 譽妥 | WuXi Biologics (藥明生物)/ GloriaBio (譽衡生物) | Aug-2021 | Recurrent or refractory classical Hodgkin's lymphoma | NA | 240mg every 2 weeks | Intravenous | NA | NO | NA | NA | NA |

*Source: Frost & Sullivan*

## China Approved PD-L1

| INN | Trade Name | Company | Approval Date | Indications | Price (RMB) | Dosage | Injection Methods | 2020 Revenue (US$ million) | NRDL Status | Annual Cost after PAP (Thousand RMB) | Half-life Period | Patent Expiration Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Atezolizumab | Tecentriq | Roche | Feb-2020 | SCLC, HCC | 1,200mg: 32,800RMB | 1,200mg every 3 weeks | Intravenous | 2,965.0 (global) | NO | 295.2 | 27 days | 2035-11-10 |
| Durvalumab | Imfinzi | AZ | Dec-2019 | NSCLC | 120mg: 6,066RMB; 500mg: 18,088RMB | 10mg/kg, every 2 weeks | Intravenous | 2,042.0 (global) | NO | 217.1 | 17 days | 2037-04-24 |
| Envafolimab | 恩維達 | 3D Medicines/ Alphamab oncology/ Simcere | Nov-2021 | MSI-H/dMMR advanced solid tumor | 200mg: 5,980RMB | 400mg every 4 weeks | Subcutaneous | NA | NO | 71.8 | 23 days | NA |
| Sugemalimab | 擇捷美 | Cstone Pharma | Dec-2021 | NSCLC | NA | NA | Intravenous | NA | NO | NA | 12 days | NA |

*Source: NMPA, Frost & Sullivan*



Shanghai Miracogen Inc.- Ex. 2032, Page 000215

The following tables illustrate the competitive landscape of late stage or NDA pipeline candidates for the PD-1/PD-L1 therapies in China:

**Pipeline Candidates for PD-1 Therapies in China (Phase III or later/NDA)**

| Drugs | Company | Indications in Phase III Clinic Trial | Injection Methods | Dosage | Development Phase | Details in Indications |
|---|---|---|---|---|---|---|
| **GB226/ Geptanolimab** | Genor Biopharma | NA | Intravenous | 3mg/kg, every 2 weeks | Submit listing application in Jul. 2020 | Indications: peripheral T-cell lymphoma |
| **HLX 10/serplulimab** | Shanghai Henlius Biotech | NSCLC, esophageal squamous cell carcinoma, CRC, cervical cancer, gastric cancer, SCLC, liver cancer | Intravenous | 4.5 mg/kg, every 3 weeks | Submit listing application in Apr. 2021 | Indications: dMMR/MSI-H solid tumor and squamous NSCLC |
| **HX008** | Akeso Biopharma, HanX Bio | G/GEJ carcinoma | Intravenous | 200mg, every 3 weeks | Submit listing application in June 2021 | Indications of listing application: melanoma and MSI-H/dMMR solid tumors |
| **Cemiplimab** | Sanofi | NSCLC | Intravenous | 350mg, every 3 weeks | Clinical phase III starts in Nov. 2019 | Indications of phase III clinical trial: NSCLC |
| **SCT-I10A** | Sinocelltech | HNSCC, NSCLC, HCC | Intravenous | 15mg/kg, every 3 weeks | Clinical phase III starts in Sep. 2019 | Indications of phase III clinical trial: Head and neck squamous cell carcinoma, NSCLC, HCC |
| **CS1003** | Cstone Pharmaceuticals | HCC | Intravenous | 200mg, every 3 weeks | Clinical phase III starts in Dec. 2019 | Indications of phase III clinical trial: HCC |
| **Sasanlimab** | Pfizer | Non-muscular invasive bladder carcinoma | Subcutaneous | 2ml, every week | Clinical phase III starts in Oct. 2020 | Indications of phase III clinical trial: Non-muscular invasive bladder carcinoma |
| **Retifanlimab/ INCMGA00012** | Incyte, ZAI Laboratory | NSCLC | Intravenous | 375mg, every 3 weeks | Clinical phase III starts in June 2020 | Indications of phase III clinical trial: NSCLC |
| **QL1604** | Qilu Pharmaceutical | HCC | Intravenous | 3mg/kg, every 3 weeks | Clinical phase II/III starts in May 2020 | Indications of phase II/III clinical trial: HCC |



Shanghai Miracogen Inc.- Ex. 2032, Page 000216

| Drugs | Company | Indications in Phase III Clinic Trial | Injection Methods | Dosage | Development Phase | Details in Indications |
|---|---|---|---|---|---|---|
| **Prolgolimab** | SPH-BIOCAD | NSCLC; Progressive recurrent or metastatic cervical cancer | Intravenous | 3mg/kg, every 3 weeks | Clinical phase III starts in Apr. 2021 | Indications of phase II/III clinical trial: NSCLC, cervical cancer |

*Source: CDE, Frost & Sullivan*

**Pipeline Candidates for PD-L1 Therapies in China (Phase II or later/NDA)**

| Drugs | Company | Indications in Phase II and III Clinic Trial | Injection Methods | Dosage | Development Phase |
|---|---|---|---|---|---|
| **ZKAB001** | Zhaoke Oncology | Osteosarcoma, ES-SCLC, melanoma, esophageal squamous cell carcinoma | Intravenous | 5mg/kg, every 3 weeks | Submit listing application in Oct. 2021. The indication is recurrent and metastatic cervical cancer |
| **KL-A167** | Kelun Biotech | Classical Hodgkin's lymphoma, lymphoma | Intravenous | 900mg, every 2 weeks | Submit listing application in Nov. 2021. The indication is recurrent and metastatic nasopharyngeal cancer |
| **SHR-1316** | Hengrui | SCLC, NSCLC | Intravenous | 12ml:0.6g, every 3 weeks | Submit listing application in Jan. 2022 |
| **Avelumab** | Merck/Pfizer | NSCLC | Intravenous | 10mg/kg, every 1-2 weeks | Clinical phase III starts in Nov. 2017 |
| **TQB2450** | Chia Tai Tianqing Pharmaceutical | Primary mediastinal large B-cell lymphoma, triple negative breast cancer, biliary system adenocarcinoma, non-small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin's lymphoma, cervical cancer, renal cell carcinomas, ES-SCLC | Intravenous | 1,200mg, every 3 weeks | Clinical phase III starts in Feb. 2019 |



Shanghai Miracogen Inc.- Ex. 2032, Page 000217

| Drugs | Company | Indications in Phase II and III Clinic Trial | Injection Methods | Dosage | Development Phase |
|---|---|---|---|---|---|
| **GR1405** | Genrix Bio | TNBC, NPC, HNSCC | Intravenous | 10mg/kg, every 3 weeks | Clinical phase III starts in May. 2021 |
| **LP002** | Taizhou Houdeoke Technology | ES-SCLC | Intravenous | 10mg/kg, every 2 weeks | Clinical phase II stars in Jul. 2020 |
| **Whole human anti-PD-L1 antibody** | Guilin Sanjin | Muscle invasive bladder cancer, renal cancer, penile cancer | Intravenous | 10mg/kg, every 2 weeks | Clinical phase II starts in Sep. 2021 |
| **HS636** | Zhejiang Hisun Pharmaceutical | Primary mediastinal large B-cell lymphoma | Intravenous | 0.01, 10, 20, 30mg/kg, every 3 weeks | Clinical phase II starts in Mar. 2021 |

*Note:* only PD-1 mAbs in clinical stage II or later stages before February 1, 2022 are included, no bispecific antibodies or ADC.

*Source: CDE, Frost & Sullivan*

***The PD-1/PD-L1 Combination Therapy Market***

PD-1/PD-L1 therapies have been shown to be an effective monotherapy for some forms of cancer. Improved response and extended survival rates as observed with such immunotherapies have led pharmaceutical companies to explore the synergistic potential of combination immunotherapy to inhibit complementary immunosuppressive pathways simultaneously. With its established anti-tumor activity and favorable toxicity profile, PD-1/PD-L1 inhibition has served as the foundation for many new combination immunotherapy strategies. The PD-1/PD-L1 combination therapies currently approved by the FDA include mainly the combination of PD-1/PD-L1 mAb with chemotherapy, targeted therapy (VEGF/R) and immunotherapy (CTLA-4). Globally, the number of combination trials has increased from 857 in 2017 to 2,900 in 2020. During the same period, the number of combination target groups increased from 124 to 253 in ongoing clinical trials.

In the near future, the PD-1/PD-L1 mAb combination therapy market is expected to demonstrate the following trends:

- **Combination therapy as the main direction for clinical trial development**: A number of experimental results show that combination therapy can significantly improve the effect of monotherapy, and the efficacy of combination therapy are generally much higher than that of monotherapy. Therefore, combination therapy is expected to become the main direction for clinical trial development.



Shanghai Miracogen Inc.- Ex. 2032, Page 000218

- **Combination with a wide variety of treatment methods**: PD-1/PD-L1 mAb can be used in combination with traditional tumor treatment methods, including immunotherapy, targeted drugs, chemotherapy or radiotherapy, oncolytic virus and cancer vaccine, to achieve a breakthrough in treatment effect. At present, the combinations of PD-1/PD-L1 mAb with treatment methods such as CTLA-4, cancer vaccine, VEGF/VEGFR drugs, chemotherapy drugs and radiotherapy have demonstrated promising effect.

- **Combination with proprietary pipeline products by pharmaceutical companies**: Biopharmaceutical companies developing PD-1/PD-L1 mAb generally have the choice to develop combination therapy for their PD-1/PD-L1 mAb in combination with other proprietary pipeline products, if available. In this way, biopharmaceutical companies may speed up their progress of clinical trials.

The following tables illustrate the competitive landscape of PD-1 mAbs in combination with PD-L1 and oncolytic virus pipeline in China, respectively:

**PD-1 mAbs in combination with PD-L1 mAbs pipelines**

| PD-(L)1 Drug Type and Name | Combination Drug Target and Name | Company | Clinical Phase | First Posted Time | Indications in Clinical Trials |
|---|---|---|---|---|---|
| PD-1: HX008 | PD-L1: LP002 | The Group | Phase I | Aug. 2020 | Locally advanced or metastatic melanoma with prior treatment of PD-1/PD-L1 |

*Source: CDE, Frost & Sullivan*

**PD-1 mAbs in combination with oncolytic virus pipelines**

| PD-(L)1 Drug Type and Name | Combination Drug Target and Name | Company | Clinical Phase | First Posted Time | Indications in Clinical Trials |
|---|---|---|---|---|---|
| PD-1: HX008 | Herpes virus: Recombinant human GM-CSF oncolytic herpes simplex virus type 2 | Wuhan Binhui | Phase I | Aug. 2020 | Melanoma |

*Source: CDE, Frost & Sullivan*



Shanghai Miracogen Inc.- Ex. 2032, Page 000219

## REPORT COMMISSIONED BY FROST AND SULLIVAN

In connection with the Global Offering, we have engaged Frost & Sullivan to conduct a detailed analysis and prepare an industry report on the therapeutic biologics market in China and the United States. Frost & Sullivan is an independent global market research and consulting company which was founded in 1961 and is based in the United States. Services provided by Frost & Sullivan include market assessments, competitive benchmarking and strategic and market planning for a variety of industries. The contract sum to Frost & Sullivan is RMB1 million for the preparation of the Frost & Sullivan Report. The payment of such amount was not contingent upon our successful Listing or on the results of the Frost & Sullivan Report. Except for the Frost & Sullivan Report, we did not commission any other industry report in connection with the Global Offering. We have included certain information from the Frost & Sullivan Report in this prospectus because we believe such information facilitates an understanding of the biologics market for potential investors. The Frost & Sullivan Report is prepared through extrapolating publicly available data, such as information provided by the government, annual reports of public companies, trade and medical journals, industry reports and other available information gathered by non-profit organizations. Frost & Sullivan also adopted the following primary assumptions while making projections on the macroeconomic environment, the overall pharmaceutical market and various segment markets in the PRC for the forecast period: the overall social, economic and political environment in the PRC remains stable; China's economic and industrial development remains stable; key industry drivers, such as accelerated population aging, growing demands from healthcare institutions, increasing prevalence of chronic diseases and technology innovation continue to drive the growth of China's pharmaceutical market; and no extreme force majeure or industry regulation will dramatically or fundamentally affect the market. Frost & Sullivan believes that these assumptions are factual, correct and not misleading. Frost & Sullivan has independently analyzed the information, but the accuracy of the conclusions of its review largely relies on the accuracy of the information collected. Frost & Sullivan research may be affected by the accuracy of these assumptions and the choice of these primary and secondary sources.


Shanghai Miracogen Inc.- Ex. 2032, Page 000220

## PRINCIPAL REGULATORY AUTHORITIES

In addition to supervision and management under authorities that perform general regulation on companies in the PRC, our operations in the PRC are mainly subject to supervision and management under the following authorities:

### National Health Commission

National Health Commission of the People's Republic of China (the "**NHC**"), a main national administrative body in charge of public health and family planning, is responsible for formulating national health policies, coordinating and deepening the reform of the medical and health systems, organizing the formulation of the national system for essential drugs, supervising and managing public health, medical services and health emergency response, and the management and services of family planning.

### National Medical Product Administration

National Medical Product Administration of the People's Republic of China (the "**NMPA**", formerly known as China Food and Drug Administration), a body supervised by the State Administration for Market Regulation, is responsible for supervision and management of safety of drugs and medical devices, formulating policy planning for the relevant department and administration, drafting relevant laws and regulations, formulating relevant department regulations and supervising the relevant implementation. It is also responsible for registration and management of drugs and medical devices, establishing the system for relevant registration and management and performing stringent review and approval of drugs applied for marketing; management of quality of drugs and medical devices, formulating and supervising the implementation of regulations on quality management, formulating the regulations on quality management of production and supervising the relevant implementation within its authority, risk management of drugs and medical devices that have been launched to the market, organizing monitor, test, evaluation and handling of cases in relation to adverse reaction or events arising from drugs and medical devices, guiding the supervising and inspecting work on drugs and medical devices, exchanges and cooperation with other parties, guiding work of authorities responsible for supervision and management of drugs in provinces, autonomous regions and municipalities directly under the central government.

### National Healthcare Security Administration

The National Healthcare Security Administration is responsible for drafting and implementing policies, plans and standards on medical insurance, maternity insurance and medical assistance; administrating relevant health care fund; optimizing the national administration and settlement platform for medical treatment received in different places; establishing and adjusting the price and charging standard of drugs and medical services; drafting and supervising the implementation of the policy on bidding and purchasing of drugs and medical disposables; regulating and administrating medical services and medical expenditure covered by medical insurance.



Shanghai Miracogen Inc.- Ex. 2032, Page 000221

**Ministry of Commerce of the People's Republic of China**

The Ministry of Commerce of the People's Republic of China (the "**MOFCOM**") is the department in charge of the domestic and the international trade and international economic cooperation of the PRC, drafting strategies and policies on development of regulations and formulating relevant departmental regulations on domestic and the international trade and international economic cooperation, drafting laws and regulations and formulating relevant departmental regulations on domestic and international trade, foreign investment, overseas investment and economic cooperation with other countries, guiding the foreign investment in the PRC, formulating policies and plans of reform for foreign investment and organizing the relevant implementation, approving the establishment and changes of foreign investment enterprises in accordance with the laws. The MOFCOM is also responsible for handling filing and registration of foreign trade dealers engaging in import and export of goods or technologies. The Company is also subject to the commerce departments' supervision and management for matters of overseas investment such as overseas acquisitions or investment and establishment of enterprises.

**National Development and Reform Commission of the People's Republic of China**

The National Development and Reform Commission of the People's Republic of China (the "**NDRC**") is an authority that studies and formulates economic and social development policies, carries out overall balances and guides the overall economic system reform from an all-rounded macro perspective. It is responsible for promoting the development, formulating and implementing the national strategic emerging industries development plan, coordinating high-stake foreign investment projects. The Company is also subject to NDRC's supervision and management on overseas investment in regards to establishment of enterprises outside China.

**General Administration of Customs of the People's Republic of China**

The General Administration of Customs of the People's Republic of China (the "**GACC**") is a directly affiliated institution of the State Council. The GACC is the state's customs supervision and administration authority and is responsible for collection and management of import/export duties and other taxes and fees, outbound and inbound health quarantine and entry-exit inspection and quarantine of animals and plants and the related products, inspection of import and export commodities under the laws, compilation of customs statistics for national trading of items including import/export goods, formulating and implementing planning to develop customs technologies and the planning to support the development of laboratories and technologies. According to the Decision on the State Council Institutional Reform Proposal issued by the State Council and effective on March 17, 2018, the duty of the entry-exit inspection and quarantine management and relevant staff of the former State Administration for Quality Supervision and Inspection and Quarantine were assigned to the GACC.


Shanghai Miracogen Inc.- Ex. 2032, Page 000222

## PRINCIPAL LAWS AND REGULATIONS RELATED TO OUR BUSINESSES IN THE PRC

### Laws and Regulations in Relation to Foreign Investment

According to the Company Law of the PRC (《中華人民共和國公司法》), which was approved by the Standing Committee of the National People's Congress (the "**SCNPC**") on December 29, 1993 and subsequently amended in 1999, 2004, 2005, 2013 and 2018, and the latest amended version of which was effective on October 26, 2018, a company established under the PRC laws and within the territory of the PRC may take the form of a limited liability company or a company limited by shares. The Company Law of the PRC shall also be applicable to foreign-invested limited liability companies and companies limited by shares, unless otherwise provided by the relevant laws and regulations.

Investment activities in the PRC by foreign investors are governed by the Guiding Foreign Investment Direction (《指導外商投資方向規定》), which was promulgated by the State Council on February 11, 2002 and came into effect on April 1, 2002, and the Special Administrative Measures (Negative List) for Foreign Investment Access (《外商投資准入特別管理措施(負面清單)(2020年版)》, the "**Negative List (2020 Edition)**"), which was amended and promulgated by the MOFCOM and NDRC on June 23, 2020 and took effective on July 23, 2020. The Negative List (2020 Edition) set out in a unified manner the restrictive measures, such as the requirements on shareholding percentages and management, for the access of foreign investments, and the industries that are prohibited for foreign investment. The Negative List (2020 Edition) covers 12 industries, and any field not falling in the Negative List (2020 Edition) shall be administrated under the principle of equal treatment to domestic and foreign investment.

Foreign Investment Law of the People's Republic of China (《中華人民共和國外商投資法》) ("**Foreign Investment Law**") was promulgated by SCNPC on March 15, 2019 and became effective on January 1, 2020. After the Foreign Investment Law came into force, the Law on Wholly Foreign-owned Enterprises (《中華人民共和國外資企業法》), the Law on Sino-foreign Equity Joint Ventures (《中華人民共和國中外合資經營企業法》) and the Law on Sino-foreign Contractual Joint Ventures (《中華人民共和國中外合作經營企業法》) have been repealed simultaneously. The investment activities of foreign natural persons, enterprises or other organizations (hereinafter referred to as foreign investors) directly or indirectly within the territory of China shall comply with and be governed by the Foreign Investment Law: (1) establishing by foreign investors of foreign-invested enterprises in China alone or jointly with other investors; (2) acquiring by foreign investors of shares, equity, property shares, or other similar interests of Chinese domestic enterprises; (3) investing by foreign investors in new projects in China alone or jointly with other investors; (4) other forms of investment prescribed by laws, administrative regulations or the State Council.


Shanghai Miracogen Inc.- Ex. 2032, Page 000223

On December 26, 2019, the State Council issued the Regulations on Implementing the Foreign Investment Law of the PRC (《中華人民共和國外商投資法實施條例》), which came into effect on January 1, 2020. After the Regulations on Implementing the Foreign Investment Law of the PRC came into effect, the Regulation on Implementing the Sino-Foreign Equity Joint Venture Enterprise Law (《中華人民共和國中外合資經營企業法實施條例》), Provisional Regulations on the Duration of Sino-Foreign Equity Joint Venture Enterprise Law (《中外合資經營企業合營期限暫行規定》), the Regulations on Implementing the Wholly Foreign-Invested Enterprise Law (《中華人民共和國外資企業法實施細則》) and the Regulations on Implementing the Sino-foreign Cooperative Joint Venture Enterprise Law (《中華人民共和國中外合作經營企業法實施細則》) have been repealed simultaneously.

On December 30, 2019, the MOFCOM issued the Measures for the Reporting of Foreign Investment Information (《外商投資信息報告辦法》), which came into effect on January 1, 2020. After the Measures for the Reporting of Foreign Investment Information came into effect, the Interim Measures on the Administration of Filing for Establishment and Change of Foreign Investment Enterprises (《外商投資企業設立及變更備案管理暫行辦法》) has been repealed simultaneously. Since January 1, 2020, for foreign investors carrying out investment activities directly or indirectly in China, the foreign investors or foreign-invested enterprises shall submit investment information to the commerce authorities pursuant to these measures.

**Regulations on Overseas Investment**

The Measures for Overseas Investment Management (《境外投資管理辦法》) was promulgated by the MOFCOM on September 6, 2014 and came into effect on October 6, 2014. As defined by the Measures for Overseas Investment Management, overseas investment means that the enterprises legally incorporated in the PRC own the non-financial enterprises or obtain the ownership, control and operation management rights of the existing non-financial enterprises in foreign countries through incorporation, merger and acquisition and other means. If the overseas investments involve sensitive countries and regions or sensitive industries, they shall be subject to the approval of competent authorities. For other overseas investments, they shall be subject to filing administration. Local enterprises shall be filed with the provincial commercial administration authorities where they are located. The qualified enterprises will be put into record and granted with Overseas Investment Certificate for Enterprise by the relevant provincial commercial administration authorities.

The Administrative Measures for Outbound Investment by Enterprises (《企業境外投資管理辦法》) was promulgated by the NDRC on December 26, 2017 and came into effect on March 1, 2018. As defined therein, overseas investment means any investment activities in which a domestic enterprise of the PRC obtains overseas ownership, control, operation and management rights and other relevant interests directly or through its controlled overseas enterprise by way of investing assets, rights or interests or providing financing and/or guarantee. To conduct overseas investment, certain procedures shall be compiled with, including approval and record-filing of overseas investment project, reporting relevant information and cooperating with the supervision and inspection. The NDRC promulgated the Catalog of Sensitive Sectors for Outbound Investment (2018 Edition) (《境外投資敏感行業目錄(2018年版)》), which was promulgated by the NDRC on January 31, 2018 and came into effect on March 1, 2018, to list the current sensitive industries in detail.


Shanghai Miracogen Inc.- Ex. 2032, Page 000224

## Regulations on Drug Research and Development & Registration Services

### *Research and Development of New Drugs*

Pursuant to the Drug Administration Law of the PRC (《中華人民共和國藥品管理法》, last amended on August 26, 2019 and effective on December 1, 2019), the dossier on a new drug research and development, including the manufacturing method, quality specifications, results of pharmacological and toxicological tests and the related data, documents and the samples, shall, in accordance with the regulations of NMPA be truthfully submitted to the said department for approval before clinical trial is conducted. The medical products administration under the State Council shall, within 60 working days from the date on which the application for such clinical trial is accepted, decide on whether to approve it and then notify the clinical trial applicant. In the case of failure to notify the applicant within the prescribed time limit, it shall be deemed as approved. When a new drug has gone through the clinical trial and passed the evaluation, a drug registration certificate shall be issued upon approval by NMPA. The institutions for non-clinical safety evaluation and study and clinical trial organizations shall respectively implement the Good Laboratory Practice for Non-Clinical Laboratory Studies (the "**GLP**") (《藥物非臨床研究質量管理規範》, effective on September 1, 2017) and Good Clinical Practice (the "**GCP**") (《藥物臨床試驗質量管理規範》, effective on July 1, 2020). If certain actions in the preclinical trial research and clinical research conducted for a clinical application trial, and/or in the application procedures for registration of medicines, are in violation of the relevant rules and regulations, the China Food and Drug Administration (the "**CFDA**") is authorized to handle such cases pursuant to the Measures regarding Noncompliance with Relevant Rules of Research and Application for Registration of Medicines (《藥品研究和申報註冊違規處理辦法(試行)》) effective from September 1, 1999. On July 22, 2015, the CFDA issued Notice No. 117 (CFDA notice in relation to self-review of clinical trials data) (《國家食品藥品監督管理總局關於開展藥物臨床試驗數據自查核查工作的公告》), which required the current applicants in respect of the existing 1,622 drug manufacturing or drug import applications to the CFDA to reassess the clinical trials data in respect of each application. On April 23, 2020, the NMPA and NHC further revised the Good Clinical Practice of Pharmaceutical Products (《藥物臨床試驗質量管理規範》) which became effective on July 1, 2020, in order to further improve the quality of clinical trials and encourage innovation.

### *Drug Registration*

*Examination and Approval of New Drug Application*

On January 22, 2020, the State Administration for Market Regulation promulgated the Revised Administrative Measures for Drug Registration which became effective on July 1, 2020 (the "**Drug Registration Measures (2020)**") (《藥品註冊管理辦法(2020)》). According to the Drug Registration Measures (2020), drug registration is regulated according to the classification into Chinese medicine, chemical medicine and biological products. The NMPA shall establish a system to expedite drug registration, and support drug innovation guided by clinical value. Where an application for drug registration satisfies the criteria, the applicant



Shanghai Miracogen Inc.- Ex. 2032, Page 000225

may apply for breakthrough therapy drug, conditional approval, prioritized/special review and approval. Drug registration inspection for overseas-manufactured drug shall be implemented by port pharmaceutical inspection agencies organized by the National Institutes for Food and Drug Control (中國食品藥品檢定研究院, the "**NIFDC**"), and for application for registration of overseas-manufactured drug, where an applicant applies for drug registration inspection prior to acceptance of the application for drug registration, it shall request for random sampling pursuant to the provisions, and deliver the samples, materials required for inspection and standard substances to the NIFDC.

In March 2016, the CFDA issued the Reform Plan for Registration Category of Chemical Medicine (《化學藥品註冊分類改革工作方案》) (the "**Reform Plan**"), which outlined the reclassifications of drug applications under the Registration Measures. Under the Reform Plan, Category 1 drugs refer to new drugs that have not been marketed anywhere in the world. Improved new drugs that are not marketed anywhere in the world fall into Category 2. Generic drugs, that have equivalent quality and efficacy to the originator's drugs have been marketed abroad but not yet in China, fall into Category 3. Generic drugs, that have equivalent quality and efficacy to the originator's drugs and have been marketed in China, fall into Category 4. Category 5 drugs are drugs which have already been marketed abroad, but are not yet approved in China. Category 1 drugs and Category 5 drugs can be registered through the Domestic NDA and the Imported Drug Application procedures under the Registration Measures, respectively.

According to the Special Examination and Approval of Registration of New Drugs (《新藥註冊特殊審批管理規定》), (the "**Special Examination and Approval Provisions**"), which was promulgated and implemented since January 7, 2009 by the State Food and Drug Administration, the NMPA conducts special examination and approval for new drug registration applications when: (1) the effective constituent of drug extracted from plants, animals, minerals, etc. as well as the preparations thereof have never been marketed in China, and the material medicines and the preparations thereof are newly discovered; (2) the chemical raw material medicines as well as the preparations thereof and the biological product have not been approved for marketing home and abroad; (3) the new drugs are for treating AIDS, malignant tumors and orphan diseases, etc., and have obvious advantages in clinic treatment; or (4) the new drugs are for treating diseases with no effective methods of treatment.

The Special Examination and Approval Provisions provide that the applicant may file for special examination and approval at the clinical trial application stage if the drug candidate falls within items (1) or (2). The provisions provide that for drug candidates that fall within items (3) or (4), the application for special examination and approval cannot be made until filing for production.


Shanghai Miracogen Inc.- Ex. 2032, Page 000226

*Fast Track Approval for Clinical Trial and Registration*

In November 2015, the CFDA released the Circular Concerning Several Policies on Drug Registration Review and Approval (《關於藥品註冊審評審批若干政策的公告》), which further clarified the following policies, potentially simplifying and accelerating the approval process of clinical trials:

- a one-time umbrella approval procedure allowing the overall approval of all phases of a new drug's clinical trials, replacing the current phase-by-phase application and approval procedure, will be adopted for new drugs' clinical trial applications; and

- a fast track drug registration or clinical trial approval pathway for the following applications: (1) registration of innovative new drugs for treating HIV, cancer, serious infectious diseases and orphan diseases; (2) registration of pediatric drugs; (3) registration of geriatric drugs and drugs treating PRC-prevalent diseases in elders; (4) registration of drugs listed in national major science and technology projects or national key research and development plan; (5) registration of innovative drugs using advanced technology, using innovative treatment methods, or having distinctive clinical benefits; (6) registration of foreign innovative drugs to be manufactured locally in China; (7) concurrent applications for new drug clinical trials which are already approved in the United States or European Union or concurrent drug registration applications for drugs which have applied to the competent drug approval authorities for marketing authorization and passed such authorities' onsite inspections in the United States or European Union and are manufactured using the same production line in China; and (8) clinical trial applications for drugs with urgent clinical need and patent expiry within three years, and manufacturing authorization applications for drugs with urgent clinical need and patent expiry within one year.

On May 17, 2018, the NMPA and NHC jointly promulgated the Circular on Issues Concerning Optimizing Drug Registration Review and Approval (《關於優化藥品註冊審評審批有關事宜的公告》), which further simplified and accelerated the clinical trial approval process.

*Administrative Protection and Monitoring Periods for New Drugs*

According to the Registration Measures, the Implementing Regulations of the Drug Administration Law (《藥品管理法實施條例》) and the Reform Plan, the NMPA may, for the purpose of protecting public health, provide for an administrative monitoring period of five years for Category 1 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 of a new drug, the NMPA will not accept other applications for new drugs containing the same active ingredient. This renders an actual five-year exclusivity protection for Category 1 new drugs. The only exception is that the NMPA will continue to handle any application if, prior to the commencement of the monitoring period, the NMPA has already approved the applicant's


Shanghai Miracogen Inc.- Ex. 2032, Page 000227

clinical trial for a similar new drug. If such application conforms to the relevant provisions, the NMPA may approve such applicant to manufacture or import the similar new drug during the remainder of the monitoring period.

*Registration of Generic Drugs*

According to the Registration Measures, the applicants which apply for registration of generic drugs shall be manufacturer of the same drugs. The applicant's drugs shall also be within the manufacturing scope specified in the Pharmaceutical Manufacturing Permit. Furthermore, clinical trials are required to be conducted in accordance with the Registration Measures. According to the Circular on Implementation of Record-filing Management of Bioequivalence Trials of Chemical Drug (《關於化學藥生物等效性試驗實行備案管理的公告》), the management of bioequivalence trials of chemical drug has been changed from examination and approval to record-filing. With reference to the technical review opinions, the NMPA will either grant a drug registration number or issue a disapproval notice.

Pursuant to the Opinions on Conducting the Consistency Evaluation for the Quality and Efficacy of Generic Drugs issued by the General Office of the State Council (《國務院辦公廳關於開展仿製藥質量和療效一致性評價的意見》) promulgated on February 6, 2016 and the Opinions of Relevant Matters Concerning Implementing the Opinions on Conducting the Consistency Evaluation for the Quality and Efficacy of Generic Drugs issued by the NMPA (《關於落實<國務院辦公廳關於開展仿製藥質量和療效一致性評價的意見>的有關事項的意見》), promulgated on May 25, 2016, generic drugs approved for marketing before the implementation of the new registration classification of chemical drugs, including domestic generic drugs, imported generic drugs and the indigenous varieties of the original developed drugs, shall carry out consistency evaluation. In principle, the consistency evaluation should be completed before the end of 2018 for the oral solid preparations of generic chemicals approved for sale before October 1, 2007 listed in the National Essential Drug List (2012 version) (《國家基本藥物目錄 (2012年版)》). For any other generic drugs approved for marketing before the implementation of the new classification of registration of chemical drugs, after a drug produced by a pharmaceutical enterprise passes the consistency evaluation, other pharmaceutical enterprises shall complete the consistency evaluation for their identical drugs within three years in principle; no registration will be granted in case of failure to do so as required within the prescribed time limit.

Pursuant to the Circular on Relevant Matters Concerning Consistency Evaluation for Quality and Curative Effect of Generic Drugs (《關於仿製藥質量和療效一致性評價有關事項的公告》) further promulgated by NMPA on December 28, 2018, the time limit for evaluation of the varieties included in the National Essential Drug List (2018 version) will no longer be set uniformly. For generic drugs, including essential drug varieties, approved for listing before the implementation of new registration and classification of chemical drugs, after the first variety has passed the consistency evaluation, the same variety of other drug manufacturers should complete the consistency evaluation within 3 years in principle. If it is not completed


Shanghai Miracogen Inc.- Ex. 2032, Page 000228

within the time limit, the enterprise may apply to the local provincial drug regulatory authority for an extension of the evaluation if it is deemed to be clinically necessary and in short supply in the market. If the registration is not completed within the prescribed time limit, it shall not be re-registered.

**Regulations on Drug Manufacturing**

Pursuant to the Drug Administration Law of the PRC and the Implementing Regulations of the Drug Administration Law, a drug manufacturing enterprise is required to obtain a drug manufacturing license (藥品生產許可證) from the relevant provincial drug administration authority of the PRC. The grant of such license is subject to an inspection of the manufacturing facilities, and an inspection to determine whether the sanitary condition, quality assurance systems, management structure and equipment meet the required standards. Pursuant to the Regulations of Implementation of the Drug Administration Law of the PRC and the Measures on the Supervision and Administration of the Manufacture of Drugs (《藥品生產監督管理辦法》, effective on August 5, 2004,amended on November 17, 2017 and January 22, 2020), the drug manufacturing license is valid for five years and shall be renewed at least six months prior to its expiration date upon a re-examination by the relevant authority. In addition, the name, legal representative, registered address and type of the enterprise specified in the drug manufacturing certificate shall be identical to that set forth in the business license as approved and issued by the industrial and commercial administrative department.

The Good Manufacturing Practice for Drugs (2010 revised edition) (《藥品生產質量管理規範》, effective on March 1, 2011), comprises a set of detailed standard guidelines governing the manufacture of drugs, which includes institution and staff qualifications, production premises and facilities, equipment, hygiene conditions, production management, quality controls, product operation, raw material management, maintenance of sales records and manner of handling customer complaints.

Pursuant to the Drug Administration Law of the PRC, the Measures on the Supervision and Administration of the Manufacture of Drugs (《藥品生產監督管理辦法》) and the Administrative Measures for Certification of the Good Manufacturing Practice for Drugs (《藥品生產質量管理規範認證管理辦法》, effective on August 2, 2011), the application for Good Manufacturing Practice (the "**GMP**") certificate shall be made to the relevant drug supervision and administration department by the new drug manufacturer or existing drug manufacturer which builds a new drug production workshop or adds new production forms in 30 days after obtaining the drug manufacturing license or production approval, in order to obtain the relevant certificate. A GMP certificate shall be renewed at least six months prior to its expiration date upon re-examination by the relevant authority.

On January 22, 2020, the State Administration for Market Regulation promulgated the newly revised Administrative Measures on Supervision of Drug Manufacturing (the "**Revised Administrative Measures of Drug Manufacturing**") (《藥品生產監督管理辦法 (2020)》), which took effect on July 1, 2020. The Revised Administrative Measures of Drug Manufacturing further implement the dug marketing authorization holder system as stipulated



Shanghai Miracogen Inc.- Ex. 2032, Page 000229

in the Drug Administration Law of the PRC (《中華人民共和國藥品管理法》). Drug marketing authorization holder entrusting others to manufacture preparations shall enter into an outsourcing agreement and a quality agreement with a qualified drug manufacturing enterprise and submit the relevant agreements together with the actual manufacturing site application materials to the competent drug administrative authority to apply for a drug manufacturing license. The Revised Administrative Measures of Drug Manufacturing no longer require GMP certificate for drug manufacturing enterprises, but the competent drug administrative authorities shall, based on regulatory needs, conduct compliance inspection of drug manufacturing quality control examination before drug marketing procedure.

**Regulations on Drug Distribution**

***Medicine Operation Certificate***

The Measures for the Supervision and Administration of Drug Distribution (《藥品流通監督管理辦法》), which was issued by the State Food and Drug Administration on December 8, 2006 and came into effect on May 1, 2007, detailed provisions are imposed on aspects such as the purchase, sale, transportation and storage of medicines.

The establishment of a wholesale pharmaceutical distribution company requires the approval of the provincial medicine administrative authorities. Upon approval, the authority will grant a Medicine Operation Certificate in respect of the wholesale pharmaceutical product distribution company. The establishment of a retail pharmacy store requires the approval of the local medicine administrative authorities at or above the county level. Upon approval, the authority will grant an Operation Certificate in respect of the retail pharmacy store.

Under the Measures for the Administration of Pharmaceutical Operation Certificate (《藥品經營許可證管理辦法》) promulgated on February 4, 2004 and became effective from April 1, 2004 and amended on November 17, 2017 by the NMPA, a Medicine Operation Certificate is valid for five years. Each holder of the Medicine Operation Certificate must apply for an extension of its permit six months prior to expiration.

***Good Supply Practices***

GSP constitutes the basic standards in management of operation quality of medicines and shall apply to enterprises exclusively or concurrently engaged in medicine operation within China. The current applicable GSP standards require pharmaceutical operators to implement strict controls on its operation of pharmaceutical products, including standards regarding staff qualifications, premises, warehouses, inspection equipment and facilities, management and quality control. Under the Administrative Measures for Certification of Good Supply Practices (《藥品經營質量管理規範認證管理辦法》) promulgated on and became effective from April 24, 2003 by the NMPA, the GSP certificate is generally valid for five years and may be extended three months prior to the expiry of its valid term. Pursuant to the Drug Administration Law of PRC (《中華人民共和國藥品管理法》), the GSP certification is canceled but pharmaceutical operators are still required to comply with the GSP standards.



Shanghai Miracogen Inc.- Ex. 2032, Page 000230

## Regulations on Import and Export of Goods

### *Import and Export of Goods*

Pursuant to the Administrative Provisions on the Registration of Customs Declaration Entities of the PRC (《中華人民共和國海關報關單位註冊登記管理規定》) (Order No. 221 of the General Administration of Customs, effective on March 13, 2014, amended on December 20, 2017 and May 29, 2018 respectively), the import and export of goods shall be declared by the consignor or consignee itself, or by a customs declaration enterprise entrusted by the consignor or consignee and duly registered with the customs authority. Consignors and consignees of imported and exported goods shall go through customs declaration entity registration formalities with the competent customs departments in accordance with the applicable provisions. After completing the registration formalities with the customs, consignors and consignees of the imported and exported goods may handle their own customs declarations at customs ports or localities where customs supervisory affairs are concentrated within the customs territory of the PRC.

### *Import and Export of Special Articles*

Pursuant to the Administrative Provisions on the Sanitation and Quarantine of Entry/Exit Special Articles (《出入境特殊物品衛生檢疫管理規定》) (Order No. 160 of the General Administration of Quality Supervision, Inspection and Quarantine, effective on March 1, 2015 and amended on October 18, 2016, April 28, 2018, May 29, 2018 and November 23, 2018 respectively), the import or export of special articles, including micro-organisms, human tissues, biological products, blood and blood products shall be subject to the supervision and administration over health quarantine. The customs office is responsible for the health quarantine and approval of import and export of special articles in its relevant jurisdictions. The enterprise conducting import or export of special articles shall establish safety management system for special articles, and shall produce, use or sell the special articles in strict accordance with the purposes for the approval of such special articles.

### *Export of Drugs*

According to the Approval by NMPA on Certain Issues of Pharmaceutical Products Export (《國家藥品監督管理局關於藥品出口有關問題的批覆》), promulgated and effective on September 20, 1999, whether the enterprise can obtain the right to operate import and export business and the qualification shall be approved by relevant foreign trade authority. The pharmaceutical products export shall mainly comply with the requirements of the importing country, so long as there is no special requirement by the importation country, the NMPA support the export in principal based on the national policy of encouraging exports. However, under the Pharmaceutical Administration Law, the export licenses issued by the relevant NMPA are required for the export of narcotics and psychotropic substances falling within the restricted scope prescribed by the State.


Shanghai Miracogen Inc.- Ex. 2032, Page 000231

**Other Related Regulations in the PRC Pharmaceutical Industry**

***Price Controls***

According to the Pharmaceutical Administration Law, the Regulations of Implementation of the Law of the People's Republic of China on the Administration of Pharmaceuticals, the pharmaceutical products are subject to fixed or directive pricing system or to be adjusted by the market. Those pharmaceutical products included in the Medical Insurance Catalogs and the National Essential Drug List and those drugs the production or trading of which are deemed to constitute monopolies, are subject to price controls by the PRC government in the form of fixed retail prices or maximum retail prices. Manufacturers and distributors cannot set the actual retail price for any given price-controlled product above the maximum retail price or deviate from the fixed retail price set by the government. The retail prices of pharmaceutical products that are subject to price controls are administered by the NDRC and provincial and regional price control authorities. From time to time, the NDRC publishes and updates a list of pharmaceutical products that are subject to price controls. According to the Notice Regarding Measures on Government Pricing of Pharmaceutical Products Issued by NDRC (《國家計委關於印發藥品政府定價辦法的通知》) effective on December 25, 2000, maximum retail prices for pharmaceutical products shall be determined based on a variety of factors, including production costs, the profit margins that the relevant government authorities deem reasonable, the product's type, and quality, as well as the prices of substitute pharmaceutical products.

Further, pursuant to the Notice Regarding Further Improvement of the Order of Market Price of Pharmaceutical Products and Medical Services (《關於進一步整頓藥品和醫療服務市場價格秩序的意見》) jointly promulgated by the NDRC, the State Council Legislative Affairs Office and the State Council Office for Rectifying, the MOH, the NMPA, the MOFCOM, the MOF and Ministry of Labor and Social Security on May 19, 2006 and effective on the same day, the PRC government exercises price control over pharmaceutical products included in the Medical Insurance Catalogs and made an overall adjustment of their prices by reducing the retail price of certain overpriced pharmaceutical products and increasing the retail price of certain underpriced pharmaceutical products in demand for clinical use but that have not been produced in large quantities by manufacturers due to their low retail price level. In particular, the retail price charged by hospitals at the county level or above may not exceed 115% of the procurement cost of the relevant pharmaceutical products or 125% for Chinese herbal pieces.

On May 4, 2015, the NDRC, the National Health and Family Planning Commission, the Ministry of Human Resources and Social Security, the Ministry of Industry and Information Technology of the PRC, the Ministry of Finance, the MOFCOM and the NMPA issued the Opinion on Furthering Pharmaceutical Price Reform (《推進藥品價格改革的意見》) (the "**Price Reform Opinion**") and the Notice on Issuing the Opinion on Furthering Pharmaceutical Price Reform (《關於印發推進藥品價格改革意見的通知》) (the "**Price Reform Notice**"). Pursuant to the Price Reform Notice, government price controls on pharmaceutical products (other than narcotic drugs and psychiatric drugs of category I) has been lifted on June 1, 2015. According to the Price Reform Opinion, after price controls are



Shanghai Miracogen Inc.- Ex. 2032, Page 000232

lifted, prices of pharmaceutical products will be mainly determined by market competition. Instead of direct price controls, the government will regulate prices mainly by establishing a consolidated procurement mechanism, revising medical insurance reimbursement standards and strengthening regulation of medical and pricing practices.

***Drug Purchases by Hospitals***

According to the Opinion on the Guidance of the Reform of Urban Medical and Health Care System (《關於城鎮醫藥衛生體制改革的指導意見》) promulgated and took into effect on February 16, 2000 and the Opinion on the Implementation of Classification Management of Urban Medical Institutions (《關於城鎮醫療機構分類管理的實施意見》) promulgated on July 18, 2000 and became effective from September 1, 2000, a medical institution must be defined as a profit-making or non-profit-making institution at the time when it is established. A non-profit-making medical institution is established to provide services to the general public, with its revenue used for maintaining and developing such institution, while a profit-making medical institution is established by investors for the purpose of investment return. The PRC government does not establish any profit-making medical institutions, while non-government entities may establish profit-making medical institutions. Any non-profit-making medical institutions must implement a collective tender system in respect of any drug purchases and any profit-making medical institutions need not to implement such a system according to PRC law.

According to the Notice on the Trial Implementation of the Centralized Tender with Respect to Drug Purchases by Medical Institutions (《關於印發醫療機構藥品集中招標採購試點工作若干規定的通知》) promulgated and became effective on July 7, 2000, the Notice on the Further Standardizing of the Centralized Tender with respect to Drug Purchases By Medical Institutions (《關於進一步做好醫療機構藥品集中招標採購工作的通知》) promulgated and became effective on August 8, 2001 and the Opinions concerning Further Regulating Purchase of Medicines by Medical Institutions through Centralized Tendering (《關於進一步規範醫療機構藥品集中採購工作的意見》) promulgated and took into effect on January 17, 2009, any non-profit-making medical institutions established and/or controlled by any government at a county level or above must implement the centralized tender system in respect of purchase of any drugs which are contained in the Medicines List for National Basic Medical Insurance and are generally used for clinical purposes and purchased in relatively large amount.

The Circular on the Good Practice of Medical Institutions with respect to Centralized Procurement of Drugs (《醫療機構藥品集中採購工作規範》) promulgated and was effective on July 7, 2010, provides stipulations in detail in respect of the catalog for centralized procurement and methods, procedures, evaluators, expert database construction and management of drugs, further regulating the centralized drug procurement and clarifying the code of conduct on the part of purchasing parties. According to the Good Practice of Medical Institutions with respect to Centralized Procurement of Drugs, any non-profit-making medical institutions established by the government at the county level or above or state-owned enterprises (including stock-holding enterprises) must participate in the centralized procurement of medical institutions. The centralized procurement management authority at provincial (municipal or district) level is responsible for compiling the catalog of drugs for



Shanghai Miracogen Inc.- Ex. 2032, Page 000233

centralized procurement by medical institutions within its own administrative region, and narcotic drugs and first class psychoactive drugs with respect to which the special administration is carried out by the state are not included in such catalog for centralized procurement; second class psychoactive drugs, radioactive pharmaceuticals, toxic drugs for medical use, crude drugs, traditional Chinese medicinal materials and traditional Chinese medicine decoction pieces may be excluded from such catalog for centralized procurement.

According to the Guidance Opinion of the General Office of the State Council on the Improvement of the Drug Centralized Procurement Work of Public Hospitals (《國務院辦公廳關於完善公立醫院藥品集中採購工作的指導意見》) promulgated and came into effect on February 9, 2015, the centralized procurement work of public hospitals will be improved through the classification purchase of drugs. All drugs used by public hospitals (with the exception of traditional Chinese medicine decoction pieces) should be procured through a provincial centralized pharmaceutical procurement platform. The provincial procurement agency should work out a summary of the procurement plans and budget submitted by hospitals and compile reasonably a drug procurement catalog of the hospitals with its own administration region, listing by classification the drugs to be procured through bids, negotiations, direct purchases by hospitals or to be manufactured by appointed manufacturers.

***The Drug Centralized Procurement in "4+7 Cities" and Wider Areas***

On November 15, 2018, the Joint Procurement Office published the Papers on Drug Centralized Procurement in "4+7 Cities" (《4+7城市藥品集中採購文件》, the "**Paper**"), which launched the national pilot scheme for drugs centralized tendering with minimum procurement quantities. The pilot scheme will be carried out in 11 cities, including Beijing, Tianjin, Shanghai, Chongqing, Shenyang, Dalian, Xiamen, Guangzhou, Shenzhen, Chengdu and Xian (the "**4+7 cities**").

On January 1, 2019, the General Office of the State Council also published the Notice of Issuing Pilot Program of the Centralized Procurement and Use of Drugs Organized by the State (《國務院辦公廳關於印發國家組織藥品集中採購和使用試點方案的通知》), which provides the detailed measures in the implementation of the national pilot scheme for drugs centralized tendering with minimum procurement quantities in the 4+7 cities.

According to the Implementing Opinions on Expanding the Pilot Program for Conducting Centralized Procurement and Use of Drugs by the State to Wider Areas (《關於國家組織藥品集中採購和使用試點擴大區域範圍的實施意見》) promulgated and came into effect September 25, 2019, together with the Documents on National Centralized Drug Procurement (GY-YD2021-1) (《全國藥品集中採購文件》) issued by the Joint Procurement Office on January 15, 2021, the model of centralized procurement with target quantity in the pilot program for conducting centralized procurement and use of drugs by the State will be promoted nationwide and all manufacturers of drugs within the scope of centralized procurement marketed in Mainland China, with the approval of the medical products administration, may participate in the pilot program.



Shanghai Miracogen Inc.- Ex. 2032, Page 000234

The drug being offered for tender must belong to one of the following categories:

- an originator drug or reference preparations used for consistency evaluation designated by NMPA;
- a generic drug that has passed the consistency evaluation;
- a generic drug approved for registration according to the NMPA Notice No. 51(2016); or
- a drug included in the Catalogue of the Drugs Marketed in China (《中國上市藥品目錄集》).

The tenderer must also ensure that its annual production and sales capacity can satisfy the intended minimum quantity requirement. Public hospitals must prioritize their drug purchasing from the successful bidder during the procurement cycle, calculated from the execution date of the successful bid result, until the quantity commitment has been satisfied. If the quantity commitment is satisfied, the excess is still procured at the selected price until the expiration of the procurement cycle.

***Two-invoice System***

In order to further optimize the order of purchasing and selling pharmaceutical products and reduce circulation steps, as required at the executive meeting of the State Council dated April 6, 2016 and under the 2016 List of Major Tasks in Furtherance of the Healthcare and Pharmaceutical Reforms (《深化醫療衛生體制改革2016年重點工作任務》) issued by the General Office of the State Council on April 21, 2016, the "**two-invoice System**" (兩票制) will be fully implemented in the PRC. According to the Circular on Issuing the Implementing Opinions on Carrying out the Two-invoice System for Drug Procurement among Public Medical Institutions (for Trial Implementation) 《印發<關於在公立醫療機構藥品採購中推行"兩票制"的實施意見(試行)>的通知》) (the "**Circular**"), which was effective from December 26, 2016, the two-invoice system means one invoice between the pharmaceutical manufacturer and the pharmaceutical distributor, and one invoice between the pharmaceutical distributor and the hospital, and thereby only allows a single level of distributor for the sale of pharmaceutical products from the pharmaceutical manufacturer to the hospital. According to the Circular, two-invoice system will be promoted in pilot provinces (autonomous regions and municipalities directly under the Central Government) involved in the comprehensive medical reform program and pilot cities for public hospital reform on a priority basis, while other regions are encouraged to implement such system, so that such system can be promoted in full swing nationwide in 2018.


Shanghai Miracogen Inc.- Ex. 2032, Page 000235

***Drug recall***

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

**Environmental Regulations**

***Environmental Assessment and Acceptance of Environmental Protection Facilities***

Pursuant to the Law of Environmental Impact Assessment of the PRC (《中華人民共和國環境影響評價法》) (Order No. 77 of the PRC President, effective on September 1, 2003 and amended on July 2, 2016, and December 29, 2018 respectively), Regulations on Environmental Protection Management for Construction Projects (《建設項目環境保護管理條例》) (Order No. 253 of the State Council, effective on November 29, 1998 and amended on July 16, 2017), where effects may be exerted on the environment after the completion of construction projects, the construction enterprise shall submit an environmental impact report (form) or environmental impact registration form to the relevant environmental protection department. The project that is required to prepare the environmental impact report (form) in accordance with the law shall obtain the approval from the relevant environmental protection department for its environmental impact assessment documents; otherwise it shall not start the construction. After the construction project is completed, the construction enterprise shall apply for environmental protection acceptance of the construction project and make acceptance report pursuant to the standard and formality set by the environmental protection authority.

***Safety Management Supervision***

Pursuant to the Law on Work Safety of the PRC (《中華人民共和國安全生產法》) (Order No. 70 of the PRC President, effective on November 1, 2002 and amended on August 27, 2009 and August 31, 2014 respectively), enterprises engaged in production activities must strengthen safety production management, establish and improve the responsibility system for safe production and ensure a safe production environment. The state establishes and implements a system for the accountability of production safety accidents. If the company fails to comply with the provisions of the Law on Work Safety, the supervisory authority on production safety may issue a rectification order, impose a fine, order the company to cease production and operation, or revoke the relevant permit.


Shanghai Miracogen Inc.- Ex. 2032, Page 000236

Some chemical materials needed for new drug research and development, such as toluene and hydrochloric acid, are hazardous chemicals. Pursuant to the Regulations on Safety Management of Hazardous Chemicals (《危險化學品安全管理條例》) (Order No. 344 of the State Council, effective on March 15, 2002 and amended on March 2, 2011 and December 7, 2013, respectively), the production, storage, use, operation, and transportation of hazardous chemicals must be in accordance with the safety management regulations. The hazardous chemical units shall oblige to the safety conditions required by laws and administrative regulations and state and industry standards, establish and improve safety management rules and post safety responsibility systems, and provide safety education and legal education and occupation technical training for employees. Employees should accept such education and training, and may begin working only after qualifying the relevant assessment. Where it requires employees to have certain qualification to assume a post, an enterprise shall only designated employees having such qualification to assume the post.

**Regulations on Employment**

The Labor Contract Law of the PRC (《中華人民共和國勞動合同法》) (Order No. 65 of the PRC President, effective on January 1, 2008 and amended on December 28, 2012) and the Regulations on Implementation of the Labor Contract Law of the PRC (《中華人民共和國勞動合同法實施條例》) (Order No. 535 of the State Council, effective on September 18, 2008) provide for the establishment of labor relationship between employing entities and workers, as well as the concluding, performance, dissolution and revision of the labor contracts. To establish a labor relationship, a written labor contract shall be signed. In the event that no written labor contract is signed at the time when a labor relationship is established, such contract shall be signed within one month as of the date when the employing enterprise employs the employee.

Pursuant to Social Insurance Law of the PRC (《中華人民共和國社會保險法》), (Order No. 35 of the PRC President, effective on July 1, 2011, and amended on December 29, 2018), Interim Regulations on Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》) (Order No. 259 of the State Council, effective on January 22, 1999 and amended on March 24, 2019), Trial Measures for Enterprise Staff Maternity Insurance (《企業職工生育保險試行辦法》) (No. 504 [1994] the Ministry of Labor, effective on January 1, 1995), Regulations on Work-Related Injury Insurance (《工傷保險條例》) (Order No. 375 of the State Council, effective on January 1, 2004 and amended on December 20, 2010), and Regulations on Management of Housing Provident Fund (《住房公積金管理條例》) (Order No. 262 of the State Council, effective on April 3, 1999 and amended on March 24, 2002, March 24, 2019, respectively), employing entity must pay basic pension insurance, unemployment insurance, basic medical insurance, work-related injury insurance, maternity insurance and housing provident fund for its employees. If an employing entity fails to go through the formalities or does not pay the full amount as scheduled, the relevant administration department shall order it to make rectification or make up the payment within the prescribed time limit. If the rectification for social insurance registration is not made within the stipulated period, the employing entity shall be imposed a fine. If the payment for social insurance premiums is not made within the stipulated period, the relevant administration


Shanghai Miracogen Inc.- Ex. 2032, Page 000237

department shall impose a fine. If an employing entity fails to undertake payment and deposit registration of housing provident fund or fails to go through the formalities of opening housing provident fund account for its employees by the expiration of the time limit, a fine shall be imposed. If an employing entity fails to make the payment and deposit of the housing provident fund within a prescribed time limit, an application may be made to the people's court for compulsory enforcement.

**Regulations on Intellectual Property**

***Copyright and Software Registration***

The Standing Committee of National People's Congress of PRC promulgated the Copyright Law (《著作權法》) in 1990 and amended it in 2001, 2010 and 2020, respectively. The Copyright Law provides that Chinese citizens, legal persons, or other organizations shall, whether published or not, enjoy copyright in their works, including computer software. The purpose of the Copyright Law is to encourage the creation and dissemination of works which contribute to the construction of socialist spiritual and material civilization and promote the development and prosperity of socialist cultural and scientific pursuit.

The Regulation on Computers Software Protection (《計算機軟件保護條例》), which was promulgated by the State Council on December 20, 2001 and amended in 2011 and 2013, respectively, was formulated for the purposes of protecting the rights and interests of copyright owners of computer software, regulating the relationship of interests generated in the development, dissemination and use of computer software, encouraging the development and application of computer software, and promoting the development of software industry and the informatization of national economy. According to the Regulation on Computer Software Protection, Chinese citizens, legal entities or other organizations are entitled to the copyright in the software which they have developed, whether published or not. A software copyright owner may register with the software registration institution recognized by the copyright administration department of the State Council. A registration certificate issued by the software registration institution is a preliminary proof of the registered items. The Measures for the Registration of Computer Software Copyright (《計算機軟件著作權登記辦法》), which was promulgated by the National Copyright Administration on February 20, 2002, regulates registrations of software copyright, exclusive licensing contracts for software copyright and transfer contracts. The National Copyright Administration shall be the competent authority for the nationwide administration of software copyright registration and the Copyright Protection Center of China (the "**CPCC**") is designated as the software registration authority. The CPCC shall grant registration certificates to the computer software copyright applicants which conforms to the provisions of both the Measures for the Registration of Computer Software Copyright and the Regulation on Computers Software Protection.



Shanghai Miracogen Inc.- Ex. 2032, Page 000238

***Trademark***

Trademarks are protected by the Trademark Law of the PRC (《中華人民共和國商標法》) which was promulgated in 1982 and subsequently amended in 1993, 2001, 2013 and 2019, as well as the Implementation Regulation of the Trademark Law of the PRC (《中華人民共和國商標法實施條例》) promulgated by the State Council in 2002 and amended in 2014. The Trademark Office under the SAIC handles trademark registrations and grants a term of ten years to registered trademarks which may be renewed for consecutive ten-year periods upon request by the trademark owner. Trademark license agreements must be filed with the Trademark Office for record. The Trademark Law has adopted a "first-to-file" principle with respect to trademark registration. Where a trademark for which a registration has been made is identical or similar to another trademark which has already been registered or been subject to a preliminary examination and approval for use on the same kind of or similar commodities or services, the application for registration of such trademark may be rejected. Any person applying for the registration of a trademark may not prejudice the existing right first obtained by others, nor may any person register in advance a trademark that has already been used by another party and has already gained a "sufficient degree of reputation" through such party's use.

***Patent***

The Standing Committee of the National People's Congress promulgated the Patent Law of the PRC (《中華人民共和國專利法》) in 1984 and amended it in 1992, 2000, 2008 and 2020, respectively. A patentable invention, utility model or design must meet three conditions: novelty, inventiveness and practical applicability. Patents cannot be granted for scientific discoveries, rules and methods for intellectual activities, methods used to diagnose or treat diseases, animal and plant breeds or substances obtained by means of nuclear transformation. The Patent Office under the State Intellectual Property Office is responsible for receiving, examining and approving patent applications. A patent is valid for a twenty-year term for an invention and a ten-year term for a utility model or design, starting from the application date. Except under certain specific circumstances provided by law, any third party user must obtain consent or a proper license from the patent owner to use the patent, or else the use will constitute an infringement of the rights of the patent holder.

***Domain Name***

Pursuant to the Administrative Measures for Internet Domain Names (《互聯網域名管理辦法》), which was promulgated by the MIIT on August 24, 2017 and became effective on November 1, 2017, domain names are registered on a "first-come, first-served" basis. The domain names registered or used by an organization or individual shall not contain any contents prohibited by laws and administrative regulations. A domain name registration applicant shall provide the domain name registration service agency with truthful, accurate and complete identity information on the domain name holder.



Shanghai Miracogen Inc.- Ex. 2032, Page 000239

**Regulations on Taxation**

***Enterprise Income Tax***

According to the Enterprise Income Tax Law of PRC (《中華人民共和國企業所得税法》), which was promulgated by the NPC on March 16, 2007, implemented on January 1, 2008, and subsequently revised on February 24, 2017 and December 29, 2018 respectively, and the Implementation Rules for the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得税法實施條例》) enacted on December 6, 2007 by the State Council and became effective on January 1, 2008, and amended on April 23, 2019 (collectively, the "**EIT Law**"), a resident enterprise shall pay EIT on its income originating from both inside and outside PRC at an EIT rate of 25%. Foreign invested enterprises in the PRC falls into the category of resident enterprises, which shall pay EIT for the income originated from domestic and overseas sources at an EIT rate of 25%. A non-resident enterprise having no office or establishment inside China, or for a non-resident enterprise whose incomes has no actual connection to its office or establishment inside China must pay enterprise income tax on the incomes derived from China at a rate of 10%.

***Value-added Tax***

According to the Interim Regulations of the PRC on Value-Added Tax (《中華人民共和國增值税暫行條例》) which was promulgated by the State Council on December 13, 1993, and amended on November 10, 2008, February 6, 2016 and November 19, 2017, and the Detailed Rules for the Implementation of the Provisional Regulations of the PRC on Value-added Tax (《中華人民共和國增值税暫行條例實施細則》) which was promulgated by the Ministry of Finance on December 25, 1993 and subsequently amended on December 15, 2008 and October 28, 2011 (collectively, the "**VAT Law**"), all enterprises and individuals that engage in the sale of goods, the provision of processing, repair and replacement services, sales of service, intangible assets and real estate and the importation of goods within the territory of the PRC shall pay value-added tax at the rate of 17%, except when specified otherwise.

In accordance with Circular on Comprehensively Promoting the Pilot Program of the Collection of Value-added Tax in Lieu of Business Tax (《關於全面推開營業税改徵增值税試點的通知》), which was promulgated on March 23, 2016 and came into effect on May 1, 2016, upon approval of the State Council, the pilot program of the collection of VAT in lieu of business tax shall be promoted nationwide in a comprehensive manner starting from May 1, 2016.

The Notice on the Adjustment to VAT Rates (《關於調整增值税税率的通知》), promulgated by the MOF and the SAT on April 4, 2018 and became effective as of May 1, 2018 adjusted the applicative rate of VAT, and the deduction rates of 17% and 11% applicable to the taxpayers who have VAT taxable sales activities or imported goods are adjusted to 16% and 10%, respectively.

According to the Announcement on Relevant Policies for Deepening Value-Added Tax Reform (《關於深化增值税改革有關政策的公告》promulgated on March 20, 2019 and became effective on April 1, 2019, with respect to VAT taxable sales or imported goods of a VAT general taxpayer, where the VAT rate of 16% applies currently, it shall be adjusted to 13%.



Shanghai Miracogen Inc.- Ex. 2032, Page 000240

**Regulations Related to the "Full Circulation" of H-share**

"Full circulation" means listing and circulating on the Hong Kong Stock Exchange of the domestic unlisted shares of a domestic joint stock company ("**H-share listed company**"), including unlisted domestic shares held by domestic shareholders prior to overseas listing, unlisted domestic shares additionally issued after overseas listing, and unlisted shares held by foreign shareholders. On November 14, 2019, CSRC announced the Guidelines for the "Full Circulation" Program for Domestic Unlisted Shares of H-share Listed Companies (Announcement of the CSRC [2019] No. 22) (《H股公司境內未上市股份申請"全流通"業務指引》(中國證監會公告[2019]22號)) ("**Guidelines for the 'Full Circulation'**").

According to the Guidelines for the "Full Circulation", shareholders of domestic unlisted shares may determine by themselves through consultation the amount and proportion of shares, for which an application will be filed for circulation, provided that the requirements laid down in the relevant laws and regulations and set out in the policies for state-owned asset administration, foreign investment and industry regulation are met, and the corresponding H-share listed company may be entrusted to file the said application for "full circulation". To file an application for "full circulation", an H-share listed company shall file the application with the CSRC according to the administrative licensing procedures necessary for the "examination and approval of public issuance and listing (including additional issuance) of shares overseas by a joint stock company". An H-share listed company may apply for "Full Circulation" separately or when applying for refinancing abroad. An unlisted domestic joint stock company may apply for "full circulation" when applying for an overseas initial public offering. After the application for "full circulation" has been approved by the CSRC, an H-share listed company shall submit a report on the relevant situation to the CSRC within 15 days after the registration with the CSDC of the shares related to the application has been completed. After domestic unlisted shares are listed and circulated on the Stock Exchange, they may not be transferred back to China.

On December 31, 2019, CSDC and Shenzhen Stock Exchange ("**SZSE**") jointly announced the Measures for Implementation of H-share "Full Circulation" Business (《H股"全流通"業務實施細則》) ("**Measures for Implementation**"). The businesses of cross-border transfer registration, maintenance of deposit and holding details, transaction entrustment and instruction transmission, settlement, management of settlement participants, services of nominal holders, etc. in relation to the H-share "full circulation business", are subject to the Measures for Implementation. Where there is no provision in the Measures for Implementation, it shall be handled with reference to other business rules of the CSDC and CSDC (Hong Kong) and SZSE.

According to the Measures for Implementation, after having completed relevant information disclosure, the H-share listed companies with the approval of the CSRC to engage in the H-share "Full Circulation" business shall apply to the CSDC for the deregistration of part or all of the non-foreign listed shares, and shall re-register the fully circulated H-shares which are not pledged, frozen, restricted to transfer to the share register institutions in Hong Kong. Such shares shall become eligible for listing and circulation on the Stock Exchange. Relevant



Shanghai Miracogen Inc.- Ex. 2032, Page 000241

securities are centrally deposited in CSDC for settlement. As the nominal holder of the above-mentioned securities, CSDC handles the depository and holding details maintenance, cross-border clearing and settlement and other businesses involved in the "full circulation" of H-shares, and provides nominal holder services for investors. The H-share listed company shall be authorized by "Full Circulation" shareholders to choose domestic securities companies that participate in the "full circulation" business of H-shares. "Full Circulation" shareholders submit trading instructions of H-shares "Full Circulation" shares through domestic securities companies. Domestic securities companies shall select a Hong Kong securities company to submit trading instructions of their "Full Circulation" shareholders to Hong Kong Stock Exchange for trading. After the transaction is concluded, CSDC and CSDC (Hong Kong) shall handle the cross-border clearing and settlement of relevant shares and funds. The settlement currency of H-share "full circulation" transaction business is Hong Kong dollars. Where an H-share listed company entrusts CSDC to distribute cash dividends, it shall file an application with CSDC. An H-share listed company distributing cash dividends may apply to the CSDC for the holding details of relevant "fully-tradable" shareholders on the securities registration date. The non-H-share "fully circulated" securities listed on the Stock Exchange obtained due to the distribution and conversion of H-share "fully circulated" securities may be sold but shall not be purchased. Where the right to subscribe for the shares listed on Hong Kong Stock Exchange is obtained and the subscription right is listed on Hong Kong Stock Exchange, it may be sold, but shall not be exercised.

In order to fully promote the reform of H-shares "full circulation" and clarify the business arrangement and procedures for the relevant shares' registration, custody, settlement and delivery, CSDC has promulgated the Circular on Issuing the Guide to the Program for Full Circulation of H-shares (《關於發佈<H股"全流通"業務指南>的通知》) in February 2020, which specified the business preparation, account arrangement, cross-boarder share transfer registration and overseas centralized custody, etc.



Shanghai Miracogen Inc.- Ex. 2032, Page 000242

## OVERVIEW

We are an innovation-driven biopharmaceutical company with a strong Chinese root and global vision.

In early 2017, Dr. Pu, our founder and Controlling Shareholder, and Mr. Su Rongyu (蘇榮譽), decided to start a biopharmaceutical company focusing on cancer therapeutics. For such purpose, Dr. Pu established our Company as a limited liability company in Shanghai, the PRC on January 19, 2018.

With Dr. Pu's rich industry and commercialization experience, Dr. Pu has formulated visionary corporate roadmap and differentiated strategies, contributing his experience and expertise to the build-up of pipeline portfolios and end-to-end biopharma platform of the Company.

## OUR BUSINESS MILESTONES

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

| Time | Event |
|---|---|
| January 2018 | Our Company was established under the name of Lepu Biopharma Co., Ltd. (樂普生物科技有限公司) with Dr. Pu as our Controlling Shareholder. |
| June 2018 | We acquired PD-1 and PD-L1 pipeline products by acquiring controlling equity interest in Taizhou Hanzhong and Taizhou Aoke. |
| July 2018 | We acquired controlling equity interest in Miracogen Shanghai which owned our ADC platform. |
| September 2018 | We obtained approval from NMPA for conducting Phase II registration trial of melanoma and MSI-H solid tumors.<br><br>We initiated a Phase II registration trial for HX008 in MSI-H/dMMR solid tumors. |
| October 2018 | We initiated a single arm, open-label, Phase II registration trial of HX008 in locally advanced or metastatic melanoma after failure of standard treatment. |



Shanghai Miracogen Inc.- Ex. 2032, Page 000243

| Time | Event |
|---|---|
| February 2019 | We obtained IND approval from NMPA and Phase I clinical trial approval from NMPA for MRG001 in relapsed/refractory CD20-positive B-cell NHL. |
| March 2019 | We in-licensed the development, manufacturing and commercialization right of CG0070, an oncolytic virus, in Mainland China, Hong Kong and Macao from CG Oncology. |
| October 2019 | We commenced the operation of a 2,000L GMP-compliant antibody production line in Beijing. |
| January 2020 | We obtained IND approval from NMPA regarding the combination therapy of LP002 with OH2 in advanced solid tumors. |
| March 2020 | We incorporated CtM Bio, a research and development platform for the discovery of new drug candidates. |
| April 2020 | We obtained IND approval from NMPA regarding the combination therapy of HX008 with OH2 in advanced unresectable solid tumors for which standard treatment has failed. |
| May 2020 | We obtained IND clearance from FDA regarding MRG002 in HER2 positive locally advanced or metastatic gastric/gastroesophageal junction cancer.<br><br>Miracogen Shanghai became our wholly owned subsidiary. |
| July 2020 | We obtained approval from NMPA for conducting Phase III clinical trial for HX008 in combination with irinotecan in second-line treatment of advanced gastric or gastroesophageal junction cancer. |
| February 2021 | We obtained IND clearance from FDA for MRG004A in treatment of TF-positive solid tumors. |
| June 2021 | We filed an NDA of HX008 in melanoma with the NMPA. |
| August 2021 | We obtained IND approval from NMPA for MRG004A. |
| October 2021 | We filed an NDA of HX008 with the NMPA in MSI-H/dMMR solid tumors. |
| November 2021 | We obtained IND approval from NMPA for CG0070. |



Shanghai Miracogen Inc.- Ex. 2032, Page 000244

## CORPORATE DEVELOPMENT

The following sets forth the corporate history and shareholding changes of our Company.

### Incorporation of our Company

Upon incorporation of our Company in January 2018, our Company had a registered capital of RMB1.00 billion and was owned by Ningbo Houde Yimin and Lepu Medical as to 80% and 20%, respectively. Ningbo Houde Yimin is wholly owned by Beijing Houde Yimin with Dr. Pu Zhongjie being its ultimate beneficial owner and Lepu Medical is a company listed on the Shenzhen Stock Exchange (stock code: 300003) with Dr. Pu being its Actual Controller(1) and deemed to be interested in approximately 25.25% voting interest.

### Subsequent Capital Increase and Equity Transfer

After incorporation, our Company underwent several rounds of major shareholding changes: (i) transfer by Ningbo Houde Yimin to Mr. Su Rongyu, our co-founder, and Ms. Pu Jue, Dr. Pu Zhongjie's daughter, in December 2019; (ii) transfer by Ningbo Houde Yimin to establish the employee incentive platform of the Company in December 2019; (iii) investments by the Series A Investors in April 2020; (iv) issue of consideration Shares for acquisition of the remaining equity interest of Miracogen Shanghai in May 2020; (v) subscriptions by the Series B Investors in July 2020; and (vi) subscriptions by the Series C Investors in April 2021.

#### *Transfer by Ningbo Houde Yimin to Mr. Su Rongyu, our co-founder, and Ms. Pu Jue, Dr. Pu Zhongjie's daughter, in December 2019*

On December 30, 2019, Mr. Su Rongyu acquired 10% of our equity interest from Ningbo Houde Yimin at a total consideration of RMB100 million, reflecting the amount of registered capital of our Company being transferred. As of the Latest Practicable Date, Mr. Su served at the Institute for History of Natural Sciences, Chinese Academy of Sciences (中國科學院自然科學史研究所). Mr. Su and Dr. Pu attended Xi'an Jiaotong University (西安交通大學) between 1979 and 1983 and knew each other since then. Mr. Su may from time to time co-invest alongside with Dr. Pu's investment, including Lepu Medical, Beijing Tiandi Harmony Technology Co., Ltd. (北京天地和協科技有限公司), a wholly owned subsidiary of Lepu Medical engaging in the medical device business, and our Company.

On the same date, Ningbo Houde Yimin also transferred 9% of the equity interest of our Company to Shanghai Lvyuan, a special purpose investment vehicle ultimately wholly owned by Ms. Pu Jue, the daughter of Dr. Pu Zhongjie, at a total consideration of RMB90 million, equivalent to the amount of registered capital of our Company being transferred.

(1) According to Article 13.1(6) of Shenzhen Stock Exchange Gem Stock Listing Rules (Amended in December 2020), "Actual Controller" refers to the person who can actually control the behavior of the company through investment relationship, agreement or other arrangements.



Shanghai Miracogen Inc.- Ex. 2032, Page 000245

***Transfer by Ningbo Houde Yimin to establish the employee incentive platform of the Company in December 2019***

On December 30, 2019, Ningbo Houde Yimin transferred 5% of equity interest of our Company to Shanghai Chunrui, a limited partnership incorporated on December 12, 2019 as an employee incentive platform of our Company, at the consideration of RMB50 million reflecting the amount of registered capital of our Company being transferred. See section "5. Employee Share Ownership Plan" in Appendix VIII for further details on the employee incentive platform of the Company.

Immediately after the transfer by Ningbo Houde Yimin to Mr. Su Rongyu, Shanghai Lvyuan and Shanghai Chunrui, our Company was owned by Ningbo Houde Yimin, Lepu Medical, Mr. Su Rongyu, Shanghai Lvyuan and Shanghai Chunrui as to 56%, 20%, 10%, 9% and 5%, respectively.

***Investments by the Series A Investors in April 2020***

On April 21, 2020, Series A Investors subscribed for a total of 22.50% equity interest of our Company at a consideration of RMB900 million through the following means:

- ***Subscription of equity interest by conversion of convertible loans issued by our Company to Series A Investors***: on April 21, 2020, the Series A Investors (other than Lepu Medical) subscribed for 9% of the equity interest of our Company by converting the convertible loans issued by our Company to such Series A Investors (other than Lepu Medical) on March 4, 2019 in the total amount of RMB360 million for the development of the Company ("Convertible Loans"). Such Convertible Loans were interest free under the relevant agreement and have all been converted into our equity interest, with no amount outstanding after such conversion.

- ***Acquisition of equity interest from Ningbo Houde Yimin***: on April 21, 2020, the Series A Investors (other than Lepu Medical) acquired 11.25% of our equity interest from Ningbo Houde Yimin with consideration settled by the loans extended by Series A Investors (other than Lepu Medical) to Ningbo Houde Yimin in the amount of RMB450 million ("Controlling Shareholder Loans") on March 4, 2019. Such Controlling Shareholder Loans were interest free under the relevant agreement and have all been settled with Ningbo Houde Yiming's 11.25% equity interest in our Company, with no amount outstanding after such settlement.

- ***Cash subscription***: on April 21, 2020, Lepu Medical further subscribed for 2.25% of our equity interest for a cash consideration of RMB90 million.


Shanghai Miracogen Inc.- Ex. 2032, Page 000246

Set forth below is our shareholding structure immediately before and after the above investments by the Series A Investors:

| Shareholders | Amount of the Convertible Loans *(RMB)* | Amount of the Controlling Shareholder Loans *(RMB)* | Total consideration paid by the Series A Investors *(RMB)* | Approx. % of shareholding immediately before the investments by the Series A Investors | Approx. % of shareholding immediately after the investments by the Series A Investors |
|---|---|---|---|---|---|
| Ningbo Houde Yimin | – | – | – | 56% | 38.4500% |
| Lepu Medical | – | – | 90,000,000 | 20% | 20.0000% |
| Mr. Su Rongyu | – | – | – | 10% | 8.8750% |
| Shanghai Lvyuan | – | – | – | 9% | 7.9875% |
| Shanghai Chunrui | – | – | – | 5% | 4.4375% |
| Suzhou Danqing | 111,111,111 | 138,888,889 | 250,000,000 | – | 6.2500% |
| Suzhou Private Capital Investment | 88,888,889 | 111,111,111 | 200,000,000 | – | 5.0000% |
| Kaiyuan Guochuang | 44,444,444 | 55,555,556 | 100,000,000 | – | 2.5000% |
| Kington Capital | 35,555,556 | 44,444,444 | 80,000,000 | – | 2.0000% |
| Suzhou Suzi | 31,111,111 | 38,888,889 | 70,000,000 | – | 1.7500% |
| Suzhou Xinrui | 22,222,222 | 27,777,778 | 50,000,000 | – | 1.2500% |
| Jiaxing Danqing | 17,777,778 | 22,222,222 | 40,000,000 | – | 1.0000% |
| Linzhi Lecheng | 8,888,889 | 11,111,111 | 20,000,000 | – | 0.5000% |
| **Total** | **360,000,000** | **450,000,000** | **900,000,000** | **100%** | **100%** |

Please see the section headed "– Pre-IPO Investments" for further details on the investment by Series A Investors.

***Issue of consideration Shares for acquisition of the remaining equity interest of Miracogen Shanghai in May 2020***

Immediately prior to the subscription by Miracogen HK, Miracogen Shanghai was owned by our Company and Miracogen HK as to 63.01% and 36.99%, respectively. For the overall strategic development of our Company and to further strengthen our pipelines, we decided to acquire the remaining 36.99% equity interest in Miracogen Shanghai. On May 16, 2020, our Company issued, and Miracogen HK subscribed for, 10.98% of equity interest in our Company, in consideration for Miracogen HK transferring to our Company 36.99% equity interest it held in Miracogen Shanghai. Upon completion of the transfer, Miracogen Shanghai became a wholly owned subsidiary of our Company.



Shanghai Miracogen Inc.- Ex. 2032, Page 000247

Set forth below is our shareholding structure immediately before and after the subscription by Miracogen HK:

| Shareholders | Approx. % of shareholding immediately before subscription by Miracogen HK | Approx. % of shareholding immediately after subscription by Miracogen HK |
|---|---|---|
| Ningbo Houde Yimin | 38.4500% | 34.2282% |
| Lepu Medical | 20.0000% | 17.8040% |
| Miracogen HK | – | 10.9800% |
| Mr. Su Rongyu | 8.8750% | 7.9005% |
| Shanghai Lvyuan | 7.9875% | 7.1105% |
| Shanghai Chunrui | 4.4375% | 3.9503% |
| Suzhou Danqing | 6.2500% | 5.5638% |
| Suzhou Private Capital Investment | 5.0000% | 4.4510% |
| Kaiyuan Guochuang | 2.5000% | 2.2255% |
| Kington Capital | 2.0000% | 1.7804% |
| Suzhou Suzi | 1.7500% | 1.5579% |
| Suzhou Xinrui | 1.2500% | 1.1127% |
| Jiaxing Danqing | 1.0000% | 0.8902% |
| Linzhi Lecheng | 0.5000% | 0.4451% |
| **Total** | **100%** | **100%** |

Please see the section headed "– Pre-IPO Investments" for further details on the subscription by Miracogen HK.

***Subscriptions by the Series B Investors in July 2020***

On July 30, 2020, Series B Investors subscribed for approximately 15.20% of our equity interest at a total consideration of RMB1,291 million.



Shanghai Miracogen Inc.- Ex. 2032, Page 000248

Set forth below is our shareholding structure immediately before and after the subscriptions by the Series B Investors:

| Shareholders | Consideration *(RMB)* | Approx. % of shareholding immediately before the subscription by Series B Investors | Approx. % of shareholding immediately after the subscription by Series B Investors |
|---|---|---|---|
| Ningbo Houde Yimin | – | 34.2282% | 29.0240% |
| Lepu Medical | – | 17.8040% | 15.0970% |
| Miracogen HK | – | 10.9800% | 9.3106% |
| Mr. Su Rongyu | – | 7.9005% | 6.6993% |
| Shanghai Lvyuan | – | 7.1105% | 6.0294% |
| Suzhou Danqing | – | 5.5638% | 4.7178% |
| Suzhou Private Capital Investment[(1)] | – | 4.4510% | 3.7743% |
| Shanghai Chunrui | – | 3.9503% | 3.3497% |
| Kaiyuan Guochuang | – | 2.2255% | 1.8871% |
| Kington Capital | – | 1.7804% | 1.5097% |
| Suzhou Suzi | – | 1.5579% | 1.3210% |
| Suzhou Xinrui | – | 1.1127% | 0.9436% |
| Jiaxing Danqing | – | 0.8902% | 0.7548% |
| Linzhi Lecheng | – | 0.4451% | 0.3774% |
| Tianjin Pingan | 250,000,000 | – | 2.9443% |
| Haitong Capital | 200,000,000 | – | 2.3554% |
| Sunshine Insurance | 200,000,000 | – | 2.3554% |
| Ronghui Sunshine | 150,000,000 | – | 1.7666% |
| China Reform | 150,000,000 | – | 1.7666% |
| SDIC Unity Capital | 150,000,000 | – | 1.7666% |
| Minxin Qiyuan | 100,000,000 | – | 1.1777% |
| Mr. Guo Tongjun (郭同軍) | 30,000,000 | – | 0.3533% |
| Mr. Wang Lei (王磊) | 15,000,000 | – | 0.1767% |
| Haihui Quanxing | 10,000,000 | – | 0.1178% |
| Mr. Wang Xinglin (王興林) | 10,000,000 | – | 0.1178% |
| Mr. Wei Zhanjiang (魏戰江) | 7,000,000 | – | 0.0824% |
| Ms. Zhang Xia (張霞) | 5,000,000 | – | 0.0589% |
| Ms. Wang Yong (王泳) | 5,000,000 | – | 0.0589% |
| Ms. Chen Juan (陳娟) | 4,500,000 | – | 0.0530% |
| Xinye Guangzhou | 2,500,000 | – | 0.0294% |
| Mr. Lin Yi (林儀) | 2,000,000 | – | 0.0236% |
| **Total** | **1,291,000,000** | **100%** | **100%** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000249

*Note:* On November 20, 2020, for internal restructuring purpose, Suzhou Private Capital Investment transferred the entire 3.77% equity interest it held in our Company to Kington Capital, a fund managed by Suzhou Private Capital Investment, for a consideration of RMB288,450,708, which was settled on March 9, 2021.

Please see the section headed "– Pre-IPO Investments" for further details on the subscriptions by the Series B Investors.

***Conversion***

On December 16, 2020, our Company was converted into a joint stock company with limited liability and was renamed as Lepu Biopharma Co., Ltd. (樂普生物科技股份有限公司). Immediately after the Conversion, our Company had a share capital of approximately RMB1,492.69 million and our Shareholders and their respective shareholding percentages remain unchanged immediately before and after the Conversion.

Set forth below is our shareholding structure immediately before and after the Conversion:

| **Shareholders** | **Approx. % of shareholding immediately before the Conversion** | **Approx. % of shareholding immediately after the Conversion** |
|---|---|---|
| Ningbo Houde Yimin | 29.0240% | 29.0240% |
| Lepu Medical | 15.0970% | 15.0970% |
| Miracogen HK | 9.3106% | 9.3106% |
| Mr. Su Rongyu | 6.6993% | 6.6993% |
| Shanghai Lvyuan | 6.0294% | 6.0294% |
| Suzhou Danqing | 4.7178% | 4.7178% |
| Shanghai Chunrui | 3.3497% | 3.3497% |
| Kaiyuan Guochuang | 1.8871% | 1.8871% |
| Kington Capital | 5.2840% | 5.2840% |
| Suzhou Suzi | 1.3210% | 1.3210% |
| Suzhou Xinrui | 0.9436% | 0.9436% |
| Jiaxing Danqing | 0.7548% | 0.7548% |
| Linzhi Lecheng | 0.3774% | 0.3774% |
| Tianjin Pingan | 2.9443% | 2.9443% |
| Haitong Capital | 2.3554% | 2.3554% |
| Sunshine Insurance | 2.3554% | 2.3554% |
| Ronghui Sunshine | 1.7666% | 1.7666% |
| China Reform | 1.7666% | 1.7666% |
| SDIC Unity Capital | 1.7666% | 1.7666% |
| Minxin Qiyuan | 1.1777% | 1.1777% |
| Mr. Guo Tongjun (郭同軍) | 0.3533% | 0.3533% |
| Mr. Wang Lei (王磊) | 0.1767% | 0.1767% |



Shanghai Miracogen Inc.- Ex. 2032, Page 000250

| Shareholders | Approx. % of shareholding immediately before the Conversion | Approx. % of shareholding immediately after the Conversion |
|---|---|---|
| Haihui Quanxing | 0.1178% | 0.1178% |
| Mr. Wang Xinglin (王興林) | 0.1178% | 0.1178% |
| Mr. Wei Zhanjiang (魏戰江) | 0.0824% | 0.0824% |
| Ms. Zhang Xia (張霞) | 0.0589% | 0.0589% |
| Ms. Wang Yong (王泳) | 0.0589% | 0.0589% |
| Ms. Chen Juan (陳娟) | 0.0530% | 0.0530% |
| Xinye Guangzhou | 0.0294% | 0.0294% |
| Mr. Lin Yi (林儀) | 0.0236% | 0.0236% |
| **Total** | **100%** | **100%** |

***Subscriptions by the Series C Investors in April 2021***

On April 8, 2021, the Series C Investors subscribed for approximately 2.54% of our equity interest at a total consideration of RMB261.12 million.

Set forth below is our shareholding structure immediately before and after the subscriptions by the Series C Investors:

| Shareholders | Consideration *(RMB)* | Approx. % of shareholding immediately before the subscription by Series C Investors | Approx. % of shareholding immediately after the subscription by Series C Investors |
|---|---|---|---|
| Ningbo Houde Yimin | – | 29.0240% | 28.2855% |
| Lepu Medical | – | 15.0970% | 14.7128% |
| Miracogen HK | – | 9.3106% | 9.0736% |
| Mr. Su Rongyu | – | 6.6993% | 6.5288% |
| Shanghai Lvyuan | – | 6.0294% | 5.8759% |
| Suzhou Danqing | – | 4.7178% | 4.5978% |
| Shanghai Chunrui | – | 3.3497% | 3.2644% |
| Kaiyuan Guochuang | – | 1.8871% | 1.8391% |
| Kington Capital | – | 5.2840% | 5.1495% |
| Suzhou Suzi | – | 1.3210% | 1.2874% |
| Suzhou Xinrui | – | 0.9436% | 0.9196% |
| Jiaxing Danqing | – | 0.7548% | 0.7356% |



Shanghai Miracogen Inc.- Ex. 2032, Page 000251

| Shareholders | Consideration *(RMB)* | Approx. % of shareholding immediately before the subscription by Series C Investors | Approx. % of shareholding immediately after the subscription by Series C Investors |
|---|---|---|---|
| Linzhi Lecheng | – | 0.3774% | 0.3678% |
| Tianjin Pingan | – | 2.9443% | 2.8694% |
| Haitong Capital | – | 2.3554% | 2.2955% |
| Sunshine Insurance | – | 2.3554% | 2.2955% |
| Ronghui Sunshine | – | 1.7666% | 1.7216% |
| China Reform | – | 1.7666% | 1.7216% |
| SDIC Unity Capital | – | 1.7666% | 1.7216% |
| Minxin Qiyuan | – | 1.1777% | 1.1477% |
| Mr. Guo Tongjun (郭同軍) | – | 0.3533% | 0.3443% |
| Mr. Wang Lei (王磊) | – | 0.1767% | 0.1722% |
| Haihui Quanxing | – | 0.1178% | 0.1148% |
| Mr. Wang Xinglin (王興林) | – | 0.1178% | 0.1148% |
| Mr. Wei Zhanjiang (魏戰江) | – | 0.0824% | 0.0803% |
| Ms. Zhang Xia (張霞) | – | 0.0589% | 0.0574% |
| Ms. Wang Yong (王泳) | – | 0.0589% | 0.0574% |
| Ms. Chen Juan (陳娟) | – | 0.0530% | 0.0516% |
| Xinye Guangzhou | – | 0.0294% | 0.0287% |
| Mr. Lin Yi (林儀) | – | 0.0236% | 0.0230% |
| Vivo Capital | 163,200,000 | – | 1.5905% |
| SHC | 97,920,000 | – | 0.9543% |
| **Total** | **261,120,000** | **100%** | **100%** |

Please see the section headed "– Pre-IPO Investments" for further details on the subscriptions by Series C Investors.



Shanghai Miracogen Inc.- Ex. 2032, Page 000252

## OUR KEY SUBSIDIARIES AND MAJOR SHAREHOLDING CHANGES

We conduct our business principally through the following subsidiaries which made a material contribution to our results of operations during the Track Record Period:

| Name | Principal business activities | Date of establishment | Place of establishment | Percentage of equity interest held by our Company |
|---|---|---|---|---|
| Miracogen Shanghai | Research and development focusing on ADC related pipelines | January 27, 2014 | PRC | 100% |
| Taizhou Hanzhong | Research and development focusing on PD-1 related pipelines | November 25, 2016 | PRC | 72% |
| Taizhou Aoke | Research and development focusing on PD-L1 related pipelines | March 23, 2018 | PRC | 70% |
| CtM Bio | Discovery of new drug candidates | March 26, 2020 | PRC | 70% |
| Lepu Beijing | Operation of our manufacturing site in Beijing | July 30, 2018 | PRC | 100% |
| Innocube Limited | Holding company of Innocube Biosciences Inc. which is a platform for overseas clinical development | July 30, 2020 | BVI | 100% |

### Miracogen Shanghai

Miracogen Shanghai, a research and development platform for ADC related pipelines, was established by Dr. Hu Chaohong (胡朝紅), our executive Director and the co-chief executive officer of our Company, through a holding company, together with an Independent Third Party in January 2014. The entire equity interest of Miracogen Shanghai was later fully transferred to Miracogen HK, a special purpose investment vehicle ultimately and wholly owned by Dr. Hu, in June 2018. In July 2018, we acquired 63.01% equity interest in Miracogen Shanghai by way of both subscribing for RMB29,372,000 registered capital in Miracogen Shanghai and acquiring 3.52% equity interest from Miracogen HK for a total consideration of RMB350,000,000 based on arm's length negotiations after taking into consideration the business value of Miracogen Shanghai being approximately RMB557,734,000 at the time of the investment. In May 2020, we further acquired the remaining 36.99% equity interest in Miracogen Shanghai from Miracogen HK by issuing 10.98% equity interest of our Company to Miracogen HK based on arm's length negotiations after taking into consideration the


Shanghai Miracogen Inc.- Ex. 2032, Page 000253

business value of Miracogen Shanghai being approximately RMB1,484,000,000 appraised by an independent valuer and the business value of our Company and our subsidiaries being approximately RMB4,994,469,000 appraised by an independent valuer at the time of the investment, and Miracogen Shanghai became a wholly owned subsidiary of our Company. For further information, see "– Issue of consideration Shares for acquisition of the remaining equity interest of Miracogen Shanghai in May 2020" in this section. On November 1, 2021, the registered capital of Miracogen Shanghai was increased from RMB49,371,981 to RMB99,371,981 through a capital injection in the amount of RMB50 million by our Company.

**Taizhou Hanzhong**

Taizhou Hanzhong, a research and development platform for PD-1 related products, was established by HanX as its wholly owned subsidiary in November 2016. In December 2017, Ningbo Houde Yimin acquired 38.46% equity interest in Taizhou Hanzhong from HanX for a consideration of RMB50 million and further subscribed for RMB2,692,300 registered capital in Taizhou Hanzhong by way of injection of new capital for a consideration of RMB70 million, after which Taizhou Hanzhong was held by Ningbo Houde Yimin and HanX as to 60% and 40%, respectively. In June 2018, we entered into an equity transfer agreement with Ningbo Houde Yimin, pursuant to which we agreed to acquire from Ningbo Houde Yimin 51% equity interest of Taizhou Hanzhong at a consideration of RMB112.20 million, and in August 2018, Suzhou Danqing acquired from Ningbo Houde Yimin 9% equity interest of Taizhou Hanzhong at a consideration of RMB19.80 million. Both of the foregoing transfers were based on arm's length negotiations after taking into consideration the business value of Taizhou Hanzhong being approximately RMB220 million at the time of investment.

In September 2019, we entered into an equity purchase agreement with HanX to further acquire the 40% equity interest held by HanX in Taizhou Hanzhong for a consideration of RMB350 million ("Fixed Price") and an annual payment of 4.375% of the net sales revenue of HX008 (PD-1 mAb), one of our Core Products, after its commercialization, with the Fixed Price to be paid and equity interest to be transferred in instalments with no other pre-conditions attached thereto. As of the Latest Practicable Date, a total of RMB200 million has been paid by us and the rest of the Fixed Price will be paid by us by the end of 2022.

The transfers of 21% and 10% of equity interest in Taizhou Hanzhong have been respectively completed in September 2019 and October 2021 and we plan to complete the remaining 9% equity interest transfer by no later than the end of 2022. Upon completion of such transfer, we will own 91% of the equity interest in Taizhou Hanzhong, with the remaining 9% owned by Suzhou Danqing. As of the Latest Practicable Date, Taizhou Hanzhong was owned by us, HanX and Suzhou Danqing as to 82%, 9% and 9%, respectively.

Pursuant to the PRC Company Law and the articles of association of Taizhou Hanzhong, shareholders of Taizhou Hanzhong shall decide (i) by two thirds of votes on matters including amendment to the articles of association, increase or decrease of registered capital, merger, division, dissolution or change of the form of the company and (ii) by a majority of votes on matters including dividend declaration, and appointment and removal of directors, while the


Shanghai Miracogen Inc.- Ex. 2032, Page 000254

executive director of Taizhou Hanzhong shall carry out general management duties, such as formulating business plan and budget plan. None of HanX or Suzhou Danqing shall have any veto rights as a shareholder of Taizhou Hanzhong. As such, we do not expect any circumstances under which the non-controlling shareholders of Taizhou Hanzhong may be in a position to impede the research and development and commercialization of our product candidates.

**Taizhou Aoke**

Taizhou Aoke, a research and development platform for PD-L1 related products, was established by Ningbo Houde Yimin in March 2018. In June 2018, we acquired 70% equity interest in Taizhou Aoke by way of subscribing RMB78.40 million registered capital in Taizhou Aoke at a consideration of RMB78.40 million, and Taizhou Aoke was owned by us and Ningbo Houde Yimin as to 70% and 30%, respectively. In August 2018, Ningbo Houde Yimin transferred 30% equity interest in Taizhou Aoke to Suzhou Danqing, one of our Pre-IPO Investors. After such transfer and as of the Latest Practicable Date, Taizhou Aoke was owned by us and Suzhou Danqing as to 70% and 30%, respectively.

Pursuant to the PRC Company Law and the articles of association of Taizhou Aoke, shareholders of Taizhou Aoke shall decide (i) by unanimous votes (including vote of Suzhou Danqing) on matters including (a) amendment to the articles of association of the company; (b) increase or decrease in the registered capital, merger, division, reorganization, bankruptcy, liquidation or dissolution; (c) issuing new shares or similar securities; and (d) sale or disposal of all or most of the intellectual property of the company or its subsidiaries (if any) and (ii) by a majority of votes on other matters including approving business plan, budget plan and dividend payment, and director appointment. The board of Taizhou Aoke shall decide (i) by unanimous votes (including vote of Suzhou Danqing) on matters that also require unanimous votes of shareholders; and (ii) by a majority of votes on other matters including formulating business plan and budget plan, dividend declaration, capital increase or decrease plan. As the research and development and commercialization of our product candidates are not subject to the approval from the shareholders of Taizhou Aoke and could be determined by the board of directors of Taizhou Aoke, we do not expect any circumstances under which the non-controlling shareholders of Taizhou Aoke may be in a position to impede the research and development and commercialization of our product candidates.

**CtM Bio**

CtM Bio was incorporated by us as our wholly owned subsidiary in March 2020. In July 2020, we transferred 30% equity interest in CtM Bio to Dr. Fang Lei, our vice president, for nil consideration and Dr. Fang Lei paid the registered capital of such transferred equity interest in the amount of RMB9 million in full in December 2020. As of the Latest Practicable Date, CtM Bio is owned by our Company and Dr. Fang Lei as to 70% and 30%, respectively.



Shanghai Miracogen Inc.- Ex. 2032, Page 000255

Pursuant to the PRC Company Law and the articles of association of CtM Bio, shareholders of CtM Bio shall decide (i) by two thirds of votes on matters including (a) amendment to the articles of association of the company; (b) increase or decrease in the registered capital; and (c) merger, division, dissolution or change of the form of the company; and (ii) by a majority of votes on other matters including approving business plan and budget plan, dividend declaration and appointment and removal of directors, while the executive director of CtM Bio shall carry out general management of the company such as formulating business plan and budget plan. Dr. Fang Lei shall not have any veto rights as a shareholder of CtM Bio. As such, we do not expect any circumstances under which the non-controlling shareholders of CtM Bio may be in a position to impede the research and development and commercialization of our product candidates.

**Lepu Beijing and Innocube Limited**

Lepu Beijing and Innocube Limited have been incorporated as wholly owned subsidiaries of our Company, and as of the Latest Practicable Date, there is no shareholding change in relation to these two subsidiaries.

## CONFIRMATION BY THE PRC LEGAL ADVISORS

As advised by our PRC legal advisors, (i) all the changes in the registered capital and shareholding of our Company, and any equity transfers in respect of our Company have been duly completed pursuant to the applicable PRC laws, regulations and rules and are legally valid under the applicable PRC laws, regulations and rules; (ii) all necessary consents, approvals, authorizations and permissions required to be obtained for the Conversion, have been obtained, and all the Conversion steps have been duly completed pursuant to the applicable PRC laws, regulations and rules; and (iii) each of the acquisitions by our Company of our key subsidiaries, details of which are set out in "– Our Key Subsidiaries and Major Shareholding Changes" in this section, have been duly completed pursuant to the applicable PRC laws, regulations and rules and are legally valid under the applicable PRC laws, regulations and rules.


Shanghai Miracogen Inc.- Ex. 2032, Page 000256

## PRE-IPO INVESTMENTS

### Principal terms of the Pre-IPO Investments

The table below summarizes the principal terms of the Pre-IPO Investments:

| Investors | Series A Investors | Miracogen HK | Series B Investors | Series C Investors |
|---|---|---|---|---|
| **Date of investment agreement(s)** | April 21, 2020 | May 16, 2020 | July 30, 2020 | April 8, 2021 |
| **Amount of consideration paid (RMB million)** | 900.00[1] | 548.39 | 1,291.00 | 261.12 |
| **Basis of consideration** | ***Series A Investors, Series B Investors and Series C Investors***<br>The consideration was determined after arm's length negotiations between our Company on the one hand and the Series A Investors, Series B Investors and Series C Investors on the other hand, with reference to the business of our Company, the timing of the investments and the prospects of our business.<br><br>***Miracogen HK***<br>The consideration was settled by Miracogen HK transferring 36.99% of Miracogen Shanghai, the appraised value of which was RMB548.39 million, to our Company. The consideration was determined after arm's length negotiations between our Company and Miracogen HK with reference to business prospects and appraised value of Miracogen HK, the business of our Company, the timing of the investment and the prospects of our business. | | | |
| **Date on which investment was settled** | April 22, 2020 | May 28, 2020 | August 3, 2020 | April 17, 2021 |
| **Approximate investment cost per Share (RMB)** | 3.55 | 3.95 | 5.69 | 6.70 |
| **Discount to the IPO price[2]** | 39.11% | 32.25% | 2.40% | Premium over midpoint of IPO price of 14.92% |
| **Post-money valuation of our Company (RMB million)** | 4,000.00 | 5,850.00[3] | 8,491.00[4] | 10,261.12[5][6] |
| **Approximate shareholding in our Company after completion of the Pre-IPO Investments and immediately before the Global Offering[7]** | 29.61% | 9.07% | 14.82% | 2.54% |
| **Lock-up period** | Our Shares held by the Pre-IPO Investors are subject to a lock-up period of 12 months after the date of Listing on the Stock Exchange. See the section headed "Share Capital" of this prospectus for details. | | | |



Shanghai Miracogen Inc.- Ex. 2032, Page 000257

| Investors | Series A Investors | Miracogen HK | Series B Investors | Series C Investors |
|---|---|---|---|---|
| **Special rights**[8] | As of the Latest Practicable Date, the Series A Investors did not have any special rights. In the event that the application for Listing is rejected, denied or refused or approval for Listing is not granted within 12 months of the application of Listing, certain special rights of the Series A Investors will take effect, but such special rights would cease to be effective upon the Listing. | No special rights were granted to Miracogen HK. | As of the Latest Practicable Date, the Series B Investors did not have any special rights. In the event that the application for Listing is rejected, denied or refused or approval for Listing is not granted within 12 months of the application of Listing, certain special rights of the Series B Investors will take effect, but such special rights would cease to be effective upon the Listing. | As of the Latest Practicable Date, the Series C Investors did not have any special rights. In the event that the application for Listing is rejected, denied or refused or approval for Listing is not granted within 12 months of the application of Listing, certain special rights of the Series C Investors will take effect, but such special rights would cease to be effective upon the Listing. |
| **Use of proceeds** | For the total RMB900 million consideration,<br>(i) we have received an aggregate of RMB450 million comprising the Convertible Loans in an amount of RMB360 million and the subscription price of Lepu Medical in an amount of RMB90 million, all of which have been utilized in full as our general working capital; and<br>(ii) we have not received the remaining RMB450 million as such investment was made by the Series A Investors (other than Lepu Medical) through settlement of the Controlling Shareholder Loans with Ningbo Houde Yimin. | Our Company did not receive any proceeds from the investment as the investment was settled by transferring the equity interest in Miracogen Shanghai to us. | The proceeds have been utilized as our general working capital. | The proceeds have not been utilized as of the Latest Practicable Date and will be utilized towards the research and development of our pipeline assets, construction of production line, purchase of pipeline assets and development of business approved by our Board. |



Shanghai Miracogen Inc.- Ex. 2032, Page 000258

| Investors | Series A Investors | Miracogen HK | Series B Investors | Series C Investors |
|---|---|---|---|---|
| **Strategic benefits to our Company** | Our Directors were of the view that the investments by these seasoned investors demonstrated their confidence in our Company and our Company would benefit from the additional capital that would be provided by the investors. | Our Directors were of the view that, taking into account the prospects of the ADC products pipeline of Miracogen Shanghai, the acquisition of the remaining equity interest of Miracogen Shanghai would benefit our biopharmaceutical business. | Our Directors were of the view that the investments by these seasoned investors demonstrated their confidence in our Company and our Company would benefit from the additional capital that would be provided by the investors. | Our Directors were of the view that the investments by the seasoned investors demonstrated their confidence in our Company and our Company would benefit from the additional capital that would be provided by the investors. |

*Notes:*

(1) The RMB900 million investment made by Series A Investors comprises (i) the conversion of the Convertible Loans in an amount of RMB360 million into our equity interest; (ii) the exchange of the Controlling Shareholder Loans in an amount of RMB450 million for the equity interest of the Company held by Ningbo Houde Yimin; and (iii) RMB90 million cash subscription of our equity interest. See "– Investments by the Series A Investors in April 2020" in this section for details.

(2) Calculated on the basis of the Offer Price of HK$7.13, the mid-point of the proposed range of the Offer Price.

(3) The increased valuation for Miracogen HK subscription as compared to the investment by Series A Investors was mainly due to (i) the advancement in the research and development of MRG002; and (ii) our acquisition of 100% of Miracogen Shanghai's business.

(4) The increased valuation for the investment by Series B Investors as compared to Miracogen HK subscription was mainly due to the advancement in the research and development of HX008.

(5) The increased valuation for the investment by Series C Investors as compared to the investment by Series B Investors was mainly due to the advancement in the research and development of MRG003, MRG002, HX008 and CG0070.

(6) Calculated on the basis of the Offer Price of HK$7.13 (the mid-point of the indicative Offer Price range and assuming the Over-allotment Option is not exercised), the valuation of the Company upon Global Offering will be approximately HK$11.83 billion (the "Proposed IPO Valuation").

(7) See "– Our Shareholding Structure" for further details.

(8) Series A Investors (other than Lepu Medical), Series B Investors and Series C Investors have been granted under certain conditions, customary special rights, including but not limited to anti-dilution right and liquidation preferences.



Shanghai Miracogen Inc.- Ex. 2032, Page 000259

**Information about the Pre-IPO Investors**

***Vivo Capital***

Vivo Capital is an investment fund organized under the laws of Delaware, U.S. The general partner of Vivo Capital is Vivo Capital IX, LLC. Vivo Capital is under the management of Vivo Capital LLC. Founded in 1996, Vivo Capital LLC is a global healthcare investment firm with approximately US$5.8 billion in assets under management as of December 31, 2020, and provides a multi-fund investment platform, covering private equity including buyout, venture capital, and public equity. Funds managed by Vivo Capital LLC primarily invest in the United States and China, spanning the areas of biotechnology, pharmaceuticals, medical devices, and healthcare services. The ultimate beneficial owners of Vivo Capital are Independent Third Parties.

***Suzhou Danqing and Jiaxing Danqing***

Both Suzhou Danqing and Jiaxing Danqing are funds managed by Shenzhen Shiyu. Shenzhen Shiyu is ultimately controlled by Mr. Zhang Jian (張健), an Independent Third Party holding approximately 50.55% interest in Shenzhen Shiyu. Mr. Yang Hongbing (楊紅冰), our non-executive Director and co-founder of Shenzhen Shiyu, is interested in Shenzhen Shiyu as to approximately 32.17%. The remaining 17.28% interest of Shenzhen Shiyu are held by Independent Third Parties. Shenzhen Shiyu is a sophisticated investor focusing on equity investment in pharmaceutical and healthcare industry, with assets under management of approximately RMB6,866 million as of December 31, 2020. Shenzhen Shiyu's pharmaceutical investments include but are not limited to Jacobio Pharmaceuticals Group Co., Ltd. (加科思藥業集團有限公司), a company listed on the Stock Exchange (stock code: 1167), JD Health International Inc. (京東健康股份有限公司), a company listed on the Stock Exchange (stock code: 6618), JW (Cayman) Therapeutics Co., Ltd. (藥明巨諾(開曼)有限公司), a company listed on the Stock Exchange (stock code: 2126), Ascentage Pharma Group International (亞盛醫藥集團), a company listed on the Stock Exchange (stock code: 6855), and Shanghai Allist Pharmaceuticals Co., Ltd. (上海艾力斯醫藥科技股份有限公司), a company listed on the Shanghai Stock Exchange (stock code: 688578).

Suzhou Danqing is principally engaged in equity investment in the pharmaceutical industry and a limited partnership established in the PRC. The general partner of Suzhou Danqing is Ningbo Meishan Bonded Area Qiyu Equity Investment Management Limited Partnership (寧波梅山保稅港區齊玉股權投資管理合夥企業(有限合夥)), ultimately controlled by Shenzhen Shiyu. Lepu Medical and Mr. Yang Hongbing (楊紅冰), our non-executive Director, each holds approximately 3.14% and 0.37% limited partnership interest in Suzhou Danqing. The other limited partners of Suzhou Danqing are Independent Third Parties and none of them holds more than one-third of the partnership interest in Suzhou Danqing.

Jiaxing Danqing is principally engaged in equity investment and assets management and is a limited partnership established in the PRC. The general partner of Jiaxing Danqing is Tibet Danqing Investment Management Limited Partnership (西藏丹青投資管理合夥企業(有限合夥)), ultimately controlled by Shenzhen Shiyu. One of the limited partners of Jiaxing Danqing, Mr. Ma Jianan (馬嘉楠) who is an Independent Third Party, holds 36.36% partnership interest in Jiaxing Danqing. Mr. Yang Hongbing (楊紅冰), our non-executive Director, holds approximately 1.48% partnership interest in Jiaxing Danqing. The other limited partners of Jiaxing Danqing are Independent Third Parties and none of them holds more than one-third of the partnership interest in Jiaxing Danqing.



Shanghai Miracogen Inc.- Ex. 2032, Page 000260

***SDIC Unity Capital***

SDIC Unity Capital is a sophisticated investor principally engaged in equity investment and assets management, with assets under management of around RMB3 billion in the pharmaceutical industry as of December 31, 2020. As a limited partnership established in the PRC, the general partner of SDIC Unity Capital is SDIC Unity Fund Management Co., Ltd. (國投創合基金管理有限公司). SDIC Unity Capital primarily invests in seven emerging national strategic industries, including the biological, next-generation information technology and high-end equipment manufacturing industries.

***Tianjin Pingan and Haihui Quanxing***

Tianjin Pingan is a fund managed by Ping An Capital Co., Ltd. (平安資本有限責任公司), a company ultimately controlled by China Pingan Insurance (Group) Company of China, Ltd. (中國平安保險(集團)股份有限公司) ("Ping An Group").

Tianjin Pingan is principally engaged in equity investment and assets management and is a limited partnership established in the PRC, the general partner of which is Shenzhen Pingan Decheng Investment Co., Ltd. (深圳市平安德成投資有限公司) ("Ping An Decheng"), a company ultimately controlled by Ping An Group and holding 0.88% partnership interest in Tianjin Pingan. One of the limited partners of Tianjin Pingan, Shenzhen Pingan Zhiye Investment Co., Ltd. (深圳市平安置業投資有限公司) which in turn is ultimately controlled by Ping An Group, holds 54.43% partnership interest in Tianjin Pingan. The remaining limited partners of Tianjin Pingan are Independent Third Parties and none of them holds more than one-third of the partnership interest in Tianjin Pingan.

Haihui Quanxing is principally engaged in equity investment and assets management and a limited partnership established in the PRC. The general partner of Haihui Quanxing is Ping An Wealth Management Co., Ltd. (平安財富理財管理有限公司), a wholly-owned subsidiary of Ping An Group, which holds approximately 9.05% partnership interest in Haihui Quanxing. The remaining approximately 90.95% partnership interest of Haihui Quanxing is held by Ping An Capital Co., Ltd. (平安資本有限責任公司), a wholly-owned subsidiary of Ping An Group.

Ping An Group is a sophisticated investor listed on the Stock Exchange (stock code: 2318) and the Shanghai Stock Exchange (stock code: 601318) and an Independent Third Party.

***Kington Capital and Suzhou Suzi***

Kington Capital and Suzhou Suzi are funds managed by Suzhou Kington Equity Investment Fund Management Co., Ltd. (蘇州翼樸股權投資基金管理有限公司) ("Suzhou Kington"), a company wholly owned by Suzhou Private Capital Investment. Suzhou Private Capital Investment is held by 21 shareholders, all of which are Independent Third Parties, and none of them holds more than one-third of equity interest in Kington Capital or Suzhou Suzi.



Shanghai Miracogen Inc.- Ex. 2032, Page 000261

Kington Capital is principally engaged in equity investment and assets management and is a limited partnership established in the PRC. The general partner of Kington Capital is Suzhou Yipu No. 1 Chuangzhe Management Consultation Limited Partnership (蘇州翼樸一號創喆管理諮詢合夥企業(有限合夥)), ultimately controlled by Suzhou Private Capital Investment. Among the limited partners of Kington Capital, (i) none of the limited partners of Kington Capital holds more than one-third of the partnership interest in Kington Capital; and (ii) other than Mr. Lin Xianghong (林向紅), a non-executive Director of our Company and a limited partner of Kington Capital, holding 0.93% partnership interest in Kington Capital, the other limited partners of Kington Capital are Independent Third Parties.

Suzhou Suzi is principally engaged in equity investment and assets management and is a limited partnership established in the PRC. The general partner of Suzhou Suzi is Suzhou Zisu Investment Consultation Limited Partnership (蘇州梓蘇投資諮詢合夥企業(有限合夥)), ultimately controlled by Suzhou Private Capital Investment. One of the limited partners of Suzhou Suzi is Yinhua Changan Capital Management (Beijing) Co., Ltd. (銀華長安資本管理(北京)有限公司, formerly known as 銀華資本管理(珠海橫琴)有限公司), which is ultimately controlled by the State-Owned Assets Supervision and Administration Commission of Chongqing Municipal Government, holding 69.47% partnership interest in Suzhou Suzi. The other limited partners of Suzhou Suzi are Independent Third Parties and none of them holds more than one-third of the partnership interest in Suzhou Suzi.

***Kaiyuan Guochuang***

Kaiyuan Guochuang is a fund managed by Kaiyuan Guochuang Capital Management Co., Ltd. (開元國創資本管理有限公司) ("Kaiyuan Capital Management"), a company owned by Suzhou Kington and Guokai Kaiyuan Equity Investment Fund Management Co., Ltd. (國開開元股權投資基金管理有限公司) ("Guokai Kaiyuan") as to 55% and 45% respectively. Guokai Kaiyuan is ultimately controlled by China Development Bank (國家開發銀行).

Kaiyuan Guochuang is principally engaged in equity investment and assets management and is a limited partnership established in the PRC, the general partner of which is Suzhou Industrial Park Kaiyuan Guochuang Chengyun Investment Limited Partnership (蘇州工業園區開元國創承運投資合夥企業(有限合夥)), a limited partnership managed by Kaiyuan Capital Management. Kaiyuan Capital Management is controlled by Suzhou Kington. The limited partners of Kaiyuan Guochuang are Independent Third Parties and none of them holds more than one-third of the partnership interest in Kaiyuan Guochuang.

***Suzhou Xinrui***

Suzhou Xinrui is principally engaged in equity investment and assets management and is a limited partnership established in the PRC, the general partner and the fund manager of which is Suzhou Huyanglin Capital Management Co., Ltd. (蘇州胡楊林資本管理有限公司), ultimately controlled by Mr. Zhang Fuping (張福平), an Independent Third Party. One of the limited partners of Suzhou Xinrui, Mr. Li Tianhao (李天豪), is an Independent Third Party and holds 30% of the partnership interests in Suzhou Xinrui. The remaining limited partners of Suzhou Xinrui are Independent Third Parties and none of them holds more than one-third of the partnership interest in Suzhou Xinrui.



Shanghai Miracogen Inc.- Ex. 2032, Page 000262

***Linzhi Lecheng***

Linzhi Lecheng is principally engaged in consulting and service in pharmaceutical industry and is a limited liability company incorporated under the laws of PRC. Linzhi Lecheng is wholly owned by Linzhi Lekang Medical Industry Investment Co., Ltd. (林芝樂康醫療產業投資有限公司), a wholly owned subsidiary of Linzhi Legeng Investment Co., Ltd. (林芝樂耕投資有限公司), which in turn is owned by two Independent Third Parties, namely Mr. Chang Yunzhuan (常運專) and Mr. Chang Lixun (常立勳), in equal shares.

***Sunshine Insurance***

Sunshine Insurance is principally engaged in various insurance business and securities investment funds trading business and is a company limited by shares incorporated under the laws of PRC. Sunshine Insurance is owned as to 99.9999% and 0.0001% by Sunshine Insurance Group Co., Ltd. (陽光保險集團股份有限公司), of which none of its shareholders holds more than one-third of its equity interest, and Lahsa Huiju Enterprise Consultation Co., Ltd. (拉薩市慧聚企業管理諮詢有限公司), a company ultimately controlled by an Independent Third Party, Mr. Song Ning (宋寧), respectively.

***Ronghui Sunshine***

Ronghui Sunshine is principally engaged in equity investment and assets management and is a limited partnership established in the PRC, the general partner and fund manager of which is Sunshine Ronghui Capital Investment Management Co., Ltd. (陽光融匯資本投資管理有限公司) ("Ronghui Capital Management"), which is ultimately controlled by Ms. Zhang Wenwen (張文雯), an Independent Third Party, and Ms. Zhang is interested in 65% equity interest of Ronghui Capital Management. Sunshine Insurance Group Co., Ltd. (陽光保險集團股份有限公司), the shareholder of Sunshine Insurance, is interested in 35% of Ronghui Capital Management. Among the limited partners of Ronghui Sunshine: (i) Sunshine Insurance holds 79.50% partnership interest in Ronghui Sunshine; and (ii) the other limited partners of Ronghui Sunshine are also Independent Third Parties and none of them holds more than one-third of the partnership interest in Ronghui Sunshine.

***Haitong Capital***

Haitong Capital is principally engaged in securities investment, financial products investment and equity investment and a limited liability company incorporated under the laws of PRC. Haitong Capital is wholly owned by Haitong Securities Co., Ltd., (海通證券股份有限公司), a company listed on the Shanghai Stock Exchange (stock code: 600837) and Hong Kong Stock Exchange (stock code: 6837) and an Independent Third Party.



Shanghai Miracogen Inc.- Ex. 2032, Page 000263

***China Reform and Xinye Guangzhou***

China Reform and Xinye Guangzhou are funds managed by China Reform State-owned Enterprise Operation Investment Fund Management (Guangzhou) Co., Ltd. (國新央企運營投資基金管理(廣州)有限公司) ("China Reform Fund"). China Reform Fund is ultimately controlled by China Reform Holdings Corporation Ltd. (中國國新控股有限責任公司), a company wholly owned by the State Council of the PRC.

China Reform is principally engaged in equity investment and assets management and is a limited partnership established in the PRC, the general partner of which is China Reform Fund. One of the limited partners of China Reform is Shanghai Puyin Ansheng Asset Management Co., Ltd. (上海浦銀安盛資產管理有限公司), which is ultimately controlled by Shanghai Pudong Development Bank Co., Ltd. (上海浦東發展銀行股份有限公司) ("SPD Bank"), holds 59.88% partnership interest in China Reform. SPD Bank is a company listed on Shanghai Stock Exchange (stock code: 600000) and is an Independent Third Party. The other limited partners of China Reform are Independent Third Parties and none of them holds more than one-third of the partnership interest in China Reform.

Xinye Guangzhou is principally engaged in equity investment and is a limited partnership established in the PRC. The general partner of Xinye Guangzhou is China Reform Fund. All of the limited partners of Xinye Guangzhou are Independent Third Parties and none of them holds more than one-third of the partnership interest in Xinye Guangzhou.

***Minxin Qiyuan***

Minxin Qiyuan is principally engaged in equity investment and assets management and is a limited partnership established in the PRC. The general partner and fund manager of Minxin Qiyuan is Lahsa Minhe Investment Management Co., Ltd. (拉薩民和投資管理有限公司), which holds 9% partnership interest in Minxin Qiyuan, and is ultimately controlled by Mr. Han Bing (韓冰), an Independent Third Party. Qingdao Chengtou Technology Development Co., Ltd. (青島城投科技發展有限公司) is the limited partner of Minxin Qiyuan holding 91% partnership interest in Minxin Qiyuan, and is ultimately controlled by Qingdao Municipal Construction Investment (Group) Co., Ltd. (青島城市建設投資(集團)有限責任公司), a company wholly-owned by the State-Owned Assets Supervision and Administration Commission of Qingdao Municipal Government.

***SHC***

SHC is principally engaged in equity investment in the pharmaceutical industry in China and is a limited partnership established in the PRC. The general partner of SHC is Shanghai Healthcare Capital Management Co., Ltd. (上海生物醫藥產業股權投資基金管理有限公司), an Independent Third Party. All of the limited partners of SHC are Independent Third Parties and none of them holds more than one-third of the partnership interest in SHC.



Shanghai Miracogen Inc.- Ex. 2032, Page 000264

***Miracogen HK***

Miracogen HK, a limited liability company established under the laws of Hong Kong, is a special purpose investment vehicle ultimately wholly owned by Dr. Hu Chaohong (胡朝紅), our executive Director and co-chief executive officer.

***Other individual investors***

Mr. Wang Xinglin (王興林) is the chairman of the supervisory board of Lepu Medical, and each of Mr. Guo Tongjun (郭同軍), Mr. Wang Lei (王磊), Mr. Wei Zhanjiang (魏戰江), Ms. Zhang Xia (張霞), Ms. Wang Yong (王泳), Ms. Chen Juan (陳娟) and Mr. Lin Yi (林儀) is a senior management and/or employee of Lepu Medical. None of them is a director or senior management of the Company.

**Compliance with Interim Guidance**

On the basis that (i) the consideration for the Pre-IPO Investments (apart from the investment by Series C Investors) was settled more than 28 clear days before the date of our first submission of the listing application form to the Stock Exchange in relation to the listing, (ii) the consideration for the investment by Series C Investors was settled no less than 120 clear days before the Listing Date, and (iii) all special rights granted to the Pre-IPO Investors have been terminated or will cease to be effective prior to the Listing, the Joint Sponsors have confirmed that the Pre-IPO Investments are in compliance with the Interim Guidance on Pre-IPO Investments issued by the Stock Exchange on October 13, 2010, as updated in March 2017, the Guidance Letter HKEX-GL43-12 issued by the Stock Exchange in October 2012, as updated in July 2013 and March 2017, and the Guidance Letter HKEX-GL44-12 issued by the Stock Exchange in October 2012, as updated in March 2017.

**PUBLIC FLOAT**

Upon Listing, the H Shares directly held by Ningbo Houde Yimin, Lepu Medical, Shanghai Lvyuan, Miracogen HK and King Star Med LP will not count towards the public float. Except as stated above, all the H Shares directly held by other Shareholders will be counted towards the public float for the purpose of Rule 8.08 of the Listing Rules.

Based on the information on the Company's capitalization upon Listing and assuming all the Domestic Shares and Unlisted Foreign Shares are converted into H Shares as applied in the "Full Circulation", as shown in the table at "– Our Shareholding Structure" of this section below, upon completion of the Global Offering, without taking into account any Shares to be issued under the Over-allotment Option and based on an Offer Price of HK$6.87 per Share (being the low-end of the indicative Offer Price range), 694,020,819 H Shares (representing 41.85% of the total issued Share capital of the Company) will count towards the public float of the Company. Hence, our Company will meet the public float requirement under the Listing Rules.


Shanghai Miracogen Inc.- Ex. 2032, Page 000265

Immediately upon Listing, assuming that (i) 126,876,000 H Shares are issued and sold in the Global Offering; (ii) the Over-allotment Option is not exercised; and (iii) 1,658,545,838 Shares are issued and outstanding upon Listing, based on an Offer Price of HK$6.87 per Share (being the low-end of the indicative Offer Price range), the Company will have a market capitalization of at least HK$375 million held by public pursuant to Rule 18A.07 of the Listing Rules.

## ACQUISITION OF INTEREST IN KYM

On December 31, 2020, Innocube Limited entered into a stock purchase agreement with Miracogen HK to acquire the 30% equity interest held by Miracogen HK in KYM at a consideration of USD100 ("KYM Acquisition"). The consideration was negotiated and determined by the parties after arm's length negotiations with reference to the share capital contribution made by Miracogen HK in KYM.

KYM is principally engaged in the development and commercialization of CMG901 in both China and the U.S. The KYM Acquisition has been completed on January 26, 2021 and KYM is currently owned by Innocube Limited and iBridge as to 30% and 70% respectively. According to the unaudited financial statements of KYM, the total assets of KYM is USD164,582.03 as of December 31, 2020, the total revenue of KYM is nil for the financial year ended December 31, 2020, the loss before taxation of KYM is USD135,417.97 for the year ended December 31, 2020 and the total R&D expense and administrative expenses is USD135,377.97 for the year ended December 31, 2020.

Our Directors believe that the terms of the acquisition of interest in KYM are fair and reasonable and in the interests of our Company and our Shareholders as a whole. The acquisition of interests in KYM, including its CMG901 research and development project, diversifies our ADC product pipelines and enhances our international business footprint. See "Business – Drug Candidates We Co-developed Through Joint Venture – CMG901" for further details.


Shanghai Miracogen Inc.- Ex. 2032, Page 000266

## OUR SHAREHOLDING STRUCTURE

The table below summarizes the shareholding structure of our Company as of the Latest Practicable Date and immediately prior to the completion of the Global Offering (assuming the Over-allotment Option is not exercised) and immediately following the completion of the Global Offering (assuming the Over-allotment Option is not exercised):

| | | As of the Latest Practicable Date | | | Immediately following the completion of the Global Offering (assuming the Over-Allotment Option is not exercised) |
|---|---|---|---|---|---|
| **Class of Shares** | **Shareholder** | **Number of Shares held** | **Approximate percentage of shareholding in the relevant class of Shares** | **Approximate percentage of shareholding in total issued Share capital of our Company** | **Approximate percentage of shareholding in total issued Share capital of our Company** |
| Domestic Shares[(1)] | Ningbo Houde Yimin | 433,239,436 | 31.6619% | 28.2855% | 26.1216% |
| | Lepu Medical | 225,352,113 | 16.4691% | 14.7128% | 13.5873% |
| | Mr. Su Rongyu | 100,000,000 | 7.3082% | 6.5288% | 6.0294% |
| | Shanghai Lvyuan | 90,000,000 | 6.5774% | 5.8759% | 5.4264% |
| | Kington Capital | 78,873,241 | 5.7642% | 5.1495% | 4.7556% |
| | Suzhou Danqing | 70,422,536 | 5.1466% | 4.5978% | 4.2460% |
| | Shanghai Chunrui | 50,000,000 | 3.6541% | 3.2644% | 3.0147% |
| | Tianjin Pingan | 43,949,259 | 3.2119% | 2.8694% | 2.6499% |
| | Haitong Capital | 35,159,408 | 2.5695% | 2.2955% | 2.1199% |
| | Sunshine Insurance | 35,159,408 | 2.5695% | 2.2955% | 2.1199% |
| | Kaiyuan Guochuang | 28,169,014 | 2.0586% | 1.8391% | 1.6984% |
| | Ronghui Sunshine | 26,369,556 | 1.9271% | 1.7216% | 1.5899% |
| | China Reform | 26,369,556 | 1.9271% | 1.7216% | 1.5899% |
| | SDIC Unity Capital | 26,369,556 | 1.9271% | 1.7216% | 1.5899% |
| | Suzhou Suzi | 19,718,310 | 1.4410% | 1.2874% | 1.1889% |
| | Minxin Qiyuan | 17,579,704 | 1.2848% | 1.1477% | 1.0599% |
| | SHC | 14,616,446 | 1.0682% | 0.9543% | 0.8813% |
| | Suzhou Xinrui | 14,084,507 | 1.0293% | 0.9196% | 0.8492% |
| | Jiaxing Danqing | 11,267,606 | 0.8235% | 0.7356% | 0.6794% |
| | Linzhi Lecheng | 5,633,802 | 0.4117% | 0.3678% | 0.3397% |
| | Mr. Guo Tongjun (郭同軍) | 5,273,911 | 0.3854% | 0.3443% | 0.3180% |
| | Mr. Wang Lei (王磊) | 2,636,956 | 0.1927% | 0.1722% | 0.1590% |
| | Mr. Wang Xinglin (王興林) | 1,757,970 | 0.1285% | 0.1148% | 0.1060% |



Shanghai Miracogen Inc.- Ex. 2032, Page 000267

| | | As of the Latest Practicable Date | | | Immediately following the completion of the Global Offering (assuming the Over-Allotment Option is not exercised) |
|---|---|---|---|---|---|
| **Class of Shares** | **Shareholder** | **Number of Shares held** | **Approximate percentage of shareholding in the relevant class of Shares** | **Approximate percentage of shareholding in total issued Share capital of our Company** | **Approximate percentage of shareholding in total issued Share capital of our Company** |
| | Haihui Quanxing | 1,757,970 | 0.1285% | 0.1148% | 0.1060% |
| | Mr. Wei Zhanjiang (魏戰江) | 1,230,579 | 0.0899% | 0.0803% | 0.0742% |
| | Ms. Zhang Xia (張霞) | 878,985 | 0.0642% | 0.0574% | 0.0530% |
| | Ms. Wang Yong (王泳) | 878,985 | 0.0642% | 0.0574% | 0.0530% |
| | Ms. Chen Juan (陳娟) | 791,087 | 0.0578% | 0.0516% | 0.0477% |
| | Xinye Guangzhou | 439,493 | 0.0321% | 0.0287% | 0.0265% |
| | Mr. Lin Yi (林儀) | 351,594 | 0.0257% | 0.0230% | 0.0212% |
| **Subtotal** | | **1,368,330,988** | **100%** | | |
| Unlisted Foreign Shares[(2)] | Miracogen HK | 138,978,106 | 85.0858% | 9.0736% | 8.3795% |
| | Vivo Capital | 24,360,744 | 14.9142% | 1.5905% | 3.4458% |
| **Subtotal** | | **163,338,850** | **100%** | | |
| **Total** | | **1,531,669,838** | | **100%** | **94.3271%** |

*Notes:*

(1) Immediately after completion of the Global Offering (assuming that the Over-allotment Option is not exercised) and conversion of Domestic Shares into H Shares, the number of total issued Domestic Shares will be 54,268,364, accounting for approximately 3.27% of the enlarged issued share capital after the Global Offering.

(2) Immediately after completion of the Global Offering (assuming that the Over-allotment Option is not exercised) and conversion of Unlisted Foreign Shares into H Shares, there will be no Unlisted Foreign Shares.

(3) Taking into account the subscription of Offer Shares by Vivo Capital, at a total consideration of US$30,000,000 (based on the Offer Price of HK$7.13 per Offer Share, being the mid-point of the Offer Price range set out in this Prospectus), pursuant to the relevant cornerstone investment agreement as further described under the section headed "Cornerstone Investors" in this Prospectus.

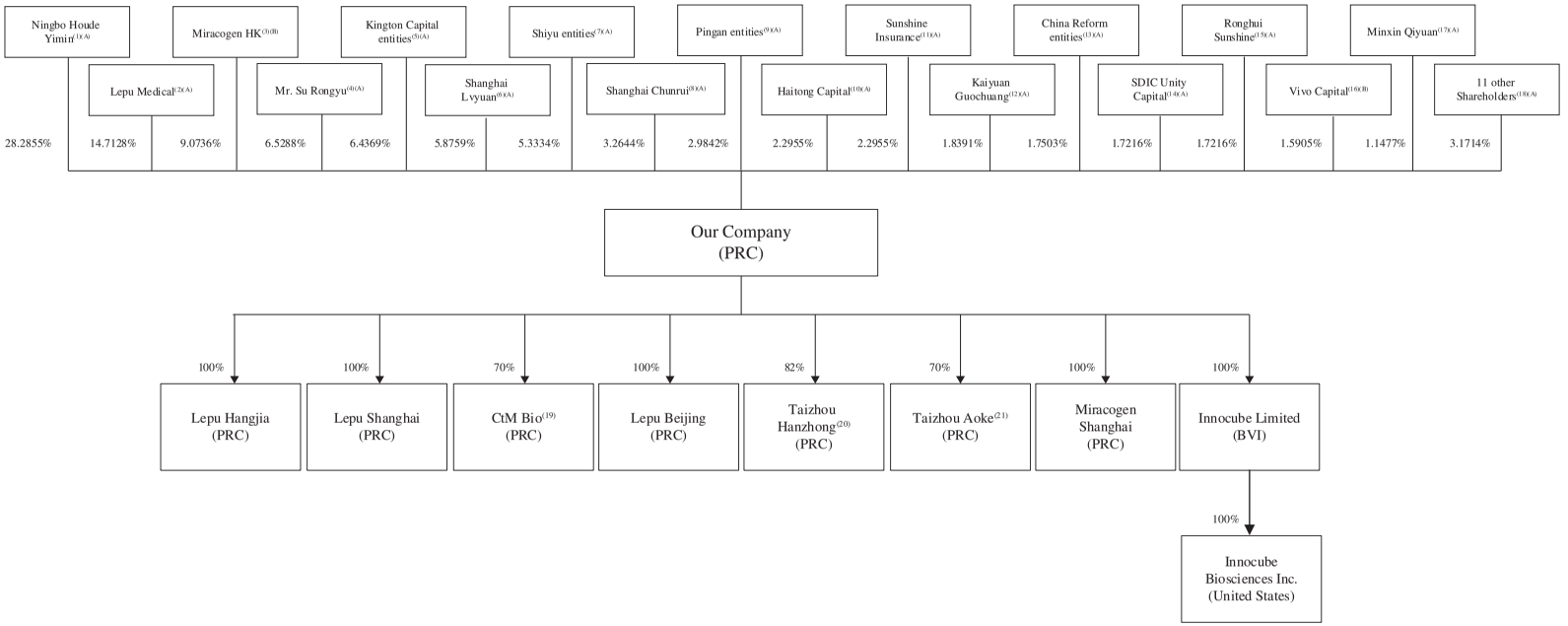


Shanghai Miracogen Inc.- Ex. 2032, Page 000268

## CORPORATE STRUCTURE

### Corporate structure immediately before completion of the Global Offering

The following chart sets forth our shareholding structure as of the Latest Practicable Date and immediately before completion of the Global Offering:




*Notes:*

(1) Ningbo Houde Yimin, a limited liability company incorporated under the laws of the PRC on March 29, 2017, is wholly owned by Beijing Houde Yimin with Dr. Pu Zhongjie being its ultimate beneficial owner.

(2) Lepu Medical, a joint stock company incorporated under the laws of the PRC on June 11, 1999, is listed on the Shenzhen Stock Exchange (stock code: 300003) with Dr. Pu Zhongjie being its Actual Controller holding approximately 25.25% voting interest.



Shanghai Miracogen Inc.- Ex. 2032, Page 000269

(3) Miracogen HK, a limited liability company established under the laws of Hong Kong, is a special purpose investment vehicle wholly-owned by Miracogen Inc., a company wholly-owned by Dr. Hu Chaohong (胡朝紅), our executive Director and the co-chief executive officer of our Company.

(4) Mr. Su Rongyu (蘇榮譽) is an analyst in the Institute for History of Natural Sciences, Chinese Academy of Sciences (中國科學院自然科學史研究所).

(5) Kington Capital entities include Kington Capital and Suzhou Suzi, being our Pre-IPO Investors and holding 5.1495% and 1.2874% of the Shares of our Company immediately before completion of Global Offering, and 4.7556% and 1.1889% of the Shares immediately following completion of the Global Offering (assuming the Over-Allotment Option is not exercised), respectively, in our Company. Kington Capital entities are limited partnerships established in the PRC whose general partners are ultimately controlled by Suzhou Private Capital Investment. To the best knowledge of our Directors, other than Mr. Lin Xianghong (林向紅), our non-executive Director and a limited partner of Kington Capital holding 0.9300% partnership interest in Kington Capital, the ultimate beneficial owners of Kington Capital and Suzhou Suzi are Independent Third Parties.

(6) Shanghai Lvyuan is a special purpose investment vehicle ultimately owned by Ms. Pu Jue (蒲珏), the daughter of Dr. Pu.

(7) Shiyu entities include Suzhou Danqing and Jiaxing Danqing, being our Pre-IPO Investors and holding 4.5978% and 0.7356% of the Shares of our Company immediately before completion of Global Offering, and 4.2460% and 0.6794% of the Shares immediately following completion of the Global Offering (assuming the Over-Allotment Option is not exercised), respectively, in our Company. Shiyu entities are limited partnerships established in the PRC whose general partners are ultimately controlled by Shenzhen Shiyu, a sophisticated investor founded by Mr. Yang Hongbing (楊紅冰) and ultimately controlled by an Independent Third Party. To the best knowledge of our Directors, other than Lepu Medical holding 3.1400% limited partnership interest in Suzhou Danqing and Mr. Yang Hongbing (楊紅冰), our non-executive Director, holding 0.3715% and 1.4823% partnership interest in Suzhou Danqing and Jiaxing Danqing, respectively, the ultimate beneficial owners of Suzhou Danqing and Jiaxing Danqing are Independent Third Parties.

(8) Shanghai Chunrui is a limited partnership incorporated on December 12, 2019 as an employee incentive platform of our Company. See section headed "5. Employee Share Ownership Plan" in Appendix VIII for further details of Shanghai Chunrui.

(9) Pingan entities include Tianjin Pingan and Haihui Quanxing, being our Pre-IPO Investors and holding 2.8694% and 0.1148% of the Shares of our Company immediately before completion of Global Offering, and 2.6499%, and 0.1060% of the Shares immediately following completion of the Global Offering (assuming the Over-Allotment Option is not exercised), respectively, in our Company. Pingan entities are limited partnership established in the PRC whose general partners are ultimately controlled by Ping An Group, an Independent Third Party to the best knowledge of our Directors. The ultimate beneficial owners of Pingan entities are Independent Third Parties to the best knowledge of our Directors.

(10) Haitong Capital, being our Pre-IPO Investor, is a limited liability company incorporated in the PRC and wholly-owned by Haitong Securities Co., Ltd., (海通證券股份有限公司), a company listed on the Shanghai Stock Exchange (stock code: 600837) and Hong Kong Stock Exchange (stock code: 6837) and an Independent Third Party to the best knowledge of our Directors.

(11) Sunshine Insurance, being our Pre-IPO Investor, holds 2.2955% of the Shares of our Company immediately before completion of Global Offering, and 2.1199% of the Shares immediately following completion of the Global Offering (assuming the Over-Allotment Option is not exercised). Sunshine Insurance is a limited liability company incorporated under the laws of the PRC. To the best knowledge of our Directors, the ultimate beneficial owners of Sunshine Insurance are Independent Third Parties.

(12) Kaiyuan Guochuang, being our Pre-IPO Investor, is a limited partnership established in the PRC and is ultimately controlled by Independent Third Parties to the best knowledge of our Directors. The ultimate beneficial owners of Kaiyuan Guochuang are Independent Third Parties to the best knowledge of our Directors.



Shanghai Miracogen Inc.- Ex. 2032, Page 000270

(13) China Reform entities include China Reform and Xinye Guangzhou, being our Pre-IPO Investors and holding 1.7216% and 0.0287% Shares of our Company immediately before completion of Global Offering, and 1.5899%, and 0.0265% of the Shares immediately following completion of the Global Offering (assuming the Over-Allotment Option is not exercised), respectively, in our Company. Each of China Reform and Xinye Guangzhou is a limited partnership established in the PRC whose fund manager and general partner is China Reform Fund, ultimately controlled by the State Council of the PRC. The ultimate beneficial owners of both China Reform and Xinye Guangzhou are Independent Third Parties to the best knowledge of our Directors.

(14) SDIC Unity Capital, being our Pre-IPO Investor, is a limited partnership established in the PRC whose general partner is ultimately controlled by the State-Owned Assets Supervision and Administration Commission of the PRC. The ultimate beneficial owners of SDIC Unity Capital are Independent Third Parties to the best knowledge of our Directors.

(15) Ronghui Sunshine, being our Pre-IPO Investor, holds 1.7216% of the Shares of our Company immediately before completion of Global Offering, and 1.5899% of the Shares immediately following completion of the Global Offering (assuming the Over-Allotment Option is not exercised). Ronghui Sunshine is a limited partnership established in the PRC. To the best knowledge of our Directors, the ultimate beneficial owners of Ronghui Sunshine are Independent Third Parties.

(16) Taking into account the subscription of Offer Shares by Vivo Capital, at a total consideration of US$30,000,000 (based on the Offer Price of HK$7.13 per Offer Share, being the mid-point of the Offer Price range set out in this Prospectus), pursuant to the relevant cornerstone investment agreement as further described under the section headed "Cornerstone Investors" in this Prospectus. Vivo Capital, being our Pre-IPO Investor, is an investment fund organized under the laws of Delaware, U.S. and ultimately controlled by Independent Third Parties to the best knowledge of our Directors. The ultimate beneficial owners of Vivo Capital are Independent Third Parties to the best knowledge of our Directors.

(17) Minxin Qiyuan, being our Pre-IPO Investor, is a limited partnership established in the PRC and ultimately controlled by Independent Third Parties to the best knowledge of our Directors. The ultimate beneficial owners of Minxin Qiyuan are Independent Third Parties to the best knowledge of our Directors.

(18) Such 11 other Shareholders include SHC, Suzhou Xinrui, Linzhi Lecheng, Mr. Guo Tongjun (郭同軍), Mr. Wang Lei (王磊), Mr. Wang Xinglin (王興林), Mr. Wei Zhanjiang (魏戰江), Ms. Zhang Xia (張霞), Ms. Wang Yong (王泳), Ms. Chen Juan (陳娟) and Mr. Lin Yi (林儀), holding 0.9543%, 0.9196%, 0.3678%, 0.3443%, 0.1722%, 0.1148%, 0.0803%, 0.0574%, 0.0574%, 0.0516% and 0.0230% of the Shares of our Company immediately before completion of the Global Offering, 0.8813%, 0.8492%, 0.3397%, 0.3180%, 0.1590%, 0.1060%, 0.0742%, 0.0530%, 0.0530%, 0.0477% and 0.0212% of the Shares immediately following completion of the Global Offering (assuming the Over-Allotment Option is not exercised), respectively, in our Company. To the best knowledge of our Directors, Minxin Qiyuan, Suzhou Xinrui and Linzhi Lecheng are ultimately controlled by Independent Third Parties. Mr. Wang Xinglin (王興林) is the chairman of the supervisory board of Lepu Medical, and each of Mr. Guo Tongjun (郭同軍), Mr. Wang Lei (王磊), Mr. Wei Zhanjiang (魏戰江), Ms. Zhang Xia (張霞), Ms. Wang Yong (王泳), Ms. Chen Juan (陳娟) and Mr. Lin Yi (林儀) is a senior management and/or employee of Lepu Medical.

(19) Dr. Fang Lei (方磊), our vice president, holds the remaining 30% of the equity interests in CtM Bio.

(20) The remaining 18% of Taizhou Hanzhong is held by HanX and Suzhou Danqing as to 9% and 9%, respectively. HanX is a company controlled by Mr. Zhang Faming (張發明), the director of Miracogen Shanghai, and Suzhou Danqing is a Pre-IPO Investor of our Company.

(21) Suzhou Danqing, a Pre-IPO Investor of our Company, holds the remaining 30% of the equity interests in Taizhou Aoke.

*Remarks:*

(A) The Shares held by these Shareholders are Domestic Shares.

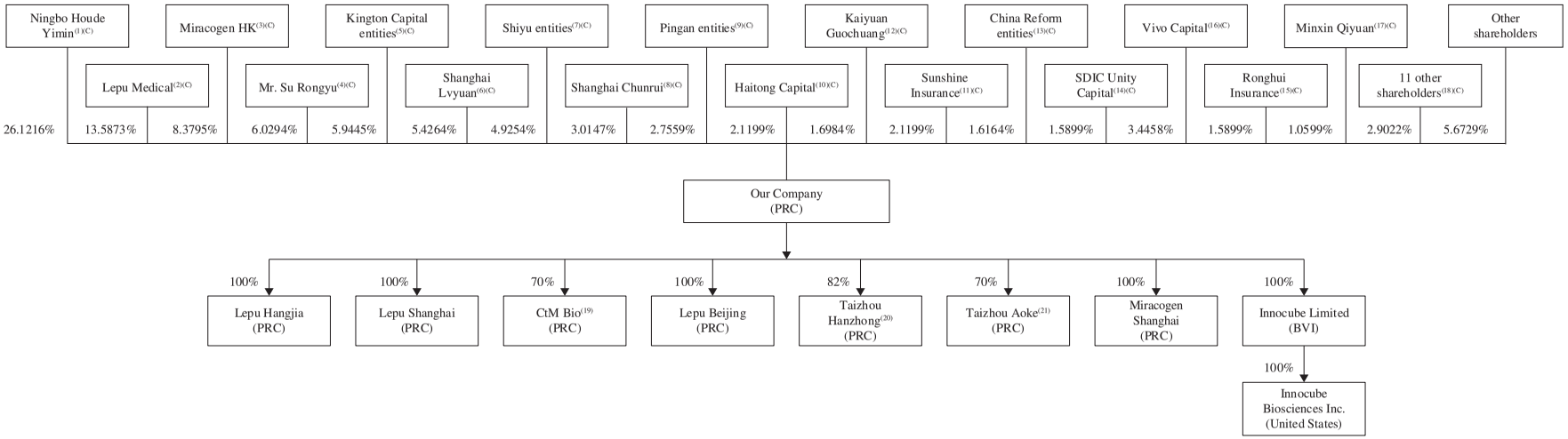
(B) The Shares held by these Shareholders are Unlisted Foreign Shares.



Shanghai Miracogen Inc.- Ex. 2032, Page 000271

## Corporate structure immediately following completion of the Global Offering

The following chart sets forth our shareholding structure immediately following completion of the Global Offering (assuming the Over-Allotment Option is not exercised and no changes in the following shareholdings since the Latest Practicable Date):




*Notes:*

Please refer to notes 1-21 in the paragraphs headed "– corporate structure immediately before completion of the Global Offering" in this section.

*Remark:*

(C) The 1,477,401,474 Shares held by these entities and individuals will be converted into H Shares.

Following the completion of the Global Offering, there will be 54,268,364 Domestic Shares comprising (i) 39,436,620 Domestic Shares held by Kington Capital, (ii) 9,859,155 Domestic Shares held by Suzhou Suzi, (iii) 1,318,478 Domestic Shares held by Mr. Wang Lei, and (iv) 3,654,111 Domestic Shares held by SHC. The Company currently did not have any plan to apply for full circulation to convert the foregoing Domestic Shares into H Shares.



Shanghai Miracogen Inc.- Ex. 2032, Page 000272

## OVERVIEW

Incorporated on January 19, 2018, we are a biopharmaceutical company focusing on oncology therapeutics. Our pipeline has been designed with a range of oncology products. The anti-PD-1 and anti-PD-L1 antibody candidates, underpinning our immunotherapy, are the backbone of our pipeline. We believe the broad spectrum of indications covered by anti-PD1 antibody drugs would prompt us to rapidly expand our commercialization capabilities. We filed an NDA with the NMPA in October 2021 for our anti-PD-1 antibody candidate HX008 (pucotenlimab) in MSI-H/dMMR. We are also devoted to the development of ADC and oncolytic virus drug products. We house the leading ADC drug candidate pipeline in China in terms of the number of clinical-stage ADC drug candidates, according to Frost & Sullivan. Our ADC drug candidates are the core of our targeted therapies. We have developed ADC drug candidates, including MRG003, MRG002 and MRG001 in-house since our acquisition of Miracogen Shanghai, developed in-house our ADC drug candidate MRG004A and own their global rights. MRG003 and MRG001 are ADC drug products targeting EGFR and CD20, respectively. We are conducting Phase I and Phase II clinical trials of MRG003, MRG002 and MRG001 in various indications. We received the IND clearance of MRG004A from the FDA in February 2021 for a Phase I/II clinical trial in the U.S. and we received IND approval of MRG004A from the NMPA in August 2021. We are also co-developing CMG901, the first CLDN18.2-targeted ADC to have received the IND approval globally, according to Frost & Sullivan, through a joint venture, KYM. Our oncolytic virus drug candidates include CG0070, for which we own the development and commercialization rights in Mainland China, Hong Kong and Macau, and OH2 which we co-developed with a business partner. We believe that our comprehensive ADC and oncolytic virus pipeline creates synergies and maximizes our competitive strength in commercialization.

As of the Latest Practicable Date, we had (i) eight clinical-stage drug candidates, including four Core Products acquired through acquisitions of all equity interests or controlling stake in the relevant subsidiaries, with three of them subject to in-license arrangements and one of them co-developed through a joint venture, (ii) three pre-clinical drug candidates, and (iii) three clinical-stage combination therapies of the candidates in our pipeline. Among the eight clinical-stage drug candidates, five are in targeted therapy and three are in immunotherapy, with two of the three being immune checkpoint drugs and one being oncolytic virus drug. As of the Latest Practicable Date, we had initiated 28 clinical trials, among which three had entered registration trial phase and two were ongoing in the U.S. The following chart summarizes the development status of our clinical-stage and pre-clinical drug candidates:


Shanghai Miracogen Inc.- Ex. 2032, Page 000273

Shanghai Miracogen Inc.- Ex. 2032, Page 000274

*Notes:*

* Denotes our core product candidates

** Denotes registration trials

1 MRG003 received IND approval from the NMPA in August 2017, which includes Phase Ia, Ib clinical study protocol and subsequent Phase II and Phase III study draft protocols. We acquired MRG003 at the Phase Ia stage and completed MRG003 Phase Ia trial in January 2020 and MRG003 Phase Ib trial in March 2021. As advised by our PRC Legal Advisor and taking into account the industry practice as advised by Frost & Sullivan, the MRG003 Phase Ia trial was a complete clinical trial with its main purpose aligning with the overall purpose of a conventional phase I trial, and the completion of the MRG003 Phase Ia trial is thus equivalent to the completion of a conventional Phase I trial. The MRG003 Phase II trials had been duly registered with the NMPA per the relevant regulatory requirements without any objection from the NMPA to our clinical development plans with respect to the regulatory review or approval process of MRG003. We have obtained all necessary approvals from the NMPA to proceed with the MRG003 Phase II trials. As of the Latest Practicable Date, we were conducting Phase II clinical trials of MRG003 in recurrent or metastatic advanced HNSCC, NPC, advanced NSCLC and BTC in China and expect to initiate Phase Ia/Ib clinical trials in recurrent or metastatic advanced HNSCC in the U.S.

2 MRG002 received IND approval from the NMPA in May 2018, which includes Phase Ia, Ib clinical study protocol and subsequent Phase II and Phase III study draft protocols. We acquired MRG002 when it obtained IND approval and completed MRG002 Phase Ia trial in August 2020. As advised by our PRC Legal Advisor and taking into account the industry practice as advised by Frost & Sullivan, the MRG002 Phase Ia trial was a complete clinical trial with its main purpose aligning with the overall purpose of a conventional phase I trial, and the completion of the MRG002 Phase Ia trial is thus equivalent to the completion of a conventional Phase I trial. Additionally, as part of the application to the NMPA for the combination program of MRG002 with HX008, the results of the MRG002 Phase Ia trial have been submitted to the NMPA for assessment. In January 2021, the NMPA confirmed in writing that, based on the pre-clinical and clinical data submitted to the NMPA (including the results of the MRG002 Phase Ia trial and the HX008 Phase Ia trial), we have provided support to proceed with phase I/II trial for the combination program of MRG002 with HX008. The MRG002 Phase II trials had been duly registered with the NMPA per the relevant regulatory requirements without any objection from the NMPA to our clinical development plans with respect to the regulatory review or approval process of MRG002. We have obtained all necessary approvals from the NMPA to proceed with the MRG002 Phase II trials. As of the Latest Practicable Date, we had initiated Phase II clinical trials of MRG002 in HER2 low-expressing and over-expressing breast cancer, UC (urothelial cancer) and HER2 over-expressing BTC. For HER2 over-expressing breast cancer, we had completed patient enrollment and were in the follow-up period, and had obtained approval from the NMPA of registration trial as of the Latest Practicable Date. In addition, we had initiated a Phase I/II clinical trial of MRG002 in gastric cancer in the U.S. and China as of the Latest Practicable Date.

3 HX008 received IND approval from the NMPA in August 2017, which includes Phase Ia, Ib clinical study protocol and subsequent Phase II and Phase III study draft protocols. We obtained HX008 at the Phase Ia stage and its Phase Ia trial was completed with MTD and RP2D determined per the clinical trial protocol in May 2018 and the final CSR issued in May 2020. As advised by our PRC Legal Advisor and taking into account the industry practice as advised by Frost & Sullivan, the HX008 Phase Ia trial was a complete clinical trial with its main purpose aligning with the overall purpose of a conventional phase I trial, and the completion of the HX008 Phase Ia trial is thus equivalent to the completion of a conventional Phase I trial. We filed an NDA of HX008 with the NMPA in melanoma in June 2021. We submitted pre-NDA meeting application of HX008 in MSI-H/dMMR solid tumors in July 2021, filed an NDA of HX008 with the NMPA in MSI-H/dMMR solid tumors in October 2021 and was granted priority review. According to our PRC Legal Advisor, we have obtained all necessary approvals from the NMPA to, proceed with the HX008 Phase II registration trials. As of the Latest Practicable Date, we had completed patient enrollment and were in the follow-up period for Phase Ib clinical trial of HX008 in advanced solid tumor and for Phase II clinical trials in NSCLC, TNBC (triple-negative breast cancer), gastric cancer and HCC. We were also conducting a Phase II clinical trial in NMIBC and a Phase III clinical trial in the second-line gastric cancer. We plan to initiate the Phase III clinical trials of HX008 in melanoma and in MSI-H/dMMR solid tumors after obtaining the respective approvals.

4 LP002 received IND approval from the NMPA in August 2018, which includes Phase Ia, Ib clinical study protocol and subsequent Phase II and Phase III study draft protocols. We obtained LP002 at its pre-clinical stage and completed LP002 Phase Ia trial in April 2019. As advised by our PRC Legal Advisor and taking into account the industry practice as advised by Frost & Sullivan, the LP002 Phase Ia trial was a complete clinical trial with its main purpose aligning with the overall purpose of a conventional Phase I trial, and thus is equivalent to the completion of a conventional Phase I trial. The data from the LP002 Phase Ia trial on its own has been accepted by the NMPA as sufficient to proceed with the LP002 Phase II trial. The LP002 Phase II trial for ES-SCLC indication had been duly registered with the NMPA pursuant to the relevant regulatory requirements without any objection from the NMPA to our clinical development plans with respect to its regulatory review or approval process. We have obtained all necessary approvals from the NMPA to proceed with LP002 Phase II trials. As of the Latest Practicable Date, we were in the process of a cohort expansion trial in advanced digestive system cancer and had completed patient enrollment and entered the follow-up period for Phase II clinical trial in ES-SCLC (extensive stage small-cell lung cancer).

5 Miracogen Shanghai acquired the co-ownership of the TF-targeted mAb and the joint right to develop ADCs based on the TF-targeted mAb from Fudan University and SIMMCAS. See "Business – Collaboration, Licensing and Transfer Arrangements – Collaboration with Fudan University and SIMMCAS." We received the IND clearance of MRG004A from the FDA in February 2021 to initiate Phase I/II clinical trials in patients with TF-positive advanced or metastatic solid tumors and we received IND approval of MRG004A from the NMPA in August 2021.



Shanghai Miracogen Inc.- Ex. 2032, Page 000275

6 CMG901 is co-developed by Keymed and us through KYM, a joint venture owned by us and Keymed's affiliate, iBridge, in which we owned 30.0% equity interest as of the Latest Practicable Date. See "– Collaboration, Licensing and Transfer Arrangements – Collaboration with Keymed and iBridge." KYM was enrolling patients for a Phase I clinical trial of CMG901 in advanced gastric cancer and pancreatic cancer in China as of the Latest Practicable Date and submitted an IND application to the FDA in February 2021 for a Phase I clinical trial in advanced unresectable or metastatic G/GEJ carcinoma.

7 We in-licensed the rights to develop, manufacture and commercialize CG0070 in Mainland China, Hong Kong and Macau from CG Oncology. See "Business – Collaboration, Licensing and Transfer Arrangements – Collaboration with CG Oncology." CG Oncology had completed a Phase II clinical trial (BOND II) of CG0070 in BCG-unresponsive NMIBC in the U.S., and we obtained IND approval for CG0070 from the NMPA in November 2021.

8 OH2 is an oncolytic virus developed by Wuhan Binhui. As of the Latest Practicable Date, we had initiated a Phase I clinical trial for LP002 in combination with OH2 for the treatment of advanced solid tumors. See "– Combination Therapies within Our Pipeline."

9 The status below refers to the clinical development progress of the relevant drug candidates and combination therapies in China except as otherwise specified.

10 According to the Technical Guidelines for the Communication of Clinical Aspects of Single-arm Trials to Support Pre-marketing License Applications for Marketed Antineoplastic Drugs (《單臂試驗支持上市的抗腫瘤藥上市許可申請前臨床方面溝通交流技術指導原則》) issued by the NMPA, we must conduct Phase III clinical trials for HX008. We plan to initiate the Phase III clinical trials for HX008 in melanoma and in MSI-H/dMMR solid tumors after obtaining the respective approvals.



Shanghai Miracogen Inc.- Ex. 2032, Page 000276

We have the global rights to develop and commercialize our clinical-stage and pre-clinical drug candidates and the drug candidate we co-developed through a joint venture apart from CG0070 for which we were granted the right to develop, manufacture and commercialize in Mainland China, Hong Kong and Macau.

Our major pipeline assets consist of four Core Products, namely, MRG003, MRG002, HX008 and LP002, and three key clinical-stage drug candidates:

➢ *ADC drug candidates (core products)*

- MRG003 (Core Product): MRG003 is the most advanced EGFR-targeted ADC in clinical-stage development in China and has the potential to seize market opportunities, as there was no approved EGFR-targeted ADC in China as of the Latest Practicable Date, according to Frost & Sullivan. MRG003 was recognized as one of the National Scientific and Technological Major Projects for "Major Drug Innovation" ("重大新藥創制"科技重大專項) in China in 2019. We acquired MRG003 at the Phase Ia stage and completed MRG003 Phase Ia trial in January 2020 and MRG003 Phase Ib trial in March 2021. MRG003 demonstrated encouraging safety and efficacy results in the data from our Phase Ib clinical trials in advanced solid tumors, including HNSCC and NPC in China, with a 40.0% ORR and an 100.0% DCR for HNSCC and a 44.4% ORR and a 88.8% DCR for NPC among efficacy evaluable patients. The ORR and DCR for CRC patients was nil and 25.0%, respectively. Based on the Phase Ia and Ib clinical trial results, we are conducting Phase II clinical trials of MRG003 in recurrent or metastatic advanced HNSCC, advanced NSCLC, BTC and NPC in China. In light of the encouraging clinical trial results in China, we expect to initiate clinical trials in recurrent or metastatic advanced HNSCC in the U.S. and expand MRG003 indications based on the clinical data obtained, further expanding the overall addressable market with the aim of achieving international commercialization with MRG003.

  Please refer to the following comparison of the efficacy of MRG003 with other globally marketed EGFR-ADC.

| Drug Name | Indications (Clinical trial stage, as applicable) | ORR | DCR | CR | PR | SD |
|---|---|---|---|---|---|---|
| Cetuximab Sarotalocan Sodium | Head and Neck Cancer | 43.4% | N/A | 13.3% | 30.0% | 36.7% |
| MRG003 | >2L HNSCC (Phase Ib) | 40.0% | 100.0% | N/A | N/A | N/A |
| | >2L NPC (Phase Ib) | 44.4% | 88.8% | N/A | N/A | N/A |



Shanghai Miracogen Inc.- Ex. 2032, Page 000277

Abbreviations: ORR = objective response rate; DCR = disease control rate; CR = complete response; PR = partial response; SD = stable disease;

*Source: PMDA, Literature Review, Frost & Sullivan*

*Notes:*

1. N/A refers to data not available.

2. No head-to-head comparison was conducted between drugs. Clinical trials of a drug cannot be directly compared to the clinical trials of another drug and may not be representative of the overall data.

- MRG002 (Core Product): MRG002 is an innovative HER2-targeted ADC. Our pre-clinical studies revealed better efficacy as compared to T-DM1 (trastuzumab emtansine) in multiple Herceptin-resistant HER2 over- and low-expressing PDX models of the gastric cancer and breast cancer. We acquired MRG002 when it obtained IND approval. We have completed the Phase Ia dose escalation stage trial of MRG002 in HER2 over-expressing solid tumors in China. As of the Latest Practicable Date, we had initiated Phase II clinical trials of MRG002 in HER2 low-expressing and over-expressing breast cancer, UC (urothelial cancer) and HER2 over-expressing BTC. For HER2 over-expressing breast cancer, we had completed patient enrollment and were in the follow-up period, and had obtained approval from the NMPA of registration trial as of the Latest Practicable Date. MRG002 demonstrated promising results in safety and efficacy in the preliminary data from our Phase Ia and Ib clinical trials, with ORR of 45.5% in Phase Ia and 53.2% in Phase Ib, respectively, and ORR of 54.9% among efficacy evaluable patients with breast cancer and received MRG002 treatment at dose above RP2D. We have initiated a Phase I/II clinical trial in the gastric cancer in the U.S. and China.

  Please refer to the following comparison of the efficacy of MRG002 with other globally marketed HER2-ADC.

| Drug Name | Indications (Clinical trial stage, as applicable) | ORR | DCR | CR | PR | SD | DOR (months) | PFS (months) | OS (months) |
|---|---|---|---|---|---|---|---|---|---|
| Trastuzumab deruxtecan-nxki | HER2-positive breast cancer | 60.9% | 97.3% | 6.0% | 54.9% | 36.4% | 14.8 | 16.4 | 24.6 |
| Adotrastuzumab emtansine | HER2-positive breast cancer | 43.6% | N/A | N/A | N/A | N/A | 12.6 | 9.6 | 30.9 |
| Disitamab Vedotin | Locally advanced or metastatic gastric cancer and gastroesophageal junction adenocarcinoma | 24.4% | N/A | N/A | N/A | N/A | N/A | 4.1 | 7.6 |
| MRG002 | HER2-positive advanced solid tumors (Phase Ia) | 45.5% | 81.8% | 0.0% | 45.5% | 36.4% | N/A | N/A | N/A |
| | HER2-positive advanced solid tumor (Phase Ib) | 53.2% | 93.6% | 0.0% | 53.2% | 40.4% | N/A | N/A | N/A |



Shanghai Miracogen Inc.- Ex. 2032, Page 000278

Abbreviations: ORR = objective response rate; DCR = disease control rate; CR = complete response; PR = partial response; SD = stable disease; DOR = duration of objective response; PFS = progression-free survival; OS = overall survival

*Source: FDA, CDE, Literature Review, Frost & Sullivan*

*Notes:*

1. N/A refers to data not available.

2. No head-to-head comparison was conducted between drugs. Clinical trials of a drug cannot be directly compared to the clinical trials of another drug and may not be representative of the overall data.

➢ *Anti-PD-1/anti-PD-L1 drug candidates*

- HX008 (Core Product): HX008 is a humanized antagonist mAb to human PD-1. We obtained HX008 at the Phase Ia stage and its Phase Ia trial was completed with MTD and RP2D determined per the clinical trial protocol in May 2018 and the final CSR issued in May 2020. We have completed the registration trials in melanoma and MSI-H/dMMR solid tumors HX008 demonstrated efficacy and a good safety profile in the completed Phase Ia clinical trial in solid tumors, allowing us to proceed to the Phase II registration trials in melanoma and MSI-H/dMMR solid tumors which are substantially completed pending only the end of the two-year follow-up period, which we expect to finish in the fourth quarter of 2022. As of February 2021, the ORR and DCR in the Phase II clinical trial in melanoma reached 18.5% and 44.5%, respectively. As of June 2021, the ORR and DCR in the Phase II clinical trial in MSI-H/dMMR solid tumors reached 46.0% and 70.0%, respectively. We filed an NDA of HX008 with the NMPA in melanoma in June 2021. We submitted pre-NDA meeting application of HX008 in MSI-H/dMMR solid tumors in July 2021, filed an NDA of HX008 with the NMPA in MSI-H/dMMR solid tumors and was granted priority review in October 2021. As of the Latest Practicable Date, we had completed patient enrollment and were in the follow-up period for Phase Ib clinical trial of HX008 in advanced solid tumor and for the Phase II clinical trial of HX008 in NSCLC, TNBC (triple-negative breast cancer), gastric cancer and HCC. We were also in the process of conducting a Phase II clinical trial of HX008 in NMIBC and a Phase III clinical trial of HX008 in the second-line gastric cancer as of the Latest Practicable Date.



Shanghai Miracogen Inc.- Ex. 2032, Page 000279

Please refer to the following comparison of the efficacy of HX008 with other marketed PD-1 mAbs with the same indications.

| Drug name | Indications (Clinical trial stage, as applicable) | ORR | DCR | CR | PR | SD | DOR (months) | PFS (months) | OS (months) |
|---|---|---|---|---|---|---|---|---|---|
| HX008 | MSI-H/dMMR solid tumors (Phase II) | 46.0% | 70.0% | N/A | N/A | N/A | N/A | N/A | N/A |
| Pembrolizumab | MSI-H/dMMR solid tumors | 39.6% | N/A | 7.4% | 32.2% | N/A | NR | N/A | N/A |
| Nivolumab | MSI-H/dMMR CRC | 32.0% | N/A | 9.0% | 23.0% | N/A | N/A | N/A | N/A |
| HX008 | Melanoma (Phase II) | 18.5% | 44.5% | N/A | N/A | N/A | N/A | 2.9 | N/A |
| Pembrolizumab | Melanoma | 16.7% | 38.2% | 1.0% | 15.7% | 21.6% | 8.4 | 2.8 | 12.1 |
| Toripalimab | Melanoma | 17.3% | 57.5% | 0.8% | 16.5% | 40.2% | NR | 3.6 | 22.2 |
| HX008 | First-line advanced gastric cancer (Phase II) | 60.0% | 77.1% | 2.9% | 57.1% | N/A | 12.7 | 9.2 | 12.9 |
| | Second-line advanced gastric cancer (Phase II) | 27.6% | 60.3% | N/A | N/A | 32.8% | 12.8 | 4.2 | 12.1 |
| Pembrolizumab | Gastric cancer | 48.6% | N/A | N/A | N/A | N/A | N/A | 6.9 | 12.5 |
| Nivolumab | Gastric cancer | 58.0% | N/A | 10.0% | 48.0% | 28.0% | 8.5 | 7.7 | 13.8 |
| HX008 | Advanced solid tumor (Phase Ia) | 16.7% | 36.7% | 0.0% | 16.7% | 20.0% | N/A | N/A | N/A |

Abbreviations: ORR = objective response rate; DCR = disease control rate; CR = complete response; PR = partial response; SD = stable disease; DOR = duration of objective response; PFS = progression-free survival; OS = overall survival; NR = not reached;

*Source: FDA, CDE, Literature Review, Frost & Sullivan*

*Notes:*

1. N/A refers to data not available.

2. No head-to-head comparison was conducted between drugs. Clinical trials of a drug cannot be directly compared to the clinical trials of another drug and may not be representative of the overall data.

- LP002 (Core Product): LP002 is a humanized mAb against PD-L1. We obtained LP002 at its pre-clinical stage and completed LP002 Phase Ia trial in April 2019. We are in the process of a cohort expansion trial in advanced digestive system cancer and have completed patient enrollment and entered the follow-up period for Phase II clinical trials in ES-SCLC in China. LP002 demonstrated encouraging results in safety and efficacy in the preliminary data from the clinical trials covering indications such as ES-SCLC. LP002 has shown a favorable safety profile in a Phase Ia clinical study in advanced solid tumors, with an overall ORR of 15.2% and an overall DCR of 51.5%, as of December 2020.



Shanghai Miracogen Inc.- Ex. 2032, Page 000280

Please refer to the following comparison of the efficacy of LP002 with other China marketed PD-L1 mAbs.

| Drug name | Indications (Clinical trial stage, as applicable) | ORR | DCR | CR | PR | SD | DOR (months) | PFS (months) | OS (months) |
|---|---|---|---|---|---|---|---|---|---|
| Atezolizumab | SCLC | 60.0% | N/A | 2.0% | 58.0% | N/A | 4.2 | 5.2 | 12.3 |
| | HCC | 29.8% | N/A | 7.7% | 22.1% | 44.2% | 18.1 | 6.8 | 19.2 |
| Durvalumab | NSCLC | 28.4% | N/A | 1.4% | 27.1% | 52.6% | N/A | 16.8 | N/A |
| LP002 | Advanced solid tumor (Phase Ia) | 15.2% | 51.5% | N/A | N/A | N/A | N/A | N/A | N/A |

Abbreviations: ORR = objective response rate; DCR = disease control rate; CR = complete response; PR = partial response; SD = stable disease; DOR = duration of objective response; PFS = progression-free survival; OS = overall survival

*Source: FDA, CDE, Literature Review, Frost & Sullivan*

*Notes:*

1. N/A refers to data not available.

2. No head-to-head comparison was conducted between drugs. Clinical trials of a drug cannot be directly compared to the clinical trials of another drug and may not be representative of the overall data.

➢ *Other ADC drug candidates*

- MRG001: MRG001 is a clinically advanced CD20-targeted ADC. With MRG001, we seek to address medical needs of B-cell NHL patients with primary drug resistance to rituximab and B-cell NHL patients with acquired drug resistance to the combination therapy of rituximab and standard chemotherapies. Pre-clinical *in vivo* studies of MRG001 demonstrated significantly better efficacy in the rituximab-resistant PDX model. We have completed the Phase Ia dose escalation study of MRG001 in China which has shown encouraging safety and efficacy results. One FL patient at the dose level of 0.15 mg/kg achieved PR, one DLBCL patient at the dose level of 1.8 mg/kg achieved CR, one FL patient at the dose level of 2.5 mg/kg achieved PR and other SD responses were observed across different dose levels, as of February 2021. As of the Latest Practicable Date, we were conducting the subsequent dose expansion study of MRG001 in China.



Shanghai Miracogen Inc.- Ex. 2032, Page 000281

- MRG004A: MRG004A is a novel TF-targeted site-specifically conjugated ADC. Although the clinical trial of MRG004A is initiating clinical sites to enroll patients in the U.S. and no safety and efficacy data of MRG004A is available, it exhibited better stability in blood circulation and enhanced efficacy in animal models of TNBC compared to conventionally conjugated ADCs. It also showed strong anti-tumor activities in pancreatic cancer and ovarian cancer PDX models. We received the IND clearance of MRG004A from the FDA in February 2021 for a Phase I/II clinical trial in the U.S. We received IND approval of MRG004A from the NMPA in August 2021.

➢ *Oncolytic virus drug candidate*

- CG0070: CG0070 was the most advanced oncolytic adenovirus for the treatment of bladder cancer in clinical-stage development as of the Latest Practicable Date, according to Frost & Sullivan. We in-licensed CG0070 from CG Oncology and were granted the rights to develop, manufacture and commercialize it in Mainland China, Hong Kong and Macau. CG0070 demonstrated encouraging results in safety and efficacy in the Phase II clinical trials conducted by CG Oncology for the treatment of high-grade NMIBC after Bacillus Calmette-Guerin (BCG) failure in the U.S., with a three-month CR rate of 46.2% and a 12-month CR rate of 29.2% in the BOND2 trial. We obtained IND approval from the NMPA for CG0070 in November 2021.

Since our inception, we have established an integrated end-to-end platform across drug discovery, clinical development and CMC and GMP-compliant manufacturing, and are building dedicated sales and marketing forces.

As an innovation-driven biopharmaceutical company leveraging an internationally integrated research and development system, we are committed to fulfilling current medical needs. We continuously invest in our research and development infrastructure and talent pool. Our research and development system is underpinned by three core technology platforms: (i) a clinically-validated ADC platform with advanced conjugation and CMC technologies; (ii) an antibody discovery platform with multispecific antibody construction and discovery capabilities and a $10^{11}$-scale antibody library; and (iii) an advanced process and analytical development platform.

We keep abreast of the latest trends and technology breakthroughs in the development of innovative biopharmaceuticals globally. We have a dedicated clinical development team in China to fulfil our clinical development strategy with high efficiency and quality. We are building a research and development center in Houston, Texas, the U.S., aiming to focus on the translational medical research and clinical development of innovative drugs in the international markets.


Shanghai Miracogen Inc.- Ex. 2032, Page 000282

Intellectual property is pivotal to the sustainable development and commercialization of drugs. As of the Latest Practicable Date, we had (i) 11 issued patents in China, 20 in the U.S., nine in Japan, seven in the European Union and one in each of South Korea, Australia, Chile, India, Colombia, Indonesia, New Zealand and Israel, and (ii) 74 pending patent applications, consisting of 15 in Mainland China and 59 in overseas jurisdictions such as the U.S., Japan, South Korea, Australia, Israel, India and the European Union. Our patent portfolio spans across mAb structure, targeted epitope, CMC, usage, biopharmaceutical formulation and indications. We endeavor to ensure global full-life-cycle IP protection for drug candidates.

While advancing our drug candidates, we have mapped out and are implementing our manufacturing and commercialization strategies. We commenced the operation of a 2,000L GMP-compliant antibody production line in Beijing in 2019 in support of clinical trials for our antibody products. We are building a production line for oncolytic virus drugs in Beijing with a designed capacity of 200L, as well as a biologics manufacturing center in Shanghai Biotech Park (上海生物園) with laboratories and manufacturing facilities. The Shanghai Biotech Park production line has a designed capacity of 12,000L initially and one production line with capacity of 6,000L is under construction. We are building our sales and marketing forces in China and seeking partnership opportunities to support international expansion and commercialization.

Our visionary management team has extensive industry experience with a proven track record of bringing novel therapies from early-stage discovery through clinical development to commercialization. Our founder and chairman of the Board of Directors, Dr. Pu Zhongjie, has accumulated rich industry resources and commercialization experience for decades, from which our commercialization efforts will benefit. Our Co-CEO, Dr. Hu Chaohong, founded Miracogen Shanghai and led the clinical development of three innovative ADC candidates in China. Dr. Hu previously served as a department director at ID Biomedical Corporation, GlaxoSmithKline plc and Seagen Inc., where she participated in the development of Adcetris, the second approved ADC product globally. Our Global CMO, Dr. Frederick Herman Hausheer, is an internationally recognized expert in commercial oncology drug global development and translational science and medicine, with nearly 30 years of experience in commercial and academic settings, and is certified in internal medicine by the American Board of Internal Medicine. Dr. Hausheer was previously the global chief medical officer of WuXi AppTec, Inc. and was previously a faculty member of The Johns Hopkins Oncology Center in Medical Oncology. Our chief technology officer, Dr. Qin Minmin, has over 20 years of experience in CMC development and commercial manufacturing. Dr. Qin has previously served as a senior director of Five Prime Therapeutics and BioMarin Pharmaceutical Inc. and led the development, technology transfer, process characterization, process validation and technology support for commercial manufacturing of Aldurazyme and Naglazyme.


Shanghai Miracogen Inc.- Ex. 2032, Page 000283

## OUR STRENGTHS

### Product pipeline with clinical efficacy and commercialization synergies

Our product pipeline features broad-spectrum anti-tumor drugs, including primarily the anti-PD-1 antibody candidate, as the backbone, and a dual focus on ADC and oncolytic virus drug candidates, maximizing synergies in both drug efficacy and commercialization and enabling us to expand indications and addressable market.

***Anti-PD-1 antibody candidate as the cornerstone of our immunotherapies***

HX008 specifically recognizes a glycosylated epitope on PD-1 and employs an innovative molecular design that can extend the protein half-life of HX008. Compared to all competing anti-PD-1 antibodies that were marketed or had entered Phase III clinical trial, the engineered Fc region of HX008 allows significant extension of protein half-life to 17.15-23.51 days (single dose) and 18.41-38.16 days (stable), which lowers the treatment frequency, increases patient compliance rate and improves patient convenience and accessibility. Notably, the extension of the half-life of HX008 demonstrated favorable efficacy results without compromising the safety profile. We design and conduct clinical trials to expand the clinical application of HX008. For example, MSI-H/dMMR solid tumors are among the indications initially included under the registration trials for HX008 in China.

We filed an NDA of HX008 in melanoma in June 2021; we also filed an NDA of HX008 in MSI-H/dMMR solid tumors with the NMPA, and was granted priority review in October 2021. HX008's promising efficacy in treating MSI-H/dMMR solid tumors which cover multiple indications helps us to build sales and marketing channels in major hospital departments including gastroenterology, gynecology, urology, respiratory and dermatology. To further expand the indications of HX008, as of the Latest Practicable Date, we had completed patient enrollment and were in the follow-up period for Phase Ib clinical trial in advanced solid tumor and for Phase II clinical trial in NSCLC, first- and second-line gastric cancer, TNBC and HCC, and had initiated a Phase II clinical trial in NMIBC and extended second-line gastric cancer to Phase III clinical trial.

***A dual focus on innovative ADC and oncolytic virus candidates***

We focus on the development of innovative drugs including ADC and oncolytic virus candidates. We believe our new generation of therapeutic regimens have the potential to overcome drug resistance of various mechanisms compared to traditional treatments. ADC represents a novel therapeutic approach in oncology which functions by selectively delivering potent chemotherapeutic cytotoxins directly to tumor cells. Such therapeutic regimens can also treat additional indications not addressed by conventional treatments. For example, as the most advanced EGFR-targeted ADC in clinical-stage development in China as of the Latest Practicable Date according to Frost & Sullivan, MRG003 is able to overcome several types of acquired drug resistance such as resistance to EGFR-TKIs due to EGFR mutations or other mutations on key proteins occurring downstream of EGFR signaling cascade as well as other mechanisms, and thus provides new treatment options for the vast patient population with EGFR-positive. CG0070 was the most advanced oncolytic adenovirus for the treatment of



Shanghai Miracogen Inc.- Ex. 2032, Page 000284

bladder cancer in clinical-stage development as of the Latest Practicable Date, according to Frost & Sullivan. It aims to capture the medical needs of the patient population with high-grade NMIBC after BCG failure who currently have no alternative to cystectomy. We believe we will be able to expedite the clinical development and commercialization of CG0070 in China by leveraging the clinical trials of CG0070 conducted by CG Oncology in the U.S. The pipeline complementary effect and the distinctive efficacy on specific indications of our ADC and oncolytic virus drug candidates position them well to leverage the commercialization infrastructure to be established for our broad-spectrum antibody drug candidate and benefit from significant commercialization synergies.

***Differentiated combination therapies***

With profound insights into targeted cancer therapy and immunotherapy, we have formulated and executed our drug development strategy covering primary checkpoints in the cancer immune cycle: we have developed targeted therapeutics led by ADCs, oncolytic virus and novel T cell receptor trispecific antibody drug candidates to treat immune-desert tumors as well as our anti-PD-1 and anti-PD-L1 antibody candidates to treat inflamed tumors. Our ADC and oncolytic virus candidates can kill tumor cells directly, release tumor antigens and stimulate a systemic anti-tumor immune response, resulting in the conversion of immune-desert tumors to inflamed tumors. Such mechanism shows potential for further combination therapies of ADC and oncolytic virus candidates with anti-PD-1 antibody candidates. We are conducting the clinical development of the combination therapy of OH2 and HX008 in advanced hepatocellular carcinoma and advanced solid tumors, and are exploring the combination therapy potential of ADCs and HX008 in advanced solid tumors. The synergy in efficacy generated from the combination therapies combining the strengths of our ADC, oncolytic virus and antibody drug candidates is expected to expand the indications and patient population covered by our individual product candidates.

**Innovative ADC candidates**

We are the leading ADC developer in China in terms of the number of clinical stage ADC drug candidates, according to Frost & Sullivan, and have accumulated comprehensive experience in a broad spectrum spanning across antibody technology, conjugation technology and overall biological evaluation system of a drug's safety and efficacy profile. We are simultaneously expediting the international development and clinical trials of four ADC candidates, including the clinical trials being conducted in China and the U.S. and planned clinical trials for combination therapies, and are also preparing for international commercialization with endeavors in business development and marketing collaborations with our overseas business partners.


Shanghai Miracogen Inc.- Ex. 2032, Page 000285

***MRG003***

MRG003 is the most advanced EGFR-targeted ADC in clinical-stage development in China and has the potential to seize market opportunities, as there was no approved EGFR-targeted ADC in China as of the Latest Practicable Date, according to Frost & Sullivan. It was recognized as one of the National Scientific and Technological Major Projects for "Major Drug Innovation" in China in 2019. Compared to a confirmed ORR of 13.0% by a monotherapy of a EGFR monoclonal antibody product on the market in the second-line treatment for recurrent and metastatic advanced HNSCC, MRG003 demonstrated encouraging safety and efficacy results in preliminary data from the Phase Ib clinical trials in HNSCC and NPC patients, with a confirmed ORR of 40.0% in EGFR-positive recurrent and metastatic HNSCC and a confirmed ORR of 44.4% in EGFR-positive recurrent and metastatic NPC among efficacy evaluable patient population. Pre-clinical development showed that MRG003 exhibited significant efficacy in colorectal cancer animal models with KRAS mutations and in NSCLC models with EGFR mutations and an acquired drug resistance to osimertinib. EGFR is a relatively broadly expressed tumor antigen which is overexpressed in a variety of human tumors. According to Frost & Sullivan, the size of the China head and neck cancer market was RMB3.0 billion in 2020 and is expected to reach RMB7.4 billion by 2025 and RMB13.0 billion by 2030, respectively. The size of the China nasopharyngeal cancer market was RMB0.6 billion in 2020 and is expected to reach RMB1.6 billion by 2025 and RMB2.8 billion by 2030, respectively. The size of the NSCLC market in China was RMB42.3 billion in 2020 and is estimated to reach RMB111.7 billion and RMB177.5 billion by 2025 and 2030, respectively.

***MRG001***

MRG001 is a clinically advanced CD20-targeted ADC with potential in the treatment of CD20-positive recurrent or refractory B-cell NHL. We are conducting a Phase I dose escalation of MRG001 in recurrent or refractory NHL. The pre-clinical *in vivo* studies of MRG001 demonstrated significant efficacy in the PDX model of rituximab resistance. With significant market potential in China and the U.S., MRG001 signifies a key step of our expansion in the hematology market. In addition, unlike the mechanism of action of mAb, MRG001 has the potential to overcome the widespread drug resistance to CD20-targeted drugs, enabling us to cover the CD20-targeted drug-resistance market and offer urgently needed treatments for the addressable patient population. MRG001 in the PDX models for pre-clinical development on rituximab resistance showed significant potency and has the potential to address urgent medical needs of NHL patients with primary or acquired drug-resistant B-cell NHL who are non-responsive or acquire resistance to the combination therapy of rituximab and standard chemotherapies. The market size of lymphoma in China reached RMB12.0 billion in 2020 and is expected to reach RMB37.9 billion and RMB62.5 billion in 2025 and 2030, respectively, according to Frost & Sullivan.



Shanghai Miracogen Inc.- Ex. 2032, Page 000286

***MRG004A: increased linker stability and therapeutic window***

MRG004A is a novel TF-targeted site-specifically conjugated ADC. We utilized GlycoConnect™ specific conjugation technology, which is in-licensed from Synaffix, to conjugate the MMAE with a TF-targeted mAb, which demonstrates precision control at sites of conjugation, enhanced drug stability in circulation and advanced molecular design to mitigate safety risks compared to conventional conjugation technologies. We believe that MRG004A has promising potential in the global market where there were only one marketed TF-targeted ADC as of the Latest Practicable Date. MRG004A exhibited better stability in blood circulation and enhanced efficacy in animal models of TNBC in pre-clinical development compared to the conventionally conjugated ADCs. It also showed strong anti-tumor activity in pancreatic cancer and ovarian cancer PDX models. We believe that this may potentially translate into favorable clinical results with improved safety and efficacy, reduced clinical toxicity and increased therapeutic window in the treatment of cancer patients. MRG004A has the potential to become one of the leading TF-targeted ADCs based on clinical progress. We received the IND clearance of MRG004A from the FDA in February 2021 and have initiated a Phase I/II clinical trial in the U.S., with the first patient dosed on August 2. We received IND approval of MRG004A from the NMPA in August 2021.

**Discovery and development capabilities**

We have three synergistic core technology platforms around our pipeline specializing in ADC technology, antibody discovery and advanced process and analytical development. We have demonstrated capabilities in the development of innovative drugs spanning across early-stage molecular target identification and validation, pre-clinical development and CMC development.

***Clinically-validated ADC Development Platform***

We have a fully integrated ADC technology platform covering discovery, process and analytical development and manufacturing. In addition, we are able to design and create new molecules with innovative mechanisms and utilize cutting-edge technology, such as GlycoConnect™ site-specific conjugation technology. We have, among others, the following cutting-edge ADC technologies:

- Sophisticated DAR control technology. Supported by our study on the relationship between the manufacturing parameter and the ratio of payload and antibody, we are able to adjust the parameters to precisely control the ratio of payload and antibody based on the biological properties of the target in certain indications;

- Advanced ADC conjugation technology. We conduct the modification of antibodies and ADC conjugation in the same closed container to make it a continuous process. Leveraging our knowledge on ADC development, we also reduce the impurities generated during the manufacturing. As a result, we lower our production costs and improve the yield to around 100%;



Shanghai Miracogen Inc.- Ex. 2032, Page 000287

- identification and validation of early-stage molecular targets, which enables us to screen a panel of combinations of conjugation methods, linkers and payloads to optimize molecular composition and tailor for specific targets, indications and mechanisms of action and to achieve high potency with minimal toxicity; and

- ADC process development, coupled with a well-established quality analysis system to ensure GMP-compliant manufacturing.

In addition, we have continuously optimized our conjugation technology to ensure successful development of ADCs. Our ADC candidates have exhibited outstanding quality stability for a period of over 18 months, primarily due to our prominent capabilities in developing ADCs and our well-developed formulation and lyophilization process.

***Antibody Discovery Platform***

We have constructed a full human naive antibody library of $10^{11}$ scale. Leveraging phage display technology, our *in vitro* screening system on the platform reduces the reliance on animal immune systems to produce antibodies. The screening technology allows us to significantly shorten the development period of innovative drug candidates to four to six weeks, compared to the traditional hybridoma technology which generally takes four to six months. We have also constructed a trispecific antibody T cell engager platform by utilizing protein binding domains, such as nanobodies and scFv, to augment T cells' response to solid tumors.

***Advanced Process and Analytical Development Platform***

We have an advanced process and analytical development platform for antibodies and ADCs. To ensure a standardized process and analytical development and quality control, we have implemented a comprehensive set of quality analysis methods and inspection technology to assess and control the product quality in the course of process and analytical development and production to fulfill the requirements for registration.

**Manufacturing facilities**

We commenced the operation of a 2,000L antibody production line in Beijing in 2019. For the manufacturing of oncolytic viruses, we introduced and own serum-free suspension culture and ATF perfusion culture, and established CMC development platforms for lentivirus, adeno-associated virus vectors and oncolytic viruses, including herpes virus, vaccinia virus and Newcastle disease virus. We are building a production line for oncolytic virus drugs in Beijing with a designed capacity of 200L and a biologics manufacturing center in Shanghai Biotech Park with laboratories and manufacturing facilities. The Shanghai Biotech Park production line has a designed capacity of 12,000L at the initial phase.


Shanghai Miracogen Inc.- Ex. 2032, Page 000288

**Seasoned and visionary management team and strong shareholder support**

We are led by a team of seasoned industry executives with experience in leading pharmaceutical companies in China and globally and complementary expertise to achieve a strategic and collaborative synergy. Our research and development team is captained by Dr. Hu Chaohong, Dr. Li Hu and Dr. Fang Lei; our clinical development strategy and medical team is led by Dr. Frederick Herman Hausheer; our manufacturing and CMC development team is managed by Dr. Hu Chaohong and Dr. Qin Minmin; our commercialization team is led by Dr. Pu Zhongjie and Dr. Sui Ziye; and our operations and strategy execution is directed by Dr. Sui Ziye. We also benefit from the strong support of our shareholder, Lepu Medical, to buttress our strategic execution and business development.

Our founder and chairman of the Board of Directors, Dr. Pu Zhongjie, has accumulated rich industry resources and commercialization experience for decades. As a leader witnessing major changes and development in China healthcare industry, he has formulated a visionary corporate roadmap and differentiated strategies, contributing his experience and expertise to the commercialization of our drug candidates.

Dr. Sui Ziye, our Director and CEO, has over ten years of managerial experience in the pharmaceutical sector. Prior to becoming our CEO, Dr. Sui served as an international marketing manager and a vice president of Lepu Medical and as the CEO of several subsidiaries of Lepu Medical. Dr. Sui has extensive experience in the expansion of international sales channels and international investment. She also has comprehensive operational and managerial experience in the development, manufacturing and sales of biopharmaceuticals.

Dr. Hu Chaohong, our Director and Co-CEO, has around 20 years of experience in the biotech and biopharmaceutical sector. Dr. Hu is an expert in bioassay development and CMC development for vaccines, mAb and ADC. She was responsible for several development programs of innovative drug candidates with strong potential. Dr. Hu was a former director of the molecular biology and clinical immunology department at ID Biomedical Corporation and GlaxoSmithKline, and a former director of the bioassay development and process analytics department at Seagen Inc. She received second prize of National Natural Science Award by the State Council of the PRC (國務院) in 1995. She also chaired the second World ADC Asia Conference held in Shanghai in 2019.

Dr. Frederick Herman Hausheer, our Global CMO, has nearly 30 years of experience in oncology translational medicine and global Phase I-III commercial oncology drug development. He has internationally recognized commercial development and scientific expertise in internal medicine, medical oncology, clinical pharmacology, drug safety and ICH good clinical practices and pre-clinical research and development of novel therapeutic agents for cancer treatment. Dr. Hausheer was previously the global chief medical officer of WuXi AppTec, Inc., and was previously a faculty member of the Johns Hopkins Oncology Center. Dr. Hausheer is certified in internal medicine by the American Board of Internal Medicine. He has


Shanghai Miracogen Inc.- Ex. 2032, Page 000289

co-authored over 200 scientific publications and is an inventor/co-inventor on over 400 issued international pharmaceutical patents. Dr. Hausheer has received the Computerworld Leadership Award for Breakthrough Computational Science from Medicine, Smithsonian in 1997.

Dr. Qin Minmin, our chief technology officer, has approximately 25 years of experience in biopharma research and development and is a well-recognized CMC expert in the development and commercialization of various therapeutics including antibodies, fusion proteins, recombinant proteins, and ADCs encompassing various development stages from preclinical development to commercial production. Dr. Qin has extensive experience in IND and BLA filing in China and the U.S. as well as in biopharma development strategies. Dr. Qin has previously served as a senior director for CMC development of Five Prime Therapeutics and BioMarin Pharmaceutical Inc. and led the development, technology transfer, process characterization, process validation, and technical support for the commercial manufacturing of Aldurazyme and Naglazyme.

Dr. Fang Lei, our vice president, has over ten years of experience in oncology clinical drug development and is an expert in immunology, development strategy and early-stage clinical trials for innovative drugs and translational medical science. Dr. Fang has applied for over 20 patents in the fields of mAbs, protein medicine, bispecific antibodies platform and drug development. Dr. Fang has previously served as a scientist in the research department of GSK (Shanghai) Drug Development Co., Ltd. and a co-founder of I-Mab.

Dr. Li Hu, our vice president, has over 20 years of experience in oncology drug development. Dr. Li has led our ADC pre-clinical biology team to successfully obtain IND clearance for multiple ADC candidates. He has previously served as a Manager and Group Leader of GlaxoSmithKline plc and received five bronze awards from GlaxoSmithKline's plc for recognition of his research and development contribution during his service.

Ms. Li Geman, our vice president, has over 20 years of experience in drug registration for chemical pharmaceuticals and biopharmaceuticals. Ms. Li has in-depth knowledge of the IND and NDA processes in multiple jurisdictions, including the U.S., Canada, Europe and China, with extensive experience in the areas of international regulatory regimes for biopharmaceutical products and drug registration.

In addition to our seasoned and visionary management team, we also benefit from the strong support of our shareholder, Lepu Medical. Lepu Medical is an industry-leading medical device and pharmaceutical company dedicated to the development, manufacturing and sales of cardiovascular products. We plan to strengthen our collaborative relationships with Lepu Medical and expect to benefit from its market access and distribution resources that are valuable and can be leveraged to accelerate the build-out of our own commercialization capabilities.



Shanghai Miracogen Inc.- Ex. 2032, Page 000290

## OUR STRATEGIES

### Expedite immune checkpoint inhibitor therapy development for marketing approval and commercialization

We submitted an NDA filing of HX008 in melanoma to the NMPA in June 2021, aiming to obtain the marketing approval in 2022. In addition, we submitted an pre-NDA meeting application of HX008 in MSI-H/dMMR solid tumors in July 2021, filed an NDA of HX008 with the NMPA in MSI-H/dMMR solid tumors and was granted priority review in October 2021.

Leveraging the broad spectrum of indications covered by MSI-H/dMMR solid tumors, we aim to achieve expedited and adequate market coverage of HX008 through both medical institutions and direct-to-patients distribution channels. We plan to form a strong commercialization team in China dedicated to the academic promotion, marketing and commercialization of HX008.

Through the commercialization of HX008, we expect to establish effective sales channels and strengthen our commercialization capabilities, which we believe would also benefit our efforts to commercialize other drug candidates. We plan to seek strategic partnerships with preeminent pharmaceutical companies internationally to maximize the clinical and commercial value of our immune checkpoint inhibitors.

### Advance the clinical development of our drug candidates and combination therapies

We strive to advance the clinical development of our drug candidates including ADC candidates, oncolytic virus candidates and combination therapies.

#### *ADC candidates*

We are conducting Phase II clinical trials of our MRG003 in recurrent or metastatic advanced HNSCC, NSCLC, BTC and NPC in China. We endeavor to commence registration trials in the relevant indications in 2021 and submit an NDA application for MRG003 to the NMPA in 2023. We had initiated Phase II clinical trials of MRG002 in HER2-expressing urothelial cancer, HER2 over-expressing BTC and HER2 over-expressing and low-expressing breast cancer, and had obtained approval from the NMPA of registration trial of HER2 over-expressing breast cancer as of the Latest Practicable Date. We plan to submit an NDA application to the NMPA in 2023. We have received an IND clearance for MRG004A from the FDA in February 2021 and have initiated a Phase I/II clinical trial in the U.S., with the first patient dosed on August 2. We will commence the Phase I/II clinical trial in multiple TF high-expressing indications in China followed by the IND approval from the NMPA in August 2021. We have completed the Phase Ia dose escalation study and are conducting the Phase Ib dose expansion study of MRG001. We expect to commence a Phase II clinical trial of MRG001 in China in 2022. In addition, we are collaborating with Keymed and its affiliates in the development of CMG901, which is a CLDN18.2-targeted ADC through our joint venture,



Shanghai Miracogen Inc.- Ex. 2032, Page 000291

KYM. KYM is in the process of recruiting patients for the dose escalation stage in a Phase I clinical trial in China to evaluate CMG901 in advanced solid tumors. KYM submitted an IND application for advanced unresectable or metastatic G/GEJ carcinoma to the FDA in February 2021 and subsequently received an IND clearance from the FDA in March 2021.

***Oncolytic virus candidates and combination therapies***

We obtained IND approval from the NMPA for CG0070 in November 2021 and plan to commence a bridging Phase I clinical study on patients with NMIBC and solid tumors in 2022. CG Oncology has completed a Phase II clinical trial (BOND2) for BCG-unresponsive NMIBC in the U.S. We plan to join multi-regional clinical trials subject to the clinical development of CG0070 in the U.S. We are also exploring OH2's combination therapy potential with HX008 or LP002, as well as the combination therapies of ADCs with HX008.

**Create a pipeline for novel therapies, design and develop innovative products and build advanced technology platforms**

We plan to stay focused on the development of innovative products and to further build advanced technology platforms for such development. We plan to develop bispecific and trispecific immune agonist antibody platforms and alternatives for CAR-T bispecific antibodies. We have been dedicated to the development and cultivation of ADCs, establishing an ecosystem comprising a in-house and in-licensed ADC conjugation technology platform, biological analysis method and systematic ADC evaluation and development. Building upon our track record of successful development through our technology platforms, we expect to further increase our investment in our pipeline of innovative drugs, expand our industry-leading technology platforms and further strengthen our collaborations with leading companies in and outside of China. We plan to further promote the advantages of candidates which utilize site-specific conjugation technology and design and develop novel targets, innovative linkers and payloads, facilitating the development of next-generation ADCs with technology advantages. In the meantime, we plan to improve our technical and biological know-how on known and potential targets and explore new targets, continuously rolling out candidates with leading potential.

**Capture international opportunities for our products and technologies**

We are committed to strengthening our overseas business development for our pipeline, enhancing our brand awareness and continuously exploring the commercial value of our products and technology in the international market. For our innovative candidates and combination therapies with competitive advantages, we will execute our international development strategy. Our subsidiary in the U.S., with its research and development center and clinical teams, is able to support our international clinical development and business development with global collaborators. We have initiated a Phase I/II clinical trial for MRG004A in the U.S. with the first patient dosed on August 2. We also plan to file an IND for MRG003 to the FDA and start a Phase I/II clinical trial in 2022.



Shanghai Miracogen Inc.- Ex. 2032, Page 000292

We will make efforts to pursue out-licensing partnership opportunities in overseas markets. We expect to continuously explore the commercial value of our product candidates and technology through international collaborations, licenses and the transfer of technology and execution of our international development strategy to enhance our brand awareness and facilitate the introduction of our innovative drug products in overseas markets.

**Expand GMP-compliant manufacturing facilities to increase capacity and enhance product quality**

To meet the commercialization demand, we are dedicated to building a GMP-compliant commercial production facility to ensure quality. We are building two GMP-compliant production lines and affiliated facilities, one for oncolytic virus drugs in Beijing with a designed capacity of 200L and the other in Shanghai Biotech Park which encompasses two production lines with a designed capacity of 6,000L each. One of the 6,000L production lines is under construction. In particular, we are planning to further expand our manufacturing facility in Shanghai.

**Further enhance our management and research and development teams with global vision and strong execution capabilities**

We believe a professional and aspirational management team with global vision is vital for our long-term strategy, international expansion and the enhancement of our technology and product competitiveness. In line with our international expansion and the growth of our product pipeline, we expect to enhance our management team by recruiting experienced business development personnel, legal professionals and sales associates. We plan to further expand our development and commercialization teams, attracting talents with experience in the therapeutic areas of immuno-oncology and targeted cancer therapy. The global market is an essential part of our future strategy and we plan to focus on strengthening our international development and commercialization capabilities, seeking overseas collaborators and realizing our potential in overseas markets. We also plan to set up a scientific advisory committee by inviting reputable industry experts and scientists to support the design of clinical trials and the selection of candidates and targets.

## OUR BUSINESS MODEL

We have built a pipeline of drug candidates focusing on oncology therapeutics in several indications. The majority of our pipeline products were obtained through acquisitions of subsidiaries, in-licensing and joint venture. We relied on our research and development team to carry out the subsequent clinical trials and research and development activities.

We obtained global rights to the ADC drug candidates of MRG003, MRG002 and MRG001 in our pipeline by acquiring the controlling equity interest in Miracogen Shanghai in July 2018, and developed our ADC drug candidate MRG004A in-house. We are also collaborating with Keymed and its affiliate, iBridge HK Holding Limited ("**iBridge**"), in the development of CMG901.



Shanghai Miracogen Inc.- Ex. 2032, Page 000293

- ***Background of relevant acquisitions***: Miracogen Shanghai is a biotech company focusing on the development of ADC drugs. It was previously controlled by Miracogen HK, a special purpose investment vehicle ultimately wholly owned by Dr. Hu Chaohong, our executive Director and co-chief executive officer. We retained the original research and development staff from Miracogen Shanghai and relied on the combined efforts from them and our in-house research and development team to carry out the subsequent clinical trials and research and development activities, which demonstrates our capabilities in discovering novel molecules with desired mechanisms of action and developing them into drugs to address current medical needs.

- ***MRG003***: We acquired MRG003 at the Phase Ia stage. Since our acquisition of Miracogen Shanghai in 2018, we completed MRG003 Phase Ia trial in January 2020 and MRG003 Phase Ib trial in March 2021; we also initiated Phase II clinical trials of MRG003 in various indications. As of the Latest Practicable Date, we were conducting Phase II clinical trials of MRG003 in recurrent or metastatic advanced HNSCC (head and neck squamous cell carcinoma), NPC (nasopharyngeal cancer), advanced NSCLC (non-small cell lung cancer) and BTC (biliary tract cancer) in China, and expect to initiate Phase Ia/Ib clinical trials in recurrent or metastatic advanced HNSCC in the U.S.

- ***MRG002***: We acquired MRG002 when it obtained IND approval. Since our acquisition of Miracogen Shanghai in July 2018, we completed MRG002 Phase Ia trial in August 2020. As of the Latest Practicable Date, we had initiated Phase II clinical trials of MRG002 in HER2 low-expressing and over-expressing breast cancer, UC (urothelial cancer) and HER2 over-expressing BTC. For HER2 over-expressing breast cancer, we had completed patient enrollment and were in the follow-up period, and had obtained approval from the NMPA of registration trial as of the Latest Practicable Date. In addition, we were conducting a Phase I/II clinical trial of MRG002 in gastric cancer in the U.S. and China as of the Latest Practicable Date.

- ***MRG001***: We acquired MRG001 at pre-clinical stage. We have completed the Phase Ia dose escalation study and are conducting the Phase Ib dose expansion study of MRG001 in CD20-positive B-cell NHL (non-Hodgkin's lymphoma) in China.

- ***MRG004A***: We developed in-house MRG004A. We received the IND clearance of MRG004A from the FDA for advanced or metastatic solid tumors and we received IND approval of MRG004A from the NMPA in August 2021.

- ***CMG901***: We are collaborating with Keymed and its affiliate, iBridge, in the development of CMG901, a CLDN18.2-targeted ADC through our joint venture, KYM. KYM has the exclusive rights to develop, make, have made, use, sell, offer for sale, import and commercialize CMG901 globally.


Shanghai Miracogen Inc.- Ex. 2032, Page 000294

In March 2019, we in-licensed our oncolytic virus product CG0070 from a third-party business partner CG Oncology, Inc. ("**CG Oncology**") with the rights to develop, manufacture and commercialize it in Mainland China, Hong Kong and Macau. Since the in-licensing of CG0070, we have completed the technology transfer to support our CMC (chemistry, manufacturing and controls) development. We obtained IND approval from the NMPA for CG0070 in November 2021. We plan to initiate a Phase I clinical trial of CG0070 on patients with NMIBC and solid tumors in China.

We obtained our anti PD-1 antibody candidate, HX008, and our anti PD-L1 antibody candidate, LP002, by acquiring the controlling equity interest in Taizhou Hanzhong Biotechnology Co., Ltd. ("**Taizhou Hanzhong**") and Taizhou Houde Aoke Technology Co., Ltd. ("**Taizhou Aoke**"), respectively.

- ***Background of relevant acquisitions***: We acquired 51% equity interest in Taizhou Hanzhong from Ningbo Houde Yimin in June 2018, and entered into an equity purchase agreement with HanX in September 2019 to further acquire the 40% equity interest held by HanX in Taizhou Hanzhong, of which the acquisition of 31% equity interest has been completed and the 9% equity interest transfer will be completed by no later than the end of 2022; thereby, we owned 82% equity interest in Taizhou Hanzhong as of the Latest Practicable Date. We acquired 70% equity interest in Taizhou Aoke from Ningbo Houde Yimin in June 2018. Therefore, Taizhou Hanzhong and Taizhou Aoke are now two subsidiaries of our Company. We did not retain the original research and development staff of Taizhou Hanzhong or Taizhou Aoke. We relied on our research and development team to carry out the subsequent clinical trials and research and development activities and own the global rights of HX008 and LP002, which demonstrates our capabilities in identifying promising early-stage drug candidates and successfully conducting clinical development through designing and performing sophisticated clinical trials.

- ***HX008***: We obtained HX008 at Phase Ia stage. Since our acquisition of Taizhou Hanzhong from Ningbo Houde Yimin in June 2018 and from HanX pursuant to the equity purchase agreement entered in September 2019, the HX008 Phase Ia stage was completed with MTD and RP2D determined per the clinical trial protocol in May 2018 and final CSR issued in May 2020; its main purpose aligned with the overall purpose of a conventional phase I trial as advised by our PRC Legal Advisor and taking into account the industry practice as advised by Frost & Sullivan. As of the Latest Practicable Date, we completed patient enrollment and were in the follow-up period for Phase Ib clinical trial of HX008 in advanced solid tumor and for Phase II clinical trials in NSCLC, gastric cancer, TNBC (triple-negative breast cancer) and HCC. We were also conducting a Phase II clinical trial in NMIBC as of the Latest Practicable Date. We initiated registration trials in melanoma and MSI-H/dMMR (high levels of microsatellite instability/deficient mismatch repair) solid tumors. We are also in the process of a Phase III clinical trial in the second-line gastric cancer. We filed an NDA of HX008 with the NMPA in melanoma in June 2021. We submitted pre-NDA meeting application of HX008 in MSI-H/dMMR solid tumors in July 2021, filed an NDA of HX008 with the NMPA in MSI-H/dMMR solid tumors and was granted priority review in October 2021.


Shanghai Miracogen Inc.- Ex. 2032, Page 000295

- ***LP002***: We obtained LP002 at pre-clinical stage. Since our acquisition of Taizhou Aoke from Ningo Houde Yimin in June 2018, we completed LP002 Phase Ia clinical trial in April 2019. As of Latest Practicable Date, we were in the process of a cohort expansion trial in advanced digestive system cancer, and had completed patient enrollment and entered the follow-up period for a Phase II clinical trial in ES-SCLC (extensive stage small-cell lung cancer).

## OUR DRUG CANDIDATES

We have developed a strong oncology-focused pipeline of drug candidates, including ADCs, oncolytic virus drugs and immunotherapies at clinical and pre-clinical stages. These candidates cover a wide variety of selected and validated therapeutic targets and span across multiple major indications of oncology.

As of the Latest Practicable Date, we had (i) eight clinical-stage drug candidates, including four Core Products acquired through acquisitions of all equity interests or controlling stake in the relevant subsidiaries with three of them subject to in-license arrangements and one co-developed through a joint venture, (ii) three pre-clinical drug candidates, and (iii) three clinical-stage combination therapies of the candidates in our pipeline. Among the eight clinical-stage drug candidates, five are in targeted therapy and three are in immunotherapy, with two of the three being immune checkpoint drugs and one being oncolytic virus drug. As of the Latest Practicable Date, we had initiated 28 clinical trials, among which three had entered registration trial phase and two were ongoing in the U.S. The following chart summarizes the development status of our clinical-stage and pre-clinical drug candidates:


Shanghai Miracogen Inc.- Ex. 2032, Page 000296

Shanghai Miracogen Inc.- Ex. 2032, Page 000297

*Notes:*

* Denotes our core product candidates

** Denotes registration trials

1 MRG003 received IND approval from the NMPA in August 2017, which includes Phase Ia, Ib clinical study protocol and subsequent Phase II and Phase III study draft protocols. We acquired MRG003 at the Phase Ia stage and completed MRG003 Phase Ia trial in January 2020 and MRG003 Phase Ib trial in March 2021. As advised by our PRC Legal Advisor and taking into account the industry practice as advised by Frost & Sullivan, the MRG003 Phase Ia trial was a complete clinical trial with its main purpose aligning with the overall purpose of a conventional phase I trial, and the completion of the MRG003 Phase Ia trial is thus equivalent to the completion of a conventional Phase I trial. The MRG003 Phase II trials had been duly registered with the NMPA per the relevant regulatory requirements without any objection from the NMPA to our clinical development plans with respect to the regulatory review or approval process of MRG003. We have obtained all necessary approvals from the NMPA to proceed with the MRG003 Phase II trials. As of the Latest Practicable Date, we were conducting Phase II clinical trials of MRG003 in recurrent or metastatic advanced HNSCC, NPC, advanced NSCLC and BTC in China and expect to initiate Phase Ia/Ib clinical trials in recurrent or metastatic advanced HNSCC in the U.S.

2 MRG002 received IND approval from the NMPA in May 2018, which includes Phase Ia, Ib clinical study protocol and subsequent Phase II and Phase III study draft protocols. We acquired MRG002 when it obtained IND approval and completed MRG002 Phase Ia trial in August 2020. As advised by our PRC Legal Advisor and taking into account the industry practice as advised by Frost & Sullivan, the MRG002 Phase Ia trial was a complete clinical trial with its main purpose aligning with the overall purpose of a conventional phase I trial, and the completion of the MRG002 Phase Ia trial is thus equivalent to the completion of a conventional Phase I trial. Additionally, as part of the application to the NMPA for the combination program of MRG002 with HX008, the results of the MRG002 Phase Ia trial have been submitted to the NMPA for assessment. In January 2021, the NMPA confirmed in writing that, based on the pre-clinical and clinical data submitted to the NMPA (including the results of the MRG002 Phase Ia trial and the HX008 Phase Ia trial), we have provided support to proceed with phase I/II trial for the combination program of MRG002 with HX008. The MRG002 Phase II trials had been duly registered with the NMPA per the relevant regulatory requirements without any objection from the NMPA to our clinical development plans with respect to the regulatory review or approval process of MRG002. We have obtained all necessary approvals from the NMPA to proceed with the MRG002 Phase II trials. As of the Latest Practicable Date, we had initiated Phase II clinical trials of MRG002 in HER2 low-expressing and over-expressing breast cancer, UC (urothelial cancer) and HER2 over-expressing BTC. For HER2 over-expressing breast cancer, we had completed patient enrollment and were in the follow-up period, and had obtained approval from the NMPA of registration trial as of the Latest Practicable Date. In addition, we had initiated a Phase I/II clinical trial of MRG002 in gastric cancer in the U.S. and China as of the Latest Practicable Date.

3 HX008 received IND approval from the NMPA in August 2017, which includes Phase Ia, Ib clinical study protocol and subsequent Phase II and Phase III study draft protocols. We obtained HX008 at the Phase Ia stage and its Phase Ia trial was completed with MTD and RP2D determined per the clinical trial protocol in May 2018 and the final CSR issued in May 2020. As advised by our PRC Legal Advisor and taking into account the industry practice as advised by Frost & Sullivan, the HX008 Phase Ia trial was a complete clinical trial with its main purpose aligning with the overall purpose of a conventional phase I trial, and the completion of the HX008 Phase Ia trial is thus equivalent to the completion of a conventional Phase I trial. We filed an NDA of HX008 with the NMPA in melanoma in June 2021. We submitted pre-NDA meeting application of HX008 in MSI-H/dMMR solid tumors in July 2021, filed an NDA of HX008 with the NMPA in MSI-H/dMMR solid tumors in October 2021 and was granted priority review. According to our PRC Legal Advisor, we have obtained all necessary approvals from the NMPA to, proceed with the HX008 Phase II registration trials. As of the Latest Practicable Date, we had completed patient enrollment and were in the follow-up period for Phase Ib clinical trial of HX008 in advanced solid tumor and for Phase II clinical trials in NSCLC, TNBC (triple-negative breast cancer), gastric cancer and HCC. We were also conducting a Phase II clinical trial in NMIBC and a Phase III clinical trial in the second-line gastric cancer. We plan to initiate the Phase III clinical trials of HX008 in melanoma and in MSI-H/dMMR solid tumors after obtaining the respective approvals.

4 LP002 received IND approval from the NMPA in August 2018, which includes Phase Ia, Ib clinical study protocol and subsequent Phase II and Phase III study draft protocols. We obtained LP002 at its pre-clinical stage and completed LP002 Phase Ia trial in April 2019. As advised by our PRC Legal Advisor and taking into account the industry practice as advised by Frost & Sullivan, the LP002 Phase Ia trial was a complete clinical trial with its main purpose aligning with the overall purpose of a conventional Phase I trial, and thus is equivalent to the completion of a conventional Phase I trial. The data from the LP002 Phase Ia trial on its own has been accepted by the NMPA as sufficient to proceed with the LP002 Phase II trial. The LP002 Phase II trial for ES-SCLC indication had been duly registered with the NMPA pursuant to the relevant regulatory requirements without any objection from the NMPA to our clinical development plans with respect to its regulatory review or approval process. We have obtained all necessary approvals from the NMPA to proceed with LP002 Phase II trials. As of the Latest Practicable Date, we were in the process of a cohort expansion trial in advanced digestive system cancer and had completed patient enrollment and entered the follow-up period for Phase II clinical trial in ES-SCLC (extensive stage small-cell lung cancer).

5 Miracogen Shanghai acquired the co-ownership of the TF-targeted mAb and the joint right to develop ADCs based on the TF-targeted mAb from Fudan University and SIMMCAS. See "Business – Collaboration, Licensing and Transfer Arrangements – Collaboration with Fudan University and SIMMCAS." We received the IND clearance of MRG004A from the FDA in February 2021 to initiate Phase I/II clinical trials in patients with TF-positive advanced or metastatic solid tumors and we received IND approval of MRG004A from the NMPA in August 2021.



Shanghai Miracogen Inc.- Ex. 2032, Page 000298

6 CMG901 is co-developed by Keymed and us through KYM, a joint venture owned by us and Keymed's affiliate, iBridge, in which we owned 30.0% equity interest as of the Latest Practicable Date. See "– Collaboration, Licensing and Transfer Arrangements – Collaboration with Keymed and iBridge." KYM was enrolling patients for a Phase I clinical trial of CMG901 in advanced gastric cancer and pancreatic cancer in China as of the Latest Practicable Date and submitted an IND application to the FDA in February 2021 for a Phase I clinical trial in advanced unresectable or metastatic G/GEJ carcinoma.

7 We in-licensed the rights to develop, manufacture and commercialize CG0070 in Mainland China, Hong Kong and Macau from CG Oncology. See "Business – Collaboration, Licensing and Transfer Arrangements – Collaboration with CG Oncology." CG Oncology had completed a Phase II clinical trial (BOND II) of CG0070 in BCG-unresponsive NMIBC in the U.S., and we obtained IND approval for CG0070 from the NMPA in November 2021.

8 OH2 is an oncolytic virus developed by Wuhan Binhui. As of the Latest Practicable Date, we had initiated a Phase I clinical trial for LP002 in combination with OH2 for the treatment of advanced solid tumors. See "– Combination Therapies within Our Pipeline."

9 The status below refers to the clinical development progress of the relevant drug candidates and combination therapies in China except as otherwise specified.

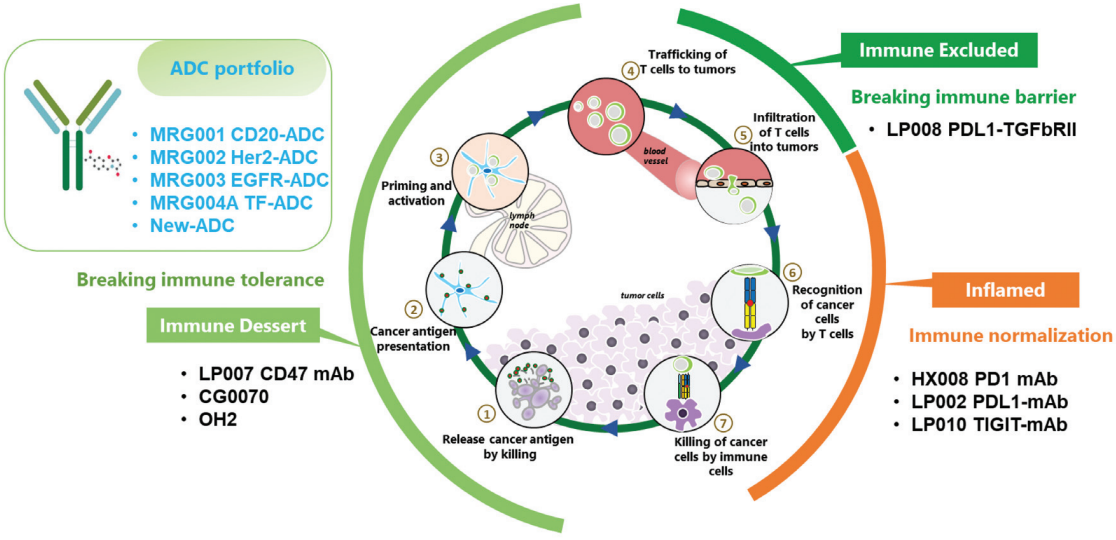
10 According to the Technical Guidelines for the Communication of Clinical Aspects of Single-arm Trials to Support Pre-marketing License Applications for Marketed Antineoplastic Drugs (《單臂試驗支持上市的抗腫瘤藥上市許可申請前臨床方面溝通交流技術指導原則》) issued by the NMPA, we must conduct Phase III clinical trials for HX008. We plan to initiate the Phase III clinical trials for HX008 in melanoma and in MSI-H/dMMR solid tumors after obtaining the respective approvals.



Shanghai Miracogen Inc.- Ex. 2032, Page 000299

With our profound knowledge, experience and insights in targeted cancer therapy and immunotherapy, we have designed our pipeline to unlock the great potential of the cancer immune cycle. Our pipeline and target indications are vital to our competitive strengths and position us well to achieve strong and sustainable growth. Our ADC candidates are the core of our targeted therapies, our anti-PD-1/anti-PD-L1 antibody candidates underpin our immunotherapy and the overall portfolio has strong potential to develop differentiated and successful combination therapies. See "– Combination Therapies within Our Pipeline."

**Unlocking the Great Potential of the Cancer Immune Cycle**




## CLINICAL-STAGE DRUG CANDIDATES

Our clinical-stage drug candidates comprise of (i) four ADC products, namely MRG003, MRG002, MRG001 and MRG004A, (ii) one oncolytic virus product, namely CG0070, and (iii) two anti-PD-1/anti-PD-L1 antibody products, namely HX008 and LP002. As of the Latest Practicable Date, we had initiated 28 clinical trials for our drug candidates, among which three clinical trials had entered registration trial stage and two additional clinical trials were being conducted in the U.S. MRG003, MRG002, HX008 and LP002 are our Core Products.

### MRG003

MRG003, one of our Core Products, is an ADC comprised of an EGFR-targeted mAb conjugated with the potent microtubulin disrupting payload MMAE via a vc linker. It binds specifically with high affinity to human EGFR on the surface of tumor cells, releases the potent payload upon internalization and lysosomal protease cleavage of the linker and results in tumor cell death.


Shanghai Miracogen Inc.- Ex. 2032, Page 000300

MRG003 is the most advanced EGFR-targeted ADC in clinical-stage development in China and has the potential to seize market opportunities, as there had been no approved EGFR-targeted ADC in China as of the Latest Practicable Date, according to Frost & Sullivan. It was recognized as one of the National Scientific and Technological Major Projects for "Major Drug Innovation" in China in 2019.

Our commercial development strategy for MRG003 aims at realizing its efficacy potential in common malignancies. We seek to address current medical needs in underserved inoperable advanced or metastatic patient population involving second and later lines of systemic therapy failure, including HNSCC, NPC and advanced NSCLC.

MRG003 demonstrated encouraging results in safety and efficacy through the data from Phase Ib clinical trials in HNSCC and NPC patients, with a 40.0% ORR and an 100.0% DCR for HNSCC and a 44.4% ORR and a 88.8% DCR for NPC among efficacy evaluable patients. Its molecular design offers differentiation in (i) its promising potential to expand into clinical indications to include a wider spectrum of cancer types that overexpress EGFR; (ii) a broad spectrum of potent anti-tumor activity in *in vitro* assays and *in vivo* xenograft studies; and (iii) its potential in overcoming several different types of drug resistance due to common mutations.

We acquired MRG003 at the Phase Ia stage and completed MRG003 Phase Ia trial in January 2020 and MRG003 Phase Ib trial in March 2021. We are conducting multiple Phase II adaptive trials, including Phase II multiple-arm trials in HNSCC, NPC and advanced NSCLC in China. We plan to initiate clinical trials in recurrent or metastatic advanced HNSCC in the U.S. and expand MRG003 indications, further broadening the overall addressable market with the aim of achieving commercial success with MRG003 as well as the combination therapy with HX008. For the details with respect to the combination of MRG003 and HX008, see "– Combination Therapies within Our Pipeline."

We hold the patents related to MRG003 in the U.S. and China through Miracogen Shanghai. We also hold the rights to develop and commercialize MRG003 globally.

***Mechanism of Action***

ADCs represent an emerging class of anti-tumor targeted therapies that combine a mAb with a potent tumor cell-killing payload via a linker. These three components in an ADC drug must be carefully designed and evaluated based on the biological characteristics of a targeted tumor antigen and intended indications:

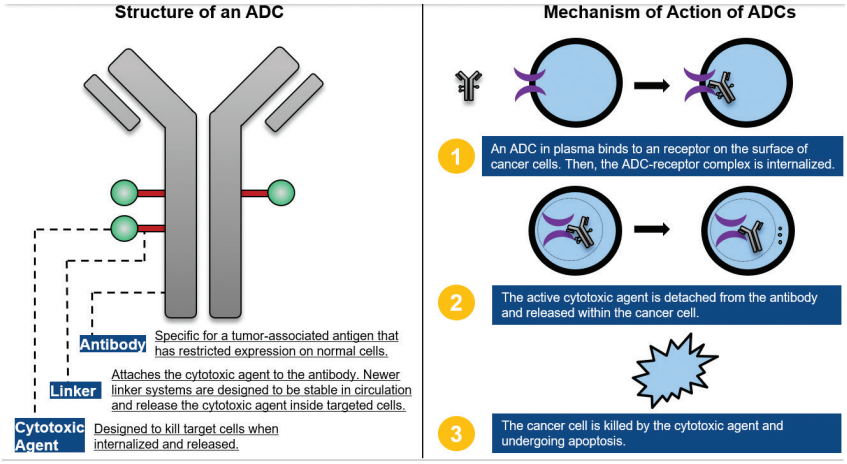
- For the mAb component, its high specificity and optimal affinity to its targeted tumor antigen are important features;

- For the selected payload, its cell-killing potency, toxicity profile and mode of action (for instance, inhibition of tubulin polymerization or DNA cross-linking and alkylation or inhibition of topoisomerase) should be well characterized; and


Shanghai Miracogen Inc.- Ex. 2032, Page 000301

- For the linker connecting the payload to the mAb component, it needs to be examined for its balanced ability to maintain stability in blood circulation and release active payload effectively upon internalization.

The structure and mechanism of action of ADCs are illustrated in the figure below:




*Source: Nature Reviews Clinical Oncology. 18, 327-344, 2021, Frost & Sullivan*

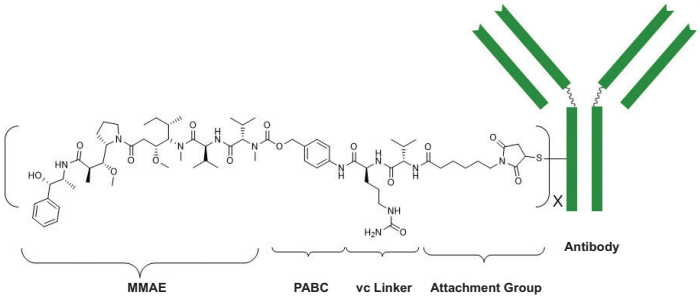
ADCs specifically bind to a targeted tumor cell antigen and deliver the payload into tumor cells, thus leading to the death of tumor cells while sparing healthy normal cells. Unlike traditional standard chemotherapies which often cause intolerable systemic toxicities, ADCs are designed to deliver the tumor cell-killing payload only into specifically targeted tumor cells utilizing the binding specificity of a mAb. Due to their innovative targeting and delivery modality, well designed ADCs can bring better safety and enhanced efficacy to cancer patients to improve survival rate and quality of life. ADCs have demonstrated great potential in addressing medical needs, as evidenced by the ten ADCs approved for hematologic malignancies and solid tumors by the FDA and other regulatory authorities. In addition to these approved ADCs, there has been a significant expansion in the global pipeline of ADCs with over 200 agents in early-and-late-stage clinical trials.

EGFR is a transmembrane RTK of the EGF receptor family. EGFR is overexpressed in a variety of human tumors, including colorectal, head and neck, breast, lung, prostate, kidney, pancreas, ovary, brain and bladder cancer. In these tumors, EGFR contributes to signaling cascades that modulate cancer cell growth, signaling, differentiation, adhesion, migration and survival. Due to its multi-dimensional roles in cancer biology as well as its broad overexpression in many types of cancer, EGFR has been recognized and pursued as an attractive therapeutic target. As a clinically-validated target in multiple cancer types, EGFR-targeted drugs with different mechanisms of action are under substantial demand to meet the challenges.


Shanghai Miracogen Inc.- Ex. 2032, Page 000302

MRG003 is an ADC consisting of a humanized anti-EGFR mAb conjugated to a potent cytotoxic small molecule MMAE via an enzyme-cleavable vc linker. The schematic structure of MRG003 is illustrated in the figure below.

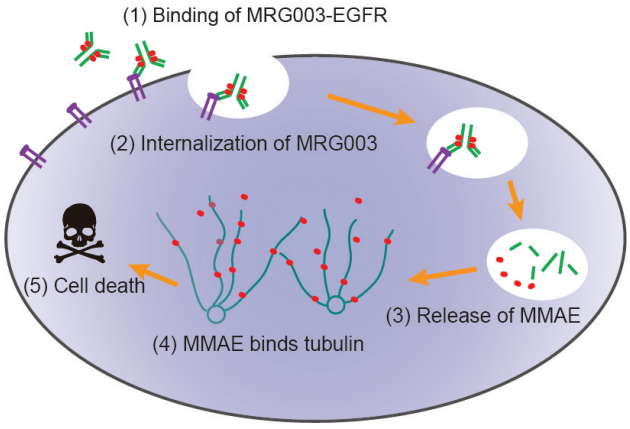
**Schematic Structure of MRG003**




*Source: Company data*

MRG003 specifically recognizes and binds EGFR on the surface of tumor cells, and then internalizes into tumor cells through EGFR-mediated endocytosis. Upon lysosomal protease cleavage of the linker, MMAE is released into the cytoplasm, binds to tubulin and inhibits tubulin polymerization, thereby disrupting various physiological functions involved in tubulin, including mitosis and leading to tumor cell death. The mechanism of action of MRG003 is illustrated in the figure below.

**Mechanism of Action of MRG003**




*Source: Company data*


Shanghai Miracogen Inc.- Ex. 2032, Page 000303

We believe that MRG003 may overcome several different types of drug resistance due to common mutations. Particularly, common acquired drug resistances to EGFR-TKIs may be due to EGFR mutations occurring in the cytoplasmic domain as well as other mechanisms, such as small-cell transformation, amplification/mutation of C-Met, ALK, and ERBB2 (Erb-B2 receptor tyrosine kinase 2). MRG003, on the other hand, can bind specifically to the extracellular domain of EGFR, internalize and release the cytotoxic agent inside the tumor cells, and exert tumor killing independently of EGFR resistance mutations as well as other acquired tumor-mediated resistance mechanisms that limit the utility of EGFR-TKIs or antibody targeted agents. Compared to the EGFR-targeted mAbs, such as cetuximab, MRG003 is an empowered antibody with a highly potent cytotoxic agent, which has demonstrated substantially enhanced anti-tumor activity in multiple EGFR expressing human tumor models including a human KRAS mutated CRC tumor model and a T790M mutated NSCLC tumor model in our pre-clinical studies.

***Market Opportunity and Competition***

MRG003 faces fierce competition from other EGFR-targeted ADC drugs from the market. The commercial value of EGFR-targeted therapies for various cancers, such as osimertinib and cetuximab, is well recognized by the market.

The table below sets out the global market sizes and the incidence in China and globally of HNSCC, NPC and NSCLC for the periods indicated.

**Global and China Market Sizes of HNC, NPC and NSCLC**

| | 2020 | 2025E | 2030E | CAGR 2020-2025E | CAGR 2025E-2030E |
|---|---|---|---|---|---|
| Global HNC Market Size (Billion USD) | 3.9 | 6.0 | 8.7 | 9.0% | 7.9% |
| China HNC Market Size (Billion RMB) | 3.0 | 7.4 | 13.0 | 19.8% | 12.3% |
| Global NPC Market Size (Billion USD) | 0.4 | 0.6 | 0.8 | 9.1% | 8.6% |
| China NPC Market Size (Billion RMB) | 0.6 | 1.6 | 2.8 | 19.5% | 12.6% |
| Global NSCLC Market Size (Billion USD) | 52.8 | 108.5 | 172.8 | 15.5% | 9.7% |
| China NSCLC Market Size (Billion RMB) | 42.3 | 111.7 | 177.5 | 21.4% | 9.7% |

*Source: Frost & Sullivan*



Shanghai Miracogen Inc.- Ex. 2032, Page 000304

**Incidence of HNC, NPC and NSCLC in China and Globally**

| | 2020 | 2025E | 2030E | CAGR 2020-2025E | CAGR 2025E-2030E |
|---|---|---|---|---|---|
| Incidence of HNC Globally (Thousand) | 931.9 | 1,035.6 | 1,138.6 | 2.1% | 1.9% |
| Incidence of HNC in China (Thousand) | 143.1 | 157.2 | 169.5 | 1.9% | 1.5% |
| Incidence of NPC Globally (Thousand) | 133.4 | 146.9 | 159.9 | 2.0% | 1.7% |
| Incidence of NPC in China (Thousand) | 62.4 | 66.5 | 69.4 | 1.3% | 0.9% |
| Incidence of NSCLC Globally (Thousand) | 1,875.8 | 2,141.4 | 2,420.7 | 2.7% | 2.5% |
| Incidence of NSCLC in China (Thousand) | 785.5 | 920.2 | 1,057.3 | 3.2% | 2.8% |

*Source: NCCR, IARC, Frost & Sullivan*

HNSCC occurs in the mucous membranes of mouth, nose, and throat and accounts for more than 90.0% of head and neck tumors. Over 90.0% of HNC is head and neck squamous cell carcinoma (HNSCC), and the EGFR-positive rate among HNSCC is 86.5%. The second line progression percentage is 95.9% in HNSCC in China. According to Frost & Sullivan, in China, the treatment of HNSCC mainly involves cetuximab in combination with chemotherapy and pembrolizumab, both of which showed certain limitations: among the patients in China treated by cetuximab and chemotherapy, the overall Grade 3 or 4 AE of cetuximab and chemotherapy for the treatment of HNSCC happened in 88.0% of the patients, including gastrointestinal toxicity and mucositis; the most common Grade 3 or 4 nonhematological AE happened in 56.0% of the patients; in addition, cetuximab-induced skin rashes happened in 64% of the patients. Frontline pembrolizumab monotherapy showed an improvement in overall survival and duration of response compared to the standard therapy in patients with PD-1–positive recurrent or metastatic HNSCC; however, it showed no improvement in progression-free survival or overall response rate with the PD-1 inhibitor. The median OS was 12.3 months with pembrolizumab versus 10.3 months with cetuximab in combination with chemotherapy; the median PFS was 3.2 months with pembrolizumab versus 5.0 months with cetuximab in combination with chemotherapy; the ORR was 19.0% with pembrolizumab versus 35.0% with cetuximab in combination with chemotherapy. The progression-free survival and overall response rate is relatively low compared to standard treatment of cetuximab in combination with chemotherapy. The large number of HNSCC cases and the limitations in the traditional treatments demonstrate considerable market opportunities in the HNSCC market in China.



Shanghai Miracogen Inc.- Ex. 2032, Page 000305

NPC is a specific subtype of HNC, which occurs when cancer cells form in the tissues of the nasopharynx. The EGFR-positive rate for NPC is 82.7% and the five-year survival rate of NPC in China and the U.S. are 45.5% and 61.3%, respectively. The first-line drug treatments for NPC in both China and the U.S. are similar, which mainly involve chemotherapy and radiotherapy. Immunotherapy is applied for NPC in the U.S. as the second-line treatment, while there are limited options for second-line NPC treatment in China. The second line progression percentage is 88.8% in NPC in China. The currently recommended first-line treatment of metastatic NPC is cetuximab in combination with carboplatin. We believe that and as advised by Frost & Sullivan, the efficacy of this treatment is very limited; the overall response rate of cetuximab combined with carboplatin was only 11.7%, and the median time to progression was only about 2.7 months. For NPC patients treated with chemotherapy, frequent recurrences can occur due to the development of MDR against chemotherapy agents, which becomes a major clinical obstacle in the successful treatment of patients with metastatic NPC. In addition, the traditional treatments demonstrate concerning results in safety profile. According to Frost & Sullivan, 51.7% of patients treated with cetuximab plus carboplatin experienced Grade 3 or 4 AEs. The poor safety profile and the MDR in traditional treatment for NPC present an urgent need for an alternative and effective medical treatment with better safety profile and potential to overcome MDR.

The EGFR-positive rate for NSCLC is 60.0% and the five-year survival rate of lung cancer in China and the U.S. is 19.7% and 19.4%, respectively. Treatment approaches to advanced NSCLC are substantially driven by molecular pathological staging and methods, and the current treatment modalities include surgery, immunotherapy, chemotherapy, radiotherapy and targeted therapies. The second line progression percentage is 91.2% in NSCLC in China. The current challenges to improving outcomes for patients with advanced NSCLC include optimizing treatment paradigms based on molecular and genomic profiling as well as engaging therapeutic strategies to prevent or overcome acquired tumor-mediated drug resistance mechanisms. Drug resistance is a major cause for therapeutic failure in NSCLC, leading to tumor recurrence and disease progression. First- and second-generation EGFR-TKIs acquire a drug resistance after nine to 14 months, and 60.0% of patients with third-generation EGFR-TKIs treatment (Osimertinib) would develop drug resistance after seven months to two years. For patients with explosive progression after drug resistance, chemotherapy is the main treatment, applied either as monotherapy or in combination with targeted therapy such as Bevacizumab or Anlotinib. Other innovative drugs are expected to be developed for the patients with Osimertinib resistance or Osimertinib no-response. First-line treatment with single-agent Osimertinib (Tagrisso) induced a response rate of 77.0% in patients with EGFR-mutated NSCLC, indicating there are 23.0% of patients that fail to respond to Osimertinib. Despite the success of Osimertinib in the first-line treatment and as a salvage therapy in the presence of the T790M secondary mutation, there is inevitable progression after approximately ten months. Currently available innovative drugs such as anti-PD-1 antibody products did not show significant efficacy in the treatment of NSCLC. The ORR of pembrolizumab was 19.4%, and the median PFS and the OS were 3.7 months and 12.0 months, respectively, for 495 unselected NSCLC patients. The ORR, PFS, and OS were all relatively low compared to Osimertinib. More innovative drugs are expected to be developed for the NSCLC treatment after Osimertinib drug resistance.


Shanghai Miracogen Inc.- Ex. 2032, Page 000306

The following table illustrates the competitive landscape of marketed EGFR-targeted ADC drugs globally:

| Generic name | Product name | Company | Indications | Locations | PMDA Approval Date | Price (million JYP) | Annual cost (million JYP) | Patent Expiration Date | 2020 Revenue (US$ Million) |
|---|---|---|---|---|---|---|---|---|---|
| Cetuximab Sarotalocan Sodium | Akalux | Rakuten Medical Inc. | unresectable locally recurrent head and neck cancer | Japan | Sep. 2020 | 250mg: 1.5 | 24.0 | August, 2036 | N.A. |

*Source: PMDA, Frost & Sullivan*

The following table sets forth other major EGFR-targeted ADC competitors:

| Product Candidate | Company | Therapeutic Strategy | Location | Clinical Phase | First Posted Time | Indications |
|---|---|---|---|---|---|---|
| MRG003 | The Group | Mono | China | II | Sept. 2020 | Advanced NSCLC, HNSCC, NPC, BTC, GC |
| M1231 | EMD Serono Research & Development Institute, Inc. | Mono | US, Canada | I | Jan. 2021 | Metastatic solid tumors Metastatic NSCLC, ESCC |
| EGFR(V)-EDV-Dox | Engeneic Pty Limited | Mono | US | I | May 2016 | Glioblastoma Astrocytoma, Grade IV |
| ZV0203 | Hisun Pharmaceutical | Mono | China | I | Nov. 2021 | HER2 expressing advanced solid tumor |
| BL-B01D1 | Sichuan Baili Pharmaceutical | Mono | China | I | Jan. 2022 | Locally advanced or metastatic urinary system tumors and other solid tumors, Locally advanced or metastatic gastrointestinal tumors and other solid tumors |

*Source: PMDA, Frost & Sullivan*

For other information regarding our competitive landscape, see "Industry Overview."

***Competitive Advantages***

MRG003 is the most advanced EGFR-targeted ADC in clinical-stage development in China, and has the potential to seize market opportunities, as there was no approved EGFR-targeted ADC in China as of the Latest Practicable Date, according to Frost & Sullivan. MRG003 targets the treatment of EGFR-positive solid tumors (including HNSCC, NPC and advanced NSCLC) with drug resistance in underserved inoperable advanced or metastatic patient population involving second and later lines of systemic therapy failure.



Shanghai Miracogen Inc.- Ex. 2032, Page 000307

The following table sets forth a comparison between MRG003 and other major EGFR-targeted ADC competitors:

| Generic name | Product name | Status | Indications | Major components | Efficacy | Safety |
|---|---|---|---|---|---|---|
| Cetuximab Sarotalocan Sodium (ASP-1929)[(1)] | Akalux | PMDA approval in Japan in September 2020;<br><br>Clinical trial in the US | PMDA approved: Unresectable locally recurrent HNSCC<br><br>Clinical trial phase III in US: Locoregional, recurrent HNSCC | mAb: Cetuximab; Drug: a light activatable dye, IRDye® 700DX; Linker: Undisclosed | PMDA approved HNSCC: ORR=43.4% | PMDA approval: In the phase IIa part of Study 101, grade >=3 adverse events reported by >2 patients were anemia in 3 patients (10.0%), and application site pain, localized oedema, dysphagia, oral pain, hyponatremia, pneumonia, tumor pain, and tumor hemorrhage in 2 patients each (6.7%). Reported serious adverse events were pneumonia in 3 patients (10.0%), tumor hemorrhage in 2 patients (6.7%).<br><br>In Study 102, a reported Grade >=3 adverse event was application site pain in 1 patient (33.3%). |
| | | Clinical trial in US | Phase I/II: EGFR expressing advanced solid tumors | | NA | NA |
| M1231 | NA | Clinical trial in US and Canada | Phase I: Metastatic solid tumors; Esophageal cancer; NSCLC | Ab: a bispecific antibody targeting EGFR and MUC1; Drug: hemiasterlin-related toxic warhead; Linker: a cleavable valine-citruline-based linker | NA | NA |
| EGFR(V)-EDV-Dox | NA | Clinical trial in US | Phase I: Glioblastoma astrocytoma, grade iv | Ab: bispecific antibodies (BsAb) targeting EGFR; Drug: a toxic payload, Doxorubicin; Linker (Package): a bacterially derived minicell which packages the drug into a 400 nm particle | NA | NA |



Shanghai Miracogen Inc.- Ex. 2032, Page 000308

| Generic name | Product name | Status | Indications | Major components | Efficacy | Safety |
|---|---|---|---|---|---|---|
| MRG003[2] | NA | Clinical trial in China | Phase II: Locally advanced or metastatic HNSCC; Locally advanced or metastatic NPC; Locally advanced or metastatic NSCLC; Locally advanced or metastatic BTC | mAb: an EGFR-targeted mAb; Drug: the potent microtubulin disrupting payload MMAE; Linker: an enzyme-cleavable vc linker | Phase Ib HNSCC: ORR=40.0%, DCR=100.0% | Phase Ia, all 22 patients reported at least one AE, and 16 patients (72.7%) reported TRAE. Most of the AE were Grade 1 or 2, and four (18.2%) reported TRAE of Grade 3 or higher. In Phase Ib, all 39 patients reported at least one AE, and 38 (97.4%) reported TRAE. Ten patients (25.6%) reported TRAE of Grade 3 or higher, 15 patients (38.5%) reported SAE, and ten patients (26.0%) reported SAEs that were related to MRG003. Two cases of death were reported as TRAE in the trial as of December 2020. One was due to a pulmonary infection while the other was due to a grade 5 multi-organ failure. The principal investigator did not rule out the relevance of the study drug in the death cases. Our Global CMO, on behalf of us as the trial sponsor, believed that both cases were primarily related to the patients' existing conditions and were possibly not related to the study drug. |

*Notes:*

(1) Akalux (ASP-1929, cetuximab sarotalocan sodium) is the only approved EGFR-ADC in the market which was approved by PMDA in 2020 as a photoimmunotherapy indicated for unresectable locally advanced or recurrent head and neck cancer. This therapy is complex and time-consuming. First, Akalux is administered as an intravenous infusion over 2 hours or longer once daily. Then, a laser beam generated by the patented investigational laser and fibre-optics is applied to the lesion 20 to 28 hours after the end of intravenous infusion. Compared with Akalux, MRG003 is administered as an intravenous infusion over 1-1.5 hours, which largely improves convenience and operability, and hence patients' compliance.

(2) Other than the marketed product, MRG003 is the most advanced EGFR-ADC among its clinical competitive pipelines in China. The clinical trials of MRG003 are all in phase II, while the clinical trials of its competitors are all in phase I.

MRG003 demonstrated encouraging results in safety and efficacy through the data from the Phase Ib clinical trial in HNSCC and NPC patients. The ORR and DCR of HNSCC patients was 40.0% and 100.0%, respectively. The ORR and DCR of NPC patients was 44.4% and 88.8%, respectively.



Shanghai Miracogen Inc.- Ex. 2032, Page 000309

MRG003 was recognized as one of the National Scientific and Technological Major Projects for "Major Drug Innovation" in China in 2019.

EGFR is overexpressed in a wide variety of human tumors. It has been an active target for multiple successfully marketed therapies including mAbs and targeted small molecule drugs such as EGFR-TKIs. To overcome acquired resistance to the EGFR-TKIs and limited efficacy of EGFR-targeted mAbs such as cetuximab and panitumumab, several EGFR-targeted ADCs have been investigated in clinical trials outside China, and many of these programs have been terminated or failed mainly due to safety or efficacy reasons. In comparison, MRG003 has demonstrated the following competitive advantages:

*Uniquely designed to utilize a humanized anti-EGFR mAb, a clinically-validated MMAE cytotoxic payload and a cleavable vc linker*

The three components in MRG003 are carefully designed:

- The mAb component of MRG003 is a humanized antibody, which has approximately six to sevenfold increased binding affinity to human EGFR, compared with cetuximab. It facilitates rapid internalization of MRG003 into tumor cells as demonstrated in our *in vitro* assays.

- The MMAE payload conjugated in MRG003 is a well-validated and widely used cytotoxic payload for clinical-stage as well as marketed ADCs, including brentuximab vedotin (Adcetris), polatuzumab vedotin (Polivy) and enfortumab vedotin (Padcev). MMAE is a tubulin binder and prevents tubulin polymerization, thus disrupting the mitotic process and leading to tumor cell death. The cell-killing potency and bystander effect of MMAE have been demonstrated in a variety of cancer models.

- The cleavable vc linker adopted in MRG003 is a linker that is adequately stable in blood circulation and also cleaved effectively by the lysosomal cathepsin enzyme after the ADC is internalized and enters into lysosome. This helps to release the MMAE molecule in its active form quickly into cytoplasm, so MMAE can bind to tubulin and lead to tumor cell death.

In addition, DAR is one of the critical factors in designing an ADC molecule to optimize the balance of safety and efficacy. Appropriate DAR of MRG003 is carefully examined and precisely controlled by the well-developed manufacturing process.

Based on the foregoing considerations, we believe that MRG003 has promising potential to expand into clinical indications to include a wider spectrum of cancer types that overexpress EGFR. The safety profile for MMAE-related clinical AE profile is well understood. Therefore, the safety risk of MRG003 clinical development can be better managed and controlled.

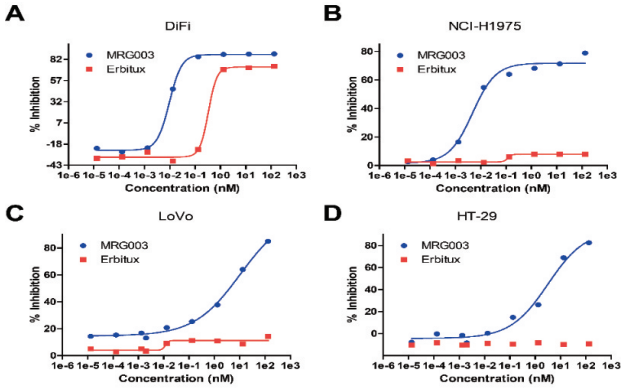


Shanghai Miracogen Inc.- Ex. 2032, Page 000310

*A broad spectrum of potent anti-tumor activity in in vitro assays and in vivo xenograft studies*

A broad spectrum of potent anti-tumor activities have been demonstrated in EGFR expressing cells carrying EGFR mutations, and in cells carrying KRAS or BRAF mutations *in vitro* assays. The cytotoxic activity of MRG003 was evaluated in a battery of EGFR-expressing cancer cell lines of different tumor types and some of these cell lines carry various mutations. MRG003 displayed significant cytotoxicity against cancer cells over-expressing both wild-type and mutant forms of EGFR with IC50 values ranging from 0.020 nM to 45 nM. In contrast, cetuximab (Erbitux®) only showed significant cytotoxicity in EGFR high-expressing colorectal cancer cell line DiFi (IC50 of 0.61 nM, which was ten times less potent than MRG003) while no activity for cetuximab was observed in other cell lines tested. It is worth noting that MRG003 was effective in inhibiting cell proliferation of EGFR medium- or low-expressing colon cancer cell line LoVo and colorectal cancer cell line HT-29 carrying KRAS and BRAF mutations respectively, as well as the NCI-H1975 NSCLC cell line carrying T790M mutation (IC50 of 0.020 nM). These results support potential expansion of MRG003 clinical development into EGFR medium- and low-expressing as well as selected EGFR mutant patient populations. Because drug resistance ultimately develops in most patients with advanced NSCLC regardless of primary treatment modality and EGFR is commonly overexpressed in NSCLC tumors, we believe that MRG003 has the potential to define several new standards of care in multiple patient populations with EGFR activating mutations, and potentially independently of ALK, ROS1, BRAF, cMET, NTRK and KRAS status as well as potentially in PD-1 expressing tumor types. The figure below demonstrates the anti-tumor activities of MRG003 in *in vitro* cytotoxic assays.

**Anti-tumor Activities of MRG003 by *In Vitro* Cytotoxic Assays**



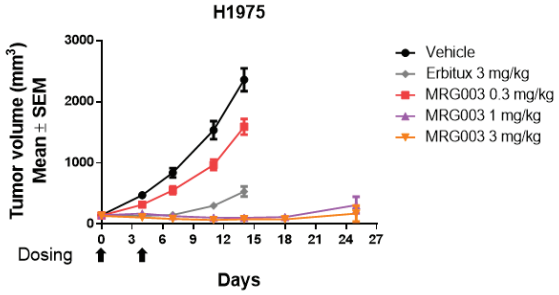

*Source: Company data*

Potent broad-spectrum anti-tumor efficacy for MRG003 was also demonstrated in tumor xenograft mouse studies including multiple CDX models and more clinically relevant PDX models. The strong anti-tumor effects of MRG003 were demonstrated in the CDX models of multiple cancer types, including colorectal cancer cell line DiFi, epidermal carcinoma cell line


Shanghai Miracogen Inc.- Ex. 2032, Page 000311

A431, hypopharyngeal carcinoma cell line FaDu, NSCLC cell line NCI-H1975 and colorectal cancer cell line LoVo. The figure below presents the anti-tumor activities of MRG003 in CDX model of NSCLC T790M mutated cell line NCI-H1975.

**Anti-tumor Activity of MRG003 in CDX Model of NSCLC T790M Mutated Cell Line NCI-H1975**

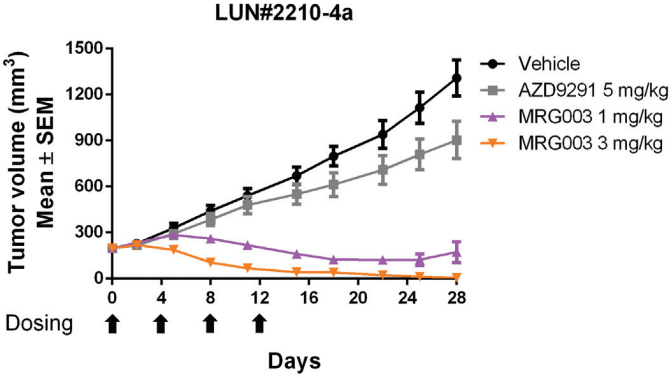



*Source: Company data*

Furthermore, PDX xenograft models are specifically considered to possess a greater degree of capability to preserve the heterogeneity, molecular diversity and histological characteristics of original tumors, and are therefore of higher value in correlation with potential efficacy in clinical indications. To this end, we tested the anti-tumor activity of MRG003 in an osimertinib-resistant NSCLC PDX model LUN2210-4a. In this model, MRG003 demonstrated dose-dependent anti-tumor activity on a Q4D×4 (every fourth day for a total of 4 injections) regimen and 3mg/kg led to complete tumor eradication on Day 28. This model is presented in the figure below.

**Anti-tumor Activity of MRG003 in Osimertinib Resistant NSCLC PDX Model**

LUN2210-4a with loss of CDKN2A/2B (cyclin-dependent kinase inhibitor 2A/2B) and loss of STK11 (serine/threonine kinase 11)




*Source: Company data*

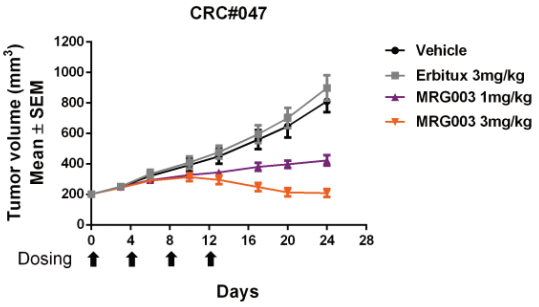


Shanghai Miracogen Inc.- Ex. 2032, Page 000312

We also tested the anti-tumor activity of MRG003 in a colon and rectal cancer model (CRC#47) carrying KRAS G12D mutation. In this model, 1 and 3 mg/kg MRG003 (Q4D×4) showed anti-tumor activity in a dose-dependent manner and 3 mg/kg of MRG003 caused tumors to regress by 12 days (Day 24) after the fourth dose. In contrast, cetuximab (Ertibux®) at the same dose level and schedule demonstrated no tumor growth inhibition (TGI) at all. This model is presented in the figure below.

**Anti-tumor Activity of MRG003 in KRAS Mutant CRC PDX Model**

Colon and Rectal Cancer PDX Model CRC#47 Carrying KRAS G12D Mutation




*Source: Company data*

This finding is important and relevant, since KRAS mutations are common and important resistance factors which act by by-passing the EGFR signaling cascade and lead to non-responsiveness to the approved EGFR-targeted therapies. Based on these scientific findings, it is clear that the mechanism of action of MRG003 has the potential to overcome tumor-mediated drug resistance due to KRAS mutations. This observation has significant implications for clinical development in a variety of common solid tumors where KRAS resistance mechanisms are common.

*Encouraging safety and efficacy data from the Phase Ia and Phase Ib clinical study*

A Phase Ia clinical trial in HNSCC, NPC and CRC patients has completed dose escalation enrollment of 22 patients who were not pre-screened for EGFR expression. An additional 39 EGFR IHC-positive patients have been enrolled and treated in the Phase Ib dose expansion cohorts. Three expansion cohorts in Phase Ib included 12 patients in metastatic CRC, 13 patients in advanced HNSCC, and 14 patients in advanced NPC. All patients in Phase Ib were heavily pre-treated and had failed multiple prior treatments. Analysis of Phase Ib showed that among evaluable patients who had at least one RECISTv1.1 imaging tumor assessment post treatment with independent radiological review confirmation: (i) four out of ten HNSCC patients experienced PR with an ORR of 40.0%; (ii) four out of nine NPC patients achieved PR for an ORR of 44.4%; and (iii) two patients with SD have been observed among eight


Shanghai Miracogen Inc.- Ex. 2032, Page 000313

evaluable mCRC patients. MRG003 was well-tolerated and among 61 patients enrolled in Phase Ia and Phase Ib clinical study, 14 patients (23%, four patients in Phase Ia and ten patients in Phase Ib) reported TRAE of Grade 3 or above. All Grade 3 or higher related AEs occurred in the 2.5 mg/kg dose group.

***Summary of Clinical Trial Results***

*Clinical Trial in HNSCC, NPC and CRC*

MRG003 demonstrated encouraging results in safety and efficacy through the data from the Phase Ia and Ib clinical trial in HNSCC and NPC patients, indicating a promising commercial and therapeutic potential to address the sizable and growing market.

*Trial Design and Progress*: This trial was an open label, multi-center clinical study in advanced solid tumors, comprising a Phase Ia dose escalation stage and a Phase Ib dose expansion stage. As of December 11, 2020, the Phase Ia clinical trial had enrolled 22 patients and the Phase Ib clinical trial had enrolled 39 EGFR-positive patients with solid tumors, including relapsed and metastatic HNSCC, NPC and CRC at dose levels of 0.1 to 2.5 mg/kg. This trial was conducted (i) to identify MTD and RP2D; and (ii) to evaluate the safety, tolerability, pharmacokinetics, immunogenicity and anti-tumor activity of MRG003 in the treatment of advanced solid tumors, including HNSCC, NPC and CRC. The main enrollment criteria for the Phase Ib dose expansion trial include that the patient: (i) has EGFR-positive HNSCC, NPC or CRC; (ii) failed standard treatment; and (iii) has at least one measurable lesion. The trial has completed enrollment as of December 11, 2020. The MRG003 Phase Ia trial was completed in January 2020. The MRG003 Phase Ib trial was completed in March 2021.

*Efficacy Data*: Among the 22 patients enrolled in Phase Ia (doses 0.1 to 2.5 mg/kg) with EGFR status assessed retrospectively, 19 patients completed at least one tumor evaluation with one PR (including one NPC patient) and five SD (including one CRC patient, two HNSCC patients, and two NPC patients), resulting in an ORR of 5.3% (one out of 19 patients) and a DCR of 31.6% (six out of 19 patients). SD was observed at 1.5, 2.0 and 2.5 mg/kg and objective tumor response was observed at 2.5 mg/kg. Nine of 19 patients tested with EGFR-positive (IHC range 5.0% to 90.0%), one PR and five SD (dose range 1.5 to 2.5 mg/kg), with an ORR of 11.1% (one out of nine patients) and a DCR of 67% (six out of nine patients). Patients with EGFR-positive status received MRG003 at the effective dose greater than 1.5 mg/kg achieved tumor response or tumor control. In the Phase Ib dose expansion, patients with EGFR-positive tumors prescreened and confirmed by IHC were enrolled as the target population.


Shanghai Miracogen Inc.- Ex. 2032, Page 000314

Among the 39 patients enrolled in Phase Ib at the dose of 2.5 mg/kg, 27 patients completed at least one efficacy assessment, eight patients achieved PR (four patients with HNSCC and four patients with NPC), 12 patients achieved SD (two patients with CRC, six patients with HNSCC and four patients with NPC), and six patients had disease progression. All eight patients with an objective response had confirmed PR. Among efficacy evaluable patients, the overall ORR was 29.6% and the DCR was 74.0%. Among them, the ORR was 40.0% (four out of ten patients) and DCR was 100.0% (ten out of ten patients) in the HNSCC patient group; the ORR was 44.4% (four out of nine patients) and DCR was 88.8% (seven out of nine patients) in the NPC patient group; the ORR was 0 and DCR was 25.0% (two out of eight patients) in the CRC patient group. Evidence of anti-tumor activity is presented as BOR. The BOR for all efficacy evaluable patients treated with MRG003 in Phase Ia and Phase Ib is summarized in the table below:

**Summary of Best Objective Response**

| | Ia Dose Group (mg/kg) | | | | | | | | Ib (mg/kg) |
|---|---|---|---|---|---|---|---|---|---|
| **Best Objective Response** | **0.1 (n = 1)** | **0.3 (n = 1)** | **0.6 (n = 3)** | **1.0 (n = 2)** | **1.5 (n = 3)** | **2.0 (n = 3)** | **2.5 (n = 5)** | **Ia Total (n = 19)** | **2.5 (n = 27)** |
| | *n (%)* | *n (%)* | *n (%)* | *n (%)* | *n (%)* | *n (%)* | *n (%)* | *n (%)* | *n (%)* |
| CR | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| PR | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (20) | 1 (5) | 8 (30) |
| SD | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (33) | 3 (100) | 1 (20) | 5 (26) | 12 (44) |
| PD | 1 (100) | 1 (100) | 3 (100) | 2 (100) | 2 (67) | 0 (0) | 3 (60) | 12 (63) | 6 (22) |
| NE* | 0 (0) | 0 (0) | 0 (0) | 1 (33) | 0 (0) | 0 (0) | 0 (0) | 1 (5) | 1 (4) |

*Note: Duration of SD 6-19 weeks.*

* Patients started other anti-tumor treatment before evaluation and were therefore considered as not evaluable.

*Safety Data*: Among the 61 patients enrolled in Phase Ia and Phase Ib of this study, 14 patients (23.0%, four patients in Phase Ia and ten patients in Phase Ib) reported TRAE of Grade 3 or higher. All Grade 3 and higher related AEs occurred in the 2.5 mg/kg dose group. In Phase Ia, all 22 patients reported at least one AE, and 16 patients (72.7%) reported TRAE. Most of the AE were Grade 1 or 2, and four (18.2%) reported TRAE of Grade 3 or higher. In Phase Ib, all 39 patients reported at least one AE, and 38 (97.4%) reported TRAE. Ten patients (25.6%) reported TRAE of Grade 3 or higher, 15 patients (38.5%) reported SAE, and ten patients (26.0%) reported SAEs that were related to MRG003. Two cases of death were reported as TRAE in the trial as of December 2020. One was due to a pulmonary infection while the other was due to a grade 5 multi-organ failure. The principal investigator did not rule out the relevance of the study drug in the death cases. Our Global CMO, on our behalf as the trial sponsor, believed that both cases were primarily related to the patients' existing conditions and were possibly not related to the study drug.



Shanghai Miracogen Inc.- Ex. 2032, Page 000315

The table below sets forth the TRAEs reported in the trial in HNSCC, NPC and CRC as of December 2020:

| Grade | Major Identified TRAEs | Number of Patients (61 in Total) | Percentage |
|---|---|---|---|
| **TRAE** | | 54 | 88.5% |
| **Grade 1 TRAE** | Anemia, Neutropenia, diarrhea | 52 | 85.2% |
| **Grade 2 TRAE** | Fatigue, Rash, Anorexia | 36 | 59.0% |
| **TRAE ≥Grade 3** | Hyponatremia, Neutropenia, Decreased Red Blood Cell Count | 14 | 23.0% |

| Age of Patients | Number of Patients Reported TRAE | Percentage |
|---|---|---|
| **<65** | 46 | 75.4% |
| **≥65** | 8 | 13.1% |

*Source: Company data*

***Clinical Development Plan***

Our clinical development plan for MRG003 is focused on initial exploratory and registration trials in China involving treatment of eligible advanced or metastatic HNSCC, NPC, NSCLC and BTC patient population.

The table below sets forth the details of our clinical development plan for MRG003 in EGFR-positive unresectable locally advanced or metastatic solid tumors:

| Indication | Clinical Phase | Location and Competent Authorities | Expected Number of Patients | Expected Time[(1)] |
|---|---|---|---|---|
| Locally advanced or metastatic HNSCC | II | China/NMPA | 120 | Complete in the first half of 2023 |
| Locally advanced or metastatic NPC | II | China/NMPA | 151 | Complete in the first half of 2023 |
| Locally advanced or metastatic NSCLC | II | China/NMPA | 90 | Complete in 2022 |



Shanghai Miracogen Inc.- Ex. 2032, Page 000316

| Indication | Clinical Phase | Location and Competent Authorities | Expected Number of Patients | Expected Time[(1)] |
|---|---|---|---|---|
| Locally advanced or metastatic BTC | II | China/NMPA | 80 | Complete in the fourth quarter of 2023 |
| Locally advanced or metastatic HNSCC | I/II | US/FDA | 30 | Initiate in 2022 |

*Note:*

(1) Indicates the expected time to gather sufficient data for the primary endpoint.

***Licenses, Rights and Obligations***

We have the global rights to develop and commercialize MRG003.

***Material Communications with Competent Authorities***

MRG003 received IND approval from the NMPA in August 2017, which included the phase Ia, Ib clinical study protocol and subsequent phase II and phase III study draft protocols. The MRG003 Phase Ia trial was completed in January 2020. As advised by our PRC Legal Advisor and taking into account the industry practice as advised by Frost & Sullivan, its main purpose aligns with the overall purpose of a conventional phase I trial regulated by the NMPA, which seeks to evaluate the safety and tolerability of a product to determine the MTD and RP2D. The MRG003 Phase Ib trial, which was considered as a standalone trial regulated by the NMPA as confirmed by our PRC Legal Advisor and Frost & Sullivan taking into account its clinical trial objective and clinical study protocol, was completed in March 2021. Based on the due diligence performed (including discussions with the Company, our PRC Legal Advisor and Frost & Sullivan), the Joint Sponsors concur with the foregoing views of our PRC Legal Advisor and Frost & Sullivan. Therefore, since our acquisition of Miracogen Shanghai in July 2018, we have completed both the MRG003 Phase Ia trial (which was ongoing at the time of acquisition) and the MRG003 Phase Ib trial.

Leveraging the MTD and RP2D identified in the MRG003 phase Ia and sufficient safety data generated from the MRG003 Phase Ia trial, the Phase II clinical trial protocols (together with the supporting materials) for (i) locally advanced or metastatic HNSCC, (ii) locally advanced or metastatic NPC, (iii) locally advanced or metastatic NSCLC, and (iv) locally advanced or metastatic BTC indications ("**MRG003 Phase II Trials**") were approved by the ethics committees (including the Ethics Committee of Drug Clinical Trials of Shanghai Dongfang Hospital, the Ethics Committee of Sun Yat-sen University Cancer Center, and the Ethics Committee of Tumor Hospital of Chinese Academy of Medical Sciences) in February 2021, April 2021, September 2020 and September 2020, respectively, ("**MRG003 Ethics Approval**"). After completion of the MRG003 Ethics Approval, the MRG003 Phase II Trials were registered with the Drug Clinical Trial Information Platform of the CDE in March 2021,



Shanghai Miracogen Inc.- Ex. 2032, Page 000317

May 2021, September 2020, and November 2020, respectively. We plan to engage in specific communications with regulatory authorities regarding trial designs before we commence relevant registration trials. As advised by our PRC Legal Advisor, on the basis that (i) the registration of the MRG003 Phase II trials with the NMPA was duly completed as required by the NMPA Registration Regulation, (ii) the IND approval granted by the NMPA in August 2017 was a one-time umbrella approval for the clinical trials of MRG003 including all four phases of Phase Ia, Ib, II and III, which was confirmed by Frost & Sullivan with reference to the industry practice and concurred by the Joint Sponsors based on the due diligence performed, and (iii) the MRG003 Ethics Approval has been granted, we have obtained all necessary approvals from the NMPA to proceed with the MRG003 Phase II Trials, and no further approval from the NMPA is required for the Company to commence the MRG003 Phase II Trials.

As of the Latest Practicable Date, we were not aware of any legal claims or proceedings that may have an adverse effect on our development for MRG003. As of the Latest Practicable Date, we had commenced the MRG003 Phase II Trials and had received no objections to our clinical development plans with respect to the regulatory review or approval process of MRG003, and no material adverse change had occurred with respect to the regulatory review or approval process of MRG003.

**Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange: WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET MRG003 SUCCESSFULLY.**

**MRG002**

MRG002, one of our Core Products, is an innovative HER2-targeted ADC, a molecular target abnormally overexpressed in many cancer types including breast cancer, gastroesophageal junction cancer and gastric cancer. Compared to competing HER2-targeted ADCs, MRG002 has demonstrated competitive advantages in safety, efficacy and pharmacokinetics profile through the following, as of September 2021: (i) our pre-clinical studies revealed better efficacy than T-DM1 in multiple Herceptin-resistant HER2 over-expressing and low-expressing PDX models of gastric cancer and breast cancer, (ii) the preliminary data from clinical studies of MRG002 showed that no patient has reported any SAEs of interstitial pneumonia and ocular events which are commonly caused by other ADCs with the same target in the market or under clinical studies; (iii) in the Phase Ia dose escalation stage in China, MRG002 generated an ORR of 45.5% and a DCR of 81.8% among efficacy evaluable patients who were heavily pretreated and had HER2-positive breast cancer, salivary gland cancer, colorectal cancer and gastric cancer with manageable safety and tolerability; (iv) in the Phase Ib clinical trials in China, MRG002 generated an ORR of 53.2% and a DCR of 93.6% for HER2-positive breast cancer, gastric cancer and colorectal cancer among efficacy evaluable patients; (v) in the Phase Ia & Ib clinical trials, MRG002 generated an ORR of 54.9% among breast cancer patients who received MRG002 treatment at dose above RP2D, while the ORR is 73.9% among patients with liver metastases, and 68.2% among patients with positive HR and HER-2; and (vi) in the Phase Ia & Ib clinical trials, MRG002 generated an ORR of 60.0% and a DCR of 80.0% for gastric cancer.


Shanghai Miracogen Inc.- Ex. 2032, Page 000318

Our clinical development strategy for MRG002 in China aims at realizing the efficacy potential of MRG002 in various common malignancies, especially for second- or later-line systemic therapy of breast cancer, gastric cancer/gastroesophageal junction cancer.

As one of the pioneer HER2-targeted ADCs to reach clinical-stage development in China according to Frost & Sullivan, MRG002 demonstrated better safety and tolerability in patients while maintaining sufficiently enhanced anti-tumor efficacy through a uniquely designed and innovatively modified trastuzumab, which is a sugar-modified trastuzumab conjugated with MMAE payload via a vc linker. It binds specifically with the high affinity of trastuzumab to human HER2 antigen on the surface of tumor cells, internalizes and releases cytotoxic payload in the cytoplasm and ultimately kills the tumor cells. The innovatively modified trastuzumab has a selectively high level of fucosylation in the Fc region, resulting in a reduced Fc binding to CD16a expressed on effector immune cells, minimizing potential killing of CD16a expressing immune cells by MRG002 and therefore reducing potential adverse effects on patients.

We acquired MRG002 when it obtained IND approval from NMPA and completed MRG002 Phase Ia trial in August 2020. We received the IND clearance from the FDA in May 2020 and appointed several clinical sites for a Phase I/II clinical study of MRG002 in HER2-expressing gastric cancer and gastroesophageal junction cancer in the U.S. in the second half of 2020. We had commenced Phase II trials for MRG002 in HER2 over-expressing and low-expressing breast cancer; for MRG002 in HER2 over-expressing breast cancer, we have completed the patient enrollment process and were in the follow-up period. We had obtained approval from the NMPA of registration trial of HER2 over-expressing breast cancer as of the Latest Practicable Date. Additionally, we had initiated exploratory Phase II clinical trials in HER2-expressing advanced urothelial cancer and BTC in China in April and June 2021, respectively.

We have developed MRG002 since our acquisition of Miracogen Shanghai. We have filed applications for patents related to MRG002 in the U.S., China and other jurisdictions through Miracogen Shanghai, one of our wholly-owned subsidiaries. We hold the rights to develop and commercialize MRG002 globally.

***Mechanism of Action***

HER2 is a member of the EGFR family encoded by the human HER2 gene and its overexpression has been recognized as a genetic driver of the high incidence of many cancer types. An acquired somatic alteration of this gene, which results in the amplification and overexpression of HER2, occurs in approximately 15.0%-30.0%, 23.0%-80.0%, 10.0%-30.0%, and 20.0% of human breast, bladder, gastric, and lung cancers, respectively. Amplification and overexpression of HER2 may result in increased proliferative replication and invasive potential of cancer cells and are recognized adverse prognostic factors in breast cancer. This increase in proliferative stimuli results in increased tumor growth, as well as resistance to conventional therapies. Upregulated or constitutive HER2 activity is believed to be the driving force of malignances with HER2-expressing tumor cells. Trastuzumab, an HER2-targeted mAb initially developed by Roche, binds to HER2 and inhibits the tyrosine kinase signal pathway by preventing the necessary dimerization of HER2 or heterodimerization with other members of the HER family, which in turn inhibits the growth of HER2 over-expressing cancer cells. To


Shanghai Miracogen Inc.- Ex. 2032, Page 000319

further improve the therapeutic benefit of HER2-targeted antibody therapies, Roche launched T-DM1. However, T-DM1's limited clinical benefit has prompted the development of a new generation of antibody-drug conjugates with alternative cytotoxic agents, linkers or conjugation chemistry that potentially offer better potency and safety profiles.

MRG002 is an innovative ADC consisting of a sugar-modified trastuzumab conjugated with a vc-MMAE platform, similar to the molecular design of MRG003. See "– Our Clinical-stage Drug Candidates – MRG003 – Mechanism of Action." The sugar-modified design has a selectively high level of fucosylation in the Fc region. Such modification is intended to decrease the binding of MRG002 to CD16a expressed on effector immune cells and minimize the potential killing of CD16a expressing immune cells. We believe that such molecular differentiation may translate into better safety and tolerability in patients and maintain anti-tumor effects. Upon binding to HER2 receptors on the surface of tumor cells, MRG002 is internalized via receptor-mediated endocytosis and then releases MMAE through lysosomal protease cleavage in lysosomes. The released MMAE inhibits tubulin polymerization of microtubule, and thereby disrupts microtubule-related functions such as mitosis, which eventually leads to tumor cell death.

***Market Opportunity and Competition***

MRG002 faces fierce competition from other HER2-targeted ADC drugs from the market. There is a significant market potential in China and globally for HER2-targeted ADC drugs, according to Frost & Sullivan. The commercial value of ADC therapy for HER2-expressing cancers is well-recognized by the market. Major indications of HER2-targeted ADC drugs include breast cancer, gastric cancer and urothelial carcinoma. We believe that MRG002 has great potential to address this sizable and growing market.

The tables below set out market sizes and the incidence in China and/or globally of breast cancer, gastric cancer and urothelial carcinoma for the periods indicated.

**Market Sizes of Breast Cancer and Gastric Cancer in China or Globally**

| | 2020 | 2025E | 2030E | CAGR 2020-2025E | CAGR 2025E-2030E |
|---|---|---|---|---|---|
| China Breast Cancer Market Size (Billion RMB) | 50.7 | 81.8 | 124.6 | 10.0% | 8.8% |
| Global Gastric Cancer Market Size (Billion USD) | 14.4 | 24.2 | 36.4 | 11.0% | 8.5% |
| China Gastric Cancer Market Size (Billion RMB) | 28.0 | 51.4 | 83.2 | 12.8% | 10.2% |

*Source: Frost & Sullivan*



Shanghai Miracogen Inc.- Ex. 2032, Page 000320

**Incidence of Breast Cancer, Gastric Cancer and Urothelial Cancer in China or Globally**

| | 2020 | 2025E | 2030E | CAGR 2020-2025E | CAGR 2025E-2030E |
|---|---|---|---|---|---|
| Incidence of Breast Cancer in China (Thousand) | 331.6 | 355.6 | 372.4 | 1.4% | 0.9% |
| Incidence of Gastric Cancer Globally (Thousand) | 1,089.1 | 1,255.6 | 1,435.3 | 2.9% | 2.7% |
| Incidence of Gastric Cancer in China (Thousand) | 469.6 | 545.6 | 622.4 | 3.0% | 2.7% |
| Incidence of Urothelial Cancer in China (Thousand) | 77.1 | 91.0 | 105.9 | 3.4% | 3.1% |

*Source: NCCR, Frost & Sullivan*

Breast cancer is the most common cancer among women, and its annual incidence increases continuously. In the U.S., T-DM1 is considered as the standard treatment in the second-line therapy for the treatment of patients with metastatic HER2-positive breast cancer who previously received trastuzumab, pertuzumab and taxane in the first-line therapy. Combination therapies with chemotherapy are recommended as the third-line treatment in the U.S., while they are adopted as the first-line and second-line treatment in China. The HER2 positive rate for breast cancer is approximately 25.4%. The second line progression percentage is 94.3% in breast cancer in China. Traditional treatments of HER2-positive breast cancer demonstrate several limitations. For example, although new drugs such as tucatinib and trastuzumab deruxtecan emerged, treatment options for HER2-positive breast cancer patients whose disease has progressed are limited. In addition, drug resistance of traditional treatments including trastuzumab remains a serious concern, and the treatment of patients with prior trastuzumab failure has long represented an area of clinical need.

Gastric cancer develops from the lining of the stomach. Chemotherapy and targeted therapy are the main treatments for advanced metastatic gastric cancer. According to Frost & Sullivan, there is only one HER2-targeted antibody trastuzumab on the market treating HER2-positive advanced gastric cancer, calling for more HER2-targeted drugs for gastric cancer with higher efficacy and lower cost. The HER2 positive rate for gastric cancer is approximately 23.7%. The second line progression percentage is 94.6% in gastric cancer in China.

Urothelial carcinoma accounts for about 90.0% of all bladder cancers. It also accounts for 10.0% to 15.0% of kidney cancers diagnosed in adults. The HER2-positive rate of urothelial cancer is approximately 36.0%. The second-line progression percentage is 81.5% in bladder cancer in China. The mainstream treatments for metastatic urothelial carcinoma include dose-dense methotrexate, vinblastine, doxorubicin, and cisplatin or gemcitabine and cisplatin/carboplatin, atezolizumab, pembrolizumab, and avelumab maintenance therapy. Such treatments suffer from high recurrence rates and low recovery rates. The total recurrence rate of NMIBC after trans urethral resection of bladder tumor was 60.0%. Patients are prone to have local and systemic complications during the treatment process. Local complications include chemical cystitis which may lead to lower urinary tract symptoms such as urgency of urination, frequency of urination, pain or hematuria. Systemic complications may lead to bone marrow suppression, renal insufficiency and other systemic symptoms.



Shanghai Miracogen Inc.- Ex. 2032, Page 000321

The following table illustrates the competitive landscape of marketed HER2-targeted ADC drugs in China and globally. For pipeline competitors of HER2-targeted ADC drugs, see "Industry Overview – the ADC Market – HER2-targeted ADC Drug Market."

**Marketed HER2-targeted ADC Drugs in China and Worldwide**

| Generic name | Product Name | Company | Indications | Location | FDA/ NMPA Approval Date | Price (US$) | Annual cost (US$ thousand)[4] | Patent Expiration Date | NRDL Status | 2020 Revenue (USD Million) |
|---|---|---|---|---|---|---|---|---|---|---|
| Trastuzumab deruxtecan-nxki | **Enhertu** | AstraZeneca | See Note (1) below | US, EU, Japan | Dec. 2019/ N.A. | 2,442.45 | $134.5 | 2033 | N.A. | 383 |
| Adotrastuzumab emtansine | **Kadcyla** | Genentech (Roche) | See Note (2) below | US, China, EU, Japan | Feb. 2013/ Jan. 2020 | 100mg: 3,451.0; 160mg: 5,515.9 | $126.7 | 2023 | No | 1,745 |
| **Disitamab Vedotin** | **Aidixi** | RemeGen Co., Ltd | See Note (3) below | China | N.A./ Jun. 2021 | 60mg: RMB3,800.0 | RMB266.8 thousand | 2034 | 2021.11 | 0 |

*Notes:*

(1) For the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting.

(2) For the treatment of patients with HER2-positive, metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination; as the adjuvant treatment of patients with HER2-positive early breast cancer who have residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment.

(3) locally advanced or metastatic gastric cancer (including gastroesophageal junction adenocarcinoma) who have received at least 2 types of systemic chemotherapy; locally advanced or metastatic urothelial carcinoma who have previously received platinum based chemotherapy and HER2 overexpression, i.e. immunohistochemical results of 2 + or 3 +.

(4) The annual cost refers to the annual cost after considering the patient assistance program, assuming that the patient weighs 65kg and the annual medication time is 52 weeks.

*Source: NMPA, FDA, Frost & Sullivan*

### *Competitive Advantages*

HER2-targeted therapies have been actively developed and proven to be highly successful in multiple marketed mAbs including trastuzumab (Herceptin) and pertuzumab (Perjeta), as well as marketed ADCs, notably T-DM1 (Kadcyla) fam-trastuzumab deruxtecan-nxki (Enhertu), and more recently disitamab vedotin (Aidixi).

In the HER2-positive breast cancer and gastric cancer, marketed ADCs have shown significant benefit in relapsed or metastatic patients after first-line treatment of trastuzumab combined with standard chemotherapy. However, T-DM1 has been approved for breast cancer only and not for gastric cancer. Enhertu demonstrated certain safety issues, including ILD. The ILD rate of Enhertu was 13.6% and deaths of approximately 2.2% of the patients were due to ILD. The administration frequency of Aidixi is every two weeks. To improve the safety and efficacy of HER2-targeted therapies, several mAbs and ADCs are being actively studied in the early and late stage of clinical development in China and other regions. MRG002 is carefully designed to aim for improved safety and efficacy in the trastuzumab-failed or T-DM1-failed patient population.



Shanghai Miracogen Inc.- Ex. 2032, Page 000322

The following table sets forth a comparison between MRG002 and other major HER2-targeted ADC competitors:

| Generic name | Product name | Status | Indications | Major components | Efficacy | Safety | Administration frequency | FDA boxed warning |
|---|---|---|---|---|---|---|---|---|
| Trastuzumab deruxtecan-nxki[(1)] | Enhertu | FDA conditional approval | FDA approved: unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting; Locally advanced or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen | mAb: a humanized anti-HER2 IgG1 monoclonal antibody, trastuzumab biosimilar; Drug: a topoisomerase inhibitor; Linker: a tetrapeptide-based cleavable linker | Breast cancer: ORR=60.9% DCR=97.3%; | 57.1% had an adverse event of grade 3 or higher. 13.6% had interstitial lung disease related to the treatment of trastuzumab deruxtecan, as determined by an independent adjudication committee. Four deaths (2.2% of the patients) were attributed to interstitial lung disease by independent adjudication. | Every three weeks | BOXED WARNINGS: INTERSTITIAL LUNG DISEASE and EMBRYO-FETAL TOXICITY Interstitial lung disease (ILD) and pneumonitis, including fatal cases, have been reported with ENHERTU. Permanently discontinue ENHERTU in all patients with Grade 2 or higher ILD/pneumonitis. Exposure to ENHERTU during pregnancy can cause embryo-fetal harm. |



Shanghai Miracogen Inc.- Ex. 2032, Page 000323

| Generic name | Product name | Status | Indications | Major components | Efficacy | Safety | Administration frequency | FDA boxed warning |
|---|---|---|---|---|---|---|---|---|
| Adotrastuzumab emtansine[1] | Kadcyla | FDA and NMPA full approval | FDA approved: HER2-positive, metastatic breast cancer patients who previously received trastuzumab and a taxane, separately or in combination; Adjuvant treatment of patients with HER2-positive early breast cancer who have residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment.<br>NMPA approved: Adjuvant treatment of patients with HER2-positive early breast cancer who have residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment. | mAb: the humanized anti-HER2 IgG1, trastuzumab; Drug: DM1 (a maytansine derivative); Linker: MCC(4-[N-maleimidomethyl] cyclohexane-1-carboxylate) linker | Breast cancer: PFS=9.6m, OS=30.9m, ORR=43.6%, DOR=12.6m | The proportion of patients with a grade 3 or worse adverse event was 48% of patients in the trastuzumab emtansine group. Thrombocytopenia was the most frequently reported grade 3 or worse adverse event in patients given trastuzumab emtansine (14%), followed by increased aspartate aminotransferase (5%), and anaemia (4%). Overall, adverse events led to four deaths in the trastuzumab emtansine group (metabolic encephalopathy, neutropenic sepsis, pneumonia, and acute myeloid leukaemia). | Every three weeks | BOXED WARNINGS: HEPATOTOXICITY, CARDIAC TOXICITY, EMBRYO-FETAL TOXICITY Serious hepatotoxicity has been reported, including liver failure and death in patients treated with KADCYLA. KADCYLA administration may lead to reductions in left ventricular ejection fraction (LVEF). Exposure to KADCYLA during pregnancy can result in embryo-fetal harm. |



Shanghai Miracogen Inc.- Ex. 2032, Page 000324

| Generic name | Product name | Status | Indications | Major components | Efficacy | Safety | Administration frequency | FDA boxed warning |
|---|---|---|---|---|---|---|---|---|
| Disitamab Vedotin[(2)] | Aidixi | NMPA conditional approval | NMPA approved: Locally advanced or metastatic gastric cancer patients (including gastroesophageal junction adenocarcinoma) who have received at least two types of systemic chemotherapy | mAb: Disitamab; Drug: monomethyl auristatin E (MMAE); Linker: A protease cleavable linker | Gastroesophageal junction adenocarcinoma: ORR= 24.4%, PFS= 4.1m, OS=7.6m | The most commonly reported treatment-related AEs were leukopenia (52.0%), alopecia (51.2%), neutropenia (48.0%), and fatigue (42.5%). | Every two weeks | NA |



Shanghai Miracogen Inc.- Ex. 2032, Page 000325

| Generic name | Product name | Status | Indications | Major components | Efficacy | Safety | Administration frequency | FDA boxed warning |
|---|---|---|---|---|---|---|---|---|
| MRG002 | NA | Clinical trials in China and US | Phase II: HER2 low expression locally advanced or metastatic breast cancer; HER2-positive, unresectable locally advanced or metastatic breast cancer; Locally advanced/metastatic urothelial carcinoma; Advanced/metastatic biliary tract cancer;<br><br>Phase I/II (in US): Locally advanced or metastatic gastric/gastroesophageal junction (GEJ) cancer<br><br>Phase Ib: HER2-positive advanced solid tumors | mAb: a sugar-modified trastuzumab; Drug: monomethyl auristatin E (MMAE); Linker: an enzyme-cleavable vc linker | HER2-positive advanced solid tumors (Phase Ib): ORR=53.2%, DCR=93.6% | The most common Grade 3 or higher side effects possibly related to the study drug was decreased neutrophil count, with an incidence of 21.6%. No death was reported as TRAE in the trial as of September 2021. | Every three weeks | NA |



Shanghai Miracogen Inc.- Ex. 2032, Page 000326

*Notes:*

(1) There are two approved HER2-ADC for breast cancer in the global market: trastuzumab deruxtecan-nxki and adotrastuzumab emtansine. Both drugs have boxed warnings on their FDA label. Interstitial lung disease (ILD) and pneumonitis, including fatal cases, have been reported with trastuzumab deruxtecan-nxki. The ILD rate of Enhertu was 13.6% and deaths of approximately 2.2% of the patients were due to ILD. Exposure to trastuzumab deruxtecan-nxki during pregnancy can cause embryo-fetal harm. Serious hepatotoxicity has been reported, including liver failure and death in patients treated with adotrastuzumab emtansine. Adotrastuzumab emtansine administration may lead to reductions in left ventricular ejection fraction (LVEF). Exposure to adotrastuzumab emtansine during pregnancy can result in embryo-fetal harm. Overall, adverse events led to four deaths in the trastuzumab emtansine group. No death was reported as TRAE in the MRG002 clinical study as of September 2021. The preliminary data from clinical studies of MRG002 showed that no patient has reported any SAEs of interstitial pneumonia and hepatotoxicity which are commonly caused by other ADCs with the same target in the market.

(2) The administration frequency of disitamab vedotin is every two weeks, and the administration frequency of MRG002 is every three weeks, which represents better compliance and consistency.

Compared with competing HER2-targeted ADCs, MRG002 has demonstrated competitive advantages in safety, efficacy and pharmacokinetics profile through the following: (i) the preliminary data from our clinical studies of MRG002 showed that no patient has reported any SAEs of interstitial pneumonia and ocular events that were caused by the competing HER2-targeted ADCs in the market or under clinical studies; (ii) in the Phase Ia dose escalation stage in China, MRG002 generated an ORR of 45.5% and a DCR of 81.8% among efficacy evaluable patient population with heavily pretreated HER2-positive breast cancer, salivary gland cancer, colorectal cancer and gastric cancer with manageable safety and tolerability; (iii) in the Phase Ib clinical trials in China, MRG002 generated an ORR of 53.2% and a DCR of 93.6% for HER2-positive breast cancer, gastric cancer and colorectal cancer among efficacy evaluable patients; (iv) in the Phase Ia & Ib clinical trials, MRG002 generated an ORR of 54.9% among breast cancer patients who received MRG002 treatment at dose above RP2D, while the ORR is 73.9% among patients with liver metastases, and 68.2% among patients with positive HR and HER-2; and (v) in the Phase Ia & Ib clinical trials, MRG002 generated an ORR of 60.0% and a DCR of 80.0% for gastric cancer.

*Innovatively designed to utilize a high affinity anti-HER2 mAb that is sugar-modified trastuzumab, a clinically-validated payload MMAE and a cleavable vc linker*

The three components of MRG002 are carefully designed:

- The mAb component utilized in MRG002 is a sugar-modified trastuzumab conjugated with a vc-MMAE platform. The sugar-modified design with a selectively high level of fucosylation in the Fc region is intended to decrease the binding of MRG002 to CD16a expressed on effector immune cells, and minimizes the potential killing of CD16a expressing immune cells. In the meantime, the HER2 antigen binding affinity and specificity of MRG002 remains identical to trastuzumab, which has been clinically proven to be beneficial and also allows effective internalization of MRG002 into tumor cells in our *in vitro* assays.


Shanghai Miracogen Inc.- Ex. 2032, Page 000327

- The MMAE payload conjugated in MRG002 is a well-validated and widely used payload in the clinical-stage ADCs as well as approved ADCs including brentuximab vedotin (Adcetris), polatuzumab vedotin (Polivy) and enfortumab vedotin (Padcev). MMAE is a tubulin binder and prevents tubulin polymerization, thereby disrupting the mitotic process and leading to tumor cell death. The cell-killing potency and bystander effect of MMAE have been demonstrated in a variety of cancer cells, which enhances MRG002's potential for expanding clinical indications into all cancer types that are over-expressing HER2, particularly in gastric cancer where MRG002 has shown strong anti-tumor activity in the T-DM1 resistant tumor models in our pre-clinical studies. The safety profile for MMAE-related clinical symptoms is well-studied and understood. Therefore, the safety risk of MRG002 clinical development is well-managed and controlled.

- The cleavable vc linker adopted in MRG002 is a linker that is adequately stable in blood circulation and cleaved effectively by the lysosomal cathepsin enzyme after the ADC is internalized and enters into lysosome. This helps to release active MMAE molecule quickly into cytoplasm to bind to tubulin and lead to tumor cell death.

DAR is one of the critical factors in designing an ADC molecule to optimize the balance of safety and efficacy. Appropriate DAR of MRG002 is carefully examined and precisely controlled by the well-developed manufacturing process.

*Significant anti-tumor activity in the in vitro assay and in vivo xenograft studies*

We determine the ability of MRG002 to inhibit tumor cell proliferation in multiple human cancer cell lines with various levels of HER2 expression. We performed *in vitro* cell-based assays to determine the cytotoxic activity of MRG002 compared with the reference molecule T-DM1, and tested three different breast cancer cell lines SKBR-3, BT-474, and MDA-MB-453, and a gastric cancer cell line NCI-N87. The results of such tests showed that MRG002 generally killed HER2-positive cancer cells more effectively than T-DM1, as MRG002 demonstrated approximately 2.6, 26, and 5.3-fold higher anti-tumor activity than that of T-DM1 in SKBR-3, BT-474, and NCI-N87 cell lines, respectively, but similar potency in MDA-MB-453 cells.

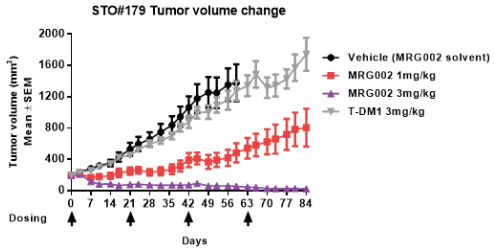
The strong anti-tumor activity of MRG002 was also demonstrated in tumor xenograft models. The efficacy of MRG002 was investigated in several CDX and PDX mouse models. CDX models included the HER2-expressing breast cancer cell line BT-474 and gastric cancer cell line NCI-N87. To preserve the heterogeneity, molecular diversity and histological characteristics of original tumors, and to better predict clinical efficacy, MRG002 was evaluated in eight gastric cancer and three breast cancer PDX models expressing varying levels of HER2, and most of these cancer models are Herceptin resistant while some are T-DM1 resistant. MRG002 displayed more potent anti-tumor response in these models than that of


Shanghai Miracogen Inc.- Ex. 2032, Page 000328

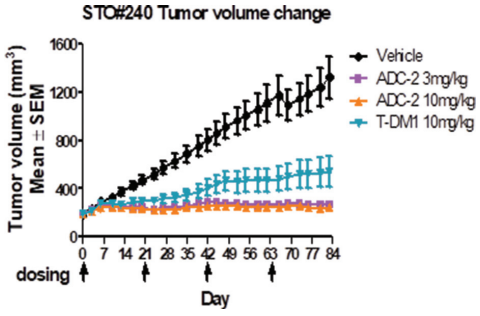
T-DM1 at equivalent doses. The figure below demonstrates a much stronger anti-tumor effect by MRG002 than T-DM1 in a Herceptin resistant HER2 high-expressing gastric cancer PDX model as well as a HER2 low-expressing model.

**Anti-tumor Effect Comparison of MRG002 and T-DM1 in Gastric Cancer PDX Models**

HER2 High-expressing STO#179 (IHC 3+)




HER2 Low-expressing STO#240 (IHC 1+)




*Source: Company data*

*Encouraging preliminary safety and efficacy data from the Phase Ia & Ib clinical study*

We had completed Phase Ia dose escalation enrollment of 25 patients with HER2-positive advanced solid tumors. MRG002 Phase Ia clinical trial was completed in August 2020, and we were in the process of enrolling patients in the Phase Ib dose expansion stage as of the Latest Practicable Date. Among the 22 efficacy evaluable patients treated with MRG002 in the Phase Ia dose escalation, ten out of 22 patients achieved PR, eight out of 22 patients had SD and four out of 22 patients had PD, resulting in an ORR of 45.5% and a DCR of 81.8% among efficacy evaluable patients.



Shanghai Miracogen Inc.- Ex. 2032, Page 000329

We are conducting a Phase Ib clinical study which enrolled 51 patients with HER2-positive advanced solid tumors. As of September 2021, MRG002 showed considerable efficacy. Among the 47 efficacy evaluable patients treated with MRG002 in the Phase Ib clinical study, 25 out of 47 patients achieved PR, 19 out of 47 patients had SD and three out of 47 patients had PD, resulting in an ORR of 53.2% and a DCR of 93.6% among efficacy evaluable patients.

We observed considerable efficacy for gastric cancer and breast cancer in the Phase Ia & Ib study. Six of the 76 enrolled patients in the Phase Ia & Ib study had gastric cancer and were efficacy evaluable. Among the six patients, the ORR was 60.0% and the DCR was 80.0%. Of the 76 enrolled patients, 55 had breast cancer and received MRG002 treatment at dose above RP2D, 51 of which were efficacy evaluable. The ORR was 54.9% among the 51 patients, 73.9% among patients with liver metastasis, and 68.2% among patients with positive HR and HER-2.

We observed a favorable safety profile in the Phase Ia & Ib clinical study. As of September 2021, all 25 patients enrolled in Phase Ia study had at least one AE considered possibly related to MRG002. The majority of patients had Grade 1 or 2 AEs. 14 patients had Grade 3 or above AEs which were considered to be possibly related to MRG002 treatment.

In Phase Ib study, most of AEs related with MRG002 were Grade 1 or 2, and in the clinical study, the most common Grade 3 or above TRAE was decreased neutrophil count, with an incidence of 21.6%, and followed by decreased white blood cell count (15.7%) and Ileus (5.9%). No death was reported as TRAE in the trial as of September 2021.

***Summary of Clinical Trial Results***

*Clinical Trial in HER2-Positive Advanced Solid Tumors*

*Trial Design and Progress*: This trial was an open label, multi-center clinical study to evaluate safety, tolerability, pharmacokinetics and anti-tumor activity in HER2-positive advanced solid tumors. The trial was conducted (i) to determine MTD and RP2D; and (ii) to assess safety, pharmacokinetics, immunogenicity and preliminary anti-tumor activity in HER2-positive patients. The main enrollment criteria for the trial include that the patient: (i) has HER2-positive advanced solid tumors; (ii) failed standard treatment; and (iii) has at least one measurable lesion. Phase Ia was completed in August 2020 and Phase Ib was ongoing as of the Latest Practicable Date. We expect to complete the trial in 2022.

*Efficacy Data*: As of September 2021, there were 22 efficacy evaluable patients among all 25 patients enrolled in the Phase Ia clinical study and 47 among 51 patients in the Phase Ib study. Evidence of anti-tumor activity was presented as BOR. The BOR assessed by the investigator for all efficacy evaluable patients treated with MRG002 by cohort is summarized in the table below:


Shanghai Miracogen Inc.- Ex. 2032, Page 000330

**Summary of Best Objective Response for Patients Treated with MRG002 (Phase Ia)**

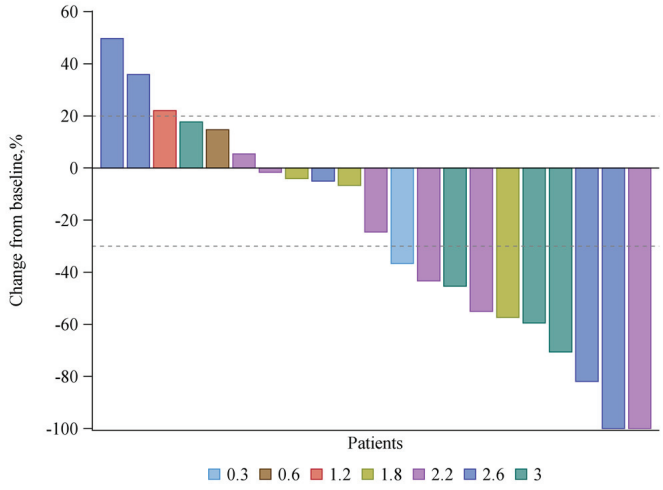
| | Dose Cohort (mg/kg) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Best Objective Response** | **0.3 (n=1)** | **0.6 (n=1)** | **1.2 (n=1)** | **1.8 (n=3)** | **2.2 (n=5)** | **2.6 (n=5)** | **3.0 (n=6)** | **Total (n=22)** |
| | *n (%)* | *n (%)* | *n (%)* | *n (%)* | *n (%)* | *n (%)* | *n (%)* | *n (%)* |
| Complete response (CR) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 0 (0) |
| Partial response (PR) | 1 (100) | 0 (0) | 0 (0) | 1 (33) | 3 (60) | 2 (40) | 3 (50) | 10 (45) |
| Stable disease[(1)] (SD) | 0 (0) | 1 (100) | 1 (100) | 1 (33) | 2 (40) | 1 (20) | 2 (33) | 8 (36) |
| Progressive disease (PD) | 0 (0) | 0 (0) | 0 (0) | 1 (33) | 0 (0) | 2 (40) | 1 (17) | 4 (18) |

*Note:*

(1) The response of SD was observed for ≥ 6 weeks.

The efficacy data of the Phase Ia clinical trial, measured by change from baseline in sum of longest diameters, is illustrated in the table below:

**Efficacy Measured by Change from Baseline in Sum of Longest Diameters**




*Source: Company data*

In all 22 efficacy evaluable patients in the Phase Ia study, the BOR was PR for ten patients, SD for eight patients, and PD for four patients. The ORR was 45.5% and the DCR was 81.8%. PR were achieved at the starting dose of 0.3 mg/kg and in the 1.8 mg/kg, 2.2 mg/kg, 2.6 mg/kg and 3.0 mg/kg cohorts. SD was achieved in the 0.6 mg/kg, 1.2 mg/kg, 1.8 mg/kg, 2.2 mg/kg, 2.6 mg/kg and 3.0 mg/kg cohorts. Of 22 patients in the efficacy evaluation, all patients had at least one post-treatment tumor assessment. Tumor size reductions were observed in 15 patients. Greater tumor reduction was observed at doses greater than 1.8 mg/kg.


Shanghai Miracogen Inc.- Ex. 2032, Page 000331

In all 47 efficacy evaluable patients in the Phase Ib clinical study, 25 out of 47 patients achieved PR, 19 out of 47 patients had SD and three out of 47 patients had PD, resulting in an ORR of 53.2% and a DCR of 93.6% among efficacy evaluable patients. In Phase Ia & Ib study, six of the 76 enrolled patients had gastric cancer and were efficacy evaluable, among whom the ORR was 60.0% and the DCR was 80.0%. Out of the 76 enrolled patients, 55 had breast cancer and received MRG002 treatment at dose above RP2D, 51 of which were efficacy evaluable. The ORR was 54.9% among the 51 patients, 73.9% among patients with liver metastasis, and 68.2% among patients with positive HR and HER2.

*Safety Data*: As of September 2021, all 25 patients enrolled in the Phase Ia study had at least one AE considered possibly related to MRG002. The majority of patients had Grade 1 or 2 AEs. 14 patients had AEs of Grade 3 or higher which were possibly related to MRG002 treatment. There were no AEs leading to death. Two patients in the 1.8 mg/kg cohort, two patients in the 2.2 mg/kg cohort, one patient in the 2.6 mg/kg cohort and one patient in the 3.0 mg/kg cohort had reported at least one treatment-related SAE, respectively. Treatment was well tolerated in the 1.8, 2.2 and 2.6 mg/kg cohorts with major objective responses observed.

The most common Grade 3 or higher side effects possibly related to the study drug in the Phase Ia study were decreased neutrophil count, increased blood triglycerides, both with an incidence of 12.0%, This was followed by increased γ-glutamyl transferase, increased aspartate aminotransferase, decreased ejection fraction, decreased white blood cell count, decreased red blood cell count, decreased hemoglobin, increased creatine phosphokinase, decreased blood glucose, myalgia, limb discomfort, peripheral neuropathy, and hypertension, all of which had one patient each (4.0%). No death was reported as TRAE in the trial as of September 2021.

In the Phase Ib study, most of AEs related with MRG002 were Grade 1 or 2, and in the clinical study, the most common Grade 3 or above TRAE was decreased neutrophil count, with an incidence of 21.6%, and followed by decreased white blood cell count (15.7%) and Ileus (5.9%). No death was reported as TRAE in the trial as of September 2021.


Shanghai Miracogen Inc.- Ex. 2032, Page 000332

The table below sets forth the TRAEs reported in the trial in HER2-positive advanced solid tumors as of September 2021:

**Phase Ia**

| Grade | Major Identified TRAEs | Number of Patients (25 in Total) | Percentage |
|---|---|---|---|
| **TRAE** | | 25 | 100.0% |
| **Grade 1 TRAE** | Increased aspartate aminotransferase, increased blood lactate dehydrogenase, decreased white blood cell count, etc. | 25 | 100.0% |
| **Grade 2 TRAE** | Leukopenia, Increased γ-glutamyltransferase, Neutropenia | 19 | 76.0% |
| **TRAE ≥Grade 3** | Increased Blood Triglycerides, Neutropenia, Increased Alanine Aminotransferase | 14 | 56.0% |

| Age of Patients | Number of Patients Reported TRAE | Percentage |
|---|---|---|
| **<65** | 24 | 96.0% |
| **≥65** | 1 | 4.0% |

*Source: Company data*

**Phase Ib**

| Grade | Major Identified TRAEs | Number of Patients (51 in Total) | Percentage |
|---|---|---|---|
| **TRAE** | | 48 | 94.1% |
| **Grade 1 TRAE** | Increased blood creatine phosphokinase MB, increased blood lactate dehydrogenase, decreased neutrophil count, increased aspartate aminotransferase | 47 | 92.2% |
| **Grade 2 TRAE** | Decreased white blood cell count, hair loss, decreased neutrophil count | 45 | 88.2% |
| **TRAE ≥Grade 3** | Decreased neutrophil count, decreased white blood cell count, bowel obstruction | 22 | 43.1% |

| Age of Patients | Number of Patients Reported TRAE | Percentage |
|---|---|---|
| **<65** | 46 | 90.2% |
| **≥65** | 2 | 3.6% |



Shanghai Miracogen Inc.- Ex. 2032, Page 000333

***Clinical Development Plan***

In China, we had initiated several Phase II clinical trials of MRG002 in unresectable locally advanced or metastatic HER2-expressing urothelial cancer, HER2 over-expressing BTC and HER2 over-expressing and low-expressing breast cancer in 2021 and had obtained approval from the NMPA of registration trial of HER2 over-expressing breast cancer as of the Latest Practicable Date. We aim to file an NDA application for MRG002 with the NMPA in 2023. In the U.S., we are conducting a Phase I/II clinical study of MRG002 in unresectable locally advanced or metastatic HER2-expressing (including low-expressing) G/GEJ carcinoma patients, and once the Phase I stage of dose confirmation is completed, clinical sites in China will be added to join the Phase II stage of the study.

The table below sets forth the details of our clinical development plan for MRG002 in HER2-positive unresectable locally advanced or metastatic solid tumors:

| Indication | Clinical Phase | HER2 Status | Location and Competent Authorities | Expected Number of Patients | Expected Time[(1)] |
|---|---|---|---|---|---|
| Locally advanced or metastatic G/GEJ carcinoma | I/II | IHC 3+/IHC 2+ (FISH +) or IHC 2+ (FISH -)/IHC 1+ | US/FDA | 146 | Complete in the fourth quarter of 2024 |
| Locally advanced or metastatic BC | II/III | IHC 3+/IHC 2+ (FISH+) | China/NMPA | II: 30-60; III: 560 | Complete in the third quarter of 2023 |
| Locally advanced or metastatic BC | II | IHC 2+ (FISH -)/IHC 1+ | China/NMPA | 66 | Complete in the first quarter of 2022 |
| Locally advanced or metastatic UC | II | IHC 3+/IHC 2+ (FISH +) | China/NMPA | 58 | Complete in the fourth quarter of 2022 |
| Locally advanced or metastatic BTC | II | IHC 3+/IHC 2+ (FISH +) | China/NMPA | 80-86 | Complete in the first quarter of 2024 |

*Note:*

(1) Indicates the expected time to gather sufficient data for the primary endpoint.

***Licenses, Rights and Obligations***

We have the global rights to develop and commercialize MRG002.



Shanghai Miracogen Inc.- Ex. 2032, Page 000334

***Material Communications with Competent Authorities***

MRG002 received IND approval from the NMPA in May 2018, which included clinical study protocols for phase Ia, Ib and subsequent phase II and phase III. We also received IND clearance of Phase I/II clinical study of MRG002 from the FDA in May 2020. After our acquisition of Miracogen Shanghai in July 2018, MRG002 Phase Ia clinical trial was completed in August 2020. As advised by our PRC Legal Advisor and taking into account the industry practice as advised by Frost & Sullivan, its main purpose aligns with the overall purpose of a conventional phase I trial regulated by the NMPA, which seeks to evaluate the safety and tolerability of a product to determine the MTD and RP2D. Based on the due diligence performed (including discussions with the Company, our PRC Legal Advisor and Frost & Sullivan), the Joint Sponsors concur with the foregoing view of our PRC Legal Advisor and Frost & Sullivan.

Leveraging the MTD and RP2D identified in MRG002 Phase Ia trial and sufficient safety data generated from the MRG002 Phase Ia trial, the Phase II clinical trial protocols (together with the supporting materials) for (i) locally advanced or metastatic HER2 high expressing BC, (ii) locally advanced or metastatic HER2 low-expressing BC, (iii) locally advanced or metastatic HER2 positive UC, and (iv) locally advanced or metastatic HER2 positive BTC ("**MRG002 Phase II Trials**") were approved by the ethics committees (including The Medical Ethics Committee of the Chinese People's Liberation Army General Hospital, the Fifth Medical Center of the Chinese People's Liberation Army General Hospital, and the Ethics Committee of the Cancer Hospital of the Chinese Academy of Medical Sciences) in April 2021, January 2021, September 2020 and September 2020, respectively, ("**MRG002 Ethics Approval**"). After completion of the MRG002 Ethics Approval, the MRG002 Phase II Trials were later registered with the Drug Clinical Trial Information Platform of the CDE in May 2021, February 2021, February 2021 and February 2021, respectively. Additionally, as part of the application to the NMPA for the combination program of MRG002 with HX008, the results of the MRG002 Phase Ia trial have been submitted to the NMPA for assessment. In January 2021, the NMPA confirmed in writing that, based on the pre-clinical and clinical data submitted to the NMPA (including the results of the MRG002 Phase Ia trial and the HX008 Phase Ia trial), we have provided support to proceed with phase I/II trial for the combination program of MRG002 with HX008. We plan to engage in specific communications with regulatory authorities regarding trial designs before we commence relevant registration trials. As advised by our PRC Legal Advisor, on the basis that (i) the registration of the MRG002 Phase II trials with the CDE was duly completed as required by the NMPA Registration Regulation, (ii) the IND approval granted by the NMPA in May 2018 was a one-time umbrella approval for the clinical trials of MRG002 including all four phases of Phase Ia, Ib, II and III, which was confirmed by Frost & Sullivan with reference to the industry practice and concurred with by the Joint Sponsors based on the due diligence performed, and (iii) the MRG002 Ethics Approval has been granted, we have obtained all necessary approvals from the NMPA to proceed with the MRG002 Phase II Trials and no further approval from the NMPA is required for the Company to commence the MRG002 Phase II Trials.


Shanghai Miracogen Inc.- Ex. 2032, Page 000335

As of the Latest Practicable Date, we were not aware of any legal claims or proceedings that may have an adverse effect on our development of MRG002. As of the Latest Practicable Date, we had commenced the MRG002 Phase II Trials and had received no objections to our clinical development plans with respect to the regulatory review or approval process of MRG002 and no material adverse change had occurred with respect to the regulatory review or approval process of MRG002.

**Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange: WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET MRG002 SUCCESSFULLY.**

**HX008**

HX008 (pucotenlimab), one of our Core Products, is a humanized antagonist mAb against human PD-1 by using human IgG4 isotype, which can antagonize the PD-1 signal to restore the capability of the immune cells to kill cancer cells through blocking PD-1 binding to their ligands PD-L1 and PD-L2. HX008 employs an innovative molecular design to extend its half-life and demonstrated strong clinical anti-tumor activity and a favorable safety profile. It innovatively employs antibody engineering techniques to introduce mutations in Fc portion to increase FcRn binding, thereby significantly improving its half-life and leading to encouraging clinical efficacy and drug compliance of patients. Compared with all competing anti-PD-1 antibodies that were marketed or had entered a Phase III clinical trial, HX008 demonstrated a half-life of 17.15-23.51 days (single dose) and 18.41-38.16 days (stable) in the completed Phase Ia clinical trial. Furthermore, as the extension of the half-life of HX008 did not cause any additional AE along with its encouraging clinical efficacy profile. We filed an NDA of HX008 with the NMPA in melanoma in June 2021. We submitted a pre-NDA meeting application of HX008 in MSI-H/dMMR solid tumors in July 2021, filed an NDA of HX008 with the NMPA in MSI-H/dMMR solid tumors and was granted priority review in October 2021.

HX008 demonstrated efficacy and good safety profile in the completed Phase Ia clinical trial in solid tumors, allowing us to proceed to the Phase II registration trials in melanoma and MSI-H/dMMR solid tumors which are substantially completed pending only the end of the follow-up period. HX008 has competitive advantages based on the following: (i) the ORR and DCR in Phase II clinical trial in MSI-H/dMMR solid tumors reached 46.0% and 70.0%, respectively, outperforming the corresponding indicators of its competitors; and (ii) the ORR and DCR in the clinical trial in melanoma reached 18.5% and 44.5%, respectively, which are at par with the historical data of the best marketed drugs.

We obtained HX008 at the Phase Ia stage and its Phase Ia trial was completed with MTD and RP2D determined per the clinical trial protocol in May 2018 and the final CSR issued in May 2020. We formulate and conduct clinical trials of HX008 and seek approval from the NMPA through an accelerated development pathway, and in the meantime expand the clinical application in additional indications. Based on the favorable results, we had completed patient enrollment and were in the follow-up period for Phase Ib clinical trial in advanced solid tumor and the Phase II clinical trial in NSCLC, TNBC (triple-negative breast cancer), gastric cancer


Shanghai Miracogen Inc.- Ex. 2032, Page 000336

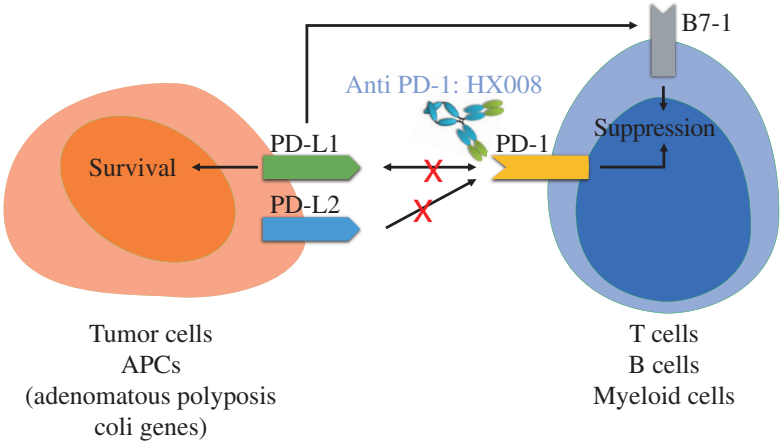
and HCC as of the Latest Practicable Date, and are conducting multiple clinical trials on an ongoing basis, including a Phase II clinical trial for NMIBC and a Phase III clinical trial for second-line treatment of gastric or gastroesophageal junction cancer. In addition, supported by HX008's encouraging safety results,we are conducting two clinical trials on combination therapies with HX008, including HX008 in combination with OH2 in advanced hepatocellular carcinoma and HX008 in combination with LP002 in advanced melanoma refractory to anti-PD-1 therapy. See "– Combination Therapies within Our Pipeline."

We acquired our anti-PD-1 antibody candidate HX008 by acquiring the controlling equity interest in Taizhou Hanzhong. We then conducted clinical development and hold the global rights to manufacture, develop and commercialize the anti-PD-1 antibody products. We plan to commence commercialization activities in 2022. We are building a strong commercialization team in China dedicated to the academic promotion and marketing of our pipeline products. See "– Commercialization – Our Commercialization Team."

The experience and recognition to be gained from the commercialization of HX008 is expected to help us swiftly penetrate various indications of oncology therapeutics as well as different levels of medical institutions, establish a dedicated commercialization team of a considerable scale and strengthen our commercialization capabilities.

***Mechanism of Action***

PD-1 is a protein on the surface of activated T-cells and is one of the proteins referred to as an "immune checkpoint," a major negative immune regulator controlling T cell activation, exhaustion, and tolerance. PD-1 is also expressed on NK cells and B cells and macrophages, inhibiting their effector functions. PD-1 has two ligands, PD-L1 and PD-L2. Tumor cells and other cells in tumor microenvironment can express high levels of PD-L1, helping such cells evade T-cell attacks. HX008 binds to PD-1 on T cells and blocks its binding to both PD-L1 and PD-L2, allowing the T-cells to kill the cancer cells. The mechanism of action of HX008 is illustrated in the figure below.




*Source: Company data*



Shanghai Miracogen Inc.- Ex. 2032, Page 000337

HX008 is a high affinity humanized antagonist mAb against human PD-1 containing the Fc domain of human IgG4 with S228P and S254T/V308P/N434A mutations. HX008 has no ADCC or CDC by using IgG4 Fc isotype to avoid killing of PD-1 expressing immune cells. S228P mutation can prevent Fab arm exchange to improve the manufacturing capabilities of the IgG4 antibody. HX008 mainly recognizes glycosylated PD-1 through its unique epitope. S254T/V308P/N434A mutations in Fc part result in increased FcRn binding that extends the half-life of HX008. HX008 employed a extended half-life design in clinics compared with all competing anti-PD-1 antibodies that were marketed or had entered Phase III clinical trial.

***Market Opportunity and Competition***

HX008 faces fierce competition from other anti-PD-1 drugs from the market. There are medical needs for anti-PD-1/anti-PD-L1 mAb drugs in China, according to Frost & Sullivan. Anti-PD-1/anti-PD-L1 inhibitors have been increasingly used for a variety of malignancies, including melanoma, NSCLC, head and neck cancer, bladder cancer and renal cancer. Traditional treatments for these indications include primarily surgery, radiotherapy and chemotherapy. In addition, currently available clinical data suggests that some of the most prevalent cancers in China, such as lung, liver, stomach, colorectal and esophageal cancers, are potentially responsive to the anti-PD-1/anti-PD-L1 mAb drugs.

In China, the market size of anti-PD-1/anti-PD-L1 antibody therapies has been constantly growing and is expected to further expand in the near future. The market size of anti-PD-1/anti-PD-L1 antibody therapies in China was RMB13.7 billion in 2020 and is expected to reach RMB51.9 billion and RMB58.2 billion in 2025 and 2030, respectively, representing a CAGR of 30.5% from 2020 to 2025 and a CAGR of 2.3% from 2025 to 2030, according to Frost & Sullivan. Anti-PD-1/anti-PD-L1 antibody therapies target multiple indications, including melanoma, MSI-H/dMMR solid tumors, gastric cancer and NSCLC. We believe that HX008 has great potential to address the sizable and growing market.

With its competitive advantages, we believe that HX008 can gain significant market share and a strong competitive position upon commercialization. In addition, driven by the growing number of oncological patients, the increasing recognition of the treatment, the additional indications approved, the increased efficacy and sales resulted from combination therapies, as well as the gradual expansion of medical insurance coverage in the PRC, we believe the demand for HX008 will continue to grow.

There are a number of anti-PD-1 antibodies that have been approved in China and in the U.S., and a large number of anti-PD-1 antibody drug candidates in clinical trial stage. These antibodies have revolutionized cancer treatment, demonstrating unprecedented clinical efficacy in patients with hard-to-treat cancers. The following table sets forth the current marketed anti-PD-1 antibody drugs, which are potential competitors for HX008:


Shanghai Miracogen Inc.- Ex. 2032, Page 000338

**Marketed PD-1 mAb drugs approved by the FDA and NMPA**

**FDA Approved PD-1**

| Company | Drugs | Product | FDA Approval Time | NMPA Approval Time | FDA Approved Indications | Injection Methods | 2020 Global Revenue *(US$ million)* |
|---|---|---|---|---|---|---|---|
| MSD | Pembrolizumab | Keytruda | Sep-14 | July-18 | Melanoma, NSCLC, SCLC, HNSCC, Classical HL, PMBL, Urothelial Carcinoma, MSI-H/dMMR, GC, Esophageal cancer, Cervical carcinoma, HCC, Merkel Cell Carcinoma, Renal Cell Carcinoma, Endometrial carcinoma, TMB-H Solid Tumor, Cutaneous squamous cell carcinoma, TNBC | Intravenous | 14,380.0 |
| BMS | Nivolumab | Opdivo | Dec-14 | June-18 | Melanoma, NSCLC, SCLC, MPM, Renal Cell Carcinoma, Classical HL, HNSCC, Urothelial Carcinoma, MSI-H/dMMR, CRC, HCC, ESCC | Intravenous | 6,992.0 |
| Regeneron | Cemiplimab | Libtayo | Sep-18 | N/A | Cutaneous Squamous cell carcinoma | Intravenous | 270.7 |
| GSK | Dostarlimab-gxly | Jemperli | April-21 | N/A | dMMR endometrial cancer, dMMR recurrent or advanced solid tumor | Intravenous | NA |



Shanghai Miracogen Inc.- Ex. 2032, Page 000339

**NMPA approved PD-1 mAbs**

| INN | Trade Name | Company | Approval Date | Indications | Price (RMB) | Dosage | Injection Methods | 2020 Revenue (US$ million) | NRDL Status | Annual Cost after PAP or NRDL (Thousand RMB) | Half-life Period | Patent Expiration Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Nivolumab | Opdivo | BMS | Jun-2018 | NSCLC, squamous cell carcinoma of the head and neck, adenocarcinoma of the stomach or gastroesophageal junction, pleural mesothelioma | 100mg: 9,250RMB; 40mg: 4,587RMB | 3mg/kg every 2 weeks | Intravenous | 6,992.0 (Global) | NO | 108.2[1] | 26.7 days | 2037-04-10 |
| Pembrolizumab | Keytruda | MSD | Jul-2018 | Melanoma, NSCLC, esophageal squamous cell carcinoma, head and neck squamous cell carcinoma, colorectal cancer | 100mg: 17,918RMB | 2mg/kg every 3 weeks | Intravenous | 14,380.0 (Global) | NO | 93.2[2] | 25 days | 2036-02-22 |
| Toripalimab | Tuoyi 拓益 | Junshi (君實生物) | Dec-2018 | Melanoma, nasopharyngeal carcinoma, urothelial carcinoma | 80mg: 906RMB | 3mg/kg every 2 weeks | Intravenous | 160.5 | Class B | 57.4 | 12.6 days | 2033-06-26 |
| Sintilimab | Daboshu 達伯舒 | Innovent (信達生物) | Dec-2018 | classical Hodgkin lymphoma, NSCLC, HCC | 100mg: 2,843RMB | 200mg every 3 weeks | Intravenous | 359.7 | Class B | 102[3] | 19.6 days | 2036-08-09 |
| Camrelizumab | Airuika 艾瑞卡 | Hengrui (江蘇恒瑞) | May-2019 | classical Hodgkin lymphoma, HCC, NSCLC, Esophageal squamous cell carcinoma | 200mg: 2,928RMB | 200mg every 2 weeks | Intravenous | 480.0 | Class B | 76.1 | 5.5 days | 2034-11-14 |
| Tislelizumab | Baizean 百澤安 | Beigene (百濟神州) | Dec-2019 | classical Hodgkin lymphoma, urothelial carcinoma, HCC, NSCLC | 100mg: 2,180RMB | 200mg every 3 weeks | Intravenous | 165.6 | Class B | 74.1 | 26 days | 2033-09-13 |
| Penpulimab | Annike 安尼可 | Chia Tai Tianqing (正大天晴)/ Akeso Biopharma (康方生物) | Aug-2021 | Recurrent or refractory classical Hodgkin's lymphoma | NA | 200mg every 2 weeks | Intravenous | NA | NO | NA | NA | NA |
| Zimberelimab | Yutuo 譽妥 | WuXi Biologics (藥明生物)/ GloriaBio (譽衡生物) | Aug-2021 | Recurrent or refractory classical Hodgkin's lymphoma | NA | 240mg every 2 weeks | Intravenous | NA | NO | NA | NA | NA |

*Source: CDE, Frost & Sullivan*

### *Competitive Advantage*

HX008 is a humanized antagonist mAb against human PD-1 by using human IgG4 isotype, which can inhibit the PD-1 signal to restore the capability of the immune cells to kill cancer cells through blocking PD-1 binding to their ligands PD-L1 and PD-L2. HX008 employs an innovative molecular design to extend its half-life and demonstrated strong clinical anti-tumor activity and a favorable safety and efficacy profile. It innovatively employs antibody engineering techniques to introduce mutations into Fc portion, thereby significantly improving its half-life and leading to encouraging clinical efficacy and drug compliance of patients. HX008 demonstrated a half-life of 17.15-23.51 days (single dose) and 18.41-38.16 days (stable) in the completed Phase Ia clinical trial. Furthermore, as the extension of the half-life of HX008 did not cause any unexpected AEs, along with its encouraging efficacy profile.



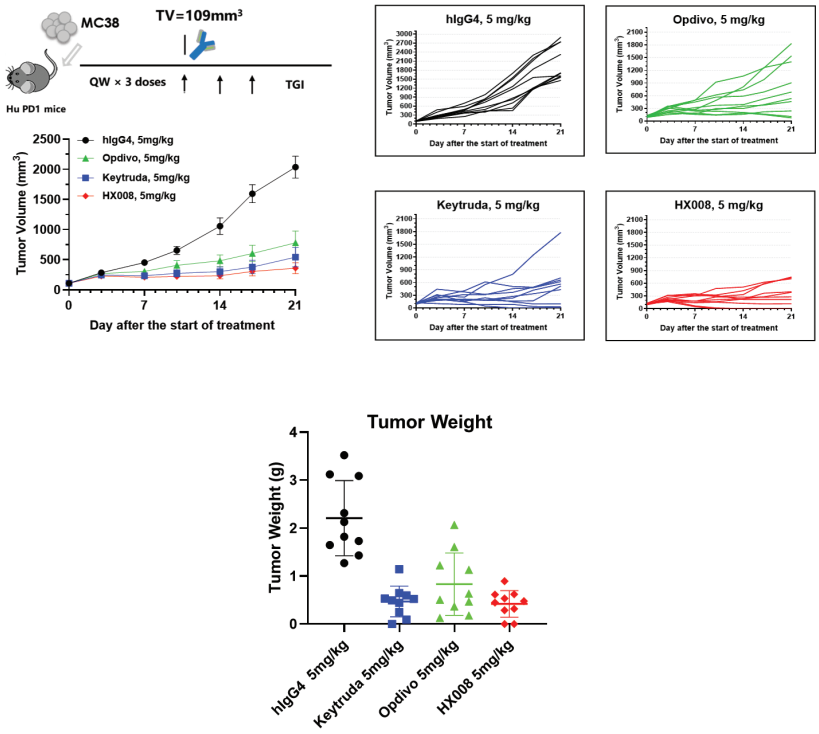
Shanghai Miracogen Inc.- Ex. 2032, Page 000340

We believe that HX008 has the following major competitive advantages:

*Strong anti-tumor activity and clinical efficacy*

We have designed the *in vivo* efficacy study by using PD-1 gene humanized mice on MC38 tumor model. Different from traditional dosing regimen (two doses per week), we applied a weekly dosing strategy to compare HX008, Keytruda and Opdivo at a dosage level of 5mg/kg. HX008 demonstrated good efficacy in tumor growth and tumor weight. In terms of tumor-free mice, there were two tumor-free mice in HX008 group, one in Keytruda group and zero in Opdivo at a weekly dosage level 5mg/kg weekly for three doses. The results of the *in vivo* efficacy study are illustrated in the figures below:

***in vivo* Efficacy Study on MC38 Tumor Model**




*Source: Company data*



Shanghai Miracogen Inc.- Ex. 2032, Page 000341

We have initiated two Phase II registration trials for HX008 in China: one on locally advanced or metastatic melanoma, and the other on MSI-H/dMMR advanced multiple solid tumors. The ORR and DCR in the clinical trial in melanoma are at par with the historical data of the best marketed drugs. Notably, the ORR and DCR in the clinical trial in MSI-H/dMMR solid tumors outperform the corresponding indicators of its competitors. The table below sets forth the ORR and DCR in the clinical trials for HX008 as of June 2021:

| **Indication** | **ORR** *(%)* | **DCR** *(%)* |
|---|---|---|
| Melanoma | 18.5 | 44.5 |
| MSI-H/dMMR solid tumors | 46.0 | 70.0 |

We filed an NDA of HX008 with the NMPA in melanoma in June 2021. We submitted a pre-NDA meeting application of HX008 in MSI-H/dMMR solid tumors in July 2021, filed an NDA of HX008 with the NMPA in MSI-H/dMMR solid tumors and was granted priority review in October 2021. We have also initiated clinical trials exploring the clinical efficacy of HX008 in combination therapy with chemotherapy in first-line and second-line gastric cancer, and TNBC in Phase II clinical trials.

The table below sets forth the ORR and DCR in the clinical trials for HX008 in combination therapy with chemotherapy:

| **Indication** | **ORR** *(%)* | **DCR** *(%)* |
|---|---|---|
| First-line gastric cancer | 60.0 | 77.1 |
| Second-line gastric cancer | 27.6 | 60.3 |
| TNBC | 80.6 | 100.0 |

*Good clinical efficacy ensured by extended half-life design*

HX008 has used S254T/V308P/N434A mutations in IgG4 to increase the binding of antibody to FcRn to improve the half-life of antibody. HX008 innovatively employs a extended half-life design in clinics compared with all competing anti-PD-1 antibodies that were marketed or had entered Phase III clinical trial. Pharmacokinetic study in cynomolgus monkeys has demonstrated that these triple mutations improve the T half-life compared with its wild-type counterpart (268.96h vs. 224.00h). Furthermore, HX008 demonstrated a half-life of 17.15-23.51 days (single dose) and 18.41-38.16 days (stable) in the completed Phase Ia clinical trial. Compared with other competing anti-PD-1 antibodies that were marketed or had entered Phase III clinical trial, HX008 is an anti-PD-1 antibody which shows a clear advantage in average half-life in stable stage, as illustrated in the table below. The PK profile of HX008 supports a three-week regime that facilitates combination therapy with chemotherapy, which could increase the drug compliance of patients. In addition, based on the PK profile of HX008,


Shanghai Miracogen Inc.- Ex. 2032, Page 000342

we are planning to explore the fixed dose of 400mg every six weeks, which will further increase drug compliance. We believe that this will help to reduce the burden on both patients and hospitals, especially during the COVID-19 outbreak.

| Drug Name | Antibody Type | Average Half-life (days) (single dose) | Average Half-life (days) (stable) | PK Linear Range mg/kg |
|---|---|---|---|---|
| HX008 | IgG4/κ | 17.15 (dose level at 3mg/kg) | 36.06 (dose level at 3mg/kg) | 1~10 |
| Pembrolizumab | IgG4 | N/A | 25 | 1~10 |
| Nivolumab | IgG4 | 25 (unspecified single dose or stable) | | 0.1~10 |
| Toripalimab | IgG4/κ | 12.6 (unspecified single dose or stable) | | 1~10 |
| Sintilimab | IgG4 | 13.7 | 19.6 | 1~10 |
| Camrelizumab | IgG4/κ | 5.5 | N/A | 1~10 |
| Cemiplimab | IgG4 | N/A | 20.3 | 1~10 |

*Source: Company data, FDA, CDE*

*Favorable safety profile*

HX008 demonstrated favorable safety and tolerability in cancer patients in various clinical trials. In all completed and ongoing trials, HX008 shows a good safety profile with no new TRAEs reported. As of April 19, 2021, the TRAE incidence of HX008 is generally consistent with that of its competitors, as illustrated in the table below.

**Safety Data Comparison of HX008 and its Competitors**

| Drug Name | Number of Patients | TRAE | TRAE ≥ Grade 3 |
|---|---|---|---|
| HX008(1) | 323 | 87.3% | 29.4% |
| Toripalimab(1) | 598 | 93.8% | 29.4% |
| Camrelizumab | 1,116 | 94.1% | N/A |
| Sintilimab(1) | 540 | 86.1% | 30.6% |

*Note:*

(1) includes definitely related, possibly related and possibly unrelated TRAEs

*Source: Company data, FDA, CDE*



Shanghai Miracogen Inc.- Ex. 2032, Page 000343

In a Phase Ia clinical study with 30 patients enrolled for the treatment of advanced solid tumors, No DLTs were observed, and only 33.3% of patients experienced TRAEs of Grade 3 or higher, as illustrated in the table below.

**Safety Data of HX008**

| | Indication/Study IDs | | | | | |
|---|---|---|---|---|---|---|
| | Monotherapy | | | Combotherapy | | |
| | Solid Tumors (HX008-Ia) | ≥2L Melanoma (HX008-II-MM-01) | ≥2L MSI-H/dMMR Tumors (HX008-II-02 cohort 2) | 1L (G/GEJ) (HX008-II-GC-01) | 2L (G/GEJ) (HX008-II-02 cohort 1) | 1L TNBC (HX008-Ib/II-TNBC-01) |
| TRAE[(1)] | 93.3% | 76.5% | 81.0% | 80.0% | 82.8% | 100.0% |
| TRAE ≥ Grade 3 | 33.3% | 13.4% | 14.0% | 42.9% | 32.8% | 87.1% |
| SAE related to HX008 | 23.3% | 8.4% | 4.0% | 8.6% | 13.8% | 16.1% |

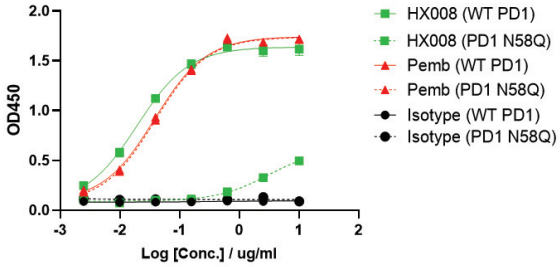
*Note:*

(1) includes definitely related and possibly related TRAEs

The extended half-life design of HX008 did not show any increased TRAEs in clinics.

*Glycosylation dependent PD-1 epitope*

PD-1 has four N-glycosylation sites, namely N49, N58, N74 and N116, and is extensively N-glycosylated in T cells. PD-1 N58-glycosylation is essential for mediating the interaction with PD-L1. Compared with pembrolizumab, the binding of HX008 to PD-1 is dependent on N58-glycosylation. Such comparison is illustrated in the chart below.




*Source: Company data*



Shanghai Miracogen Inc.- Ex. 2032, Page 000344

***Summary of Clinical Trial Results***

We are currently evaluating HX008 in a series of clinical trials in order to explore its potential to address several indications. As of the Latest Practicable Date, the safety and efficacy profile of HX008 in the completed Phase Ia clinical trial and 11 clinical trials covering various indications had been evaluated.

*Clinical Trial in Advanced Solid Tumor*

The Phase Ia clinical trial for HX008 for the treatment of advanced solid tumor in Fudan University Shanghai Cancer Center was conducted between January 2018 and December 2019. We have initiated the corresponding Phase Ib clinical trial in three hospitals, namely, Hunan Cancer Hospital, Wuhan Union Hospital and the First Affiliated Hospital of Bengbu Medical College since August 2019.

Phase Ia clinical trial in advanced solid tumor

*Trial Design and Progress*: This trial was an open, single-center, dose escalation study in patients with advanced solid tumor to explore the appropriate dose level, including MTD and RP2D, of HX008. This trial was conducted among 30 patients, divided into four dose cohorts to receive HX008 (at dose levels of 1mg/kg, 3mg/kg, 10mg/kg and 200mg). The trial was conducted to evaluate the safety and tolerability of HX008 and determine the MTD and/or RP2D of HX008. The trial was completed with MTD and RP2D determined per the clinical trial protocol in May 2018, and final CSR issued in May 2020.

*Efficacy Data*: Upon completion, the study results demonstrated an ORR of 16.7% and a DCR of 36.7%. Among the 30 patients, five demonstrated PR and six reached SD. HX008 started demonstrating anti-tumor effect at the initial dose level of 1mg/kg. The table below sets forth the details of the efficacy data.

| | **1mg/kg (N=6)** | **3mg/kg (N=8)** | **10mg/kg (N=6)** | **200mg (N=10)** | **Total (N=30)** |
|---|---|---|---|---|---|
| CR, n (%) | 0 | 0 | 0 | 0 | 0 |
| PR, n (%) | 1 (16.7) | 0 | 2 (33.3) | 2 (20.0) | 5 (16.7) |
| SD, n (%) | 1 (16.7) | 3 (37.5) | 0 | 2 (20.0) | 6 (20.0) |
| PD, n (%) | 4 (66.7) | 5 (62.5) | 4 (66.7) | 5 (50.0) | 18 (60.0) |
| NE, n (%) | 0 | 0 | 0 | 1 (10.0) | 1 (3.3) |
| ORR (95% CI) | 16.7 (0.42~64.12) | 0 | 33.3 (4.33~77.72) | 20.0 (2.52~55.61) | 16.7 (5.64~34.72) |
| DCR (95% CI) | 33.3 (4.33~77.72) | 37.5 (8.52~75.51) | 33.3 (4.33~77.72) | 40.0 (12.16~73.76) | 36.7 (19.93~56.14) |



Shanghai Miracogen Inc.- Ex. 2032, Page 000345

*Safety Data*: The safety profile of HX008 was evaluated among the patients who received at least one HX008 treatment. The incidence of TRAEs was 93.3% and most of the TRAEs were Grade 1 or 2. The most commonly reported TRAEs were proteinuria, fatigue, weight loss, fever, increased aspartate aminotransferase, rash, anorexia, cough, increased alanine aminotransferase, leukopenia, increased blood bilirubin, decreased neutrophil count, hematuria, decreased free triiodothyronine, sinus tachycardia, dyspnea, hypokalemia, decreased free thyroxine, elevated conjugated bilirubin, increased thyroid-stimulating hormone, nausea, gastrointestinal bleeding, and anemia. The incidence of Grade 3 and above TRAEs was 33.3%. No death was reported as TRAE in the trial as of December 2019.

The table below sets forth the TRAEs reported in the trial in advanced solid tumor as of December 2019:

| Grade | Major Identified TRAEs | Number of Patients (30 in Total) | Percentage |
|---|---|---|---|
| **TRAE** | | 28 | 93.3% |
| **Grade 1 TRAE** | Fatigue, Proteinuria, Weight Loss, Increased Aspartate Aminotransferase, Rash | 27 | 90.0% |
| **Grade 2 TRAE** | Proteinuria, Fever, Leukopenia | 21 | 70.0% |
| **TRAE ≥Grade 3** | Dyspnea, Gastrointestinal Bleeding, Hypoglycemia, Embolism | 10 | 33.3% |

| Age of Patients | Number of Patients Reported TRAE | Percentage |
|---|---|---|
| **<65** | 23 | 76.7% |
| **≥65** | 5 | 16.7% |

| | Major Identified TRAEs | Number of Patients | Percentage |
|---|---|---|---|
| **Immune-related TRAE** | Hypothyroidism, Lung Disease, Lung Inflammation | 3 | 10.0% |

*Source: Company data*



Shanghai Miracogen Inc.- Ex. 2032, Page 000346

Phase Ib trial in advanced solid tumor

*Trial Design and Progress*: This trial was an open, single-arm study in patients with advanced solid tumor to evaluate the safety, tolerability, pharmacokinetic characteristics, immunogenicity and efficacy on anti-tumor activities. We initiated the enrollment of patients in August 2019; as of January 2021, we had enrolled 42 patients. We had completed patient enrollment and were in the follow-up period for Phase Ib clinical trial of HX008 in advanced solid tumor as of the Latest Practicable Date.

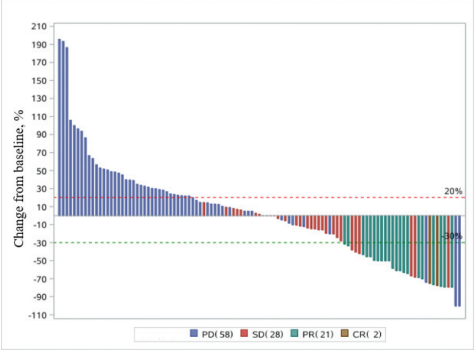
*Clinical Trial in Melanoma*

In November 2018, we initiated a Phase II clinical trial for HX008 for the treatment of melanoma in 11 hospitals, including the Beijing Cancer Hospital.

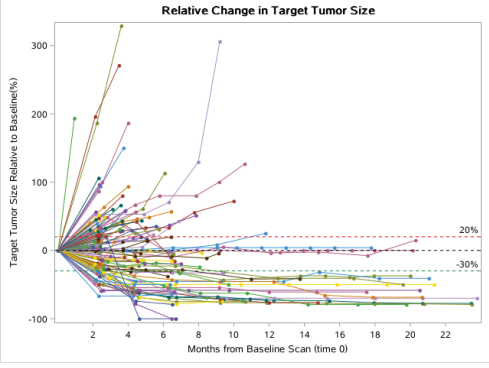
*Trial Design and Progress*: This trial was an open, single-arm Phase II clinical trial aimed at evaluating the safety and efficacy of HX008 in the treatment of patients who failed standard treatment. This trial was conducted among 119 patients to evaluate the ORR of patients with melanoma treated by HX008. We have gathered sufficient data for the primary endpoint and have finished the clinical data analysis for the trial as required by the NMPA before filing the NDA. The trial was in the two-year progression-free or survival follow-up period as required by the clinical protocol as of the Latest Practicable Date, and we expect to complete the follow-up period in the fourth quarter of 2022.

*Efficacy Data*: As of January 2021, the trial demonstrated an ORR of 18.5%, a DCR of 44.5%, the median PFS of 2.89 months, the six-month OS rate of 80.8% and the 12-month OS rate of 63.9%. The six-month DOR rate was 95.0%, and the 12-month DOR rate was 80.9%. The efficacy data of the clinical trial in melanoma, measured by change from baseline in sum of longest diameters, is illustrated in the table below:

**Best Change from Baseline in the Size of Target Tumor Lesion**




**Percent Change in the Size of Target Tumor Lesion from Baseline**






Shanghai Miracogen Inc.- Ex. 2032, Page 000347

The table below sets forth a comparison of efficacy data for the treatment of melanoma of HX008 and its competitors:

| | **HX008** *N=119* | **Pembrolizumab** *N=102* | **Toripalimab** *N=127* |
|---|---|---|---|
| **ORR (%)** | 18.5% | 16.7% | 17.3% |
| **DCR (%)** | 44.5% | 38.2% | 57.5% |
| **6-month DOR Rate (%)** | 95.0% | 65.6% | 90.2% |
| **12-month DOR Rate (%)** | 80.9% | N/A | 83.7% |
| **Median PFS (month)** | 2.89 | 2.8 | 3.6 |
| **6-month OS Rate (%)** | 80.8% | 75.7% | 87.8% |
| **12-month OS rate (%)** | 63.9% | 50.6% | 69.3% |

*Source: Company data, FDA, CDE*

*Safety Data*: As of January 2021, all 119 patients reported at least one AE. The incidence of TRAE was 76.5% (91 patients). The TRAEs with incidence greater than 10% include increased aspartate aminotransferase, increased thyroid-stimulating hormone, rash, increased alanine aminotransferase, hypothyroidism, elevated blood bilirubin, and hypopigmented skin. The incidence TRAE of Grade 3 and above was 13.4% (27 cases among 16 patients). The TRAEs of Grade 3 and above with an incidence rate greater than 1% include hypertriglyceridemia, increased aspartate aminotransferase, increased blood bilirubin, increased blood creatine phosphokinase, increased lipase, increased γ-glutamyl transferase, hyperglycemia, hypokalemia, and diabetic ketoacidosis. The incidence of SAEs that were related to HX008 was 8.4% (14 cases among ten patients). Such SAEs include diabetic ketoacidosis, increased blood bilirubin, hyperglycemia, blurred vision, uveitis, local infection, myositis, lung inflammation, adrenal insufficiency, fever, abdominal distension, and lymphedema. No death was reported as TRAE in the trial as of September 2021.



Shanghai Miracogen Inc.- Ex. 2032, Page 000348

The table below sets forth the TRAEs reported in the trial in melanoma as of January 2021:

| Grade | Major Identified TRAEs | Number of Patients (119 in Total) | Percentage |
|---|---|---|---|
| **TRAE** | | 91 | 76.5% |
| **Grade 1 TRAE** | Increased Aspartate Aminotransferase, Increased Thyroid-stimulating Hormone, Elevated Blood Bilirubin, Increased Alanine Aminotransferase, Hypopigmented Skin | 87 | 73.1% |
| **Grade 2 TRAE** | Hypothyroidism, Anemia, Rash, increased Blood Bilirubin | 36 | 30.3% |
| **TRAE ≥Grade 3** | Hypertriglyceridemia, Hyperglycemia, Increased Blood Creatine Phosphokinase, Increased Lipase | 16 | 13.4% |

| Age of Patients | Number of Patients Reported TRAE | Percentage |
|---|---|---|
| **<65** | 68 | 57.1% |
| **≥65** | 23 | 19.3% |

| | Major Identified TRAEs | Number of Patients | Percentage |
|---|---|---|---|
| **Immune-related TRAE** | Hypopigmented Skin, Increased Aspartate Aminotransferase, Hypothyroidism, Rash | 57 | 47.9% |

*Source: Company data*

*Clinical Trial in MSI-H/dMMR Solid Tumors*

We initiated a Phase II clinical trial for HX008 for the treatment of advanced solid tumors in 27 hospitals, including Cancer Hospital Chinese Academy of Medical Sciences in September 2018. The trial was an open, single-arm study with two cohorts. Set forth below are the details of the second cohort trial.

*Trial Design and Progress*: This trial was an open, single-arm study in patients with MSI-H/dMMR solid tumors to evaluate the safety and efficacy of HX008 as monotherapy on the treatment of MSI-H/dMMR solid tumors. We initiated the recruitment of patients in September 2018. As of January 2021, we had recruited 100 patients. As of the Latest Practicable Date, we had filed an NDA of HX008 with the NMPA in MSI-H/dMMR solid tumors and was granted priority review in October 2021.



Shanghai Miracogen Inc.- Ex. 2032, Page 000349

*Efficacy Data*: As of June 2021, the trial demonstrated an ORR of 46.0% and a DCR of 70.0%. Based on the assessment of the principal investigator, the six-month, nine-month and 12-month PFS rate was 59.3%, 56.9% and 55.1%, respectively. The six-month, nine-month and 12-month OS rate was 86.0%, 79.4% and 76.6%, respectively.

The table below sets forth a comparison of efficacy data for the treatment of MSI-H/dMMR solid tumors of HX008 and its competitors:

| | **HX008** *N=100* | **Pembrolizumab** *N=149* | **Nivolumab** *N=53* |
|---|---|---|---|
| **ORR (%)** | 46.0% | 39.6% | 32.0% |
| **DCR (%)** | 70.0% | N/A | N/A |
| **Median PFS (month)** | N/A | N/A | N/A |
| **Six-month PFS Rate (%)** | 59.3% | N/A | N/A |
| **12-Month PFS Rate (%)** | 55.1% | N/A | N/A |

*Source: Company data, FDA, CDE*

*Note:* No head-to-head comparison was conducted between drugs. Clinical trials of a drug cannot be directly compared to the clinical trials of another drug and may not be representative of overall data.

*Safety Data*: 81.0% of the reported TRAEs were considered to be related to HX008 in this trial. The most commonly reported TRAEs were aspartate aminotransferase, increased alanine aminotransferase, anemia, hypothyroidism and leukopenia. 14.0% of Grade 3 or 4 TRAEs were considered to be related to HX008 and the most frequently reported (>1%) Grade 3 or above TRAEs were anemia and leukopenia. 4.0% of the SAEs were considered to be related to HX008. No death was reported as TRAE in the trial as of February 2021.

The table below sets forth the TRAEs reported in the trial in MSI-H/dMMR solid tumors as of February 2021:

| **Grade** | **Major Identified TRAEs** | **Number of Patients (100 in Total)** | **Percentage** |
|---|---|---|---|
| **TRAE** | | 81 | 81.0% |
| **Grade 1 TRAE** | Increased Aspartate Aminotransferase, Increased Thyroid-stimulating Hormone, Elevated Blood Bilirubin, Increased Alanine Aminotransferase, Hypopigmented Skin | 32 | 32.2% |
| **Grade 2 TRAE** | Hypothyroidism, Anemia, Rash, Increased Blood Bilirubin | 35 | 35.0% |
| **TRAE ≥Grade 3** | Hypertriglyceridemia, Hyperglycemia, Increased Blood Creatine Phosphokinase, Increased Lipase | 14 | 14.0% |



Shanghai Miracogen Inc.- Ex. 2032, Page 000350

| Age of Patients | | Number of Patients Reported TRAE | Percentage |
|---|---|---|---|
| **<65** | | 68 | 68.0% |
| **≥65** | | 13 | 13.0% |
| | **Major Identified TRAEs** | **Number of Patients** | **Percentage** |
| **Immune-related TRAE** | Increased Aspartate Aminotransferase, Anemia, Alanine Aminotransferase, Hypothyroidism | 17 | 17.0% |

*Source: Company data*

*Clinical Trial in Advanced Gastric Cancer*

We initiated two Phase II clinical trials in 27 hospitals, including Harbin Medical University Cancer Hospital and Cancer Hospital Chinese Academy of Medical Sciences, to assess the safety and efficacy of HX008 in combination with chemotherapy, as first-line and second-line for the treatment for advanced gastric cancer, respectively. The patient enrollment has been completed for both studies. The combination therapy showed a promising efficacy and manageable safety profile at the preliminary stage. We also initiated a randomized, double-blind, multi-center Phase III clinical trial of HX008 in combination with irinotecan against a placebo in combination with irinotecan as second-line treatment for advanced gastric or gastroesophageal junction cancer in 64 hospitals, including the Cancer Hospital Chinese Academy of Medical Sciences and Shanghai Central Hospital, to evaluate its efficacy and safety as of the Latest Practicable Date.

Second-line Phase II clinical trial in advanced gastric cancer

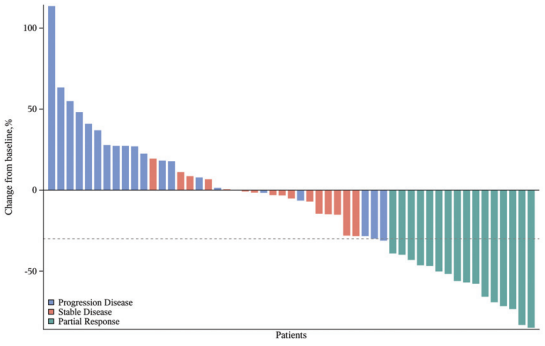
We initiated a Phase II clinical trial for HX008 for the treatment of advanced solid tumors in 27 hospitals, including Cancer Hospital Chinese Academy of Medical Sciences in September 2018. The trial was an open, single-arm study with two cohorts. As of the Latest Practicable Date, we had completed the patient enrollment and were in the follow-up period for Phase II clinical trial of HX008 in gastric cancer.

*Trial Design and Progress*: This trial was an open, single-arm study. We conducted this trial to evaluate the safety and efficacy of HX008 in combination therapy with irinotecan in the treatment of gastric cancer; 58 patients were enrolled in the trial which was ongoing as of the Latest Practicable Date. We gathered sufficient data for the primary endpoint of the trial in June 2020. The progression-free or survival follow-up period is expected to end in the fourth quarter of 2022.

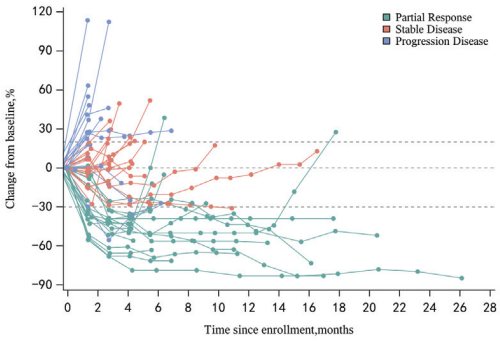

Shanghai Miracogen Inc.- Ex. 2032, Page 000351

*Efficacy Data*: As of February 2021, the trial results demonstrated an ORR of 27.6% and a DCR of 60.3%. Among the 58 patients, 16 demonstrated PR and 19 reached SD. The median PFS was 4.2 months, the median DOR was 12.8 months and the median OS was 12.1 months. The efficacy data of the second-line Phase II clinical trial in advanced gastric cancer, measured by change from baseline in the sum of longest diameters, is illustrated in the table below:

**Best Change from Baseline in the Size of Target Tumor Lesion**




**Percent Change in the Size of Target Tumor Lesion from Baseline**




*Safety Data*: The safety profile of HX008 was evaluated among the patients who received at least one HX008 treatment. 82.8% of the reported TRAEs were related to HX008. The most commonly reported TRAEs were leukopenia, neutropenia, nausea, vomiting, decreased appetite, fatigue, anemia, diarrhea, decreased lymphocyte count and weight loss. Grade 3 or 4 TRAEs occurred in 19 patients (32.8%). SAEs that were related to HX008 occurred in eight (13.8%) patients. No death was reported as TRAE in the trial as of February 2021.

The table below sets forth the TRAEs reported in the second-line Phase II clinical trial in advanced gastric cancer as of February 2021:

| Grade | Major Identified TRAEs | Number of Patients (58 in Total) | Percentage |
|---|---|---|---|
| **TRAE** | | 48 | 82.8% |
| **Grade 1 TRAE** | Fatigue, Proteinuria, Diarrhea, Alanine Aminotransferase | 15 | 25.9% |
| **Grade 2 TRAE** | Fatigue, Anemia, Vomit, Hypothyroidism, Leukopenia | 14 | 24.1% |
| **TRAE ≥Grade 3** | Decreased Neutrophil, Anemia, Leukopenia, Increased Aspartate Aminotransferase | 19 | 32.8% |


Shanghai Miracogen Inc.- Ex. 2032, Page 000352

| Age of Patients | | Number of Patients Reported TRAE | Percentage |
|---|---|---|---|
| **<65** | | 33 | 56.9% |
| **≥65** | | 15 | 25.9% |
| | **Major Identified TRAEs** | **Number of Patients** | **Percentage** |
| **Immune-related TRAE** | Hypothyroidism, Alanine Aminotransferase, Increased Conjugated Bilirubin | 11 | 19.0% |

*Source: Company data*

Second-line Phase III clinical trial in advanced gastric or gastroesophageal junction cancer

*Trial Design and Progress*: This trial was a multi-center, randomized, double-blind and placebo-controlled Phase III clinical study on HX008 in combination therapy with irinotecan. This study was initiated in May 2020 and started recruitment of patients in December 2020. This study was conducted in 68 clinical centers, including the Cancer Hospital Chinese Academy of Medical Sciences and Shanghai Central Hospital, 54 of which had started as of January 2021. As of January 2021, we had recruited a total of 35 patients. We expect to gather sufficient data for the primary endpoint of the trial in the third quarter of 2023. The progression-free or survival follow-up period is expected to end in the fourth quarter of 2023.

First-line Phase II clinical trial in advanced gastric cancer

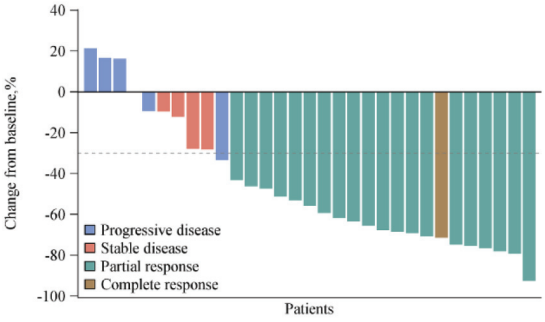
We initiated a Phase II clinical trial for HX008 for the treatment of advanced gastric cancer in the Fifth Medical Center, Chinese PLA General Hospital in July 2018.

*Trial Design and Progress*: This trial was an open, multi-center, single-arm Phase II clinical trial aimed at evaluating the safety and efficacy of HX008 in combination treatment with chemotherapy as first-line treatment for patients who had not received standard treatment. The trial was conducted to evaluate the safety of patients with advanced gastric cancer treated by the combination of HX008 and chemotherapy through AE and SAE measurement. As of the Latest Practicable Date, we had completed the patient enrollment and were in the follow-up period for first-line Phase II clinical trial of HX008 in gastric cancer.

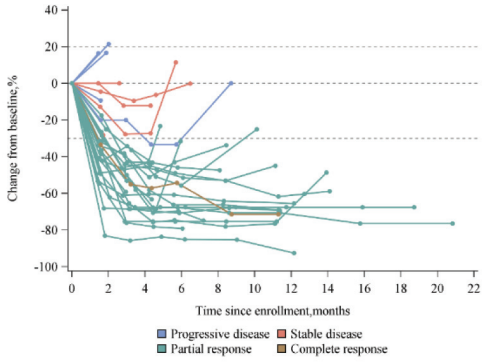

Shanghai Miracogen Inc.- Ex. 2032, Page 000353

*Efficacy Data*: As of April 2021, the trial results demonstrated an ORR of 60.0%, with CR in one patient and PR in 20 patients, and a DCR of 77.1%. The median DOR was 12.7 months, the median PFS was 9.2 months, and the 12-month PFS rate was 43.1%. The median OS was 12.9 months. The efficacy data of the first-line Phase II clinical trial in advanced gastric cancer, measured by change from baseline in sum of longest diameters, is illustrated in the table below:

**Best Change from Baseline in the Size of Target Tumor Lesion**




**Percent Change in the Size of Target Tumor Lesion from Baseline**




The table below sets forth a comparison of efficacy data for the treatment of advanced gastric cancer of HX008 and its competitors:

| | **HX008** *N=35* | **Pembrolizumab** *N=257* | **Nivolumab** *N=789* |
|---|---|---|---|
| **ORR (%)** | 60.0% | 48.6% | 58.0% |
| **DCR (%)** | 77.1% | N/A | N/A |
| **Median DOR (month)** | 12.7 | N/A | 8.5 |
| **Median PFS (month)** | 9.2 | 6.9 | 7.7 |
| **Median OS (month)** | 12.9 | 12.5 | 13.8 |

*Source: Company data, FDA, CDE*

*Safety Data*: 28 out of the 35 patients experienced TRAEs. The most common TRAEs were neutropenia, thrombocytopenia, anemia, leukopenia, aspartate aminotransferase increased, fatigue, vomit, and hypoalbuminemia. Grade 3 or above TRAEs occurred in 15 patients (42.9%). SAEs that were related to HX008 occurred in three (8.6%) patients. No death was reported as TRAE in the trial as of April 2021.


Shanghai Miracogen Inc.- Ex. 2032, Page 000354

The table below sets forth the TRAEs reported in the first-line Phase II clinical trial in advanced gastric cancer as of April 2021:

| Grade | Major Identified TRAEs | Number of Patients (35 in Total) | Percentage |
|---|---|---|---|
| **TRAE** | | 28 | 80.0% |
| **Grade 1 TRAE** | Neutropenia,Leukopenia, Nausea, Hypothyroidism | 5 | 14.3% |
| **Grade 2 TRAE** | Neutropenia,Leukopenia, Decreased Platelet, Anemia, Vomit | 8 | 22.9% |
| **TRAE ≥Grade 3** | Neutropenia,Leukopenia, Fatigue, Decreased Platelet, Anemia | 15 | 42.9% |

| Age of Patients | Number of Patients Reported TRAE | Percentage |
|---|---|---|
| **<65** | 17 | 48.6% |
| **≥65** | 11 | 31.4% |

| | Major Identified TRAEs | Number of Patients | Percentage |
|---|---|---|---|
| **Immune-related TRAE** | Rash, Hypothyroidism, Fever | 6 | 17.1% |

*Source: Company data*

*Clinical Trial in Combination with Chemotherapy in NSCLC*

We initiated a Phase II/III clinical trial for HX008 for the treatment of NSCLC in ten hospitals, including Shanghai Pulmonary Hospital, and had completed the patient enrollment and were in the follow-up period for Phase II clinical trial in NSCLC as of the Latest Practicable Date. This trial is a randomized, positive control, single-blind trial. The Phase II clinical trial aims at evaluating the safety and efficacy of HX008 in combination treatment with chemotherapy as first-line treatment for patients with ORR as the endpoint. The Phase III clinical trial aims at comparing PFS of HX008 in combination with chemotherapy as well as pembrolizumab in combination with chemotherapy as first-line treatment for NSCLC patients. The progression-free or survival follow-up period is expected to end in 2022.


Shanghai Miracogen Inc.- Ex. 2032, Page 000355

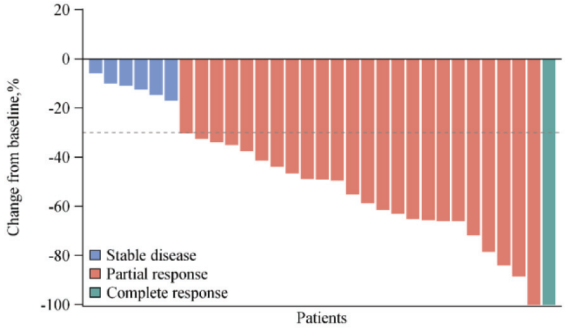
*Clinical Trial in TNBC*

We initiated a Phase Ib/II clinical trial for HX008 for the treatment of TNBC in Fudan University Shanghai Cancer Center in February 2019.

*Trial Design and Progress*: This trial was a first-stage open, single-arm, multi-center Phase Ib clinical trial aimed at evaluating the safety and efficacy of HX008 in combination with chemotherapy in the treatment of TNBC, and a subsequent second-stage open, single-arm, multi-center Phase II clinical trial to further evaluate the safety and efficacy profile of HX008 in combination with chemotherapy. As of the Latest Practicable Date, we had completed patient enrollment and were in the follow-up period for the Phase II clinical trial of HX008 in TNBC. We gathered sufficient data for the primary endpoint of the trial in September 2020. The primary endpoint of Phase II is one-year PFS rate. The trial was ongoing as of the Latest Practicable Date and the progression-free or survival follow-up period is expected to end in the first quarter of 2022.

*Efficacy Data*: As of June 2020, the study results demonstrated an ORR of 80.7% and a DCR of 100%. Among the 31 patients, the six-month PFS rate was 74.0%. As of April 2021, the median PFS was 9.0 months, and the 12-month PFS rate was 14.5%. The median DOR was 7.3 months. The six-month and 12-month OS rate was 93.6% and 83.4%, respectively. The efficacy data of the clinical trial in TNBC, measured by change from baseline in sum of longest diameters, is illustrated in the table below:

**Best Change from Baseline in the Size of Target Tumor Lesion**




*Safety Data*: TRAEs were reported among all of the 31 patients enrolled in this trial. The most commonly observed TRAEs include anemia (100%), decreased white blood cell (100%), decreased neutrophil (93.55%), decreased platelet (80.65%), and hypomagnesemia (90.32%). The incidence of TRAE of Grade 3 or above was 87.1%. The most commonly observed TRAEs of Grade 3 or above (with incidence greater than 10%) include decreased neutrophil (70.97%), decreased white blood cell (48.39%), anemia (35.48%), and decreased platelet (32.26%). In this trial, the most commonly reported TRAEs were considered to be related to three drugs without specifying the correlation therebetween. No death was reported as TRAE in the trial as of June 2020.


Shanghai Miracogen Inc.- Ex. 2032, Page 000356

The table below sets forth the TRAEs reported in the trial in TNBC as of June 2020:

| Grade | Major Identified TRAEs | Number of Patients (31 in Total)[1] | Percentage |
|---|---|---|---|
| **TRAE** | | 31 | 100.0% |
| **Grade 1 TRAE** | Decreased Appetite, Fatigue, Nausea, Hypomagnesemia, Hyponatremia | 0 | 0 |
| **Grade 2 TRAE** | Leukopenia, Anemia, Hypocalcemia, Hypertriglyceridemia | 4 | 12.9% |
| **TRAE ≥Grade 3** | Neutropenia, Leukopenia, Anemia, Decreased Platelet | 27 | 87.1% |

| Age of Patients | Number of Patients Reported TRAE | Percentage |
|---|---|---|
| **<65** | 29 | 93.5% |
| **≥65** | 2 | 6.5% |

| | Major Identified TRAEs | Number of Patients | Percentage |
|---|---|---|---|
| **Immune-related TRAE** | Hypothyroidism, Rash, Fever | 7 | 25.8% |

*Source: Company data*

*Note:*

(1) for the same patient, the highest grade of TRAE was counted

***Clinical Development Plan***

We have obtained the CDE approval for melanoma NDA submission and filed an NDA of HX008 in melanoma with the NMPA in June 2021. We submitted a pre-NDA meeting application of HX008 in MSI-H/dMMR solid tumors in July 2021, filed an NDA of HX008 with the NMPA in MSI-H/dMMR solid tumors and was granted priority review in October 2021. As of the Latest Practicable Date, we had completed patient enrollment and were in the follow-up period for Phase Ib clinical trial of HX008 in advanced solid tumor and for the Phase II clinical trial of HX008 in NSCLC, TNBC (triple-negative breast cancer), gastric cancer and HCC.



Shanghai Miracogen Inc.- Ex. 2032, Page 000357

The table below sets forth the details of our development plan of HX008:

| Indication | Clinical Phase | Location and Competent Authorities | Expected Time[1] |
|---|---|---|---|
| 2L Advanced gastric or gastroesophageal junction cancer | III | China/NMPA | Complete in the third quarter of 2023 |
| NSCLC | III | China/NMPA | Initiate after communication with the CDE |

*Note:*

(1) Indicates the expected time to gather sufficient data for the primary endpoint.

For combination therapy development plan of HX008, we have been exploring the efficacy of HX008 plus targeted therapies in pre-clinical studies, and of HX008 combined with chemotherapy or targeted therapies in several clinical trials as well. As of the Latest Practicable Date, we had initiated Phase III clinical trial of HX008 combined with irinotecan in advanced gastric or gastroesophageal junction cancer, and plan to commence the Phase III clinical trial of HX008 combined with chemotherapy in NSCLC.

The table below sets forth the details of our combination therapy development plan of HX008:

| | Indication | Clinical Phase | Location and Competent Authorities | Expected Time |
|---|---|---|---|---|
| **HX008 + irinotecan[1]** | Advanced Gastric or Gastroesophageal Junction Cancer | III | China/NMPA | Complete in the third quarter of 2023 |
| **HX008 + chemotherapy[2]** | NSCLC | III | China/NMPA | Initiate after communication with the CDE |

*Notes:*

(1) Versus placebo plus irinotecan as second-line treatment.

(2) Versus pembrolizumab plus chemotherapy as first-line treatment.

Our commercial development strategy for HX008 aims at helping us establish effective sales channels and strengthen our commercialization capabilities, which will also benefit our other drug candidates. Leveraging our capabilities in developing anti-PD-1 antibody drug candidates demonstrating favorable safety and efficacy results, we plan to continue to explore the path of approval and commercialization of HX008 for the treatment of various indications. We expect to initiate clinical trials for combination therapies of HX008 and CG0070 for the treatment of patients with advanced non-muscle invasive bladder cancer. We also plan to focus on the combination therapies of oncolytic virus candidates OH2 and mAb immune checkpoint inhibitors, and further expand the relevant markets of HX008 through combination therapy.



Shanghai Miracogen Inc.- Ex. 2032, Page 000358

***Licenses, Rights and Obligations***

Akeso and HanX co-developed the anti-PD-1 antibody candidate, HX008, and jointly applied for patents directed to HX008. We entered into an equity purchase agreement with Ningbo Houde Yimin in June 2018 to obtain the controlling interest of Taizhou Hanzhong. See "History, Development and Corporate Structure – Our Key Subsidiaries and Major Shareholding Changes – Taizhou Hanzhong." Taizhou Hanzhong then entered into an agreement with HanX and Akeso regarding the transfer of HX008 in August 2018. Pursuant to the agreement, HanX transferred its rights jointly held with Akeso in HX008 to Taizhou Hanzhong with nil consideration. Akeso, as the co-developer, agreed to waive its global rights and is not entitled to any other right to disallow or restrict our use of HX008-related patents or technology. Akeso is entitled to a mid single-digit percentage of global sales revenue once HX008 is commercialized until the expiry of the patents. See "– Collaboration, Licensing and Transfer Arrangements – Arrangements among us, HanX and Akeso." Through such arrangement, we then obtained HX008 at Phase Ia stage. As of the Latest Practicable Date, we had completed patient enrollment and were in the follow-up period for Phase Ib clinical trial in advanced solid tumor and Phase II clinical trial in NSCLC, gastric cancer, TNBC (triple-negative breast cancer) and HCC. We had also initiated since our acquisition the Phase II clinical trial in NMIBC and registration trials in melanoma and MSI-H/dMMR (high levels of microsatellite instability/deficient mismatch repair) solid tumors. We are also in the process of a Phase III clinical trial in second-line gastric cancer. We filed an NDA of HX008 with the NMPA in melanoma in June 2021. We submitted a pre-NDA meeting application of HX008 in MSI-H/dMMR solid tumors in July 2021, filed an NDA of HX008 with the NMPA in MSI-H/dMMR solid tumors and was granted priority review in October 2021. In addition, nothing has come to our attention that Akeso used the HX008-related patent or technology in its development of AK105, its own pipeline candidate for PD-1 therapies, based on the publicly available information about AK105 and the related patents.

We separately entered into a technology development agreement with HanX in February 2019. The services originally covered included various technology service support in purchases of raw materials, CMC manufacturing, testing, and process optimization and preparation of regulatory filings, for an aggregate amount of up to RMB87.6 million (excluding tax, or RMB92.9 million including tax, representing payments to HanX for the coordination services rendered thereunder and payments through HanX to third-party CROs and CDMOs) depending on the actual services rendered, payable in eight installments. Despite the original service scope, the actual services rendered by HanX were primarily coordination services.

The duration of the technology development agreement was from February 13, 2019 to March 31, 2021. During such period, we remained in charge of the overall technical discussion and supervision, decision-making, monitoring and regulatory filings for HX008, contributed by a team of 33 members directly involved in the HX008 project. Our team members have extensive CMC experience, including process development, technology transfer, process characterization and validation, and clinical and commercial manufacturing. Six of our team members have PhD degrees, and ten have master's degrees. HanX was mainly in charge of coordination, supported by their project managers. We did not renew the technology



Shanghai Miracogen Inc.- Ex. 2032, Page 000359

development agreement as we strengthened our manufacturing and development capability and may manage third-party CROs and CDMOs directly by ourselves since it would be more efficient and cost-effective. Our first production line with capacity of 6,000L is under construction and is expected to support the commercial manufacturing of anti-PD-1 and anti-PD-L1 mAb products.

As we required HanX to provide only a small part of the services originally covered under the technology development agreement prior to its expiration in March 2021 with only a few milestones achieved, we have agreed with HanX to pay a total of RMB25.0 million (representing payments to HanX for the coordination services rendered and the payments made through HanX to third-party CROs and CDMOs). HanX also agreed that we do not need to pay the remaining RMB67.9 million (including tax) as we have no further payment obligations for services HanX did not provide. The payment of RMB25.0 million was completely settled before July 31, 2021. Any potential dispute relating to this technology development agreement shall be referred to arbitration and settled by Beijing Arbitration Commission. We did not have any dispute with HanX as of the Latest Practicable Date.

Set forth below are the types of services and contractual amount covered under the technology development agreement, and the actual services rendered by HanX:

| | **Services covered (the original milestones) under the technology development agreement** | **Actual services rendered by HanX** | **Our contribution in the process** | **Contractual amount (excluding tax) for each part of the services originally covered under the agreement** |
|---|---|---|---|---|
| Part I | The technology transfer from Akeso to Chime Biologics Limited ((鼎康(武漢)生物醫藥 有限公司), the CDMO engaged by us for clinical and commercial manufacturing. | Coordination services rendered.<br>Managing the technology transfer process. | Technical discussion and supervision, decision-making and monitoring. | RMB400,000 |
| Part II | Preparation for manufacturing process scale up to 2000L. | Coordination services rendered. | Technical discussion and supervision, decision-making and monitoring. | RMB2,250,000 |
| Part III | Drug substance and drug product manufacturing for clinical supplies. | Coordination services rendered.<br>Coordinating manufacturing activities. | Technical discussion and supervision, decision-making and monitoring. | RMB7,300,000 |



Shanghai Miracogen Inc.- Ex. 2032, Page 000360

| | Services covered (the original milestones) under the technology development agreement | Actual services rendered by HanX | Our contribution in the process | Contractual amount (excluding tax) for each part of the services originally covered under the agreement |
|---|---|---|---|---|
| Part IV | Purchasing key raw materials for manufacturing. | Coordination services rendered. Coordinating the purchase processes. | Decision-making and managing delivery progress. | RMB15,100,000 |
| Part V | Various third-party testing services. | Coordination services rendered. Coordinating with third-party CROs for provision of various testing services. | Monitoring all technology issues and reviewing the final testing reports. | RMB7,400,000 |
| Part VI | Preparing regulatory filings. | Providing partial raw data generated by third-party CROs and used in the preparation of the regulatory filings. | Preparing regulatory filings for CDE approval. | RMB2,100,000 |
| Part VII | Commercial manufacturing. | We required no service. | Planned manufacturing at Chime Biologics Limited. | RMB22,000,000 |
| Part VIII | Process optimization. | Coordination services rendered. Coordinating with third-party CROs for provision of process optimization services. | Parallel process optimization done with promising outcome by our own development and manufacturing team. | RMB31,050,000 |

***Material Communications with Competent Authorities***

HX008 received IND approval from the NMPA in August 2017, which included clinical study protocols for phase Ia, Ib and subsequent phase II and phase III. The HX008 Phase Ia trial was completed with MTD and RP2D determined per the clinical trial protocol in May 2018 and final CSR issued in May 2020. As advised by the PRC Legal Advisor and taking into account the industry practice as advised by Frost & Sullivan, its main purpose aligns with the overall purpose of a conventional phase I trial regulated by the NMPA, which seeks to evaluate the safety and tolerability of a product to determine the MTD and RP2D. Based on the due diligence performed (including discussions with the Company, our PRC Legal Advisor and Frost & Sullivan), the Joint Sponsors concur with the foregoing view of our PRC Legal Advisor and Frost & Sullivan. We had a formal consultation with the NMPA ("**NMPA HX008 Consultation**") regarding the Phase II registration trials of HX008 in melanoma ("**HX008 Phase II Melanoma Registration Trial**") and MSI-H/dMMR solid tumors ("**HX008 Phase II Solid Tumors Registration Trial**", together with the HX008 Phase II Melanoma Registration


Shanghai Miracogen Inc.- Ex. 2032, Page 000361

Trial, the "**HX008 Phase II Registration Trials**") in September 2018 and received no objection from the NMPA. As advised by our PRC Legal Advisor, on the basis that (i) the registration of the HX008 Phase II Registration Trials with the NMPA was duly completed as required by the NMPA Registration Regulation, (ii) the IND approval granted by the NMPA in August 2017 was a one-time umbrella approval for the clinical trials of HX008 including all four phases of Phase Ia, Ib, II and III, which was confirmed by Frost & Sullivan with reference to the industry practice and concurred with by the Joint Sponsors based on the due diligence performed, (iii) the ethics approvals have been granted in August 2018 and July 2018, and (iv) the NMPA confirmed no objection to proceed with the HX008 Phase II Registration Trials in the NMPA HX008 Consultation, the Company has obtained all necessary approvals from the NMPA to proceed with the HX008 Phase II Registration Trials and no further approval from the NMPA is required for the Company to commence the HX008 Phase II Registration Trials.

After our acquisition of Taizhou Hanzhong in June 2018, the HX008 Phase II Melanoma Registration trial was completed in January 2021 with its clinical study objective achieved as per the clinical trial protocol. In April 2021, the NMPA acknowledged the achievement of clinical study objectives of the HX008 Phase II Melanoma Registration trial and consented to the filing of the NDA. In June 2021, we filed with the NMPA the NDA of HX008 in melanoma, which was subsequently accepted by the NMPA in July 2021. We submitted the trial design on the Phase III clinical trial of HX008 in second-line gastric cancer to the CDE in May 2020 and received no objection from the CDE. We also obtained CDE approval for the IND submission of the combination therapy of HX008 with MRG002 in January 2021. We submitted a pre-NDA meeting application of HX008 in MSI-H/dMMR solid tumors in July 2021, filed an NDA of HX008 with the NMPA in MSI-H/dMMR solid tumors and was granted priority review in October 2021.

As of the Latest Practicable Date, we had filed an NDA of HX008 with the NMPA in MSI-H/dMMR solid tumors and was granted priority review in October 2021; we were not aware of any legal claims or proceedings that may have an adverse effect on our development for HX008.

**Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange: WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET HX008 SUCCESSFULLY.**

**LP002**

LP002, one of our Core Products, is a humanized anti-PD-L1 mAb with unique targeted epitope, which employs IgG1 isotype with aglycosylated mutation. It demonstrated favorable safety and efficacy in clinical trials, which serves as the basis for the development of combination therapies with immunotherapy.

LP002 has shown a favorable safety profile in a Phase Ia clinical study in advanced solid tumors, with an overall ORR of 15.2% and an overall DCR of 51.5%.



Shanghai Miracogen Inc.- Ex. 2032, Page 000362

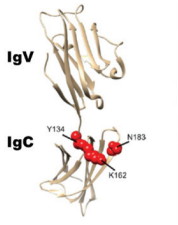
We are formulating and conducting clinical trials to expand the clinical applications of LP002 in additional indications. We are currently evaluating LP002 as a monotherapy in multiple cancer indications. In addition, we also initiated clinical studies to explore the combination of LP002 with multiple drugs in different indications, including the combination therapy with HX008 in PD-1 resistant/refractory melanoma, the combination therapy with chemotherapy in SCLCs, and the combination therapy with OH2 in digestive system tumors. See "– Combination Therapies within Our Pipeline."

We acquired our anti-PD-L1 antibody candidate LP002 at its pre-clinical stage from I-Mab Shanghai, where Dr. Fang Lei was one of the key scientists responsible for the development of LP002. After acquisition, we completed LP002 Phase Ia trial in April 2019. We conducted subsequent clinical development, and had a global license under certain patents and know-how of I-Mab Shanghai to develop, manufacture and commercialize the anti-PD-L1 antibody product. We have initiated multiple clinical trials since the acquisition of LP002, and are are fully responsible for the development and commercialization of LP002.

***Mechanism of Action***

PD-L1 is a 40kDa type 1 transmembrane protein and an important ligand protein that can engage PD-1, immune checkpoint receptor. PD-L1 has two ligands PD-1 and B7-1. The binding of PD-L1 to PD-1 or B7-1 transmits an inhibitory signal which reduces the proliferation of CD8-positive T cells, leading to inhibition on immune response. PD-L1 is believed to play a major role in suppressing the immune system during particular events such as pregnancy, tissue allografts, autoimmune disease and cancers. In particular, PD-L1 is abundantly expressed in various human cancers and cells in the tumor microenvironment, which helps these cells evade T-cell attacks and results in immunosuppression.

As an anti-PD-L1 antibody, LP002 is designed to specifically bind to PD-L1 in order to block the PD-1/PD-L1 inhibitory pathway and enable T cells to recover anti-tumor immune response. LP002 is a humanized antibody against the extracellular domain of PD-L1 containing the Fc domain of human IgG1 with a specific mutation of 297 asparagine to alanine to decrease ADCC. This modification results in a non-glycosylated antibody, which is demonstrated to have no Fcγ receptor. LP002 binds to human PD-L1, thereby inhibiting the interaction of PD-L1 with PD-1 and B7-1 receptors. The mechanism of action of LP002 is illustrated in the figure below.




*Source: Company data*



Shanghai Miracogen Inc.- Ex. 2032, Page 000363

PD-L1 has two domains: IgV (PD-1 binding domain) and IgC domain. Different from other clinical-stage anti-PD-L1 antibodies in clinics, LP002 binds to Y134, K162 and N183 that are located in IgC domain steric proximal to IgV domain. Although using a different mechanism, LP002 showed comparable *in vitro* and *in vivo* efficacy to Atezolizumab.

***Market Opportunity and Competition***

LP002 faces fierce competition from other anti-PD-L1 drugs from the market. There is significant market potential in China for anti-PD-1 or anti-PD-L1 antibody drugs, according to Frost & Sullivan. Currently available clinical data suggests that some of the most prevalent cancers in China, such as lung, liver, stomach, colorectal and esophageal cancers, are potentially responsive to the anti-PD-1/anti-PD-L1 class of drugs. In China, the market size of anti-PD-1/anti-PD-L1 antibody therapies has been constantly growing and is expected to further expand in the near future. According to Frost & Sullivan, the market size of PD-1/PD-L1 therapies in China was RMB13.7 billion in 2020 and is expected to reach RMB51.9 billion and RMB58.2 billion in 2025 and 2030, respectively, representing a CAGR of 30.5% from 2020 to 2025 and a CAGR of 2.3% from 2025 to 2030. Some of the major indications of anti-PD-1/anti-PD-L1 antibody therapies include melanoma, MSI-H/dMMR solid tumors, gastric cancer and NSCLC. LP002 has great potential to address the sizable and growing market.

There are medical needs for anti-PD-1/anti-PD-L1 mAb drugs, while LP002 has the potential to become a promising candidate with a favorable safety profile and unique potential to use in combination therapy with anti-PD-1 mAbs. In addition, driven by the growing number of oncological patients, the increasing recognition of the treatment, the additional indications approved, the increased efficacy and sales resulted from combination therapies, as well as the gradual expansion of medical insurance coverage in the PRC, we believe the demand for LP002 will continue to grow.


Shanghai Miracogen Inc.- Ex. 2032, Page 000364

The following table sets forth the current marketed anti-PD-L1 antibody drugs, which are potential competitors for LP002:

**Marketed PD-L1 mAb drugs approved by the FDA**

| Company | Drugs | Product | FDA Approval Time | FDA Approved Indications | Injection Methods | 2020 Global Revenue (US$ million) |
|---|---|---|---|---|---|---|
| Roche/Genentech | Atezolizumab | Tecentriq | May-16 | Urothelial Carcinoma, NSCLC, TNBC, SCLC, HCC, Melanoma | Intravenous | 2,965.0 |
| Merck | Avelumab | Bavencio | March-17 | Merkel Cell Carcinoma, Urothelial Carcinoma, Renal Cell Carcinoma | Intravenous | 180.4 |
| AZ | Durvalumab | Imfinzi | May-17 | Urothelial Carcinoma, NSCLC, SCLC | Intravenous | 2,042.0 |

*Source: FDA, Frost & Sullivan*

**Marketed PD-L1 mAb drugs approved by the NMPA**

| INN | Trade Name | Company | Approval Date | Indications | Price (RMB) | Dosage | Injection Methods | 2020 Revenue (US$ million) | NRDL Status | Annual Cost after PAP (Thousand RMB) | Half-life Period | Patent Expiration Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Atezolizumab | Tecentriq | Roche | Feb-2020 | SCLC, HCC | 1,200mg: 32,800RMB | 1,200mg every 3 weeks | Intravenous | 2,965.0 (global) | NO | 295.2[1] | 27 days | 2035-11-10 |
| Durvalumab | Imfinzi | AZ | Dec-2019 | NSCLC | 120mg: 6,066RMB; 500mg: 18,088RMB | 10mg/kg, every 2 weeks | Intravenous | 2,042.0 (global) | NO | 217.1[2] | 17 days | 2037-04-24 |
| Envafolimab | 恩维達 | 3D Medicines/ Alphamab oncology/ Simcere | Nov-2021 | MSI-H/dMMR advanced solid tumor | 200mg: 5,980RMB | 400mg every 4 weeks | Subcutaneous | NA | NO | 71.8[3] | 23 days | NA |
| Sugemalimab | 擇捷美 | Cstone Pharma | Dec-2021 | NSCLC | NA | NA | Intravenous | NA | NO | NA | 12 days | NA |



Shanghai Miracogen Inc.- Ex. 2032, Page 000365

***Competitive Advantages***

LP002 is a humanized anti-PD-L1 mAb with a unique targeted epitope, which employs IgG1 isotype with aglycosylated mutation. It demonstrated promising safety and efficacy in clinical trials, which serves as the basis for the development of combination therapies with immunotherapy.

LP002 has shown a promising safety profile in the completed Phase Ia clinical study in advanced solid tumors, with an overall ORR of 15.2% and an overall DCR of 51.5%.

We are formulating and conducting clinical trials to expand the clinical applications of LP002 in additional indications. We are currently evaluating LP002 in multiple tumors. In addition, we also initiated clinical studies to explore the combination of LP002 with multiple drugs in different indications, including the combination therapy with HX008 in PD-1 resistant/refractory melanoma, the combination therapy with chemotherapy in SCLCs, and the combination therapy with OH2 in digestive system tumors. See "– Combination Therapies within Our Pipeline."

In comparison with its competitors, LP002 has demonstrated the following competitive advantages:

*Good safety profile*

In the four-week cynomolgus monkey GLP IND toxicity study, LP002 showed a good safety profile with NOAEL (no observed adverse effect level) reaching 60mg/kg/dose. In a Phase Ia clinical study, LP002 showed a promising safety profile. The major commercialized PD-L1 drug is Atezolizumab. The most frequent TRAEs revealed in Atezolizumab's Phase I clinical trials are fatigue, loss of appetite, pruritus, rash and diarrhea. LP002, in its Phase Ia clinical trial, had lower occurrence rate of these TRAEs as indicated in the charts below. Other TRAEs in LP002's Phase Ia clinical trial are all lower than Grade 3, such as weight loss, fatigue, proteinuria increased aspartate aminotransferase and increased thyroid-stimulating hormone. LP002's Phase Ia clinical trial did not reveal any unexpected TRAE. In all 33 enrolled patients, most of TRAEs were Grade 1 and 2 and few Grade 3 TRAEs had been observed. The promising safety profile marked LP002's good potential to function in combination with other immune therapy drugs. See "– Combination Therapies within Our Pipeline."

| | **Identified TRAEs** | | | | | |
|---|---|---|---|---|---|---|
| | **Fatigue** | **Loss of Appetite** | **Pruritus** | **Nausea** | **Rash** | **Diarrhea** |
| **LP002** | 4(12.1%) | 0(0.0%) | 1(3.0%) | 0(0.0%) | 2(6.1%) | 1(3.0%) |
| **Atezolizumab** | 17(17.9%) | 12(12.6%) | 12(12.6%) | 11(11.6%) | 8(8.4%) | 7(7.4%) |
| **Durvalumab** | 114(24.0%) | NA | 59(12.4%) | 68(14.3%) | 58(12.2%) | 88(18.5%) |
| **Avelumab** | 44(50.0%) | 18(20.5%) | 9(10.2%) | 19(21.6%) | 19(21.6%) | 20(22.7%) |

*Source: Company data, CDE*



Shanghai Miracogen Inc.- Ex. 2032, Page 000366

*Unique epitope recognizing non-PD-1 competing part of PD-L1*

LP002 has a unique epitope, recognizing the non-PD-1 competing part of PD-L1. Although using a different mechanism, LP002 showed comparable in vitro function with other PD-L1 mAb drugs. Compared with other marketed PD-L1 drugs, LP002 showed promising safety profile at similar dose level without compromising its antagonist potency as evidenced by antigen binding and receptor blocking activities, as illustrated in the table below. The advantage of LP002 on its safety profile may be attributed to its unique epitope, as the epitope of the antibody plays an important role in an antibody's functional property.

The following table sets forth a comparison between LP002 and other marketed major anti-PD-L1 antibody competitors:

| | | | | | PD-L1 binding potency | | PD-L1 blocking potency | |
|---|---|---|---|---|---|---|---|---|
| Generic name | Product name | Status | Indications | Epitope | ELISA (EC50, nM) | SPR (nM) | PD-1 blocking assay (IC50, nM) | B7-1 blocking assay (IC50, nM) |
| Atezolizumab | Tecentriq | FDA and NMPA approval | FDA approved: Urothelial carcinoma, NSCLC, TNBC, SCLC, HCC, and melanoma; NMPA approved: SCLC and HCC. | IgV (N-terminal) | 0.075 | 0.104 | 0.856 | 0.692 |
| Durvalumab | Imfinzi | FDA and NMPA approval | FDA approved: Urothelial carcinoma, NSCLC and SCLC; NMPA approved: NSCLC. | IgV (N-terminal) | 0.051 | 0.667 | 0.110 | 0.040 |
| Avelumab | Bavencio | FDA approval | FDA approved: Urothelial carcinoma, Merkel cell carcinoma and renal cell carcinoma. | IgV (N-terminal) | 0.042 | 0.610 | 0.080 | 0.098 |
| LP002 | NA | Clinical trial in China | Phase II: ES-SCLC; Phase I: Advanced digestive system tumors; Advanced solid tumor. | IgC (C-terminal) | 0.033 | 0.378 | 0.996 | 0.819 |

*Source: FDA, Literature Review, Frost & Sullivan*

***Summary of Clinical Trial Results***

We are in the process of evaluating LP002 in a series of clinical trials in order to explore its potential to address several indications. As of the Latest Practicable Date, we had evaluated the safety and efficacy profile of LP002 in four clinical trials covering advanced solid tumors, advanced digestive system cancer and ES-SCLC.



Shanghai Miracogen Inc.- Ex. 2032, Page 000367

*Clinical Trial in Advanced Solid Tumors*

*Trial Design and Progress*: This trial was an open, single-center, multi-dose exploratory Phase Ia clinical study in 33 patients with advanced solid tumors, at dose levels of 1mg/kg, 3mg/kg, 10mg/kg, 20mg/kg and 900mg. This trial was conducted to evaluate the safety and tolerance of LP002, and to determine MTD and RP2D. The trial was conducted in Fudan University Shanghai Cancer Center. We gathered sufficient data for the primary endpoint of the trial in June 2020. 33 patients had been recruited in the trial as of January 2021 and the trial was ongoing as of the Latest Practicable Date and the progression-free or survival follow-up period is expected to end in the first quarter of 2022.

*Efficacy Data*: Among the 33 patients involved in the trial, study results demonstrated five cases of PR and 12 cases of SD. The study results demonstrated an overall ORR of 15.2% and an overall DCR of 51.5%, as of December 2020. The median PFS was 2.7 months. The median OS had not been reached.

*Safety Data*: Among the 33 patients involved in the trial, most of the TRAEs were Grade 1 and 2, while very few Grade 3 or above TRAEs were observed. The incidence of TRAE was 100.0% and the incidence of Grade 3 or above TRAEs was 15.2%. The most frequent AR which may be related to LP002 include proteinuria, weight loss, increased aspartate aminotransferase, increased thyroid stimulating hormone, hyponatremia, hyperglycemia and anemia. No death was reported as TRAE in the trial as of December 2020.

The table below sets forth the TRAE cases reported in the trial in advanced solid tumors as of December 2020:

| Grade | Major Identified TRAEs | Number of Patients (33 in Total) | Percentage |
|---|---|---|---|
| **TRAE** | | 33 | 100.0% |
| **Grade 1 TRAE** | Proteinuria, Weight Loss, Increased Aspartate Aminotransferase, Increased Thyroid-stimulating Hormone | 33 | 100.0% |
| **Grade 2 TRAE** | Proteinuria, Weight Loss, Hypothyroidism, Fatigue | 21 | 63.6% |
| **TRAE ≥Grade 3** | Hyponatremia, Hypokalemia, Increased Blood Bilirubin, Syncope, Epiglottitis | 5 | 15.2% |



Shanghai Miracogen Inc.- Ex. 2032, Page 000368

| Age of Patients | | Number of Patients Reported TRAE | Percentage |
|---|---|---|---|
| **<65** | | 26 | 78.8% |
| **≥65** | | 7 | 21.2% |
| | **Major Identified TRAEs** | **Number of Patients** | **Percentage** |
| **Immune-related TRAE** | Immune-mediated Hypothyroidism, Lung Inflammation, Epiglottitis | 5 | 15.2% |

*Source: Company data*

*Clinical Trial in Advanced Digestive System Cancer*

*Trial Design and Progress*: This trial was an open, multi-center Phase Ib clinical study in patients with advanced digestive system cancer in five hospitals, including the Cancer Hospital Chinese Academy of Medical Sciences, Henan Cancer Hospital and Liaoning Cancer Hospital in June 2019, December 2020 and March 2021, respectively. This trial was conducted among five cohorts. Patients in the first cohort are involved in a dose-escalation trial (at dose levels of 600mg and 900mg) to evaluate the safety and tolerance of LP002 as a monotherapy. Patients in cohort B were involved in a trial in which LP002 was used as a third-line monotherapy treatment. Cohort B was an expanded group on the basis of the selected dose in cohort A. Patients in cohorts C, D and E were involved in a trial in which LP002 was used in combination with chemotherapy or OH2 as a combination therapy. The trial aims at evaluating the tolerability and safety of LP002. The trial was ongoing as of the Latest Practicable Date. We expect to gather sufficient data for the primary endpoint of the trial and finish the progression-free or survival follow-up period in 2022. As of February 2021, we had recruited seven, five, one, 14 and 12 patients for cohorts A, B, C, D and E, respectively.

*Clinical Trial in ES-SCLC*

*Trial Design and Progress*: This trial was a Phase II clinical study in patients with ES-SCLC. This trial was conducted to evaluate the PFS of patients with ES-SCLC treated by the combination therapy of LP002 and chemotherapy. The dose level was 10mg/kg. As of the Latest Practicable Date, we had initiated the trial at six clinical centers, including Fudan University Shanghai Cancer Center and Yunnan Cancer Hospital in August 2020 and January 2021, respectively. As of the Latest Practicable Date, we had completed patient enrollment of 50 patients and entered the follow-up period for the Phase II clinical trial in ES-SCLC.


Shanghai Miracogen Inc.- Ex. 2032, Page 000369

***Clinical Development Plan***

We had completed patient enrollment and entered follow-up period for the Phase II clinical trial in ES-SCLC (extensive stage small-cell lung cancer). We plan to commence the corresponding Phase III of such clinical trial in 2022, subject to the results of Phase II. We also plan to focus on the combination therapies of oncolytic virus candidates OH2 and mAb immune checkpoint inhibitors, and further expand the relevant markets of LP002 through combination therapy.

***Licenses, Rights and Obligations***

We acquired our anti-PD-L1 antibody candidate LP002 at an early stage from I-Mab Shanghai, conducted subsequent clinical development in-house, and own the global rights of the anti-PD-L1 antibody products. We have initiated multiple clinical trials since the acquisition of LP002. We are fully responsible for the development and commercialization of LP002. See "– Clinical-Stage Drug Candidates – LP002 – Summary of Clinical Trial Results", "– Clinical-Stage Drug Candidates – LP002 – Clinical Development Plan" and "– Collaboration, Licensing and Transfer Arrangements – Collaboration with I-Mab Shanghai and Hangzhou HealSun."

***Material Communications with Competent Authorities***

We received IND approval from the NMPA for LP002 in August 2018, which included clinical study protocols for phase Ia, Ib and subsequent phase II and phase III. After our acquisition of Taizhou Aoke in June 2018, the LP002 Phase Ia trial was completed in April 2019 with the MTD and RP2D determined per the clinical trial protocol. As advised by our PRC Legal Advisor and taking into account the industry practice as advised by Frost & Sullivan, its main purpose aligns with the overall purpose of a conventional phase I trial regulated by the NMPA, which seeks to evaluate the safety and tolerability of a product to determine the MTD and RP2D. Based on the due diligence performed (including discussions with the Company, our PRC Legal Advisor and Frost & Sullivan), the Joint Sponsors concur with the foregoing view of our PRC Legal Advisor and Frost & Sullivan.

After determination of the MTD and RP2D, we initiated the discussion with the NMPA and submitted the results of the LP002 Phase Ia trial to discuss with the NMPA regarding the phase II clinical study for ES-SCLC indication. In August 2019, the NMPA has confirmed in writing that we may proceed with the phase II clinical study for ES-SCLC indication ("**NMPA LP002 Confirmation**"). Leveraging the MTD and RP2D identified and sufficient safety data generated from the LP002 Phase Ia trial and the NMPA LP002 Confirmation, the Phase II clinical trial protocol (together with the supporting materials) for ES-SCLC indication ("**LP002 Phase II Trial**") was approved by the ethics committee in July 2020 ("**LP002 Ethics Approval**"). After completion of the LP002 Ethics Approval, the LP002 Phase II Trial was registered with the NMPA in July 2020. As advised by our PRC Legal Advisor, on the basis that (i) the registration of the LP002 Phase II trial with the NMPA was duly completed as required by the NMPA Registration Regulation, (ii) the IND approval granted by the NMPA in August 2018 was a one-time umbrella approval for the clinical trials of LP002 including all four phases of Phase Ia, Ib, II and III, which was confirmed by Frost & Sullivan with reference to the industry practice and concurred with by the Joint Sponsors based on the due diligence performed, and (iii) the LP002 Ethics Approval has been granted, we have obtained all necessary approvals from the NMPA to proceed with the LP002 Phase II Trial and no further approval from the NMPA is required for the Company to commence the LP002 Phase II Trial.



Shanghai Miracogen Inc.- Ex. 2032, Page 000370

As of the Latest Practicable Date, we were not aware of any legal claims or proceedings that may have an adverse effect on our development of LP002. As of the Latest Practicable Date, we had commenced the LP002 Phase II Trial had received no objections to our clinical development plans with respect to the regulatory review or approval process of LP002, and no material adverse change had occurred with respect to the regulatory review or approval process of LP002.

**Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange: WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET LP002 SUCCESSFULLY.**

**MRG001**

MRG001 is a clinically advanced CD20-targeted ADC, which is a cell surface receptor expressed across most of the committed stages of normal B-cell development and an attractive target for B-cell malignancies such as B-cell NHL. We believe that, and as advised by Frost & Sullivan, MRG001 is a clinically advanced CD20-targeted ADC with potential in the treatment of CD20-positive recurrent or refractory B-cell NHL, addressing current medical needs in the NHL patients with primary or acquired drug-resistant B-cell NHL who are non-responsive or acquire resistance to the combination therapy of rituximab and standard chemotherapies. Our pre-clinical *in vivo* studies of MRG001 demonstrated significant efficacy in the PDX model of rituximab resistance.

MRG001 is our key product in the hematological oncology field with significant market potential in China and the U.S. The market size of lymphoma in China reached US$12.0 billion in 2020 and is expected to reach US$37.9 billion and US$62.5 billion in 2025 and 2030, respectively, representing a CAGR of 25.9% from 2020 to 2025 and 10.5% from 2025 to 2030, respectively, according to Frost & Sullivan. CD20 is an actively pursued target by various modalities including CD20-targeted mAb, CAR-T and CD20-CD3 bispecific antibody for the treatment of NHL, according to Frost & Sullivan. MRG001 is optimally designed to deliver better safety and enhanced efficacy in relapsed and refractory B-NHL patients and overcome drug resistance among CD20-targeted drugs with an off-the-shelf formulation.

As of February 2021, 18 patients of FL, DLBCL and MZL were enrolled in the Phase Ia dose escalation stage. As of the Latest Practicable Date, the dose escalation study was completed, and we were conducting the subsequent Phase Ib dose expansion study.

We have developed MRG001 since our acquisition of Miracogen Shanghai. We have submitted applications for the patents related to MRG001 in the U.S. and China through Miracogen Shanghai. We hold the rights to develop and commercialize MRG001 globally.


Shanghai Miracogen Inc.- Ex. 2032, Page 000371

***Mechanism of Action***

CD20 is an attractive target for B-cell malignancies, particularly given the impressive commercial success of rituximab since its approval by the FDA in 1997. However, it is reported that approximately 30.0% to 60.0% of antibody-naïve indolent NHL patients are resistant to rituximab at baseline; additionally, in patients relapsing after a course of single-agent rituximab, approximately 60.0% will fail to achieve a PR or CR with a second course of single-agent rituximab. The rituximab resistance mechanisms vary, but the incidence of complete CD20 loss after rituximab therapy seems low, which provides opportunities for CD20-targeted therapies of different modalities, such as ADCs to play roles in overcoming rituximab resistance to meet current medical needs.

MRG001 is an ADC consisting of a chimeric rituximab conjugated to a vc-MMAE platform. Upon binding to CD20 receptors on the cell surface, MRG001 is swiftly internalized and then releases MMAE through protease cleavage in lysosome. Released MMAE inhibits tubulin polymerization, and disrupts microtubule-related functions such as mitosis, which eventually leads to cell death. Although rituximab does not internalize upon binding to CD20, MRG001 can be internalized effectively utilizing rituximab as its antibody moiety of the ADC molecule as confirmed in our pre-clinical studies.

***Market Opportunity and Competition***

There is a significant market potential in China for CD20-targeted ADC drugs. The market size of lymphoma in China reached US$12.0 billion in 2020 and is expected to reach US$37.9 billion and US$62.5 billion in 2025 and 2030, respectively, representing a CAGR of 25.9% from 2020 to 2025 and 10.5% from 2025 to 2030, respectively, according to Frost & Sullivan.

NHL is one of the two main categories of lymphoma, a type of cancer that occurs in the lymphatic system. NHL accounts for approximately 90.0% of lymphomas, with varieties of subtypes. The number of new cases of lymphoma in China was 99.7 thousand in 2020 and is expected to reach 112.4 thousand and 124.9 thousand in 2025 and 2030, respectively, representing a CAGR of 2.4% from 2020 to 2025 and a CAGR of 2.1% from 2025 to 2030, according to the same source. The five-year survival rate of lymphoma in China is 37.2%. The major treatment options for NHL in China vary by patient condition and NHL subtype, but generally involve applying a CD20-targeted mAb, such as rituximab, in combination with chemotherapies. Such options generally have limited efficacy due to drug resistance and therefore lead to high relapse rates. About 50.0% of NHL patients experience disease progression due to drug resistance, indicating a need for new treatment options. In particular, approximately 15.0% of DLBCL patients are characterized as primary refractory towards first-line R-CHOP therapy.

There were no approved products of CD20-targeted ADC globally as of the Latest Practicable Date, despite the significant potential in commercial value of ADC therapy for CD20 expressing cancers, according to Frost & Sullivan.



Shanghai Miracogen Inc.- Ex. 2032, Page 000372

The following table illustrates the pipeline competitors of CD20-targeted ADC drugs in China and globally:

**Pipeline Candidates for CD20-targeted ADC Drugs in China**

| Drug Name | Company | Therapeutic Strategy | Location | Clinical Phase | First Posted Date | Indications |
|---|---|---|---|---|---|---|
| MRG001 | Lepu Biopharma Co., Ltd. | Mono | China | Phase I | May. 5, 2019 | NHL |
| TRS005 | Teruisi Pharmaceutical | Mono | China | Phase I | Nov 29, 2018 | Relapsed/refractory CD20-positive B-cell non Hodgkin's lymphoma |

*Source: CDE, Clinicaltrials.gov, Frost & Sullivan*

***Competitive Advantages***

MRG001 is a clinically advanced CD20-targeted ADC with potential in the treatment of CD20-positive recurrent or refractory B-cell NHL, addressing current medical needs in patients with primary or acquired drug-resistant B-cell NHL malignancies who are non-responsive or acquire resistance to the combination therapy of rituximab and standard chemotherapies. The pre-clinical *in vivo* studies of MRG001 demonstrated significant efficacy in the PDX model of rituximab resistance.

MRG001 is our key product in the hematological oncology field with significant market potential in China. CD20 is an actively pursued target by various modalities including CD20-targeted mAb, CAR-T and anti-CD20xCD3 bispecific antibody for the treatment of NHL, according to Frost & Sullivan. Both anti-CD20 CAR-T and anti-CD20xCD3 bispecific antibody in the ongoing clinical trials have recently demonstrated promising efficacy in relapsed and refractory B-NHL, but severe and life-threatening AR of cytokine storm syndrome has been a common safety concern. Additionally, CAR-T therapies are rather expensive and have to go through a complex and lengthy manufacturing process with no guarantee of success in the T cell expansion and engineering for each individual patient.

MRG001 is optimally designed to deliver improved safety and efficacy in relapsed and refractory B-NHL patients, and overcome the widespread drug resistance among CD20-targeted drugs with an off-the-shelf formulation. The preliminary results in our ongoing Phase I clinical study of MRG001 indicated a favorable safety profile and promising efficacy signal: one FL patient achieved PR at the starting dose of 0.15 mg/kg, one DLBCL patient achieved CR at 1.8 mg/kg, one FL patient achieved PR at 2.5 mg/kg and multiple SD responses were observed across different dose levels.



Shanghai Miracogen Inc.- Ex. 2032, Page 000373

*Optimally designed to utilize a mature anti-CD20 mAb, a clinically-validated MMAE payload and a cleavable vc linker*

The mAb component of MRG001 is an anti-CD20 rituximab biosimilar antibody which demonstrates high similarity in physiochemical, immunological and biological properties to originator rituximab. The MMAE payload conjugated in MRG001 is a well-validated and widely used cytotoxic payload for clinical-stage ADCs as well as marketed ADCs including brentuximab vedotin (Adcetris), polatuzumab vedotin (Polivy) and enfortumab vedotin (Padcev). MMAE is a tubulin binder and prevents tubulin polymerization, thus disrupting the mitotic process and leading to the death of actively dividing tumor cells. The cell-killing potency of MMAE in B-cell tumor models was demonstrated in multiple rituximab resistant PDX models. The cleavable vc linker adopted in MRG001 is a linker that is adequately stable in blood circulation and also cleaved effectively by the lysosomal cathepsin enzyme after the ADC is internalized and enters into lysosome. This helps to release the MMAE molecule in its active form effectively into cytoplasm, so MMAE can bind to tubulin and lead to tumor cell death. The DAR of MRG001 is carefully examined and precisely controlled by the well-developed manufacturing process to optimize the balance of safety and efficacy.

In addition, MRG001 was shown to internalize effectively upon binding to CD20 on the cell surface. The CD20 binding affinity of MRG001 was shown to remain similar to rituximab. We believe MRG001 has the potential to overcome rituximab resistance in the relapsed and refractory patient population.

*Potent anti-tumor activity in in vitro assays and in vivo xenograft studies*

Potent anti-tumor activity was demonstrated in CD20-expressing cells in cell-based *in vitro* cytotoxicity assay with multiple NHL cell lines including Daudi, Jeko-1, Raji and Ramos. MRG001 displayed a significant cytotoxic effect in these cells. The table below presents the *in vitro* anti-tumor activity of MRG001 in different cell lines and in comparison, rituximab showing little activity in this assay.

**Anti-tumor Activity of MRG001 in Various Cell Lines by *in vitro* Cytotoxic Assay**

| Cell Line | Subtype | MRG001 | Rituximab |
|---|---|---|---|
| Raji | Burkitt's lymphoma | ++ | – |
| Ramos | Burkitt's lymphoma | ++++ | – |
| Daudi | Burkitt's lymphoma | ++ | – |
| Jeko-1 | Mantle cell lymphoma | ++++ | – |

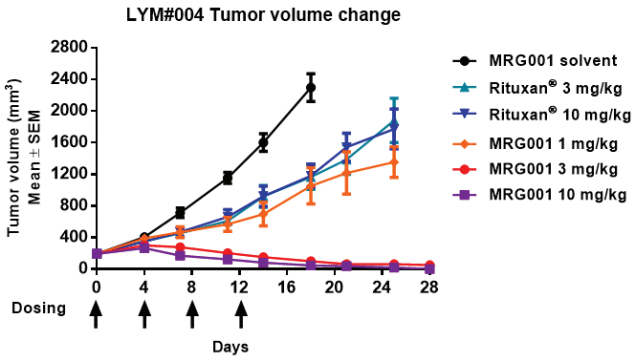
*Source: Company data*



Shanghai Miracogen Inc.- Ex. 2032, Page 000374

Strong anti-tumor activity of MRG001 was demonstrated in tumor xenograft mouse studies including multiple PDX models, two of them being rituximab resistant tumors. As shown in the figure below, in this DLBCL LYM#004 PDX model, MRG001 demonstrated dose-dependent anti-tumor activity on a Q4D×4 regimen and 3 mg/kg led to complete tumor eradication on Day 28 while rituximab did not show significant activity. In this particular model, MRG001 appeared to possess at least a ten fold increased potency in anti-tumor growth compared with rituximab.

**Anti-tumor Activity of MRG001 in PDX Model of Rituximab Resistant DLBCL LYM#004**




*Source: Company data*

*Encouraging preliminary safety and efficacy data from the ongoing Phase I clinical study*

We are conducting a Phase I clinical study of MRG001 with 18 patients enrolled in the dose escalation stage as of February 2021. Preliminary results indicated a favorable safety profile and promising efficacy signal. Encouragingly, one FL patient achieved PR at the starting dose of 0.15 mg/kg, one DLBCL patient achieved CR at 1.8 mg/kg, one FL patient achieved PR at 2.5 mg/kg and multiple SD responses were observed across different dose levels.

***Summary of Clinical Trial Results***

*Clinical Trial in CD20-positive B-cell NHL*

*Trial Design and Progress:* We are conducting an open-label, multi-center, Phase I clinical trial to assess the safety, tolerability, anti-tumor activity and pharmacokinetics of MRG001 in patients with relapsed and refractory CD20-positive B-cell NHL. As of February 2021, 18 patients were enrolled in the Phase Ia dose escalation stage. As of the Latest Practicable Date, the dose escalation study was completed, and we were conducting the subsequent Phase Ib dose expansion study.


Shanghai Miracogen Inc.- Ex. 2032, Page 000375

*Efficacy Data:* One FL patient at the dose level of 0.15 mg/kg achieved PR, one DLBCL patient at the dose level of 1.8 mg/kg achieved CR, one FL patient at the dose level of 2.5 mg/kg achieved PR and other SD responses were observed across different dose levels.

*Safety Data:* Two DLT events were reported for two patients at the dose level of 2.5 mg/kg, including one patient with Grade 4 neutropenia and one patient with Grade 3 blood triglyceride increased. Both DLT events were resolved without medical intervention. No death was reported as TRAE in the trial as of February 2021.

The table below sets forth the TRAEs reported in the trial in CD20-positive B-cell NHL as of February 2021:

| Grade | Major Identified TRAEs | Number of Patients (21 in Total) | Percentage |
|---|---|---|---|
| **TRAE** | | 18 | 85.7% |
| **Grade 1 TRAE** | Neutropenia, Increased Lactate Dehydrogenase, Fever | 18 | 85.7% |
| **Grade 2 TRAE** | Prolonged QT Interval, Leukopenia, Increased Aspartate Aminotransferase | 15 | 71.4% |
| **TRAE ≥Grade 3** | Neutropenia, Hyperlipidemia, Leukopenia | 8 | 38.1% |

| Age of Patients | Number of Patients Reported TRAE | Percentage |
|---|---|---|
| **<65** | 12 | 57.1% |
| **≥65** | 6 | 28.6% |

*Source: Company data*

***Clinical Development Plan***

We will continue to explore the path of approval and commercialization of MRG001 for the treatment of relapsed and refractory NHL including subtypes of FL, DLBCL and others. Depending on the safety and efficacy data in the Phase I clinical study, we expect to initiate Phase II clinical trials of MRG001 in promising indications of possibly FL and DLBCL.

***Licenses, Rights and Obligations***

We have the global rights to develop and commercialize MRG001.



Shanghai Miracogen Inc.- Ex. 2032, Page 000376

***Material Communications with Competent Authorities***

We received IND approval from the NMPA for MRG001 in February 2019. As of the Latest Practicable Date, we were not aware of any legal claims or proceedings that may have an adverse effect on our development of MRG001. As of the Latest Practicable Date, we had completed the phase Ia dose escalation study of MRG001 in China which has shown encouraging safety and efficacy results, had received no objections to our clinical development plans with respect to the regulatory review or approval process of MRG001, and no material adverse change had occurred with respect to the regulatory review or approval process of MRG001.

**Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange: WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET MRG001 SUCCESSFULLY.**

**MRG004A**

MRG004A is a novel TF-targeted site-specific conjugated ADC, comprised of a TF-targeted mAb conjugated with the highly potent anti-microtubule agent MMAE via a protease-cleavable BCN-valyl-citrulline linker. Compared with the TF-targeted ADC developed by Seagen Inc. and Genmab A/S which utilizes a conventional conjugation technology via interchain thiol groups, MRG004A is a conjugate of covalently attaching MMAE to the modified glycan at the Fc region of a TF-targeted mAb through the utilization of GlycoConnect™ site-specific conjugation technology and HydraSpace™ polar spacer technology, both of which were in-licensed from Synaffix, to conjugate the MMAE with a TF-targeted mAb.

Based on its unique molecular design, MRG004A has promising potential in the international markets where there was only one marketed TF-targeted ADC as of the Latest Practicable Date according to Frost & Sullivan, as it exhibited improved stability in blood circulation and enhanced efficacy in animal models of pancreatic cancer, ovarian cancer and TNBC in the pre-clinical study compared with the conventionally conjugated ADCs. We believe this may potentially translate into favorable clinical results with improved efficacy, reduced clinical toxicity and increased therapeutic window in the treatment of cancer patients.

Our commercial development strategy for MRG004A in China aims at realizing the efficacy potential of MRG004A in various types of cancers, such as breast, prostate, cervical, ovarian, colorectal and pancreatic cancer, where there are medical needs in advanced or metastatic underserved patient population involving second and later lines of systemic therapies.

We received the IND clearance of MRG004A from the FDA in February 2021 to initiate an open-label, multi-center, Phase I/II clinical trial to assess the safety, tolerability, anti-tumor activity and pharmacokinetics of MRG004A in patients with TF-positive advanced or metastatic solid tumors. We received IND approval of MRG004A from the NMPA in August 2021.



Shanghai Miracogen Inc.- Ex. 2032, Page 000377

Miracogen Shanghai acquired the co-ownership of the TF-targeted mAb and the joint right to develop ADCs based on the TF-targeted mAb from Fudan University and SIMMCAS. GlycoConnect™ was in-licensed from Synaffix. Based on the foregoing in-licensing arrangements, we have developed MRG004A in-house.

We hold the rights to develop and commercialize MRG004A globally.

***Mechanism of Action***

TF is a transmembrane glycoprotein essential for hemostasis, which is aberrantly expressed by tumor cells and contributes to a variety of pathologic processes, including thrombosis, metastasis, tumor growth, and tumor angiogenesis. High levels of TF overexpression have been observed in a number of cancers including glioma, breast cancer, lung cancer, colon cancer, prostate cancer, pancreatic cancer, ovarian carcinoma, and hepatocellular carcinoma. Aberrant expression of TF has been associated with poor prognosis, unsatisfactory clinical outcomes and increased metastatic potential in solid tumors. Due to its key role in cancer biology as well as its broad and differential overexpression in many types of cancer, TF has been recognized and pursued as an attractive therapeutic target to address current medical needs in a broad range of solid tumors.

TF binds to the coagulation serine protease factor VII/VIIa (FVII/VIIa) and forms a bimolecular complex (TF:FVIIa complex) which functions as the primary initiator of coagulation *in vivo*. The TF:FVIIa complex is able to proteolytically cleave transmembrane G protein-coupled protease activated receptors (PARs), and the resulting activation of PAR2 on tumor cells increases tumor growth via an undefined mechanism. In addition to activating PARs, TF:FVIIa complex is also able to activate RTKs and integrins. Tumor cells may trigger venous thromboembolism in cancer patients while releasing TF-positive procoagulant microparticles into the circulation. TF on tumor cells in the circulation leads to the coating of the cells with fibrin, trapping them within the microvasculature and facilitating hematogenous metastasis. Tumors utilize these signaling pathways to increase cell proliferation, angiogenesis, metastasis and cancer stem-like cell maintenance.

Upon binding specifically to TF on the surface of target cancer cells, MRG004A is internalized and trafficked to lysosomes, and then releases MMAE through lysosomal protease cleavage. The released MMAE is subsequently bound to microtubulin, which eventually leads to tumor cell death. Although MRG004A is designed to deliver the cytotoxic agent targeting TF-expressing tumor cells, MMAE released by dead tumor cells could penetrate and kill surrounding tumor cells with or without TF expression. Such bystander killing mechanism may potentially offer additional therapeutic effects to the cancer cells with heterogeneous expression levels of TF.

Furthermore, the site-specific conjugation of MRG004A on Asn297 residue of the mAb abrogates the Fc binding to CD16a expressed on NK cells, thereby eliminating the ADCC activity, which may potentially result in reduced clinical toxicity in patients and increased therapeutic window of MRG004A.


Shanghai Miracogen Inc.- Ex. 2032, Page 000378

***Market Opportunity and Competition***

TF signaling pathways play a key role in cancer biology and the treatment of a broad range of solid tumors. We believe that MRG004A has great potential to address the sizable and growing market. As of the Latest Practicable Date, only one TF targeted therapies were approved and marketed globally, and Seagen Inc. and Genmab A/S gain FDA approval of the ADC tisotumab vedotin for the treatment of recurrent or metastatic cervical cancer progressed on or following standard chemotherapy in September 2021, according to Frost & Sullivan. Such BLA is based on clinical data from Phase II InnovaTV 204 clinical trial, in which the ADC induced an ORR of 24.0% (95.0% CI, 15.9% to 33.3%) in patients with recurrent or metastatic cervical cancer who previously received doublet chemotherapy and bevacizumab (Avastin), including a CR of 7.0% and a PR of 17.0%, and a median duration of response of 8.3 months (95.0% CI, 4.2 months to NR). The most common treatment-related AEs (no less than 20.0%) included alopecia (Grade 1 or 2 at 38.0%), epistaxis (nose bleeds, Grade 1 or 2 at 30.0%), nausea (Grade 1 or 2 at 27.0%), conjunctivitis (Grade 1 or 2 at 26.0%), fatigue (Grade 1 or 2 at 24.0%, Grade 3 or above at 2.0%) and dry eye (Grade 1 or 2 at 23%). Pre-specified AEs associated with tisotumab vedotin treatment included ocular events, bleeding and peripheral neuropathy.

The table below sets out the incidence of cervical cancer, ovarian cancer and pancreatic cancer in China for the periods indicated.

**Incidence of Cervical Cancer, Ovarian Cancer and Pancreatic Cancer in China**

| | 2020 | 2025E | 2030E | CAGR 2020-2025E | CAGR 2025E-2030E |
|---|---|---|---|---|---|
| Incidence of Cervical Cancer in China (Thousand) | 118.5 | 123.3 | 125.9 | 0.8% | 0.4% |
| Incidence of Ovarian Cancer in China (Thousand) | 55.3 | 59.5 | 62.7 | 1.5% | 1.1% |
| Incidence of Pancreatic Cancer in China (Thousand) | 112.0 | 133.1 | 155.8 | 3.5% | 3.2% |

*Source: Frost & Sullivan*

Cervical cancer develops in a woman's cervix and almost all cervical cancer cases are associated with infection with high-risk human papillomaviruses (HPV), an extremely common virus transmitted through sexual contact. Cervical cancer is the fourth most common cancer and the fourth most common cause of death from cancer in women globally. The incidence of



Shanghai Miracogen Inc.- Ex. 2032, Page 000379

cervical cancer in China is constantly growing and is expected to steadily increase in the future. For patients with recurrence or metastasis of cervical cancer which is inoperable or not able to be treated with radiotherapy, chemotherapy is the preferred option with unsatisfactory overall effect. Bevacizumab is the only targeted therapy recommended which is associated with an increased incidence of hypertension, thromboembolic events and gastrointestinal fistulas compared with chemotherapy treatment.

Ovarian cancer is one of the most common malignant tumors in female genital organs, and its incidence is slightly lower than those of cervical cancer and endometrial cancer. 70.0% of patients with ovarian cancer are at advanced stage when first diagnosed. The five-year survival rate of ovarian cancer is less than 30.0%. Ovarian cancer is relatively sensitive to first-line chemotherapy; however, there are approximately 70.0% of patients having drug resistance and recurrence after initial treatment. With the progression of disease, effective drugs for subsequent lines of treatments are limited other than chemotherapy in combination with bevacizumab.

Pancreatic cancer is caused by the abnormal and uncontrolled growth of cells in the pancreas, a large gland that is part of the digestive system. Patients diagnosed with pancreatic cancer have one of the poorest survival prognoses compared with patients with other types of cancer. The five-year survival rate of pancreatic cancer is about 6.0% globally and 7.2% in China. Major treatments of pancreatic cancer include, among others, surgical treatment, radiotherapy, chemotherapy, interventional therapy, ERCP (endoscopic retrograde cholangiopancreatography) related treatment and TCM treatment, while targeted therapies are relatively limited. Certain targeted therapies other than erlotinib have been assessed in combination with gemcitabine, but none yielded strong results.

***Competitive Advantages***

MRG004A is a novel TF-targeted site-specifically conjugated ADC. MRG004A is a conjugate of covalently attaching MMAE to the modified glycan at the Fc region of a TF-targeted mAb through the utilization of GlycoConnect™ site-specific conjugation technology and HydraSpace™ polar spacer technology, both of which were in-licensed from Synaffix, to conjugate the MMAE with a TF-targeted mAb.

Based on its unique molecular design, we believe MRG004A has promising potential in the international markets where there were only one marketed TF-targeted ADC as of the Latest Practicable Date according to Frost & Sullivan, as it exhibited improved stability in blood circulation and enhanced efficacy in animal models of pancreatic cancer, ovarian cancer and TNBC in the pre-clinical study compared with conventionally conjugated ADCs, which may potentially translate into favorable clinical results with improved efficacy, reduced clinical toxicity and increased therapeutic window in the treatment of cancer patients.


Shanghai Miracogen Inc.- Ex. 2032, Page 000380

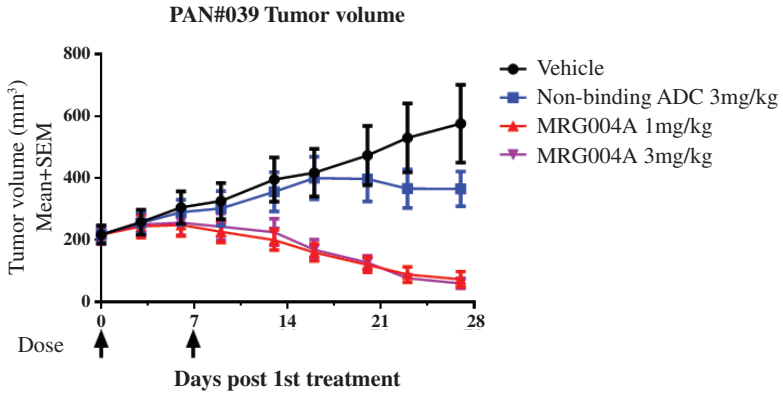
*Innovatively designed to utilize a humanized anti-TF mAb with high affinity TF for rapid internalization*

MRG004A utilizes a humanized anti-TF mAb of high binding affinity, with binding constant KD (dissociation constant) ranging from $2.049\times10^{-9}$M to $2.290\times10^{-9}$M. In the immunofluorescence microscopic experiments which utilize TF-expressing SKOV-3 cells, the internalization of MRG004A was observed within one hour and increased substantially over 24 hours. This rapid internalization is expected to enable MRG004A to penetrate and kill target tumor cells efficiently.

*Potent anti-tumor activity*

In cell-based cytotoxic activity assay, MRG004A exhibited potent cytotoxicity in TF-expressing cancer cells *in vitro*, with an IC50 ranging from 7.30±0.74 ng/mL to 9.99±0.72 ng/mL. The *in vivo* anti-tumor activity of MRG004A was evaluated in multiple PDX models, including the PDX models for human ovarian cancer, pancreatic cancer and breast cancer. The figures below present the anti-tumor activity of MRG004A in PDX models of (i) pancreatic cancer carrying KRAS G12V mutation and (ii) ovarian cancer.

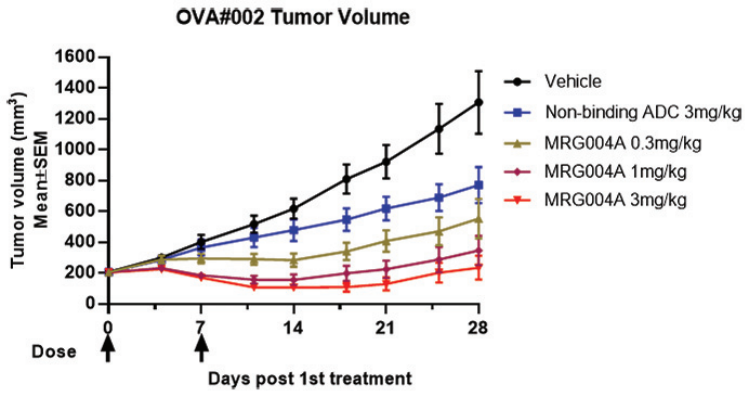
**Anti-Tumor Effect of MRG004A in PDX Model of Pancreatic Cancer Carrying KRAS G12V Mutation**





Shanghai Miracogen Inc.- Ex. 2032, Page 000381

**Anti-Tumor Effect of MRG004A in PDX Model of Ovarian Cancer**




*Source: Company data*

*Neither binding to CD16a nor ADCC activity detected for MRG004A*

As the site-specific conjugation of MRG004A is achieved at the glycosylation site of Asn297 by utilizing GlycoConnect™, the binding of MRG004A to CD16a is completely abolished and thus neither the binding of CD16a nor ADCC activity was detected, which would potentially translate into reduced toxicity of ADC in immune systems.

***Clinical Development Plan***

We received the IND clearance of MRG004A from the FDA in February 2021 to initiate an open-label, multi-center, Phase I/II clinical trial to assess the safety, tolerability, anti-tumor activity and pharmacokinetics of MRG004A in patients with TF-positive advanced or metastatic solid tumors. The trial was conducted (i) to define the safety and tolerability of MRG004A in patients with TF-positive advanced solid tumors in Phase I dose escalation stage; (ii) to determine MTD or RP2D of MRG004A in Phase I dose escalation stage; and (iii) to evaluate the preliminary anti-tumor activity of MRG004A in patient population with specific diseases in Phase II dose expansion stage.

We received IND approval of MRG004A from the NMPA in August 2021. We will continue to identify the appropriate indications for future clinical studies of MRG004A depending on safety and anti-tumor activity of MRG004A in various TF over-expressing tumors following the Phase I/II clinical trial.


Shanghai Miracogen Inc.- Ex. 2032, Page 000382

***Licenses, Rights and Obligations***

Miracogen Shanghai acquired the co-ownership of the TF-targeted mAb and the joint right to develop ADCs based on the TF-targeted mAb from Fudan University and SIMMCAS. GlycoConnect™ was in-licensed from Synaffix. We hold the rights to develop and commercialize MRG004A globally. See "– Collaboration, Licensing and Transfer Arrangements – Collaboration with Fudan University and SIMMCAS."

***Material Communications with Competent Authorities***

We received the IND clearance of MRG004A from the FDA in February 2021, and we received IND approval of MRG004A from the NMPA in August 2021. As of the Latest Practicable Date, we were not aware of any legal claims or proceedings that may have an adverse effect on our development of MRG004A. As of the Latest Practicable Date, we had received no objections to our clinical development plans with respect to the regulatory review or approval process of MRG004A and no material adverse change had occurred with respect to the regulatory review or approval process of MRG004A.

**Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange: WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET MRG004A SUCCESSFULLY.**

**CG0070**

CG0070 was the most advanced oncolytic adenovirus for the treatment of bladder cancer in clinical-stage development as of the Latest Practicable Date, according to Frost & Sullivan.

CG0070 is a oncolytic adenovirus drug candidate with strong anti-tumor activity by a combination of two mechanisms, destruction of cancer cells and stimulation of anti-tumor immune response. We in-licensed the rights to develop, manufacture and commercialize CG0070 in Mainland China, Hong Kong and Macau from CG Oncology, who granted us an exclusive, royalty bearing, non-transferable license.

CG0070 is positioned to address China's current medical needs for treatment for bladder cancer, a group of cancers arising from the tissues of the urinary bladder. The incidence of bladder cancer in China is constantly growing and is expected to steadily increase in the future. The treatments for bladder cancer are subject to various limitations, including the low recovery rate of patients, the likelihood of having complication during bladder cancer postoperative perfusion and limited treatment options with high costs.

CG0070 demonstrated a strong efficacy and favorable safety profile through its Phase II clinical trial (BOND2) completed by CG Oncology for the treatment of high-grade NMIBC after Bacillus Calmette-Guerin (BCG) failure in the U.S., with a three-month CR rate of 46.2% and a 12-month CR rate of 29.2% in the BOND2 trial, outperforming the corresponding CRs of pembrolizumab, which are 40.6% and 18.7%, respectively.



Shanghai Miracogen Inc.- Ex. 2032, Page 000383

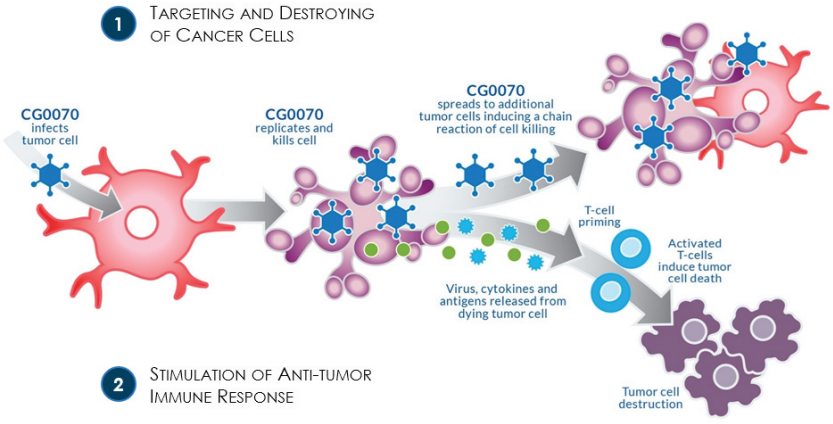
In China, we plan to study the clinical efficacy in CG0070 as a treatment for bladder cancer and further expand other indications such as CRC, liver and breast cancers. We obtained IND approval from the NMPA for CG0070 in November 2021 and plan to initiate a Phase I clinical trial of CG0070 on patients with NMIBC and solid tumors in China.

In terms of combination therapy, CG Oncology has collaborated with Merck to evaluate the combination of CG0070 with the anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in a Phase II clinical trial for the treatment of high-grade NMIBC in the BCG-unresponsive patient population. CG Oncology also works closely with BMS to explore the combination of CG0070 plus OPDIVO® (nivolumab) in patients with MIBC who are ineligible for cisplatin-based chemotherapy.

We plan to initiate clinical trials on combination therapies within our pipeline, including CG0070 in combination with HX008, with the belief that such combination therapy has great potential in starting a revolution in immunotherapy. We plan to initiate a clinical trial evaluating the safety and efficacy of CG0070 in combination with an anti-PD-1 antibody drug for late-stage NMIBC. See "– Combination Therapies within Our Pipeline."

***Mechanism of Action***

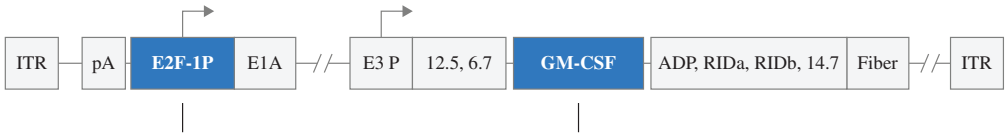
CG0070 is a conditional replicating oncolytic adenovirus designed to work in two important and complementary ways. First, it replicates and kills the tumor cells. Then the rupture of the cancer cells releases tumor-derived antigens, along with GM-CSF, stimulating a systemic anti-tumor immune response that involves the body's own white blood cells. The mechanism of actions of CG0070 is illustrated in the figures below.




*Source: CG Oncology*


Shanghai Miracogen Inc.- Ex. 2032, Page 000384

CG0070 is coded through a conditionally replicating recombinant oncolytic adenoviral (serotype 5) vector inserted with a human E2F-1 promoter and circulating tumor DNA encoding human GM-CSF. Such process is illustrated in the figure below:




**E2F Promoter** along with **GM-CSF transgene** inserted into wild-type adenovirus backbone

| Gene/Protein | Function |
|---|---|
| E2F | Enables cancer-selective replication in RB-pathway defective cells |
| E1A/E3 | Viral gene retains wild-type adenovirus lytic ability |
| GM-CSF | Instigates production of GM-CSF cytokines, danger signals that activate and matures antigen-presenting cells (the immune system) to fight cancer |

*Source: CG Oncology*

The sequences for human E2F-1 promoter drive expression of essential E1 viral genes and restrict viral replication to Rb pathway-defective cancer cells, making the oncolytic virus able to specifically replicate in tumor cells while sparing normal cells. Rb pathway deficiency is frequently observed across a spectrum of human cancer types. In addition, the E2F-1 transcription factor required for CG0070 gene expression is highly expressed in the majority of solid tumors. Tumor types including bladder, CRC, liver, prostate and breast cancers are both E2F-1 transcription factor highly expressed and Rb pathway-defective.

The secretion of human GM-CSF induces the potent anti-tumor immune response. Tumor cell death induced by virus infection can lead to the release of tumor antigen. GM-CSF, a potent cytokine produced by viral vector, can then further activate dendritic cells and macrophages to process the tumor antigen and initiate the adaptive immune response to control tumor.

Expression of the GM-CSF transgene is controlled by the endogenous viral E3 promoter, and the E3 promoter is in turn activated by E1A. Both viral replication and GM-CSF expression are ultimately under the control of the tumor-selective E2F-1 promoter.

Across a panel of tumor and non-tumor cell lines that differed in Rb-pathway status, replication and cytotoxicity of CG0070 was shown to correlate with Rb-pathway dysfunction. Dependence of viral protein expression, including GM-CSF, was also demonstrated.


Shanghai Miracogen Inc.- Ex. 2032, Page 000385

***Market Opportunity and Competition***

In China, an increasing number of pharmaceutical companies are in the process of pre-clinical studies or preparing for INDs for oncolytic virotherapy, covering a wide range of indications. One of the indications of oncolytic viruses is bladder cancer. Bladder cancer is a group of cancers arising from the tissues of the urinary bladder, in which cells grow abnormally and have the potential to spread to other parts of the body. The annual incidence of bladder cancer in China is constantly growing and is expected to steadily increase in the future. According to Frost & Sullivan, the number of new cases of bladder cancer in China was 85.7 thousand in 2020 and is expected to reach 101.1 thousand and 117.6 thousand in 2025 and 2030, respectively, representing a CAGR of 3.4% from 2020 to 2025 and a CAGR of 3.1% from 2025 to 2030. Bladder cancer is the most common malignant tumor of the urinary system, accounting for the highest incidence of urogenital tumors in China. The five-year survival rate of bladder cancer in China is 72.9% and the mortality rate of bladder cancer in China is approximately 15.0%. The current treatments for bladder cancer are subject to various limitations, including the low recovery rate of patients, the likelihood of having complication during bladder cancer postoperative perfusion and limited treatment options with high costs. For example, the radical cystectomy combined with radiotherapy and chemotherapy, the major treatment available in China as of the Latest Practicable Date, imposes a great physiological and psychological burden on patients as the patients may require life-long urination assistance after operation and suffer from SAEs such as bleeding and surgical wound infections.

***Competitive Advantages***

CG0070 was the most advanced oncolytic adenovirus for the treatment of bladder cancer in clinical-stage development as of the Latest Practicable Date, according to Frost & Sullivan. CG0070 has demonstrated the following competitive advantages in comparison with its competitors:

*Cancer-selective oncolytic immunotherapy designed for tolerability and potency*

CG0070 is an investigational oncolytic immunotherapy based on a modified adenovirus backbone and contains a cancer-specific promoter and a GM-CSF transgene. CG0070 works to destroy cancer cells as well as stimulate anti-tumor immune response. The scientific rationale and clinical profile of CG0070 make it an ideal agent to be developed for a variety of solid tumor types to be used alone or in combination with immune checkpoint modulators. CG0070 demonstrated a remarkable ability to efficiently and selectively transduce and replicate in transitional cell carcinoma (TCC) bladder cell lines, with the production of GM-CSF in a dose-related fashion at levels predicted to stimulate anti-tumor protective immunity *in vivo*. In xenograft models, including bladder TCC, prostate, and hepatocellular carcinoma, CG0700 demonstrated significantly greater anti-tumor activity compared with controls.


Shanghai Miracogen Inc.- Ex. 2032, Page 000386

*Encouraging clinical efficacy*

CG Oncology completed the BOND2 of CG0070 in the U.S., which was a Phase II clinical study that evaluated the safety and efficacy of CG0070 oncolytic virus regimen for high-grade NMIBC among the BCG-unresponsive population. Most patients with high-grade NMIBC (Cis, Cis with Ta and/or T1, Ta or T1) who have failed BCG intravesical therapy (standard of care) usually have no other choice but to proceed to cystectomy. In BOND2, CG0070 has reached a three-month CR rate of 46.2% and a 12-month CR rate of 29.2%, which is better than pembrolizumab (three-month CR rate of 40.6% and 12-month CR rate of 18.7%). Pembrolizumab was approved in this indication. We believe that CG0070 could serve to provide a therapeutic alternative for this patient population in need.

***Summary of Clinical Trial Results***

CG Oncology has completed a Phase I clinical trial (V-0046) and a Phase II clinical trial (BOND2) of CG0070 in BCG-unresponsive NMIBC in the U.S. We obtained IND approval from the NMPA for CG0070 in November 2021.

*Clinical Trial in NMIBC by CG Oncology*

CG Oncology has completed a Phase I clinical trial (V-0046) and a Phase II clinical trial (BOND2) of CG0070 in BCG-unresponsive NMIBC in the U.S.

Phase I Clinical Trial (V-0046)

*Trial Design and Progress:* This trial was an open label, dose escalation study in patients with BCG-unresponsive NMIBC. This trial was conducted among four dose cohorts ($1 \times 10^{12}$, $3 \times 10^{12}$, $1 \times 10^{13}$ and $3 \times 10^{13}$ vp), with three to six patients in each cohort, to evaluate the safety and efficacy of a single dose of CG0070. Subsequently, such trial was expanded to additional dose cohorts, with three to six patients in each cohort, to evaluate the safety and efficacy of multiple doses of CG0070 (once every four weeks, or once every week).

The trial was conducted (i) to define the maximum-tolerated dose (MTD) or maximum feasible dose (MFD) in single and multi-dose regimens of CG0070 administered by intravesical instillation for the treatment of superficial transitional cell carcinoma of bladder after Bacillus Calmette-Guerin (BCG) failure; and (ii) to assess the safety and feasibility of CG0070 administered by intravesical instillation in single dose and multi-dose regimens. The trial was completed in December 2008.


Shanghai Miracogen Inc.- Ex. 2032, Page 000387

*Efficacy Data*: Overall, the study results demonstrated a 45.7% (16/35) CR. The CR was 23.1% (3/13) among patients who received a single dose, and 59.1% among patients who receive multiple doses. The cohort with the lowest dose level ($1 \times 10^{12}$ vp) demonstrated a CR of 61.5%, higher than the corresponding CRs in other dose cohorts (44.4% in the $3 \times 10^{12}$ vp cohort, 40.0% in the $1 \times 10^{13}$ vp cohort and 0.0% in the $3 \times 10^{13}$ vp cohort.) The CR was 50.0% (4/8) among the "CIS only" sub-group. The median duration of CR was 8.4 months, with the responses ongoing at 17.0 months. The table below sets forth other efficacy data in this clinical trial.

| Sub-Groups | N | %CR (Patients with CR/N) | Median duration of CR (Months) |
|---|---|---|---|
| All Patients | 35 | 45.7% (16/35) | 8.4 |
| **Dose Level** | | | |
| $1 \times 10^{12}$ vp | 13 | 61.5% (8/13) | 8.2 |
| $3 \times 10^{12}$ vp | 9 | 44.4% (4/9) | Not reached |
| $1 \times 10^{13}$ vp | 10 | 40.0% (4/10) | 6.2 |
| $3 \times 10^{13}$ vp | 3 | 0.0% (0/3) | – |
| **Tumor Stage** | | | |
| Ta | 15 | 66.7% (10/15) | 7.9 |
| T1 | 3 | 0.0% (0/3) | – |
| Ta+CIS | 2 | 50.0% (1/2) | Not reached |
| T1+CIS | 7 | 14.3% (1/7) | 6.2 |
| CIS only | 8 | 50.0% (4/8) | 8.4 |
| **Tumor Grade** | | | |
| 1 | 6 | 83.3% (5/6) | 8.2 |
| 2 | 6 | 50.0% (3/6) | 11.8 |
| 3 | 10 | 50.0% (5/10) | Not reached |

*Source: CG Oncology*

*Safety Data*: In this trial, the maximum dosage level was $3 \times 10^{13}$ vp for the single dose cohort and $1 \times 10^{13}$ vp for the multiple dose cohort. TRAEs were reported among 77.1% (27/35) of the patients participated in this trial. In addition, 71.4% (25/35) of patients reported AEs related to bladder and urinary tract diseases, including the following (frequency $\geq$ 10%): dysuria (48.6%), pollakiuria (31.4%), hematuria (25.7%), urine abnormalities (25.7%), bladder spasm (17.1%), nocturia (14.3%) and bladder discomfort (14.3%). Other AEs reported by patients were those often observed in the administration of immunotherapies and in adenovirus infections, including fatigue (11.4%), arthralgia (11.4%), abdominal pain (11.4%), myalgia (11.4%), and influenza-like illness (11.4%). Three patients reported six AEs of Grade 3 or higher: pollakiuria (two), lymphopenia (one), dysuria (one), micturition urgency (one), and nocturia (one). Among such AEs, only the lymphopenia case was considered a DLT, as other AEs resolved to Grade 2 or lower within seven days, the topical AE is not considered a dose-limiting event. The DLT of Grade 3 lymphopenia was observed in one patient at a dosage



Shanghai Miracogen Inc.- Ex. 2032, Page 000388

level of $1 \times 10^{12}$ vp, with multiple doses of CG0070 taken once every four weeks. Since such DLT resulted from an accident in traumatic catheterization, it was not considered as an SAE or of clinical significance. No death was reported as TRAE in the trial as of December 2008.

The table below sets forth the TRAEs reported in the Phase I clinical trial in NMIBC as of December 2008:

| Grade | Major Identified TRAEs | Number of Patients (35 in Total) | Percentage |
|---|---|---|---|
| **TRAE** | | 27 | 77.1% |
| **Grade 1 TRAE** | Arthralgia, Myalgia, Incontinence, Pollakiuria, Dysuria | 10 | 28.6% |
| **Grade 2 TRAE** | Fatigue, Urine Abnormalities, Micturition Urgency, Dysuria | 14 | 40.0% |
| **TRAE ≥Grade 3** | Pollakiuria, Nocturia, Dysuria | 3 | 8.6% |

| Age of Patients | Number of Patients Reported TRAE | Percentage |
|---|---|---|
| **<65** | 10 | 28.6% |
| **≥65** | 17 | 48.6% |

*Source: CG Oncology*

Phase II Clinical Trial in NMIBC (BOND2)

Based on the good tolerance and favorable safety of Phase I clinical study, CG Oncology conducted a Phase II clinical trial in NMIBC at a dosage level of $1 \times 10^{12}$ vp (once every week) to further evaluate the safety and efficacy of CG0070.

*Trial Design and Progress:* This trial was an open-label, single-arm, multi-center study in patients with NMIBC who had failed BCG therapy and refused cystectomy. The trial was conducted to evaluate the safety and efficacy of CG0070 for the treatment of high-grade NMIBC patients who had failed BCG therapy and refused cystectomy. The trial was terminated in March 2017 due to regulatory uncertainties regarding the primary endpoint for BCG-unresponsive NMIBC before the issuance of relevant official FDA guidance in 2018. 68 patients had been recruited prior to the termination.

*Efficacy Data:* DCRs at 18 months were 17.6% in the Intent-to-Treat (ITT) population and 18.5% in the Dosed Patient Population (DPP). 61.5% of the DPP achieved a CR at any timepoint in the study. The three-month, six-month and 12-month CRs were 46.2%, 41.5% and 29.2%, respectively.



Shanghai Miracogen Inc.- Ex. 2032, Page 000389

*Safety Data:* 31.7% of the reported TRAEs were related to CG0070. 98.3% of the reported TRAEs related to CG0070 were lower than Grade 3 TRAEs, and no Grade 4 or above TRAE related to CG0070 was reported. The most common TRAEs were bladder spasm, hematuria, dysuria, micturition urgency and pollakiuria. 20.6% of the reported TRAEs were considered to be related to DDM, 97.4% of which were lower than Grade 3 TRAEs. No Grade 4 or above TRAE related to DDM was reported. No death was reported as TRAE in the trial as of March 2017.

The table below sets forth the TRAEs reported in the Phase II clinical trial in NMIBC as of March 2017:

| Grade | Major Identified TRAEs | Cases of TRAEs | Percentage |
|---|---|---|---|
| **TRAE** | | 117 | 31.7% |
| **Grade 1 TRAE** | Bladder Spasm, Hematuria, Micturition Urgency, Pollakiuria | 84 | 22.8% |
| **Grade 2 TRAE** | Dysuria, Micturition Urgency, Urinary Tract Infection, Bladder Spasm | 31 | 8.4% |
| **TRAE ≥Grade 3** | Dysuria, Hypotension | 2 | 0.5% |

| Age of Patients | Cases of TRAEs | Percentage |
|---|---|---|
| **<65** | 24 | 6.5% |
| **≥65** | 93 | 25.2% |

*Source: CG Oncology*

***Clinical Development Plan***

We obtained IND approval from the NMPA for CG0070 in November 2021 and plan to commence a bridging Phase I clinical study on patients with NMIBC and solid tumors in 2022. CG Oncology has completed a Phase II clinical trial (BOND2) for BCG-unresponsive NMIBC in the U.S. We will join multi-regional clinical trials subject to the clinical development of CG0070 in the U.S.

***Licenses, Rights and Obligations***

We in-licensed CG0070 from CG Oncology, who granted us an exclusive, royalty-bearing, non-transferable license to develop, manufacture and commercialize CG0070 in Mainland China, Hong Kong and Macau. See "– Collaboration, Licensing and Transfer Arrangements – Collaboration with CG Oncology."



Shanghai Miracogen Inc.- Ex. 2032, Page 000390

***Material Communications with Competent Authorities***

We submitted an IND application of CG0070 intravesical administration for NMIBC and for other solid tumors to the NMPA in February 2021. As of the Latest Practicable Date, we were not aware of any legal claims or proceedings that may have an adverse effect on our development of CG0070. As of the Latest Practicable Date, we had received no objections to our clinical development plans with respect to the regulatory review or approval process of CG0070 and no material adverse change had occurred with respect to the regulatory review or approval process of CG0070.

**Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange: WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CG0070 SUCCESSFULLY.**

**COMBINATION THERAPIES WITHIN OUR PIPELINE**

Based on our substantial accumulated industry experience and in-depth insights in both oncology immunotherapy and targeted therapy, we believe combinations of immunotherapy and targeted therapeutics possess potential to achieve enhanced efficacy and/or balanced safety as well as to overcome the drug resistance. According to Frost & Sullivan, there is an increasing number of experimental results demonstrating that combination therapies can significantly improve the effect of monotherapies, which has become a direction of research and development. See "Industry Overview."

Effective anti-cancer immunity functions through a series of stepwise events in the cancer immune cycle, including tumor antigen release, presentation and T cell priming, trafficking and infiltration of T cell into tumors, and recognition and killing of cancer cells. We have designed our pipeline targeting key steps across the cancer immune cycle to unlock the great potential of anti-cancer immune response by combinations of these therapeutics developed in-house. See "– Our Drug Candidates." We have built up the ADC pipeline and oncolytic virus products, which can directly kill tumors, promote tumor antigen presentation and prime T cells to treat immune desert type of cancer. We also target immune-barrier cancers by synergizing both blockade of PD-L1 and TGF-beta pathways through anti-PD-L1/TGFBRII bispecific antibody LP008. We have established our immune oncology cornerstone therapeutics anti-PD-1 antibody HX008 and anti-PD-L1 antibody LP002 and additional key immune checkpoint inhibitors (LP010, anti-TIGIT antibody) to treat inflamed tumors. We strive to unlock the great potential of the cancer immune cycle through converting the immune phenotype from immune desert or excluded to inflamed tumor type by our drug candidates and then combining with PD-1 therapy.

Specifically, the combination of oncolytic viruses and anti-PD-1/anti-PD-L1 monoclonal antibodies has become an emerging treatment of advanced malignancies. Oncolytic viruses can stimulate a systemic anti-tumor immune response, thereby enhancing the anti-tumor activity of immunotherapy. A number of clinical studies have reported that the combination of anti-PD-1 monoclonal antibodies and oncolytic viruses demonstrated positive synergistic effects in the treatment of a variety of tumors, including melanoma, NSCLC and bladder cancer. We have


Shanghai Miracogen Inc.- Ex. 2032, Page 000391

initiated the clinical trials for HX008/LP002 in combination with OH2 in liver cancers and HX008 in combination with LP002 in advanced melanoma. We plan to develop a combination therapy of CG0070 and HX008 to provide a revolutionary treatment option to bladder cancer patients. We also plan to explore ADCs in combination with HX008 in multiple advanced solid tumors. Our combination therapies are expected to drive and strengthen the potential commercial value of our pipeline drug candidates and further expand our market share in the targeted therapeutic areas and address current medical needs for oncology treatment.

As of the Latest Practicable Date, we had received IND approval from the NMPA for combination therapies of each of HX008 and LP002 with OH2 as well as HX008 and LP002 and commenced the corresponding Phase I clinical trial. We also aim to realize the efficacy potential of such combination therapies in the treatment of patients with advanced liver cancer and metastatic colorectal cancer. The third dose escalation stage was commenced in both Phase I clinical trials of LP002 in combination with OH2 and HX008 in combination with LP002.

**HX008 in combination with OH2**

***Phase I clinical trial of HX008 in combination with OH2 in advanced hepatocellular carcinoma***

We initiated a Phase I clinical trial of HX008 in combination with OH2 for the treatment of advanced hepatocellular carcinoma at Zhong Shan Hospital in November 2020. This trial is an open-label, multi-center, single-arm Phase I clinical trial. This trial aims at (i) evaluating the safety and tolerability of HX008 in combination with OH2 in advanced hepatocellular carcinoma; and (ii) evaluating the objective response rate and 12-month overall survival rate of HX008 in combination with OH2 in advanced hepatocellular carcinoma.

This trial commenced in November 2020 and as of the Latest Practicable Date, the enrollment was ongoing.

**LP002 in combination with OH2**

We initiated a Phase I clinical trial for LP002 in combination with OH2 for the treatment of advanced solid tumors in the Cancer Hospital Chinese Academy of Medical Sciences in June 2019. This trial is an open, multi-center Phase I clinical trial. This trial aims at evaluating the tolerability and safety of the combination therapy. We expect to enroll up to 30 patients and as of the Latest Practicable Date, we had recruited 37 patients.

We have completed the dose escalation stage for three dose levels and commenced the trial of the fourth dose level.

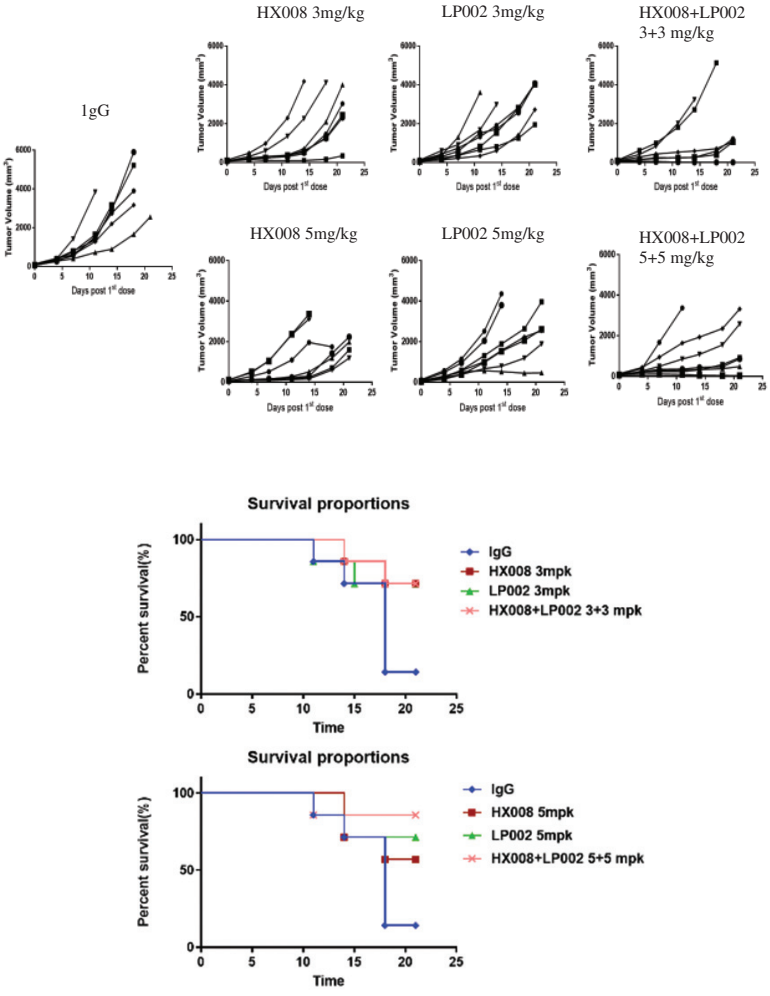
We expect to collect preliminary safety and efficacy results of the Phase Ia/Ib clinical trial in 2022.



Shanghai Miracogen Inc.- Ex. 2032, Page 000392

**HX008 in combination with LP002**

In pre-clinical study, we evaluated the combination therapy of LP002 and HX008 in B16F10 melanoma model which is a PD-1 resistant melanoma model. Notably, the combination treatment of HX008 and LP002 showed survival advantages over monotherapy and control group in B16F10 model. In this study, HX008, LP002 and the combination therapy were evaluated in PD-L1 gene humanized B16F10 tumor and PD-L1 gene humanized mice model.




*Source: Company data*

We initiated a Phase I clinical trial for HX008 in combination with LP002 for the treatment of advanced melanoma refractory to anti-PD-1 antibody therapy in Beijing Cancer Hospital in July 2020. This trial is an open, single-center Phase Ia/Ib clinical trial. The Phase Ia clinical trial aims at (i) evaluating the safety and tolerability of HX008 in combination with LP002 for patients who failed standard treatment; (ii) exploring MTD and RP2D of the combination therapy with LP002 in dose escalation and HX008 at 200mg fixed dose level; and (iii) observing the PK characteristics of the combination therapy. Phase Ib aims at (i) evaluating the safety and tolerability of HX008 combined with LP002, (ii) evaluating the


Shanghai Miracogen Inc.- Ex. 2032, Page 000393

efficacy of HX008 combined with LP002, and (iii) evaluating the efficacy of LP002 monotherapy. As of February 28, 2021, we had recruited nine patients. We have completed the dose escalation stage for three dose levels and commenced the trial of the four dose level. We expect to collect preliminary safety and efficacy results of the Phase I clinical trial in 2022.

**Planned Combination Therapies of ADCs with HX008**

The main focus of the planned combination programs of ADCs with HX008 is to elucidate a compelling biologic and pharmacologic rationale for applying the combination as supported by scientific evidence of substantial *in vivo* activity. In addition, we also seek to elucidate justification for the combination therapy in a defined patient population and offer alternative treatments to standards of care. We believe that simultaneous development of combination therapies targeting multiple therapeutic areas has the potential to dramatically improve the response to treatment and survival rates in cancer patients, while we understand that combination therapy involves additional uncertainty, complexity and risks. We plan to mitigate such risks by implementing approaches including exploring the safety, pharmacokinetics and efficacy profiles of MRG003 and MRG002 in order to engage scientifically and medically sound alternative study designs, which include *in vivo* model data and pharmacodynamic studies.

To support clinical development of MRG003 in combination with anti-PD-1 antibody HX008, we have conducted a mouse PDX model study of NSCLC with EGFR L858R amplification and cMET amplification as well as osimertinib resistance and PD-L1 low expression. All mice in the study showed good tolerance. Significant synergistic effect of inhibiting tumor growth was observed for the combination of MRG003 and HX008. We had obtained IND approval from the NMPA for the combination therapy as of the Latest Practicable Date.

To support clinical development of anti-HER2 ADC MRG002 in combination with anti-PD-1 antibody HX008, we have conducted a humanized mouse PDX model study of gastric cancer with HER2 IHC2-positive and FISH-positive as well as Herceptin resistance. All mice in the study showed good tolerance. Significant synergistic effect of inhibiting tumor growth was observed for the combination of MRG002 and HX008. We had obtained IND approval from the NMPA for the combination therapy as of the Latest Practicable Date.

**PRE-CLINICAL DRUG CANDIDATES**

In addition to our clinical-stage drug candidates, we are also developing a number of pre-clinical drug candidates in our pipeline. We meticulously evaluate these drug candidates' toxicity and pharmacological effects in a variety of pre-clinical studies using *in vitro* and *in vivo* laboratory testing techniques, and we actively explore their clinical development opportunities both in and outside China. As of the Latest Practicable Date, we were evaluating three IND-enabling candidates' pharmacokinetic and toxicokinetic in a variety of pre-clinical studies. These candidates have shown encouraging preliminary results in our pre-clinical studies.


Shanghai Miracogen Inc.- Ex. 2032, Page 000394

**LP007**

LP007 is a humanized anti-CD47 mAb employing human IgG4 Fc isotype. CD47, which is a ubiquitously expressed 50-kDa cell surface transmembrane Ig superfamily member protein, interacts with integrins (e.g., αvβ3, αIIbβ3, and α2β1), thrombospondin-1, and serves as a ligand for signal regulatory protein alpha (SIRPα). CD47 is overexpressed on a majority of hematological and solid tumors, with particularly high levels on cancer stem cells (CSCs). Cancer cells can upregulate their CD47 to escape immunosurveillance and dampen anti-tumor responses. However, CD47 is also expressed on red blood cells. Anemia is the target related adverse effect of anti-CD47 antibody in clinics. Therefore, LP007 is a macrophage checkpoint in immune oncology. LP007 can block the interaction between CD47 and its ligand SIRPα stimulated macrophage phagocytosis and was highly effective in leukemia xenograft models. LP007 exhibited no red blood cell agglutination *in vitro* assay and, more importantly, showed good safety in cynomolgus monkey toxicity study. We believe that LP007 has good potential to be used in combination with CD20-targeted therapies. LP007 is being evaluated in multiple pre-clinical studies. We plan to file an IND submission for LP007 to the NMPA in 2022. We have the global rights to develop and commercialize LP007.

**LP010**

LP010 is a humanized anti-TIGIT mAb employing human IgG1 Fc isotype. The immune checkpoint co-inhibitory receptor TIGIT (T cell immunoglobulin and immunoreceptor tyrosine-based inhibitory motif) is expressed on activated or tumor infiltrating CD4-positive T, CD8-positive T, NK cells and regulatory T cells (Tregs). Blocking TIGIT ligation with its ligand CD155 can re-activate tumor antigen-specific CD8-positive T cells and NK cells from immune suppression state and inhibit Treg-mediated immuno suppression in a tumor microenvironment. Roche Tiragolumab showed good clinical efficacy in combination with anti-PD-L1 Tecentriq in NSCLCs in a Phase II clinical trial. Tiragolumab is undergoing Phase III clinical trials in multiple advanced solid tumors. LP010 is a high affinity anti-TIGIT antagonist antibody ($4.62 \times 10^{-11}$M by BIACORE™). LP010 exhibits better cell-based binding, cell-based functional assay and TGI in a MC38-TIGIT humanized mouse model than Tiragolumab. We are developing LP010 as a combination therapy with HX008 for the treatment of solid tumors. LP010 is being evaluated in multiple pre-clinical studies. We plan to file an IND submission for LP010 to the NMPA in 2022. We have the global rights to develop and commercialize LP010.

**LP008**

LP008 is bi-functional protein composed of an anti-PD-L1 mAb fused to the extracellular domain of human TGF-β receptor II, which functions as a "trap" for all three TGF-β isoforms. TGF-β has a pro-tumorigenic role in advanced cancers by promoting immunosuppression, angiogenesis, metastasis, tumor cell EMT (epithelial-mesenchymal transition), and fibroblast activation. Furthermore, TGF-β pathway is activated in PD-1/PD-L1 non-responder and associated with reduced overall survival. Anti-PD-L1-TGFBRII fusion protein can simultaneously antagonize PD-1/PD-L1 pathway and block TGF-β in EMT which reaches the


Shanghai Miracogen Inc.- Ex. 2032, Page 000395

balance of anti-tumor efficacy and safety. M7824 is the anti-PD-L1-TGFBRII bifunctional molecule developed by Merck. M7824 showed good efficacy in NSCLCs, HPV-positive tumors and pancreatic cancer in Phase I clinical trials. LP008 is the anti-PD-L1-TGFBRII fusion protein. LP008 showed better *in vitro* and *in vivo* efficacy than M7824. We believe that LP008 has the potential to treat solid tumor unresponsive to anti-PD-1/anti-PD-L1 antibody therapies. LP008 is being evaluated in multiple pre-clinical studies. We had submitted an IND application with the NMPA for LP008 in December 2021. We have the global rights to develop and commercialize LP008.

## DRUG CANDIDATES WE CO-DEVELOPED THROUGH JOINT VENTURE

### CMG901

CMG901 is a CLDN18.2-targeted ADC for the treatment of G/GEJ carcinoma and pancreatic adenocarcinoma in which CLDN18.2 is highly expressed. It is the first CLDN18.2-targeted ADC to have received the IND approval globally and the most advanced CLDN18.2 ADC to enter clinical development, according to Frost & Sullivan. CLDN18.2 is identified as a highly selective marker for advanced gastric and pancreatic malignancies, as (i) its expression is observed in approximately 60.0% of gastric adenocarcinoma incidences and 50.0% to 70.0% of pancreatic adenocarcinoma incidences; and (ii) its expression remains in gastric cancer metastases following malignant transformation, making it a promising therapeutic target for G/GEJ carcinoma and pancreatic adenocarcinoma.

CMG901 is the first CLDN18.2-targeted ADC entering clinical development globally, according to Frost & Sullivan. It is being co-developed by us and Keymed through KYM, which is a joint venture by us and iBridge, an affiliate of Keymed, and in which we owned 30.0% equity interest as of the Latest Practicable Date. KYM has the exclusive rights to develop, make, have made, use, sell, offer for sale, import and commercialize CMG901 globally.

#### *Mechanism of Action*

CLDN18 is a highly specific tissue junction protein in stomach, expressed in fetal and adult normal gastric mucosa. CLDN18.1 and CLDN18.2 are the two isoforms of CLDN18, which are specific for pulmonary and gastric tissues, respectively.

CLDN18.2 has emerged as one of the promising targets for ADC development in the treatment of G/GEJ carcinoma and pancreatic adenocarcinoma based on its structural advantages. CLDN18 contains four transmembrane domains and two short extracellular loops, with the N- and C-terminals located in the cytoplasm. CLDN18 gene encodes two variants that differ in the first exon, giving rise to the two isoforms (CLDN18.1 and CLDN18.2) which differ in the N-terminal 69 amino acids located at the first extracellular loop.


Shanghai Miracogen Inc.- Ex. 2032, Page 000396

CLDN18.2 is identified as a highly selective marker for advanced gastric malignancy. Its expression is observed in approximately 60.0% of gastric adenocarcinoma and 50.0% to 70.0% of pancreatic adenocarcinoma. CLDN18.2 is normally restricted in gastric mucosa tight junctions and only expresses on the surface of cancer cells following malignant transformation, and its expression remains in gastric cancer metastases following malignant transformation, making it a promising therapeutic target for G/GEJ carcinoma and pancreatic adenocarcinoma.

CMG901 is comprised of a humanized anti-CLDN18.2 antibody (CM311), a highly cytotoxic microtubule disrupting MMAE and a protease-cleavable linker that covalently attaches MMAE to CM311. CMG901 specifically binds CLDN18.2 expressed on the surface of tumor cells and then is internalized into tumor cells through target-mediated endocytosis. Upon lysosomal protease cleavage of the linker, MMAE is released into the cytoplasm, binds to microtubule and inhibits polymerization of microtubule, thereby disrupting microtubule-related functions and eventually leads to tumor cell death.

***Market Opportunity and Competition***

There was no marketed CLDN18.2-targeted therapy in and outside China as of the Latest Practicable Date, according to Frost & Sullivan.

To realize the therapeutic potential of CLDN18.2-targeted antibody therapies, several CLDN18.2-targeted drug candidates have registered clinical trials for the treatment of G/GEJ carcinoma. Notably, zolbetuximab is a chimeric IgG1 antibody exclusively against CLDN18.2, which binds to CLDN18.2 on the surface of tumor cells to stimulate cellular and soluble immune effectors that activate ADCC and CDC. The combination therapy of CLDN18.2 and chemotherapy showed promising efficacy results yet with multiple SAEs, including Grade 3 nausea and vomiting, in the patients enrolled in the clinical trials, thereby prompting the development of additional treatment options that potentially offer better potency and safety profiles. We believe CLDN18.2-targeted ADCs are among the alternative treatment options with reduced toxicity and enhanced efficacy and safety.

Gastric cancer is among the most prevalent and deadly cancers, being the third leading cause of cancer deaths worldwide. Currently, the only potentially curative treatment is surgical resection; however, many patients present with advanced metastatic disease. Despite significant advancement in the treatment of this malignancy, the average five-year survival rate for advanced metastatic gastric adenocarcinoma is approximately 5.0%. There are clear medical needs driving the development of more effective medicines for patients with gastric cancer.


Shanghai Miracogen Inc.- Ex. 2032, Page 000397

***Competitive Advantages***

*Binding of CLDN18.2 with high specificity and high affinity*

In *in vitro* studies jointly conducted by us and Keymed through KYM, CMG901 demonstrated high specificity and optimal affinity in its binding to human CLDN18.2 with a half maximum effective concentrations (EC50) in human cells ranging from 3.39 nM to 6.43 nM.

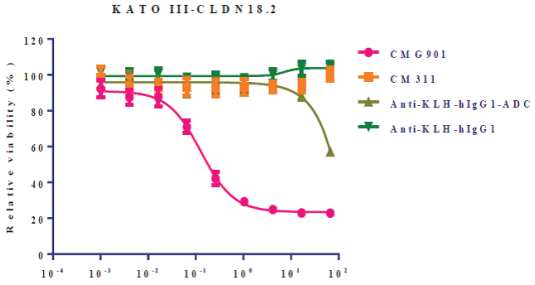
*Strong ability to be internalized into cancer cells rapidly*

In the pre-clinical study using immunofluorescence and flow cytometry methods, CMG901 was found to be internalized into target cells within two hours after administration.

*Potent cancer cell-killing activity*

In a cell-based cytotoxic activity assay, CMG901 induced concentration-dependent cytotoxicity and specificity against target cells at a half maximum inhibitory concentration (IC50) of 0.13 nM.

**Potent *in vitro* cytotoxic activity of CMG901**




| | CMG901 |
|---|---|
| $IC_{50}$(nM) | 0.13 |

*Source: KYM*

*In vivo* anti-tumor activity of CMG901 was evaluated in CLDN18.2 high expressing gastric and pancreatic PDX models in mice. The results demonstrated (i) the *in vivo* anti-tumor activity of CMG901 with tumor regression (-87.9% growth) and stasis (-9.1% growth) occurring at an intravenous (IV) dose of 3 mg/kg in gastric and pancreatic PDX models, respectively; (ii) tumor growth inhibition (TGI) of approximately 60.0% or above was observed at 1 mg/kg in both PDX models. In comparison, the unconjugated antibody CM311 was not effective at comparable doses in these PDX models.


Shanghai Miracogen Inc.- Ex. 2032, Page 000398

*Clinical Development Plan*

KYM was enrolling patients for the Phase I clinical trial of CMG901 in advanced solid tumors including gastric cancer and pancreatic cancer in China as of the Latest Practicable Date. In the meantime, an IND application was submitted to the FDA in February 2021 and approved in March 2021 for a multi-center, open-label, Phase I clinical trial in the U.S. to evaluate the safety, tolerability, and pharmacokinetics of CMG901 in patients with advanced unresectable or metastatic G/GEJ carcinoma.

*Licenses, Rights and Obligations*

CMG901 is being co-developed by us and Keymed through KYM, which is a joint venture established in the U.S. by us and iBridge, and in which Innocube owned 30.0% equity interest as of the Latest Practicable Date. KYM has the exclusive rights to develop, make, have made, use, sell, offer for sale, import and commercialize CMG901 globally. See "– Collaboration, Licensing and Transfer Arrangements – Collaboration with Keymed and iBridge."

*Material Communications with Competent Authorities*

CMG901 received IND approval from the NMPA in October 2020 and the IND clearance from the FDA in March 2021. As of the Latest Practicable Date, we were not aware of any legal claims or proceedings that may have an adverse effect on our development for CMG901. As of the Latest Practicable Date, KYM had received no objections to the clinical development plans with respect to the regulatory review or approval process of CMG901 and no material adverse change had occurred with respect to the regulatory review or approval process of CMG901.

**Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange: WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CMG901 SUCCESSFULLY.**

## COLLABORATION, LICENSING AND TRANSFER ARRANGEMENTS

### Collaboration with JMT

On March 2, 2015, Miracogen Shanghai entered into a patent licensing agreement (the "**JMT Agreement**") with JMT with respect to the development, manufacturing and commercialization of ADCs in China under the licensed patent related to human anti-epidermal growth factor receptor (anti-EGFR) antibodies (the "**Licensed Patent**"). The Licensed Patent was subsequently used in the development of MRG003.



Shanghai Miracogen Inc.- Ex. 2032, Page 000399

**Nature of the rights**: Under the JMT Agreement, JMT granted to Miracogen Shanghai an exclusive, royalty-bearing, non-sublicensable license under the Licensed Patent to develop, manufacture and commercialize ADCs against the target covered by the Licensed Patent. The exclusivity period lasts throughout the contract term. JMT retains the right to use the Licensed Patent for the development, manufacturing and commercialization of antibody drugs or drugs other than ADCs.

**Payments**: As of the Latest Practicable Date, Miracogen Shanghai had paid to JMT (i) a one-time upfront payment of RMB1.5 million; and (ii) RMB5.5 million of the milestone payments upon achievement of certain development milestones, and shall further pay (i) the remaining RMB8 million of the milestone payments as the development advances; and (ii) tiered royalty payments of a low single-digit percentage from the annual sales of the ADCs products under the Licensed Patent. For the purpose of this agreement, "sales" means the invoiced gross sales amount (tax excluded).

**Term and termination**: The JMT Agreement shall remain effective until October 17, 2032 and the exclusivity term shall be the same. The JMT Agreement can be otherwise terminated by JMT if Miracogen Shanghai is unable to perform its obligations under the JMT Agreement.

**Dispute resolution**: Any dispute relating to the JMT Agreement shall be referred to arbitration and settled by Shanghai Arbitration Commission.

**Related drug candidate**: The Licensed Patent was subsequently used in the development of MRG003.

As of the Latest Practicable Date, we did not have any material disputes with JMT in association with the JMT Agreement, and we expect to maintain close and stable relationship with JMT. However, we may not be able to use rights granted under the JMT Agreement if it is terminated in the event where Miracogen Shanghai fails to perform its obligations under the JMT Agreement; and if in the worst case scenario where JMT grants the exclusive licenses underlying the JMT Agreement to other parties, we might no longer be able to commercialize MRG003.

We do not have any residual right under the JMT agreement after expiration.

For intellectual-property-related disputes with third parties, JMT is responsible for prosecution and defense.



Shanghai Miracogen Inc.- Ex. 2032, Page 000400

**Arrangements among us, HanX and Akeso**

Akeso and HanX co-developed the anti-PD-1 antibody candidate, HX008, and jointly applied for patents directed to HX008. We entered into an equity purchase agreement with Ningbo Houde Yimin in June 2018 to obtain the controlling interest of Taizhou Hanzhong. See "History, Development and Corporate Structure – Our Key Subsidiaries and Major Shareholding Changes – Taizhou Hanzhong." Taizhou Hanzhong then entered into an agreement with HanX and Akeso regarding the transfer of HX008 in August 2018. Pursuant to the agreement, HanX transferred its rights jointly held with Akeso in HX008 to Taizhou Hanzhong with nil consideration. Akeso, as the co-developer, agreed to waive its global rights and is not entitled to any other right to disallow or restrict our use of HX008-related patent or technology. Akeso is entitled to a mid single-digit percentage of global sales revenue once HX008 is commercialized until the expiry of the patents. Through such arrangement, we obtained HX008 at Phase Ia stage. Since our acquisition, we initiated a Phase Ib clinical trial in advanced solid tumor and Phase II clinical trials in gastric cancer, NSCLC, TNBC (triple-negative breast cancer), NMIBC and HCC. We initiated registration trials in melanoma and MSI-H/dMMR (high levels of microsatellite instability/deficient mismatch repair) solid tumors. We are also in the process of a Phase III clinical trial in the second-line gastric cancer. We filed an NDA of HX008 with the NMPA in melanoma in June 2021. We submitted pre-NDA meeting application of HX008 in MSI-H/dMMR solid tumors in July 2021, filed an NDA of HX008 with the NMPA in MSI-H/dMMR solid tumors and was granted priority review in October 2021. In addition, nothing has come to our attention that Akeso used the HX008-related patent or technology in its development of AK105, its own pipeline candidate for PD-1 therapies, based on the publicly available information about AK105 and the related patents.

**Patent Arrangements**: As HanX transferred its rights jointly held with Akeso in HX008 to Taizhou Hanzhong in 2018 and Akeso agreed to waive its global rights, Taizhou Hanzhong became the new co-applicant replacing HanX for patents directed to HX008, and shall own the global rights to manufacture, develop and commercialize HX008.

**Termination**: Both parties may terminate the agreement in the event of force majeure and development failure.

**Dispute Resolution**: Parties agree to first try to resolve any dispute through negotiation and mediation, failing which the dispute shall be resolved through legal proceedings before competent local courts in the PRC.

**Related drug candidate**: HX008 (Core Product).

For intellectual-property-related disputes with third parties, HanX is responsible for prosecution and defense. We have the right to independently prosecute upon approval from HanX, or the right to join HanX in such prosecution.



Shanghai Miracogen Inc.- Ex. 2032, Page 000401

As of the Latest Practicable Date, we did not have any material disputes with HanX in association with the license agreement of HX008-related patent or technology, and we expect to maintain close and stable relationship with HanX. However, we may not be able to use rights granted under the agreement if it is terminated in the event of force majeure or development failure; and if in the worst case scenario where HanX grants the exclusive licenses of HX008-related patent or technology to other parties, we might no longer be able to commercialize HX008.

We do not have any no residual right under the agreement after expiration.

We separately entered into a technology development agreement with HanX in February 2019. The services originally covered included various technology service support in purchases of raw materials, CMC manufacturing, testing, and process optimization and preparation of regulatory filings, for an aggregate amount of up to RMB87.6 million (excluding tax, or RMB92.9 million including tax, representing payments to HanX for the coordination services rendered thereunder and payments through HanX to third-party CROs and CDMOs) depending on the actual services rendered, payable in eight installments. Despite the original service scope, the actual services rendered by HanX were primarily coordination services.

The duration of the technology development agreement was from February 13, 2019 to March 31, 2021. During such period, we remained in charge of the overall technical discussion and supervision, decision-making, monitoring and regulatory filings for HX008, contributed by a team of 33 members directly involved in the HX008 project. Our team members have extensive CMC experience, including process development, technology transfer, process characterization and validation, and clinical and commercial manufacturing. Six of our team members have PhD degree, and ten have master's degree. HanX was mainly in charge of coordination, supported by their project managers. We did not renew the technology development agreement as we strengthened our manufacturing and development capability and may manage third-party CROs and CDMOs directly by ourselves since it would be more efficient and cost-effective. Our first production line with capacity of 6,000L is under construction and is expected to support the commercial manufacturing of anti-PD-1 and anti-PD-L1 mAb products.

As we required HanX to provide only a small part of the services originally covered under the technology development agreement prior to its expiration in March 2021 with only a few milestones achieved, we have agreed with HanX to pay a total of RMB25.0 million (representing payments to HanX for the coordination services rendered and the payments made through HanX to third-party CROs and CDMOs). HanX also agreed that we do not need to pay the remaining RMB67.9 million (including tax) as we have no further payment obligations for services HanX did not provide. The payment of RMB25.0 million was completely settled before July 31, 2021. Any potential dispute relating to this technology development agreement shall be referred to arbitration and settled by Beijing Arbitration Commission. We did not have any dispute with HanX as of the Latest Practicable Date.


Shanghai Miracogen Inc.- Ex. 2032, Page 000402

Set forth below are the types of services and contractual amount covered under the technology development agreement, and the actual services rendered by HanX:

| | Services initially offered (the original milestones) under the technology development agreement | Actual services rendered by HanX | Our contribution in the process | Contractual amount (excluding tax) for each part of the services originally covered under the agreement |
|---|---|---|---|---|
| Part I | The technology transfer from Akeso to Chime Biologics Limited ((鼎康(武漢)生物醫藥有限公司), the CDMO engaged by us for clinical and commercial manufacturing. | Coordination services rendered.<br>Managing the technology transfer process. | Technical discussion and supervision, decision-making and monitoring. | RMB400,000 |
| Part II | Preparation for manufacturing process scale up to 2,000L. | Coordination services rendered. | Technical discussion and supervision, decision-making and monitoring. | RMB2,250,000 |
| Part III | Drug substance and drug product manufacturing for clinical supplies. | Coordination services rendered.<br>Coordinating manufacturing activities. | Technical discussion and supervision, decision-making and monitoring. | RMB7,300,000 |
| Part IV | Purchasing key raw materials for manufacturing. | Coordination services rendered.<br>Coordinating the purchase processes. | Decision-making and managing delivery progress. | RMB15,100,000 |
| Part V | Various third-party testing services. | Coordination services rendered. Coordinating with third-party CROs for provision of various testing services. | Monitoring all technology issues and reviewing the final testing reports. | RMB7,400,000 |
| Part VI | Preparing regulatory filings. | Providing partial raw data generated by third-party CROs and used in the preparation of the regulatory filings. | Preparing regulatory filings for CDE approval. | RMB2,100,000 |
| Part VII | Commercial manufacturing. | We required no service. | Planned manufacturing at Chime Biologics Limited. | RMB22,000,000 |
| Part VIII | Process optimization. | Coordination services rendered. Coordinating with third-party CROs for provision of process optimization services. | Parallel process optimization done with promising outcome by our own development and manufacturing team. | RMB31,050,000 |



Shanghai Miracogen Inc.- Ex. 2032, Page 000403

**Collaboration with I-Mab Shanghai and Hangzhou HealSun**

On April 26, 2017, Ningbo Houde Yimin entered into a technology transfer agreement with I-Mab Shanghai, a third-party biopharmaceutical company focusing on novel biologics, and Hangzhou HealSun, a biopharmaceutical company focusing on therapeutic antibody development, with respect to the development of an anti-PD-L1 mAb drug (the "**Yimin Transfer Agreement**"). Hangzhou HealSun is a third-party collaborator for the purpose of developing the anti-PD-L1 mAb drug with I-Mab Shanghai pursuant to the Yimin Transfer Agreement, and they agreed to transfer the cell line for the anti-PD-L1 mAb expression, and exclusively license to Ningbo Houde Yimin certain intellectual property rights for the development, manufacturing and commercialization of the anti-PD-L1 mAb drug globally. The exclusivity period lasts throughout the contract term.

On June 22, 2018, Ningbo Houde Yimin entered into a technology transfer agreement with Taizhou Aoke, under which Ningbo Houde Yimin transferred (i) its rights and obligations under the Yimin Transfer Agreement, (ii) the rights over its subsequent development of the anti-PD-L1 mAb drugs since the Yimin Transfer Agreement, and (iii) its rights and obligations under certain CMC development cooperation arrangements to Taizhou Aoke (the "**Aoke Transfer Agreement**"). An aggregate consideration of RMB112 million was agreed between Ningbo Houde Yimin and Taizhou Aoke, taking into consideration the original RMB80 million consideration under the Yimin Transfer Agreement and the additional rights and obligations being transferred. Taizhou Aoke then held an exclusive, royalty-bearing and sublicensable license to use the rights granted under the Aoke Transfer Agreement effective as of the date of the agreement.

On April 21, 2021, Ningbo Houde Yimin, I-Mab Shanghai, Hangzhou HealSun and Taizhou Aoke entered into an amendment and restatement to the technology transfer and license agreement to amend, ratify and confirm the rights and obligations under the aforementioned agreements (together with the Yimin Transfer Agreement and the Aoke Transfer Agreement, the "**I-Mab Agreements**").

**Nature of the rights and obligations**:

(i) Patent arrangements: Under the I-Mab Agreements, I-Mab Shanghai granted Taizhou Aoke an exclusive, royalty-bearing and sublicensable license to use such existing rights under certain patents and know-how of I-Mab Shanghai for the development of an anti-PD-L1 antibody and the product thereof globally. I-Mab Shanghai is entitled to a preemptive right to repurchase such rights from Taizhou Aoke if the latter seeks to sell or otherwise transfer any of such rights. Taizhou Aoke is entitled to any and all intellectual property rights generated from the research and development activities under the I-Mab Agreements, either developed by itself or by other parties. Any intellectual property rights developed by Taizhou Aoke based on the existing results and intellectual property rights of I-Mab Shanghai and Hangzhou


Shanghai Miracogen Inc.- Ex. 2032, Page 000404

HealSun shall belong to Taizhou Aoke. Hangzhou HealSun does not hold any material intellectual property rights generated from the research and development activities under the I-Mab Agreements.

(ii) R&D arrangements: I-Mab Shanghai and Hangzhou HealSun agreed to assist Taizhou Aoke in the development of the anti-PD-L1 antibody and the product thereof in research and development activities including selecting novel and full-human anti-PD-L1 antibody, selecting cell lines and building cell library, developing production methods and producing the sample drugs, toxicity and pharmacokinetics testing, clinical report preparation and clinical trial applications, with the aim to obtain the IND approval from the NMPA which shall be held in the name of Taizhou Aoke.

(iii) Confidentiality requirements: the parties agree to be bound by confidentiality obligations which prohibit the disclosure of technology, research and product related information to third parties.

**Payments**: Since the Aoke Transfer Agreement, Taizhou Aoke assumed Ningbo Houde Yimin's rights and obligations under the Yimin Transfer Agreement. An aggregate consideration of RMB112 million was agreed between Ningbo Houde Yimin and Taizhou Aoke, taking into consideration the original RMB80 million consideration under the Yimin Transfer Agreement and the additional rights and obligations being transferred. As of the Latest Practicable Date, we had paid up such consideration, while after the first commercial sale of the anti-PD-L1 drug candidate in a jurisdiction, I-Mab Shanghai is entitled to a royalty equal to low single-digit percentage of the net sales of the anti-PD-L1 product, including combination therapies involving the relevant anti-PD-L1 product, in the jurisdiction where we obtain the marketing approval for the anti-PD-L1 drug candidate on an annual basis. For purpose of this agreement, "net sales" means the invoiced gross sales amount excluding primarily amounts of returns, discounts, taxes, freight, handling and insurance costs and any invoiced amounts of products provided free for clinical trials, compassionate use, designated patients in poverty, samples and patient assistance programs.

**Term and termination**: The I-Mab Agreements shall terminate upon fulfillment of contractual obligations by the parties and may be terminated by the non-defaulting party in the event of a breach or by all parties with mutual consent in the event of insurmountable technical difficulties.

**Dispute resolution**: Any dispute relating to the I-Mab Agreements shall be settled by litigation.

**Related drug candidate**: The relevant intellectual property rights under the I-Mab Agreements were subsequently used in the development of LP002 (Core Product).



Shanghai Miracogen Inc.- Ex. 2032, Page 000405

For intellectual-property-related disputes with third parties, I-Mab Shanghai is responsible for prosecution and defense. I-Mab Shanghai has priority in prosecution and we have the right to prosecute if I-Mab Shanghai decides not to proceed.

As of the Latest Practicable Date, we did not have any material disputes with I-Mab Shanghai in association with the I-Mab Agreements, and we expect to maintain close and stable relationship with I-Mab Shanghai. However, we may not be able to use the rights granted under the I-Mab agreements if they are terminated in the event of our material breach or insurmountable technical difficulties; and if in the worst case scenario where I-Mab Shanghai grants the exclusive licenses underlying the I-Mab Agreements to other parties, we might no longer be able to commercialize LP002.

We do not have any residual right under the I-Mab Agreements after expiration.

**Collaboration with CG Oncology**

In March 2019, we entered into a development and license agreement (the "**CG Licensing Agreement**") with CG Oncology for CG Oncology's CG0070 recombinant adenovirus. Under the CG Licensing Agreement, CG Oncology granted us and our affiliates an exclusive, royalty-bearing, non-transferable license under licensed patents and licensed know-how, to develop, manufacture and commercialize CG0070 recombinant adenovirus and/or n-Dodecyl-beta-Maltoside to treat and/or prevent cancer in Mainland China, Hong Kong and Macau. The exclusivity period lasts throughout the contract term. We shall use commercially reasonable efforts to develop CG0070 recombinant adenovirus and/or n-Dodecyl-beta-Maltoside in Mainland China, Hong Kong and Macau at our sole expense, and to commercialize CG0070 recombinant adenovirus and/or n-Dodecyl-beta-Maltoside product in Mainland China, Hong Kong and Macau after receipt of marketing authorization approval. CG Oncology retains the right to manufacture, commercialize and develop CG0070 recombinant adenovirus and/or n-Dodecyl-beta-Maltoside to treat and/or prevent cancer in jurisdictions other than Mainland China, Hong Kong and Macau.

**Joint development committee**: We, together with CG Oncology, shall establish a joint development committee consisting of two representatives from each party. The committee shall oversee, guide, and monitor the development (including conducting clinical trials) and regulatory approval efforts for the products in the use of treating and preventing cancer in Mainland China, Hong Kong and Macau, by (a) reviewing and discussing the progress of the development activities, including any significant difficulties encountered or anticipated in connection therewith, and (b) reviewing and approving any amendments to the development plan. One goal of the joint development committee is to maximize the commercial potential of products in Mainland China, Hong Kong and Macau in the use of treating and preventing cancer while coordinating such efforts with the development and commercialization of the same or similar products outside Mainland China, Hong Kong and Macau) in the use of treating and preventing cancer.


Shanghai Miracogen Inc.- Ex. 2032, Page 000406

**Payments**: As of the Latest Practicable Date, we had paid to CG Oncology a one-time upfront payment of US$4.5 million, and we shall further pay (i) milestone payments upon achieving certain regulatory and commercial sale milestones in the aggregate amount of US$60 million; and (ii) royalty payments of a high single-digit percentage from the annual net sales of CG0070. For the purpose of this agreement, "net sales" means the invoiced gross sales amount excluding primarily amounts of returns, discounts, reimbursements, taxes (except income taxes and withholding taxes), reasonable freight, handling and insurance costs and allowances for non-collectable sales receivables.

**Term and termination**: This agreement shall remain effective until its termination. We may terminate this agreement upon 90 days' prior written notice to CG Oncology on a product-by-product basis. In addition, in the event of a material default, the non-defaulting party is entitled to terminate this agreement, subject to certain conditions. On a product-by-product basis, in the event of termination, (a) all rights and licenses granted to us on a product-by-product basis herein shall terminate and revert to CG Oncology on termination, if any; (b) in the event that we have any ongoing clinical studies with respect to the relevant product as of the effective date of termination, we agree, at CG Oncology's request, to either promptly transition such clinical studies to CG Oncology or continue to conduct and complete such clinical studies, at CG Oncology's expense; (c) we shall, at our own expense, promptly provide CG Oncology with all data and results pertaining, on a product-by-product basis, to the applicable products; (d) we shall, at our own expense, promptly assign or transfer, or cause to be assigned and transferred to CG Oncology (or if not so assignable, we shall take all reasonable actions to make available to CG Oncology the benefits of), all regulatory filings, manufacturing documentation and marketing authorization approvals concerning the relevant products; and (e) all rights granted by us to CG Oncology under this agreement shall survive termination.

**Dispute resolution**: Any dispute relating to the CG Licensing Agreement shall be referred to arbitration and finally settled under the Rules of Arbitration of the International Chamber of Commerce. The arbitration shall take place in the City and State of New York. Each party shall select an arbitrator, and the two arbitrators shall then agree on a third arbitrator who shall be the president of the tribunal.

**Related drug candidate**: CG0070.

For intellectual-property-related disputes with third parties, we are responsible for prosecution and defense, and CG Oncology can join us in such prosecution.

**Collaboration with SYNAFFIX**

On April 9, 2019, Miracogen Shanghai entered into a commercial license and option agreement (the "**Synaffix Licensing Agreement**") with Synaffix with respect to the development, manufacturing and commercialization of ADC globally under GlycoConnect™ and HydraSpace™ (collectively, the "**Licensed Technology**"). The Licensed Technology was applied on MRG004A.



Shanghai Miracogen Inc.- Ex. 2032, Page 000407

**Nature of the rights**: Under the Synaffix Licensing Agreement, Synaffix granted to Miracogen Shanghai:

i. a non-exclusive, transferable, royalty-bearing, sublicensable license under the Licensed Technology to develop, manufacture and commercialize ADCs against human TF, a target with a UniProtKB/Swiss-Prot number of P13726 selected by Miracogen Shanghai (the "**Initial Target**");

ii. an option to obtain a non-exclusive, transferable, royalty-bearing, sublicensable license under the Licensed Technology to develop, manufacture and commercialize ADCs against another target chosen by the Miracogen Shanghai (the "**Second Target**") has been exercised in December 2019.

**Licensed Technology**: The Licensed Technology, including GlycoConnect™ and HydraSpace™, refers to the licensed patents and the know-how that is reasonably necessary to practice the licensed patents. The licensed patents refer to the patents controlled by Synaffix or its affiliates that are reasonably necessary to develop, manufacture, and commercialize an ADC obtained by:

a) (i) enzymatic remodeling of a mAb by concerted action of an endoglycosidase and a glycosyltransferase in the presence of a UDP-sugar; followed by (ii) copper-free click conjugation, or

b) any process or method that constitutes, in whole or in part, a modification, improvement, alternation or enhancement to clauses (i) and (ii) above.

**Sublicensing**: Miracogen Shanghai shall have the right to grant sublicenses to third parties pursuant to a written sublicense agreement.

**Payments**: As of the Latest Practicable Date, Miracogen Shanghai had paid to Synaffix on a target-by-target basis a one-time non-refundable and non-creditable upfront license issuance fee of low seven-figures in US dollars and US$0.8 million in September 2021 upon reaching the first milestone, and shall further pay on a target-by-target basis (i) a one-time non-refundable and non-creditable option exercise fee regarding the Second Target of low seven-figures in US dollars; (ii) non-refundable, non-creditable milestone payments in the aggregate amount of low nine-figures in US dollars upon achievement of certain development and sales milestones; and (iii) tiered royalty payments of low single-digit percentage based on aggregate annual net sales of the ADC products against a licensed target. For the purpose of this agreement, "net sales" means the invoiced gross sales amount excluding primarily amounts of returns, discounts, taxes (except income taxes), freight, handling and insurance costs and reasonable allowances for non-collectable sales receivables.



Shanghai Miracogen Inc.- Ex. 2032, Page 000408

**Term and termination**: The Synaffix Licensing Agreement shall remain effective on a country-by-country and target-by-target basis, unless terminated earlier in accordance with the terms of the Synaffix Licensing Agreement, until the last to expire of any royalty term for each product against each licensed target in such country. Miracogen Shanghai is entitled to terminate the Synaffix Licensing Agreement in its entirety or on a target-by-target basis, upon 30 days' prior notice. Synaffix is not entitled to unilaterally terminate the Synaffix Licensing Agreement. In addition, the Synaffix Licensing Agreement may be terminated due to events including material default, patent challenge and bankruptcy.

**Dispute resolution**: Any dispute relating to the Synaffix Licensing Agreement shall first be presented to the parties' respective executive officers for resolution. If the parties are unable to resolve a given dispute after discussion between the executive officers, the parties consent to the exclusive jurisdiction of the courts located in the Southern District of New York for any action, suit or proceeding.

**Related drug candidate**: The Licensed Technology was subsequently used in the development of MRG004A.

For intellectual-property-related disputes with third parties, Synaffix is responsible for prosecution and defense.

**Collaboration with Keymed and iBridge**

On October 30, 2017, Miracogen Shanghai, a then subsidiary of Miracogen HK, entered into a patent licensing framework agreement with Keymed (the "**Framework Agreement**"). The Framework Agreement was renewed and supplemented on March 3, 2020 pursuant to a supplemental agreement and further supplemented on December 22, 2020 pursuant to another supplemental agreement. As supplemented, (i) Miracogen Shanghai and Keymed agreed to jointly develop and commercialize CMG901 through a joint venture, KYM; (ii) the Framework Agreement is effective until March 2030 and may be renewed by the parties based on arms' length negotiation; (iii) all clinical data and results shall belong to the joint venture to be established; and (iv) any intellectual property rights directed to CMG901 shall be jointly owned by both parties with Miracogen Shanghai holding 30% and Keymed holding 70%.

In July 2018, we acquired 63.01% equity interest in Miracogen Shanghai from Miracogen HK. See "History, Development and Corporate Structure – Our Key Subsidiaries and Major Shareholding Changes – Miracogen Shanghai."

Miracogen HK entered into a joint venture, KYM, with iBridge in February 2020. Miracogen HK hold 30% equity interest in KYM by then. Miracogen HK later agreed to transfer its joint venture interest to us at a nominal value, as we shall assume the rights and obligations under the Framework Agreement through Miracogen Shanghai since our acquisition of the latter's controlling interest.



Shanghai Miracogen Inc.- Ex. 2032, Page 000409

In May 2020, we acquired the remaining 36.99% of the equity interest in Miracogen Shanghai from Miracogen HK, making Miracogen Shanghai our wholly owned subsidiary.

On December 31, 2020, Innocube entered into a stock purchase agreement with Miracogen HK to acquire the 30% equity interest held by Miracogen HK in KYM for a nominal consideration of US$100. The transaction was completed on February 2, 2021.

On January 11, 2021, Innocube, our wholly owned subsidiary, entered into a joint venture agreement (the "**Joint Venture Agreement**") and a stockholders' agreement with, among others, iBridge, for a joint venture, KYM, to develop and commercialize CMG901. On the same date, iBridge and Innocube each entered into a license agreement (collectively, the "**License Agreements**") and a services agreement (collectively, the "**Services Agreements**") for the licensing and services arrangement in connection with CMG901. Under these agreements, KYM shall be responsible for the global development, manufacturing and commercialization of pharmaceutical products based on CMG901 at KYM's own cost and expense. These agreements specify the rights and obligations of the parties to the collaboration under the Framework Agreement.

**Background of the parties**:

(i) Miracogen Shanghai: our wholly owned subsidiary since May 2020.

(ii) Innocube: our wholly owned subsidiary.

(iii) Miracogen HK: a special purpose investment vehicle ultimately wholly owned by Dr. Hu Chaohong, our executive Director and co-chief executive officer.

(iv) Keymed: a third-party biotechnology company focusing on the in-house discovery and development of innovative biological therapies in the autoimmune and oncology therapeutic areas.

(v) iBridge: an affiliate of Keymed.

**Obligations of the parties**: Under the Joint Venture Agreement, Innocube and iBridge agreed (i) to make a capital contribution to KYM of US$30,000 and US$70,000, respectively; (ii) to assign and transfer to KYM their respective rights, title and interest in a patent application covering CMG901; and (iii) to transfer all Miracogen Shanghai and its affiliates' interest in the know-how relating to the manufacturing of CMG901 to KYM.

Under the License Agreements, Innocube and iBridge each granted KYM an exclusive, royalty free and sub-licensable license under the patents and know-how that are related to the antibody drug conjugate containing vcMMAE, and the anti-CLDN18.2 antibody, respectively, for the development, manufacturing and commercialization of CMG901 and retained the rights to use the licensed patents, patent applications and know-how covering CMG901 in order to perform its obligations under the relevant agreements. The exclusivity period lasts throughout the contract term.


Shanghai Miracogen Inc.- Ex. 2032, Page 000410

Under the Services Agreements, iBridge agreed to supply CMG901 antibody and provide research and development, regulatory and operational services to KYM, and Innocube agreed to provide KYM with CMC services for the development of CMG901.

**Nature of the rights**: Under the Joint Venture Agreement, Innocube and iBridge own 30.0% and 70.0%, respectively, equity interests in KYM. The business management and operations of KYM will be controlled and supervised by its board of directors, consisting of three members, with two designated by iBridge and one by Innocube. KYM will fund its operation by the paid-in capital, operating cash flow and additional financing through bank facilities, shareholder loans and/or additional capital contributions if necessary. Innocube and iBridge are entitled to distributable profits of KYM in proportion to the respective equity ownership in KYM.

Under the Services Agreements, KYM shall pay Innocube for the services performed in an amount equal to the service costs plus a prescribed markup.

**Dispute resolution**: Any dispute relating to the Joint Venture Agreement that is not resolved by the parties by negotiation shall be resolved exclusively by binding arbitration before a single arbitrator, conducted by the American Arbitration Association. The parties shall, by mutual agreement, select one independent, neutral arbitrator. If the parties failed to reach agreement upon the selection of arbitrator within 20 business days after a party's written request for binding arbitration, the arbitrator shall be designated by the American Arbitration Association.

**Term and termination**: The Joint Venture Agreement will remain in effect until its termination. The Joint Venture Agreement can be terminated by mutual consent or by either party upon, among others, written notice in the event of (i) uncured material breach, (ii) acquisition of all capital stock by one party, and (iii) change of control of one party.

The License Agreements shall be effective until the expiration or termination of the Joint Venture Agreement.

The Services Agreements shall be effective until the expiration or termination of the Joint Venture Agreement and KYM may terminate the Services Agreements by giving 30 days' written notice to Innocube or iBridge.

**Related drug candidate**: CMG901.

For intellectual-property-related disputes with third parties, iBridge is responsible for prosecution and defense. iBridge has the priority in prosecution and other parties have the right to prosecute without prejudicing iBridge's interest.



Shanghai Miracogen Inc.- Ex. 2032, Page 000411

**Collaboration with Fudan University and SIMMCAS**

On June 4, 2018, Miracogen Shanghai entered into a technology development agreement (the "**Fudan SIMMCAS Agreement**") with Fudan University and the SIMMCAS, with respect to the development of a new ADC, TF-ADC.

**Nature of the rights and obligations**: Under the Fudan SIMMCAS Agreement, Fudan University and the SIMMCAS granted Miracogen Shanghai an exclusive right to use the technology, patent and know-how developed by Fudan University and the SIMMCAS related to TF-ADC (the "**TF-ADC Technology**") to develop, manufacture and commercialize TF-ADC in China. The exclusivity period lasts throughout the contract term. Miracogen Shanghai is obligated to keep Fudan University and the SIMMCAS informed regarding the process of development, manufacturing and commercialization of TF-ADC in China, while Fudan University and the SIMMCAS are obligated to provide Miracogen Shanghai with necessary support to the commercialization of TF-ADC in China. In relation to the overseas development, Miracogen Shanghai is obligated to file and maintain relevant patent applications overseas, apply for the necessary approvals for pre-clinical studies and conduct clinical studies overseas. The profit for overseas development will be distributed among the parties based on their respective contribution upon mutual agreement.

**Payments**: With respect to the development, manufacturing and commercialization of TF-ADC in China, as of the Latest Practicable Date, Miracogen Shanghai had paid to Fudan University and the SIMMCAS a one-time, upfront technology transfer fee of RMB10 million, and shall further pay (i) milestone payments upon achievement of certain development milestones in the aggregate amount of RMB50 million; and (ii) sales commission accounting for less than 10.0% of the aggregate annual sales of the TF-ADC products under the TF-ADC Technology. For purpose of this agreement, "sales" means the invoiced gross sales amount (tax excluded).

**Term and termination**: The Fudan SIMMCAS Agreement shall remain effective until June 30, 2038. If any party deems that any matter stipulated in the Fudan SIMMCAS Agreement has not been addressed, such party shall, according to the Fudan SIMMCAS Agreement, notify the other party in writing to renew the Fudan SIMMCAS Agreement or memorandum after negotiation in good faith.

**Dispute resolution**: Any dispute relating to the Fudan SIMMCAS Agreement shall be referred to arbitration and settled by Shanghai Arbitration Commission.

**Related drug candidate**: MRG004A.

For intellectual-property-related disputes with third parties, all parties have the right to prosecute and defend. Fudan University and the SIMMCAS can delegate the responsibilities to Miracogen Shanghai, but all parties shall defray the expenses and costs equally.



Shanghai Miracogen Inc.- Ex. 2032, Page 000412

## RESEARCH AND DEVELOPMENT

We are committed to developing innovative biopharmaceutical drugs in targeted therapy, represented by our ADC candidates, and immuno-oncology therapy, represented by our anti-PD-1/anti-PD-L1 antibody candidates. See "– Clinical-Stage Drug Candidates" and "– Pre-clinical Drug Candidates." We are also dedicated to the development of combination therapies, which we believe to be a significant improvement in terms of efficacy as compared to monotherapies due to the synergies from the combination of targeted therapy and immuno-oncology therapy. See "– Combination Therapies Within Our Pipeline." We incurred research and development expenses of RMB229.2 million, RMB354.4 million and RMB509.5 million in 2019, 2020 and the eight months ended August 31, 2021, respectively.

### Our Research and Development Platforms

Our biopharmaceutical research and development capabilities consist of three specialized platforms targeting a variety of biological therapies, including the ADC technology platform, the antibody discovery platform, and the advanced process and analytical development platform. This system serves as a solid foundational technology solution for discovering and developing next-generation ADC and immuno-oncology candidates.

#### *Clinically-validated ADC Technology Platform*

Our ADC technology platform enables us to design and develop ADC candidates with strong safety and efficacy profile.

We have a fully integrated ADC technology platform covering the whole process of research, development and manufacturing of ADCs. The key functionalities of our ADC platform include (i) process development for antibody, linker and payload; (ii) advanced conjugation technologies; (iii) optimization technologies that realize precise control of DAR; (iv) quality analysis and evaluation for antibody, linker and payload; and (v) manufacturing and quality control of ADC DS and DP in compliance with the cGMP standards.

The complex structure of ADCs leads to the more technically difficult and complex CMC development and manufacturing than those of mAbs. Depending on clinical needs, we can select through our ADC platform antibodies with desirable binding properties, payloads with well-validated cell-killing potency and manageable toxicity, and linkers that are adequately stable in blood circulation and release payloads effectively when the ADC is internalized. Such optimal combination helps the accurate targeting and effective release of the payload, resulting in tumor cell death. Supported by our study on the relationship between the manufacturing parameter and the ratio of payload and antibody, our platform is also able to carefully examine and precisely control the DAR in the manufacturing process, to achieve the optimal balance of safety and efficacy. We conduct the modification of antibodies and ADC conjugation in the closed container to make it a continuous process. Leveraging our in-depth knowledge on ADC development, we also reduce the impurities generated during the manufacturing. As a result, we lower our production costs and improve the yield to around 100%. Based on our ADC


Shanghai Miracogen Inc.- Ex. 2032, Page 000413

technology platform, we are also able to realize the GMP-compliant manufacturing process and high quality for ADCs under an effective quality management system. Our ADC platform is supported by a team of 15 well-trained and specialized staff. We incurred expenses of RMB5.3 million, RMB3.5 million and RMB3.1 million in 2019 and 2020 and the eight months ended August 31, 2021, respectively, for our ADC platform.

We in-licensed GlycoConnect™ site-specific conjugation technology, HydraSpace™ polar spacer technology and relevant patents directed to our ADC platform from Synaffix. See "– Intellectual Property Rights."

Leveraging our ADC technology platform, we have developed four clinical-stage ADC drug candidates, and one drug candidate jointly developed with a third-party through a joint venture. Our leading ADC products, MRG003 and MRG002 have demonstrated favorable efficacy and safety profiles in clinical studies. See "– Clinical-Stage Drug Candidates."

***Antibody Discovery Platform***

We have constructed a full human naive antibody library of $10^{11}$ scale. Leveraging phage display technology, our *in vitro* screening system on the platform reduces the reliance on animal immune systems to produce antibodies. The screening technology allows us to significantly shorten the development period of innovative drug candidates to four to six weeks, compared to the traditional hybridoma technology which generally takes four to six months. We have also constructed a trispecific antibody T cell engager platform by utilizing protein binding domains, such as nanobodies and scFv, to augment T cells' response to solid tumors. Our antibody discovery platform is supported by three research and development staff. We incurred expenses of RMB0.6 million and RMB1.4 million in 2020 and the eight months ended August 31, 2021, respectively, for our antibody discovery platform.

The core technology of our antibody discovery platform is the phage display technology. The key patent rights directed to the phage display technology entered into the public domain since 2011, giving us free access to such technology. In addition, the application of such core technology requires experience and expertise of qualified research and development staff. Such expertise does not commonly take the forms of patentable processes and technologies. See "Risk Factors – If we are unable to obtain and maintain patent and other intellectual property protection for our drug candidates, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and our ability to successfully commercialize any product or technology may be adversely affected."


Shanghai Miracogen Inc.- Ex. 2032, Page 000414

***Advanced Process and Analytical Development Platform***

The cultivation and manufacturing of antibodies can be challenging in multiple aspects such as process and analytical issues, production yield and purity. Our process and analytical development platform for antibodies and ADCs supports mass production in a cost-effective manner.

Our process and analytical development platform includes the following main functionalities: (i) the construction of GMP-compliant cell banks; (ii) the separation and purification process which improves product purity; and (iii) the analytical methods and detection technology for the biopharmaceutical characteristics of antibodies.

Our process and analytical development platform includes the following main functionalities:

(i) the construction of GMP-compliant cell banks supported by cell line screening and targeted optimization of product quality;

(ii) the separation and purification process which improves product purity;

(iii) the analytical methods and detection technology for the biopharmaceutical characteristics of antibodies, including physiochemical analysis, biological activity analysis and structure elucidation, which enable us to control and optimize the quality of our antibody products; and

(iv) formulation development that enables us to develop stable mAbs, which could be stored at a temperature between 2°C to 8°C for up to four years.

Our process and analytical development platform is supported by 35 research and development staff. We incurred expenses of RMB4.0 million, RMB14.6 million and RMB7.6 million in 2019, 2020 and the eight months ended August 31, 2021, respectively, for our process and analytical development platform.

The process and analytical development relies heavily on the experience and expertise of our research and development staff. The designs of such processes are constantly adjusted and improved and may vary significantly in different settings. As a result, the know-how related to such designs are typically not protected through intellectual property rights. We believe that the risk of our design infringing third-party intellectual property right is remote. See "Risk Factors – If we are unable to obtain and maintain patent and other intellectual property protection for our drug candidates, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and our ability to successfully commercialize any product or technology may be adversely affected."

Leveraging our process and analytical development platform, we have optimized the manufacturing process of our pipeline products HX008 and LP002, which have demonstrated promising safety and efficacy profiles in clinical studies. See "– Pre-clinical Drug Candidates."



Shanghai Miracogen Inc.- Ex. 2032, Page 000415

**Our Research and Development Team**

Our dedicated research and development team engages in pre-clinical studies and clinical development. As of the Latest Practicable Date, our research and development team had 200 members. Key members of our research and development team are experts in the biopharmaceutical industry. Many of our research and development team members have worked on biotechnology research at renowned research institutions and multinational corporations and have profound experience in drug discovery and development. On average, senior members of our research and development team have 20 years' experience working on the research and development of oncology drug products.

Our pre-clinical study section focuses on identifying molecules with proven or highly potential efficacy and significant market opportunities, and early process development. As of the Latest Practicable Date, it was comprised of 112 members. Our pre-clinical study section identifies, at an early stage, characteristics of a drug candidate that could hinder clinical trials or the efficient manufacturing of a drug candidate so these issues can be addressed efficiently before the drug candidate progresses to the next stage of development.

Our clinical development section manages processes including clinical trial design, implementation, the collection and analysis of trial data, and regulatory affairs. As of the Latest Practicable Date, it was comprised of 88 members. Our clinical development sector is primarily responsible for the following: (i) design of clinical trials, (ii) selection of registration pathways, (iii) efficient execution of clinical trials and data quality, and (iv) constructive dialogs with the regulators to achieve optimal clinical efficacy and accelerate the approval process of our drug candidates.

We are also dedicated to the implementation of our clinical development activities in overseas markets. To execute our international development strategy, as of the Latest Practicable Date, we were building up a research and development center in Houston, Texas, the U.S. and had recruited six personnel for duties including research and development and operational management.

**Engagement of Third Parties in Research and Development**

To reduce risk and improve efficiency, we engage experienced and qualified third parties such as CROs, SMOs, CDMOs and hospitals to manage, conduct and support our pre-clinical studies and clinical trials in China and the U.S., which is in line with the general practice in the industry.

We engage CROs to provide research services including (i) molecular screening and efficacy and toxicokinetic study at the pre-clinical-stage; and (ii) screening clinical research sites, recruiting patient participants, training of clinical trial staff and verification and analysis of the data recorded in clinical studies according to the relevant laws and regulations as well as our clinical study processes and procedures at the clinical stage.



Shanghai Miracogen Inc.- Ex. 2032, Page 000416

We engage SMOs to provide clinical trial site management services. According to the requirements of relevant hospital and research centers, SMOs designate qualified clinical study coordinators to conduct site management services, including data collection and patient follow up, which are not related to the diagnosis and treatment.

We engage CDMOs to manufacture drug candidates for clinical trial use and provide manufacturing process development and optimization services.

We procured readily available clinical trial facilities and services from hospitals. In addition, we collaborate with principal investigators, who are generally chief physicians or associate chief physicians from Class III Grade A hospitals in China, and are responsible for the implementation, quality and safety of clinical trials and the protection of patient rights. The principal investigators make medical decisions related to the clinical trials and are obliged to ensure that the patients are given proper treatment.

We are the owner of the drug candidates and the sponsor of the relevant clinical development activities. We are in charge of the full lifecycle management of the of the drug candidate, including research and development, manufacturing and commercialization. We make key decisions regarding the overall development direction, clinical trial plans and procedures, and provide funding.

The involvement and roles of third-parties service providers in the development of novel molecule drug candidates are typically standardized and similar among different projects. The work scope of these third parties in the development of our drug candidates may have slight variation, subject to our overall management and instructions.

The following table sets forth the number of third parties including CROs, SMOs, CDMOs and hospitals we engaged during the Track Record Period.

| | 2019 | 2020 | The eight months ended August 31, 2021 |
|---|---|---|---|
| **CRO** | 28 | 91 | 140 |
| **SMO** | 8 | 13 | 12 |
| **CDMO** | 11 | 8 | 7 |
| **Hospitals** | 47 | 136 | 154 |

The total fees paid by us to third parties including CROs, SMOs, CDMOs and hospitals involved in our research and development activities and clinical trials were RMB139.1 million, RMB229.0 million and RMB261.6 million in 2019, 2020 and the eight months ended August 31, 2021, respectively.



Shanghai Miracogen Inc.- Ex. 2032, Page 000417

The following table sets forth the identities and background of the key CROs, SMOs, CDMOs, and hospitals engaged by us, and the amount of service fees paid to each of them.

| | Name/ Background | Involvement | Service fee paid by us during the Track Record Period | Service fee paid by us during the Track Record Period as a percentage of the total fees paid by us to third parties including CROs, SMOs, CDMOs and hospitals |
|---|---|---|---|---|
| **CRO** | Beijing Highthink Pharmaceutical Technology Service Co., Ltd. (北京海金格醫藥科技股份有限公司) | Provision of clinical trial project management, inspection and verification services in the development of our anti-PD-1 and PD-L1 drug candidates. | RMB30.6 million | 4.9% |
| | WuXi Clinical Development Services (Shanghai) Co., Ltd. (上海康德弘翼醫學臨床研究有限公司) | Provision of clinical trial project management, inspection and verification services in the development of MRG001, MRG002 and MRG003. | RMB52.7 million | 8.4% |



Shanghai Miracogen Inc.- Ex. 2032, Page 000418

| | Name/ Background | Involvement | Service fee paid by us during the Track Record Period | Service fee paid by us during the Track Record Period as a percentage of the total fees paid by us to third parties including CROs, SMOs, CDMOs and hospitals |
|---|---|---|---|---|
| **SMO** | SMO ClinPlus Co., Ltd. (普蕊斯(上海)醫藥科技開發股份有限公司) | Provision of clinical trial site management services in the development of our anti-PD-1 and PD-L1 drug candidates. | RMB7.1 million | 1.1% |
| | Medpison (Guangzhou) Medical Technology Co., Ltd. (比遜(廣州)醫療科技有限公司) | | RMB4.0 million | 0.6% |
| **CDMO** | Chime Biologics Limited (鼎康(武漢)生物醫藥有限公司 | Provision of manufacturing process development and optimization services in the development of HX008. | RMB36.4 million | 5.8% |
| | WuXi Biologics (Shanghai) Co., Ltd. (上海藥明生物技術有限公司) | Provision of manufacturing in the development of MRG001, MRG002, MRG003 and MRG004A. | RMB35.8 million | 5.7% |



Shanghai Miracogen Inc.- Ex. 2032, Page 000419

| | Name/ Background | Involvement | Service fee paid by us during the Track Record Period | Service fee paid by us during the Track Record Period as a percentage of the total fees paid by us to third parties including CROs, SMOs, CDMOs and hospitals |
|---|---|---|---|---|
| **Hospitals** | An oncology hospital in Beijing | Designated doctors to act as the principal investigator responsible for the implementation, quality and safety of clinical trials and the protection of patient rights in the clinical trial of anti-PD-1 and PD-L1 drug candidates. | RMB14.7 million | 2.3% |
| | An oncology hospital in Beijing | | RMB7.4 million | 1.2% |
| | An oncology hospital in Shanghai | | RMB6.8 million | 1.1% |

Except for Beijing Highthink Pharmaceutical Technology Service Co., Ltd. where Dr. Pu Zhongjie serves as a director, none of the above mentioned key CROs, SMOs, CDMOs and hospitals has any past or present relationships (business, employment, family, trust, financing or otherwise) with us, our Directors, Shareholders, senior management or any of their respective associates other than the above mentioned transactions during the Track Record Period.

We selected our CROs, SMOs, CDMOs, hospitals and other third-party service providers weighing various factors, such as professional experience, qualification and industry reputation. We closely monitor these third-party service providers to ensure their compliance with our quality control procedures and applicable laws and the integrity of the data resulting from our trials and studies. We also have procedures in place to prevent potential infringement and leakage of our intellectual property rights. All intellectual property rights arising from third-party assisted researches and trials will be owned by us.



Shanghai Miracogen Inc.- Ex. 2032, Page 000420

## INTELLECTUAL PROPERTY RIGHTS

Intellectual property rights, including patents, trade secrets, trademarks and copyrights are critical to our business. Our success depends in part on our ability to obtain and maintain proprietary intellectual property protection for our drug candidates, discoveries, product development technologies, inventions, improvements and know-how. Our success also depends in part on our ability to defend and enforce our patents including any patent that we have or may issue from our patent applications, preserve the confidentiality of our trade secrets and other confidential or proprietary information, and operate without infringing, misappropriating or otherwise violating intellectual property rights of other parties. To this end, we have set up our own intellectual property department housing experienced and trained professionals, and hired external patent firms to assist us in intellectual property rights work and disputes, including work and disputes related to our licensing agreements. With the support of our intellectual property department and external patent counsels, we conduct due diligence work on the intellectual property rights of potential products targeted for in-license arrangements prior to the license-in, with the aim to spot red flags and escalate these issues if found any. We won't enter into a formal licensing agreements if any of the red-flagged issues cannot be fully resolved. In addition, to further protect ourselves from potential intellectual property disputes, we require licensors to provide representations and warranties in their in-license agreements.

We have a portfolio of patents to protect our drug candidates and technologies. As of the Latest Practicable Date, we had (i) 11 issued patents in China, 20 in the U.S., nine in Japan, seven in the European Union and one in each of South Korea, Australia, Chile, India, Colombia, Indonesia, New Zealand and Israel, and (ii) 74 pending patent applications, consisting of 15 in Mainland China, and 59 in overseas jurisdictions such as the U.S., Japan, South Korea, Australia, Israel, India and the European Union. Our patent portfolio spans across mAb structure, targeted epitope, CMC, usage, biopharmaceutical formulation and indications. With respect to our Core Products, we had six issued patents and five pending patent applications in China, as well as 18 issued patents and 27 pending patent applications in overseas jurisdictions as of the Latest Practicable Date.

The patent portfolio for our clinical-stage drug candidates and platform as of the Latest Practicable Date is summarized below:

- **MRG003**: As of the Latest Practicable Date, we were granted one Chinese patent and one U.S. patent, and were licensed by JMT with one issued Chinese patent for MRG003. The Chinese patents are expected to expire in February 2036 and October 2032, respectively and the U.S. patent is expected to expire in September 2036. We had three pending patent applications in Mainland China, one pending PCT patent application and one pending patent application in Hong Kong. The Chinese patent that may be issued from the currently pending patent application is expected to expire in February 2036, without taking into account any possible patent term adjustments or extensions and assuming payments of all appropriate maintenance, renewal, annuity and other government fees will be timely made.


Shanghai Miracogen Inc.- Ex. 2032, Page 000421

- **MRG002**: As of the Latest Practicable Date, we had one pending Chinese patent application and three pending patents in overseas jurisdictions such as the U.S., the EU and Japan. The patents that may be issued from the currently pending patent application is expected to expire in June 2038, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees will be timely made.

- **HX008**: As of the Latest Practicable Date, we and Akeso jointly owned two issued Chinese patents, two issued U.S. patents, two issued European patents, one issued Japan patent, three pending patent applications in overseas jurisdictions in Japan related to HX008. The issued Chinese patents are expected to expire in April 2036 and January 2037, respectively. The issued U.S. patents are expected to expire in January 2037 and October 2036, respectively, the issued European patents are expected to expire in October 2036 and January 2037, and the issued Japanese patent is expected to expire in October 2036. As of the Latest Practicable Date, we were licensed by HanX with one issued Japanese patent and two pending patent applications in overseas jurisdictions including the European Union and the U.S. related to HX008. The issued Japanese patent is expected to expire in January 2037. The patents that may be issued from the currently pending patent applications are expected to expire within the period from October 2036 to January 2037, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees will be timely made.

- **LP002**: As of the Latest Practicable Date, we were licensed by I-Mab Shanghai with one issued Chinese patent, one PCT patent (with one issued Chinese patent and eleven patents issued in overseas jurisdictions such as the U.S., Japan, South Korea, Australia, Chile, Colombia, Indonesia, Israel and New Zealand) related to LP002, which is expected to expire within the period from 2036 to 2037. We were licensed by I-Mab Shanghai with 17 pending patent applications in overseas jurisdictions and one pending patent application in Mainland China. The patents that may be issued from the currently pending patent application is expected to expire in June 2037, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees will be timely made.

- **MRG001**: As of the Latest Practicable Date, we had one pending PCT patent application. The patent that may be issued from the currently pending patent application is expected to expire in May 2040, without taking into account any possible patent term adjustments or extensions and assuming payments of all appropriate maintenance, renewal, annuity and other government fees will be timely made.


Shanghai Miracogen Inc.- Ex. 2032, Page 000422

- **MRG004A**: As of the Latest Practicable Date, we owned two issued Chinese patents, two issued Japanese patents and one issued U.S. patent related to MRG004A. The issued Chinese patents are expected to expire in August 2036 and March 2037, respectively, the issued Japanese patents are expected to expire in February 2037 and June 2037, respectively, and the issued U.S. patent is expected to expire in February 2037; we had three pending patent applications in overseas jurisdictions including the U.S. and the European Union. The patents that may be issued from the currently pending patent application are expected to expire within the period from February 2037 to June 2037, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees will be timely made.

- **CG0070**: As of the Latest Practicable Date, we were licensed by CG Oncology with three pending Chinese patents related to CG0070, which is expected to expire within the period from 2036 to 2038.

- **CMG901**: As of the Latest Practicable Date, Miracogen Shanghai and Keymed jointly owned one pending Chinese patent related to CMG901. The patent that may be issued from the currently pending patent application is expected to expire in October 2040, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees will be timely made.

- **ADC Platform**: As of the Latest Practicable Date, related to our ADC platform, we were licensed by Synaffix with three issued patents in China, ten in the U.S., five in the European Union, four in Japan and one in India, which are expected to expire within the period from 2031 to 2037. We were licensed by Synaffix with five pending Chinese patent applications and 19 pending patent applications in overseas jurisdictions. The patents that may be issued from the currently pending patent application are expected to expire within the period from 2031 to 2037, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees will be timely made.


Shanghai Miracogen Inc.- Ex. 2032, Page 000423

The following table summarizes the details of the material granted patents and the filed patent applications owned by us or shared with our collaborators on our clinical-stage drug candidates:

| Product | Applicant/ Patentee | Title of Patent/ Patent Application | Jurisdiction | Status | Application Date | Expiration Date | Commercial Rights |
|---|---|---|---|---|---|---|---|
| | Miracogen Shanghai | Antibody-Drug Conjugate | Mainland China | Granted | February 16, 2016 | February 16, 2036 | All rights in Mainland China |
| | Miracogen Shanghai | Antibody-Drug Conjugate | U.S. | Granted | February 16, 2016 | September 28, 2036 | All rights in the U.S. |
| | Miracogen Shanghai | Antibody-Drug Conjugate (抗體藥物偶聯物) | Mainland China, Hong Kong | Pending | Range from February 16, 2016 to October 14, 2020 | N/A | All rights in related jurisdictions |
| | Miracogen Shanghai | Use of Antibody-drug Conjugate, Combination Drug and Use thereof (抗體藥物偶聯物的用途及聯合用藥物及其用途) | Mainland China | Pending | September 16, 2021 | N/A | All rights in Mainland China |
| MRG003 | Miracogen Shanghai | Composition of Antibody-drug Conjugate and Use thereof (抗體藥物偶聯物製劑及其用途) | Mainland China | Pending | September 16, 2021 | N/A | All rights in Mainland China |
| | Miracogen Shanghai | Composition of Antibody-drug Conjugate and Use Thereof (抗體藥物偶聯物製劑及其用途) | PCT | Pending | September 16, 2021 | N/A | All rights worldwide |
| | JMT | Humanized antibody against epidermal growth factor receptor and application thereof (人源化抗表皮生長因子受體抗體及其用途) | Mainland China | Granted | October 17, 2012 | October 17, 2032 | Exclusive license to develop and commercialize in Mainland China |
| MRG002 | Miracogen Shanghai | Methods and Materials for Treating Cancer (治療癌症的方法和材料) | PCT (U.S., Europe Union, Mainland China, Japan) | Pending | June 15, 2018 | N/A | All rights worldwide |



Shanghai Miracogen Inc.- Ex. 2032, Page 000424

| Product | Applicant/ Patentee | Title of Patent/ Patent Application | Jurisdiction | Status | Application Date | Expiration Date | Commercial Rights |
|---|---|---|---|---|---|---|---|
| HX008 | Taizhou Hanzhong and Akeso[1] | Anti-PD-1 Monoclonal Antibody (抗PD-1的單克隆抗體) | Mainland China | Granted | April 1, 2016 | April 1, 2036 | All rights in Mainland China |
| | Taizhou Hanzhong and Akeso[1] | Monoclonal Antibody Resisting Against PD-1 and Applications Thereof (抗PD-1的單克隆抗體及其應用) | Mainland China | Granted | January 13, 2017 | January 13, 2037 | All rights in Mainland China |
| | Taizhou Hanzhong and Akeso[1] | Monoclonal Antibody Resisting Against PD-1 and Applications Thereof | U.S., European Union | Granted | January 13, 2017 | January 13, 2037 | All rights in the related jurisdictions |
| | Taizhou Hanzhong and Akeso[1] | Anti-PD-1 Monoclonal Antibody | PCT (Japan) | Pending | October 28, 2016 | N/A | All rights in related jurisdictions |
| | Taizhou Hanzhong and Akeso[1] | Anti-PD-1 monoclonal antibody | PCT (Japan, U.S., European Union) | Granted | October 28, 2016 | October 28, 2036 | All rights in related jurisdictions |
| | Taizhou Hanzhong and Akeso[1] | Monoclonal Antibody Resisting Against PD-1 and Applications Thereof | PCT (Japan) | Pending | January 13, 2017 | N/A | All rights in Japan |
| | HanX[2] | Method for increasing binding affinity of IGG-Like antibody to FcRn and prolonging serum half-life period thereof | PCT (European Union, U.S.) | Pending | January 13, 2017 | N/A | Non-exclusive license to develop and commercialize worldwide |
| | Han X | Method for increasing binding affinity of IGG-Like antibody to FcRn and prolonging serum half-life period thereof | PCT (Japan) | Granted | January 13, 2017 | January 13, 2037 | Non-exclusive license to develop and commercialize in Japan |



Shanghai Miracogen Inc.- Ex. 2032, Page 000425

| Product | Applicant/ Patentee | Title of Patent/ Patent Application | Jurisdiction | Status | Application Date | Expiration Date | Commercial Rights |
|---|---|---|---|---|---|---|---|
| | I-Mab Shanghai[3] | Anti-PD-L1 Antibodies and Uses Thereof (PD-L1抗體及其用途) | Mainland China | Granted | June 13, 2016 | June 13, 2036 | Exclusive license to develop and commercialize in Mainland China |
| | I-Mab Shanghai[3] | Anti-PD-L1 Antibodies and Uses Thereof (PD-L1抗體及其用途) | PCT (Mainland China, US, South Korea, Japan, Australia, Chile, Colombia, Indonesia, Israel, New Zealand) | Granted | June 13, 2017 | June 13, 2037 | Exclusive license to develop and commercialize in related jurisdictions |
| LP002 | I-Mab Shanghai[3] | Anti-PD-L1 Antibodies and Uses Thereof (PD-L1抗體及其用途) | PCT (Mainland China, U.S., European Union, Canada, Eurasian Patent Organization, Japan, Australia, Singapore, Brazil, Mexico, Malaysia, Philippines, India, South Africa, Peru, Ukraine, Hong Kong) | Pending | June 13, 2017 | N/A | Exclusive license to develop and commercialize in related jurisdictions |
| MRG001 | Miracogen Shanghai | ADC and Preparations Thereof | PCT | Pending | May 3, 2020 | N/A | All rights worldwide |
| MRG004A (mAb TF) | Miracogen Shanghai and Fudan University | Antibody Targeted to TF, Preparation Method Thereof, and Use Thereof | Mainland China | Granted | August 22, 2016 | August 22, 2036 | All rights |
| | Miracogen Shanghai and Fudan University | Antibody Targeted to TF, Preparation Method Thereof, and Use Thereof | PCT (U.S., Japan) | Granted | February 20, 2017 | February 20, 2037 | Joint development and technology transfer |
| | Miracogen Shanghai and Fudan University | Antibody Targeted to TF, Preparation Method Therefor, and Use Thereof | PCT (European Union) | Pending | February 20, 2017 | N/A | Joint development and technology transfer |



Shanghai Miracogen Inc.- Ex. 2032, Page 000426

| Product | Applicant/ Patentee | Title of Patent/ Patent Application | Jurisdiction | Status | Application Date | Expiration Date | Commercial Rights |
|---|---|---|---|---|---|---|---|
| MRG004A (ADC) | Miracogen Shanghai, Fudan University and SIMMCAS | Tissue Factor-Targeted Antibody-Drug Conjugate (靶向於組織因子的抗體-藥物偶聯物) | Mainland China | Granted | March 3, 2017 | March 3, 2037 | All rights |
| | Miracogen Shanghai, Fudan University and SIMMCAS | Tissue Factor-Targeted Antibody-Drug Conjugate | PCT (Japan) | Granted | June 9, 2017 | June 9, 2037 | Joint development and technology transfer |
| | Miracogen Shanghai, Fudan University and SIMMCAS | Tissue Factor-Targeted Antibody-Drug Conjugate | PCT (European Union, U.S.) | Pending | June 9, 2017 | N/A | Joint development and technology transfer |
| CG0070 | CG Oncology | Methods of Treating Bladder Cancer (治療膀胱癌的方法) | PCT (Mainland China) | Pending | April 13, 2018 | N/A | Exclusive license to develop and commercialize in Mainland China |
| | CG Oncology | Methods of Treating Solid or Lymphatic Tumors by Combination Therapy (通過聯合療法來治療實體瘤或淋巴瘤的方法) | PCT (Mainland China) | Pending | March 9, 2017 | N/A | Exclusive license to develop and commercialize in Mainland China |
| | CG Oncology | Methods of Treating Solid or Lymphatic Tumors by Combination Therapy (通過組合療法治療實體或淋巴腫瘤的方法) | PCT (Mainland China) | Pending | October 18, 2016 | N/A | Exclusive license to develop and commercialize in Mainland China |
| CMG901 | Miracogen Shanghai and Keymed | ADC and Applications Thereof | Mainland China | Pending | October 15, 2020 | N/A | Exclusive rights via KYM |



Shanghai Miracogen Inc.- Ex. 2032, Page 000427

| Product | Applicant/ Patentee | Title of Patent/ Patent Application | Jurisdiction | Status | Application Date | Expiration Date | Commercial Rights |
|---|---|---|---|---|---|---|---|
| | Synaffix | Fused Cyclooctyne Compounds and Their Use in Metal-Free Click Reactions | PCT (Mainland China, European Union, Japan, U.S., India) | Granted | April 26, 2011 | April 26, 2031 | Non-exclusive license to develop and commercialize in related jurisdictions |
| ADC Platform | Synaffix | Fused Cyclooctyne Compounds and Their Use in Metal-Free Click Reactions | PCT (U.S.) | Granted | April 26, 2011 | July 1, 2031 | Non-exclusive license to develop and commercialize in related jurisdictions |
| | Synaffix | Fused Cyclooctyne Compounds and Their Use in Metal-Free Click Reactions | PCT (Mainland China, European Union) | Pending | April 26, 2011 | N/A | Non-exclusive license to develop and commercialize in related jurisdictions |
| | Synaffix | Modified Antibody, Antibody-Conjugate and Process for the Preparation Thereof | PCT (Mainland China, European Union, Japan, U.S.) | Granted | October 23, 2013 | October 23, 2033 | Non-exclusive license to develop and commercialize in related jurisdictions |
| | Synaffix | Modified Antibody, Antibody-Conjugate and Process for the Preparation Thereof | PCT (U.S.) | Granted | October 23, 2013 | March 22, 2034 | Non-exclusive license to develop and commercialize in related jurisdictions |
| | Synaffix | Modified Antibody, Antibody-Conjugate and Process for the Preparation Thereof | PCT (Mainland China, European Union, Japan, U.S., India) | Pending | October 23, 2013 | N/A | Non-exclusive license to develop and commercialize in related jurisdictions |
| | Synaffix | Enzymes for Trimming Of Glycoproteins | PCT (U.S.) | Granted | February 08, 2017 | February 8, 2037 | Non-exclusive license to develop and commercialize in related jurisdictions |
| | Synaffix | Enzymes for Trimming of Glycoproteins | PCT (European Union, U.S.) | Pending | February 08, 2017 | N/A | Non-exclusive license to develop and commercialize in related jurisdictions |



Shanghai Miracogen Inc.- Ex. 2032, Page 000428

| Product | Applicant/ Patentee | Title of Patent/ Patent Application | Jurisdiction | Status | Application Date | Expiration Date | Commercial Rights |
|---|---|---|---|---|---|---|---|
| | Synaffix | Process for the Modification of a Glycoprotein Using a Glycosyltransferase that is or is Derived from a ß(1,4)-N-Acetylgalactosaminyl transferase | PCT (European Union, U.S., Japan) | Granted | April 25, 2016 | April 25, 2036 | Non-exclusive license to develop and commercialize in related jurisdictions |
| | Synaffix | Process for the Modification of a Glycoprotein Using a Glycosyltransferase that is or is Derived from a ß(1,4)-N-Acetylgalactosaminyl transferase | PCT (Mainland China, European Union, U.S., India) | Pending | April 25, 2016 | N/A | Non-exclusive license to develop and commercialize in related jurisdictions |
| | Synaffix | Sulfamide Linker, Conjugates Thereof, and Methods of Preparation | PCT (Mainland China, European Union, Japan, U.S.) | Granted | October 5, 2015 | October 5, 2035 | Non-exclusive license to develop and commercialize in related jurisdictions |
| | Synaffix | Sulfamide Linker, Conjugates Thereof, and Methods of Preparation | PCT (U.S.) | Granted | October 5, 2015 | April 7, 2036 | Non-exclusive license to develop and commercialize in related jurisdictions |
| | Synaffix | Sulfamide Linker, Conjugates Thereof, and Methods of Preparation | Mainland China, European Union, India, PCT (U.S.) | Pending | October 5, 2015 | N/A | Non-exclusive license to develop and commercialize in related jurisdictions |
| | Synaffix | Improved Sulfamide Linkers for Use in Bioconjugates | PCT (U.S.) | Granted | February 08, 2017 | February 8, 2037 | Non-exclusive license to develop and commercialize in related jurisdictions |



Shanghai Miracogen Inc.- Ex. 2032, Page 000429

| Product | Applicant/ Patentee | Title of Patent/ Patent Application | Jurisdiction | Status | Application Date | Expiration Date | Commercial Rights |
|---|---|---|---|---|---|---|---|
| | Synaffix | Improved Sulfamide Linkers for Use in Bioconjugates | PCT (European Union, U.S.) | Pending | February 08, 2017 | N/A | Non-exclusive license to develop and commercialize in related jurisdictions |
| | Synaffix | Bioconjugates Containing Sulfamide Linkers for Use in Treatment | PCT (Mainland China, European Union, U.S., India) | Pending | February 08, 2017 | N/A | Non-exclusive license to develop and commercialize in related jurisdictions |

*Notes:*

(1) Akeso and HanX co-developed the anti-PD-1 antibody candidate, HX008, and jointly applied for patents directed to HX008. We acquired HX008 from HanX through acquiring the controlling interest in Taizhou Hanzhong. See "History, Development and Corporate Structure – Our Key Subsidiaries and Major Shareholding Changes – Taizhou Hanzhong" and "– Clinical-Stage Drug Candidates – HX008 – Licenses, Rights and Obligations." Pursuant to the relevant agreements, Akeso agreed to waive its global rights as a co-developer and is entitled to a mid single-digit percentage of global sales revenue once HX008 is commercialized until the expiry of the patents.

(2) In addition to transferring its rights over HX008, HanX granted non-exclusive licenses to patents related to an antibody platform technology. Such technology is used not only in the development of HX008, but may also be used in potentially many other drug candidates. We consider such non-exclusive licenses of patents sufficient given that we are granted the freedom-to-operate. We believe that such non-exclusive licenses do not have restrictions on our further development and commercialization of HX008.

(3) Under I-Mab Agreements, I-Mab Shanghai granted Taizhou Aoke an exclusive, royalty-bearing and sublicensable license to use such existing rights under certain patents and know-how of I-Mab Shanghai for the development of an anti-PD-L1 antibody and the product thereof globally. See "– Collaboration, Licensing and Transfer Arrangements – Collaboration with I-Mab Shanghai and Hangzhou HealSun." I-Mab Shanghai applied for patents directed to LP002 before granting such patents to us.

The terms of individual patents may vary based on the countries in which they are obtained. In most countries in which we file patent applications, including China and the U.S., the term of an issued patent is generally 20 years from the filing date of the earliest non-provisional patent application on which the patent is based in the applicable country.

With respect to any issued patents in the U.S. and the European Union, we may be entitled to obtain an extension of the patent's term from the respective regulatory authority that reviews and approves NDAs provided that we meet the applicable requirements for obtaining such patent term extensions. For example, in the U.S., we may apply for a patent term extension of up to five years as compensation for the patent term lost during clinical trials and the FDA regulatory review process under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The exact duration of the extension depends on the time we spend in clinical studies, as well as in getting an NDA approval from the FDA and is subject to certain restrictions. In certain other foreign jurisdictions, similar extensions as compensation for regulatory delays are also available.


Shanghai Miracogen Inc.- Ex. 2032, Page 000430

In the future, if and when our product candidates receive approval from the FDA in the U.S. or similar governmental authorities in other jurisdictions, we expect to apply for patent term adjustments and extensions on issued patents covering those product candidates in jurisdictions where such adjustments and extensions are available; however, there is no guarantee that the applicable authorities, including the USPTO and the FDA, will agree with our assessment of whether such adjustments and extensions should be granted, and even if granted, the length of such adjustments and extensions.

Alternatively, the term of a U.S. patent may be shortened if the patent is terminally disclaimed over, and will expire on the same day as, a commonly owned patent having an earlier expiration date.

The actual protection afforded by a patent varies on a claim-by-claim and country-by-country basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of any patent term extensions or adjustments, the availability of legal remedies in a particular country and the validity and enforceability of the patent. We cannot provide any assurance that patents will issue with respect to any of our owned or licensed pending patent applications or any applications that we may file in the future, nor can we provide any assurance that any of our owned or licensed issued patents or any such patents that may be issued in the future will be commercially useful in protecting our drug candidates and methods of manufacturing the same.

We may also rely, in some circumstances, on trade secrets, confidential information, know-how, unpatented technology and other proprietary information to protect aspects of our technology. We seek to protect our trade secrets and other proprietary or confidential technology and processes, in part, by entering into confidentiality agreements with consultants, scientific advisors and contractors. We have entered into confidentiality agreements and non-competition agreements with our senior management and key members of our research and development team and other employees who have access to our trade secrets and other proprietary or confidential information relating to our business.

These agreements may not provide sufficient protection of our trade secrets and other proprietary or confidential information. These agreements may also be breached, resulting in the misappropriation of our trade secrets and other proprietary or confidential information, and we may not have an adequate remedy for any such breach. In addition, our trade secrets and other proprietary or confidential information may become known or be independently developed by a third party or misused by any collaborator or other third party to whom we disclose such information. Despite any measures taken to protect our trade secrets, confidential or proprietary information and other intellectual property, unauthorized parties may attempt to or successfully copy aspects of our products or to obtain or use information that we regard as proprietary without our consent. As a result, we may be unable to sufficiently protect our trade secrets and proprietary information.


Shanghai Miracogen Inc.- Ex. 2032, Page 000431

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and electronic security of our information technology systems. Despite any measures taken to protect our data and intellectual property, unauthorized parties may attempt to or successfully gain access to and use information that we regard as proprietary. Please refer to the paragraph headed "Risk Factors – Risks Relating to Our Business – Risk Relating to Our Intellectual Property" for a description of risks related to our intellectual property.

We conduct our business under the brand name of "Lepu" ("樂普生物"). As of the Latest Practicable Date, we had registered 21 trademarks in Mainland China and other jurisdictions. We are also the registered owner of 21 domain names and have irrevocable licenses for 21 domain names. We enter into collaboration agreements and other relationships with pharmaceutical companies and other industry participants to leverage our intellectual property and gain access to the intellectual property of others. See "– Collaboration, Licensing and Transfer Arrangements."

As of the Latest Practicable Date, our Directors confirm that we were not involved in any proceedings in respect of, and we had not received notice of any claims of infringements of, any third-party intellectual property that are threatened or pending. See "Statutory and General Information – 2. Further Information about Our Business – B. Intellectual Property Rights" in Appendix VIII to this prospectus.

## PROCUREMENT AND SUPPLY

Our procurement team is responsible for the procurement of raw materials, as well as technical services, equipment and infrastructure construction services needed for the operation of our business.

The main raw materials that we procure for manufacturing and our clinical trials include culture medium, resins, auxiliary materials, packaging materials, reagents and clinical trial drugs. As of the Latest Practicable Date, anti-PD-1 drugs for clinical trials and the antibodies, cytotoxic small molecules, and linker parts in ADC products were supplied by third-party CDMOs; and OH2 oncolytic virus drugs for clinical trials were manufactured by Wuhan Binhui.

In addition, we procure equipment for the development and manufacturing of our drug candidates from reputable manufacturers and suppliers. We also procure technical services, including CRO and CDMO services and consulting services that support our clinical trials and pre-clinical studies. See "– Research and Development."


Shanghai Miracogen Inc.- Ex. 2032, Page 000432

Our procurement team conducts procurement activities in accordance with our *Rules for Procurement Control Management* and our *Technical Service Supplier Management Policy*. For raw materials and packaging materials that are mass-produced, our procurement team summarizes the procurement requirements from each department and makes a procurement plan by taking into consideration the actual research and development plan, manufacturing plan and the existing inventory level of our raw and auxiliary materials. For purchases that need to be made outside the ordinary procurement plans, the department making such purchase request is required to fill in a purchase request form. Our procurement team will make the purchase from qualified vendors after the procurement plan and the purchase request forms are approved following the corresponding procedures.

We only procure materials from qualified suppliers. We have established relationship with preferred suppliers of raw materials for our manufacturing activities, who we believe have sufficient capacity to meet our demands. See "– Suppliers." Our procurement team selects and maintains a list of qualified suppliers based on a number of factors including quality, price, delivery time, stability, billing time, post-sales support, experience, reputation and customer base. Many of our suppliers hold qualifications such as the ISO9001, ISO13485, and CE certification. Our procurement team dispatches personnel to conduct on-site audit of our suppliers on a regular basis and updates the list of qualified suppliers quarterly.

For each procurement order, we require three or more suppliers to provide price quotations. We conduct a comprehensive evaluation on the quotations submitted by the suppliers, based on factors such as quality, price, delivery time, stability, billing time, post-sales support, experience, reputation and customer base, and then further negotiate the final price and terms with the suppliers. We supervise these third-party service providers closely to ensure that they perform their tasks for us in a manner that complies with our protocols and applicable laws and that protects the integrity of the data resulting from our trials and studies. See "– Manufacturing and Quality Control – Quality Control."

In addition, we believe that we have adequate alternative sources for such suppliers, and we have developed alternative sourcing strategies to decrease our reliance on existing suppliers. We continue to maintain business relationship with alternative sources based on our assessment on the risk of supply continuity.

We engage experienced and qualified third parties such as CROs, CDMOs and SMOs to support our researches and trials. We supervise these third-party service providers closely to ensure their compliance with our quality control procedures and applicable laws and the integrity of the data resulting from our trials and studies.


Shanghai Miracogen Inc.- Ex. 2032, Page 000433

## MANUFACTURING AND QUALITY CONTROL

Since our inception, we have been building GMP-compliant manufacturing facilities. As our late-stage drug candidates approach the commercialization stage, we are preparing for commercial-scale manufacturing that can produce high-quality biologics in large scale.

### Our Manufacturing Facilities

As of the Latest Practicable Date, all of our products remained in the research and development stage, and our manufacturing activities are mainly conducted in support of our clinical trials. We commenced the operation of a 2,000L GMP-compliant bioreactor production line at our Beijing manufacturing plant in 2019, for which we have received a drug manufacturing license from Beijing Municipal Medical Products Administration. In addition, we are building a production line for oncolytic virus with a designed capacity of 200L at our Beijing manufacturing plant, as well as a biologics manufacturing plant in Shanghai Biotech Park with laboratories and manufacturing facilities, which will have two production lines with a designed capacity of 6,000L each.

- ***Beijing antibody manufacturing plant***: Our Beijing plant has a 2,000L antibody production line in operation with 13,442.3 sq.m of floor space. This production line manufactures clinical materials in support of clinical trials for our antibody products. Our Beijing facility was issued a drug manufacturing license by the Beijing Municipal Medical Products Administration.

- ***Shanghai Biotech Park***: As of the Latest Practicable Date, we were building manufacturing facilities in the Shanghai Biotech Park. The facilities will be built in two phases. The first phase has a designed total capacity of 12,000L, and one production line with capacity of 6,000L is under construction. This 6,000L production line is designed to support the commercial manufacturing of anti-PD-1 and anti-PD-L1 mAb products. The second 6,000L production line will be built as sales of anti-PD-1 and anti-PD-L1 mAb products increase and more products come to commercialization. We also have additional land in the Shanghai Biotech Park allocated to the second phase construction of manufacturing capacities in the future. We expect to obtain a drug manufacturing license from the Shanghai Medical Products Administration before NDA submission.

- ***Beijing oncolytic virus manufacturing plant***: As of the Latest Practicable Date, we were building a manufacturing facility for oncolytic virus products in Beijing. This production line has a designed capacity of 200L, and we expect to commence its operation in 2022. For our manufacturing of oncolytic virus products, we have in-licensed the serum-free cultivation technology and the ATF perfusion technology, which enable us to develop a broad spectrum of oncolytic viruses. Upon completion of construction, this oncolytic virus production line is expected to support the commercial manufacturing of oncolytic virus CG0070. We expect to obtain a drug manufacturing license from the Beijing Municipal Medical Products Administration upon the commencement of operation.


Shanghai Miracogen Inc.- Ex. 2032, Page 000434

Our existing and planned manufacturing facilities have been designed according to world-class GMP standards. Our manufacturing facilities are well equipped with state of the art equipment from reputable manufacturers and suppliers. We expect our manufacturing facilities to have adequate capacity to meet our commercial manufacturing needs in the foreseeable future.

Besides manufacturing conducted in our own plants, we also engage third-party CDMOs to manufacture clinical materials used for some of our clinical trials. As of the Latest Practicable Date, anti-PD-1 drugs for clinical trials and the antibodies, cytotoxic small molecules, and linker parts in ADC products were supplied by third-party CDMOs; and OH2 oncolytic virus drugs for clinical trials were manufactured by Wuhan Binhui. We expect to engage third-party CDMOs to manufacture certain of our products after they are commercialized. HX008, the drug candidate we expect to be first commercialized, will be initially manufactured by CDMOs upon marketing approval and later transferred to our own manufacturing facility in Shanghai upon approval by competent regulatory authority. We expect to manufacture ADC products at CDMOs upon their commercial launch.

**Quality Control**

The manufacturing process of biopharmaceutical products is subject to extensive regulations that impose various procedural and documentation requirements governing record keeping, manufacturing process and controls, personnel, quality control and quality assurance and others. See "Regulatory Overview."

We have adopted a series of internal procedures and protocols including standard operating procedures for quality management of manufacturing process, product release and stability testing, storage and shipment to achieve compliant and standardized production quality control. We also have standard process procedures in place to ensure that the finished products meet the process requirements for registration.

Our quality assurance and quality control team coordinates with our production team to oversee and manage the quality of our facilities and our products in our manufacturing process. Our production team designs the production plan based on clinical development plan, procures materials according to the production plan, and issues production instructions to the production lines. We implement strict procedures for the receiving and releasing of the raw materials used in the production process, intermediate products, raw liquids, and finished products in strict compliance with the GMP requirements. Our quality control and quality assurance team, which consisted of 57 employees as of the Latest Practicable Date, inspect raw materials, intermediate products, raw liquids and finished products, and decides whether to release the above samples. Such procedures help us ensure that substandard intermediate products and raw liquids do not enter the next process and deficient products are not released for use out of the factory.


Shanghai Miracogen Inc.- Ex. 2032, Page 000435

## COMMERCIALIZATION

Any drug candidates we successfully develop and commercialize, including our Core Products, will compete with existing drugs or any new drugs that may become available in the future. We have been developing our commercialization capabilities by recruiting sales and marketing personnel and formulating our commercialization strategy. As our drug candidates reach the marketing stage, we are strengthening commercialization and distribution capabilities to maximize the reach of our product offering and expedite market acceptance of our products.

### Our Commercialization Team

We plan to establish our commercialization teams comprising 50 to 100 members to engage in the academic promotion, marketing and commercialization of our pipeline products by the first quarter of 2022. Our commercialization team is led by Dr. Pu Zhongjie and Dr. Sui Ziye. We expect to dispatch approximately five to ten members of the commercialization team to each province, depending on the local market size. Specifically, our team will include medical directors and medical science liaisons, who will be responsible for KOL engagement, medical education, medical conference management, investigator-initiated study support, and advocacy group engagement. We will also build an in-house commercialization team in collaboration with our strategic partners. Team members shall be responsible for the academic promotion of our products to hospital departments, and the general business development and management.

We expect to seek commercialization team candidates with extensive professional expertise and rich industry experience in the commercialization of pharmaceutical products. Along with the clinical development of our pipeline products, we have scheduled the recruitment, training and evaluation of our commercialization team in accordance with the clinical development progress of our pipeline products, aiming to ensure the timely commercialization of our pipeline products once they obtain relevant approvals.

### Our Commercialization Strategy

Our product pipeline features broad-spectrum anti-tumor drugs, including primarily the anti-PD-1 antibody candidate, as the base, and a dual focus on ADC and oncolytic virus drug candidates, maximizing synergies in both commercialization and drug efficacy and enabling us to expand indications and addressable markets. We plan to commercialize our pipeline products in China through dedicated sales and marketing forces and in overseas markets, such as the U.S. and European markets, via partnerships.

Our commercialization team will be responsible for market strategy, product positioning, market access, promotion activities and patient support. We have established long-term relationships with top hospitals, KOLs and doctors. Our commercialization team will help them understand the MOA, clinical data and features of our products which could assist them in finding appropriate patients. We expect to market our products with a customized marketing focus for each product depending on its indication and market coverage. Although we consider



Shanghai Miracogen Inc.- Ex. 2032, Page 000436

to seek inclusion of some of our products into NRDL and other reimbursement programs, the inclusion is determined by the relevant government authorities which is beyond our control. If we fail to have our products included into NRDL after commercialization, our revenue will be more dependent on patients' ability to pay. As an alternative, we may need to expand our sales channels and explore new collaboration patterns, such as distribution partnership, with various sales channel partners, to enhance our commercialization capability, especially on customer reach. We may also seek to create operational synergies by enriching and introducing our portfolio of drug candidates. We plan to expand our sales network by closely communicating with doctors, especially KOLs in renowned comprehensive hospitals and oncology specialty hospitals, through clinical trial cooperation and other academic activities.

In China, we plan to commence our marketing efforts before the expected approval for the commercialization of our drug candidates.

- For sales and marketing activities to medical institutions, we plan to rely on our in-house commercialization team to ensure the timely distribution of our products across most Class III and Class II hospitals across China. We plan to initiate our collaboration with hospitals once our pipeline product HX008 is approved for the treatment of MSI-H/dMMR solid tumors and melanoma, as MSI-H/dMMR solid tumors cover broad-spectrum indications.

- For our commercialization activities targeted at pharmacies, we expect to operate under the DTP pharmacy business model.

For certain risks related to our commercialization strategy, see "Risk Factors – Risks Relating to the Commercialization of our Drug Candidates."

We are committed to strengthening the presence of our product pipeline in overseas markets, improving the international reputation of our brands and constantly exploring the commercial value of our products and technologies worldwide. Specifically, we plan to adopt certain license-in and license-out arrangements to enhance our international collaboration, effectively enrich our product pipeline and promote the commercialization of our products in overseas markets.

**SUPPLIERS**

Our suppliers are primarily reputable CROs, SMOs, CDMOs and hospitals in China with whom we collaborate on pre-clinical and clinical studies in China and overseas, and from whom we procure raw materials and equipment to support the manufacturing of our drug products. We select our suppliers by taking into account a number of factors, including their qualifications, industry reputation, cost competitiveness and compliance with relevant laws and regulations. We did not experience any material difficulty in engaging CDMOs for the procurement of clinical materials during the Track Record Period. During the Track Record Period, purchases from our five largest suppliers in each year/period of 2019, 2020 and the eight months ended August 31, 2021 amounted to RMB213.3 million, RMB284.8 million and


Shanghai Miracogen Inc.- Ex. 2032, Page 000437

RMB198.1 million, respectively, representing 43.4%, 46.2% and 38.7% of our total purchase cost for the same year/period. During the Track Record Period, our largest supplier accounted for 25.5%, 25.0% and 15.2%, respectively, of our total purchase cost in the same year/period. Save for Lepu Pharmaceutical Co. Ltd. (樂普藥業股份有限公司), CG Oncology and HanX, none of our Directors, their respective associates nor any shareholder who, to the knowledge of our Directors, owned more than 5% of our issued share capital as of the Latest Practicable Date, has any interest in any of our five largest suppliers in each year/period during the Track Record Period.

We do not specify credit terms in contracts with our suppliers. Payments are made typically according to the contract terms on payment schedule. The table below sets forth the details of our five largest suppliers during the Track Record Period.

| Five Largest Suppliers for the Year ended December 31, 2019 | Principal Business of the Supplier | Nature of Products/ Services Provided | Purchase Amount (RMB'000) | Percentage of Total Purchase | Years of Business Relationship |
|---|---|---|---|---|---|
| Supplier A | Provision of contracting services for construction works | Construction works | 125,353 | 25.5% | Three |
| CG Oncology[1] | Provision of technology development services | Medical services | 29,121 | 5.9% | Two |
| Supplier B | Provision of contracting services for construction works | Construction works | 21,364 | 4.3% | Three |
| HanX[2] | Provision of technology development services | Medical services | 19,187 | 3.9% | Two |
| Supplier C | Provision of general equipment | Equipment | 18,316 | 3.7% | Three |

*Notes:*

1. The payment includes primarily the one-time upfront payment of US$4.5 million under the CG Licensing Agreement. We also paid certain consultancy service fees to CG Oncology in relation to the IND application of CG0070.

2. The payment was made under a technology development agreement we entered into with HanX in relation to HX008. See "– Clinical-Stage Drug Candidates – HX008 – Licenses, Rights and Obligations."



Shanghai Miracogen Inc.- Ex. 2032, Page 000438

| Five Largest Suppliers for the Year ended December 31, 2020 | Principal Business of the Supplier | Nature of Products/ Services Provided | Purchase Amount (RMB'000) | Percentage of Total Purchase | Years of Business Relationship |
|---|---|---|---|---|---|
| Supplier A | Provision of contracting services for construction works | Construction works | 153,829 | 25.0% | Three |
| Supplier C | Provision of general equipment | Equipment | 42,804 | 6.9% | Three |
| Lepu Pharmaceutical Co. Ltd. | Provision of medical equipment | Equipment | 34,690 | 5.6% | Two |
| Supplier D | Provision of technology development services | Medical services | 32,721 | 5.3% | Two |
| Supplier E | Provision of technology development services | Medical services | 20,755 | 3.4% | Three |

| Five Largest Suppliers for the Eight Months ended August 31, 2021 | Principal Business of the Supplier | Nature of Products/ Services Provided | Purchase Amount (RMB'000) | Percentage of Total Purchase | Years of Business Relationship |
|---|---|---|---|---|---|
| Supplier A | Provision of contracting services for construction works | Construction works | 77,742 | 15.2% | Three |
| Supplier F | Provision of technology development services | Medical services | 45,123 | 8.8% | Three |
| Supplier G | Provision of technology development services | Medical services | 34,876 | 6.8% | Two |
| Supplier I | Provision of technology development services | Medical services | 21,069 | 4.1% | Three |
| Supplier H | Provision of technology development services | Medical services | 19,330 | 3.8% | Three |

We engage experienced and qualified third parties such as CROs, CDMOs and SMOs to support our researches and trials. We supervise these third-party service providers closely to ensure their compliance with our quality control procedures and applicable laws and the integrity of the data resulting from our trials and studies. See "– Research and Development – Engagement of Third Parties in Research and Development."



Shanghai Miracogen Inc.- Ex. 2032, Page 000439

## CUSTOMERS

During the Track Record Period and up to the Latest Practicable Date, we had not generated any revenue from product sales and do not expect to generate any revenue from product sales before the commercialization of one or more of our drug candidates.

## COMPETITION

The biopharmaceutical industry is characterized by rapid market growth, fierce competition and a strong emphasis on proprietary drugs. While we believe that our research and development capabilities enable us to establish a favorable position in the industry, we encounter competition from international and domestic biopharmaceutical companies, specialty pharmaceutical and biotechnology companies of various sizes, academic institutions and research institutions. Any drug candidates that we successfully develop and commercialize will compete with existing drugs or any new drugs that may become available in the future. See "– Clinical-Stage Drug Candidates – MRG003 – Market Opportunity and Competition", "– Clinical-Stage Drug Candidates – MRG002 – Market Opportunity and Competition", "– Clinical-Stage Drug Candidates – MRG001 – Market Opportunity and Competition", "– Clinical-Stage Drug Candidates – CG0070 – Market Opportunity and Competition", "– Clinical-Stage Drug Candidates – HX008 – Market Opportunity and Competition", "– Clinical-Stage Drug Candidates – LP002 – Market Opportunity and Competition", "– Clinical-Stage Drug Candidates – MRG004A – Market Opportunity and Competition" and "– Drug Candidates We Co-developed Through Joint Venture – CMG901 – Market Opportunity and Competition."

## LAND AND PROPERTIES

The Property Valuation Report from AVISTA, an independent property valuer, set out in Appendix IV of this prospectus, sets out details of our selective property interests as of December 31, 2021. AVISTA valued these property interests at an amount of RMB698.7 million as of December 31, 2021. Except for the property interests set forth in the property valuation report from AVISTA, no single property interest that forms part of our non-property activities had a carrying amount representing 15% or more of our total assets as of December 31, 2021.

Our headquarters office is located in Shanghai, China. We own and lease properties in several cities, including Beijing and Shanghai, in China.

### Owned Properties

As of the Latest Practicable Date, we owned land use rights of two parcels of land in Shanghai, China with an aggregate site area of approximately 93,242.7 sq.m., which were primarily used as laboratories and for manufacturing and storage. We had obtained the land use right certificates for both parcels of land.


Shanghai Miracogen Inc.- Ex. 2032, Page 000440

As of the Latest Practicable Date, we did not own any buildings in China or abroad.

**Leased Properties**

As of the Latest Practicable Date, we had no leased land in China or abroad.

As of the Latest Practicable Date, we leased 18 buildings in Beijing, Shanghai and Taizhou in China with an aggregate gross floor area of approximately 25,806.39 sq.m., which were primarily used as laboratories and for manufacturing and storage. The terms of these leases range from one to five years and we believe that the prices are in line with the market prices of the similar properties in the vicinity of the properties. We do not foresee any major difficulties or impediments in renewing the relevant leases upon their expiration. We had obtained valid title certificates from relevant landlords of all of the 18 leased buildings. Among the properties we leased, we have not completed rental registration for 12 leased properties with relevant authorities, with a gross floor area of approximately 3,111.1 sq.m., representing 12.06% of the gross floor area of the properties that we leased. Our PRC Legal Advisor is of the view that the non-registration of lease agreements will not affect the validity of the lease agreements, but that the relevant local housing administrative authorities may require us to complete registrations within a specified time frame, and we may be subject to a fine of between RMB1,000 and RMB10,000 for any delay in making registration for each of such leased properties. See "Risk Factors – Risk Relating to Our Operations – We are subject to risks associated with leasing properties."

## INTERNAL CONTROL AND RISK MANAGEMENT

We have devoted ourselves to establishing and maintaining risk management and internal control systems consisting of policies, procedures and risk management methods that we consider to be appropriate for our business operations, and we are dedicated to continuously improving these systems. We have adopted and implemented comprehensive internal control and risk management policies in various aspects of our business operations such as financial reporting, information system, internal control, quality control and human resources management.

**Financial Reporting Risk Management**

We have in place a set of accounting policies in connection with our financial reporting risk management, such as financial reporting management policies and budget management policies. We have various procedures in place to implement accounting policies and our finance department reviews our management accounts based on such procedures. We also provide regular training to our finance department staff to ensure that they understand our financial management and accounting policies and implement them in our daily operations.


Shanghai Miracogen Inc.- Ex. 2032, Page 000441

**Information System Risk Management**

Sufficient maintenance, storage and protection of user data and other related information is critical to our success. We have implemented relevant internal procedures and controls to ensure that user data is protected and that leakage and loss of such data is avoided. During the Track Record Period and up to the Latest Practicable Date, we did not experience any material information leakage or loss of user data. We provide information security training to our employees and conduct ongoing trainings and discuss any issues or necessary updates from time to time.

**Patient Data Management**

We have taken measures to maintain the confidentiality of the medical records and personal data of subjects enrolled in our clinical trials we collected. The measures include encrypting such information in our information technology system so that it cannot be viewed without proper authorisation, as well as setting internal rules requiring our employees to maintain the confidentiality of our subjects' medical records.

**Internal Control Risk Management**

We have designed and adopted strict internal procedures to ensure the compliance of our business operations with the relevant rules and regulations. Our internal audit team works closely with our business units to (i) perform risk assessments and give advice on risk management strategies, (ii) improve operation efficiency and monitor internal control effectiveness, and (iii) promote risk awareness.

In accordance with our procedures, our financial and legal departments examine the agreement terms and review all relevant documents for our business operations, including licenses and permits obtained by the vendors and all the necessary underlying due diligence materials, before we enter into any agreement or business arrangements.

Our executive committee which comprises senior management and functional heads oversees and manages the overall risks associated with our business operations, including (i) reviewing and approving our risk management policy to ensure that it is consistent with our corporate objectives; (ii) reviewing and approving our corporate risk tolerance; (iii) monitoring the most significant risks associated with our business operation and our management's handling of such risks; (iv) reviewing our corporate risk in the light of our corporate risk tolerance; and (v) monitoring and ensuring the appropriate application of our risk management framework.

Our regulatory affairs department oversees the obtaining of any requisite governmental pre-approvals or consents, including (i) formulating and updating our risk management policy and target; (ii) promulgating risk management measures; (iii) providing guidance on our risk management approach to the relevant departments of our Company; (iv) reviewing the relevant departments' reporting on key risks and providing feedbacks; (v) supervising the



Shanghai Miracogen Inc.- Ex. 2032, Page 000442

implementation of our risk management measures by the relevant departments; (vi) reporting to our executive committee on our material risks; and (vii) ensuring that the appropriate structure, processes and competences are in place across our Group. For IP related issues, we have devoted and specialized outside IP legal advisors to assist us in registering and applying and reviewing the relevant patent and trademark rights of our IPs. We continually review the implementation of our risk management policies and measures to ensure our policies and implementation are effective and sufficient.

**Quality Control Risk Management**

Our quality control system is an essential component of our risk management and internal control system. Our quality control measures cover all aspects of our manufacturing operations, including design and construction of manufacturing facilities, the installation and maintenance of manufacturing equipment, procurement of raw materials and packaging materials, quality checks of raw materials, work-in-progress and finished products, monitoring adverse drug reactions and verification of documentation. The procedures and methodologies of our quality control system are based on GMP standards, the PRC Pharmacopoeia and other applicable domestic and international standards.

**Anti-bribery and Anti-kickback**

We strictly prohibit bribery or other improper payments in any of our business operations. This prohibition applies to all business activities anywhere in the world, whether involving government officials, medical professionals or private or public payors. Improper payments prohibited by this policy include bribes, kickbacks, excessive gifts or entertainment, or any other payment made or offered to obtain an undue business advantage. We keep accurate books and records that reflect transactions and asset dispositions in reasonable details. We also ensure that our commercialization team complies with applicable promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations and limitations on industry-sponsored scientific and educational activities.

**Human Resources Risk Management**

We formulate recruitment plan for the upcoming year based on current turnover rate and our future business plan, and we constantly improve our recruitment process with the aid of information technology.



Shanghai Miracogen Inc.- Ex. 2032, Page 000443

## LEGAL PROCEEDINGS AND COMPLIANCE

### Legal Proceedings

According to our PRC Legal Advisor, during the Track Record Period and up to the Latest Practicable Date, we were not a party to any actual or threatened legal or administrative proceedings which would have a material and adverse impact on our business, financial condition or results of operations, and we were not aware of any pending or threatened legal, arbitral or administrative proceedings against us or our Directors that could, individually or in the aggregate, have a material adverse effect on our business, financial condition and results of operations.

### Compliance

According to our PRC Legal Advisor, during the Track Record Period and up to the Latest Practicable Date, we had not been and were not involved in any non-compliance incidents that led to fines, enforcement actions or other penalties that could, individually or in the aggregate, have a material adverse effect on our business, financial condition or results of operations. Our Directors are of the view that, we had complied, in all material respects, with all relevant laws and regulations in the jurisdictions we operate in during the Track Record Period and up to the Latest Practicable Date.

### Licenses and Permits

According to our PRC Legal Advisor, we have obtained all material licenses, permits, approvals and certificates that are material for our business operations in the PRC and such licenses, permits, approvals and certificates are valid and subsisting.

The following table sets forth the major certificates, permits, licenses and other approvals held by us as of the Latest Practicable Date.

| Certificates/License/Permit | Holder | Date of Grant | Expiry Date |
|---|---|---|---|
| Drug production license | Lepu Beijing | February 3, 2020 | February 2, 2025 |
| Drug production license | Lepu Biopharma | June 2, 2021 | June 1, 2026 |
| Approval for Drug Clinical Study (2017L04642)[(1)] | Taizhou Hanzhong | August 28, 2017 | August 27, 2020 |
| Approval for Drug Clinical Study (2018L02964)[(1)] | Taizhou Aoke | August 20, 2018 | August 19, 2021 |
| Approval for Drug Clinical Study (2018L02554)[(1)] | Miracogen Shanghai | May 28, 2018 | May 27, 2021 |


Shanghai Miracogen Inc.- Ex. 2032, Page 000444

| Certificates/License/Permit | Holder | Date of Grant | Expiry Date |
|---|---|---|---|
| Approval for Drug Clinical Study (2017L04587)[(1)] | Miracogen Shanghai | August 18, 2017 | August 17, 2020 |
| Notification of Drug Clinical Study (CXSL2000022) | Taizhou Hanzhong | April 28, 2020 | April 27, 2023 |
| Notification of Drug Clinical Study (CXSL2000024) | Taizhou Aoke | April 29, 2020 | April 28, 2023 |
| Notification of Drug Clinical Study (CXSL2000011) | Taizhou Hanzhong | April 7, 2020 | April 6, 2023 |
| Notification of Drug Clinical Study (CXSL1900128) | Taizhou Aoke | January 23, 2020 | January 22, 2023 |
| Notification of Drug Clinical Study (CXSL1800083)[(1)] | Miracogen Shanghai | February 21, 2019 | February 20, 2022 |
| Notification of Drug Clinical Study (IND148031) | Miracogen Shanghai | May 8, 2020 | N/A |
| Notification of Drug Clinical Study (IND153115) | Miracogen Shanghai | February 5, 2021 | N/A |
| Form of Record Filing and Registration of Foreign Trade Business Operators (04000633) | Lepu Biopharma | October 30, 2019 | Permanent |
| Form of Record Filing and Registration of Foreign Trade Business Operators (02109441) | Lepu Beijing | April 28, 2019 | Permanent |
| Form of Record Filing and Registration of Foreign Trade Business Operators (04038699) | CtM Bio | November 28, 2020 | Permanent |
| Registration of the consignees or consignors of imported or exported goods (3174300022) | Lepu Biopharma | October 31, 2019 | Permanent |
| Registration of the consignees or consignors of imported or exported goods (1100211101) | Lepu Beijing | April 28, 2019 | Permanent |


Shanghai Miracogen Inc.- Ex. 2032, Page 000445

| Certificates/License/Permit | Holder | Date of Grant | Expiry Date |
|---|---|---|---|
| Customs Declaration Entity Registration Certificate (3122233122) | Miracogen Shanghai | October 17, 2018 | Permanent |
| Registration of the consignees or consignors of imported or exported goods (3165500305) | CtM Bio | November 25, 2020 | Permanent |
| Registration of the consignees or consignors of imported or exported goods (3174300022) | Lepu Biopharma | October 31, 2019 | Permanent |
| Registration of the consignees or consignors of imported or exported goods (1100211101) | Lepu Beijing | April 28, 2019 | Permanent |

*Note:*

(1) As advised by our PRC Legal Advisor, pursuant to the Administrative Measures for Drug Registration (Order of the State Administration for Market Regulation No. 27), we have initiated the relevant trial before the expiry of the respective approval or notification, which are both IND approvals of relevant drug clinical studies, and no renewal is required.

We intend to apply for renewal of the drug production licenses prior to their respective expiry dates. According to our PRC Legal Advisor, there is no legal impediment to renewing such license.

## EMPLOYEES

As of the Latest Practicable Date, we had 423 full-time employees. As of the Latest Practicable Date, 153 of our employees held a master's degree or above.

The following table sets forth the number of our employees categorized by function as of the Latest Practicable Date.

| | Number of Employees | Percentage |
|---|---|---|
| Research and development | 200 | 47.3% |
| Manufacturing and quality control | 129 | 30.5% |
| Commercial, general and administrative | 94 | 22.2% |
| **Total** | **423** | **100.0%** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000446

We are committed to establishing a competitive, fair remuneration and benefits system. In order to effectively motivate our business development team through remuneration incentives and ensure that our employees receive competitive remuneration packages, we continually refine our remuneration and incentive policies through market research and comparison with our competitors. We conduct performance evaluations of our employees to provide them with feedback on their performance. Compensation for our employees typically consists of a base salary and performance-based and year-end bonuses.

As required by PRC laws and regulations, we participate in various employee social security plans for our employees that are administered by local governments, including housing provident fund, pension insurance, medical insurance, maternity insurance, work-related injury insurance and unemployment insurance.

We pay great attention to our employees' welfare and continually improve our welfare system. We offer employees additional benefits, including annual leave, supplementary medical insurance, health examinations and medical insurance for family members.

We provide regular and specialized trainings tailored to the needs of our employees in different departments. We regularly organize training sessions conducted by senior employees or third-party consultants covering various aspects of our business operations including overall management, project execution and technical know-how. We constantly review the content of trainings and follow up with employees to evaluate the effect of such trainings. Through these trainings, we help our employees to stay up to date with both industry developments and skills and technologies. We also organize workshops from time to time to discuss specific topics.

During the Track Record Period, we did not have any strikes, protests or other material labor conflicts that may materially affect our business and image. As of the Latest Practicable Date, we had not established any labor union.

## INSURANCE

We maintain insurance policies that we consider to be in line with market practice and adequate for our business. Our principal insurance policies cover our key persons and AEs in clinical trials. We do not maintain property loss insurance or product liability insurance. See "Risk Factors – Risk Relating to Our Operations – We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources."

## ENVIRONMENTAL MATTERS, SOCIAL RESPONSIBILITY AND WORKPLACE SAFETY

We are committed to operating our business in a manner that protects environment and providing our employees with a healthy and safe workplace. We have implemented a set of policies on environment protection, employee welfare and corporate governance, which we believe are in line with industry standards and in compliance with the requirements of the Listing Rules.



Shanghai Miracogen Inc.- Ex. 2032, Page 000447

As a biopharmaceutical company focusing on oncology therapeutics, we face a variety of environmental, health or safety-related risks associated with our operations. For example, our operations involve the use of hazardous materials, including chemicals, and may produce hazardous waste products to the environment. In addition, we cannot eliminate the risks of contamination or personal injury from these materials. If we use hazardous materials in a manner that causes injury, we could be liable for damages as we do not maintain work injury insurance for injuries to our employees resulting from the use of hazardous materials. We also do not maintain insurance for environmental liability claims that may be asserted against us in connection with our storage or disposal of hazardous materials. In the event of contamination or personal injury resulting from our use of hazardous materials or our or third parties' disposal of hazardous materials, we could be held liable for any resulting damages. We may also incur significant costs associated with civil, administrative or criminal fines and penalties. In order to ensure that our operations are in compliance with the applicable laws and regulations, we have implemented group-wide environmental, health and safety policies and standard operating procedures, mainly comprising of management systems and procedures relating to wastewater generation and treatment, management of process safety and hazardous substances, employee health and safety requirements, third-party safety management and emergency planning and response. In particular, our environmental, health and safety protection measures include: (i) strict compliance with the GMP qualification requirements and relevant pollutant emissions standards during our production process to reduce pollutant emissions of air and wastewater. For example, Lepu Beijing sets its pollutant emissions standards for non-methane hydrocarbon, chemical oxygen demand and ammonia nitrogen to 0.03 tons per year, 1.27 tons per year and 0.09 tons per year, respectively, among others; (ii) implementation of safety guidelines with respect to employee health and safety, environmental protection and operational and manufacturing safety in laboratories and manufacturing facilities, and closely monitor internal compliance with these guidelines; (iii) storage of hazardous substances in special warehouse and contract with qualified third parties for the disposal of hazardous materials and waste on a quarterly basis; and (iv) conducting periodic environmental evaluations on exhaust gas detection and emissions, hazardous waste disposals, noise emissions, and waste water detection and emissions to make sure all operations are in compliance with the applicable laws and regulations. We incurred environment protection expenses of RMB20,300, RMB152,350 and RMB480,398 in 2019, 2020 and the eight months ended August 31, 2021, respectively. As advised by our PRC Legal Advisors, during the Track Record Period and up to the Latest Practicable Date, we were in compliance with the relevant environmental and occupational health and safety laws and regulations in all material aspects, and we did not have any workplace accident.

In respect of social responsibilities, we have entered into employment agreements with our employees in accordance with the applicable PRC laws and regulations. We hire employees based on their qualifications and experiences and it is our corporate policy to offer equal opportunities to our employees regardless of gender, age, race, religion or any other social or personal characteristics. We strive to operate our facilities in a manner that protects the environment and the health and safety of our employees and communities.


Shanghai Miracogen Inc.- Ex. 2032, Page 000448

In addition, we have implemented measures to identify and address potential risks relating to environment, health and work safety. These measures include continuous employee trainings to enhance our employees' awareness of environment, health and work safety issues and skills to comply with safety and operation standards, requirements that all our employees operating specialized equipment must have the requisite certifications, timely provision of protection equipment to our employees, periodic inspection of our operational facilities, special health examinations for employees who may have contact with hazards, medical examination for employees and establishment of procedures to appropriately handle work safety incidents.

We have security officers at our engineering department and other departments that are related to safety and environment protection. These security officers formed our group level environment, health and safety (EHS) management team and are in charge of the implementation of relevant policies and procedures and routine inspections. Upon identification of any EHS risks, our EHS management team will conduct investigation, compose risk assessment report and emergency response plan, and make filings with local governmental authority if required under local laws and regulations, and take all applicable measures to reduce the impact of such risks or incidents.


Shanghai Miracogen Inc.- Ex. 2032, Page 000449

Upon Listing, transactions between members of our Group and our connected persons will constitute connected transactions or continuing connected transactions of our Company under Chapter 14A of the Listing Rules.

## SUMMARY OF OUR CONNECTED PERSONS

### 1. Lepu Medical Connected Persons

Lepu Medical is a medical device and pharmaceutical company dedicated to the development, manufacturing and sales of cardiovascular products and our Controlling Shareholder, Dr. Pu Zhongjie, is its Actual Controller. Accordingly, (i) Lepu Medical, (ii) Shanghai Shape Memory Alloy Co., Ltd. (上海形狀記憶合金材料有限公司) ("Shanghai Alloy"), Lepu Medical's wholly owned subsidiary, and (iii) other members of the Lepu Medical Group and associates of Lepu Medical, (together "Lepu Medical Connected Persons", and, for the avoidance of doubt, excludes our Group) will become our connected persons by virtue of Rule 14A.07(4) of the Listing Rules and for the purposes of connected transactions under Chapter 14A of the Listing Rules upon the Listing.

### 2. Hubei Waterstone Pharmaceutical Co., Ltd. (湖北華世通生物醫藥科技有限公司) ("Hubei Waterstone")

Hubei Waterstone is a biotechnology company engaging in the manufacturing and sales of pharmaceutical raw materials, biological fermentation and pharmaceutical intermediates and is controlled by Mr. Zhang Faming (張發明) as to 32.13%, a former director of Miracogen Shanghai, our wholly owned subsidiary, and therefore will become a connected person of our Company upon Listing pursuant to Chapter 14A of the Listing Rules.

## ONE-OFF CONNECTED TRANSACTIONS

### Office Lease Agreements

***Principal Terms***

*Office Lease for our Company*

Our Company has entered into an office lease agreement (the "Company Office Lease Agreement") with Shanghai Alloy with effect from April 15, 2019, pursuant to which Shanghai Alloy agreed to lease to us the premises with a total gross area of approximately 872.11 sq.m. located at Room 301, Building 41, No. 258 Xinzhuan Road, Songjiang District, Shanghai, the PRC (中國上海市松江區莘磚公路258號41幢301室) (the "Company Leased Offices"), for purpose of administrative offices, equipment testing, and research and development. The annual rent is RMB532,070.72 and shall be payable by our Company on a quarterly basis.


Shanghai Miracogen Inc.- Ex. 2032, Page 000450

The Company Office Lease Agreement has an initial term commencing from April 15, 2019 till April 14, 2024. The lease may be renewed upon prior written notice by our Company and our Company will comply with the applicable Listing Rules in the event of such renewal. If our Company otherwise terminates the Company Office Lease Agreement before expiry of the initial term, we shall pay Shanghai Alloy an additional amount equal to one-month of rent and the Company Office Lease Agreement will be terminated immediately.

*Office Lease for Lepu Hangjia*

Lepu Hangjia has entered into an office lease agreement ("Lepu Hangjia Office Lease Agreement") with Shanghai Alloy, with effect from January 1, 2019, pursuant to which Shanghai Alloy agreed to lease to us the premises with a total gross area of approximately 1,822.16 sq.m. located at Room 201 and 202, Building 41, No. 258 Xinzhuan Road, Songjiang District, Shanghai, the PRC (中國上海市松江區莘磚公路258號41幢201、202室) (the "Lepu Hangjia Leased Offices", collectively with Company Leased Offices the "Leased Offices"), for purpose of administrative offices, equipment testing and research and development. The annual rent is RMB997,632 and shall be payable by Lepu Hangjia on a quarterly basis.

The Lepu Hangjia Office Lease Agreement has an initial term commencing from January 1, 2019 till December 31, 2024. The lease may be renewed upon prior written notice by Lepu Hangjia and Lepu Hangjia will comply with the applicable Listing Rules in the event of such renewal. If Lepu Hangjia otherwise terminates the Lepu Hangjia Office Lease Agreement before expiry of the initial term, we shall pay Shanghai Alloy an additional amount equal to one-month of rent and the Lepu Hangjia Office Lease Agreement will be terminated immediately.

Both the Company Office Lease Agreement and the Lepu Hangjia Office Lease Agreement were entered into (i) in the ordinary and usual course of business of our Group; (ii) on arm's length basis, and (iii) on normal commercial terms with the rent being determined with reference to, among others, the prevailing market rates for similar properties in the same area and the corresponding property management costs for the Leased Offices.

We plan to relocate to Shanghai Bio-technology Park (上海生物園) which is currently under construction. The construction of some buildings in Shanghai Bio-technology Park (上海生物園) is in progress and we will relocate when those buildings are available for use. We currently do not intend to continue to lease the Leased Offices from Shanghai Alloy after our relocation. See "Business – Owned Properties" and "Business – Our Manufacturing Facilities" for further details.

The value of the lease liabilities which includes the present value of the lease payment recognized by the Company according to IFRS 16 as at December 31, 2019 and 2020 and August 31, 2021 amounted to RMB8,259,312.95, RMB7,712,265.72 and RMB4,606,944.06, respectively.


Shanghai Miracogen Inc.- Ex. 2032, Page 000451

***Reasons for and Benefits of the Transactions***

We have been using the Leased Offices for administrative offices, equipment testing and research and development during the Track Record Period. Any relocation of our offices may cause material disruption to our business operations and incur additional costs. As such, our Directors are of the view that such arrangement is in the best interest of our Group and our Shareholders as a whole. Notwithstanding the above, our Directors (including the independent non-executive Directors) are of the view that the transactions contemplated under the Office Lease Agreements do not affect our operational independence. See "Relationship with Controlling Shareholders – Independence from Controlling Shareholders – Operational Independence".

***Listing Rules Implications***

In accordance with IFRS 16 "Leases", the Company recognized a right-of-use asset on its balance sheet in connection with the lease of the properties from Shanghai Alloy. Therefore, the lease of the Leased Offices from Shanghai Alloy under the Office Lease Agreements will be recorded as an acquisition of a capital asset and a one-off connected transaction of the Company for the purpose of the Listing Rules. Accordingly, the reporting, announcement, annual review and independent shareholders' approval requirements in Chapter 14A of the Listing Rules will not be applicable.

## SUMMARY OF OUR CONTINUING CONNECTED TRANSACTIONS

As our Company is eligible for listing on the Stock Exchange under Chapter 18A of the Listing Rules as a pre-revenue biotech company, the revenue ratio under Rule 14.07 of the Listing Rules would not be an appropriate measure of the size of the relevant continuing connected transactions set out in this section. As an alternative, we have applied a percentage ratio test based on the total expenses for R&D and administrative matters of our Group.

| **Nature of transactions** | **Applicable Listing Rules** | **Waiver sought** | **Historical amounts** *(RMB)* | **Proposed annual cap for the year ending December 31** *(RMB)* |
|---|---|---|---|---|
| **Non-exempt continuing connected transactions** | | | | |
| 1. Procurement Framework Agreement | 14A.34, 14A.35, 14A.49, 14A.52 to 14A.59, 14A.71, 14A.76 and 14A.105 | Announcement requirement under Chapter 14A of the Listing Rules | For the year ended December 31, 2019: 2,716,123.56<br>For the year ended December 31, 2020: 1,351,820.16<br>For the eight months ended August 31, 2021: 301,141.58 | 2022: 5,220,000<br>2023: 4,650,000 |



Shanghai Miracogen Inc.- Ex. 2032, Page 000452

| Nature of transactions | Applicable Listing Rules | Waiver sought | Historical amounts *(RMB)* | Proposed annual cap for the year ending December 31 *(RMB)* |
|---|---|---|---|---|
| 2. Technology Service Framework Agreement | 14A.34, 14A.35, 14A.49, 14A.52 to 14A.59, 14A.71, 14A.76 and 14A.105 | Announcement requirement under Chapter 14A of the Listing Rules | For the year ended December 31, 2019: 1,961,128.04<br>For the year ended December 31, 2020: 1,029,897.38<br>For the eight months ended August 31, 2021: 3,552,118.08 | 2022: 8,200,000<br>2023: 3,200,000 |

## NON-EXEMPT CONTINUING CONNECTED TRANSACTIONS

### 1. Procurement Framework Agreement

***Parties***

Lepu Medical (on behalf of Lepu Medical Connected Persons); and
Our Group

***Principal terms***

We entered into a procurement of products and services framework agreement ("Procurement Framework Agreement") with Lepu Medical (on behalf of Lepu Medical Connected Persons) on December 16, 2021, pursuant to which Lepu Medical Connected Persons will supply to our Group (i) raw materials and supplementary materials for clinical trials, (ii) biological sample test services for clinical trials, (iii) employee body check services and other products for employee welfare; and (iv) other services.

The initial term of the Procurement Framework Agreement shall commence on the Listing Date until December 31, 2023 and may be renewed conditional on the fulfillment of the relevant requirements under the relevant laws, regulations and the Listing Rules.

***Reasons for the transaction***

During the Track Record Period, we have been procuring (i) raw materials and supplementary materials for clinical trials; (ii) biological sample test services for clinical trials; (iii) employee body check services and other products for employee welfare; and (iv) other services from Lepu Medical Connected Persons. We will continue to procure such products and services from Lepu Medical Connected Persons for clinical trials and employee welfare as Lepu Medical Connected Persons have been providing us with such products and services with


Shanghai Miracogen Inc.- Ex. 2032, Page 000453

standard and quality commensurate with our requisite safety and quality standard. As such, we believe that Lepu Medical Connected Persons are familiar with our safety and quality standard and will be able to satisfy our demand efficiently and reliably with minimal disruption to our Group's operations and internal procedures.

We believe that we have readily available access to identical or similar raw materials, supplementary materials, biological sample test services, and employee body check services from Independent Third Parties on similar terms in the PRC, but that such procurement from Independent Third Parties would not be as efficient from a cost perspective or operation perspective as compared with our current procurement arrangements with Lepu Medical Connected Persons.

***Pricing policies***

In order to ensure that the terms of transactions in respect of the procurement of products and services by our Group from Lepu Medical Connected Persons are fair and reasonable and in line with market practices, and that the terms of transactions will be no less favorable to our Group than the terms of transactions between our Group and Independent Third Parties, our Group has adopted the following measures:

(a) to have regular contact with the suppliers of our Group (including Lepu Medical Connected Persons) to keep abreast of market developments and the price trend of products and services; and

(b) to assess, review and compare the quotations or proposals taking into account various factors including quality, payment, flexibility and after-sales services to ensure that the proposed transactions will be consistent with the general interest of our Group and our Shareholders as a whole.

Procurement of (i) raw materials and supplementary materials for clinical trials and (ii) biological sample test services for clinical trials will be priced with reference to market prices of comparable products and services, while the procurement fee for body check services will be charged based on the number of our employees enrolled. Our Group implements various internal approval and monitoring procedures, including obtaining quotations on an as-needed basis from other independent suppliers of similar products and services and consider various assessment criteria (including price, quality, suitability, payment terms, and time required for the provision and delivery of the products and services) before entering into any new procurement arrangement with Lepu Medical Connected Persons, and comparing such quotes obtained with the offer from Lepu Medical Connected Persons.


Shanghai Miracogen Inc.- Ex. 2032, Page 000454

***Historical amounts***

The total procurement amount paid by us to Lepu Medical Connected Persons for each of the years ended December 31, 2019 and 2020 and the eight months ended August 31, 2021 were RMB2,716,123.56, RMB1,351,820.16 and RMB301,141.58, respectively.

***Annual caps***

The procurement amount payable to Lepu Medical Connected Persons for the two years ending December 31, 2022 and 2023 shall not exceed the caps as set out in the table below:

| | **Proposed annual caps for the year ending December 31** *(RMB)* | |
|---|---|---|
| | **2022** | **2023** |
| Procurement amount | 5,220,000 | 4,650,000 |

***Basis of caps***

The above annual caps for procurement amount are determined with reference to the historical amount of procurement from Lepu Medical Connected Persons taking into account (i) the estimated demand for the raw materials and supplementary materials for our clinical trials, (ii) the estimated biological sample test demand based on the clinical trial development plan of our pipeline drug candidates including but not limited to the combo studies for HX008 and LP002, clinical trial for MSI-H/dMMR solid tumors, and (iii) the estimated increase in the number of new employees planned to be recruited by our Group who will receive the employee body check services and other products for employee welfare from Lepu Medical Connected Persons in the year ending December 31, 2022 and 2023. Such increase is expected to be at a rate of approximately 22% and 15%, respectively. In particular, for the proposed annual caps for the years ending December 31, 2022 and 2023, the Board has taken into account: (i) the increase biological sample test to be taken in 2022 and 2023; and (ii) the demand for raw materials for LP002 and employee body check services which did not occur during the eight months ended August 31, 2021 and planned in 2022 and 2023.

***Listing Rules implications***

As the highest applicable percentage ratio of the transactions under the Procurement Framework Agreement for each of the two years ending December 31, 2022 and 2023 calculated for the purpose of Chapter 14A of the Listing Rules is expected to be more than 0.1% but less than 5% on an annual basis. Accordingly, such transactions will, upon Listing, constitute continuing connected transactions of the Company subject to the reporting, announcement and annual review requirements but will be exempt from the independent Shareholders' approval requirement under Chapter 14A of the Listing Rules.



Shanghai Miracogen Inc.- Ex. 2032, Page 000455

**2. Technology Service Framework Agreement**

***Parties***

Hubei Waterstone; and
Our Group

***Principal terms***

We entered into a technology service framework agreement ("Technology Service Framework Agreement") with Hubei Waterstone on December 16, 2021, pursuant to which Hubei Waterstone will provide technology services including CMC and other services to us.

The initial term of the Technology Service Framework Agreement shall commence on the Listing Date until December 31, 2023 and may be renewed conditional on the fulfillment of the relevant requirements under the relevant laws, regulations and the Listing Rules.

***Reasons for the transaction***

We have outsourced CMC services to Hubei Waterstone during the Track Record Period. CMC services are essential to the development of our drug candidates especially when they enter the clinical trial phase and such CMC services require sophisticated knowledge and experience that are better handled by service providers with such capabilities. It is a common industry practice for biopharmaceutical companies to engage third party service providers to provide assistance for clinical trials. We believe that Hubei Waterstone, a reputable CMC service provider, can provide CMC services that satisfy our needs.

***Pricing policies***

Service fees will be charged at rates no less favorable than rates at which our Company pays Independent Third Parties for comparable transactions and will be determined by our Company and Hubei Waterstone through arm's length negotiation based on a number of factors applicable to all service providers, including but not limited to nature, complexity and value of tasks completed by Hubei Waterstone at each stage under each work order and the then prevailing market rates by obtaining and comparing against fee quotes provided by other companies.


Shanghai Miracogen Inc.- Ex. 2032, Page 000456

***Historical amounts***

The total service fees paid by us to Hubei Waterstone for each of the years ended December 31, 2019 and 2020 and the eight months ended August 31, 2021 were RMB1,961,128.04, RMB1,029,897.38 and RMB3,552,118.08, respectively. The significant increase in the total service fees paid by us to Hubei Waterstone for the eight months ended August 31, 2021 was mainly contributed to increase in the volume of CMC services procured in connection with pre-clinical and clinical researches of our Group based on the development plan of our Group.

***Annual caps***

The service fees payable to Hubei Waterstone for the two years ending December 31, 2023 shall not exceed the caps as set out in the table below:

| | **Proposed annual caps for the year ending December 31** | |
|---|---|---|
| | **2022** | **2023** |
| | *(RMB)* | |
| Service fee amount | 8,200,000 | 3,200,000 |

***Basis of caps***

When estimating the annual caps, our Directors have taken into consideration the pre-clinical research and development plan of our Group, the clinical development of our pipeline drug candidates, including but not limited to MRG003, MRG002 and CMG901, the type and volume of CMC services our Company expects to procure from Hubei Waterstone, and the number of relevant personnel and their work hours required for providing relevant CMC services for clinical trials, and their respective prevailing hourly rates.

***Listing Rules implications***

As the highest applicable percentage ratio of the transactions under the Technology Service Framework Agreement for each of the two years ending December 31, 2022 and 2023 calculated for the purpose of Chapter 14A of the Listing Rules is expected to be more than 0.1% but less than 5% on an annual basis. Accordingly, such transactions will, upon Listing, constitute continuing connected transactions of the Company subject to the reporting, announcement and annual review requirements but will be exempt from the independent Shareholders' approval requirement under Chapter 14A of the Listing Rules.



Shanghai Miracogen Inc.- Ex. 2032, Page 000457

## INTERNAL CONTROL MEASURES

In order to ensure that the terms under relevant framework agreements for the continuing connected transactions are fair and reasonable, or no less favorable than terms available to or from Independent Third Parties, and are carried out under normal commercial terms, we have adopted the following internal control procedures:

- we have adopted and implemented a management system on connected transactions. Under such system, the Audit Committee under the Board is responsible for conducting reviews on compliance with relevant laws, regulations, our Company's policies and the Listing Rules in respect of the continuing connected transactions. In addition, the Audit Committee under the Board, the Board and various other internal departments of the Company (including but not limited to the finance department and compliance and legal department) are jointly responsible for evaluating the terms under framework agreements for the continuing connected transactions, in particular, the fairness of the pricing policies and annual caps under each agreement;

- the Audit Committee under the Board, the Board and various other internal departments of the Company also regularly monitor the fulfillment status and the transaction updates under the framework agreements. In addition, the management of the Company also regularly reviews the pricing policies of the framework agreements;

- our independent non-executive Directors and auditors will conduct annual review of the continuing connected transactions under the framework agreements and provide annual confirmation to ensure that in accordance with Rules 14A.55 and 14A.56 of the Listing Rules that the transactions are conducted in accordance with the terms of the agreements, on normal commercial terms and in accordance with the relevant pricing policies;

- when considering the actual rental and other charges and service fees for the services to be provided to the Group by the above connected persons, the Group will constantly research into prevailing market conditions and practices and make reference to the pricing and terms between the Group and Independent Third Parties for similar transactions, to make sure that the pricing and terms offered by the above connected persons from mutual commercial negotiations (as the case may be), are fair, reasonable and are no less favorable than those offered to Independent Third Parties; and

- when considering any renewal or revisions to the framework agreements after Listing, the interested Directors and Shareholders shall abstain from voting on the resolutions to approve such transactions at board meetings or shareholders' general meetings (as the case may be), and our independent Directors and Shareholders have the right to consider if the terms of the non-exempt continuing connected



Shanghai Miracogen Inc.- Ex. 2032, Page 000458

transactions (including the proposed annual caps) are fair and reasonable, and on normal commercial terms and in the interests of our Company and our Shareholders as a whole. If the independent Directors' or independent Shareholders' approvals cannot be obtained, we will not continue the transactions under the framework agreement(s) to the extent that they constitute non-exempt continuing connected transactions under Rule 14A.35 of the Listing Rules.

## CONFIRMATION BY DIRECTORS

The Directors (including independent non-executive Directors) are of the view that the non-exempt continuing connected transactions have been and will continue to be carried out in our ordinary and usual course of business of the Company and on normal commercial terms that are fair and reasonable and in the interests of the Company and our Shareholders as a whole; and that the proposed annual caps for the non-exempt continuing connected transactions are fair and reasonable and in the interests of the Company and our Shareholders as a whole.

## CONFIRMATION BY THE JOINT SPONSORS

The Joint Sponsors have (i) reviewed the relevant documents and information provided by the Group, (ii) obtained necessary representations and confirmation from the Company and the Directors and (iii) participated in the due diligence and discussion with the management of the Company. Based on the above, the Joint Sponsors are of the view that the non-exempt continuing connected transactions have been and will continue to be carried out in the ordinary and usual course of business of the Company and on normal commercial terms that are fair and reasonable and in the interests of the Company and our Shareholders as a whole; and that the proposed annual caps of the non-exempt continuing connected transactions are fair and reasonable and in the interests of the Company and our Shareholders as a whole.

## WAIVERS GRANTED BY THE STOCK EXCHANGE

We have applied to the Stock Exchange for, and the Stock Exchange has granted us, a waiver pursuant to Rule 14A.105 of the Listing Rules from strict compliance with the announcement requirement under Rule 14A.35 of the Listing Rules in respect of the transactions under the Procurement Framework Agreement and the Technology Service Framework Agreement for the term ending December 31, 2023, subject to the condition that the total amount of transactions under the framework agreements for each of the two years ending December 31, 2022 and 2023 shall not exceed the proposed caps as set out in this section.

The independent non-executive Directors and auditors of our Company will review whether the transactions under the above continuing connected transactions have been entered into pursuant to the principal terms and pricing policies under the relevant framework agreements as disclosed in this section. The confirmation from our independent non-executive Directors and our auditors will be disclosed annually according to the requirements of the Listing Rules.



Shanghai Miracogen Inc.- Ex. 2032, Page 000459

## OVERVIEW

Our Board consists of nine Directors, including three executive Directors, three non-executive Directors and three independent non-executive Directors. Our Supervisory Committee consists of three Supervisors, including one shareholder representative Supervisor, one employee representative Supervisor and one independent Supervisor. All of our Directors, Supervisors and senior management meet the qualification requirements under the relevant PRC laws and regulations and the Listing Rules for their respective positions.

## BOARD OF DIRECTORS

The following table sets forth certain information of our Directors:

| Name | Age | Position | Date of appointment as Director | Date of joining our Group | Principal roles and responsibilities | Relationship with other Directors, Supervisors and senior management |
|---|---|---|---|---|---|---|
| Dr. Pu Zhongjie (蒲忠傑) | 58 | Chairman of the Board and executive Director | January 19, 2018 | January 2018 | Responsible for the overall affairs of the Board and general management of the Company | Dr. Pu is the father of Ms. Pu Jue (蒲珏), our non-executive Director |
| Dr. Sui Ziye (隋滋野) | 41 | Executive Director and chief executive officer | April 22, 2020 | January 2020 | Responsible for the formulation of Company's operation strategies, corporate business plans, annual operation plans and major decisions | None |
| Dr. Hu Chaohong (胡朝紅) | 55 | Executive Director and co-chief executive officer | May 16, 2020 | July 2018 | Responsible for Company's manufacture and quality control, research and development of antibody related products, especially the research and development of ADC | None |
| Ms. Pu Jue (蒲珏) | 32 | Non-executive Director | April 22, 2020 | April 2020 | Participating in the formulation of the general corporate business plans, strategies and major decisions of our Company through the Board | Ms. Pu is the daughter of Dr. Pu Zhongjie (蒲忠傑), chairman of the Board and our executive Director |



Shanghai Miracogen Inc.- Ex. 2032, Page 000460

| Name | Age | Position | Date of appointment as Director | Date of joining our Group | Principal roles and responsibilities | Relationship with other Directors, Supervisors and senior management |
|---|---|---|---|---|---|---|
| Mr. Yang Hongbing (楊紅冰) | 52 | Non-executive Director | April 22, 2020 | April 2020 | Participating in the formulation of the general corporate business plans, strategies and major decisions of our Company through the Board | None |
| Mr. Lin Xianghong (林向紅) | 50 | Non-executive Director | April 22, 2020 | April 2020 | Participating in the formulation of the general corporate business plans, strategies and major decisions of our Company through the Board | None |
| Mr. Zhou Demin (周德敏) | 54 | Independent non-executive Director | December 10, 2020 | December 2020 | Participating in the decision-making on major issues concerning our Company through the Board | None |
| Mr. Yang Haifeng (楊海峰) | 44 | Independent non-executive Director | December 10, 2020 | December 2020 | Participating in the decision-making on major issues concerning our Company through the Board | None |
| Mr. Fengmao Hua (華風茂) | 53 | Independent non-executive Director | December 16, 2021 | December 2021 | Participating in the decision-making on major issues concerning our Company through the Board | None |

## Executive Directors

**Dr. Pu Zhongjie (蒲忠傑)** aged 58, is the founder and Controlling Shareholder of the Group, serving as our executive Director and the chairman of our Board, director and the chairman of the board of Taizhou Aoke, director of Miracogen Shanghai and executive director of Lepu Beijing.

In addition to his position in our Group, Dr. Pu has consecutively held positions with Lepu Medical as its director, chief technology officer, general manager, vice chairman of the board and chairman of the board since June 1999 and is currently the chief technology officer and chairman of the board of Lepu Medical. Dr. Pu also serves as an executive director of Beijing Tiandi Harmony Technology Co., Ltd. (北京天地和協科技有限公司), a wholly owned subsidiary of Lepu Medical engaging in the medical device business since November 1999.



Shanghai Miracogen Inc.- Ex. 2032, Page 000461

Further, Dr. Pu has been serving as an executive director and the general manager of Beijing Puping Tiancheng Investment Management Consulting Co., Ltd. (北京普平天成投資管理顧問有限公司) ("Puping Tiancheng"), a company ultimately owned by Dr. Pu as to 100% and licensed to conduct investment consulting business. As of the Latest Practicable Date, Puping Tiancheng had not commenced operation of any substantial business, and as such, Dr. Pu's involvement in Puping Tiancheng would be minimal and Dr. Pu would devote his time to the management of our Company. In addition, Dr. Pu has also been serving as an executive director and the general manager of Huarui Zongheng since November 2013, an executive director and the general manager of Beijing Houde Yimin since May 2014, an executive director and the general manager of Ningbo Houde Yimin since March 2017, an executive director and the general manager of Ningbo Houde Yimin Investment Management Co., Ltd. (寧波厚德義民投資管理有限公司), a company wholly owned by Beijing Houde Yimin, since March 2017, and an independent director of Beijing Jinyi Culture Development Joint Stock Company (北京金一文化發展股份有限公司), a company listed on the Shenzhen Stock Exchange (stock code: 002721), from June 2019 to December 2020. Prior to establishing the Group, Dr. Pu served as deputy general manager of technology department of U.S. WP Medical Technologies, Inc. from November 1998 to June 1999.

Dr. Pu obtained a bachelor's degree in mechanical engineering in metal materials from Xi'an Jiaotong University (西安交通大學) in the PRC in 1983, a master's degree in metal materials from Xi'an Jiaotong University (西安交通大學) in the PRC in 1985, and a doctoral degree in metal materials from Central Iron & Steel Research Institute (鋼鐵研究總院) in the PRC in July 1990.

**Dr. Sui Ziye (隋滋野)**, aged 41, is our executive Director and the chief executive officer of our Company, a director of Miracogen Shanghai, a director of Taizhou Aoke, an executive director of CtM Bio, and the general manager of Lepu Beijing. In addition, Dr. Sui also serves as a director of Hangzhou HealSun, a company owned by us as to 23.2%, since March 2020. In addition, Dr. Sui has been a non-executive director of Star Combo Pharma Limited, a company listed on the Australian Stock Exchange (stock code: S66), since June 2018. Dr. Sui has nearly ten years of managerial experience in the pharmaceutical sector.

Prior to joining our Group, Dr. Sui held several positions in Lepu Medical and its subsidiaries, including an international sales & marketing manager and a vice president of Lepu Medical from April 2007 to January 2020, a CEO of Comed BV from March 2012 to May 2015, a CEO of Beijing Lepu Hushengtang Technology Co., Ltd. (北京樂普護生堂網絡科技有限公司) from April 2015 to December 2019, an executive director of Beijing Star GK Medical Device Co., Ltd. (北京思達醫用裝置有限公司) from October 2017 to January 2020, the chairman of the board of Zhongcheng Healthcare Industrial (Hainan) Co., Ltd. (中鈦健康產業(海南)股份有限公司), previously known as Hainan Mingshengda Pharmaceutical Co., Ltd. (海南明盛達藥業有限公司), from June 2015 to January 2020 and a director of Beijing Quinovare Medical Technology Co., Ltd. (北京快舒爾醫療技術有限公司) from September 2016 to July 2020.


Shanghai Miracogen Inc.- Ex. 2032, Page 000462

Dr. Sui obtained a bachelor's degree in medical science from Peking University (北京大學) in the PRC in July 2001 and a doctoral degree from University of Rochester in the U.S. in March 2007.

**Dr. Hu Chaohong (胡朝紅)**, aged 55, is our executive Director and co-chief executive officer of our Company, chairman of the board and general manager of Miracogen Shanghai, a company founded by Dr. Hu in 2014, and director of Innocube Limited. Dr. Hu has around twenty years of experience in development of therapeutic antibodies, antibody drug conjugates and vaccines.

Prior to founding Miracogen Shanghai, Dr. Hu served as a director of the Bioassay Development and Process Analytics department at Seagen Inc. (previously known as Seattle Genetics Inc.), a company listed on the Nasdaq Stock Exchange (stock code: SGEN), from June 2007 to October 2013, the head of Molecular Biology and Clinical Immunology department of GlaxoSmithKline plc, a company listed on the New York Stock Exchange (stock code: GSK), from January 2006 to May 2007, the research scientist and director of Molecular Biology and Clinical Immunology department of ID Biomedical Corporation, previously known as ID Vaccine Corporation, a company listed on the Nasdaq Stock Exchange (stock code: IDBE) and delisted in 2005, from October 1997 to December 2005, a postdoctoral fellow of the University of Washington from September 1992 to October 1997.

Dr. Hu obtained a bachelor's degree in biochemistry from Wuhan University (武漢大學) in the PRC in July 1986 and a doctoral degree in science from Institute of Biophysics, Chinese Academy of Sciences (中國科學院生物物理研究所) in July 1991. Dr. Hu was awarded the second prize of National Natural Science Award (國家自然科學二等獎) by the State Council of the PRC (國務院) in 1995.

**Non-executive Directors**

**Ms. Pu Jue (蒲珏)**, aged 32, is our non-executive Director. In addition to her position in our Group, she leads international business development for Lepu Medical since April 2015, with successful investments including Viralytics Limited (acquired by Merck in February 2018).

Ms. Pu serves as a director of Rgenix Inc. which develops leading immunotherapy cancer treatment agents, since October 2018 and a director of CG Oncology which develops oncolytic virus for the treatment of bladder cancer, since March 2019. As Ms. Pu Jue is not involved in the daily management and operation of our Company as a non-executive Director, and of Rgenix Inc. and CG Oncology as an investor board representative, the directorships held by Ms. Pu Jue would not give rise to any material competition issue under Rule 8.10 of the Listing Rules.

Ms. Pu obtained bachelor's degrees in both economics and engineering from the Wharton School of the University of Pennsylvania in the U.S. in May 2012 and a master's degree in material engineering from Stanford University in the U.S. in June 2013.



Shanghai Miracogen Inc.- Ex. 2032, Page 000463

**Mr. Yang Hongbing (楊紅冰)**, aged 52, is our non-executive Director. In addition to his position in our Group, Mr. Yang is the co-founder of Shenzhen Shiyu and has been serving as the chairman of the board of Shenzhen Shiyu since December 2017, the chairman of the board of Suzhou Shiyu Investment Management Co., Ltd. (蘇州拾玉投資管理有限公司), a company wholly owned by Shenzhen Shiyu, since October 2018, executive director of Qingdao Shiyu Health Technology Co., Ltd. (青島拾玉健康科技有限公司) since March 2020, and director of Zhejiang Ciji Hospital Management Co., Ltd. (浙江慈繼醫院管理有限公司). Prior to that, Mr. Yang served as (a) a manager of the sales department and subsequently general manager of Gloria Pharmaceutical Co., Ltd. (哈爾濱譽衡藥業股份有限公司), a company listed on the Shenzhen Stock Exchange (stock code: 002437), from September 2004 to December 2017 and (b) a deputy general manager of Shaanxi Dongsheng Pharmaceutical Co., Ltd. (陝西東盛醫藥有限責任公司) from May 2001 to August 2004.

As of the Latest Practicable Date, Mr. Yang Hongbing (楊紅冰) serves as a non-executive director of Gloria Pharmaceutical (Guangzhou) Co., Ltd. (廣州譽衡生物科技有限公司) ("Gloria Guangzhou"), a company with PD-1 products business. Since Mr. Yang is not involved in the daily management and operation of our Company and Gloria Guangzhou, the directorship held by Mr. Yang would not give rise to any material competition issue under Rule 8.10 of the Listing Rules.

Mr. Yang obtained a bachelor's degree in management from Northwest University (西北大學) in the PRC in July 1991 and an EMBA from China International Business School (中國國際工商學院) in the PRC in October 2011.

**Mr. Lin Xianghong (林向紅)**, aged 50, is our non-executive Director. In addition to his position in our Group, Mr. Lin has been serving as the chairman of the board and a member of investment committee of Suzhou Equity Investment Fund Management Co., Ltd. (蘇州股權投資基金管理有限公司) since December 2017, the chairman of the board and a member of investment committee of Kaiyuan Guochuang Capital Management Co., Ltd. (開元國創資本管理有限公司) since March 2017, the chief executive officer of Suzhou Private Capital Investment since April 2016, and the non-executive director of CStone Pharmaceuticals, a company listed on the Stock Exchange (stock code: 2616), since November 2020. Prior to that, Mr. Lin served as (a) the president and chairman of the board of Suzhou Yuanhe Holding Co., Ltd. (蘇州元禾控股有限公司) from September 2007 to March 2016, (b) the president and chairman of the board of Zhongxin Suzhou Industrial Park Venture Capital Co., Ltd. (中新蘇州工業園區創業投資有限公司) from November 2001 to September 2007, and (c) the deputy manager of finance department and general manager of investment department of Zhongxin Suzhou Industrial Park Development Co., Ltd. (中新蘇州工業園區開發有限公司) from April 2000 to February 2004.


Shanghai Miracogen Inc.- Ex. 2032, Page 000464

Mr. Lin obtained a bachelor's degree in auditing from Xi'an Jiaotong University (西安交通大學) in the PRC in July 1992, a master's degree in agricultural economic management from Suzhou University (蘇州大學) in the PRC in June 1999, and a doctoral degree in management of science and engineering from Xi'an Jiaotong University (西安交通大學) in the PRC in September 2009. In addition, Mr. Lin obtained the qualification of auditor from National Audit Office of PRC (中華人民共和國審計署) in November 1995, and was certified as a public accountant by the Ministry of Finance of the PRC in June 1997, and a senior economist by the Human Resources and Social Security Department of Jiangsu Province (江蘇省人力資源和社會保障廳) in October 2012.

Mr. Lin also holds various industry positions, including a member of First Technology Innovation Consultation Committee of Shanghai Stock Exchange (上海證券交易所第一屆科技創新諮詢委員會) from April 2019 to April 2021, a member of Venture Capital Committee of Asset Management Association of China (中國證券投資基金業協會創業投資基金專業委員會) since June 2015.

**Independent non-executive Directors**

**Mr. Zhou Demin (周德敏)**, aged 54, is our independent non-executive Director. In addition to his position in our Group, Mr. Zhou served consecutively as professor, deputy dean and now dean of Peking University School of Pharmaceutical Sciences since September 2008 and is an independent director of North China Pharmaceutical Co., Ltd. (華北製藥集團有限責任公司), a company listed on the Shanghai Stock Exchange (stock code: 600812) since May 2019.

Mr. Zhou obtained a bachelor's degree in chemistry and a doctoral degree in science from Peking University Health Science Centre (北京醫科大學) in the PRC in July 1990 and June 1996 respectively.

**Mr. Yang Haifeng (楊海峰)**, aged 44, is our independent non-executive Director. In addition to his position in our Group, Mr. Yang is the head of managing committee of Silkroad Law Firm (錦路律師事務所) since June 2011. Prior to that, Mr. Yang served as a director of legal and risk department of CCB International Asset Management Limited (建銀國際資產管理有限公司) from July 2009 to June 2011, and a legal manager of Simmons (英國西盟斯律師事務所香港辦公室) from October 2004 to July 2009.

Mr. Yang obtained a bachelor's degree in law from Peking University (北京大學) in the PRC in July 2000 and a master's degree in law from Northwestern University in the U.S. in June 2004. Mr. Yang was admitted to practice law in the PRC in January 2019 and New York law in the U.S. in August 2007.


Shanghai Miracogen Inc.- Ex. 2032, Page 000465

**Mr. Fengmao Hua (華風茂)**, aged 53, is our independent non-executive director. In addition to his position at our Group, Mr. Hua serves as the chairman of the Board of China Finance Strategies Investment Holdings Limited since August 2014 and the chief executive officer of Chempartner Pharmatech Co., Ltd., a company listed on Shenzhen Stock Exchange (stock code: 300149) since July 2021. Mr. Hua has more than 15 years of experience in investment banking industry. Mr. Hua previously worked at a number of investment banking firms where he was mainly responsible for corporate finance, public offering, reorganization, merger and acquisitions as well as other financial consulting work, the details of which are set forth below:

- from July 2003 to October 2005, Mr. Hua held various positions in CLSA Capital Market Limited;

- from April 2008 to August 2014, Mr. Hua served as the managing director of investment banking department and the managing director in the private equity department in BOCOM International Holdings Company Limited;

- from July 2018 to June 2021, Mr. Hua served as an executive director and the chief financial officer of Viva Biotech Holdings, a company listed on the Stock Exchange (stock code: 1873);

- since July 2021, Mr. Hua has served as an independent non-executive director of Biocytogen Pharmaceuticals (Beijing) Co., Ltd.;

- in July 2021, Mr. Hua was appointed as an independent non-executive director of Shanghai NewMed Medical Co., Ltd.;

- since December 2021, Mr. Hua has served as an independent non-executive director of Ferretti S.p.A.; and

- since December 2021, Mr. Hua has served as an independent non-executive director of Sirnaomics Ltd., a company listed on the Stock Exchange (stock code: 2257).

Mr. Hua obtained his bachelor's degree in English from Shanghai International Studies University (上海外國語大學) in the PRC in July 1989. He obtained his master's degree in Business Administration from the International University of Japan in June 1997 in Japan.



Shanghai Miracogen Inc.- Ex. 2032, Page 000466

## BOARD OF SUPERVISORS

The following table sets forth certain information of our Supervisors:

| Name | Age | Position | Date of appointment as Supervisor | Date of joining our Group | Principal roles and responsibilities | Relationship with other Directors, Supervisors and senior management |
|---|---|---|---|---|---|---|
| Mr. Xu Yang (徐揚) | 53 | Supervisor | December 10, 2020 | December 2020 | Supervising the operating and financial activities of our Company | None |
| Mr. Yang Ming (楊明) | 55 | Supervisor | December 10, 2020 | December 2020 | Supervising the operating and financial activities of our Company | None |
| Mr. Wang Jiwei (王倚瑋) | 34 | Supervisor | December 10, 2020 | May 2018 | Supervising the operating and financial activities of our Company | None |

**Mr. Xu Yang (徐揚)**, aged 53, is a Supervisor of our Company. In addition to his position in our Group, Mr. Xu is a director of Lepu Medical since January 2014 and a founding partner of Chong Guang Law Office (北京市重光律師事務所) since May 2005. Prior to that, Mr. Xu served as (i) an independent director of NAURA Technology Group Co., Ltd. (北方華創科技集團股份有限公司), a company listed on the Shenzhen Stock Exchange (stock code: 002371), from September 2010 to October 2016, and (ii) an independent director of Sino-air Transportation Co., Ltd. (中外運空運發展股份有限公司), a company previously listed on the Shanghai Stock Exchange (stock code: 600270) and delisted by way of merger and absorption in December 2018, from October 2005 to April 2012.

Mr. Xu obtained a bachelor's degree in law from Peking University (北京大學) in the PRC in July 1991. Mr. Xu was admitted to practice law in the PRC in June 1994.

**Mr. Yang Ming (楊明)**, aged 55, is a Supervisor of our Company. Mr. Yang joined our Group in December 2020 and has been serving as our Supervisor since then. In addition to his position in our Group, Mr. Yang is the vice president of research and development department of Lepu Medical since January 2013 and had held various positions in Lepu Medical, including the manager of clinical registration department from January 2007 to December 2012, the manager of marketing department from October 2005 to December 2006, and the manager of technology quality department from June 2002 to September 2005. Prior to that, Mr. Yang served as a technician of No. 725 Institution of China State Shipbuilding Corporation Limited (中國船舶重工集團公司第七二五研究所) until May 2002.



Shanghai Miracogen Inc.- Ex. 2032, Page 000467

Mr. Yang obtained a bachelor's degree in metal physics from Wuhan University (武漢大學) in the PRC in July 1988. He was qualified as a researcher of biologics material and medical device of China State Shipbuilding Corporation Limited (中國船舶重工集團公司) in March 2010. Mr. Yang has been a member of the second council of China Society for Drug Regulation (中國藥品監督管理研究會) since October 2020.

**Mr. Wang Jiwei (王倚緯)**, aged 34, is an employee representative Supervisor of our Company. Mr. Wang also serves as an administrator of the clinical department of our Company since May 2018. Prior to joining our Group, Mr. Wang served as an operator at the manufacturing product line of Lepu Medical from May 2011 to April 2018.

Mr. Wang obtained his associate's degree in E-commerce from Beijing Vocational College of Labour and Social Security (北京勞動保障職業學院) in the PRC in July 2010.

## SENIOR MANAGEMENT

The following table sets forth certain information of our senior management:

| Name | Age | Position | Date of appointment as senior management | Date of joining our Group | Principal roles and responsibilities | Relationship with other Directors, Supervisors and senior management |
|---|---|---|---|---|---|---|
| Dr. Sui Ziye (隋滋野) | 41 | Executive Director and chief executive officer | March 30, 2020 | January 2020 | Responsible for the formulation of Company's operation strategies, corporate business plans, annual operation plans and major decisions | None |
| Dr. Hu Chaohong (胡朝紅) | 55 | Executive Director and co-chief executive officer | December 10, 2020 | July 2018 | Responsible for Company's manufacture and quality control, research and development of antibody related products, especially the research and development of ADC | None |
| Dr. Frederick Herman Hausheer | 65 | Global chief medical officer | December 10, 2020 | October 2020 | Responsible for providing strategic leadership and direction for the Company's pipeline of clinical development programs; and responsible for translational research and global business development | None |



Shanghai Miracogen Inc.- Ex. 2032, Page 000468

| Name | Age | Position | Date of appointment as senior management | Date of joining our Group | Principal roles and responsibilities | Relationship with other Directors, Supervisors and senior management |
|---|---|---|---|---|---|---|
| Dr. Qin Minmin (秦民民) | 64 | Chief technology officer | December 10, 2020 | April 2019 | Responsible for research, development and commercialization of antibodies and ADCs, including process development, GMP manufacturing and quality control and assurance | None |
| Dr. Fang Lei (方磊) | 38 | Vice president | December 10, 2020 | May 2020 | Responsible for new drug development strategies planning, non-clinical development and translational medicine | None |
| Dr. Li Hu (李虎) | 56 | Vice president | December 10, 2020 | July 2018 | Responsible for preclinical research and non-clinical development of ADC projects including strategy planning, druggability assessment, IND-enabling and NDA-filing non-clinical studies, overseeing bioanalytical and biomarker assays, non-clinical and clinical pharmacokinetic studies and IP strategy | None |
| Ms. Li Maggie Geman (李歌曼) | 55 | Vice president | December 10, 2020 | July 2018 | Responsible for global drug registration and regulatory strategies and planning | None |
| Ms. Li Yunyi (李昀轶) | 41 | Chief financial officer and Board secretary | December 10, 2020 | October 2020 | Responsible for the Company's financial planning and assisting in managing the daily operation of our Company, presiding over daily management of the Shareholders' meeting and the Board | None |



Shanghai Miracogen Inc.- Ex. 2032, Page 000469

**Dr. Sui Ziye (隋滋野)** is an executive Director and chief executive officer of our Company. See "– Board of Directors" in this section for the biographical details of Dr. Sui.

**Dr. Hu Chaohong (胡朝紅)** is an executive Director and co-chief executive officer of our Company. See "– Board of Directors" in this section for the biographical details of Dr. Hu.

**Dr. Frederick Herman Hausheer**, aged 65, is the Global Chief Medical Officer of our Company. Dr. Hausheer has nearly thirty years of international experience in oncology translational medicine and global Phase I-III commercial oncology drug development. Dr. Hausheer is board certified in internal medicine by the American Board of Internal Medicine. Dr. Hausheer has internationally recognized commercial development and scientific expertise in internal medicine, medical oncology, clinical pharmacology, drug safety, and ICH good clinical practices and pre-clinical research and development of novel therapeutic agents for cancer treatment. He has co-authored over 200 scientific publications and is an inventor/co-inventor on over 400 issued international pharmaceutical patents.

Prior to joining us, Dr. Hausheer served as a senior executive and commercial oncology development advisors of many private and public multi-national oncology biotechnology companies and CROs, including a Global Chief Medical Officer and Senior Vice President of WuXi AppTec, Inc., a company listed on the Stock Exchange (stock code: 2359) and Shanghai Stock Exchange (stock code: 603259), from April 2019 to October 2020, and the founder, Chairman and Chief Executive Officer of BioNumerik Pharmaceuticals for 23 years from June 1992 to June 2015.

Dr. Hausheer received a bachelor of science degree from Graceland University in the U.S. in May 1977, a master of science degree from University of Illinois at Urbana-Champaign in the U.S. in May 1979, and his doctoral of medicine degree from University of Missouri-Columbia in the U.S. in May 1982. Dr. Hausheer completed his internship and residency training in Internal Medicine at the University of Missouri Columbia in June 1985, and completed his post-doctoral fellowship in Medical Oncology at the Johns Hopkins Oncology Center in December 1987, specializing in oncology.

Dr. Hausheer has received a number of prestigious awards and recognitions. Dr. Hausheer is also the recipient of Computerworld Smithsonian Leadership Award for Breakthrough Science at the Smithsonian Institution in 1997.


Shanghai Miracogen Inc.- Ex. 2032, Page 000470

**Dr. Qin Minmin (秦民民)**, aged 64, is the chief technology officer of our Company and senior vice president of Miracogen Shanghai responsible for CMC. Dr. Qin has over twenty years of experience in biopharma R&D and is an expert in the fields of recombinant protein, fusion protein, mAb, bispecific antibody and ADC.

Prior to joining our Group, Dr. Qin served as (a) a senior vice president and head of CMC department of Harbour BioMed Holdings Limited (和鉑醫藥控股有限公司), a company listed on the Stock Exchange (stock code: 02142), from March 2018 to April 2019, (b) a vice president of Wuxi Biologics (Cayman) Inc. (藥明生物技術有限公司), a company listed on the Stock Exchange (stock code: 02269), from August 2017 to March 2018, (c) a chief science officer of Jiangsu Pacific Meinuoke Pharmaceutical Co., Ltd. (江蘇太平洋美諾克生物藥業有限公司) from October 2016 to July 2017, (d) a chief technology officer as well as a senior vice president of Zhejiang Teruisi Pharmaceutical Co., Ltd. (浙江特瑞思藥業股份有限公司) from September 2015 to October 2016, (e) a chief technology officer of JMT from September 2012 to September 2015, (f) a senior director of Five Prime Therapeutics, a company listed on the Nasdaq Stock Exchange (stock code: FPRX), from January 2005 to August 2012, and (g) various positions, including senior director of process development, in BioMarin Pharmaceutical Inc., a company listed on the Nasdaq Stock Exchange (stock code: BMRN), from May 1997 to October 2004.

Dr. Qin obtained a bachelor's degree in agriculture from Northwest Agriculture and Forest University (西北農林科技大學), previously known as Northwest Agriculture College (西北農學院), in the PRC in December 1981, a doctoral degree from University of Wisconsin Madison in the U.S. in May 1991, and a completed a post-doctoral research from the University of California Berkeley in the U.S. in April 1997.

Dr. Qin is an adjunct professor of Xi'an Jiaotong University (西安交通大學) from June 1, 2016 to June 1, 2021. Dr. Qin was awarded Rusty Award from Five Prime Therapeutics in both 2010 and 2011.

**Dr. Fang Lei (方磊)**, aged 38, is the vice president of our Company and the general manager of CtM Bio. Dr. Fang has more than ten years of experience in oncology clinical drug development and is an expert in immunology, development strategy and early-stage clinical trials for innovative drugs and translational medical science.

Prior to joining our Group, Dr. Fang served as a director and then executive director of research and development department of I-Mab Shanghai, a subsidiary ultimately and wholly owned by I-Mab, a company listed on the New York Stock Exchange (stock code: IMAB), from September 2016 to April 2020, a director of Third Venture Biopharma (Nanjing) Co., Ltd. (南京三境生物科技有限公司), the predecessor of I-Mab, from March 2015 to August 2016, and consecutively as a research fellow and scientist of GSK (Shanghai) Drug Development Co., Ltd. (葛蘭素史克(上海)醫藥研發有限公司) from June 2010 to February 2015.

Dr. Fang obtained a bachelor's degree in biotechnology from Hebei University (河北大學) in the PRC in June 2004 and a doctoral degree in cell biology from Chinese Academy of Sciences (中國科學院). Dr. Fang received an R&D's Exceptional Science Award (卓越科學成就獎) from GSK (Shanghai) Drug Development Co., Ltd. in 2013.



Shanghai Miracogen Inc.- Ex. 2032, Page 000471

**Dr. Li Hu (李虎)**, aged 56, is the vice president of our Company and the vice president of Miracogen Shanghai. Dr. Li has more than twenty years in drug discovery and preclinical development, and is an expert in assay development, high throughput screening and translational sciences. Dr. Li has led our ADC preclinical biology team to successfully obtain IND clearance in US and China for multiple ADC candidates and successfully developed bioanalytical and immunogenicity assays for nonclinical and clinical programs.

Prior to joining our Group, Dr. Li served as a manager and group leader of GlaxoSmithKline plc, a company listed on the New York Stock Exchange (stock code: GSK), from May 1996 to February 2015.

Dr. Li obtained a bachelor's degree in chemistry from Nanjing University (南京大學) in the PRC in July 1986, a master's degree in environmental chemistry from Research Centre for Eco-Environmental Sciences, Chinese Academy of Sciences (中國科學院生態環境研究中心) in the PRC in July 1989, and a doctoral degree in biochemistry from Bryn Mawr College in the U.S. in May 1996.

Dr. Li received GlaxoSmithKline's Exceptional Sciences Award in 2006 and GlaxoSmithKline's Silver Medal Award in 2008 and 2013 separately. In 2016, Dr. Li was appointed as Expert of Shanghai Pudong Science and Technology Development Fund. In 2009, he was interviewed by Genetic Engineering and Biotechnology News Magazine on application of ADP-GLO technologies in drug screening. In 2004, he was invited as a member to the 6th Sino-American Technology Engineering Committee (中美工程技術研討會). He has co-authored over 20 scientific papers in peer-reviewed journals and is a co-inventor of several published patents.

**Ms. Li Maggie Geman (李歌曼)**, aged 55, is the vice president of our Company and the vice general manager of the regulatory affairs department of Miracogen Shanghai. Ms. Li has more than ten years of experience in regulatory affairs and drug registration in biopharmaceutic and oncology.

Prior to joining our Group, Ms. Li served as (a) a senior regulatory affairs specialist of Acucela Inc. from April 2013 to March 2014 and (b) a senior regulatory affairs specialist of Seattle Genetics Inc. from September 2009 to April 2013.

Ms. Li obtained a bachelor's degree in chemical pharmaceuticals from Shengyang Pharmaceutical University (瀋陽藥科大學), previously known as Shenyang Pharmaceutical School (瀋陽藥學院), in the PRC in July 1988 and a master's degree in healthcare administration from University of Washington in the U.S. in June 2006.

Ms. Li completed the certificate program in clinical trials of University of Washington in July 2007 and received the regulatory affairs certification accredited by the U.S. Regulatory Affairs Professionals Society in April 2008.


Shanghai Miracogen Inc.- Ex. 2032, Page 000472

**Ms. Li Yunyi (李昀軼)**, aged 41, is the chief financial officer and Board secretary of our Company. Prior to joining our Group, Ms. Li served as the deputy financial director of Lepu Medical from May 2016 to October 2020. From September 2013 to December 2015, Ms. Li served as an executive director of debt capital market of Credit Suisse Founder Securities Limited (瑞信方正證券有限責任公司). From June 2008 to August 2013, Ms. Li served consecutively as associate, senior associate, vice president of fixed income team of investment banking department of China International Capital Corporation Limited (中國國際金融有限公司), a company listed on the Stock Exchange (stock code: 03908) and Shanghai Stock Exchange (stock code: 601995). From July 2001 to May 2008, Ms. Li served as the manager of investment banking and marketing development department of China Cinda Asset Management Co., Ltd. (中國信達資產管理股份有限公司), a company listed on the Stock Exchange (stock code: 01359).

Ms. Li obtained a bachelor's degree in international finance from Beihang University (北京航空航天大學) in the PRC in July 2001 and a master's degree in applied finance from Macquarie University in Australia in November 2007.

## KINSHIP

Dr. Pu Zhongjie is the father of Ms. Pu Jue. Other than that, there is no family or blood relationship among any of the Directors, Supervisors and senior management of our Company.

## JOINT COMPANY SECRETARIES

**Ms. Li Yunyi** (李昀軼) is the chief financial officer and the secretary of the Board, and was appointed as the joint company secretary of our Company on April 18, 2021 with her appointment taking effect on the Listing Date. See "– Senior Management" above for the biographical details of Ms. Li.

**Ms. Lai Siu Kuen (黎少娟)** is the joint company secretary of our Company and was appointed on April 18, 2021 with her appointment taking effect on the Listing Date. Ms. Lai is a director of the corporate services of Tricor Services Limited ("Tricor"), a global professional services firm. She has over 20 years of professional and in-house experience in the company secretarial field. Prior to joining Tricor, she was an associate director of other professional service providers. She obtained a bachelor's degree in accountancy from The Hong Kong Polytechnic University in November 1997. She is a fellow of both The Hong Kong Institute of Chartered Secretaries and The Chartered Governance Institute (formerly known as The Institute of Chartered Secretaries and Administrators).


Shanghai Miracogen Inc.- Ex. 2032, Page 000473

## BOARD COMMITTEES

Our Company has established four Board Committees in accordance with the relevant PRC laws and regulations, the Articles and the corporate governance practice under the Listing Rules, namely the Audit Committee, the Remuneration and Appraisal Committee, the Nomination Committee and the Strategy Committee.

### Audit Committee

The Audit Committee of our Company consists of three members, including Mr. Fengmao Hua, Mr. Yang Haifeng and Ms. Pu Jue. Mr. Fengmao Hua is the chairman of the Audit Committee. The primary responsibilities of the Audit Committee are to review and supervise our financial reporting process, including:

(a) to make recommendations to the Board on the appointment, replacement and removal of the external auditor, to consider and approve the remuneration and terms of engagement of the external auditor, and any questions of its resignation or dismissal;

(b) to review and monitor the external auditor's independence and objectivity and the effectiveness of the audit process in accordance with applicable standards. The Audit Committee shall discuss with the external auditors the nature and scope of the audit and reporting obligations before the audit commences;

(c) to develop and implement policy on engaging an external auditor to provide non-audit services;

(d) to monitor internal audit system of the Company and ensure the implementation of such systems;

(e) to facilitate communications between the internal audit department and external auditors;

(f) to review the financial information and relevant disclosures of the Company; and

(g) to monitor the Company in respect of financial reporting system, risk management and internal controls system.



Shanghai Miracogen Inc.- Ex. 2032, Page 000474

**Remuneration and Appraisal Committee**

The Remuneration and Appraisal Committee of our Company consists of three Directors, including Mr. Yang Haifeng, Mr. Fengmao Hua and Dr. Pu Zhongjie. Mr. Yang Haifeng is the chairman of the Remuneration and Appraisal Committee. The primary responsibilities of the Remuneration and Appraisal Committee include:

(a) to make recommendations to the Board on our Company's remuneration policy and structure for all Directors, Supervisors and senior management, and on the establishment of a formal and transparent procedure for developing the remuneration policy;

(b) to review and approve the remuneration proposals of senior management with reference to the Board's corporate goals and objectives;

(c) to make recommendations to the Board on the remuneration packages of the executive Director and senior management or to determine, with delegated responsibility, the remuneration packages of the executive Director and senior management. The remuneration packages shall include benefits in kind, pension rights and compensation payments (including compensation for loss or termination of their office or appointment);

(d) to make recommendations to the Board on the remuneration of non-executive Directors;

(e) to consider salaries paid by comparable companies, time commitment and responsibilities and employment conditions elsewhere in our Group;

(f) to review and approve the compensation payable to the executive Director and senior management for their loss or termination of office or appointment to ensure that such compensation is consistent with the contractual terms and is otherwise fair and not excessive;

(g) to review and approve the compensation arrangements relating to dismissal or removal of the Directors for misconduct to ensure that such compensation is consistent with the contractual terms and is otherwise fair and not excessive; and

(h) to ensure that no Director or any of his associates is involved in deciding his own remuneration.



Shanghai Miracogen Inc.- Ex. 2032, Page 000475

**Nomination Committee**

The Nomination Committee of our Company consists of three members, including Mr. Zhou Demin, Mr. Yang Haifeng, Dr. Pu Zhongjie. Mr. Zhou Demin is the chairman of the Nomination Committee. The primary responsibilities of the Nomination Committee include:

(a) to review the structure, size and composition of the Board (including the skills, knowledge and experience) at least annually and make recommendations on any proposed changes to the Board to complement our Company's corporate strategy;

(b) to identify individuals suitably qualified to become board members and select and make recommendations to the Board on the selection of individuals nominated for directorships;

(c) to assess the independence of the independent non-executive Directors; and

(d) to make recommendations to the Board on the appointment or re-appointment of Directors and succession planning for Directors (in particular the chairman of the Board and the chief executive officer).

**Strategy Committee**

The Strategy Committee consists of three members, namely, Dr. Pu Zhongjie, Dr. Sui Ziye and Mr. Zhou Demin. Dr. Pu Zhongjie is the chairman of the Strategy Committee. The primary responsibilities of the Strategy Committee include:

(a) to conduct research and make recommendations for the long-term strategic development plans of our Company;

(b) to conduct research and make recommendations for major investment plans which are subject to the approval of our Board;

(c) to conduct research and make recommendations for major capital operation and asset operation projects which are subject to the approval of our Board;

(d) to review the annual investment plan of our Company;

(e) to conduct research and make recommendations for major investment programs which are subject to the approval of our Board; and

(f) other duties as conferred by our Board.



Shanghai Miracogen Inc.- Ex. 2032, Page 000476

## BOARD DIVERSITY

We have adopted the board diversity policy which sets out the objective and approach for achieving and maintaining diversity of the Board in order to enhance its effectiveness. In accordance with the board diversity policy, the Company seeks to achieve board diversity by taking into account a number of factors, including but not limited to gender, age, cultural and educational background, professional experience, skills, knowledge and/or length of service.

Our Board consists of six male members and three female members, aging from 30 to 60 years old. Based on the membership and composition of the Board, our Company is of the view that the structure of the Board is reasonable, and the experiences and skills of the Directors in various aspects and fields can enable our Company to maintain high standard of operation.

Our Nomination Committee is responsible for reviewing the diversity of the Board. After Listing, our Nomination Committee will continue to monitor and evaluate the implementation of the board diversity policy from time to time to ensure its continued effectiveness and we will disclose in our corporate governance report about the implementation of the board diversity policy, including any measurable objectives set for implementing the board diversity policy and the progress on achieving these objectives on an annual basis.

## KEY TERMS OF EMPLOYMENT CONTRACTS

We normally enter into (i) an employment contract, and (ii) an intellectual property and confidentiality agreement with our senior management members and other key personnel. Set forth below are the details of the key terms of these contracts.

### Term

The term of employment contracts for our senior management members and other key personnel is normally three years.

### Confidentiality

(a) *Scope of confidential information*: confidential information includes but not limited to test reports, clinical data, design scheme, secret recipe, sample, technology materials, trade secrets, supplier and customer lists, business strategies, fee quotes, financials etc. learned by the employee in whatever means.

(b) *Confidentiality obligation*: the employee shall keep the confidential information in strict confidence and shall not disclose, disseminate, report, publish, transmit, transfer or otherwise make available to third parties without prior consent of our Company. Upon termination of the employee's employment with our Company or transfer of the employee to other positions within the Company, the employee shall return to our Company all documents, materials, mobile storage medium or any other means of record-keeping that contain our confidential information.



Shanghai Miracogen Inc.- Ex. 2032, Page 000477

(c) *Confidential period*: the confidentiality obligation shall continue so long as the confidential information is not known to the public.

(d) *Cooling-off period*: the employee is requested to submit a resignation letter 180 days in advance (except being dismissed by the Company for negligence) which serves as a cooling-off period so that we can rearrange the work to keep such employee away from the latest confidential information.

**Employee-developed intellectual property**

All the inventions and other working products completed by the employee (i) during his or her term of office or (ii) based on the technical achievement of our Company or in relation to his or her work at our Company after employment termination, shall be owned by our Company.

**Non-compete**

During the term of the employment and for two years thereafter, unless with our prior consent, the employee shall not engaged in any business or engage in a course of employment that produces, or operates products, or provide services that are the same or similar to those offered by our Company, including acting as shareholder, partner, director, supervisor, manager, working staff, agent, advisor or any other collaborations.

## REMUNERATION OF DIRECTORS AND SUPERVISORS

Our Company offers the executive Directors, Supervisors and members of senior management, who are also employees of our Company, emolument in the form of salaries, allowances, discretionary bonus and benefits in kind. Our non-executive Directors do not receive any fees, salaries, allowances, discretionary bonus, pension schemes contribution and other benefits in kind (if applicable). Our independent non-executive Directors receive emolument based on their responsibilities (including being members or the chair of Board committees). We adopt a market and incentive-based employee emolument structure and implement a multi-layered evaluation system which focuses on performance and management goals.

The aggregate amount of remuneration paid to our Directors and Supervisors (including salaries, remuneration, pension, discretionary bonus, share-based compensation and other welfares) for the years ended December 31, 2019 and 2020, and the eight months ended August 31, 2021 were approximately nil, RMB5,375,000 and RMB14,571,000, respectively.

For each of the years ended December 31, 2019 and 2020, and the eight months ended August 31, 2021, the aggregate amount of fees, salaries, allowances, discretionary bonus, pension schemes contribution and other benefits in kind (if applicable) paid to the five highest-paid individuals of our Group were approximately RMB6,861,000, RMB13,266,000 and RMB76,162,000, respectively.



Shanghai Miracogen Inc.- Ex. 2032, Page 000478

During the Track Record Period, there was no remuneration paid or payable by our Company to our Directors, Supervisors or the five highest-paid individuals as an inducement to join or upon joining our Company. During the Track Record Period, there was no compensation paid or payable by our Company to our Directors, former Directors, Supervisors, former Supervisors or the five highest-paid individuals for the loss of any office in connection with the management of the affairs of any subsidiary of our Company.

During the Track Record Period, none of our Directors or Supervisors has waived or agreed to waive any remuneration or benefits in kind for the past two years. Save as disclosed above, there was no other payments paid or payable by our Company or any of our subsidiaries to our Directors, Supervisors or the five highest-paid individuals during the Track Record Period.

Under the remuneration policy of our Company, the Remuneration and Appraisal Committee will consider various factors such as salaries paid by comparable companies, tenure, commitment, responsibilities and performance of our Directors, Supervisors and the senior management (as the case may be), in assessing the amount of remuneration payable to our Directors, Supervisors and such employees. It is estimated that under the arrangements currently in force, the aggregate amounts of remuneration payable by our Company to our Directors and Supervisors for the year ending December 31, 2022 is approximately RMB13,567,862 (excluding any discretionary bonus).

## DIRECTORS' AND SUPERVISORS' INTEREST

Save as disclosed in this Prospectus, none of our Directors and Supervisors (i) held any other positions in our Company or any other members of our Group as of the Latest Practicable Date; (ii) had any other relationship with any Directors, Supervisors, senior management or Controlling Shareholder of our Company as of the Latest Practicable Date; and (iii) held any directorship in any other listed companies in the three years immediately prior to the date of this Prospectus.

## MANAGEMENT PRESENCE

We have applied for, and the Stock Exchange has granted, a waiver from compliance with Rule 8.12 of the Listing Rules. For further details, see the section headed "Waivers from Strict Compliance with the Listing Rules and Exemption from Strict Compliance with the Companies (Winding up and Miscellaneous Provisions) Ordinance" in this document.

## COMPLIANCE WITH THE CORPORATE GOVERNANCE CODE

We are committed to achieving high standards of corporate governance which are crucial to our development and safeguard the interests of our Shareholders. To accomplish this, we expect to comply with the corporate governance requirements under the Corporate Governance Code and Corporate Governance Report as set out in Appendix 14 to the Listing Rules after the Listing.



Shanghai Miracogen Inc.- Ex. 2032, Page 000479

## COMPLIANCE ADVISOR

We have appointed Maxa Capital Limited as our compliance advisor pursuant to Rules 3A.19 and 19A.05 of the Listing Rules. Pursuant to Rule 3A.23 of the Listing Rules, we must consult with and, if necessary, seek advice from our compliance advisor on a timely basis in the following circumstances:

(i) before the publication of any regulatory announcement, circular or financial report;

(ii) where a transaction, which might be a notifiable or connected transaction, is contemplated including but not limited to share issues and share repurchases;

(iii) where our Company proposes to use the proceeds of the Global Offering in a manner different from that detailed in this Prospectus, or where the business activities, developments or results of our Group deviate from any forecast, estimate or other information in this Prospectus; and

(iv) where the Stock Exchange makes an inquiry of our Company regarding unusual movements in the price or trading volume of its listed securities or any other matters under Rule 13.10 of the Listing Rules.

Pursuant to Rule 19A.06 of the Listing Rules, our compliance advisor will, in a timely manner, inform us of any amendments or supplements to the Listing Rules and any new or amended law, regulation or code in Hong Kong applicable to our Group. The term of the appointment of our compliance advisor shall commence on the Listing Date and end on the date when we distribute our annual report in respect of our financial results for the first full financial year commencing after the Listing Date, and such appointment may be subject to extension by mutual agreement.


Shanghai Miracogen Inc.- Ex. 2032, Page 000480

## OVERVIEW

As of the Latest Practicable Date, Dr. Pu Zhongjie, our Controlling Shareholder, was interested in approximately 43.0% of the total issued share capital of our Company. Dr. Pu Zhongjie holds his interest through (a) Beijing Houde Yimin, a wholly owned subsidiary of Dr. Pu Zhongjie, which in turn owns 100% equity interest of Ningbo Houde Yimin, and Ningbo Houde Yimin directly holds 28.3% of our Shares; and (b) Lepu Medical, of which Dr. Pu is the Actual Controller deemed to be interested in approximately 25.25% voting interest, holding 14.7% of our Shares.

Immediately following the completion of the Global Offering, Dr. Pu Zhongjie will be interested in approximately 39.7% of our total share capital (assuming the Over-allotment Option is not exercised) or approximately 39.3% of our total share capital (assuming the Over-allotment Option is exercised in full). Dr. Pu will remain as our Controlling Shareholder upon the Listing.

### Confirmation

As of the Latest Practicable Date, Dr. Pu was deemed to be interested in approximately 25.25% voting interest (including interests held by Dr. Pu indirectly and parties acting in concert with Dr. Pu) in Lepu Medical and is the chief technology officer, chairman of the board and Actual Controller of Lepu Medical. Lepu Medical is listed on the Shenzhen Stock Exchange and is principally engaged in development, manufacturing and sales of cardiovascular treatment products. During the Track Record Period, two members of our senior management team, namely Dr. Sui Ziye, our Director and chief executive officer, and Ms. Li Yunyi, our chief financial officer and joint company secretary, previously held positions in Lepu Medical, and they have resigned from their respective positions in Lepu Medical in February 2020 and October 2020, respectively. For Dr. Sui Ziye and Ms. Li Yunyi's previous positions in Lepu Medical, see "Directors, Supervisors and Senior Management" for more details. Save as disclosed above, there were no overlapping Directors, senior management or key employees between Lepu Medical and our Group during the Track Record Period. Our Group also do not share any resources or administrative functions with Lepu Medical during the Track Record Period other than the products and services we have been purchasing from Lepu Medical and its connected persons, which is further described in the section headed "Connected Transactions". In addition, as we are an innovation-driven biopharmaceutical company focusing on oncology therapeutics in which Lepu Medical is not engaged, we consider that there is a clear distinction between our business and those of Lepu Medical and our Directors (including our independent non-executive Directors) do not believe that any direct or indirect competition is or is likely to be material in nature.

As of the Latest Practicable Date, our non-executive Director, Mr. Yang Hongbing (楊紅冰), held directorship at Gloria Guangzhou which engages in PD-1 product business, and our non-executive Director, Ms. Pu Jue (蒲珏), held directorship in Rgenix Inc. which develops leading immunotherapy cancer treatment agents, and CG Oncology which develops oncolytic virus for the treatment of bladder cancer. Additionally, as of the Latest Practicable Date, Mr.


Shanghai Miracogen Inc.- Ex. 2032, Page 000481

Yang Hongbing (楊紅冰) held 2.8% equity interest in Harbin Gloria Group Co., Ltd. (哈爾濱譽衡集團有限公司), which in turn held approximately 32.1% equity interest in Harbin Gloria Pharmaceutical Co., Ltd. (哈爾濱譽衡藥業股份有限公司), a company that owned 38.99% equity interest in Gloria Guangzhou, and Ms. Pu Jue (蒲珏) did not have any shareholding interest in Rgenix Inc. or CG Oncology. On the basis that both of Mr. Yang and Ms. Pu are not involved in the daily management and operation of our Company and their respective directorship in Gloria Guangzhou, Rgenix Inc. and/or CG Oncology, are non-executive, the directorship held by Mr. Yang and Ms. Pu would not give rise to any material competition issue under Rule 8.10 of the Listing Rules. Please refer to the section headed "Directors, Supervisors and Senior Management" for further details on the directorships held by Mr. Yang and Ms. Pu.

Save as disclosed above, neither Dr. Pu nor any of our Directors was, as of the Latest Practicable Date, interested in any business which competes, or is likely to compete, directly or indirectly, with the business of our Group or would otherwise require disclosure under Rule 8.10 of the Listing Rules.

## INDEPENDENCE FROM OUR CONTROLLING SHAREHOLDER

Having considered the following factors, our Directors are satisfied that we are capable of carrying on our business independent from our Controlling Shareholder after the Listing.

### Management Independence

Our daily operational and management decisions are made collectively by our Board and our senior management. Our Board consists of three executive Directors, three non-executive Directors and three independent non-executive Directors. We believe that our Directors, Supervisors and senior management can independently perform their duties in our Company and we can operate independently from our Controlling Shareholder for the following reasons:

- Each of our Directors is aware of his/her fiduciary duties as a director of our Company which requires, among other things, that he/she acts for the benefit and in the best interests of our Company and does not allow any conflict between his/her duties as a Director and his/her personal interest.

- In the event that there is a potential conflict of interest arising out of any transaction to be entered into between our Group and our Controlling Shareholder or his associates, the interested Director(s) shall abstain from voting at the relevant Board meetings of our Company in respect of such transactions and shall not be counted in the quorum.

- Our Board has a balanced composition of executive Directors and independent non-executive Directors which ensures the independence of our Board in making decisions affecting our Company. Specifically, (a) our independent non-executive Directors are not associated with our Controlling Shareholder or his associates; (b) our independent non-executive Directors account for one-third of the Board; and


Shanghai Miracogen Inc.- Ex. 2032, Page 000482

(c) our independent non-executive Directors individually and collectively possess the requisite knowledge and experience as independent directors of listed companies and will be able to provide professional and experienced advice to our Company. In conclusion, our Directors believe that our independent non-executive Directors are able to bring impartial and sound judgment to the decision-making process of our Board and protect the interest of our Company and our Shareholders as a whole.

- We will establish corporate governance measures and adopt sufficient and effective control mechanisms to manage conflicts of interest, if any, between our Group and our Controlling Shareholder, which would support our independent management. See – "Corporate Governance Measures" in this Section.

Having considered the above factors, our Directors are satisfied that they are able to perform their managerial roles in our Company independently, and our Directors are of the view that we are capable of managing our business independently from our Controlling Shareholder after the Listing.

**Operational Independence**

Our Group holds all the relevant material intellectual properties rights, licenses, qualifications and permits required for conducting our Group's business. Our Group has sufficient capital, facilities and employees to operate our business independently from our Controlling Shareholder and his close associates. Our Group also has independent access to our clients. We have our own accounting and financial department, human resources and administration department, internal control department and technology department. We have also established a set of internal control procedures and adopted corporate governance practices to facilitate the effective operation of our business.

We believe that we are capable of carrying on our business independently of our Controlling Shareholder and his close associates. Our Directors confirmed that our Group will be able to operate independently from our Controlling Shareholder and his close associates after the Listing.

**Financial Independence**

Our Group has an independent internal control, accounting and financial management system as well as an independent finance department which makes financial decisions according to our Group's own business needs. Our Group's accounting and finance functions are independent of our Controlling Shareholder.

On September 2, 2019, we entered into an agreement with Agriculture Bank of China pursuant to which Agriculture Bank of China agrees to lend us loans ("ABC Loans") in an aggregate amount of RMB350 million for our construction of the Shanghai Bio-technology Park (上海生物園), and our Controlling Shareholder, Dr. Pu Zhongjie, provided a personal guarantee against our obligations under the ABC Loans. In April 2021, such guarantee was released by Agriculture Bank of China. See "Financial Information – Indebtedness" and Note 28 of the Accountant's Report as set out in Appendix I for more details.



Shanghai Miracogen Inc.- Ex. 2032, Page 000483

On May 25, 2020, Ningbo Houde Yimin, a company ultimately owned by the Controlling Shareholder as to 100%, extended a loan of RMB50 million ("Ningbo Houde Yimin Loans") to our Company. See Note 40 of the Accountant's Report as set out in Appendix I for more details. As of the Latest Practicable Date, we have repaid the Ningbo Houde Yimin Loans in full.

Based on the aforesaid, our Directors believe that we have the ability to conduct our business independently from our Controlling Shareholder and his close associates from a financial perspective and are able to maintain financial independence from our Controlling Shareholder and his close associates.

## CORPORATE GOVERNANCE MEASURES

Our Directors recognize the importance of good corporate governance to protect the interest of our Shareholders. We would adopt the following corporate governance measures to manage potential conflict of interests between our Group and our Controlling Shareholder:

(a) Where a Shareholders' meeting is held for considering proposed transactions in which our Controlling Shareholder has a material interest, our Controlling Shareholder shall abstain from voting on the relevant resolutions and shall not be counted in the quorum for the voting.

(b) Where a Board meeting is held for the matters in which a Director has a material interest, such Director shall abstain from voting on the relevant resolutions and shall not be counted in the quorum for the voting.

(c) In the event that our independent non-executive Directors are requested to review any conflict of interest between our Group and our Controlling Shareholder, our Controlling Shareholder shall provide the independent non-executive Directors with all necessary information and our Company shall disclose the decisions of the independent non-executive Directors either in its annual reports or by way of announcements.

(d) Our Directors (including the independent non-executive Directors) will seek independent and professional opinions from external advisors at our Company's cost as and when appropriate in accordance with the Corporate Governance Code and Corporate Governance Report as set out in Appendix 14 to the Listing Rules.

(e) Any transactions between our Company and its connected persons shall be in compliance with the relevant requirements of Chapter 14A of the Listing Rules, including the announcement, annual reporting and independent shareholders' approval requirements (if applicable) under the Listing Rules.


Shanghai Miracogen Inc.- Ex. 2032, Page 000484

(f) We have appointed Maxa Capital Limited as our compliance advisor, which will provide advice and guidance to us in respect of compliance with the applicable laws and the Listing Rules, including various requirements relating to directors' duties and corporate governance.

Based on above, our Directors are satisfied that sufficient corporate governance measures have been put in place to manage conflicts of interest between our Group and our Controlling Shareholder and/or other Directors to protect minority Shareholders' right after Listing.



Shanghai Miracogen Inc.- Ex. 2032, Page 000485

## SUBSTANTIAL SHAREHOLDERS

So far as our Directors are aware, immediately following the completion of the Global Offering, the following persons are expected to have an interest and/or short positions in the Shares or underlying Shares of our Company which would fall to be disclosed to us pursuant to the provisions of Divisions 2 and 3 of Part XV of the SFO, and, who are, directly or indirectly, interested in 10% or more of the nominal value of any class of our share capital carrying rights to vote in all circumstances at general meetings of our Company:

| | | | As of the Latest Practicable Date | | Immediately following the completion of the Global Offering (assuming the Over-Allotment Option is not exercised) | | |
|---|---|---|---|---|---|---|---|
| Name of Substantial Shareholder | Class of Shares to be held after the Global Offering | Nature of Interest | Number of Shares | Approximate percentage in the total issued Share capital of our Company | Number of Shares | Approximate percentage of shareholding in the relevant class of Shares | Approximate percentage of shareholding in the total issued Share capital of our Company |
| **Ningbo Houde Yimin** | H Shares | Beneficial interest | 433,239,436 | 28.2855% | 433,239,436 | 27.0053% | 26.1216% |
| **Beijing Houde Yimin**[(1)] | H Shares | Interest in controlled corporation | 433,239,436 | 28.2855% | 433,239,436 | 27.0053% | 26.1216% |
| **Lepu Medical** | H Shares | Beneficial interest | 225,352,113 | 14.7128% | 225,352,113 | 14.0470% | 13.5873% |
| **Dr. Pu Zhongjie**[(2)] | H Shares | Interest in controlled corporation | 658,591,549 | 42.9983% | 658,591,549 | 41.0522% | 39.7090% |
| **Kington Capital** | H Shares | Beneficial interest | 39,436,621 | 2.5747% | 39,436,621 | 2.4582% | 2.3778% |
| | Domestic Shares | Beneficial interest | 39,436,620 | 2.5747% | 39,436,620 | 72.6696% | 2.3778% |
| **Suzhou Yipu No. 1 Chuangzhe Management Consultation Limited Partnership (蘇州翼樸一號創喆管理諮詢合夥企業(有限合夥))**[(3)] | H Shares | Interest in controlled corporation | 39,436,621 | 2.5747% | 39,436,621 | 2.4582% | 2.3778% |
| | Domestic Shares | Interest in controlled corporation | 39,436,620 | 2.5747% | 39,436,620 | 72.6696% | 2.3778% |
| **Suzhou Suzi** | H Shares | Beneficial interest | 9,859,155 | 0.6437% | 9,859,155 | 0.6146% | 0.5944% |
| | Domestic Shares | Beneficial interest | 9,859,155 | 0.6437% | 9,859,155 | 18.1674% | 0.5944% |
| **Suzhou Zisu Investment Consultation Limited Partnership (蘇州梓蘇投資諮詢合夥企業(有限合夥))**[(4)] | H Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 0.6146% | 0.5944% |
| | Domestic Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 18.1674% | 0.5944% |
| **Suzhou Kington Equity Investment Fund Management Co., Ltd. (蘇州翼樸股權投資基金管理有限公司)**[(4)] | H Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 0.6146% | 0.5944% |
| | Domestic Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 18.1674% | 0.5944% |



Shanghai Miracogen Inc.- Ex. 2032, Page 000486

| Name of Substantial Shareholder | Class of Shares to be held after the Global Offering | Nature of Interest | As of the Latest Practicable Date | | Immediately following the completion of the Global Offering (assuming the Over-Allotment Option is not exercised) | | |
|---|---|---|---|---|---|---|---|
| | | | Number of Shares | Approximate percentage in the total issued Share capital of our Company | Number of Shares | Approximate percentage of shareholding in the relevant class of Shares | Approximate percentage of shareholding in the total issued Share capital of our Company |
| **Shanghai Qianyu Equity Investment Fund Management Co., Ltd. (上海前宇股權投資基金管理有限公司)[4]** | H Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 0.6146% | 0.5944% |
| | Domestic Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 18.1674% | 0.5944% |
| **Suzhou Yumeng Investment Management Co., Ltd. (蘇州宇夢投資管理有限公司)[4]** | H Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 0.6146% | 0.5944% |
| | Domestic Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 18.1674% | 0.5944% |
| **Qian Xin (錢鑫)[4]** | H Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 0.6146% | 0.5944% |
| | Domestic Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 18.1674% | 0.5944% |
| **Yinhua Changan Capital Management (Beijing) Co., Ltd. (銀華長安資本管理(北京)有限公司)[4]** | H Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 0.6146% | 0.5944% |
| | Domestic Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 18.1674% | 0.5944% |
| **Yinhua Fund Management Co., Ltd. (銀華基金管理股份有限公司)[4]** | H Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 0.6146% | 0.5944% |
| | Domestic Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 18.1674% | 0.5944% |
| **Southwest Securities Co., Ltd. (西南證券有限責任公司)[4]** | H Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 0.6146% | 0.5944% |
| | Domestic Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 18.1674% | 0.5944% |
| **Chongqing Yufu Capital Management Group Co., Ltd. (重慶渝富資本運營集團有限公司)[4]** | H Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 0.6146% | 0.5944% |
| | Domestic Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 18.1674% | 0.5944% |



Shanghai Miracogen Inc.- Ex. 2032, Page 000487

| Name of Substantial Shareholder | Class of Shares to be held after the Global Offering | Nature of Interest | As of the Latest Practicable Date | | Immediately following the completion of the Global Offering (assuming the Over-Allotment Option is not exercised) | | |
|---|---|---|---|---|---|---|---|
| | | | Number of Shares | Approximate percentage in the total issued Share capital of our Company | Number of Shares | Approximate percentage of shareholding in the relevant class of Shares | Approximate percentage of shareholding in the total issued Share capital of our Company |
| **Chongqing Yufu Holding Group Co., Ltd. (重慶渝富控股集團有限公司)[4]** | H Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 0.6146% | 0.5944% |
| | Domestic Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 18.1674% | 0.5944% |
| **State-Owned Assets Supervision and Administration Commission of Chongqing Municipal Government[4]** | H Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 0.6146% | 0.5944% |
| | Domestic Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 18.1674% | 0.5944% |
| **Suzhou Kington Equity Investment Fund Management Co., Ltd. (蘇州翼樸股權投資基金管理有限公司)[5]** | H Shares | Interest in controlled corporation | 49,295,776 | 3.2184% | 49,295,776 | 3.0728% | 2.9722% |
| | Domestic Shares | Interest in controlled corporation | 49,295,775 | 3.2184% | 49,295,775 | 90.8370% | 2.9722% |
| **Suzhou Private Capital Investment[6]** | H Shares | Interest in controlled corporation | 49,295,776 | 3.2184% | 49,295,776 | 3.0728% | 2.9722% |
| | Domestic Shares | Interest in controlled corporation | 49,295,775 | 3.2184% | 49,295,775 | 90.8370% | 2.9722% |
| **SHC** | H Shares | Beneficial interest | 10,962,335 | 0.7157% | 10,962,335 | 0.6833% | 0.6610% |
| | Domestic Shares | Beneficial interest | 3,654,111 | 0.2386% | 3,654,111 | 6.7334% | 0.2203% |
| **Shanghai Healthcare Capital Investment Fund Co., Ltd. (上海生物醫藥產業股權投資基金管理有限公司)[7]** | H Shares | Interest in controlled corporation | 10,962,335 | 0.7157% | 10,962,335 | 0.6833% | 0.6610% |
| | Domestic Shares | Interest in controlled corporation | 3,654,111 | 0.2386% | 3,654,111 | 6.7334% | 0.2203% |

*Notes:*

(1) Ningbo Houde Yimin is wholly owned subsidiary of Beijing Houde Yimin and therefore Beijing Houde Yimin is deemed to be interested in our H Shares held by Ningbo Houde Yimin.

(2) Dr. Pu Zhongjie is the 100% ultimate owner of Ningbo Houde Yimin as well as the Actual Controller of Lepu Medical. Therefore, Dr. Pu Zhongjie is deemed to be interested in our H Shares held by Ningbo Houde Yimin and Lepu Medical.

(3) Suzhou Yipu No. 1 Chuangzhe Management Consultation Limited Partnership is the general manager of Kington Capital and therefore is deemed to be interested in our Shares held by Kington Capital.



Shanghai Miracogen Inc.- Ex. 2032, Page 000488

(4) Suzhou Zisu Investment Consultation Limited Partnership is the general partner of Suzhou Suzi, with Suzhou Kington Equity Investment Fund Management Co., Ltd. being its general partner and Shanghai Qianyu Equity Investment Fund Management Co., Ltd. being its limited partners holding 50% partnership interest. Suzhou Kington Equity Investment Fund Management Co., Ltd. is wholly owned by Suzhou Private Capital Investment. Shanghai Qianyu Equity Investment Fund Management Co., Ltd. is owned as to 40% by Suzhou Yumeng Investment Management Co., Ltd., a company owned by Qian Xin as to 99.50%.

Yinhua Changan Capital Management (Beijing) Co., Ltd. is the limited partner of Suzhou Suzi holding 69.47% partnership interest, which in turn is wholly owned by Yinhua Fund Management Co., Ltd. Southwest Securities Co., Ltd. owns 49% equity interest in Yinhua Fund Management Co., Ltd. and is owned by Chongqing Yufu Capital Management Group Co., Ltd. as to 56.63%. Chongqing Yufu Capital Management Group Co., Ltd. is a wholly owned subsidiary of Chongqing Yufu Holding Group Co., Ltd., a company wholly owned by the State-Owned Assets Supervision and Administration Commission of Chongqing Municipal Government.

Therefore, each of Suzhou Zisu Investment Consultation Limited Partnership, Suzhou Kington Equity Investment Fund Management Co., Ltd., Shanghai Qianyu Equity Investment Fund Management Co., Ltd., Suzhou Yumeng Investment Management Co., Ltd., Qian Xin, Yinhua Changan Capital Management (Beijing) Co., Ltd., Yinhua Fund Management Co., Ltd., Southwest Securities Co., Ltd., Chongqing Yufu Capital Management Group Co., Ltd., Chongqing Yufu Holding Group Co., Ltd. and the State-Owned Assets Supervision and Administration Commission of Chongqing Municipal Government is deemed to be interested in our Shares held by Suzhou Suzi.

(5) Suzhou Kington Equity Investment Fund Management Co., Ltd. is the general partner of Suzhou Yipu No. 1 Chuangzhe Management Consultation Limited Partnership and Suzhou Zisu Investment Consultation Limited Partnership, therefore deemed to be interested in our Shares held by Kington Capital and Suzhou Suzi.

(6) Suzhou Private Capital Investment holds 100% equity interest in Suzhou Kington Equity Investment Fund Management Co., Ltd. and is therefore deemed to be interested in our Shares held by Kington Capital and Suzhou Suzi.

(7) Shanghai Healthcare Capital Investment Fund Co., Ltd. is the general partner of SHC and therefore is deemed to be interested in our Shares held by SHC.

Except as disclosed above, our Directors are not aware of any other person who will, immediately following the completion of the Global Offering, have any interest and/or short positions in the Shares or underlying shares of our Company which would fall to be disclosed to us pursuant to the provisions of Division 2 and 3 of Part XV of the SFO, and, who are, directly or indirectly, interested in 10% or more of the nominal value of any class of our share capital carrying rights to vote in all circumstances at general meetings of our Company or any other member of our Group. Our Directors are not aware of any arrangement which may at a subsequent date result in a change of control of our Company.



Shanghai Miracogen Inc.- Ex. 2032, Page 000489

## OUR SHARE CAPITAL

### Immediately before the Global Offering

As of the Latest Practicable Date, the registered share capital of our Company was RMB1,531,669,838, consisting of 1,368,330,988 Domestic Shares and 163,338,850 Unlisted Foreign Shares, with a nominal value of RMB1.00 each.

### Upon the Completion of the Global Offering

Immediately after the Global Offering and conversion of Domestic Shares and Unlisted Foreign Shares into H Shares (assuming that the Over-allotment Option is not exercised), the share capital of the Company will be as follows:

| Description of Shares | Number of Shares | Approximate % of the enlarged issued share capital after the Global Offering |
|---|---|---|
| Domestic Shares | 54,268,364 | 3.27% |
| H Shares to be converted from Unlisted Foreign Shares | 163,338,850 | 9.85% |
| H Shares to be converted from Domestic Shares | 1,314,062,624 | 79.23% |
| H Shares to be issued pursuant to the Global Offering | 126,876,000 | 7.65% |
| **Total** | 1,658,545,838 | 100.00% |

*Note: Please refer to "Corporate structure immediately following completion of the Global Offering" in "History, Development and Corporate Structure" for details of the identities of the Shareholders whose Shares will be converted into H Shares upon Listing.*



Shanghai Miracogen Inc.- Ex. 2032, Page 000490

Assuming the Over-allotment Option is exercised in full, the share capital of our Company immediately following the Global Offering and conversion of Domestic Shares and Unlisted Foreign Shares into H Shares will be as follows:

| Description of Shares | Number of Shares | Approximate % of the enlarged issued share capital after the Global Offering |
|---|---|---|
| Domestic Shares | 54,268,364 | 3.23% |
| H Shares to be converted from Unlisted Foreign Shares | 163,338,850 | 9.74% |
| H Shares to be converted from Domestic Shares | 1,314,062,624 | 78.33% |
| H Shares to be issued pursuant to the Global Offering | 145,907,000 | 8.70% |
| **Total** | 1,677,576,838 | 100% |

*Note: Please refer to "Corporate structure immediately following completion of the Global Offering" in "History, Development and Corporate Structure" for details of the identities of the Shareholders whose Shares will be converted into H Shares upon Listing.*

## ASSUMPTIONS

The above tables assume that the Global Offering becomes unconditional but does not take into account any Shares which may be issued or repurchased by us under the general mandates granted to our Directors as referred to below.

## CLASS OF SHARES

Upon completion of the Global Offering and conversion of Domestic Shares and Unlisted Foreign Shares into H Shares, our Shares will consist of Domestic Shares and H Shares. Domestic Shares and H Shares are both ordinary Shares in the share capital of our Company.

Our H Shares may only be subscribed for and traded in Hong Kong dollars. Our Domestic Shares, on the other hand, may only be subscribed for and traded in RMB. Apart from certain qualified domestic institutional investors in the PRC, through Shanghai-Hong Kong Stock Connect, or through Shenzhen-Hong Kong Stock Connect or other persons who are entitled to hold our H Shares pursuant to relevant PRC laws and regulations or upon approvals of any competent authorities, our H Shares generally cannot be subscribed for by or traded between legal or natural persons of the PRC.



Shanghai Miracogen Inc.- Ex. 2032, Page 000491

We shall pay all dividends in respect of H Shares in Hong Kong dollars and all dividends in respect of Domestic Shares in RMB. See "Appendix VI – Summary of Principal Legal and Regulatory Provisions" and "Appendix VII – Summary of Articles of Association" for details of the circumstances under which general meetings and class meetings of the Company are required.

Our H Shares and our Domestic Shares will rank equally with each other in all respects and, in particular, will rank equally for all dividends or distributions declared, paid or made after the date of this Prospectus, except as described in this prospectus. The differences between the two classes of Shares, provisions on class rights, dispatch of notices and financial reports to Shareholders, dispute resolution, registration of Shares on different registers of Shareholders, the procedure of transfer of Shares and appointment of dividend receiving agents as contained in the Articles of Association are summarized in "Summary of the Articles of Association" in Appendix VII to this prospectus.

Furthermore, any change or abrogation of the rights of class Shareholders shall be approved by way of a special resolution of the general meeting of Shareholders and by a separate class shareholders meeting convened by the affected class of Shareholders. The circumstances under which a general meeting and/or a class meeting is required are summarized in "Summary of the Articles of Association" in Appendix VII to this prospectus. However, the special approval process of separate classes of Shareholders is not required under the following circumstances:

i. issue of Domestic Shares or H Shares of not more than 20% of existing Domestic Shares or H Shares, respectively, either separately or concurrently in a period of 12 months, pursuant to an approval by a special resolution of the general meeting;

ii. proposal to issue Domestic Shares and H Shares of the Company upon its establishment pursuant to approval of the securities regulatory authority under the State Council, provided that such proposal is carried out within 15 months after such approval; or

iii. transfer of Domestic Shares by domestic shareholder to foreign investors and such transferred Shares are listed on overseas stock exchange as approved by the securities regulatory authority under the State Council and with the consent of the Hong Kong Stock Exchange.

Furthermore, the transfer of Domestic Shares is subject to such restrictions as PRC law may impose from time to time. Save for the Global Offering, we do not propose to carry out any public or private issue or to place securities simultaneously with the Global Offering or within the next six months from the Listing Date. As of the Latest Practicable Date, we have not approved any share issue plan other than the Global Offering.


Shanghai Miracogen Inc.- Ex. 2032, Page 000492

The Offer Shares will rank pari passu in all respects with all Shares currently in issue or to be issued as mentioned in this Prospectus and will qualify and rank equally for all dividends or other distributions declared, made or paid on the Shares on a record date which falls after the date of this Prospectus.

## CONVERSION OF OUR DOMESTIC SHARES AND UNLISTED FOREIGN SHARES INTO H SHARES

As of the Latest Practicable Date, our Shares comprise of Domestic Shares and Unlisted Foreign Shares, both being ordinary shares. Our Domestic Shares and Unlisted Foreign Shares are unlisted Shares which are currently not listed or traded on any stock exchange.

Upon completion of the Global Offering and pursuant to the approval of the CSRC dated June 24, 2021, 1,314,062,624 Domestic Shares and 163,338,850 Unlisted Foreign Shares will be converted to H Shares on a one-for-one basis and be listed for trading on the Stock Exchange as set out below. To the extent any Domestic Shares are not converted into H Shares, all unlisted Shares will comprise such number of Domestic Shares held by our Shareholders not converted into H Shares and we will have two classes of Shares, Domestic Shares and H Shares. The term "unlisted shares" is used to describe whether certain shares are listed on a stock exchange and is not unique to PRC laws.

| Shareholder | Description of Shares | Number of Shares to be converted to H Shares upon completion of the Global Offering |
|---|---|---|
| Ningbo Houde Yimin | Domestic Shares | 433,239,436 |
| Lepu Medical | Domestic Shares | 225,352,113 |
| Miracogen HK | Unlisted Foreign Shares | 138,978,106 |
| Mr. Su Rongyu | Domestic Shares | 100,000,000 |
| Shanghai Lvyuan | Domestic Shares | 90,000,000 |
| Kington Capital | Domestic Shares | 39,436,621 |
| Suzhou Danqing | Domestic Shares | 70,422,536 |
| Shanghai Chunrui | Domestic Shares | 50,000,000 |
| Tianjin Pingan | Domestic Shares | 43,949,259 |
| Haitong Capital | Domestic Shares | 35,159,408 |
| Sunshine Insurance | Domestic Shares | 35,159,408 |
| Kaiyuan Guochuang | Domestic Shares | 28,169,014 |
| SDIC Unity Capital | Domestic Shares | 26,369,556 |
| China Reform | Domestic Shares | 26,369,556 |
| Ronghui Sunshine | Domestic Shares | 26,369,556 |
| Vivo Capital | Unlisted Foreign Shares | 24,360,744 |
| Suzhou Suzi | Domestic Shares | 9,859,155 |
| Minxin Qiyuan | Domestic Shares | 17,579,704 |



Shanghai Miracogen Inc.- Ex. 2032, Page 000493

| Shareholder | Description of Shares | Number of Shares to be converted to H Shares upon completion of the Global Offering |
|---|---|---|
| SHC | Domestic Shares | 10,962,335 |
| Suzhou Xinrui | Domestic Shares | 14,084,507 |
| Jiaxing Danqing | Domestic Shares | 11,267,606 |
| Linzhi Lecheng | Domestic Shares | 5,633,802 |
| Mr. Guo Tongjun | Domestic Shares | 5,273,911 |
| Mr. Wang Lei | Domestic Shares | 1,318,478 |
| Mr. Wang Xinglin | Domestic Shares | 1,757,970 |
| Haihui Quanxing | Domestic Shares | 1,757,970 |
| Mr. Wei Zhanjiang | Domestic Shares | 1,230,579 |
| Ms. Wang Yong | Domestic Shares | 878,985 |
| Ms. Zhang Xia | Domestic Shares | 878,985 |
| Ms. Chen Juan | Domestic Shares | 791,087 |
| Xinye Guangzhou | Domestic Shares | 439,493 |
| Mr. Lin Yi | Domestic Shares | 351,594 |
| **Subtotal** | **Domestic Shares** | **1,314,062,624** |
| | **Unlisted Foreign Shares** | **163,338,850** |
| **Total** | | **1,477,401,474** |

If any of the unlisted Shares are to be converted, listed and traded as H Shares on the Hong Kong Stock Exchange, such conversion, listing and trading will need the approval of the relevant PRC regulatory authorities, including the CSRC, and the approval of the Hong Kong Stock Exchange.

***Listing Review and Approval by the CSRC***

In accordance with the Guidelines for the "Full Circulation" Program for Domestic Unlisted Shares of H-share Listed Companies (《H股公司境內未上市股份申請「全流通」業務指引》) announced by the CSRC, H-share listed companies which apply for the conversion of shares into H shares for listing and circulation on the Hong Kong Stock Exchange shall file the application with the CSRC according to the administrative licensing procedures necessary for the "examination and approval of public issuance and listing (including additional issuance) of overseas shares by a joint stock company". An H-share listed company may apply for a "Full Circulation" separately or when applying for refinancing overseas. An unlisted domestic joint stock company may apply for "full circulation" when applying for an overseas initial public offering.


Shanghai Miracogen Inc.- Ex. 2032, Page 000494

The Company applied for a "full circulation" when applying for an overseas listing with the CSRC on April 19, 2021, and submitted the application reports, authorization documents of the shareholders of unlisted shares for which an H-share "full circulation" was applied, explanation about the compliance of share acquisition and other documents in accordance with the requirements of the CSRC.

The Company has received the reply from the CSRC dated June 24, 2021 in relation to the approval of the overseas listing and "Full Circulation", pursuant to which, (1) the Company was approved to issue no more than 587,139,000 H Shares with a nominal value of RMB1.00 each, which are all ordinary shares, and upon this issuance the Company may be listed on the Main Board of the Hong Kong Stock Exchange; (2) a total of 1,477,401,474 unlisted shares (with a nominal value of RMB1.00 each) held by certain Shareholders of the Company (the "Full Circulation Participating Shareholders") were approved to be converted into H Shares, and the relevant Shares may be listed on the Hong Kong Stock Exchange upon completion of the conversion. This reply shall remain effective within 12 months from the date of approval.

***Listing Approval by the Hong Kong Stock Exchange***

We have applied to the Listing Committee of the Hong Kong Stock Exchange for the granting of listing of, and permission to deal in, our H Shares to be issued pursuant to the Global Offering (including any H Shares which may be issued pursuant to the exercise of the Over-allotment Option) and the H Shares to be converted from 1,477,401,474 Domestic Shares and Unlisted Foreign Shares on the Hong Kong Stock Exchange, which is subject to the approval by the Hong Kong Stock Exchange.

We will perform the follow procedures for the conversion of unlisted shares into H Shares after receiving the approval of the Hong Kong Stock Exchange: (1) giving instructions to our H Share Registrar regarding relevant share certificates of the converted H Shares; and (2) enabling the converted H Shares to be accepted as eligible securities by HKSCC for deposit, clearance and settlement in the CCASS. The Full Circulation Participating Shareholders may only deal in the Shares upon completion of following domestic procedures.

***Domestic Procedures***

The Full Circulation Participating Shareholders may only deal in the Shares upon completion of the below arrangement procedures for the registration, deposit and transaction settlement in relation to the conversion and listing:

i. We will appoint CSDC as the nominal holder to deposit the relevant securities at CSDC (Hong Kong), which will then deposit the securities at HKSCC in its own name. CSDC, as the nominal holder of the Full Circulation Participating Shareholders, shall handle all custody, maintenance of detailed records, cross-broader settlement and corporate actions, etc. relating to the converted H Shares for the Full Circulation Participating Shareholders;


Shanghai Miracogen Inc.- Ex. 2032, Page 000495

ii. We will engage a domestic securities company (the "Domestic Securities Company") to provide services such as the transmission of sale orders and trading messages in respect of the converted H Shares. The Domestic Securities Company will engage a Hong Kong securities company (the "Hong Kong Securities Company") for settlement of share transactions. We will make an application to CSDC, Shenzhen Branch for the maintenance of a detailed record of the initial holding of the converted H Shares held by our Shareholders. Meanwhile, we will submit applications for a domestic transaction commission code and abbreviation, which shall be confirmed by CSDC, Shenzhen Branch as authorized by SZSE;

iii. The SZSE shall authorize Shenzhen Securities Communication Co., Ltd. to provide services relating to transmission of trading orders and trading messages in respect of the Converted H Shares between the Domestic Securities Company and the Hong Kong Securities Company, and the real-time market forwarding services of the H Shares;

iv. According to the Notice of the SAFE on Issues Concerning the Foreign Exchange Administration of Overseas Listing (《國家外匯管理局關於境外上市外匯管理有關問題的通知》), the Full Circulation Shareholders that held Domestic Shares shall complete the overseas shareholding registration with the local foreign exchange administration bureau before the Shares are sold, and after the overseas shareholding registration, open a specified bank account for the holding of overseas shares by domestic investors at a domestic bank with relevant qualifications and open a fund account for the H Share "Full Circulation" at the Domestic Securities Company. The Domestic Securities Company shall open a securities trading account for the H Share "Full Circulation" at the Hong Kong Securities Company; and

v. The Full Circulation Participating Shareholders shall submit trading orders of the Converted H Shares through the Domestic Securities Company. Trading orders of the Full Circulation Participating Shareholders for the relevant Shares will be submitted to the Hong Kong Stock Exchange through the securities trading account opened by the Domestic Securities Company at the Hong Kong Securities Company. Upon completion of the transaction, settlements between each of the Hong Kong Securities Company and CSDC (Hong Kong), CSDC (Hong Kong) and CSDC, CSDC and the Domestic Securities Company, and the Domestic Securities Company and the Full Circulation Participating Shareholders, will all be conducted separately.

As a result of the conversion, the shareholding of the relevant Full Circulation Participating Shareholders in our share capital registered shall be reduced by the number of Domestic Shares and Unlisted Foreign Shares converted and increased by the number of H Shares so converted.



Shanghai Miracogen Inc.- Ex. 2032, Page 000496

A Shareholder holding Domestic Shares not converted into H Shares can work with the Company according to the Articles of Association and follow the procedures set out in this Prospectus to convert the Domestic Shares into H Shares after the Listing if they want, provided that such conversion of Domestic Shares into and listing and trading of H Shares will be subject to the approval of the relevant PRC regulatory authorities, including the CSRC, the approval of the Hong Kong Stock Exchange and the satisfaction of the public float requirement under the Listing Rules by the Company.

## RESTRICTION ON TRANSFER OF SHARES ISSUED PRIOR TO THE GLOBAL OFFERING

In accordance with Article 141 of the PRC Company Law, the shares issued prior to any public offering of shares by a company cannot be transferred within one year from the date on which such publicly offered shares are listed and traded on the relevant stock exchange. As such, the Shares issued by the Company prior to the Global Offering will be subject to such statutory restriction on transfer within a period of one year from the Listing Date.

The Company will work with the Domestic Securities Company to be engaged by the Company to restrict the trading of the H Shares converted from unlisted Shares technically within one year after the Listing. In the unlikely event that any Full Circulation Participating Shareholders trades their H Shares during such restriction period, as advised by the PRC Legal Advisor, there will be no administrative penalty on the Company under the PRC laws and regulations but there is risk that the underlying agreement for the transfer of such H Shares may be declared void pursuant to the Civil Code of the People's Republic of China.

Our Directors, Supervisors and members of senior management shall declare their shareholdings in the Company and any changes in their shareholdings. Shares transferred by our Directors, Supervisors and members of the senior management each year during their term of office shall not exceed 25% of their total respective shareholdings in the Company. The Shares that the aforementioned persons held in the Company cannot be transferred within one year from the date on which the shares are listed and traded, nor within half a year after they leave their positions in the Company. The Articles of Association may contain other restrictions on the transfer of our Shares held by our Directors, Supervisors and members of senior management.

## REGISTRATION OF SHARES NOT LISTED ON AN OVERSEAS STOCK EXCHANGE

According to the Notice of Centralized Registration and Deposit of Non-overseas Listed Shares of Companies Listed on an Overseas Stock Exchange (《關於境外上市公司非境外上市股份集中登記存管有關事宜的通知》) issued by the CSRC, the Company is required to register the Domestic Shares with the China Clearing within 15 business days upon the Listing and provide a written report to the CSRC regarding the results of centralized registration and deposit of the Domestic Shares as well as the offering and listing of the H Shares.



Shanghai Miracogen Inc.- Ex. 2032, Page 000497

## CIRCUMSTANCES UNDER WHICH GENERAL MEETINGS ARE REQUIRED

Pursuant to the PRC Company Law and the terms of the Articles of Association, our Company may from time to time by special resolution of shareholders (i) increase its capital or decrease its capital or capital redemption reserve; (ii) consolidate our shares; (iii) divide its shares into several classes; (iv) subdivide our shares; and (v) cancel any shares which have not been taken up. See "Appendix VII – Summary of Articles of Association" in this Prospectus for further details.

## GENERAL MANDATE TO ISSUE SHARES

Subject to the Global Offering becoming unconditional, our Directors have been granted a general mandate to separately or concurrently allot, issue and deal with additional Domestic Shares and H Shares (including securities convertible into Domestic Shares and/or H Shares, including to decide on the class and number of Domestic Shares and H Shares to be issued; the pricing mechanism and/or issue the issue price (or the range of issue price); the opening and closing date and time of such issue, and/or to make any proposals, enter into any agreements or grant any share options or conversion rights which may involve the exercise of the power aforementioned, provided that, the number of Domestic Shares or H Shares issued and allotted or agreed conditionally or unconditionally to be issued and allotted (whether or not by way of the exercise of share options, conversion rights or by any other means) shall not exceed 20% of the Domestic Shares in issue and H Shares in issue (as the case may be) as of the Listing Date.

This general mandate to repurchase Shares will expire at the earliest of:

(i) the conclusion of the next annual general meeting of the; or

(ii) the expiration of the period within 12-month following the Listing Date; or

(iii) the date on which it is varied or revoked by a special resolution of our Shareholders in a general meeting.

Furthermore, we need to obtain approvals from the CSRC and other relevant regulatory authorities for the additional issue of our H Shares and Domestic Shares.

See the section headed "Statutory and General Information – 1. Further Information about our Company – C. Resolutions of the Shareholders of Our Company dated April 18, 2021" in Appendix VIII to this Prospectus for further details of this general mandate to allot, issue and deal with Shares.



Shanghai Miracogen Inc.- Ex. 2032, Page 000498

## SHAREHOLDERS' GENERAL MEETINGS AND CLASS MEETINGS

For details of circumstances under which our Shareholders' general meeting and Shareholders' class meeting are required, see subsections "Notice of Shareholders' Meetings", "Quorum for Shareholders' Meetings", "Voting at Shareholders' Meetings" and "Variation of Class Rights" in "Appendix VI – Summary of Principal Legal and Regulatory Provisions".



Shanghai Miracogen Inc.- Ex. 2032, Page 000499

*You should read the following discussion and analysis together with our audited consolidated financial information, including the notes thereto, included in Appendix I to this prospectus. Our consolidated financial information has been prepared in accordance with IFRS.*

*The following discussion and analysis contain forward-looking statements that reflect our current views with respect to future events and financial performance. These statements are based on our assumptions and analysis in light of our experience and perception of historical trends, current conditions and expected future developments, as well as other factors we believe are appropriate under the circumstances. However, whether actual outcomes and developments will meet our expectations and predictions depends on a number of risks and uncertainties. In evaluating our business, you should carefully consider the information provided in this document, including but not limited to the sections headed "Risk Factors" and "Business."*

## OVERVIEW

We are an innovation-driven biopharmaceutical company focusing on oncology therapeutics. Our pipeline is designed with a range of products. As of the Latest Practicable Date, we had eight clinical-stage drug candidates (including four Core Products acquired through acquisitions of all equity interests or controlling stake in the relevant subsidiaries, with three of them subject to in-license arrangements and one co-developed through a joint venture), three pre-clinical drug candidates and three clinical-stage combination therapies of the candidates in our pipeline.

We have not generated any revenue from product sales. We were not profitable and incurred operating loss during the Track Record Period. In 2019, 2020 and the eight months ended August 31, 2021, we had operating loss of RMB454.7 million, RMB520.4 million and RMB662.2 million, respectively. Substantially all of our operating loss resulted from research and development expenses and administrative expenses, as well as fair value changes on financial assets and liabilities through profit or loss.

## BASIS OF PREPARATION

Our historical financial information has been prepared in accordance with International Financial Reporting Standards ("**IFRS**") issued by the International Accounting Standards Board ("**IASB**").

Our historical financial information has been prepared under the historical cost convention, as modified by the revaluation of financial assets and financial liabilities at fair value through profit or loss, which are carried at fair value.

We have adopted all applicable new and amended IFRSs consistently throughout the Track Record Period except for any new or interpretation that are not yet effective.



Shanghai Miracogen Inc.- Ex. 2032, Page 000500

## MAJOR FACTORS AFFECTING OUR RESULTS OF OPERATIONS

Our results of operations have been, and are expected to continue to be, materially affected by a number of factors, including the following:

### General Factors

Our business and operating results are affected by general factors affecting the global and China biologics market, which include:

- relevant laws and regulations, governmental policies and initiatives affecting the global and China biologics market;
- growth and competition environment of the global and China biologics market; and
- political, economic and social instability of different local markets.

### Company Specific Factors

While our business is influenced by general factors affecting the global and China biologics market, our results of operations are also affected by company specific factors, including the following:

***Our Ability to Successfully Develop and Commercialize our Drug Candidates***

Our business and results of operations depend on the successful development and commercialization of our drug candidates. As of the Latest Practicable Date, we had eight clinical-stage drug candidates (including four Core Products acquired through acquisitions of all equity interests or controlling stake in the relevant subsidiaries, with three of them subject to in-license arrangements and one co-developed through a joint venture), three pre-clinical drug candidates and three clinical-stage combination therapies of the candidates in our pipeline. See "Business – Our Drug Candidates." Whether our drug candidates can demonstrate favorable safety and efficacy clinical trial results, whether we can successfully complete clinical development and whether we can obtain the requisite regulatory approvals for our drug candidates, are crucial to our business and results of operations. See "Risk Factors – Risks Relating to the Research and Development of Our Drug Candidates" and "Risk Factors – Risks Relating to Regulatory Approvals and Government Regulations." In addition, once our drug candidates are commercialized, our business and results of operations will be driven by the market acceptance and sales of our commercialized drugs, which could be affected by: (i) the level of government spending on healthcare and the coverage of our drugs under government medical insurance schemes; (ii) our cooperation with potential sales channel partners; (iii) our pricing policies; and (iv) our biologics production capacity to meet the commercial demand. See "Risk Factors – Risks Relating to Commercialization of Our Drug Candidates" and "Risk Factors – Risks Relating to Manufacturing of Our Drug Candidates." Our commercialization


Shanghai Miracogen Inc.- Ex. 2032, Page 000501

strategy for our drug candidates involves building our own commercialization and distribution capabilities, seeking collaboration with leading pharmaceutical companies with relevant experience in international commercialization, and expanding our production capabilities. See "Business – Our Strategies."

***Our Cost Structure***

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

The development of drugs requires a significant investment of resources over a prolonged period of time, and we intend to continue making sustained investments in this area. We have devoted significant resources on research and development activities and our pipeline of drug candidates have been steadily advancing and expanding. We incurred research and development expenses of RMB229.2 million, RMB354.4 million and RMB509.5 million in 2019, 2020 and the eight months ended August 31, 2021, respectively, accounting for 54.4%, 78.7% and 82.4%, respectively, of our total expenses in the same periods. We incurred research and development expenses of RMB168.9 million, RMB233.8 million and RMB315.5 million attributable to our Core Products in 2019, 2020 and the eight months ended August 31, 2021, respectively. Our research and development expenses primarily consist of (i) clinical trial expenses; (ii) pre-clinical study costs; (iii) depreciation and amortization expenses; (iv) employee benefit expenses; and (v) raw materials and consumables used. See "– Description of Major Components of Our Results of Operations – Research and Development Expenses." The research and development expenses are affected by factors such as: (i) the expansion of our product pipeline as well as potential indications; (ii) the complexity of the requirements for conducting clinical trials of the drug candidates; (iii) the number of patients required for clinical trials; (iv) the location of the clinical trials (for example, whether the clinical trials are conducted in China or overseas); (v) the pre-clinical efforts needed for identifying more molecules with proven or highly potential efficacy and significant market opportunities; (vi) the number of our research and development staff; and (vii) any additional requirements imposed by competent regulatory authorities to our pre-clinical and clinical trials. See "Risk Factors – Risks Relating to the Research and Development of Our Drug Candidates." We intend to continue to advance the development of our drug candidates, and the research and development expenses are therefore expected to continue to be a major component of our operating expenses.

We incurred administrative expenses of RMB191.6 million, RMB93.8 million and RMB108.3 million in 2019, 2020 and the eight months ended August 31, 2021, respectively. Our administrative expenses primarily consist of (i) employee benefit expenses; and (ii) depreciation and amortization expenses. See "– Description of Major Components of Our Results of Operations – Administrative Expenses."


Shanghai Miracogen Inc.- Ex. 2032, Page 000502

We expect to incur significant expenses and operating loss for at least the next several years as we further our pre-clinical and clinical research and development efforts, seek regulatory approval for our drug candidates, launch commercialization of our pipeline products, and add personnel necessary to operate our business. We expect that our financial performance will fluctuate from period to period due to the development status of our drug candidates, regulatory approval timeline and commercialization of our drug candidates after approval. Subsequent to the Listing, we expect to incur costs associated with operating as a public company.

***Funding for Our Operation***

During the Track Record Period, we primarily funded our working capital requirements through capital contributions from our shareholders, private equity financing and bank loans. Going forward, in the event of a successful commercialization of one or more of our drug candidates, we expect to fund our operations in part with revenue generated from sales of our commercialized drug products. However, with the continuing expansion of our business, we may require further funding through public or private offerings, debt financing or other sources. Any fluctuation in the funding for our operations will impact our cash flow plan and our results of operations.

## CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Some of our accounting policies require us to apply estimates and assumptions as well as complex judgements related to accounting items. The estimates and assumptions we use and the judgements we make in applying our accounting policies have a significant impact on our financial position and operational results. Our management continually evaluates such estimates, assumptions and judgements based on past experience and other factors, including industry practices and expectations of future events that are deemed to be reasonable under the circumstances. There has not been any material deviation from our management's estimates or assumptions and actual results, and we have not made any material changes to these estimates or assumptions during the Track Record Period. We do not expect any material changes in these estimates and assumptions in the foreseeable future.

We set forth below those accounting policies that we believe are of critical importance to us or involve the most significant estimates, assumptions and judgements used in the preparation of our financial statements. For details of the critical accounting policies, estimates, assumptions and judgements involved in the preparation of financial statements of our Group, see Notes 2 and 4 of Appendix I to this prospectus.



Shanghai Miracogen Inc.- Ex. 2032, Page 000503

## Critical Accounting Policies

### *Intangible Assets*

Goodwill

Goodwill is measured as described in Note 2.3.2 of Appendix I to this prospectus. Goodwill on acquisitions of subsidiaries on balance sheet date is included in intangible assets. Goodwill is not amortized, but it is tested for impairment, or more frequently if events or changes in circumstances indicate that it might be impaired and is carried at cost less accumulated impairment losses. See Note 2.8.1 of Appendix I to this prospectus.

Intellectual Properties

Separately acquired intellectual properties are shown at historical cost. Intellectual properties acquired in a business combination are recognized at fair value at the acquisition date. Intellectual properties are subsequently carried at cost less accumulated amortization and impairment losses. We might acquire intellectual properties for an initial payment plus agreed additional payments contingent on future events and outcomes. See Note 2.8.2 of Appendix I to this prospectus.

Research and Development

Research expenditures are charged to the profit or loss as an expense in the period the expenditure is incurred. Development costs are recognized as assets if they can be directly attributable to a newly developed drug by satisfying the criteria specified in Note 2.8.3 of Appendix I to this prospectus. During the Track Record Period, there were no internally generated development costs meeting these criteria and capitalized as intangible assets.

### *Property, Plant and Equipment*

Property, plant and equipment are stated at historical costs less depreciation. Historical cost includes expenditure that is directly attributable to the acquisition of the items. Subsequent costs are included in the asset's carrying amount or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to us and the costs of the item can be measured reliably. The carrying amount of any component accounted for as a separate asset is derecognized when replaced. All other repairs and maintenance were charged to the consolidated statements of comprehensive loss during the Track Record Period in which they were incurred. See Note 2.7 of Appendix I to this prospectus.


Shanghai Miracogen Inc.- Ex. 2032, Page 000504

***Impairment of Non-financial Assets***

Intangible assets that have an indefinite useful life are not subject to amortization and are tested annually for impairment, or more frequently if events or changes in circumstances indicate that they might be impaired. Other assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. Non-financial assets other than goodwill that suffered an impairment are reviewed for possible reversal of the impairment at the end of each reporting period. See Note 2.9 of Appendix I to this prospectus.

***Financial Instruments with Preferred Rights at Amortized Costs***

A contract that contains an obligation to purchase our Company's equity instruments for cash or another financial asset gives rise to a financial liability for the present value of the redemption amount. Even if our Company's obligations to purchase is conditional on counterparty's exercising a right to redeem, the financial instruments with preferred rights are recognized as financial liability initially at the present value of the redemption amount and subsequently measured at amortized cost with interest charged in finance cost. We derecognize financial liabilities when, and only when, our obligations are discharged, canceled or have expired. The carrying amount of the financial instruments derecognized was credited into the equity.

***Share-based Payments***

Our share-based payments include: (i) share-based payment expenses related to Controlling Shareholder Loans (as defined in "History, Development and Corporate Structure – Corporate Development – Subsequent Capital Increase and Equity Transfer"), representing the difference between the issuance price of Controlling Shareholder Loans and the fair value of equity on its issuance date; and (ii) share-based payment expenses under our ESOP launched on December 7, 2020. See Note 27 of Appendix I to this prospectus. The fair value of awarded shares granted to employees under the ESOP less the amount paid by employees is recognized as employee benefit expenses over the relevant service period, being the vesting period of the shares, and the credit is recognized in equity in the share-based payment reserves. The fair value of the shares is measured at the grant date. The number of shares expected to vest is estimated based on the non-market vesting conditions. The estimates are revised at the end of each reporting period and adjustments are recognized in profit or loss and the share-based payment reserves. See Note 2.24 of Appendix I to this prospectus.


Shanghai Miracogen Inc.- Ex. 2032, Page 000505

***Financial liabilities at fair value through profit or loss***

Financial liabilities are recognized when the entity becomes a party to the contractual provisions of the instrument. At initial recognition, we measure a financial liability at its fair value plus or minus, in the case of a financial liability not at fair value through profit or loss, transaction costs that are incremental and directly attributable to the acquisition or issue of the financial liability, such as fees and commissions. We shall present a gain or loss on those financial liabilities at fair value through profit or loss as follows: the amount of change in the fair value of the financial liability that is attributable to changes in the credit risk of that liability shall be presented in other comprehensive income, and the remaining amount of change in the fair value of the liability shall be presented in profit or loss unless the treatment of the effects of changes in the liability's credit risk would create or enlarge an accounting mismatch in profit or loss. The financial liability is derecognized when the obligation under the liability is discharged or expires. When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as a derecognition of the original liability and a recognition of a new liability. See Note 2.30 of Appendix I to this prospectus.

**Critical Accounting Estimates**

***Goodwill Impairment***

We test whether goodwill has suffered any impairment on an annual basis. The recoverable amount of a cash-generating unit is determined based on value-in-use calculations which require the use of assumptions. Details of key assumptions are disclosed in Note 16 of Appendix I to this prospectus.

***Fair Value of Financial Liabilities through Profit or Loss***

We recognized (i) the variable consideration for our acquisition of 40% equity interests of Taizhou Hanzhong from its non-controlling shareholder and (ii) Convertible Loans issued to the Series A Investors during the Track Record Period as financial liabilities at fair value through profit or loss as set out in Note 31 and Note 34 of Appendix I to this prospectus. We evaluate the fair value of the variable consideration periodically using the discounted cash flow method under which key assumptions like the compound net revenue growth rate and the pre-tax discount rate were adopted to determine the fair value of the variable consideration. The Convertible Loans issued by us exhibit the characteristics of an embedded derivative and we have designated the entire instruments as a financial liability at fair value through profit or loss. The fair value of the convertible loans in which no quoted prices in an active market exist is established by using valuation techniques such as back-solve method and discounted cash flow method. Key assumptions, such as the discount rate, were based on our management's best estimates. Management's estimates and assumptions are reviewed periodically and are adjusted if necessary. Should any of the estimates and assumptions changed, it may lead to a change in the fair value to be recognized in the statements of comprehensive loss. See Note 4.3 of Appendix I to this prospectus.



Shanghai Miracogen Inc.- Ex. 2032, Page 000506

## DESCRIPTION OF MAJOR COMPONENTS OF OUR RESULTS OF OPERATIONS

We have not generated any revenue from product sales. We were not profitable and incurred operating loss during the Track Record Period. In 2019, 2020 and the eight months ended August 31, 2021, we had operating loss of RMB454.7 million, RMB520.4 million and RMB662.2 million, respectively. Substantially all of our operating loss resulted from research and development expenses and administrative expenses, as well as fair value changes on financial assets and liabilities through profit or loss.

The following table sets out a selected data of our consolidated statements of comprehensive loss for the periods indicated:

| | Year ended December 31, | | Eight months ended August 31, | |
|---|---|---|---|---|
| | **2019** | **2020** | **2020** | **2021** |
| | *RMB'000* | *RMB'000* | *RMB'000 (Unaudited)* | *RMB'000* |
| Other income | 5,553 | 7,964 | 2,656 | 4,601 |
| Other expenses | (892) | (1,915) | (1,380) | (707) |
| Administrative expenses | (191,551) | (93,757) | (49,727) | (108,328) |
| Research and development expenses | (229,197) | (354,427) | (196,273) | (509,483) |
| Fair value changes on financial assets and liabilities through profit and loss | (38,312) | (77,991) | (117,497) | (47,434) |
| Other (losses)/gains, net | (256) | (225) | (420) | (831) |
| **Operating loss** | **(454,655)** | **(520,351)** | **(362,641)** | **(662,182)** |
| Finance income | 397 | 5,306 | 1,019 | 3,267 |
| Finance costs | (52,559) | (86,319) | (85,144) | (3,027) |
| Finance (costs)/income, net | (52,162) | (81,013) | (84,125) | 240 |
| Share of (loss)/profit of investments accounted for using the equity method | (8,675) | (12,084) | (5,390) | (6,293) |
| **Loss before income tax** | **(515,492)** | **(613,448)** | **(452,156)** | **(668,235)** |
| Income tax expense | – | – | – | – |
| **Loss for the year/period** | **(515,492)** | **(613,448)** | **(452,156)** | **(668,235)** |
| **Loss attributable to:** | | | | |
| Owners of the Company | (447,036) | (581,849) | (427,971) | (656,392) |
| Non-controlling interests | (68,456) | (31,599) | (24,185) | (11,843) |



Shanghai Miracogen Inc.- Ex. 2032, Page 000507

**Other Income**

Our other income primarily consists of (i) investment income on financial assets at fair value through profit or loss, representing the interest we earn from structured deposits; (ii) government grants to support our research and development activities; and (iii) rental and related income.

The following table sets out a breakdown of our other income for the periods indicated:

| | Year ended December 31, | | | | Eight months ended August 31, | | | |
|---|---|---|---|---|---|---|---|---|
| | 2019 | | 2020 | | 2020 | | 2021 | |
| | *RMB'000* | *%* | *RMB'000* | *%* | *RMB'000* | *%* | *RMB'000* | *%* |
| | | | | | *(Unaudited)* | | | |
| Investment income on financial assets at fair value through profit or loss | 2,035 | 36.6 | 5,091 | 64.0 | 689 | 26.0 | 3,681 | 80.0 |
| Government grants | 2,535 | 45.7 | 774 | 9.7 | 479 | 18.0 | 146 | 3.1 |
| Rental and related income | 918 | 16.5 | 1,976 | 24.8 | 1,411 | 53.1 | 734 | 16.0 |
| Others | 65 | 1.2 | 123 | 1.5 | 77 | 2.9 | 40 | 0.9 |
| **Total** | **5,553** | **100.0** | **7,964** | **100.0** | **2,656** | **100.0** | **4,601** | **100.0** |

**Other Expenses**

Our other expenses primarily represent the depreciation of our right-of-use assets and property, plant and equipment related to rental arrangements. In 2019, 2020 and the eight months ended August 31, 2021, we had other expenses of RMB0.9 million, RMB1.9 million and RMB0.7 million, respectively.

**Research and Development Expenses**

Our research and development expenses primarily consist of (i) clinical trial expenses, mainly in relation to our engagement of CROs, SMOs, CDMOs and hospitals, see "Business – Research and Development – Engagement of Third Parties in Research and Development;" (ii) pre-clinical study costs, mainly in relation to our engagement of pre-clinical CROs and CDMOs; (iii) depreciation and amortization expenses, mainly including depreciation expenses for property, plant and equipment as well as amortization expenses for intangible assets such as intellectual properties; (iv) employee benefit expenses (mainly including wages, salaries and bonuses and share-based payment expenses) relating to our research and development staff; and (v) raw materials and consumables used, primarily representing expenses for procuring raw materials and consumables used in pre-clinical studies and clinical trials, see "Business – Research and Development – Engagement of Third Parties in Research and Development."



Shanghai Miracogen Inc.- Ex. 2032, Page 000508

The following table sets out a breakdown of our research and development expenses by nature in absolute amounts and as percentages of our total research and development expenses for the periods indicated:

| | Year ended December 31, | | | | Eight months ended August 31, | | | |
|---|---|---|---|---|---|---|---|---|
| | 2019 | | 2020 | | 2020 | | 2021 | |
| | *RMB'000* | *%* | *RMB'000* | *%* | *RMB'000* | *%* | *RMB'000* | *%* |
| | | | | | *(Unaudited)* | | | |
| Clinical trial expenses | 117,532 | 51.3 | 146,938 | 41.5 | 82,148 | 41.9 | 249,498 | 49.0 |
| Pre-clinical study costs | 32,541 | 14.2 | 66,905 | 18.9 | 39,558 | 20.2 | 54,530 | 10.7 |
| Depreciation and amortization | 35,423 | 15.5 | 49,890 | 14.0 | 33,980 | 17.3 | 50,324 | 9.9 |
| Employee benefit expenses | 23,711 | 10.3 | 48,214 | 13.6 | 23,046 | 11.7 | 109,556 | 21.5 |
| – Wages, salaries and bonuses | 19,585 | 8.5 | 39,312 | 11.1 | 20,037 | 10.2 | 36,145 | 7.1 |
| – Pension costs | 1,705 | 0.7 | 92 | 0.0 | 92 | 0.0 | 5,354 | 1.1 |
| – Other social security costs, housing benefits and other employee benefits | 2,421 | 1.1 | 6,068 | 1.7 | 2,917 | 1.5 | 8,532 | 1.7 |
| – Share-based payment expenses | – | – | 2,742 | 0.8 | – | – | 59,525 | 11.6 |
| Raw materials and consumables used | 14,464 | 6.3 | 35,298 | 10.0 | 12,037 | 6.1 | 32,540 | 6.4 |
| Others | 5,526 | 2.4 | 7,182 | 2.0 | 5,504 | 2.8 | 13,035 | 2.5 |
| **Total** | **229,197** | **100.0** | **354,427** | **100.0** | **196,273** | **100.0** | **509,483** | **100.0** |

**Administrative Expenses**

Our administrative expenses primarily consist of (i) employee benefit expenses (mainly including wages, salaries and bonuses and share-based payment expenses) relating to our administrative staff; (ii) depreciation and amortization expenses, primarily representing depreciation expenses for right-of-use assets and property, plant and equipment; and (iii) others, mainly representing utilities as well as traveling and transportation expenses. Our share-based payment expenses of RMB143.7 million in 2019 represented the difference between the issuance price of the Controlling Shareholder Loans of RMB450.0 million and the fair value of equity on its issuance date, see Note 34 and Note 27(c) of Appendix I to this prospectus. Our share-based payment expenses of RMB2.5 million in 2020 and of RMB26.3 million in the eight months ended August 31, 2021 represented employee benefit expenses relating to our administrative staff under our ESOP, see Note 8 of Appendix I to this prospectus.



Shanghai Miracogen Inc.- Ex. 2032, Page 000509

The following table sets out a breakdown of our administrative expenses in absolute amounts and as percentages of our total administrative expenses for the periods indicated:

| | Year ended December 31, | | | | Eight months ended August 31, | | | |
|---|---|---|---|---|---|---|---|---|
| | 2019 | | 2020 | | 2020 | | 2021 | |
| | *RMB'000* | *%* | *RMB'000* | *%* | *RMB'000* *(Unaudited)* | *%* | *RMB'000* | *%* |
| Employee benefit expenses | 161,188 | 84.1 | 33,350 | 35.6 | 18,980 | 38.2 | 55,953 | 51.7 |
| – Wages, salaries and bonuses | 13,651 | 7.1 | 26,686 | 28.5 | 16,515 | 33.3 | 22,582 | 20.8 |
| – Pension costs | 1,587 | 0.8 | 62 | 0.1 | 62 | 0.1 | 2,735 | 2.5 |
| – Other social security costs, housing benefits and other employee benefits | 2,255 | 1.2 | 4,120 | 4.4 | 2,403 | 4.8 | 4,357 | 4.0 |
| – Share-based payment expenses | 143,695 | 75.0 | 2,481 | 2.6 | – | – | 26,279 | 24.4 |
| Listing expenses | – | – | – | – | – | – | 27,573 | 25.5 |
| Depreciation and amortization | 13,384 | 7.0 | 33,121 | 35.3 | 21,893 | 44.0 | 12,705 | 11.7 |
| Professional services fees | 2,428 | 1.3 | 8,165 | 8.7 | 2,490 | 5.0 | 1,775 | 1.6 |
| Others | 14,551 | 7.6 | 19,122 | 20.4 | 6,364 | 12.8 | 10,322 | 9.5 |
| **Total** | **191,551** | **100.0** | **93,757** | **100.0** | **49,727** | **100.0** | **108,328** | **100.0** |

**Fair Value Changes on Financial Assets and Liabilities through Profit and Loss**

We had fair value changes on financial assets and liabilities through profit and loss of RMB38.3 million, RMB78.0 million in 2019 and 2020, and RMB117.5 million and RMB47.4 million in the eight months ended August 31, 2020 and 2021. Our financial liabilities include (i) financial liabilities at fair value through profit or loss, representing the variable part of the consideration for our acquisition of 40% equity interests of Taizhou Hanzhong from its non-controlling shareholder, being 4.375% of future annual net sales revenue of relevant PD-1 products, see "– Discussion of Certain Key Balance Sheet Items – Non-current Assets and Liabilities – Financial Liabilities at Fair Value through Profit or Loss;" and (ii) our Convertible Loans (as defined in "History, Development and Corporate Structure – Corporate Development – Subsequent Capital Increase and Equity Transfer") issued in March 2019, which were converted into financial instruments with preferred rights at amortized cost in April 2020 and were finally reclassified as equity in August 2020, see "– Discussion of Certain Key Balance Sheet Items – Current Assets and Liabilities – Convertible Loans."



Shanghai Miracogen Inc.- Ex. 2032, Page 000510

The following table sets out a breakdown of our fair value changes on financial assets and liabilities through profit and loss for the periods indicated:

| | Year ended December 31, | | Eight months ended August 31, | |
|---|---|---|---|---|
| | **2019** | **2020** | **2020** | **2021** |
| | *RMB'000* | *RMB'000* | *RMB'000* *(Unaudited)* | *RMB'000* |
| Net fair value losses on financial liabilities through profit and loss | | | | |
| – Fair value through profit or loss | (17,692) | (30,100) | (69,283) | (48,158) |
| – Convertible loans | (20,620) | (48,548) | (48,548) | – |
| Net fair value gains on financial assets through profit or loss | – | 657 | 334 | 724 |
| **Total** | **(38,312)** | **(77,991)** | **(117,497)** | **(47,434)** |

**Finance Income and Finance Costs**

Our finance income primarily represents our bank interest income. Our finance costs primarily consist of (i) interest on financial instruments with preferred rights at amortized cost, see "– Discussion of Certain Key Balance Sheet Items – Current Assets and Liabilities – Financial Instruments with Preferred Rights at Amortized Cost;" (ii) interest on lease liabilities, see "– Indebtedness – Lease liabilities;" and (iii) interest on bank borrowings, see "– Indebtedness – Borrowings."



Shanghai Miracogen Inc.- Ex. 2032, Page 000511

The following table sets out a breakdown of our finance income and finance costs for the periods indicated:

| | Year ended December 31, | | Eight months ended August 31, | |
|---|---|---|---|---|
| | **2019** | **2020** | **2020** | **2021** |
| | *RMB'000* | *RMB'000* | *RMB'000 (Unaudited)* | *RMB'000* |
| **Finance income:** | **397** | **5,306** | **1,019** | **3,267** |
| **Finance costs:** | | | | |
| Interest on financial instruments with preferred rights at amortized cost | (50,035) | (80,852) | (80,852) | – |
| Interest on bank borrowings | (571) | (7,046) | (4,478) | (4,422) |
| Interest on lease liabilities | (2,287) | (3,099) | (2,428) | (1,533) |
| Others | (237) | (1,497) | (1,449) | (1,417) |
| **Total finance costs** | **(53,130)** | **(92,494)** | **(89,207)** | **(7,372)** |
| Amount capitalized[(1)] | 571 | 6,175 | 4,063 | 4,345 |
| **Finance (costs)/income, net** | **(52,162)** | **(81,013)** | **(84,125)** | **240** |

*Notes:*

(1) The capitalization rate used to determine the amount of borrowing costs to be capitalized is the weighted average interest rate applicable to our general borrowings, which were 4.54%, 4.50%, 4.52% and 4.46% in 2019, 2020 and the eight months ended August 31, 2020 and 2021, respectively.

**Share of (Loss)/Profit of Investments Accounted for Using the Equity Method**

We incurred share of loss of investments accounted for using the equity method of RMB8.7 million in 2019, RMB12.1 million in 2020 and share of profit of investments accounted for using the equity method of RMB6.3 million in the eight months ended August 31, 2021, representing our loss of investments in four associates of our Group, namely Wuhan Binhui, Hangzhou HealSun, Hangzhou Xiyuan Biotechnology Co., Ltd. and KYM. Our share of loss of investments accounted for using the equity method relating to KYM was recorded since 2021. In October 2021, we transfer all equity interest we held in Hangzhou Xiyuan Biotechnology Co., Ltd. to an independent third party. For summarized financial information of associates that are material to us, see Note 17 of Appendix I to this prospectus.



Shanghai Miracogen Inc.- Ex. 2032, Page 000512

**Income Tax Expense**

During the Track Record Period, we recorded no income tax expense. Generally, our subsidiaries in China are subject to enterprise income tax on their taxable income in China at a rate of 25%, except that Miracogen Shanghai benefits from a preferential tax rate of 15% as it is qualified as a High and New Technology Enterprise under relevant PRC laws and regulations on November 18, 2020. According to the relevant laws and regulations promulgated by the State Administration of Taxation of the PRC effective from 2018 onwards, enterprises engaging in research and development activities are entitled to claim 175% of their research and development expenses incurred as tax deductible expenses when determining their assessable profits for that year. As of December 31, 2019 and 2020 and August 31, 2021, we had unused tax losses of RMB513.5 million, RMB1,023.5 million and RMB1,596.1 million, respectively, that can be carried forward against future taxable income. No deferred tax asset was recognized in respect of such tax losses due to the unpredictability of future taxable income. See Note 12 of Appendix I to this prospectus.

During the Track Record Period and up to the Latest Practicable Date, we had made all the required tax filings with the relevant tax authorities in the PRC and we are not aware of any outstanding or potential disputes with such tax authorities.

**PERIOD-TO-PERIOD COMPARISON OF RESULTS OF OPERATIONS**

**Eight Months Ended August 31, 2021 Compared to Eight Months Ended August 31, 2020**

***Other Income***

Our other income increased by 70.4% from RMB2.7 million in the eight months ended August 31, 2020 to RMB4.6 million in the eight months ended August 31, 2021, primarily due to an increase in our investment income on financial assets at fair value through profit or loss, representing the increase in interests we received from certain structured deposits.

***Other Expenses***

Our other expenses decreased by 50.0% from RMB1.4 million in the eight months ended August 31, 2020 to RMB0.7 million in the eight months ended August 31, 2021, which was in line with the decrease in our rental and related income.


Shanghai Miracogen Inc.- Ex. 2032, Page 000513

***Research and Development Expenses***

Our research and development expenses increased significantly from RMB196.3 million in the eight months ended August 31, 2020 to RMB509.5 million in the eight months ended August 31, 2021, primarily due to (i) an increase in the clinical trial expenses; and (ii) an increase in the employee benefit expenses in relation to our research and development staff, especially the share-based payment expenses in relation to our ESOP, see Note 8 of Appendix I to this prospectus. Such increases were all in line with our continuous research and development efforts to support our steadily advancing and expanding pipeline of drug candidates.

***Administrative Expenses***

Our administrative expenses increased significantly from RMB49.7 million in the eight months ended August 31, 2020 to RMB108.3 million in the eight months ended August 31, 2021, primarily due to (i) an increase in the employee benefit expenses in relation to our administrative staff, especially the share-based payment expenses in relation to our ESOP, see Note 8 of Appendix I to this prospectus; and (ii) an increase in the listing expenses.

***Fair Value Changes on Financial Assets and Liabilities through Profit and Loss***

Our fair value changes on financial assets and liabilities through profit and loss decreased by 59.7% from RMB117.5 million in the eight months ended August 31, 2020 to RMB47.4 million in the eight months ended August 31, 2021, primarily because i) we had lower increase in 2021 in the valuation of our variable consideration payable for our acquisition of 40% equity interests of Taizhou Hanzhong from its non-controlling shareholder, taking into consideration the sales potential of PD-1, see "– Discussion of Certain Key Balance Sheet Items – Non-current Assets and Liabilities – Financial Liabilities at Fair Value through Profit or Loss;" and ii) we had net fair value losses in relation to convertible loans of RMB48.5 million in the eight months ended August 31, 2020, while we did not have such losses in the eight months ended August 31, 2021, as our Convertible Loans issued in March 2019 were converted into financial instruments with preferred rights at amortized cost in April 2020, before they were finally reclassified as equity in August 2020. See "– Discussion of Certain Key Balance Sheet Items – Current Assets and Liabilities – Convertible Loans."

***Finance (Costs) Income, Net***

We had net finance costs of RMB84.1 million in the eight months ended August 31, 2020, compared to net finance income of RMB0.2 million in the eight months ended August 31, 2021, primarily because (i) we had interest on financial instruments with preferred rights at amortized cost of RMB80.9 million in the eight months ended August 31, 2020, while we did not have such finance costs in the eight months ended August 31, 2021, as the financial instruments with preferred rights at amortized cost were reclassified as equity in August 2020; and (ii) our finance income increased in the eight months ended August 31, 2021 due to the increase in bank interest income.



Shanghai Miracogen Inc.- Ex. 2032, Page 000514

***Share of (Loss) Profit of Investments Accounted for Using the Equity Method***

Our share of loss of investments accounted for using the equity method increased by 16.7% from RMB5.4 million in the eight months ended August 31, 2020 to RMB6.3 million in the eight months ended August 31, 2021, mainly due to an increase in the total loss of associates we invested in as a result of their increased total costs and expenses.

***Loss for the Period***

As a result of the foregoing, our loss for the period increased by 47.8% from RMB452.2 million in the eight months ended August 31, 2020 to RMB668.2 million in the eight months ended August 31, 2021.

**2020 Compared to 2019**

***Other Income***

Our other income increased by 42.9% from RMB5.6 million in 2019 to RMB8.0 million in 2020, primarily due to (i) an increase in our investment income on financial assets at fair value through profit or loss as a result of an increase in our structured deposits; and (ii) an increase in our rental and related income. Such increases were partially offset by a decrease in our government grants, as our government grants received in 2019 were primarily one-off in nature.

***Other Expenses***

Our other expenses increased significantly from RMB0.9 million in 2019 to RMB1.9 million in 2020, which was in line with the increase in our rental and related income.

***Research and Development Expenses***

Our research and development expenses increased by 54.6% from RMB229.2 million in 2019 to RMB354.4 million in 2020, primarily due to increases in clinical trial expenses, pre-clinical study costs and employee benefit expenses in relation to our research and development staff. Such increases were all in line with our continuous research and development efforts to support our steadily advancing and expanding pipeline of drug candidates.


Shanghai Miracogen Inc.- Ex. 2032, Page 000515

***Administrative Expenses***

Our administrative expenses decreased by 51.0% from RMB191.6 million in 2019 to RMB93.8 million in 2020, primarily because we recorded one-off share-based payment expenses related to Controlling Shareholder Loans of RMB143.7 million in 2019, representing the difference between the issuance price of the Controlling Shareholder Loans of RMB450.0 million and the fair value of equity on issuance date, while we did not have such expense in 2020. See "– Discussion of Certain Key Balance Sheet Items – Current Assets and Liabilities – Financial Instruments with Preferred Rights at Amortized Cost." Such decrease was partially offset by (i) an increase in wages, salaries and bonuses in relation to our administrative staff as we engaged more administrative staff to satisfy our daily operation need; and (ii) an increase in depreciation and amortization expenses, which was in line with the increases in our right-of-use assets and property, plant and equipment.

***Fair Value Changes on Financial Assets and Liabilities through Profit and Loss***

Our fair value changes on financial assets and liabilities through profit and loss increased significantly from RMB38.3 million in 2019 to RMB78.0 million in 2020, primarily due to (i) the higher increase in 2020 in the valuation of our variable consideration payable for our acquisition of 40% equity interests of Taizhou Hanzhong from its non-controlling shareholder, taking into consideration the sales potential of PD-1, see "– Discussion of Certain Key Balance Sheet Items – Non-current Assets and Liabilities – Financial Liabilities at Fair Value through Profit or Loss;" and (ii) the higher increase in the valuation of our convertible loans before they were converted into financial instruments with preferred rights at amortized cost in April 2020, and such increase was due to the increase in the valuation of our Company, see "– Discussion of Certain Key Balance Sheet Items – Current Assets and Liabilities – Convertible Loans."

***Finance Costs, Net***

Our net finance costs increased by 55.2% from RMB52.2 million in 2019 to RMB81.0 million in 2020, primarily due to an increase in interest on financial instruments with preferred rights at amortized cost in 2020, as a result of an increase in our financial instruments with preferred rights at amortized cost, mainly because (i) the Convertible Loans we issued in March 2019 were converted into financial instruments with preferred rights at amortized cost in April 2020; and (ii) the issuance of Series B financial instruments with preferred rights at amortized cost in July 2020. Such financial instruments with preferred rights at amortized cost were all finally reclassified as equity in August 2020. See Note 34 of Appendix I to this prospectus.



Shanghai Miracogen Inc.- Ex. 2032, Page 000516

***Share of Loss of Investments Accounted for Using the Equity Method***

Our share of loss of investments accounted for using the equity method increased by 39.1% from RMB8.7 million in 2019 to RMB12.1 million in 2020, mainly due to an increase in the total loss of the three associates we invested in as a result of their increased total costs and expenses.

***Loss for the Year***

As a result of the foregoing, our loss for the year increased by 19.0% from RMB515.5 million in 2019 to RMB613.4 million in 2020.

## DISCUSSION OF CERTAIN KEY BALANCE SHEET ITEMS

The following table sets out selected data from our consolidated balance sheet as of the dates indicated:

| | As of December 31, | | As of August 31, |
|---|---|---|---|
| | **2019** | **2020** | **2021** |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| Total non-current assets | 1,303,742 | 1,580,262 | 1,656,231 |
| Total current assets | 221,539 | 843,349 | 550,795 |
| **Total assets** | **1,525,281** | **2,423,611** | **2,207,026** |
| Total non-current liabilities | 495,285 | 539,668 | 748,349 |
| Total current liabilities | 1,215,636 | 382,221 | 278,675 |
| **Total liabilities** | **1,710,921** | **921,889** | **1,027,024** |
| **Total equity** | **(185,640)** | **1,501,722** | **1,180,002** |
| **Total equity and liabilities** | **1,525,281** | **2,423,611** | **2,207,026** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000517

**Current Assets and Liabilities**

The following table sets out our current assets and liabilities as of the dates indicated:

| | As of December 31, | | As of August 31, | As of December 31, |
|---|---|---|---|---|
| | **2019** | **2020** | **2021** | **2021** |
| | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* (unaudited) |
| **Current assets** | | | | |
| Inventories | 8,082 | 19,569 | 24,164 | 24,184 |
| Other receivables, prepayments and deposits | 24,912 | 70,256 | 82,713 | 84,780 |
| Financial assets at fair value through profit or loss | – | 330,657 | 132,724 | – |
| Cash and cash equivalents | 188,545 | 402,867 | 261,194 | 155,168 |
| Term deposits with initial terms of over three months | – | 20,000 | 50,000 | 50,000 |
| **Total current assets** | **221,539** | **843,349** | **550,795** | **314,132** |
| **Current liabilities** | | | | |
| Borrowings | – | – | 30,000 | 60,409 |
| Trade payables | 31,684 | 42,448 | 84,560 | 158,818 |
| Other payables and accruals | 378,278 | 321,307 | 147,927 | 311,043 |
| Lease liabilities | 27,565 | 18,466 | 16,188 | 18,787 |
| Convertible loans | 380,620 | – | – | – |
| Financial instruments with preferred rights at amortized cost | 397,489 | – | – | – |
| **Total current liabilities** | **1,215,636** | **382,221** | **278,675** | **549,057** |
| **Net current (liabilities)/assets** | **(994,097)** | **461,128** | **272,120** | **(234,925)** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000518

We had net current liabilities of RMB994.1 million as of December 31, 2019 and net current assets of RMB461.1 million as of December 31, 2020, mainly because (i) our total current assets increased significantly from RMB221.5 million as of December 31, 2019 to RMB843.3 million as of December 31, 2020, primarily due to increases in financial assets at fair value through profit or loss, as well as cash and cash equivalents; and (ii) our total current liabilities decreased by 68.6% from RMB1,215.6 million as of December 31, 2019 to RMB382.2 million as of December 31, 2020, primarily due to the decreases in convertible loans as well as financial instruments with preferred rights at amortized cost.

Our net current assets decreased by 41.0% from RMB461.1 million as of December 31, 2020 to RMB272.1 million as of August 31, 2021, primarily due to decreases in our cash and cash equivalents and financial assets at fair value through profit or loss, partially offset by a decrease in other payables and accruals. Our net current assets of RMB272.1 million as of August 31, 2021 changed to net current liabilities of RMB234.9 million as of December 31, 2021, primarily due to the increase in other payables and accruals according to the repayment schedule of consideration payable for non-controlling interest transaction, as well as the increase in our trade payables resulting from our research and development activities during such period.

***Inventories***

During the Track Record Period, our inventories represented raw materials we purchased for our production lines in Beijing for research and development purpose. See "Business – Manufacturing and Quality Control – Our Manufacturing Facilities." Our inventories increased significantly from RMB8.1 million as of December 31, 2019 to RMB19.6 million as of December 31, 2020, primarily because (i) our Beijing antibody production line started operation in late 2019; and (ii) we increased procurement of raw materials in 2020 to prevent any potential impact of the COVID-19 outbreak. Our inventories increased by 23.5% from RMB19.6 million as of December 31, 2020 to RMB24.2 million as of August 31, 2021, primarily due to our increased procurement of raw materials for our Beijing antibody production line in the eight months ended August 31, 2021.

Our Directors confirm that our inventory control system and policies have been effective and we had not experienced any material shortage in supply or overstock of inventory during the Track Record Period and up to the Latest Practicable Date.

As of December 31, 2021, we had utilized RMB4.6 million, or 19.1%, of our total inventories outstanding as of August 31, 2021.

***Current Portion of Other Receivables, Prepayments and Deposits***

Our current portion of other receivables, prepayments and deposits primarily represent prepayments for clinical trial expenses, mainly relating to research and development services we procured from CROs and hospitals.



Shanghai Miracogen Inc.- Ex. 2032, Page 000519

The following table sets out a breakdown of our other receivables, prepayments and deposits as of the dates indicated:

| | As of December 31, | | As of August 31, |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| Prepayments for: | | | |
| – property, plant and equipment | 98,444 | 64,330 | 63,003 |
| – clinical trial expenses | 15,305 | 62,267 | 67,875 |
| – professional fees | – | – | 4,384 |
| Value added tax recoverable | 51,627 | 79,566 | 76,881 |
| Others | 14,688 | 16,766 | 18,175 |
| | 180,064 | 222,929 | 230,318 |
| Less: loss allowance for other receivables, prepayments and deposits | (452) | (664) | (457) |
| | 179,612 | 222,265 | 229,861 |
| Less: non-current portion[(1)] | (154,700) | (152,009) | (147,148) |
| **Total** | **24,912** | **70,256** | **82,713** |

*Note:*

(1) The non-current portion of other receivables, prepayments and deposits include value added tax recoverable that could not be utilized in the next 12 months, prepayments to suppliers of property, plant and equipment, and deposits as guarantee of land use rights. See "– Non-current Assets and Liabilities – Non-Current Portion of Other Receivables, Prepayments and Deposits."

Our other receivables, prepayments and deposits increased by 23.8% from RMB179.6 million as of December 31, 2019 to RMB222.3 million as of December 31, 2020, primarily due to an increase in prepayments for clinical trial expenses, mainly as a result of our increased procurement of services from CROs and hospitals, which was in line with our continuous research and development efforts. Such increases were partially offset by a decrease in prepayments for property, plant and equipment, as a result of the completion of construction of our Beijing antibody production line. Our other receivables, prepayments and deposits remained relatively stable, being RMB222.3 million as of December 31, 2020 and RMB229.9 million as of August 31, 2021.

As of December 31, 2021, RMB35.4 million, or 15.4%, of our other receivables, prepayments and deposits as of August 31, 2021 had been settled.



Shanghai Miracogen Inc.- Ex. 2032, Page 000520

***Financial Assets at Fair Value through Profit or Loss***

We did not have financial assets at fair value through profit or loss as of December 31, 2019, while we had financial assets at fair value through profit or loss of RMB330.7 million as of December 31, 2020, all representing our structured deposits. Our financial assets at fair value through profit or loss decreased by 59.9% from RMB330.7 million as of December 31, 2020 to RMB132.7 million as of August 31, 2021, primarily due to the redemption of structured deposits at maturity in the eight months ended August 31, 2021.

During the Track Record Period, we had structured deposits as supplemental means to improve our utilization of cash on a short-term basis. Our structured deposits were mainly issued by reputable commercial banks such as China Merchants Bank and China Industrial Bank. Such deposits were all principal-guaranteed and floating-interest products with a maturity of up to 92 days. We have adopted internal policies to evaluate, approve and monitor investment activities. Such policies provide that:

- we may invest in structured deposits only when we have surplus cash;
- only principal-guaranteed products issued by reputable commercial banks are allowed;
- investment targets are selected based on risk exposure, expected return and liquidity;
- we typically purchase structured deposits with a maturity up to six months;
- investments in structured deposits are subject to a multi-layered approval process involving our finance and accounting departments and senior management;
- our internal accounting managers are responsible for monitoring the performance of the structured deposits that we bought and would report to our finance officer in a timely manner in the event of any significant or adverse fluctuation in the products that we bought; and
- upon the maturity dates of each investment, designated personnel at our finance department would be responsible for the redemption and disposition of the investments according to the relevant contracts.

We invested in structured deposits with expected but not guaranteed rates of return ranging from 1.6% to 2.85%, from 1.4% to 3.37%, from 1.5% to 3.05% and from 1.1% to 3.40%, respectively, per annum for 2019 and 2020 and the eight months ended August 31, 2020 and 2021. We are exposed to credit risk in relation to such investments that are measured at fair value through profit or loss. The maximum exposure at the end of the reporting period is the carrying amount of these investments.


Shanghai Miracogen Inc.- Ex. 2032, Page 000521

***Trade Payables***

Our trade payables mainly include our payables for purchasing research services from CROs and hospitals as well as our payables for purchasing raw materials. Our trade payables increased by 33.8% from RMB31.7 million as of December 31, 2019 to RMB42.4 million as of December 31, 2020, and increased by 99.5% from RMB42.4 million as of December 31, 2020 to RMB84.6 million as of August 31, 2021, primarily due to an increase in payables for purchasing services from CROs and hospitals, which was in line with our continuous research and development efforts.

The following table sets out an aging analysis of the trade payables based on their respective invoice and issue dates as of the dates indicated:

| | As of December 31, | | As of August 31, |
|---|---|---|---|
| | **2019** | **2020** | **2021** |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| Less than one year | 31,648 | 40,785 | 84,166 |
| Between one and two years | 36 | 1,663 | 394 |
| **Total** | **31,684** | **42,448** | **84,560** |

We did not have any material defaults in payment of trade payables during the Track Record Period. As of December 31, 2021, RMB32.5 million, or 38.4%, of our trade payables as of August 31, 2021 had been settled.

***Other Payables and Accruals***

Our other payables and accruals primarily consist of (i) payables for acquisitions investments related to our acquisition of 30% equity interests of Hangzhou HealSun, and 63.01% of the equity of Miracogen Shanghai, as well as 40% equity interests of Taizhou Hanzhong from its non-controlling shareholder. See Note 33 of Appendix I to this prospectus. For our acquisition of 40% equity interests of Taizhou Hanzhong from its non-controlling shareholder, part of the consideration was fixed and the unpaid part was recognized as payables for acquisitions investments, while the variable part of consideration was recognized as financial liabilities at fair value through profit or loss, see "– Discussion of Certain Key Balance Sheet Items – Non-current Assets and Liabilities – Financial Liabilities at Fair Value through Profit or Loss;" and (ii) payables for purchase of property, plant and equipment for construction of our production lines in both Beijing and Shanghai, see "Business – Manufacturing and Quality Control – Our Manufacturing Facilities."


Shanghai Miracogen Inc.- Ex. 2032, Page 000522

The following table sets out a breakdown of our other payables and accruals in absolute amounts and as percentages as of the dates indicated:

| | As of December 31, | | | | As of August 31, | |
|---|---|---|---|---|---|---|
| | 2019 | | 2020 | | 2021 | |
| | *RMB'000* | *%* | *RMB'000* | *%* | *RMB'000* | *%* |
| Payables for acquisitions investments | 342,065 | 90.4 | 250,000 | 77.8 | 50,000 | 33.8 |
| Payables for purchase of property, plant and equipment | 16,828 | 4.5 | 42,100 | 13.1 | 50,039 | 33.8 |
| Payroll and welfare payables | 9,267 | 2.4 | 18,600 | 5.8 | 18,980 | 12.8 |
| Others | 10,118 | 2.7 | 10,607 | 3.3 | 28,908 | 19.6 |
| **Total** | **378,278** | **100.0** | **321,307** | **100.0** | **147,927** | **100.0** |

Our other payables and accruals decreased by 15.1% from RMB378.3 million as of December 31, 2019 to RMB321.3 million as of December 31, 2020, primarily due to a decrease in payables for acquisitions investments as a result of our fulfillment of payment obligations under relevant acquisition agreements.

Our other payables and accruals decreased by 54.0% from RMB321.3 million as of December 31, 2020 to RMB147.9 million as of August 31, 2021, primarily due to a decrease in the payables for acquisitions investments as a result of our fulfillment of payment obligations under relevant acquisition agreements, and the reclassification of the remaining unpaid part of consideration as non-current liabilities.

***Convertible Loans***

We had convertible loans of RMB380.6 million as of December 31, 2019, in relation to the Convertible Loans we issued in March 2019. In April 2020, such convertible loans were converted into financial instruments with preferred rights at amortized cost, before they were finally reclassified as equity in August 2020, see Note 34 of Appendix I to this prospectus. We therefore did not have any convertible loans as of December 31, 2020 and August 31, 2021.



Shanghai Miracogen Inc.- Ex. 2032, Page 000523

The movements of convertible loans in 2019 and 2020 and eight months ended August 31, 2020 and 2021 are set out below:

| | Year ended December 31, | | Eight months ended August 31, | |
|---|---|---|---|---|
| | **2019** | **2020** | **2020** | **2021** |
| | *RMB'000* | *RMB'000* | *RMB'000 (Unaudited)* | *RMB'000* |
| Opening balance | – | 380,620 | 380,620 | – |
| Additions | 360,000 | – | – | – |
| Change in fair value | 20,620 | 48,548 | 48,548 | – |
| Converted into financial instruments with preferred rights at amortised cost | – | (429,168) | (429,168) | – |
| Closing balance | 380,620 | – | – | – |

***Financial Instruments with Preferred Rights at Amortized Cost***

We recognized the financial instruments with preferred rights as financial liabilities. The financial liabilities were measured at amortized cost. Such liabilities will therefore be the amount expected to be paid to the investors upon redemption which is assumed to be at the dates of issuance or when they were converted from the convertible loans. Interests from these financial instruments were charged into finance costs. See "– Description of Major Components of Our Results of Operations – Finance Income and Finance Costs."

We had financial instruments with preferred rights at amortized cost of RMB397.5 million as of December 31, 2019, representing Controlling Shareholder Loans we issued in March 2019. Although the Convertible Loans we issued in March 2019 were converted into financial instruments with preferred rights at amortized cost in April 2020 and we also issued Series B financial instruments with preferred rights at amortized cost in July 2020, we did not have financial instruments with preferred rights at amortized cost as of December 31, 2020 and August 31, 2021, because our financial instruments with preferred rights at amortized cost were all reclassified as equity in August 2020.


Shanghai Miracogen Inc.- Ex. 2032, Page 000524

The following table sets out the movements of financial instruments with preferred rights at amortized cost as of the dates indicated:

| | **Financial instruments with preferred rights** *RMB'000* |
|---|---|
| As of January 1, 2019 | – |
| Recognition of the exchangeable loans of RMB450,000,000 issued by Ningbo Houde Yimin to the Series A Investors | 347,454 |
| Charged to finance costs | 50,035 |
| **As of December 31, 2019** | **397,489** |
| As of January 1, 2020 | 397,489 |
| Recognition of the financial instruments with preferred rights issued to Series B Investors | 1,192,480 |
| Conversion of Convertible Loans | 328,762 |
| Charged to finance costs | 80,852 |
| Derecognition | (1,999,583) |
| **As of December 31, 2020** | **–** |
| As of January 1, 2021 | – |
| **As of August 31, 2021** | **–** |
| As of January 1, 2020 | 397,489 |
| Recognition of Series Preferred Rights | 1,192,480 |
| Conversion of Convertible Loans | 328,762 |
| Charged to finance costs | 80,852 |
| Derecognition | (1,999,583) |
| **As of August 31, 2020 (Unaudited)** | **–** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000525

**Non-current Assets and Liabilities**

The following table sets out our non-current assets and liabilities as of the dates indicated:

| | As of December 31, | | As of August 31, |
|---|---|---|---|
| | **2019** | **2020** | **2021** |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| **Non-current assets** | | | |
| Property, plant and equipment | 331,110 | 606,371 | 725,819 |
| Right-of-use assets | 130,721 | 163,666 | 149,600 |
| Intangible assets | 517,333 | 497,922 | 479,662 |
| Investments accounted for using the equity method | 169,878 | 160,294 | 154,002 |
| Other receivables, prepayments and deposits | 154,700 | 152,009 | 147,148 |
| **Total non-current assets** | **1,303,742** | **1,580,262** | **1,656,231** |
| **Non-current liabilities** | | | |
| Borrowings | 118,266 | 147,266 | 168,064 |
| Lease liabilities | 48,251 | 33,534 | 23,259 |
| Deferred government grants | 12,000 | 12,000 | 12,000 |
| Deferred tax liabilities | 37,687 | 37,687 | 37,687 |
| Financial liabilities at fair value through profit or loss | 279,081 | 309,181 | 357,339 |
| Other payables and accruals | – | – | 150,000 |
| **Total non-current liabilities** | **495,285** | **539,668** | **748,349** |
| **Net non-current assets** | **808,457** | **1,040,594** | **907,882** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000526

***Property, Plant and Equipment***

Our property, plant and equipment primarily consist of (i) construction-in-progress representing our production lines; (ii) equipment and instruments; and (iii) leasehold improvements.

The following table sets out our property, plant and equipment in absolute amounts and as percentages as of the dates indicated:

| | As of December 31, | | | | As of August 31, | |
|---|---|---|---|---|---|---|
| | 2019 | | 2020 | | 2021 | |
| | *RMB'000* | *%* | *RMB'000* | *%* | *RMB'000* | *%* |
| Construction-in-progress | 171,415 | 51.8 | 386,978 | 63.9 | 507,978 | 70.0 |
| Equipment and instruments | 92,298 | 27.9 | 140,314 | 23.1 | 144,562 | 19.9 |
| Leasehold improvements | 61,142 | 18.5 | 63,962 | 10.5 | 59,215 | 8.2 |
| Others | 6,255 | 1.8 | 15,117 | 2.5 | 14,064 | 1.9 |
| **Total** | **331,110** | **100.0** | **606,371** | **100.0** | **725,819** | **100.0** |

Our property, plant and equipment increased by 83.1% from RMB331.1 million as of December 31, 2019 to RMB606.4 million as of December 31, 2020, primarily due to (i) an increase in construction-in-progress representing our Shanghai Biotech Park production line and our Beijing oncolytic virus production line; and (ii) an increase in equipment and instruments mainly due to the commencement of operation of our Beijing antibody production line. These increases were all in line with the continuing expansion of our business and the development of drug candidates.

Our property, plant and equipment increased by 19.7% from RMB606.4 million as of December 31, 2020 to RMB725.8 million as of August 31, 2021, primarily due to an increase in construction-in-progress, reflecting the ongoing construction process of our Shanghai Biotech Park production line.


Shanghai Miracogen Inc.- Ex. 2032, Page 000527

***Right-of-use Assets***

Our right-of-use assets are primarily land use rights and leased properties. The following table sets out our right-of-use assets in absolute amounts and as percentages as of the dates indicated:

| | As of December 31, | | | | As of August 31, | |
|---|---|---|---|---|---|---|
| | 2019 | | 2020 | | 2021 | |
| | *RMB'000* | *%* | *RMB'000* | *%* | *RMB'000* | *%* |
| Land use rights | 68,983 | 52.8 | 118,302 | 72.3 | 114,006 | 76.2 |
| Leased properties | 59,029 | 45.2 | 45,364 | 27.7 | 35,594 | 23.8 |
| Leased equipment | 2,709 | 2.0 | – | – | – | – |
| **Total** | **130,721** | **100.0** | **163,666** | **100.0** | **149,600** | **100.0** |

Our right-of-use assets increased by 25.2% from RMB130.7 million as of December 31, 2019 to RMB163.7 million as of December 31, 2020, primarily due to an increase in land use rights as a result of our acquisition of one land parcel to facilitate the construction of our Shanghai Biotech Park production line. Such increase was partially offset by a decrease in leased properties, which was in line with the depreciation of our leased properties. Our right-of-use assets remained relatively stable as of December 31, 2020 and August 31, 2021, being RMB163.7 million and RMB149.6 million, respectively.

***Intangible Assets***

Our intangible assets were primarily intellectual properties related to our business operations. The following table sets out a breakdown of our intangible assets in absolute amounts and as percentages as of the dates indicated:

| | As of December 31, | | | | As of August 31, | |
|---|---|---|---|---|---|---|
| | 2019 | | 2020 | | 2021 | |
| | *RMB'000* | *%* | *RMB'000* | *%* | *RMB'000* | *%* |
| Intellectual properties | 464,697 | 89.8 | 445,286 | 89.4 | 427,026 | 89.0 |
| Goodwill | 52,636 | 10.2 | 52,636 | 10.6 | 52,636 | 11.0 |
| **Total** | **517,333** | **100.0** | **497,922** | **100.0** | **479,662** | **100.0** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000528

Our intangible assets decreased from RMB517.3 million as of December 31, 2019 to RMB497.9 million as of December 31, 2020, and further to RMB479.7 million as of August 31, 2021, primarily due to the amortization of our intellectual properties.

Our goodwill on acquisitions of subsidiaries is included in intangible assets. Goodwill is not amortised, and it is tested for impairment at balance sheet date, or more frequently if events or changes in circumstances indicate that it might be impaired and is carried at cost less accumulated impairment losses. Gains and losses on the disposal of business entity include the carrying amount of goodwill relating to the business sold. Goodwill is allocated to cash-generating units for the purpose of impairment testing. The allocation is made to those cash-generating units or groups of cash-generating units that are expected to benefit from the business combination in which the goodwill arose. The units or groups of units are identified at the lowest level at which goodwill is monitored for internal management purposes.

Goodwill of approximately RMB52.6 million is resulted from the acquisition of Miracogen Shanghai in 2018. Goodwill is monitored by the management at level of the CGU of Miracogen Shanghai. The management has engaged an independent qualified valuer to perform goodwill impairment assessment to assess the "value-in-use" (determined by management as the recoverable amount) of the CGU as of December 31, 2019 and 2020 and August 31, 2021 by using the discounted cash flow model. The recoverable amount of the goodwill based on the estimated value-in-use calculations was higher than the carrying amount as of December 31, 2019 and 2020 and August 31, 2021. Accordingly, no provision for impairment loss for goodwill is considered necessary.

These calculations use pre-tax cash flow forecast based on financial budgets prepared by management covering the forecast period ending December 31, 2029. The management considers the length of forecast period appropriate because it generally takes longer for a biopharma company to reach a perpetual growth mode, compared to companies in other industries, especially when ADC related products are still under clinical trial and the market of such products is at an early stage of development with substantial growth potential. Based on the result of the goodwill impairment testing using key assumptions set out in Note 16(b) of Appendix I to this prospectus, the estimated recoverable amount of the CGU far exceeded its carrying amount and the headroom was approximately RMB464.2 million, RMB1,577.5 million and RMB1,914.6 million as of December 31, 2019 and 2020 and August 31, 2021 respectively. We performed a sensitivity analysis on the basis that relevant key assumptions have been changed. Had the estimated key assumptions during the forecast period been changed as below, the headroom would be decreased to as below:

| | As of December 31, | | As of August 31, |
|---|---|---|---|
| | **2019** | **2020** | **2021** |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| Expected revenue growth rate from second commercialisation year during the forecast period decreased by 5% | 388,594 | 1,419,463 | 1,745,633 |
| Expected revenue growth rate beyond the forecast period decreased by 3% | 463,576 | 1,573,463 | 1,909,633 |



Shanghai Miracogen Inc.- Ex. 2032, Page 000529

| | As of December 31, | | As of August 31, |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| Expected market penetration rate decreased by 5% | 419,469 | 1,464,463 | 1,793,633 |
| Expected success rate of commercialisation decreased by 5% | 425,139 | 1,467,463 | 1,793,633 |
| Pre-tax discount rate increased by 1% | 449,713 | 1,548,463 | 1,881,633 |

The management believe that any reasonable possible change in any of the key assumptions would not cause the carrying amounts of the CGU to exceed its recoverable amount. The management of the Company concluded that no provision for impairment on the goodwill has to be recognized as of December 31, 2019 and 2020 and August 31, 2021.

***Investments Accounted for Using the Equity Method***

Our investments accounted for using the equity method represent our investments in four associates of our Group, namely, Wuhan Binhui, Hangzhou HealSun, Hangzhou Xiyuan Biotechnology Co., Ltd. and KYM. Our investments accounted for using the equity method relating to KYM were recorded since 2021. Our investments accounted for using the equity method decreased by 5.7% from RMB169.9 million as of December 31, 2019 to RMB160.3 million as of December 31, 2020, primarily due to the increase in the total loss of the three associates we invested as a result of their increased total costs and expenses. For summarized financial information of associates that are material to us, see Note 17 of Appendix I to this prospectus. Our investments accounted for using the equity method remained relatively stable as of December 31, 2020 and August 31, 2021, being RMB160.3 million and RMB154.0 million, respectively.

***Non-current Portion of Other Receivables, Prepayments and Deposits***

Our non-current portion of other receivables, prepayments and deposits primarily consist of non-current portion of (i) prepayments for property, plant and equipment; and (ii) value added tax recoverable in relation to property, plant and equipment and services that we procured. See "– Discussion of Certain Key Balance Sheet Items – Current Assets and Liabilities – Current Portion of Other Receivables, Prepayments and Deposits."


Shanghai Miracogen Inc.- Ex. 2032, Page 000530

***Financial Liabilities at Fair Value through Profit or Loss***

According to the equity transfer agreement in September 2019, we acquired 40% equity interests of Taizhou Hanzhong from its non-controlling shareholder and part of the consideration is variable, being 4.375% of future annual net sales of relevant PD-1 products. See "History Development and Corporate Structure – Our Key Subsidiaries and Major Shareholding Changes – Taizhou Hanzhong." We recognized such variable consideration payables as financial liabilities at fair value through profit or loss. See Note 31 of Appendix I to this prospectus.

Our financial liabilities at fair value through profit or loss increased by 10.8% from RMB279.1 million as of December 31, 2019 to RMB309.2 million as of December 31, 2020, and further increased by 15.6% to RMB357.3 million as of August 31, 2021, as a result of an increase in the valuation of our variable consideration for our acquisition of 40% equity interests of Taizhou Hanzhong from its non-controlling shareholder, taking into consideration the sales potential of PD-1. Such variable consideration will be settled annually after the commercialization of the PD-1 products.

The movements of financial liabilities at fair value through profit or loss in 2019 and 2020 and the eight months ended August 31, 2020 and 2021 are set out below:

| | **Year ended December 31,** | | **Eight months ended August 31,** | |
|---|---|---|---|---|
| | **2019** | **2020** | **2020** | **2021** |
| | *RMB'000* | *RMB'000* | *RMB'000 (Unaudited)* | *RMB'000* |
| Opening balance | – | 279,081 | 279,081 | 309,181 |
| Additions | 261,389 | – | – | – |
| Change in fair value | 17,692 | 30,100 | 69,283 | 48,158 |
| Closing balance | 279,081 | 309,181 | 348,364 | 357,339 |



Shanghai Miracogen Inc.- Ex. 2032, Page 000531

## KEY FINANCIAL RATIOS

The following table sets out our key financial ratios as of the dates indicated:

| | As of December 31, | | As of August 31, |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| Current ratio[(1)] | 18.2% | 220.6% | 197.6% |
| Quick ratio[(2)] | 17.6% | 215.5% | 189.0% |

*Notes:*

(1) Represents current assets divided by current liabilities as of the same date.

(2) Represents current assets less inventories and divided by current liabilities as of the same date.

Our current ratio increased significantly from 18.2% as of December 31, 2019 to 220.6% as of December 31, 2020, and our quick ratio increased significantly from 17.6% as of December 31, 2019 to 215.5% as of December 31, 2020, mainly due to (i) a significant increase in our current assets primarily as a result of the increase in our current financial assets at fair value through profit or loss as well as our cash and cash equivalents; and (ii) a decrease in current liabilities, primarily because we had convertible loans of RMB380.6 million and financial instruments with preferred rights at amortized cost of RMB397.5 million as of December 31, 2019, compared to nil as of December 31, 2020. Our current ratio decreased from 220.6% as of December 31, 2020 to 197.6% as of August 31, 2021, and our quick ratio decreased from 215.5% as of December 31, 2020 to 189.0%, mainly due to (i) the decrease in our current assets primarily as a result of the decrease in our current financial assets at fair value through profit or loss as well as our cash and cash equivalents; and (ii) the increase in current liabilities, primarily due to the increase in our trade payables and borrowings. See "– Discussion of Certain Key Balance Sheet Items" for a discussion of the factors affecting our key financial ratios during the respective periods.



Shanghai Miracogen Inc.- Ex. 2032, Page 000532

## LIQUIDITY AND CAPITAL RESOURCES

### Working Capital

Our principal uses of liquidity during the Track Record Period were to fund our research and development of our drug candidates, our clinical trials and the construction of our manufacturing facilities. During the Track Record Period, we primarily funded our working capital requirements through capital contributions from our shareholders, private equity financing and bank loans. We monitor our cash flows and cash balance on a regular basis and strive to maintain an optimal liquidity that can meet our working capital needs.

While we had net operating cash outflows and net losses during the Track Record Period, we believe our liquidity requirements will be satisfied by using funds from a combination of our cash and cash equivalents, unutilized loan facilities, net proceeds from the Global Offering and other funds raised from the capital markets from time to time. As of December 31, 2021, we had cash and cash equivalents of RMB155.2 million and unutilized banking facilities of RMB507.1 million. Other than the bank borrowings that we have obtained or may obtain, we currently do not have any plans for material external debt financing. Taking into account the above, together with the estimated net proceeds from the Global Offering, our Directors are of the view that we have sufficient working capital to cover at least 125% of our costs, including research and development expenses, administrative expenses, finance costs and other expenses for at least the next 12 months from the date of this prospectus.

Our cash burn rate refers to the average monthly aggregate amount of (i) net cash used in operating activities, including research and development expenses; (ii) purchase amount of property, plant and equipment; (iii) payment of lease liabilities; (iv) purchase amount of intangible assets; and (v) payment of interests. Assuming that the average cash burn rate going forward will be similar to the cash burn rate level for the 20 months ended August 31, 2021, which is primarily based on the level of the average monthly burn rate in the 20 months ended August 31, 2021 and the prospective burn rate based on the average monthly net cash used in operating activities and capital expenditure in 2021 and 2022, and excluding financial assets at fair value through profit or loss, our cash balance (including cash and cash equivalents and term deposits with initial terms of three months) will be able to maintain our financial viability for 4.9 months or, if we also take into account the estimated net proceeds (based on the low-end of the indicative offer price) from the Global Offering, 14.7 months. We expect to raise our next round of financing (not taking into account bank loans we may take out in the ordinary course of business) no earlier than September 2022. Our Directors and our management team will continue to monitor our working capital, cash flows, and our business development progress.


Shanghai Miracogen Inc.- Ex. 2032, Page 000533

**Cash Flow**

The following table sets out our cash flows for the periods indicated:

| | Year ended December 31, | | Eight months ended August 31, | |
|---|---|---|---|---|
| | **2019** | **2020** | **2020** | **2021** |
| | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* |
| Operating cash flows before movements in working capital | (225,352) | (359,011) | (189,909) | (469,527) |
| Change in working capital | (9,038) | (68,908) | (22,642) | 47,604 |
| Interest received | 396 | 5,230 | 1,019 | 3,601 |
| Net cash used in operating activities | (233,994) | (422,689) | (211,532) | (418,322) |
| Net cash used in investing activities | (415,318) | (749,669) | (763,807) | (13,519) |
| Net cash generated from financing activities | 770,394 | 1,386,679 | 1,398,812 | 291,140 |
| Interest paid | (571) | (7,433) | (4,222) | (3,127) |
| Net increase/(decrease) in cash and cash equivalents | 121,082 | 214,321 | 423,473 | (140,701) |
| Cash and cash equivalents at the beginning of the year/period | 67,462 | 188,545 | 188,545 | 402,867 |
| Effects of exchange rate changes on cash and cash equivalents | 1 | 1 | – | (972) |
| Cash and cash equivalents at the end of the year | 188,545 | 402,867 | 612,018 | 261,194 |



Shanghai Miracogen Inc.- Ex. 2032, Page 000534

***Net Cash Used in Operating Activities***

Since the commencement of our business operation, we have incurred negative cash flows from our operations. Substantially all of our operating outflows have resulted from our cash used in our operations. Net cash used in operating activities primarily comprises our loss before tax for the period adjusted by (i) non-operating items and non-cash items; and (ii) changes in working capital. We expect to improve our net operating cash outflows position through our improved research and development capabilities as we continuously invest in our research and development platforms and engage experienced members in our research and development team, which helps reduce our needs for third-party research and development services, see "Business – Research and Development;" we also expect to improve such position through revenue to be generated from sales of our drug products in the event of successful commercialization through dedicated sales and marketing forces and internationally via partnerships.

In the eight months ended August 31, 2021, our net cash used in operating activities was RMB418.3 million, which was primarily attributable to our loss before income tax of RMB668.2 million, as adjusted by (i) the add back of non-operating items and non-cash items, primarily comprising share-based payments of RMB85.8 million and change in fair value of financial liabilities at fair value through profit or loss of RMB48.2 million; and (ii) changes in working capital, primarily including an increase in other receivables, prepayments and deposits of RMB4.8 million, partially offset by an increase in trade payables, other payables and accruals of RMB57.0 million.

In 2020, our net cash used in operating activities was RMB422.7 million, which was primarily attributable to our loss before income tax of RMB613.4 million, as adjusted by (i) the add back of non-operating items and non-cash items, primarily comprising change in fair value of financial liabilities at fair value through profit or loss of RMB78.6 million, net finance costs of RMB79.9 million, amortization of intangible assets of RMB28.6 million and depreciation of property, plant and equipment and right-of-use assets of RMB55.6 million; and (ii) changes in working capital, primarily including an increase in other receivables and prepayments of RMB76.1 million, partially offset by an increase in trade payables, other payables and accruals of RMB18.7 million.

In 2019, our net cash used in operating activities was RMB234.0 million, which was primarily attributable to our loss before income tax of RMB515.5 million, as adjusted by (i) the add back of non-operating items and non-cash items, primarily comprising amortization of intangible assets of RMB26.8 million, change in fair value of financial liabilities at fair value through profit or loss of RMB38.3 million and net finance costs of RMB51.9 million; and (ii) changes in working capital, which primarily comprised an increase in other receivables and prepayments of RMB46.4 million, partially offset by an increase in trade payables, other payables and accruals of RMB33.4 million.


Shanghai Miracogen Inc.- Ex. 2032, Page 000535

***Net Cash Used in Investing Activities***

In the eight months ended August 31, 2021, our net cash used in investing activities was RMB13.5 million, which was primarily attributable to our purchases of financial assets at fair value through profit and loss of RMB944.0 million and our purchases of property, plant and equipment of RMB134.9 million, partially offset by proceeds from disposal of financial assets at fair value through profit and loss of RMB1,146.3 million.

In 2020, our net cash used in investing activities was RMB749.7 million, which was primarily attributable to our purchases of financial assets at fair value through profit and loss of RMB1,657.6 million and our purchases of property, plant and equipment of RMB239.3 million, partially offset by proceeds from disposal of financial assets at fair value through profit and loss of RMB1,332.7 million.

In 2019, our net cash used in investing activities was RMB415.3 million, which was primarily attributable to our purchases of financial assets at fair value through profit and loss of RMB509.5 million and our purchases of property, plant and equipment of RMB318.5 million, partially offset by proceeds from disposal of financial assets at fair value through profit and loss of RMB511.5 million.

***Net Cash Generated from Financing Activities***

In the eight months ended August 31, 2021, our net cash generated from financing activities was RMB291.1 million, which was primarily attributable to capital contributions of RMB261.1 million from shareholders.

In 2020, our net cash generated from financing activities was RMB1,386.7 million, which was primarily attributable to our capital contributions from shareholders of RMB1,381.0 million and proceeds from bank borrowings of RMB59.0 million, partially offset by repayments of loans from Ningbo Houde Yimin of RMB50.0 million and repayments of bank borrowings of RMB30.0 million.

In 2019, our net cash generated from financing activities was RMB770.4 million, which was primarily attributable to our proceeds from issuance of Convertible Loans of RMB360.0 million, our capital contributions from Ningbo Houde Yimin of RMB309.6 million and proceeds from bank borrowings of RMB118.3 million, partially offset by repayments of other loan from former shareholder of a subsidiary of RMB34.2 million.


Shanghai Miracogen Inc.- Ex. 2032, Page 000536

## CASH OPERATING COSTS

The following table sets out our cash operating costs for the periods indicated:

| | Year ended December 31, | | Eight months ended August 31, |
|---|---|---|---|
| | **2019** | **2020** | **2021** |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| **Research and development costs for core products** | | | |
| Clinical trial expenses | 111,371 | 177,701 | 196,222 |
| Raw materials and consumables used | 21,896 | 33,758 | 22,944 |
| Employee benefit expenses | 10,239 | 20,486 | 29,782 |
| Pre-clinical study costs | 683 | 4,373 | 6,745 |
| Others | 2,455 | 9,940 | 7,602 |
| **Research and development costs for other products** | | | |
| Pre-clinical study costs | 72,752 | 86,286 | 56,634 |
| Employee benefit expenses | 10,141 | 17,622 | 24,103 |
| Clinical trial expenses | 8,715 | 9,930 | 21,222 |
| Raw materials and consumables used | 6,633 | 19,422 | 23,160 |
| Others | 8,393 | 9,547 | 18,837 |
| **Total** | **253,278** | **389,065** | **407,251** |
| Workforce employment costs[(1)] | 18,434 | 30,313 | 25,356 |
| Direct production costs[(2)] | – | – | – |
| Non-income taxes, royalties and other governmental charges | – | – | – |
| Contingency allowances | – | – | – |
| Product marketing[(3)] | – | – | – |

*Notes:*

(1) Workforce employment costs represents non-research and development staff costs mainly including salaries and benefits.

(2) We had not commenced commercial manufacturing as of the Latest Practicable Date.

(3) We had not commenced product sales as of the Latest Practicable Date.



Shanghai Miracogen Inc.- Ex. 2032, Page 000537

## INDEBTEDNESS

### Borrowings

We had bank borrowings of RMB118.3 million as of December 31, 2019, RMB147.3 million as of December 31, 2020, RMB198.1 million as of August 31, 2021 and RMB292.9 million as of December 31, 2021, being the indebtedness date for the purpose of the indebtedness statement.

As of December 31, 2019 and 2020, August 31, 2021 and December 31, 2021, our borrowings were repayable as follows:

| | As of December 31, | | As of August 31, | As of December 31, |
|---|---|---|---|---|
| | 2019 | 2020 | 2021 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000 (Unaudited)* |
| Within one year | – | – | 30,000 | 60,409 |
| Between one and two years | – | 20,000 | 25,000 | 30,000 |
| Between two and five years | 90,000 | 127,266 | 143,064 | 180,000 |
| Over five years | 28,266 | – | – | 22,469 |
| **Total** | **118,266** | **147,266** | **198,064** | **292,878** |

Our bank borrowings as of December 31, 2019 and 2020 all represented carrying amounts of our borrowings from Agriculture Bank of China. Our bank borrowings as of December 31, 2021 represented carrying amounts of our borrowings from Agriculture Bank of China, China Merchants Bank, Bank of Communications and China Industrial Bank. We have pledged land use rights and construction-in-progress as collaterals for the long-term bank borrowings. The borrowings bear interests at float rate range from 4.20% to 4.60% per annum. Interests are payable quarterly.

In addition, Dr. Pu, the ultimate Controlling Shareholder of our Company, had been the guarantor of our aforementioned secured bank borrowings with irrevocable joint guarantee liabilities. The guarantee period is two years from September 1, 2027 to September 1, 2029. Such guarantee was released in April 2021.

As of December 31, 2021, we had unutilized banking facilities of RMB507.1 million.

Our bank borrowing agreements contain standard terms, conditions and covenants that are customary for commercial bank loans. Our Directors confirm that, there was no material covenant on any of our outstanding debt as of the Latest Practicable Date, and there was no breach of any covenants during the Track Record Period and up to the Latest Practicable Date. Our Directors further confirm that we did not experience any unusual difficulty in obtaining bank loans and other borrowings, default in payment of bank loans and other borrowings or breach of covenants during the Track Record Period and up to the Latest Practicable Date.



Shanghai Miracogen Inc.- Ex. 2032, Page 000538

**Lease Liabilities**

IFRS 16 introduced a single lessee accounting model, whereby assets and liabilities are recognized for all leases on the balance sheet, subject to certain exceptions. Our lease liabilities include the net present value of our lease payments as specified in Note 2.29 of Appendix I to this prospectus. The following table sets out our lease liabilities in absolute amounts and as percentages as of the dates indicated:

| | As of December 31, | | | | As of August 31, | | As of December 31, | |
|---|---|---|---|---|---|---|---|---|
| | 2019 | | 2020 | | 2021 | | 2021 | |
| | *RMB'000* | *%* | *RMB'000* | *%* | *RMB'000* | *%* | *RMB'000* | *%* |
| | | | | | | | *(Unaudited)* | |
| Non-current lease liabilities | 48,251 | 63.6 | 33,534 | 64.5 | 23,259 | 59.0 | 19,478 | 50.9 |
| Current lease liabilities | 27,565 | 36.4 | 18,466 | 35.5 | 16,188 | 41.0 | 18,787 | 49.1 |
| **Total** | **75,816** | **100.0** | **52,000** | **100.0** | **39,447** | **100.0** | **38,265** | **100.0** |

Our lease liabilities decreased by 31.4% from RMB75.8 million as of December 31, 2019 to RMB52.0 million as of December 31, 2020, primarily due to our payments in 2020 of rents for leased properties. Our lease liabilities decreased from RMB52.0 million as of December 31, 2020 to RMB39.4 million as of August 31, 2021, and further decreased to RMB38.3 million as of December 31, 2021, primarily due to our payments in 2021 of rents for leased properties.

**Disclaimer**

During the Track Record Period and up to the Latest Practicable Date, we had not been in violation of any of the covenants under our loan agreements. Except as disclosed above, during the Track Record Period and up to December 31, 2021, we did not have any material mortgages, charges, debentures, loan capital, debt securities, loans, bank overdrafts or other similar indebtedness, finance leases or hire purchase commitments, liabilities under acceptances (other than normal trade bills), acceptance credits, which are either guaranteed, unguaranteed, secured or unsecured, or guarantees.

**CONTINGENT LIABILITIES**

We did not have any material contingent liabilities as of December 31, 2019 and 2020, August 31, 2021 and the Latest Practicable Date.



Shanghai Miracogen Inc.- Ex. 2032, Page 000539

## CAPITAL EXPENDITURES

Our capital expenditures during the Track Record Period were primarily related to our purchases of property, plant and equipment, purchases of land use rights and intangible assets. We funded our capital expenditure requirements during the Track Record Period mainly from equity financing and bank borrowings. The following table sets out the details of our capital expenditure for the periods indicated:

| | Year ended December 31, | | Eight months ended August 31, | |
|---|---|---|---|---|
| | **2019** | **2020** | **2020** | **2021** |
| | *RMB'000* | *RMB'000* | *RMB'000 (Unaudited)* | *RMB'000* |
| Purchases of property, plant and equipment | 318,471 | 239,262 | 93,727 | 134,913 |
| Purchases of land use rights | – | 54,611 | 54,611 | – |
| Purchases of intangible assets | 45,363 | 9,140 | 9,140 | 943 |
| Acquisition of subsidiaries | 50,000 | 69,565 | 69,565 | 50,000 |
| Acquisition of associates | 10,000 | 25,000 | 25,000 | 1 |
| **Total** | **423,834** | **397,578** | **252,043** | **185,857** |

We plan to fund our planned capital expenditures using cash generated from operations and the net proceeds received from the Global Offering. See "Future Plans and Use of Proceeds." We may reallocate the fund to be utilized on capital expenditure based on our ongoing business needs. We expect that our capital expenditures for 2022 will primarily be related to the payment for the consideration of our acquisition of 40% equity interests of Taizhou Hanzhong from its non-controlling shareholder as well as the continuous construction and development of our production lines.


Shanghai Miracogen Inc.- Ex. 2032, Page 000540

## CAPITAL COMMITMENTS

We had the following capital commitments for property, plant and equipment and intangible assets as of the dates indicated:

| | As of December 31, | | As of August 31, |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| Property, plant and equipment | 418,482 | 309,104 | 204,665 |
| Intangible assets | 9,124 | – | – |
| **Total** | **427,606** | **309,104** | **204,665** |

Such capital commitments reflected capital expenditure we contracted for at the end of year but not yet incurred.

## OFF-BALANCE SHEET COMMITMENTS AND ARRANGEMENTS

As of the Latest Practicable Date, we had not entered into any off-balance sheet arrangements.

## FINANCIAL RISK DISCLOSURE

### Financial Risk Factors

We are exposed to a variety of financial risks, including market risk (foreign exchange risk and cash flow and fair value interest rate risk), credit risk and liquidity risk.

#### *Market Risk*

Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices. Market risk comprises (i) foreign exchange risk and (ii) cash flow and fair value interest rate risk.


Shanghai Miracogen Inc.- Ex. 2032, Page 000541

Foreign Exchange Risk

Foreign exchange risk arises when future commercial transactions or recognized assets and liabilities are denominated in a currency that is not our functional currency.

We manage our foreign exchange risk by performing regular reviews of our Group's net foreign exchange exposures. We did not hedge against any fluctuation in foreign currency during the Track Record Period. Our subsidiaries in PRC are exposed to foreign exchange risk arising from recognized financial assets and liabilities denominated in United States dollars. As of December 31, 2019 and 2020 and August 31, 2021, if the USD strengthened/weakened by 5% against the RMB with all other variables held constant, loss before income tax for the year/period would have been approximately RMB2,000 higher/lower, RMB2,000 higher/lower and RMB6,724,000 higher/lower, respectively.

Cash Flow and Fair Value Interest Rate Risk

Our main interest rate risk arises from long-term borrowings with variable rates, which expose us to cash flow interest rate risk. Generally, we enter into long-term borrowings at floating rates and swap them into fixed rates that are lower than those available if we borrowed at fixed rates directly. In 2019 and 2020 and the eight months ended August 31, 2020 and 2021, we had no any interest rate swap arrangements.

A 10-basis point increase or decrease represents management's assessment of the reasonably possible change in interest rates. If interest rates had been 10 basis points higher and all other variables were held constant, our loss before income tax would approximately increase by RMB1,000 and RMB6,000, RMB4,000 and RMB5,000 in 2019 and 2020 and the eight months ended August 31, 2020 and 2021, respectively.

***Credit Risk***

Credit risk is managed on a group basis.

We are exposed to credit risk primarily in relation to our cash and cash equivalents and term deposits with initial terms of over three months, financial assets at FVPL, as well as other receivables and deposits. The carrying amount of each class of the above financial assets represents our maximum exposure to credit risk in relation to the corresponding class of financial assets. To manage credit risk, cash and cash equivalents and term deposits with initial terms of over three months are mainly placed with state-owned or reputable financial institutions in the PRC and reputable international financial institutions outside of the PRC. There has been no recent history of default in relation to these financial institutions. Thus, our Directors are of the view the credit risk related to cash and cash equivalents was insignificant.


Shanghai Miracogen Inc.- Ex. 2032, Page 000542

*Impairment of financial assets*

Other financial assets at amortized cost

Other financial assets at amortized cost mainly include other receivables and deposits. We consider the probability of default upon initial recognition of other receivables and whether there has been a significant increase in credit risk on an ongoing basis throughout each reporting period. To assess whether there is a significant increase in credit risk, we compare the risk of a default on other receivables as at the reporting date with the risk of default as at the date of initial recognition. We consider available reasonable and supportive forward-looking information, especially the following indicators:

- actual or expected significant adverse changes in business, financial or economic conditions that are expected to cause a significant change to the debtors' ability to meet its obligations;

- actual or expected significant changes in the operating results of the debtors;

- significant increases in credit risk on other financial instruments of the same debtors; or

- significant changes in the expected performance and behavior of the debtors, including changes in the payment status of debtors.

For the other receivables and deposits, our management applies 3-stages model to assess the expected credit loss. Our management makes periodic collective assessments as well as individual assessment on the recoverability of other receivables based on historical settlement records and past experience.

***Liquidity Risk***

We aim to maintain sufficient cash and cash equivalents to meet operating capital requirements. For our financial liabilities into relevant maturity groupings based on the remaining period at the balance sheet date to the contractual maturity date, see Note 3.1.3 of Appendix I to this prospectus.



Shanghai Miracogen Inc.- Ex. 2032, Page 000543

***Fair Value Estimation***

We measure fair values of financial instruments using the following fair value hierarchy that reflects the observability and significance of the inputs used in making the measurements:

- Level one: The fair value of financial instruments traded in active markets (such as publicly traded derivatives and equity securities) is based on quoted market prices at the end of the reporting period. The quoted market price used for financial assets held by our Group is the current bid price. These instruments are included in level one.

- Level two: The fair value of financial instruments that are not traded in an active market (for example, over-the-counter derivatives) is determined using valuation techniques which maximize the use of observable market data and rely as little as possible on entity-specific estimates. If all significant inputs required to fair value an instrument are observable, the instrument is included in level two.

- Level three: If one or more of the significant inputs is not based on observable market data, the instrument is included in level three. This is the case for unlisted equity securities.

With respect to the valuation of our Level 3 financial instruments, our Directors, based on the professional advice received and with reference to the SFC's "Guidance note on directors' duties in the context of valuations in corporate transactions", adopted the following procedures: (i) reviewed the terms of relevant agreements; (ii) engaged independent qualified professional valuer (the "**Independent Valuer**"), who provided necessary financial and non-financial information to enable the Independent Valuer to perform valuation procedures and discussed with the Independent Valuer on relevant assumptions; (iii) carefully considered all information which may require management assessments and estimates; and (iv) reviewed the valuation working papers and results prepared by the Independent Valuer. Based on the above procedures, our Directors are of the view that the valuation analysis performed by the Independent Valuer is fair and reasonable, and the financial statements of our Group are properly prepared.

The reporting accountant's opinion on the Historical Financial Information, as a whole, of our Group for the Track Record Period is set out on pages I-2 of Appendix I to this prospectus.

In relation to the fair value assessment of the financial liabilities and assets requiring level 3 measurements under the fair value classification, the Joint Sponsors have conducted relevant due diligence work, including but not limited to, (i) obtaining and reviewing the terms of the relevant agreements and documents regarding the financial liabilities and assets; (ii) considering the qualification, independence and credentials of the Independent Valuer; (iii) obtaining and reviewing the valuation reports prepared by the Independent Valuer in respect of the level 3 financial liabilities; (iv) discussing with the Independent Valuer regarding the



Shanghai Miracogen Inc.- Ex. 2032, Page 000544

assumptions, valuation techniques and methodologies applied to determine the valuation; (v) discussing with the Company to understand its preparation of the underlying information used in the valuation of the level 3 financial liabilities and assets of the Group and the Company's views on the fairness and reasonableness of the assumptions, basis and approaches of the valuation so conducted; (vi) discussing with the reporting accountant in respect of audit procedures conducted regarding the valuation in accordance with International Standards on Auditing and discussing with the reporting accountant about the relevant accounting treatments; and (vii) reviewing the relevant notes in the Accountant's Report as contained in Appendix I to this Prospectus and the reporting accountant's opinion on the historical financial information as a whole for the Track Record Period. Based upon the due diligence work conducted by the Joint Sponsors as stated above, and having considered the views of the Directors and the reporting accountant, nothing has come to the Joint Sponsors' attention that would cause the Joint Sponsors to question the valuation performed by the Independent Valuer and the Company.

For details of our assets and liabilities that were measured at fair value as of December 31, 2019 and 2020 and August 31, 2021, see Note 3.3 of Appendix I to this prospectus.

## MATERIAL RELATED PARTY TRANSACTIONS

For more details about our related party transactions during the Track Record Period, see Note 40 of Appendix I to this prospectus.

Our Directors believe that our transactions with related parties during the Track Record Period were conducted on an arm's length basis, and they did not distort our results of operations or make our historical results not reflective of our future performance.

## DIVIDEND

No dividend was paid or declared by our Company or other entities comprising our Group during the Track Record Period.

We currently expect to retain all future earnings for use in operation and expansion of our business, and do not have any dividend policy to declare or pay any dividends in the foreseeable future. Any future declarations and payments of dividends will be at the absolute discretion of our Directors and will depend on our actual and expected results of operations, cash flow and financial position, general business conditions and business strategies, expected working capital requirements and future expansion plans, legal, regulatory and other contractual restrictions, and other factors which our Directors consider relevant. No dividend shall be declared or payable except out of our profits and reserves lawfully available for distribution. As confirmed by our PRC Legal Advisor, according to relevant PRC laws, any future net profit that we make will have to be first applied to make up for our historically accumulated losses, after which we will be obliged to allocate 10% of our net profit to our statutory common reserve fund until such fund has reached more than 50% of our registered


Shanghai Miracogen Inc.- Ex. 2032, Page 000545

capital. We will therefore only be able to declare dividends after (i) all our historically accumulated losses have been made up for; and (ii) we have allocated sufficient net profit to our statutory common reserve fund as described above.

## DISTRIBUTABLE RESERVES

As of August 31, 2021, our Company did not have any distributable reserves.

## LOSS ESTIMATE FOR THE YEAR ENDED DECEMBER 31, 2021

On the basis set out in Appendix III to this prospectus, and in the absence of unforeseen circumstances, we estimate that our unaudited consolidated loss attributable to the owners of the Company are as follows:

| | |
|---|---|
| **Estimated consolidated loss attributable to owners of the Company for the year ended December 31, 2021** | **Not more than RMB1,023 million (approximately HK$1,250 million)** *(Note)* |

*Note:* For the purpose of this estimated consolidated loss attributable to owners of the Company, the amounts stated in Renminbi are converted into Hong Kong dollars at a rate of HK$1.00 to RMB0.81824. No representation is made that Renminbi amounts have been, could have been or may be converted to Hong Kong dollars, or vice versa, at that rate.

## LISTING EXPENSE

Listing expenses represent professional fees, underwriting commission and other fees incurred in connection with the Global Offering. We expect to incur listing expenses of approximately RMB82.2 million (HK$100.4 million), comprising (i) underwriting fees of RMB29.6 million (HK$36.2 million); and (ii) non-underwriting-related expenses of RMB52.5 million (HK$64.2 million), including (a) the fees paid and payable to the legal advisors and the Reporting Accountants of RMB24.6 million (HK$30.1 million), and the Joint Sponsors' fees, the fees paid and payable to the internal control consultant, Frost & Sullivan as the industry consultant, the Property Valuer and the Independent Valuer of RMB8.3 million (HK$10.1 million); and (b) other fees and expenses of RMB19.6 million (HK$24.0 million), assuming the Over-allotment Option is not exercised and based on the Offer Price of HK$7.13 per Offer Share, being the mid-point of the Offer Price range), approximately RMB49.1 million (HK$60.0 million) of which is expected to be charged to our consolidated statements of profit or loss, and approximately RMB33.1 million (HK$40.4 million) of which is expected to be capitalized and will be deducted from equity upon the completion of the Global Offering. The listing expenses are expected to represent approximately 11.10% of the gross proceeds of the Global Offering, assuming an Offer Price of HK$7.13 per Offer Share (being the mid-point of the indicative Offer Price range) and that the Over-allotment Option is not exercised. The listing expenses above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.



Shanghai Miracogen Inc.- Ex. 2032, Page 000546

## UNAUDITED PRO FORMA STATEMENT OF ADJUSTED NET TANGIBLE ASSETS

The following is an illustrative and pro forma statement of our adjusted consolidated net tangible assets which has been prepared in accordance with Rule 4.29 of the Listing Rules and on the basis of the notes set out below for the purpose of illustrating the effect of the Global Offering on our consolidated net tangible assets attributable to the owners of the Company as of August 31, 2021 as if the Global Offering had taken place on such date.

The unaudited pro forma statement of adjusted consolidated net tangible assets has been prepared for illustrative purposes only and, because of its hypothetical nature, it may not give a true picture of the consolidated net tangible assets of the Group had the Global Offering been completed as of August 31, 2021 or at any future date.

| | **Audited consolidated net tangible assets attributable to the owners of our Company as of August 31, 2021** *Note 1* *RMB'000* | **Estimated net proceeds from the Global Offering** *Note 2* *RMB'000* | **Unaudited pro forma adjusted consolidated net tangible assets attributable to the owners of our Company** *RMB'000* | **Unaudited pro forma adjusted consolidated net tangible assets per share** *Note 3* *RMB* | *Note 4* *HK$* |
|---|---|---|---|---|---|
| Based on the Offer Price of HK$6.87 per share | 683,947 | 659,711 | 1,343,658 | 0.81 | 0.99 |
| Based on the Offer Price of HK$7.38 per share | 683,947 | 710,535 | 1,394,482 | 0.84 | 1.03 |

*Notes:*

(1) The audited consolidated net tangible assets attributable to the owners of our Company as of August 31, 2021 is extracted from the Accountant's Report set forth in Appendix I to the prospectus, which is based on the audited consolidated net assets attributable to the owners of our Company as of August 31, 2021 of RMB1,163,609,000 with an adjustment for the intangible assets attributable to the owners of our Company as of August 31, 2021 of RMB479,662,000.

(2) The estimated net proceeds from the Global Offering are based on the indicative Offer Price of HK$6.87 and HK$7.38 per share after deduction of the estimated underwriting fees and other related expenses payable by our Company (excluding RMB27,573,000 which had been charged to the consolidated statements of comprehensive loss up to August 31, 2021) and takes no account of any shares which may be issued upon the exercise of the Over-allotment Option.

(3) The unaudited pro forma adjusted consolidated net tangible assets per share are determined after the adjustments as described in note (2) above and on the basis that 1,658,545,838 shares are in issue, assuming the Global Offering had been completed on August 31, 2021 but takes no account of any shares which may fall to be issued upon the exercise of the Over-Allotment Option.



Shanghai Miracogen Inc.- Ex. 2032, Page 000547

(4) For the purpose of this unaudited pro forma adjusted net tangible assets, the balance stated in Renminbi is converted into Hong Kong dollars at a rate of HK$1.00 to RMB0.81824. No representation is made that Renminbi amounts have been, could have been or may be converted to Hong Kong dollars, or vice versa, at that rate.

(5) No adjustments have been made to the unaudited pro forma adjusted consolidated net tangible assets to reflect any trading results or other transactions of our Group entered into subsequent to August 31, 2021.

## PROPERTY INTERESTS AND PROPERTY VALUATION REPORT

Our selective property interests are set forth in the Property Valuation Report in Appendix IV to this prospectus. AVISTA, an independent property valuer, has valued our selective property interests as of December 31, 2021.

A reconciliation of the market value of our selective property interests as extracted from the Property Valuation Report as set out in Appendix IV to this prospectus as of December 31, 2021 and net book value of our selective property interests in our consolidated financial statements as of August 31, 2021 as required under Rule 5.07 of the Listing Rules is set forth below:

| | *RMB'000* |
|---|---|
| Net book value of our selective property interests as of August 31, 2021 | 559,507 |
| Movements during the four months ended December 31, 2021 | 121,093 |
| Net book value of property as of December 31, 2021 | 680,600 |
| Valuation surplus | 18,100 |
| Valuation as of December 31, 2021 as set out in Appendix IV to this prospectus | 698,700 |

## NO MATERIAL ADVERSE CHANGE

After performing sufficient due diligence work which our Directors consider appropriate and after due and careful consideration, our Directors confirm that, up to the date of this prospectus, save as disclosed in "Summary – Recent Development," there has been no material adverse change in our financial or trading position or prospects since August 31, 2021, being the end date of the periods reported on in Appendix I to this prospectus, and there has been no event since August 31, 2021 that would materially affect the information as set out in Appendix I to this prospectus.

Our Directors confirmed that the COVID-19 outbreak did not have any material adverse impact on our business operations and financial performance as of the Latest Practicable Date, primarily because: (i) there had been no material disruption of our ongoing clinical or pre-clinical trials; and (ii) we had not encountered any material supply chain disruption. We cannot foresee when the COVID-19 outbreak will become completely under control or whether COVID-19 will have a material and adverse impact on our business going forward. See "Risk Factors – Risks Relating to Our Operations – We may be subject to disasters, health epidemics



Shanghai Miracogen Inc.- Ex. 2032, Page 000548

such as COVID-19, acts of war, terrorism, business disruptions and other force majeure events, which may have a material adverse effect on our business, financial condition and results of operations." We are continually monitoring the COVID-19 situation as well as various regulatory and administrative measures adopted by local governments to prevent and control the outbreak. We will continue to monitor and evaluate any impact of the COVID-19 outbreak on us and adjust our precautionary measures according to the latest developments of the outbreak.

## DISCLOSURE UNDER RULES 13.13 TO 13.19 OF THE LISTING RULES

Our Directors confirm that, except as otherwise disclosed in this prospectus, as of the Latest Practicable Date, there was no circumstance that would give rise to a disclosure requirement under Rules 13.13 to 13.19 of the Listing Rules.



Shanghai Miracogen Inc.- Ex. 2032, Page 000549

## FUTURE PLANS

See "Business – Our Strategies" for a detailed description of our future plans.

## USE OF PROCEEDS

We estimate that we will receive the net proceeds of approximately HK$804.2 million from the Global Offering after deducting the underwriting fees and other estimated expenses in connection with the Global Offering, assuming no Over-allotment Option is exercised and assuming an Offer Price of HK$7.13 per Offer Share, being the mid-point of the indicative Offer Price range of HK$6.87 to HK$7.38 per Offer Share in this prospectus.

We intend to use the net proceeds we will receive from the Global Offering for the following purposes and in the amounts set out below, subject to changes in light of our evolving business needs and changing market condition:

(a) Approximately HK$551.0 million (representing 68.5% of the net proceeds) will be allocated to fund our Core Products, and specifically:

- approximately HK$185.0 million (representing 23.0% of the net proceeds) is expected to be used for MRG003:
  - approximately HK$155.0 million (representing 19.3% of the net proceeds) is expected to fund the clinical development and preparation for registration filings of MRG003, including the ongoing and planned clinical trials. We expect to initiate clinical trials in recurrent or metastatic advanced HNSCC in the U.S. in 2022, subject to further development opportunities and communications with regulatory authorities. See "Business – Clinical-Stage Drug Candidates – MRG003 – Clinical Development Plan;" and
  - approximately HK$30.0 million (representing 3.7% of the net proceeds) is expected to fund the manufacturing of MRG003;
- approximately HK$177.0 million (representing 22.0% of the net proceeds) is expected to be used for MRG002:
  - approximately HK$150.0 million (representing 18.7% of the net proceeds) is expected to fund the clinical development and preparation for registration filings of MRG002, including the ongoing and planned clinical trials. In China, we have initiated several Phase II clinical trials of MRG002 in unresectable locally advanced or metastatic HER2-expressing urothelial cancer, HER2 over-expressing BTC and HER2 low-expressing breast cancer in 2021. As of the Latest Practicable Date, we had obtained approval from the NMPA of registration trial of MRG002 in HER2 over-expressing breast cancer. We



Shanghai Miracogen Inc.- Ex. 2032, Page 000550

aim to file an NDA application for MRG002 with the NMPA in 2023 subject to the communications with regulatory authorities. In the U.S., we are conducting a Phase I/II clinical study of MRG002 in unresectable locally advanced or metastatic HER2-expressing (including low-expressing) G/GEJ carcinoma patients and once the Phase I stage of dose confirmation is completed, clinical sites in China will be added to join the Phase II stage of the study. See "Business – Clinical-Stage Candidates – MRG002 – Clinical Development Plan;" and

- o approximately HK$27.0 million (representing 3.4% of the net proceeds) is expected to fund the manufacturing of MRG002;

- approximately HK$130.0 million (representing 16.2% of the net proceeds) is expected to be used for HX008:

  - o approximately HK$60.0 million (representing 7.5% of the net proceeds) is expected to fund the clinical development and preparation for registration filings of HX008, including the ongoing and planned clinical trials. We filed an NDA of HX008 with the NMPA in MSI-H/dMMR solid tumors in October 2021. See "Business – Clinical-Stage Drug Candidates – HX008 – Clinical Development Plan;"

  - o approximately HK$50.0 million (representing 6.2% of the net proceeds) is expected to fund the manufacturing of HX008; and

  - o approximately HK$20.0 million (representing 2.5% of the net proceeds) is expected to fund the commercialization of HX008, including marketing and sales activities;

- approximately HK$10.0 million (representing 1.2% of the net proceeds) is expected to fund the clinical development and preparation for registration filings of LP002, including the ongoing and planned clinical trials. As of the Latest Practicable Date, we had completed patient enrollment and entered the follow-up period for Phase II clinical trial in ES-SCLC (extensive stage small-cell lung cancer) and expect to commence the corresponding Phase III of such clinical trial in 2022, subject to the results of Phase II. See "Business – Clinical-Stage Drug Candidates – LP002 – Clinical Development Plan;" and


Shanghai Miracogen Inc.- Ex. 2032, Page 000551

- approximately HK$49.0 million (representing 6.1% of the net proceeds) is expected to be used to fund the planned clinical development and other development activities of the combination therapies of HX008 and LP002 with our other products including MRG003, MRG002 and CG0070:

(b) Approximately HK$51.0 million (representing 6.3% of the net proceeds) will be allocated to fund our other key clinical-stage drug candidates and our key pre-clinical drug candidates:

- approximately HK$5.0 million (representing 0.6% of the net proceeds) is expected to be allocated to ongoing pre-clinical studies and planned clinical trials for the pre-clinical drug candidates in our pipeline. See "Business – Pre-clinical Drug Candidates;"

- approximately HK$15.0 million (representing 1.9% of the net proceeds) is expected to be used to fund the clinical development and preparation for registration filings of CG0070, including ongoing and planned clinical trials and milestone payments. We plan to initiate a Phase I clinical trial on NMIBC and solid tumors in 2022 in China and plan to join multi-regional clinical trials subject to the clinical development of CG0070 in the U.S. See "Business – Clinical-Stage Drug Candidates – CG0070 – Clinical Development Plan;"

- approximately HK$15.0 million (representing 1.9% of the net proceeds) is expected to be used to fund the clinical development and preparation for registration filings of MRG001, including ongoing and planned clinical trials. We expect to initiate Phase II clinical trials of MRG001 in selected indications where patients are shown to benefit from MRG001 including FL and DLBCL. See "Business – Clinical-Stage Drug Candidates – MRG001 – Clinical Development Plan;"

- approximately HK$15.0 million (representing 1.9% of the net proceeds) is expected to be used to fund the clinical development and preparation for registration filings of MRG004A, including ongoing and planned clinical trials. We plan to continue to identify the appropriate indications for future clinical studies of MRG004A depending on safety and anti-tumor activity of MRG004A in various TF over-expressing tumors following the Phase I/II clinical trial. See "Business – Clinical-Stage Drug Candidates – MRG004A – Clinical Development Plan;" and

- approximately HK$1.0 million (representing 0.1% of the net proceeds) is expected to be used to fund, through our contribution to KYM, the clinical development and preparation for registration filings of CMG901, including ongoing and planned clinical trials. KYM was enrolling patients for the Phase I clinical trial of CMG901 in advanced solid tumors including gastric cancer and pancreatic cancer in China as of the Latest Practicable Date. In the meantime, an IND application was submitted to the FDA in February 2021 and


Shanghai Miracogen Inc.- Ex. 2032, Page 000552

approved in March 2021 for a multi-center, open-label, Phase I clinical trial in the U.S. to evaluate the safety, tolerability, and pharmacokinetics of CMG901 in patients with advanced unresectable and metastatic G/GEJ carcinoma. See "Business – Drug Candidates We Co-developed Through Joint Venture – CMG901 – Clinical Development Plan."

(c) Approximately HK$127.0 million (representing 15.8% of the net proceeds) is expected to be allocated to acquire potential technologies and assets and expand our pipeline of drug candidates, including discovery of new drug candidates and business development activities and to fulfill our continuous payment obligation under our acquisition of HX008 from HanX. Our investment and acquisition targets shall be evaluated based on a number of factors, including but not limited to, the target's drug products and pipelines, the target's competitive strengths and potential, expertise of the target's management and research and development teams and synergies with our existing business. As confirmed by Frost & Sullivan, there are several acquisition targets available in the market that satisfy our acquisition criteria. As of the Latest Practicable Date, we have not identified any investment or acquisition target. We plan to leverage our technology platforms to design and create new molecules with innovative mechanisms and novel targets, which would allow us to enrich our product pipeline and ensure our sustainable growth.

(d) Approximately HK$75.2 million (representing 9.4% of the net proceeds) is expected to be allocated for general corporate purposes.

The above allocation of the proceeds will be adjusted on a pro rata basis in the event that the Offer Price is fixed at a higher or lower level compared to the mid-point of the estimated Offer Price range.

If the Over-allotment Option is exercised in full, and net proceeds that we will receive will be approximately HK$1,040.3 million, assuming an Offer Price of HK$7.13 per Share (being the mid-point of the indicative Offer Price range). In the event that the Over-allotment Option is exercised in full, we intend to apply the additional net proceeds to the above purpose in the proportions stated above.

To the extent that the net proceeds are not immediately applied to the above purposes and to the extent permitted by the relevant law and regulations, we intend to deposit the net proceeds into short-term demand deposits with licensed banks or authorized financial institutions in Hong Kong or the PRC. We will make an appropriate announcement if there is any change to the above proposed use of proceeds or if any amount of the proceeds will be used for general corporate purpose.


Shanghai Miracogen Inc.- Ex. 2032, Page 000553

## THE CORNERSTONE PLACING

We have entered into cornerstone investment agreements (each a "**Cornerstone Investment Agreement**", and together the "**Cornerstone Investment Agreements**") with the cornerstone investors set out below (each a "**Cornerstone Investor**", and together the "**Cornerstone Investors**"), pursuant to which the Cornerstone Investors have agreed to, subject to certain conditions, subscribe for such number of Offer Shares (rounded down to the nearest whole board lot of 1,000 Shares) that may be purchased with an aggregate maximum investment amount of US$50,000,000 (approximately HK$389,650,000) at the Offer Price (the "**Cornerstone Placing**").

Based on the Offer Price of HK$7.38 per Offer Share, being the high-end of the indicative Offer Price range set out in this prospectus, the total number of Offer Shares to be subscribed for by the Cornerstone Investors would be 52,797,000, representing approximately 41.61% of the Offer Shares and approximately 3.18% of the total issued share capital of our Company immediately upon the completion of the Global Offering (assuming the Over-allotment Option is not exercised).

Based on the Offer Price of HK$7.13 per Offer Share, being the mid-point of the indicative Offer Price range set out in this prospectus, the total number of Offer Shares to be subscribed for by the Cornerstone Investors would be 54,648,000, representing approximately 43.07% of the Offer Shares and approximately 3.29% of the total issued share capital of our Company immediately upon the completion of the Global Offering (assuming the Over-allotment Option is not exercised).

Based on the Offer Price of HK$6.87 per Offer Share, being the low-end of the indicative Offer Price range set out in this prospectus, the total number of Offer Shares to be subscribed for by the Cornerstone Investors would be 56,717,000, representing approximately 44.70% of the Offer Shares and approximately 3.42% of the total issued share capital of our Company immediately upon the completion of the Global Offering (assuming the Over-allotment Option is not exercised).

Our Company is of the view that, leveraging on the Cornerstone Investors' investment experience, the Cornerstone Placing will help raise the profile of our Company and to signify that such investors have confidence in our Company's business and prospect.

One of the Cornerstone Investors, namely Vivo Capital, being an existing Shareholder of our Company, has been permitted to participate in the Cornerstone Placing pursuant to paragraph 5.2 of Stock Exchange Guidance Letter HKEX-GL92-18 and has been granted a waiver from strict compliance with the requirements under Rule 10.04 of, and a consent under paragraph 5(2) of Appendix 6 to, the Listing Rules by the Stock Exchange.

One of the Cornerstone Investors, namely King Star Med LP ("**King Star**"), being a close associate of Mr. Lin Xianghong ("**Mr. Lin**"), our non-executive Director and therefore a core connected person of our Company, has been granted a waiver from strict compliance with the requirements under Rules 9.09 and 10.03 of, and a consent under paragraph 5(2) of Appendix 6 to, the Listing Rules by the Stock Exchange.



Shanghai Miracogen Inc.- Ex. 2032, Page 000554

For further details in relation to the abovementioned waivers and consents, see the section headed "Waivers from Strict Compliance with the Listing Rules and Exemption from Strict Compliance with the Companies (Winding Up and Miscellaneous Provisions) Ordinance" in this document.

The Cornerstone Placing forms part of the International Offering, and the Cornerstone Investors will not acquire any Offer Shares under the Global Offering other than pursuant to the Cornerstone Investment Agreements. The Offer Shares to be subscribed by the Cornerstone Investors will rank *pari passu* in all respects with the other fully paid H Shares in issue following the completion of the Global Offering and to be listed on the Stock Exchange. Save for the Offer Shares to be subscribed for by King Star, the Offer Shares to be subscribed by the Cornerstone Investors will be counted towards the public float of our Company under Rule 8.08 of the Listing Rules. All the Offer Shares to be subscribed for by the Cornerstone Investors will not count towards the public float for the purpose of Rule 18A.07 of the Listing Rules. Our Company became acquainted with each of the Cornerstone Investors through introduction by the Underwriters, existing Shareholders or a Director.

Immediately following the completion of the Global Offering, the Cornerstone Investors (i) will not become a substantial Shareholder (as defined in the Listing Rules) of our Company, and (ii) save for the fact that King Star is a close associate of Mr. Lin who is a non-executive Director, will not have any Board representation in our Company. The Cornerstone Investors do not have any preferential rights under the Cornerstone Investment Agreements compared with other public Shareholders, other than a guaranteed allocation of the relevant Offer Shares at the final Offer Price.

To the best knowledge of our Company and save for the fact that (i) King Star is a core connected person of our Company and (ii) Vivo Capital is an existing Shareholder of the Company, (a) each Cornerstone Investor is an Independent Third Party and is not our connected person (as defined under the Listing Rules), (b) each Cornerstone Investor is independent of other Cornerstone Investor, (c) the subscription of the relevant Offer Shares by the Cornerstone Investors are not financed by our Company, its subsidiaries, our Directors, chief executive, controlling Shareholder, substantial Shareholders, existing Shareholders or any of their respective close associates, and (d) each Cornerstone Investor is not accustomed to take instructions from our Company, its subsidiaries, our Directors, chief executive, controlling Shareholder, substantial Shareholders, existing Shareholders or any of their respective close associates in relation to the acquisition, disposal, voting or other disposition of the Shares registered in their name or otherwise held by them. There are no side agreements or arrangements between us and the Cornerstone Investors or any benefit, direct or indirect, conferred on the Cornerstone Investors by virtue of or in relation to the Cornerstone Placing, other than a guaranteed allocation of the relevant Offer Shares at the final Offer Price.

As confirmed by each Cornerstone Investor, its subscription under the Cornerstone Placing would be financed by its own internal financial resources. None of the Cornerstone Investors or their controlling entity is listed on any stock exchange. Each of the Cornerstone Investors has confirmed that all necessary approvals have been obtained with respect to the Cornerstone Placing and that no specific approval from any stock exchange (if relevant) or its shareholders is required for the relevant cornerstone investment as each of them has general authority to invest.



Shanghai Miracogen Inc.- Ex. 2032, Page 000555

The Offer Shares to be subscribed by the Cornerstone Investors may be affected by the reallocation in the event of over-subscription under the Hong Kong Public Offering, as described in "Structure of the Global Offering – The Hong Kong Public Offering – Reallocation and Clawback" in this document, the number of Offer Shares to be acquired by each Cornerstone Investor may be reduced on a pro rata basis in accordance with the terms of the Cornerstone Investment Agreement to satisfy the short fall, after taking into account the requirements under Appendix 6 to the Listing Rules as well as the discretion of the Joint Global Coordinators (for themselves and on behalf of the International Underwriters) to exercise the Over-allotment Option. Details of the actual number of Offer Shares to be allocated to the Cornerstone Investors will be disclosed in the allotment results announcement in the Hong Kong Public Offering to be published on or around February 22, 2022.

Each of the Cornerstone Investors has agreed that the Joint Global Coordinators may defer the delivery of all or any part of the Offer Shares it has subscribed for to a date later than the Listing Date. The delayed delivery arrangement is in place to facilitate the over-allocation in the International Offering. The consideration of the Cornerstone Placing will be settled by the Cornerstone Investors before the commencement of dealings. There will be no delayed delivery if there is no over-allocation in the International Offering. For details of the Over-allotment Option and the stabilization action by the Stabilizing Manager, see "Structure of the Global Offering – The International Offering – Over-allotment Option" and "Structure of the Global Offering – The International Offering – Stabilization" in this prospectus, respectively.

The table below sets forth details of the Cornerstone Placing:

| | | Based on an Offer Price of HK$6.87 (being the low-end of the Offer Price range) | | | |
|---|---|---|---|---|---|
| Cornerstone Investor | Subscription amount | Number of Offer Shares[1] | Assuming the Over-Allotment Option is not exercised | | Assuming the Over-Allotment Option is fully exercised | |
| | | | Approximate % of the total number of Offer Shares | Approximate % of the issued share capital[2] | Approximate % of the total number of Offer Shares | Approximate % of the issued share capital[2] |
| Vivo Capital | US$30,000,000 | 34,030,000 | 26.82% | 2.05% | 23.32% | 2.03% |
| King Star | US$20,000,000 | 22,687,000 | 17.88% | 1.37% | 15.55% | 1.35% |
| **Total** | US$50,000,000 | 56,717,000 | 44.70% | 3.42% | 38.87% | 3.38% |



Shanghai Miracogen Inc.- Ex. 2032, Page 000556

| Cornerstone Investor | Subscription amount | Based on an Offer Price of HK$7.13 (being the mid-point of the Offer Price range) Number of Offer Shares[1] | Assuming the Over-Allotment Option is not exercised | | Assuming the Over-Allotment Option is fully exercised | |
|---|---|---|---|---|---|---|
| | | | Approximate % of the total number of Offer Shares | Approximate % of the issued share capital[2] | Approximate % of the total number of Offer Shares | Approximate % of the issued share capital[2] |
| Vivo Capital | US$30,000,000 | 32,789,000 | 25.84% | 1.98% | 22.47% | 1.95% |
| King Star | US$20,000,000 | 21,859,000 | 17.23% | 1.32% | 14.98% | 1.30% |
| **Total** | US$50,000,000 | 54,648,000 | 43.07% | 3.29% | 37.45% | 3.26% |

| Cornerstone Investor | Subscription amount | Based on an Offer Price of HK$7.38 (being the high-end of the Offer Price range) Number of Offer Shares[1] | Assuming the Over-Allotment Option is not exercised | | Assuming the Over-Allotment Option is fully exercised | |
|---|---|---|---|---|---|---|
| | | | Approximate % of the total number of Offer Shares | Approximate % of the issued share capital[2] | Approximate % of the total number of Offer Shares | Approximate % of the issued share capital[2] |
| Vivo Capital | US$30,000,000 | 31,678,000 | 24.97% | 1.91% | 21.71% | 1.89% |
| King Star | US$20,000,000 | 21,119,000 | 16.65% | 1.27% | 14.47% | 1.26% |
| **Total** | US$50,000,000 | 52,797,000 | 41.61% | 3.18% | 36.19% | 3.15% |

*Notes:*

(1) Subject to rounding down to the nearest whole board lot of 1,000 Shares. Calculated based on the exchange rate set out in the section headed "Information about this Prospectus and the Global Offering – Exchange Rate Conversion".

(2) Immediately following the completion of the Global Offering.

## THE CORNERSTONE INVESTORS

The information about our Cornerstone Investors set forth below has been provided by the Cornerstone Investors in connection with the Cornerstone Placing.

### Vivo Capital

Vivo Capital is an investment fund organized under the laws of Delaware, U.S. The general partner of Vivo Capital is Vivo Capital IX, LLC. Vivo Capital is under the management of Vivo Capital LLC. Founded in 1996, Vivo Capital LLC is a global healthcare investment firm with approximately $5.8 billion in assets under management as of December 31, 2020, and provides a multi-fund investment platform, covering private equity including buyout, venture capital, and public equity. Funds managed by Vivo Capital LLC primarily invest in the United States and China, spanning the areas of biotechnology, pharmaceuticals, medical devices, and healthcare services. The ultimate beneficial owners of Vivo Capital are Independent Third Parties.



Shanghai Miracogen Inc.- Ex. 2032, Page 000557

**King Star**

King Star is an investment fund organized under the laws of the Cayman Islands, specializing in investments with a primary focus on healthcare and biotech with a fund size of approximately US$100 million. The general partner and manager of King Star, namely King Star Med Management Limited and King Star Consulting Limited, are both held by Ace Treasure Trust (through Ace Treasure Enterprises Limited), Superb Outcome Trust (through Superb Outcome Limited) and Fortune Plus Trust (through Fortune$^{+}$ Investment Limited) as to 40%, 30% and 30%, respectively. Mr. Lin, a non-executive Director nominated by Kington Capital and Suzhou Suzi, is the settlor, the protector and one of the beneficiaries of both Ace Treasure Trust and Superb Outcome Trust, and therefore in turn controls 70% interest in King Star Med Management Limited and King Star Consulting Limited, respectively. The ultimate beneficial owners of Fortune Plus Trust are Independent Third Parties. To the best knowledge of our Company, save for the fact that two limited partners of King Star, namely Hwa-An International Limited and Max Bloom Group Limited with economic interests of 46.02% and 16.07% in King Star respectively, have the same ultimate beneficial owner, namely Mr. Shi Jiangang (施建剛, "Mr. Shi"). To the best knowledge of the Company, Mr. Shi is the controlling shareholder of Jiangsu Feymer Technology Co., Ltd. (江蘇富淼科技股份有限公司, a company listed on the Shanghai Stock Exchange, stock code: 688350) and is an Independent Third Party, no other limited partners of King Star holds more than 30% economic interests and all limited partners of King Star are Independent Third Parties. King Star Med Management Limited, the general partner of King Star, is a company incorporated in the Cayman Islands. The voting and investment power of shares held by King Star is exercised by the two directors, Mr. Lin and Ms. Yu Bin (余濱, "Ms. Yu"), of King Star Med Management Limited, no one of whom may act alone to vote or dispose of the shares. The management team of King Star specializes in private equity and venture capital investment, and accumulated experience in financing for the development of biotech companies. To the best knowledge of our Company, Ms. Yu has several years of financial experience and currently serves as an independent director of GDS Holdings Limited (a company listed on the Main Board of the Stock Exchange, stock code: 9698), an independent director of Baozun Inc. (a company listed on the Nasdaq Stock Exchange, stock code: BZUN), and an independent non-executive director of iDreamSky Technology Holdings Limited (a company listed on the Main Board of the Stock Exchange, stock code: 1119). The portfolio of King Star in biotech or healthcare sectors includes Gracell Biotechnologies (a company listed on the Nasdaq Stock Exchange, stock code: GRCL), Adagene (a company listed on the Nasdaq Stock Exchange, stock code: ADAG), CStone Pharmaceuticals (a company listed on the Main Board of the Stock Exchange, stock code: 2616), JW (Cayman) Therapeutics Co. Ltd (a company listed on the Main Board of the Stock Exchange, stock code: 2126) and Transcenta Holding Ltd. (a company listed on the Main Board of the Stock Exchange, stock code: 6628).

King Star is a close associate of Mr. Lin and therefore a core connected person of our Company.



Shanghai Miracogen Inc.- Ex. 2032, Page 000558

## CLOSING CONDITIONS

The subscription obligation of each Cornerstone Investor under the respective Cornerstone Investment Agreement is subject to, among other things, the following closing conditions:

a. the underwriting agreements for the Hong Kong Public Offering and the International Offering being entered into and having become effective and unconditional (in accordance with their respective original terms or as subsequently waived or varied by agreement of the parties thereto) by no later than the time and date as specified in the Underwriting Agreements, and neither of the aforesaid underwriting agreements having been terminated;

b. the Offer Price having been agreed upon between the Company and the Joint Global Coordinators (on behalf of the underwriters of the Global Offering);

c. the Stock Exchange having granted the listing of, and permission to deal in, the H Shares (including the Offer Shares subscribed for by the Cornerstone Investors) as well as other applicable waivers and approvals and such approval, permission or waiver having not been revoked prior to the commencement of dealings in the H Shares on the Stock Exchange;

d. no applicable laws shall have been enacted or promulgated by any governmental authority which prohibits the consummation of the transactions contemplated in the Global Offering or in the respective Cornerstone Investment Agreement and there shall be no orders or injunctions from a court of competent jurisdiction in effect precluding or prohibiting consummation of such transactions; and

e. the representations, warranties, undertakings, confirmations and acknowledgements of such Cornerstone Investor and our Company (as the case may be) under the respective Cornerstone Investment Agreement are accurate and true in all material respects and not misleading and that there is no material breach of such Cornerstone Investment Agreement on the part of such Cornerstone Investor and our Company (as the case may be).

## RESTRICTIONS ON DISPOSALS BY THE CORNERSTONE INVESTORS

Each of the Cornerstone Investors has agreed that it will not, whether directly or indirectly, at any time during the period of six (6) months following the Listing Date (the "**Lock-up Period**"), dispose of any of the Offer Shares they have purchased pursuant to the relevant Cornerstone Investment Agreement, save for certain limited circumstances, such as transfers to any of its wholly-owned subsidiaries who will be bound by the same obligations of such Cornerstone Investor, including the Lock-up Period restriction.



Shanghai Miracogen Inc.- Ex. 2032, Page 000559

## HONG KONG UNDERWRITERS

China International Capital Corporation Hong Kong Securities Limited *(in alphabetical order)*

Morgan Stanley Asia Limited *(in alphabetical order)*

Haitong International Securities Company Limited

Huatai Financial Holdings (Hong Kong) Limited

China Galaxy International Securities (Hong Kong) Co., Limited

Valuable Capital Limited

Tiger Brokers (HK) Global Limited

## HONG KONG UNDERWRITING ARRANGEMENTS

### Hong Kong Public Offering

***Hong Kong Underwriting Agreement***

Pursuant to the Hong Kong Underwriting Agreement, our Company is offering initially 12,688,000 Hong Kong Offer Shares (subject to adjustment) for subscription by the public in Hong Kong at the Offer Price on and subject to the terms and conditions of this prospectus.

Subject to (a) the Stock Exchange granting listing of, and permission to deal in, the H Shares to be issued and sold pursuant to the Global Offering (including any additional H Shares which may be issued and/or sold pursuant to the exercise of the Over-allotment Option) as mentioned herein and (b) to certain other conditions set out in the Hong Kong Underwriting Agreement, the Hong Kong Underwriters have severally agreed to subscribe or procure subscriptions for their respective applicable proportions of the Hong Kong Offer Shares now being offered but which are not taken up under the Hong Kong Public Offering on the terms and conditions set out in this prospectus and the Hong Kong Underwriting Agreement.

The Hong Kong Underwriting Agreement is conditional on and subject to the International Underwriting Agreement having been signed and becoming unconditional and not having been terminated in accordance with its terms.



Shanghai Miracogen Inc.- Ex. 2032, Page 000560

***Grounds for Termination***

The Joint Global Coordinators (for themselves and on behalf of the Hong Kong Underwriters), shall be entitled by written notice to the Company to terminate the Hong Kong Underwriting Agreement with immediate effect if prior to 8:00 a.m. on the Listing Date:

(a) there shall develop, occur, exist or come into effect:

(i) any or a series of local, national, regional or international event(s) or circumstance(s) in the nature of force majeure (including any acts of government, declaration of a national or international emergency or war, calamity, crisis, epidemic and pandemic (including Severe Acute Respiratory Syndrome (SARS), Coronavirus Disease 2019 (COVID-19), H1N1 and H5N1 and such related/mutated forms and the escalation, mutation or aggravation of such diseases), or interruption or delay in transportation, outbreak, escalation, mutation or aggravation of disease, economic sanctions, labour disputes, strikes, lock-outs, fire, explosion, flooding, earthquake, volcanic eruption, civil commotion, riots, public disorder, acts of war, outbreak or escalation of hostilities (whether or not war is declared), acts of God or acts of terrorism (whether or not responsibility has been claimed)) in or directly or indirectly affecting Hong Kong, the PRC, the United States, the United Kingdom or the European Union (or any member thereof) (collectively, the "**Relevant Jurisdictions**"); or

(ii) any change, or any development involving a prospective change, or any event or circumstance likely to result in any change or development involving a prospective change, in any local, national, regional or international financial, economic, political, military, industrial, fiscal, regulatory, currency, credit or market conditions or any monetary or trading settlement system (including conditions in the stock and bond markets, money and foreign exchange markets, the interbank markets and credit markets) in or directly or indirectly affecting any Relevant Jurisdictions; or

(iii) any moratorium, suspension or restriction (including any imposition of or requirement for any minimum or maximum price limit or price range) in or on trading in securities generally on the Hong Kong Stock Exchange, the Shanghai Stock Exchange, the Shenzhen Stock Exchange, the Singapore Stock Exchange, the New York Stock Exchange, the NASDAQ Global Market or the London Stock Exchange; or

(iv) any general moratorium on commercial banking activities in the Hong Kong (imposed by the Financial Secretary or the Hong Kong Monetary Authority or other competent authority), the PRC, New York (imposed at Federal or New York State level or other competent authority), London, the PRC or any other


Shanghai Miracogen Inc.- Ex. 2032, Page 000561

Relevant Jurisdiction, or any disruption in commercial banking or foreign exchange trading or securities settlement or clearance services, procedures or matters in any Relevant Jurisdiction; or

(v) any new law, or any change or any development involving a prospective change or any event or circumstance likely to result in a change or a development involving a prospective change in (or in the interpretation or application by any court or other competent authority of) existing laws, in each case, in or affecting any of the Relevant Jurisdictions; or

(vi) the imposition of sanctions, in whatever form, directly or indirectly, under any sanction laws, or regulations in, Hong Kong, the PRC or any other Relevant Jurisdiction; or

(vii) a change or development involving a prospective change in or affecting taxation or exchange control, currency exchange rates or foreign investment regulations (including a material devaluation of the Hong Kong dollar or the Renminbi against any foreign currencies and a change in the system under which the value of the Hong Kong currency is linked to that of the currency of the United States), or the implementation of any exchange control, in any of the Relevant Jurisdictions; or

(viii) any litigation or claim of any third party being threatened or instigated against any member of the Group or any Director; or

(ix) a contravention by any member of the Group or any Director or any Supervisor of the Listing Rules or applicable laws; or

(x) non-compliance of this prospectus (or any other documents used in connection with the contemplated offer and sale of the Offer Shares) or any aspect of the Global Offering with the Listing Rules or any other applicable laws; or

(xi) the issue or requirement to issue by us of any supplement or amendment to this prospectus (or to any other documents issued or used in connection with the contemplated offer and sale of the H Shares) pursuant to the Companies Ordinance or the Companies (Winding Up and Miscellaneous Provisions) Ordinance or the Listing Rules or any requirement or request of the Hong Kong Stock Exchange and/or the SFC; or

(xii) any change or development involving a prospective change in, or a materialization of, any of the risks set out in the section headed "Risk Factors" of this prospectus; or



Shanghai Miracogen Inc.- Ex. 2032, Page 000562

(xiii) a valid demand by any creditor for repayment or payment of any indebtedness of any member of the Group or in respect of which any member of the Group is liable prior to its stated maturity; or

(xiv) a Director or a Supervisor or any member of senior management of the Company vacating his or her office; or

(xv) an authority or a political body or organisation in any Relevant Jurisdiction (including, in particular, the CSRC and its local branches and representative offices) commencing any investigation or other action, or announcing an intention to investigate or take other action, against any member of the Group or any Director or any Supervisor or a member of the Company's senior management as named in this prospectus; or

(xvi) any order or petition for the winding up or liquidation of any member of the Group (other than the Company) or any composition or arrangement made by any member of the Group (other than the Company) with its creditors or a scheme of arrangement entered into by any member of the Group (other than the Company) or any resolution for the winding-up of any member of the Group (other than the Company) or the appointment of a provisional liquidator, receiver or manager over all or part of the material assets or undertaking of any member of the Group (other than the Company) or anything analogous thereto occurring in respect of any member of the Group (other than the Company),

which, individually or in the aggregate, in the sole and absolute opinion of the Joint Global Coordinators (1) has or will have or may have a material adverse effect on the assets, liabilities, business, general affairs, management, prospects, shareholders' equity, profits, losses, results of operations, position or condition, financial or otherwise, or performance of the Group as a whole; or (2) has or will have or may have a material adverse effect on the success of the Global Offering or the level of applications under the Hong Kong Public Offering or the level of interest under the International Offering; or (3) makes or will make or may make it inadvisable or inexpedient or impracticable for the Global Offering to proceed or to market the Global Offering; or (4) has or will have or may have the effect of making any part of the Hong Kong Underwriting Agreement (including underwriting) incapable of performance in accordance with its terms or preventing the processing of applications and/or payments pursuant to the Global Offering or pursuant to the underwriting thereof; or


Shanghai Miracogen Inc.- Ex. 2032, Page 000563

(b) there has come to the notice of the Joint Global Coordinators:

(i) that any statement contained in any of the application proof, the post hearing information proof, this prospectus, the Green Application Form, the pricing disclosure package, the offering circular, the formal notice, and/or any other document, communication or information made, issued, given, arising out of or used in connection with the contemplated offering and sale of the Offer Shares or otherwise in connection with the Global Offering, all amendments or supplements thereto, whether or not approved by the Joint Sponsors, the Joint Global Coordinators, the Joint Bookrunners, the Joint Lead Managers or any of the Underwriters (collectively, the "**Offer Related Documents**") was, when it was issued, or has become, untrue, incorrect in any material respect or misleading, or that any forecast, estimate, expression of opinion, intention or expectation contained in any of the Offer Related Documents (including any supplement or amendment thereto) is not fair and honest and based on reasonable assumptions; or

(ii) that any matter has arisen or has been discovered which would, had it arisen or been discovered immediately before the date of this prospectus, constitute a material omission from, or misstatement in, any of the Offer Related Documents (including any supplement or amendment thereto); or

(iii) any material breach of any of the obligations imposed upon any party to the Hong Kong Underwriting Agreement, the International Underwriting Agreement or the Cornerstone Investment Agreements (other than upon any of the Hong Kong Underwriters or the International Underwriters); or

(iv) any event, act or omission which gives or is likely to give rise to any liability of any of the Company or the Controlling Shareholder pursuant to the indemnities given by any of them under the Hong Kong Underwriting Agreement or the International Underwriting Agreement, as applicable; or

(v) any material adverse change, or any development involving a prospective material adverse change, in or affecting the assets, liabilities, business, general affairs, management, prospects, shareholders' equity, losses, results of operations, position or condition, financial or otherwise, or performance of the Group as a whole; or

(vi) any breach of, or any event or circumstance rendering untrue or incorrect in any respect, any of the warranties given by the Company or the Controlling Shareholder in the Hong Kong Underwriting Agreement or the International Underwriting Agreement, as applicable; or



Shanghai Miracogen Inc.- Ex. 2032, Page 000564

(vii) a prohibition on the Company for whatever reason from offering, allotting, issuing or selling any of the H Shares (including the H Shares to be issued pursuant to the Over-allotment Option) pursuant to the terms of the Global Offering; or

(viii) that approval by the Listing Committee of the Hong Kong Stock Exchange of the listing of, and permission to deal in, the H Shares to be issued or sold (including any additional H Shares that may be issued or sold pursuant to the exercise of the Over-Allotment Option) under the Global Offering is refused or not granted, other than subject to customary conditions, on or before the Listing Date, or if granted, the approval is subsequently withdrawn, qualified (other than by customary conditions) or withheld; or

(ix) the Company withdraws any of the Offer Related Documents or the Global Offering; or

(x) any person (other than the Joint Sponsors) has withdrawn its consent to being named in this prospectus or to the issue of any of the application proof, the post hearing information proof, this prospectus, the Green Application Form or the formal notice; or

(xi) a Director or a Supervisor or a member of the Company's senior management as named in this prospectus being charged with an indictable offense or prohibited by operation of law or otherwise disqualified from taking part in the management or taking directorship of a company; or

(xii) any order or petition for the winding up or liquidation of the Company or any composition or arrangement made by the Company with its creditors or a scheme of arrangement entered into by the Company or any resolution for the winding-up of the Company or the appointment of a provisional liquidator, receiver or manager over all or part of the material assets or undertaking of the Company or anything analogous thereto occurring in respect of the Company; or

(xiii) that a material portion of the orders placed or confirmed in the bookbuilding process, or of the investment commitments made by any cornerstone investors under agreements signed with such cornerstone investors, have been withdrawn, terminated or cancelled.



Shanghai Miracogen Inc.- Ex. 2032, Page 000565

## UNDERTAKINGS TO THE HONG KONG STOCK EXCHANGE PURSUANT TO THE LISTING RULES

### Undertakings by Our Company

Pursuant to Rule 10.08 of the Listing Rules, we have undertaken to the Stock Exchange that, no further Shares or securities convertible into equity securities (whether or not of a class already listed) may be issued by us or from the subject of any agreement to such issue within six months from the Listing Date (whether or not such issue of Shares or our securities will be completed within six months from the Listing Date), except for: (a) any capitalization issued, capital reduction or consolidation or sub-decision of Shares; or (b) issue of Shares or securities pursuant to the Global Offering and the Over-allotment Option; or (c) for the circumstances permitted under Rule 10.08 of the Listing Rules.

### Undertakings by our Controlling Shareholder

Pursuant to Rule 10.07 of the Listing Rules, our Controlling Shareholder has undertaken to the Hong Kong Stock Exchange and the Company that, he will not, without the prior written consent of the Hong Kong Stock Exchange or unless otherwise permitted under the Listing Rules:

(a) in the period commencing on the date by reference to which disclosure of his shareholding in the Company is made in this prospectus in connection with the listing of the H Shares on the Main Board of the Stock Exchange pursuant to the Listing Rules and ending on the date which is 6 months from the Listing Date, dispose of, nor enter into any agreement to dispose of or otherwise create any options, rights, interests or encumbrances in respect of any shares of the Company in respect of which he is shown by this prospectus to be the beneficial owner; or

(b) in the period of 6 months commencing on the date on which the period referred to in the above paragraph (a) expires, dispose of, nor enter into any agreement to dispose of or otherwise create any options, rights, interests or encumbrances in respect in respect of which he is shown by this prospectus to be the beneficial owner if, immediately following such disposal or upon the exercise or enforcement of such option, rights, interests or encumbrances, he would cease to be a controlling shareholder of the Company.

Our Controlling Shareholder has further undertaken to the Stock Exchange and the Company that within the period commencing on the date by reference to which disclosure of his shareholding in the Company is made in this prospectus and ending on the date which is 12 months from the Listing Date, he will:

(i) when he pledges/charges any securities of the Company beneficially owned by him in favor of an authorized institution pursuant to Note (2) to Rule 10.07(2) of the Listing Rules, immediately inform the Company of such pledge/charge together with the number of securities so pledged/charged; and



Shanghai Miracogen Inc.- Ex. 2032, Page 000566

(ii) when he receives indications, whether verbal or written, from any pledgee or chargee of any of the pledged/charged securities of the Company will be disposed of, immediately inform the Company of any such indications.

We will also inform the Stock Exchange as soon as we have been informed of the above matters (if any) by our Controlling Shareholder and disclose such matters in accordance with the publication requirements under Rule 2.07C of the Listing Rules as soon as possible after being so informed by our Controlling Shareholder.

## UNDERTAKINGS PURSUANT TO THE HONG KONG UNDERWRITING AGREEMENT

### Undertaking by Our Company

Except for the offer or sale of the Offer Shares pursuant to the Global Offering (including pursuant to the Over-Allotment Option) and otherwise pursuant to the Listing Rules, during the period commencing on the date of the Hong Kong Underwriting Agreement and ending on, and including, the date that is six months after the Listing Date (the "**First Six-Month Period**"), the Company undertakes to each of the Hong Kong Underwriters, the Joint Global Coordinators, the Joint Bookrunners, the Joint Lead Managers, and the Joint Sponsors not to, and to procure each other member of the Group not to, without the prior written consent of the Joint Sponsors and the Joint Global Coordinators (for themselves and on behalf of the Hong Kong Underwriters) and unless in compliance with the requirements of the Listing Rules:

(a) allot, issue, sell, accept subscription for, offer to allot, issue or sell, contract or agree to allot, issue or sell, mortgage, charge, pledge, hypothecate, lend, grant or sell any option, warrant, right or contract to subscribe for or purchase, purchase or grant any option, warrant, contract or right to allot issue or sell, or otherwise transfer or dispose of or create an encumbrance over, either directly or indirectly, conditionally or unconditionally, or repurchase, any H Shares or other securities convertible into equity securities of the Company, or any interests in any of the foregoing (including any securities convertible into or exercisable or exchangeable for, or that represent the right to receive, or any warrants or other rights to purchase, any H Shares or other securities convertible into equity securities of the Company) or deposit any H Shares or other securities convertible into equity securities of the Company, as applicable, with a depositary in connection with the issue of depositary receipts; or

(b) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of any H Shares or other securities convertible into equity securities of the Company or any shares or other securities of such other member of the Group, as applicable, or any interest therein (including any securities convertible into or exchangeable or exercisable for, or represent the right to receive, or any warrants or other rights to purchase any H Shares or any shares of such other member of the Group, as applicable; or



Shanghai Miracogen Inc.- Ex. 2032, Page 000567

(c) enter into any transaction with the same economic effect as any transaction specified in (a) or (b) above; or

(d) offer to or agree to or announce any intention to effect any transaction described in (a), (b) or (c) above,

in each case, whether any of the transactions specified in paragraphs (a), (b) and (c) above is to be settled by delivery of H Shares or other securities convertible into equity securities of the Company or any shares or other securities of such other member of the Group, as applicable, or in cash or otherwise (whether or not the issue of such H Shares or other Shares or securities will be completed within the First Six-month Period).

In the event that, during the period of six months commencing on the date on which the First Six-Month Period expires (the "**Second Six-Month Period**"), the Company enters into any of the transactions specified in paragraphs (a), (b) or (c) above or offers to or agrees to or announces any intention to effect any such transactions, the Company shall take all reasonable steps to ensure that it will not create a disorderly or false market in the securities of the Company.

The Controlling Shareholder undertakes to each of the Joint Global Coordinators, the Joint Bookrunners, the Hong Kong Underwriters and the Joint Sponsors to procure the Company to comply with the undertakings.

**Undertaking by Our Controlling Shareholder**

The Controlling Shareholder has undertaken to each of the Company, the Joint Global Coordinators, the Joint Bookrunners, the Hong Kong Underwriters and the Joint Sponsors that, except pursuant to the Global Offering (including pursuant to the Over-allotment Option) without the prior written consent of the Joint Sponsors and the Joint Global Coordinators (for themselves and on behalf of the Hong Kong Underwriters) and unless in compliance with the requirements of the Listing Rules, he will not, and will procure that the relevant registered holder(s), any nominee or trustee holding on trust for him and the companies controlled by him will not, at any time during the First Six-Month Period:

(a) sell, offer to sell, contract or agree to sell, mortgage, charge, pldege, hypothecate, lend, grant or sell any option, warrant, contract or right to purchase, grant or purchase any option, warrant, contract or right to sell, or otherwise transfer or dispose of or create an encumbrance over, or agree to transfer or dispose of or create an encumbrance over, either directly or indirectly, conditionally or unconditionally, any Shares or other securities of the Company or any interest in any of the foregoing (including any securities convertible into or exchangeable or exercisable for, or that represent the right to receive, or any warrants or other rights to purchase, any Shares) (the "**Locked-up Securities**") or deposit any Shares or other securities of the Company with a depositary in connection with the issue of depositary receipts;



Shanghai Miracogen Inc.- Ex. 2032, Page 000568

(b) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of, any Locked-up Securities;

(c) enter into any transaction with the same economic effect as any transaction described in (a) or (b) above; or

(d) offer to or agree to or announce that any intention to effect any transaction described in (a), (b) or (c) above,

in each case, whether any such transaction described in paragraphs (a), (b), and (c) above is to be settled by delivery of Shares or other securities of the Company, or in cash or otherwise (whether or not the issue of such Shares or other securities will be completed within the First Six-Month Period or the Second Six Month Period);

During the Second Six Month Period, he will not enter into any transactions described in paragraphs (a), (b) or (c) above or offer to or agree to or contract to or publicly announce any intention to effect any such transaction if, immediately following any sale, transfer or disposal or upon the exercise or enforcement of any option, right, interest or encumbrance pursuant to such transaction, he would cease to be a controlling shareholder (as defined under the Listing Rules) of the Company.

Until the expiry of the Second Six-Month Period, in the event that he or the relevant registered holder(s) enters into any such transactions specified in paragraphs (a), (b) or (c) above or offers to or agrees to or announces any intention to effect any such transactions, he will take all reasonable steps to ensure that it will not create a disorderly or false market in the securities of the Company; and at any time during the First Six Month Period and the Second Six Month Period, he will (a) if and when he or it pledges or charges any Shares or other securities of the Company beneficially owned by him, immediately inform the Company and the Joint Global Coordinators in writing of such pledge or charge together with the number of Shares or other securities of the Company so pledged or charged; and (b) if and when he receives indications, either verbal or written, from any pledgee or chargee that any of the pledged or charged Shares or other securities of the Company will be disposed of, immediately inform the Company and the Joint Global Coordinators in writing of such indications.

## INTERNATIONAL OFFERING

### International Underwriting Agreement

In connection with the International Offering, it is expected that we will enter into the International Underwriting Agreement with the Joint Global Coordinators and the International Underwriters. Under the International Underwriting Agreement, the International Underwriters, subject to certain conditions set out therein, will agree severally to purchase, or procure subscribers or purchasers for, the International Offer Shares being offered pursuant to the International Offering. Please refer to the paragraph headed "Structure of the Global Offering – The International Offering" in this prospectus.



Shanghai Miracogen Inc.- Ex. 2032, Page 000569

We expect to grant the Over-allotment Option to the International Underwriters and the Joint Bookrunners, exercisable by the Joint Global Coordinators for themselves and on behalf of the International Underwriters and the Joint Bookrunners, on or before Thursday, March 17, 2022, being the 30th day from the last day for lodging applications under the Hong Kong Public Offering, to require us to issue and allot, up to an aggregate of 19,031,000 Shares, representing in aggregate approximately 15% of Offer Shares initially available under the Global Offering at the Offer Price to cover over-allocations, if any, in the International Offering. Please refer to the paragraph headed "Structure of the Global Offering – Over-allotment Option" in this prospectus.

## COMMISSION AND EXPENSES

The Underwriters will receive an underwriting commission of 3% of the aggregate Offer Price of all the Offer Shares, including Offer Shares to be issued pursuant to the Over-allotment Option. Our Company may, at our sole and absolute discretion, pay to one or more Underwriters an incentive fee up to but not exceeding 1% of the Offer Price of all the Offer Shares (including Offer Shares to be issued pursuant to the Over-allotment Option). For unsubscribed Hong Kong Offer Shares reallocated to the International Offering, we will pay an underwriting commission at the rate applicable to the International Offering and such commission will be paid to the relevant International Underwriters and not the Hong Kong Underwriters.

The aggregate commissions and fees, together with the listing fees, SFC transaction levy, the Hong Kong Stock Exchange trading fee and FRC transaction levy, legal and other professional fees, printing and other expenses payable by us relating to the Global Offering are estimated to amount to approximately RMB82.2 million (approximately HK$100.4 million) in total (based on the Offer Price of HK$7.13 per Offer Share which is the mid-point of the Offer Price range and assuming the Over-allotment Option is not exercised).

## HONG KONG UNDERWRITERS' INTERESTS IN OUR COMPANY

Save as disclosed in this prospectus, save for its obligations under the Hong Kong Underwriting Agreement, as of the Latest Practicable Date, none of the Hong Kong Underwriters has any shareholding in any member of our Group or any right or option (whether legally enforceable or not) to purchase or subscribe for or to nominate persons to purchase or subscribe for securities in any member of our Group.

Following the completion of the Global Offering, the Hong Kong Underwriters and their affiliated companies may hold a certain portion of the Shares as a result of fulfilling their obligations under the Hong Kong Underwriting Agreement and/or the International Underwriting Agreement.


Shanghai Miracogen Inc.- Ex. 2032, Page 000570

## JOINT SPONSORS' INDEPENDENCE

Each of the Joint Sponsors satisfies the independence criteria set out in Rule 3A.07 of the Listing Rules.

## ACTIVITIES BY SYNDICATE MEMBERS

The underwriters of the Hong Kong Public Offering and the International Offering (together, the "**Syndicate Members**") and their affiliates may each individually undertake a variety of activities (as further described below) which do not form part of the underwriting or stabilizing process.

The Syndicate Members and their affiliates are diversified financial institutions with relationships in countries around the world. These entities engage in a wide range of commercial and investment banking, brokerage, funds management, trading, hedging, investing and other activities for their own account and for the account of others. In the ordinary course of their various business activities, the Syndicate Members and their respective affiliates may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers. Such investment and trading activities may involve or relate to assets, securities and/or instruments the Company and/or persons and entities with relationships with the Company and may also include swaps and other financial instruments entered into for hedging purposes in connection with the Group's loans and other debt.

In relation to the H Shares, the activities of the Syndicate Members and their affiliates could include acting as agent for buyers and sellers of the H Shares, entering into transactions with those buyers and sellers in a principal capacity, including as a lender to initial purchasers of the H Shares (which financing may be secured by the H Shares) in the Global Offering, proprietary trading in the H Shares, and entering into over the counter or listed derivative transactions or listed or unlisted securities transactions (including issuing securities such as derivative warrants listed on a stock exchange) which have as their underlying assets, assets including the H Shares. Such transactions may be carried out as bilateral agreements or trades with selected counterparties. Those activities may require hedging activity by those entities involving, directly or indirectly, the buying and selling of the H Shares, which may have a negative impact on the trading price of the H Shares. All such activities could occur in Hong Kong and elsewhere in the world and may result in the Syndicate Members and their affiliates holding long and/or short positions in the H Shares, in baskets of securities or indices including the H Shares, in units of funds that may purchase the H Shares, or in derivatives related to any of the foregoing.


Shanghai Miracogen Inc.- Ex. 2032, Page 000571

In relation to issues by Syndicate Members or their affiliates of any listed securities having the Shares as their underlying securities, whether on the Hong Kong Stock Exchange or on any other stock exchange, the relevant rules of the exchange may require the issuer of those securities (or one of its affiliates or agents) to act as a market maker or liquidity provider in the security, and this will also result in hedging activity in the Shares in most cases.

All such activities may occur both during and after the end of the stabilizing period described in the section headed "Structure of the Global Offering" in this prospectus. Such activities may affect the market price or value of the Shares, the liquidity or trading volume in the Shares and the volatility of the price of the Shares, and the extent to which this occurs from day to day cannot be estimated.

It should be noted that when engaging in any of these activities, the Syndicate Members will be subject to certain restrictions, including the following:

(a) the Syndicate Members (other than the Stabilizing Manager or any person acting for it) must not, in connection with the distribution of the Offer Shares, effect any transactions (including issuing or entering into any option or other derivative transactions relating to the Offer Shares) whether in the open market or otherwise, with a view to stabilizing or maintaining the market price of any of the Offer Shares at levels other than those which might otherwise prevail in the open market; and

(b) the Syndicate Members must comply with all applicable laws and regulations, including the market misconduct provisions of the SFO, including the provisions prohibiting insider dealing, false trading, price rigging and stock market manipulation.

Certain of the Syndicate Members or their respective affiliates have provided from time to time, and expect to provide in the future, investment banking and other services to the Company and its affiliates for which such Syndicate Members or their respective affiliates have received or will receive customary fees and commissions.


Shanghai Miracogen Inc.- Ex. 2032, Page 000572

## THE GLOBAL OFFERING

This prospectus is published in connection with the Hong Kong Public Offering as part of the Global Offering. China International Capital Corporation Hong Kong Securities Limited and Morgan Stanley Asia Limited are the Joint Global Coordinators of the Global Offering.

The listing of the Shares on the Stock Exchange is sponsored by the Joint Sponsors. The Joint Sponsors have made an application on behalf of the Company to the Stock Exchange for the listing of, and permission to deal in, the H Shares in issue and to be issued as mentioned in this prospectus.

The Global Offering consists of (subject to reallocation and the Over-allotment Option):

(i) the Hong Kong Public Offering of 12,688,000 H Shares (subject to reallocation as mentioned below) in Hong Kong as described in the paragraph headed "The Hong Kong Public Offering" in this section; and

(ii) the International Offering of 114,188,000 H Shares (subject to reallocation and Over-allotment Option as mentioned below) in the United States to QIBs in reliance on Rule 144A or another available exemption from the registration requirements of the U.S. Securities Act, and outside the United States in offshore transactions in reliance on Regulation S.

The Offer Shares will represent approximately 7.65% of the total issued share capital of our Company immediately after completion of the Global Offering without taking into account the exercise of the Over-allotment Option. If the Over-allotment Option is exercised in full, the Offer Shares will represent approximately 8.70% of the total issued share capital immediately after completion of the Global Offering and the exercise of the Over-allotment Option as set out in the paragraph headed "The International Offering – Over-allotment Option" in this section.

Investors may either:

(i) apply for Hong Kong Offer Shares under the Hong Kong Public Offering; or

(ii) apply for or indicate an interest, if qualified to do so, for International Offer Shares under the International Offering,

but may not do both.

The Hong Kong Public Offering is open to members of the public in Hong Kong as well as to institutional and professional investors in Hong Kong. The International Offering will involve selective marketing of the International Offer Shares to QIBs in the United States in reliance on Rule 144A or another available exemption from the registration requirements of the U.S. Securities Act, as well as to institutional and professional investors and other investors



Shanghai Miracogen Inc.- Ex. 2032, Page 000573

expected to have a sizable demand for the International Offer Shares in Hong Kong and other jurisdictions outside the United States in offshore transactions in reliance on Regulation S. The International Underwriters and the Joint Bookrunners are soliciting from prospective investors' indications of interest in acquiring the International Offer Shares. Prospective investors will be required to specify the number of International Offer Shares under the International Offering they would be prepared to acquire either at different prices or at a particular price.

The number of Hong Kong Offer Shares and International Offer Shares to be offered under the Hong Kong Public Offering and the International Offering respectively may be subject to reallocation as described in the paragraph headed "The Hong Kong Public Offering – Reallocation and Clawback" in this section.

## THE HONG KONG PUBLIC OFFERING

### Number of Shares Initially Offered

Subject to reallocation as mentioned below, the Company is initially offering 12,688,000 H Shares at the Offer Price under the Hong Kong Public Offering for subscription by the public in Hong Kong, representing approximately 10.00% of the 126,876,000 H Shares initially available under the Global Offering. Subject to reallocation as mentioned below, the number of H Shares initially offered under the Hong Kong Public Offering will represent approximately 0.77% of our total issued share capital immediately after completion of the Global Offering, assuming that the Over-allotment Option is not exercised.

In Hong Kong, individual retail investors are expected to apply for the Hong Kong Offer Shares through the Hong Kong Public Offering and individual retail investors, including individual investors in Hong Kong applying through banks and other institutions, seeking International Offer Shares will not be allotted International Offer Shares in the International Offering.

The Joint Global Coordinators (for themselves and on behalf of the Underwriters) and the Joint Sponsors may require any investor who has been offered H Shares under the International Offering, and who has made an application under the Hong Kong Public Offering to provide sufficient information to the Joint Global Coordinators and the Joint Sponsors so as to allow them to identify the relevant applications under the Hong Kong Public Offering and to ensure that it is excluded from any application for the Hong Kong Offer Shares.

Completion of the Hong Kong Public Offering is subject to the conditions set out in the paragraph headed "Conditions of the Global Offering" in this section.



Shanghai Miracogen Inc.- Ex. 2032, Page 000574

**Allocation**

For allocation purposes only, the 12,688,000 H Shares initially being offered for subscription under the Hong Kong Public Offering (after taking into account any reallocation in the number of Offer Shares allocated between the Hong Kong Public Offering and the International Offering) will be divided equally (with any odd lots being allocated to pool A) into two pools: Pool A comprising 6,344,000 Hong Kong Offer Shares and Pool B comprising 6,344,000 Hong Kong Offer Shares, both of which are available on an equitable basis to successful applicants. All valid applications that have been received for the Hong Kong Offer Shares with a total subscription amount (excluding brokerage, SFC transaction levy, the Hong Kong Stock Exchange trading fee and FRC transaction levy) of HK$5 million or below will fall into Pool A and all valid applications that have been received for the Hong Kong Offer Shares with a total subscription amount (excluding brokerage, SFC transaction levy, Hong Kong Stock Exchange trading fee and FRC transaction levy) of over HK$5 million and up to the total value of Pool B, will fall into Pool B.

Applicants should be aware that applications in Pool A and Pool B are likely to receive different allocation ratios. If the Hong Kong Offer Shares in one pool (but not both pools) are under-subscribed, the surplus Hong Kong Offer Shares will be transferred to the other pool to satisfy demand in that other pool and be allocated accordingly. Applicants can only receive an allocation of Hong Kong Offer Shares from either Pool A or Pool B but not from both pools and only apply for Hong Kong Offer Shares in either Pool A or Pool B. When there is over-subscription, allocation of Hong Kong Offer Shares to investors under the Hong Kong Public Offering, both in relation to Pool A and Pool B, will be based on the level of valid applications received under the Hong Kong Public Offering. The basis of allocation in each pool may vary, depending on the number of Hong Kong Offer Shares validly applied for by each applicant. The allocation of Hong Kong Offer Shares could, where appropriate, consist of balloting, which would mean that some applicants may receive a higher allocation than others who have applied for the same number of Hong Kong Offer Shares and those applicants who are not successful in the ballot may not receive any Hong Kong Offer Shares.

**Reallocation and Clawback**

The allocation of Offer Shares between the Hong Kong Public Offering and the International Offering is subject to reallocation. Paragraph 4.2 of Practice Note 18 of the Listing Rules requires a clawback mechanism to be put in place which would have the effect of increasing the number of Offer Shares under the Hong Kong Public Offering to a certain percentage of the total number of Offer Shares offered under the Global Offering if certain prescribed total demand levels are reached.

If the number of H Shares validly applied for in the Hong Kong Public Offering represents (i) 15 times or more but less than 50 times, (ii) 50 times or more but less than 100 times, and (iii) 100 times or more, of the number of Hong Kong Offer Shares available under the Hong Kong Public Offering, the total number of Hong Kong Offer Shares available under the Hong Kong Public Offering will be increased to 38,063,000 (in the case of (i)), 50,751,000 (in the case of (ii)), and 63,438,000 Shares (in the case of (iii)), respectively, representing approximately 30%, 40%, and 50% of the total number of Offer Shares initially available under the Global Offering, respectively (before any exercise of the Over-allotment Option).



Shanghai Miracogen Inc.- Ex. 2032, Page 000575

In each case, the additional Offer Shares reallocated to the Hong Kong Public Offering will be allocated between pool A and pool B and the number of Offer Shares allocated to the International Offering will be correspondingly reduced in such manner as the Joint Global Coordinators deem appropriate.

In addition to any mandatory reallocation required as described above, the Offer Shares to be offered in the Hong Kong Public Offering and the Offer Shares to be offered in the International Offering may, in certain circumstances, be reallocated between these offerings at the discretion of the Joint Global Coordinators. The Joint Global Coordinators may, at their sole discretion, reallocate Offer Shares initially allocated for the International Offering to the Hong Kong Public Offering to satisfy valid applications under the Hong Kong Public Offering. In particular, if (i) the International Offering is not fully subscribed and the Hong Kong Public Offering is fully subscribed or oversubscribed; or (ii) the International Offering is fully subscribed or oversubscribed and the Hong Kong Public Offering is fully subscribed or oversubscribed with the number of Offer Shares validly applied for in the Hong Kong Public Offering representing less than 15 times of the number of Shares initially available for subscription under the Hong Kong Public Offering, the Joint Global Coordinators have the authority to reallocate International Offer Shares originally in the International Offering to the Hong Kong Public Offering in such number as they deem appropriate, provided that in accordance with Guidance Letter HKEX-GL91-18 issued by the Stock Exchange, (i) the number of International Offer Shares reallocated to the Hong Kong Public Offering should not exceed 12,688,000 Shares, representing approximately 10% of the Offer Shares initially available under the Global Offering, increasing the total number of Offer Shares available under the Hong Kong Public Offering to 25,376,000 Shares; and (ii) the final Offer Price should be fixed at the bottom end of the indicative Offer Price range (i.e., HK$6.87 per Offer Share).

If the Hong Kong Public Offering is not fully subscribed for, the Joint Global Coordinators have the authority to reallocate all or any unsubscribed Hong Kong Offer Shares to the International Offering, in such proportions as the Joint Global Coordinators deem appropriate.

Details of any reallocation of Offer Shares between the Hong Kong Public Offering and the International Offering will be disclosed in the results announcement of the Global Offering expected to be published on Tuesday, February 22, 2022.

**Applications**

Each applicant under the Hong Kong Public Offering will also be required to give an undertaking and confirmation in the application submitted by him or her that he or she and any person(s) for whose benefit he or she is making the application have not applied for or taken up, or indicated an interest for, and will not apply for or take up, or indicate an interest for, any Offer Shares under the International Offering, and such applicant's application will be rejected if the said undertaking and/or confirmation is breached and/or untrue (as the case may be) or it has been or will be placed or allocated Offer Shares under the International Offering.



Shanghai Miracogen Inc.- Ex. 2032, Page 000576

Multiple or suspected multiple applications and any application for more than 50% of the 12,688,000 H Shares initially comprised in the Hong Kong Public Offering (that is 6,344,000 Hong Kong Offer Shares) will be rejected.

The listing of the Offer Shares on the Hong Kong Stock Exchange is sponsored by the Joint Sponsors. Applicants under the Hong Kong Public Offering are required to pay, on application, the maximum Offer Price of HK$7.38 per H Share in addition to any brokerage, SFC transaction levy, Hong Kong Stock Exchange trading fee and FRC transaction levy payable on each Offer Share. If the Offer Price, as finally determined in the manner described in the paragraph headed "Pricing of the Global Offering" in this section, is less than the maximum Offer Price of HK$7.38 per Offer Share, appropriate refund payments (including the brokerage, SFC transaction levy, Stock Exchange trading fee and FRC transaction levy attributable to the surplus application monies) will be made to successful applications, without interest. Further details are set out in the section headed "How to Apply for Hong Kong Offer Shares" in this prospectus.

References in this prospectus to applications, application monies or the procedure for application relate solely to the Hong Kong Public Offering.

## THE INTERNATIONAL OFFERING

### Number of International Offer Shares Offered

The number of International Offer Shares to be initially offered by us for subscription under the International Offering will consist of an initial offering of 114,188,000 Offer Shares, representing approximately 90% of the Offer Shares under the Global Offering. Subject to any reallocation of Offer Shares between the International Offering and the Hong Kong Public Offering, the International Offer Shares will represent approximately 6.88% of our total issued share capital immediately after completion of the Global Offering assuming that the Over-allotment Option is not exercised.

### Allocation

Pursuant to the International Offering, the International Underwriters will conditionally place the International Offer Shares with QIBs in the United States in reliance on Rule 144A or another available exemption from the registration requirements under the U.S. Securities Act, as well as with institutional and professional investors and other investors expected to have a sizable demand for the Shares in Hong Kong and other jurisdictions outside the United States in reliance on Regulation S. The International Offering is subject to the Hong Kong Public Offering being unconditional.


Shanghai Miracogen Inc.- Ex. 2032, Page 000577

Allocation of the International Offer Shares pursuant to the International Offering will be determined by the Joint Global Coordinators and will be based on a number of factors including the level and timing of demand, total size of the relevant investor's invested assets or equity assets in the relevant sector and whether or not it is expected that the relevant investor is likely to buy further, and/or hold or sell Offer Shares after the Listing. Such allocation may be made to professional, institutional and corporate investors and is intended to result in a distribution of our Offer Shares on a basis which would lead to the establishment of a solid shareholder base to the benefit of our Company and our Shareholders as a whole.

The Joint Global Coordinators (on behalf of the Underwriters) may require any investor who has been offered Offer Shares under the International Offering and who has made an application under the Hong Kong Public Offering to provide sufficient information to the Joint Global Coordinators so as to allow it to identify the relevant applications under the Hong Kong Public Offering and to ensure that they are excluded from any allocation of Offer Shares under the Hong Kong Public Offering.

**Reallocation and Clawback**

The total number of International Offer Shares to be transferred pursuant to the International Offering may change as a result of the clawback arrangement described in the paragraph headed "– The Hong Kong Public Offering – Reallocation and Clawback" in this section, exercise of the Over-allotment Option in whole or in part and/or reallocation of all or any unsubscribed Hong Kong Offer Shares to the International Offering.

**Over-allotment Option**

In connection with the Global Offering, our Company is expected to grant the Over-allotment Option to the International Underwriters and the Joint Bookrunners, exercisable by the Joint Global Coordinators at their sole and absolute discretion for themselves and on behalf of the International Underwriters and the Joint Bookrunners for up to 30 days after the last day for lodging applications under the Hong Kong Public Offering. Pursuant to the Over-allotment Option, the Joint Global Coordinators will have the right to require our Company to issue and allot, at the Offer Price, up to an aggregate of additional 19,031,000 H Shares representing in aggregate approximately 15% of the number of the Offer Shares initially available under the Global Offering at the Offer Price to cover over-allocations in the International Offering, if any. An announcement will be made in the event that the Over-allotment Option is exercised.

If the Over-allotment Option is exercised in full, the additional International Offer Shares to be issued pursuant thereto will represent approximately 1.13% of the issued share capital of the Company immediately after the completion of the Global Offering.



Shanghai Miracogen Inc.- Ex. 2032, Page 000578

**Stabilization**

Stabilization is a practice used by underwriters in some markets to facilitate the distribution of securities. To stabilize, the Underwriters may bid for, or purchase, the new securities in the secondary market, during a specified period of time, to retard and, if possible, prevent any decline in the market price of the securities below the Offer Price. In Hong Kong and certain other jurisdictions, an activity aimed at reducing the market price is prohibited and the price at which stabilization is effected is not permitted to exceed the Offer Price.

In connection with the Global Offering, the Stabilizing Manager, its affiliates or any person acting for it, on behalf of the Underwriters, may, to the extent permitted by applicable laws of Hong Kong or elsewhere, over-allocate or effect short sales or any other stabilizing transactions with a view to stabilizing or maintaining the market price of the H Shares at a level higher than that which might otherwise prevail in the open market for a limited period after the last day for the lodging of applications under the Hong Kong Public Offering. Any market purchases of H Shares will be effected in compliance with all applicable laws and regulatory requirements. However, there is no obligation on the Stabilizing Manager or any person acting for it to conduct any such stabilizing activity, which if commenced, will be done at the absolute discretion of the Stabilizing Manager and may be discontinued at any time. Any such stabilizing activity is required to be brought to an end within 30 days of the last day for the lodging of applications under the Hong Kong Public Offering. The number of H Shares that may be over-allocated will not exceed the number of H Shares that may be issued and/or sold under the Over-allotment Option, namely 19,031,000 H Shares, which is approximately 15% of the Offer Shares initially available under the Global Offering.

Stabilizing action will be entered into in accordance with the laws, rules and regulations in place in Hong Kong on stabilization and stabilization action permitted in Hong Kong pursuant to the Securities and Futures (Price Stabilizing) Rules (Chapter 571W of the Laws of Hong Kong) under SFO includes: (i) over-allocation for the purpose of preventing or minimizing any reduction in the market price of the H Shares; (ii) selling or agreeing to sell the H Shares so as to establish a short position in them for the purpose of preventing or minimizing any reduction in the market price of the H Shares; (iii) purchasing or subscribing for, or agreeing to purchase or subscribe for, the H Shares pursuant to the Over-allotment Option in order to close out any position established under (i) or (ii) above; (iv) purchasing, or agreeing to purchase, any of the H Shares for the sole purpose of preventing or minimizing any reduction in the market price of the H Shares; (v) selling or agreeing to sell any Shares in order to liquidate any position held as a result of those purchases; and (vi) offering or attempting to do anything described in (ii), (iii), (iv) or (v).



Shanghai Miracogen Inc.- Ex. 2032, Page 000579

Specifically, prospective applicants for and investors in the Offer Shares should note that:

(i) the Stabilizing Manager, or any person acting for it, may, in connection with the stabilizing action, maintain a long position in the H Shares;

(ii) there is no certainty regarding the extent to which and the time period for which the Stabilizing Manager, or any person acting for it, will maintain such a position;

(iii) liquidation of any such long position by the Stabilizing Manager may have an adverse impact on the market price of the H Shares;

(iv) no stabilizing action can be taken to support the price of the H Shares for longer than the stabilizing period which will begin on the Listing Date following announcement of the Offer Price, and is expected to expire on the 30th day after the last date for lodging applications under the Hong Kong Public Offering. After this date, when no further stabilizing action may be taken, demand for the H Shares, and therefore the price of the H Shares, could fall;

(v) the price of the H Shares cannot be assured to stay at or above the Offer Price either during or after the stabilizing period by the taking of any stabilizing action; and

(vi) stabilizing bids may be made or transactions effected in the course of the stabilizing action at any price at or below the Offer Price, which means that stabilizing bids may be made or transactions effected at a price below the price paid by applicants for, or investors in, the H Shares.

In order to effect stabilization actions, the Stabilizing Manager will arrange cover of up to an aggregate of 19,031,000 H Shares, representing up to 15% of the initial Offer Shares, through delayed delivery arrangements with investors who have been allocated Offer Shares in the International Offering. The delayed delivery arrangements (if specifically agreed by an investor) relate only to the delay in the delivery of the Offer Shares to such investor and the Offer Price for the Offer Shares allocated to such investor will be fully paid on the Listing Date and before the commencement of dealings, accordingly there will be no delayed settlement of the Offer Shares.

Our Company will procure that a public announcement in compliance with the Securities and Futures (Price Stabilizing) Rules will be made within seven days of the expiration of the stabilizing period.

**Over-Allocation**

Following any over-allocation of H Shares in connection with the Global Offering, the Stabilizing Manager may cover such over-allocations by exercising the Over-allotment Option, making purchases in the secondary market at prices that do not exceed the Offer Price or by any combination of these means.



Shanghai Miracogen Inc.- Ex. 2032, Page 000580

## PRICING OF THE GLOBAL OFFERING

The Offer Price is expected to be fixed by agreement between the Joint Global Coordinators (on behalf of the Underwriters) and our Company on the Price Determination Date, when market demand for the Offer Shares will be determined. The Price Determination Date is expected to be on or around Tuesday, February 15, 2022 and in no event later than Tuesday, February 22, 2022.

The Offer Price will be not more than HK$7.38 per Offer Share and is currently expected not to be less than HK$6.87 per Offer Share unless otherwise announced, as further explained below. Applicants under the Hong Kong Public Offering are required to pay, on application, the maximum Offer Price of HK$7.38 for each Hong Kong Offer Share together with brokerage of 1%, a Hong Kong Stock Exchange trading fee of 0.005%, a SFC transaction levy of 0.0027% and a FRC transaction levy of 0.00015%. **Prospective investors should be aware that the Offer Price to be determined on the Price Determination Date may be, but is not expected to be, lower than the indicative price range stated in this prospectus**.

The International Underwriters will be soliciting from prospective investors indications of interest in acquiring Offer Shares in the International Offering. Prospective professional and institutional investors will be required to specify the number of Shares under the International Offering they would be prepared to acquire either at different prices or at a particular price. This process, known as "book-building", is expected to continue up to, and to cease on or about, the last day for lodging applications under the Hong Kong Public Offering.

If, based on the level of interest expressed by prospective institutional, professional and other investors during the book-building process, the Joint Global Coordinators (for themselves and on behalf of the Underwriters) and the Joint Sponsors consider it appropriate, with our consent the number of Offer Shares being offered under the Global Offering and/or the indicative Offer Price range stated in this prospectus may be reduced at any time on or prior to the morning of the last day for lodging applications under the Hong Kong Public Offering. In such a case, we will, as soon as practicable following the decision to make such reduction, and in any event not later than the morning of Tuesday, February 15, 2022, being the last day for lodging applications under the Hong Kong Public Offering, cause to be published on the Hong Kong Stock Exchange's website at **www.hkexnews.hk**, and on our Company's website at **http://www.lepubiopharma.com** notice of such reduction in the number of Offer Shares being offered under the Global Offering and/or the indicative Offer Price range. Such notice will also include confirmation or revision, as appropriate, of the working capital statement and the offering statistics as currently set out in this prospectus and any other financial information which may change as a result of such reduction. Upon issue of such notice, the number of Offer Shares in the Global Offering and/or the revised Offer Price range will be final and conclusive and the Offer Price, if agreed upon between the Joint Global Coordinators (for themselves and on behalf of the Underwriters) and the Company, will be fixed within such revised Offer Price range.


Shanghai Miracogen Inc.- Ex. 2032, Page 000581

As soon as practicable after such reduction of the number of Offer Shares and/or the indicative Offer Price range, we will also issue a supplemental prospectus updating investors of such reduction together with an update of all financial and other information in connection with such change, and, where appropriate, extend the period under which the Hong Kong Public Offering is open for acceptance, and give potential investors who had applied for the Offer Shares to withdraw their applications.

In the absence of any such notice and supplemental prospectus so published, the number of Offer Shares will not be reduced and/or the Offer Price, if agreed upon between our Company and the Joint Global Coordinators (on behalf of the Underwriters), will under no circumstances be set outside the Offer Price range stated in this prospectus.

Before submitting applications for the Hong Kong Offer Shares, applicants should have regard to the possibility that any announcement of a reduction in the number of Offer Shares being offered under the Global Offering and/or the indicative Offer Price range may not be made until the day which is the last day for lodging applications under the Hong Kong Public Offering.

If applications for Hong Kong Offer Shares have been submitted prior to the day which is the last day for lodging applications under the Hong Kong Public Offering, in the event that the number of Offer Shares and/or the Offer Price is so reduced, such applications can subsequently be withdrawn. All applicants who have already submitted an application will be entitled to withdraw their applications and will need to confirm their applications in accordance with the procedures set out in the supplemental prospectus. All unconfirmed applications will not be valid.

The Hong Kong Offer Shares and the International Offer Shares may, in certain circumstances, be reallocated as between the Hong Kong Public Offering and International Offering at the discretion of the Joint Global Coordinators and the Joint Sponsors.

The final Offer Price, the level of applications in the Hong Kong Public Offering, the level of indications of interest in the International Offering, the basis of allocations of the Hong Kong Offer Shares and the results of applications in the Hong Kong Public Offering are expected to be announced on Tuesday, February 22, 2022 through a variety of channels described in the paragraph headed "How to Apply for Hong Kong Offer Shares – Publication of Results" in this prospectus.


Shanghai Miracogen Inc.- Ex. 2032, Page 000582

## UNDERWRITING ARRANGEMENTS

The Hong Kong Public Offering is fully underwritten by the Hong Kong Underwriters under the terms of the Hong Kong Underwriting Agreement, subject to agreement on the Offer Price between the Joint Global Coordinators (on behalf of the Underwriters) and us on the Price Determination Date.

We expect that our Company will, on or about Tuesday, February 15, 2022, enter into the International Underwriting Agreement relating to the International Offering. Underwriting arrangements, the Hong Kong Underwriting Agreement and the International Underwriting Agreement are summarized in the section headed "Underwriting" in this prospectus.

## CONDITIONS OF THE GLOBAL OFFERING

Acceptance of all applications for the Offer Shares will be conditional on, inter alia:

- the Stock Exchange granting approval for the listing of, and permission to deal in, the H Shares to be issued pursuant to the Global Offering (including pursuant to the exercise of the Over-allotment Option) on the Main Board of the Stock Exchange and such listing and permission not subsequently having been revoked prior to the commencement of dealings in the H Shares on the Stock Exchange;

- the Offer Price having been agreed between the Joint Global Coordinators (on behalf of the Underwriters) and the Company;

- the execution and delivery of the International Underwriting Agreement on or around the Price Determination Date;

- our Company having submitted to the HKSCC all requisite documents to enable the Offer Shares to be admitted to trade on the Hong Kong Stock Exchange; and

- the obligations of the Underwriters under the respective Underwriting Agreements becoming and remaining unconditional (unless and to the extent such conditions are validly waived on or before such dates and times) and not having been terminated in accordance with the terms of the respective agreements,

in each case on or before the dates and times specified in the respective Underwriting Agreements (unless and to the extent such conditions are validly waived on or before such dates and times) and in any event not later than the date which is 30 days after the date of this prospectus.

If for any reason, the Offer Price is not agreed by Tuesday, February 22, 2022 between us and the Joint Global Coordinators (on behalf of the Underwriters), the Global Offering will not proceed and will lapse.



Shanghai Miracogen Inc.- Ex. 2032, Page 000583

If the above conditions are not fulfilled or waived prior to the times and dates specified, the Global Offering will lapse and the Hong Kong Stock Exchange will be notified immediately. We will cause a notice of the lapse of the Hong Kong Public Offering to be published by us on the websites of the Company at **http://www.lepubiopharma.com**, and the Hong Kong Stock Exchange at **www.hkexnews.hk**, respectively on the next day following such lapse. In such event, all application monies will be returned, without interest, on the terms set out in the section headed "How to Apply for Hong Kong Offer Shares" in this prospectus. In the meantime, the application monies will be held in separate bank account(s) with the Company's receiving banker(s) or other bank(s) in Hong Kong licensed under the Banking Ordinance (Chapter 155 of the Laws of Hong Kong) (as amended).

The consummation of each of the Hong Kong Public Offering and the International Offering is conditional upon, amongst other things, the other becoming unconditional and not having been terminated in accordance with its terms.

Share certificates for the Offer Shares are expected to be issued on Tuesday, February 22, 2022 but will only become valid certificates of title at 8:00 a.m. on the date of commencement of the dealings in our H Shares, which is expected to be on Wednesday, February 23, 2022, provided that (i) the Global Offering has become unconditional in all respects at or before that time and (ii) neither of the Underwriting Agreements has been terminated in accordance with its terms. Investors who trade H Shares prior to the receipt of Share certificates or prior to the Share certificates bearing valid certificates of title do so entirely at their own risk.

## DEALING ARRANGEMENTS

Assuming that the Hong Kong Public Offering becomes unconditional at or before 8:00 a.m. in Hong Kong on Wednesday, February 23, 2022, it is expected that dealings in Shares on the Hong Kong Stock Exchange will commence on Wednesday, February 23, 2022. Shares will be traded in board lots of 1,000 Shares each and the stock code will be 2157.



Shanghai Miracogen Inc.- Ex. 2032, Page 000584

**IMPORTANT NOTICE TO INVESTORS:**
**FULLY ELECTRONIC APPLICATION PROCESS**

*We have adopted a fully electronic application process for the Hong Kong Public Offering. We will not provide any printed copies of this prospectus or any printed copies of any application forms for use by the public.*

*This prospectus is available at the website of the Stock Exchange at* ***www.hkexnews.hk*** *under the "HKEXnews > New Listings > New Listing Information" section, and our website at* ***http://www.lepubiopharma.com****. If you require a printed copy of this prospectus, you may download and print from the website addresses above.*

*The contents of the electronic version of the prospectus are identical to the printed prospectus as registered with the Registrar of Companies in Hong Kong pursuant to Section 342C of the Companies (Winding Up and Miscellaneous Provisions) Ordinance.*

*Set out below are procedures through which you can apply for the Hong Kong Offer Shares electronically. We will not provide any physical channels to accept any application for the Hong Kong Offer Shares by the public.*

*If you are an intermediary,* ***broker*** *or agent, please remind your customers, clients or principals, as applicable, that this prospectus is available online at the website addresses above.*

*If you have any question about the application for the Hong Kong Offer Shares, you may call the enquiry hotline of our H Share Registrar and* **White Form eIPO** *Service Provider, Computershare Hong Kong Investor Services Limited, at +852 2862 8629 on the following dates and times:*

| | | |
|---|---|---|
| Thursday, February 10, 2022 | – | 9:00 a.m. to 9:00 p.m. |
| Friday, February 11, 2022 | – | 9:00 a.m. to 9:00 p.m. |
| Monday, February 14, 2022 | – | 9:00 a.m. to 9:00 p.m. |
| Tuesday, February 15, 2022 | – | 9:00 a.m. to 12:00 noon |


Shanghai Miracogen Inc.- Ex. 2032, Page 000585

## 1. HOW TO APPLY

**We will not provide any printed application forms for use by the public.**

To apply for Hong Kong Offer Shares, you may:

(1) apply online via the **White Form eIPO** service at **www.eipo.com.hk**; or

(2) apply through **CCASS EIPO** service to electronically cause HKSCC Nominees to apply on your behalf, including by:

(i) instructing your **broker** or **custodian** who is a CCASS Clearing Participant or a CCASS Custodian Participant to give **electronic application instructions** via CCASS terminals to apply for the Hong Kong Offer Shares on your behalf; or

(ii) (if you are an existing CCASS Investor Participant) giving **electronic application instructions** through the CCASS Internet System (**https://ip.ccass.com**) or through the CCASS Phone System by calling +852 2979 7888 (using the procedures in HKSCC's "An Operating Guide for Investor Participants" in effect from time to time). HKSCC can also input **electronic application instructions** for CCASS Investor Participants through HKSCC's Customer Service Centre at 1/F, One & Two Exchange Square, 8 Connaught Place, Central, Hong Kong by completing an input request.

If you apply through channel (1) above, the Hong Kong Offer Shares successfully applied for will be issued in your own name.

If you apply through channels (2)(i) or (2)(ii) above, the Hong Kong Offer Shares successfully applied for will be issued in the name of HKSCC Nominees and deposited directly into CCASS to be credited to your or a designated CCASS Participant's stock account.

None of you or your joint applicant(s) may make more than one application, except where you are a nominee and provide the required information in your application.

The Company, the Joint Global Coordinators, the designated **White Form eIPO** Service Provider and their respective agents may reject or accept any application in full or in part for any reason at their discretion.



Shanghai Miracogen Inc.- Ex. 2032, Page 000586

## 2. WHO CAN APPLY

### Eligibility for the Application

You can apply for Hong Kong Offer Shares if you or the person(s) for whose benefit you are applying:

- are 18 years of age or older;
- have a Hong Kong address;
- are outside the United States; and
- are not a legal or natural person of the PRC.

If an application is made by a person under a power of attorney, the Joint Global Coordinators may accept it at their discretion and on any conditions they think fit, including requiring evidence of the attorney's authority.

The number of joint applicants may not exceed four and they may not apply by means of the **White Form eIPO** service for the Hong Kong Offer Shares.

Unless permitted by the Listing Rules, you cannot apply for any Hong Kong Offer Shares if you are:

- an existing beneficial owner of Shares in the Company and/or any its subsidiaries;
- a Director, Supervisor or chief executive officer of the Company and/or any of its subsidiaries;
- a close associate (as defined in the Listing Rules) of any of the above; and
- have been allocated or have applied for any International Offer Shares or otherwise participate in the International Offering.

### Items Required for the Application

If you apply for the Hong Kong Offer Shares online through the **White Form eIPO** service, you must:

(a) have a valid Hong Kong identity card number; and

(b) provide a valid e-mail address and a contact telephone number.



Shanghai Miracogen Inc.- Ex. 2032, Page 000587

If you are applying for the Hong Kong Offer Shares online by instructing your **broker** or **custodian** who is a CCASS Clearing Participant or a CCASS Custodian Participant to give **electronic application instructions** via CCASS terminals, please contact them for the items required for the application.

## 3. TERMS AND CONDITIONS OF AN APPLICATION

By applying through the application channels specified in this prospectus, you:

(i) undertake to execute all relevant documents and instruct and authorize the Company and/or the Joint Global Coordinators (or their agents or nominees), as agents of the Company, to execute any documents for you and to do on your behalf all things necessary to register any Hong Kong Offer Shares allocated to you in your name or in the name of HKSCC Nominees as required by the Articles of Association;

(ii) agree to comply with the Companies (Winding Up and Miscellaneous Provisions) Ordinance and the Articles of Association;

(iii) confirm that you have read the terms and conditions and application procedures set out in this prospectus and agree to be bound by them;

(iv) confirm that you have received and read this prospectus and have only relied on the information and representations contained in this prospectus in making your application and will not rely on any other information or representations except those in any supplement to this prospectus;

(v) confirm that you are aware of the restrictions on the Global Offering in this prospectus;

(vi) agree that none of the Company, the Joint Global Coordinators, the Joint Sponsors, the Joint Bookrunners, the Joint Lead Managers, the Underwriters, their respective directors, officers, employees, partners, agents, advisors and any other parties involved in the Global Offering is or will be liable for any information and representations not in this prospectus (and any supplement to it);

(vii) undertake and confirm that you or the person(s) for whose benefit you have made the application have not applied for or taken up, or indicated an interest for, and will not apply for or take up, or indicate an interest for, any Offer Shares under the International Offering nor participated in the International Offering;

(viii) agree to disclose to the Company, our H Share Registrar, receiving bank(s), the Joint Global Coordinators, the Joint Sponsors, the Joint Bookrunners, the Joint Lead Managers, the Underwriters and/or their respective advisors and agents any personal data which they may require about you and the person(s) for whose benefit you have made the application;



Shanghai Miracogen Inc.- Ex. 2032, Page 000588

(ix) if the laws of any place outside Hong Kong apply to your application, agree and warrant that you have complied with all such laws and none of the Company, the Joint Global Coordinators and the Underwriters nor any of their respective officers or advisors will breach any law outside Hong Kong as a result of the acceptance of your offer to purchase, or any action arising from your rights and obligations under the terms and conditions contained in this prospectus;

(x) agree that once your application has been accepted, you may not rescind it because of an innocent misrepresentation;

(xi) agree that your application will be governed by the laws of Hong Kong;

(xii) represent, warrant and undertake that (i) you understand that the Hong Kong Offer Shares have not been and will not be registered under the U.S. Securities Act; and (ii) you and any person for whose benefit you are applying for the Hong Kong Offer Shares are outside the United States or are a person described in paragraph (h)(3) of Rule 902 of Regulation S;

(xiii) warrant that the information you have provided is true and accurate;

(xiv) agree to accept the Hong Kong Offer Shares applied for, or any lesser number allocated to you under the application;

(xv) authorize the Company to place your name(s) or the name of the HKSCC Nominees, on the Company's register of members as the holder(s) of any Hong Kong Offer Shares allocated to you, and the Company and/or its agents to send any share certificate(s) and/or any e-Refund payment instructions and/or any refund cheque(s) to you or the first-named applicant for joint application by ordinary post at your own risk to the address stated on the application, unless you have fulfilled the criteria mentioned in "14. Despatch/Collection of Share Certificates and Refund Monies – Personal Collection" in this prospectus to collect the share certificate(s) and/or refund cheque(s) in person;

(xvi) declare and represent that this is the only application made and the only application intended by you to be made to benefit you or the person for whose benefit you are applying;

(xvii) understand that the Company and the Joint Global Coordinators will rely on your declarations and representations in deciding whether or not to make any allotment of any of the Hong Kong Offer Shares to you and that you may be prosecuted for making a false declaration;

(xviii) (if the application is made for your own benefit) warrant that no other application has been or will be made for your benefit by giving **electronic application instructions** to HKSCC or to the designated **White Form eIPO** Service Provider by



Shanghai Miracogen Inc.- Ex. 2032, Page 000589

you or by any one as your agent or by any other person; and (if you are making the application as an agent for the benefit of another person) warrant that (i) no other application has been or will be made by you as agent for or for the benefit of that person or by that person or by any other person as agent for that person giving **electronic application instructions** to HKSCC; and (ii) you have due authority to give **electronic application instructions** on behalf of that other person as their agent.

For the avoidance of doubt, the Company and all other parties involved in the preparation of this prospectus acknowledge that each applicant and CCASS Participant who gives or causes to give **electronic application instructions** is a person who may be entitled to compensation under Section 40 of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (as applied by Section 342E of the Companies (Winding Up and Miscellaneous Provisions) Ordinance).

## 4. MINIMUM APPLICATION AMOUNT AND PERMITTED NUMBERS

Your application through **White Form eIPO** service or the **CCASS EIPO** service must be for a minimum of 1,000 Hong Kong Offer Shares and in one of the numbers set out in the table below. You are required to pay the amount next to the number you select.

**Lepu Biopharma Co., Ltd. (Stock Code: 2157)**

**(HK$7.38 per Hong Kong Offer Share)**

**NUMBER OF HONG KONG OFFER SHARES THAT MAY BE APPLIED FOR AND PAYMENTS**

| No. of Hong Kong Offer Shares applied for | Amount payable on application HK$ | No. of Hong Kong Offer Shares applied for | Amount payable on application HK$ | No. of Hong Kong Offer Shares applied for | Amount payable on application HK$ | No. of Hong Kong Offer Shares applied for | Amount payable on application HK$ |
|---|---|---|---|---|---|---|---|
| 1,000 | 7,454.38 | 15,000 | 111,815.70 | 80,000 | 596,350.35 | 900,000 | 6,708,941.39 |
| 2,000 | 14,908.76 | 20,000 | 149,087.59 | 90,000 | 670,894.14 | 1,000,000 | 7,454,379.33 |
| 3,000 | 22,363.14 | 25,000 | 186,359.49 | 100,000 | 745,437.94 | 1,500,000 | 11,181,569.00 |
| 4,000 | 29,817.52 | 30,000 | 223,631.38 | 200,000 | 1,490,875.86 | 2,000,000 | 14,908,758.66 |
| 5,000 | 37,271.91 | 35,000 | 260,903.28 | 300,000 | 2,236,313.80 | 2,500,000 | 18,635,948.33 |
| 6,000 | 44,726.28 | 40,000 | 298,175.17 | 400,000 | 2,981,751.73 | 3,000,000 | 22,363,137.99 |
| 7,000 | 52,180.65 | 45,000 | 335,447.08 | 500,000 | 3,727,189.67 | 4,000,000 | 29,817,517.32 |
| 8,000 | 59,635.03 | 50,000 | 372,718.96 | 600,000 | 4,472,627.60 | 5,000,000 | 37,271,896.65 |
| 9,000 | 67,089.41 | 60,000 | 447,262.76 | 700,000 | 5,218,065.53 | 6,000,000 | 44,726,275.98 |
| 10,000 | 74,543.79 | 70,000 | 521,806.55 | 800,000 | 5,963,503.47 | 6,344,000(1) | 47,290,582.48 |

(1) Maximum number of Hong Kong Offer Shares you may apply for.

No application for any other number of the Hong Kong Offer Shares will be considered and any such application is liable to be rejected.



Shanghai Miracogen Inc.- Ex. 2032, Page 000590

## 5. APPLYING THROUGH THE WHITE FORM eIPO SERVICE

### General

Individuals who meet the criteria in the paragraph headed "– 2. Who can apply" in this section may apply through the **White Form eIPO** Service Provider for the Hong Kong Offer Shares to be allotted and registered in their own names through the designated website at **www.eipo.com.hk**.

Detailed instructions for application through the **White Form eIPO** service are on the designated website. If you do not follow the instructions, your application may be rejected and may not be submitted to the Company. If you apply through the designated website, you authorize the **White Form eIPO** Service Provider to apply on the terms and conditions in this prospectus, as supplemented and amended by the terms and conditions of the **White Form eIPO** Service Provider.

If you have any questions on how to apply through the **White Form eIPO** service for the Hong Kong Offer Shares, please contact the telephone enquiry line of the **White Form eIPO** Service Provider at +852 2862 8629 on the following dates and times:

**Thursday, February 10, 2022 – 9:00 a.m. to 9:00 p.m.**
**Friday, February 11, 2022 – 9:00 a.m. to 9:00 p.m.**
**Monday, February 14, 2022 – 9:00 a.m. to 9:00 p.m.**
**Tuesday, February 15, 2022 – 9:00 a.m. to 12:00 noon**

### Time for Submitting Applications under the White Form eIPO

You may submit your application to the designated **White Form eIPO** Service Provider at **www.eipo.com.hk** (24 hours daily, except on the last application day) from 9:00 a.m. on Thursday, February 10, 2022 until 11:30 a.m. on Tuesday, February 15, 2022 and the latest time for completing full payment of application monies in respect of such applications will be 12:00 noon on Tuesday, February 15, 2022 or such later time under the paragraph headed "– 10. Effect of Bad Weather on the Opening and Closing of the Application Lists" in this section.

### No Multiple Applications

If you apply by means of **White Form eIPO**, once you complete payment in respect of any **electronic application instruction** given by you or for your benefit through the **White Form eIPO** service to make an application for Hong Kong Offer Shares, an actual application shall be deemed to have been made. For the avoidance of doubt, giving an **electronic application instruction** under **White Form eIPO** more than once and obtaining different application reference numbers without effecting full payment in respect of a particular reference number will not constitute an actual application.


Shanghai Miracogen Inc.- Ex. 2032, Page 000591

If you are suspected of submitting more than one application through the **White Form eIPO** service or by any other means, all of your applications are liable to be rejected.

**Section 40 of the Companies (Winding Up and Miscellaneous Provisions) Ordinance**

For the avoidance of doubt, the Company and all other parties involved in the preparation of this document acknowledge that each applicant who gives or causes to give electronic application instructions is a person who may be entitled to compensation under Section 40 of the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

**Commitment to sustainability**

The obvious advantage of the **White Form eIPO** is to save the use of paper via the self-serviced and electronic application process. Computershare Hong Kong Investor Services Limited being the designated **White Form eIPO** Service Provider, will contribute HK$2 for each "Lepu Biopharma Co., Ltd." **White Form eIPO** application submitted via the website **www.eipo.com.hk** to support sustainability.

## 6. APPLYING THROUGH CCASS EIPO SERVICE

**General**

You may instruct your **broker** or **custodian** who is a CCASS Clearing Participant or a CCASS Custodian Participant to give **electronic application instructions** via CCASS terminals to apply for the Hong Kong Offer Shares on your behalf. CCASS Participants may give **electronic application instructions** to apply for the Hong Kong Offer Shares and to arrange payment of the money due on application and payment of refunds under their participant agreements with HKSCC and the General Rules of CCASS and the CCASS Operational Procedures.

If you are a CCASS Investor Participant, you may give these **electronic application instructions** through the CCASS Internet System (**https://ip.ccass.com**) or through the CCASS Phone System by calling +852 2979 7888 (using the procedures in HKSCC's "An Operating Guide for Investor Participants" in effect from time to time). HKSCC can also input **electronic application instructions** for CCASS Investor Participants through HKSCC's Customer Service Center at 1/F, One & Two Exchange Square, 8 Connaught Place, Central, Hong Kong if you complete an input request.

You will be deemed to have authorized HKSCC and/or HKSCC Nominees to transfer the details of your application to the Company, the Joint Global Coordinators and our H Share Registrar.



Shanghai Miracogen Inc.- Ex. 2032, Page 000592

**Applying through CCASS EIPO service**

Where you have given **electronic application instructions** to apply for the Hong Kong Offer Shares (either indirectly through a **broker** or **custodian** or directly) and an application is made by HKSCC Nominees on your behalf:

(i) HKSCC Nominees will only be acting as a nominee for you and is not liable for any breach of the terms and conditions of this prospectus;

(ii) HKSCC Nominees will do the following things on your behalf:

- agree that the Hong Kong Offer Shares to be allotted shall be issued in the name of HKSCC Nominees and deposited directly into CCASS for the credit of the CCASS Participant's stock account on your behalf or your CCASS Investor Participant's stock account;
- agree to accept the Hong Kong Offer Shares applied for or any lesser number allocated;
- undertake and confirm that you have not applied for or taken up, will not apply for or take up, or indicate an interest for, any Offer Shares under the International Offering;
- (if the **electronic application instructions** are given for your benefit) declare that only one set of **electronic application instructions** has been given for your benefit;
- (if you are an agent for another person) declare that you have only given one set of **electronic application instructions** for the other person's benefit and are duly authorized to give those instructions as their agent;
- confirm that you understand that the Company, the Directors and the Joint Global Coordinators will rely on your declarations and representations in deciding whether or not to make any allotment of any of the Hong Kong Offer Shares to you and that you may be prosecuted if you make a false declaration;
- authorize the Company to place HKSCC Nominees' name on the Company's register of members as the holder of the Hong Kong Offer Shares allotted to you and to send share certificate(s) and/or refund monies under the arrangements separately agreed between the Company and HKSCC;
- confirm that you have read the terms and conditions and application procedures set out in this prospectus and agree to be bound by them;


Shanghai Miracogen Inc.- Ex. 2032, Page 000593

- confirm that you have received and/or read a copy of this prospectus and have relied only on the information and representations in this prospectus in causing the application to be made, save as set out in any supplement to this prospectus;

- agree that none of the Company, the Joint Global Coordinators, the Underwriters, their respective directors, officers, employees, partners, agents, advisors and any other parties involved in the Global Offering, is or will be liable for any information and representations not contained in this prospectus (and any supplement to this prospectus);

- agree to disclose your personal data to the Company, our H Share Registrar, receiving banks, the Joint Global Coordinators, the Underwriters and/or its respective advisors and agents;

- agree (without prejudice to any other rights which you may have) that once HKSCC Nominees' application has been accepted, it cannot be rescinded for innocent misrepresentation;

- agree that any application made by HKSCC Nominees on your behalf is irrevocable before the fifth day after the time of the opening of the application lists (excluding any day which is Saturday, Sunday or public holiday in Hong Kong), such agreement to take effect as a collateral contract with us and to become binding when you give the instructions and such collateral contract to be in consideration of the Company agreeing that it will not offer any Hong Kong Offer Shares to any person before the fifth day after the time of the opening of the application lists (excluding any day which is Saturday, Sunday or public holiday in Hong Kong), except by means of one of the procedures referred to in this prospectus. However, HKSCC Nominees may revoke the application before the fifth day after the time of the opening of the application lists (excluding for this purpose any day which is a Saturday, Sunday or public holiday in Hong Kong) if a person responsible for this prospectus under Section 40 of the Companies (Winding Up and Miscellaneous Provisions) Ordinance gives a public notice under that section which excludes or limits that person's responsibility for this prospectus;

- agree that once HKSCC Nominees' application is accepted, neither that application nor your **electronic application instructions** can be revoked, and that acceptance of that application will be evidenced by the Company's announcement of the Hong Kong Public Offering results;

- agree to the arrangements, undertakings and warranties under the participant agreement between you and HKSCC, read with the General Rules of CCASS and the CCASS Operational Procedures, for the giving **electronic application instructions** to apply for Hong Kong Offer Shares;



Shanghai Miracogen Inc.- Ex. 2032, Page 000594

- agree with the Company, for itself and for the benefit of each Shareholder (and so that the Company will be deemed by its acceptance in whole or in part of the application by HKSCC Nominees to have agreed, for itself and on behalf of each of the Shareholders, with each CCASS Participant giving **electronic application instructions**) to observe and comply with the Companies (Winding Up and Miscellaneous Provisions) Ordinance and the Articles of Association;

- agree with the Company, for itself and for the benefit of each shareholder of the Company and each director, supervisor, manager and other senior officer of the Company (and so that the Company will be deemed by its acceptance in whole or in part of this application to have agreed, for itself and on behalf of each shareholder of the Company and each director, supervisor, manager and other senior officer of the Company, with each CCASS Participant giving **electronic application instructions**):

  (a) to refer all differences and claims arising from the Articles of Association of the Company or any rights or obligations conferred or imposed by the Company Law or other relevant laws and administrative regulations concerning the affairs of the Company to arbitration in accordance with the Articles of Association of the Company;

  (b) that any award made in such arbitration shall be final and conclusive; and

  (c) that the arbitration tribunal may conduct hearings in open sessions and publish its award;

- agree with the Company (for the Company itself and for the benefit of each shareholder of the Company) that H Shares in the Company are freely transferable by their holders;

- authorize the Company to enter into a contract on its behalf with each director and officer of the Company whereby each such director and officer undertakes to observe and comply with his obligations to shareholders stipulated in the Articles of Association of the Company; and

- agree that your application, any acceptance of it and the resulting contract will be governed by the laws of Hong Kong.



Shanghai Miracogen Inc.- Ex. 2032, Page 000595

**Effect of Applying through CCASS EIPO service**

By applying through **CCASS EIPO** service, you (and, if you are joint applicants, each of you jointly and severally) are deemed to have done the following things. Neither HKSCC nor HKSCC Nominees shall be liable to the Company or any other person in respect of the things mentioned below:

- instructed and authorized HKSCC to cause HKSCC Nominees (acting as nominee for the relevant CCASS Participants) to apply for the Hong Kong Offer Shares on your behalf;

- instructed and authorized HKSCC to arrange payment of the maximum Offer Price, brokerage, SFC transaction levy, the Stock Exchange trading fee and FRC transaction levy by debiting your designated bank account and, in the case of a wholly or partially unsuccessful application and/or if the Offer Price is less than the maximum Offer Price per Offer Share initially paid on application, refund of the application monies (including brokerage, SFC transaction levy, the Stock Exchange trading fee and FRC transaction levy) by crediting your designated bank account; and

- instructed and authorized HKSCC to cause HKSCC Nominees to do on your behalf all the things stated in this prospectus.

**Time for Inputting Electronic Application Instructions[(1)]**

CCASS Clearing/Custodian Participants can input **electronic application instructions** at the following times on the following dates:

- Thursday, February 10, 2022 – 9:00 a.m. to 8:30 p.m.

- Friday, February 11, 2022 – 8:00 a.m. to 8:30 p.m.

- Monday, February 14, 2022 – 8:00 a.m. to 8:30 p.m.

- Tuesday, February 15, 2022 – 8:00 a.m. to 12:00 noon

CCASS Investor Participants can input **electronic application instructions** from 9:00 on Thursday, February 10, 2022 until 12:00 noon on Tuesday, February 15, 2022 (24 hours daily, except on Tuesday, February 15, 2022, the last application day).

The latest time for inputting your **electronic application instructions** will be 12:00 noon on Tuesday, February 15, 2022, the last application day or such later time as described in the paragraph headed "– 10. Effect of Bad Weather on the Opening and Closing of the Application Lists" in this section.

*Note:*

(1) These times in this sub-section are subject to change as HKSCC may determine from time to time with prior notification to CCASS Clearing/Custodian Participants and/or CCASS Investor Participants.



Shanghai Miracogen Inc.- Ex. 2032, Page 000596

If you are instructing your **broker** or **custodian** who is a CCASS Clearing Participant or a CCASS Custodian Participant to give **electronic application instructions** via CCASS terminals to apply for the Hong Kong Offer Shares on your behalf, you are advised to contact your **broker** or **custodian** for the latest time for giving such instructions which may be different from the latest time as stated above.

**Personal Data**

The following Personal Information Collection Statement applies to any personal data held by the Company, the H Share Registrar, the receiving bank(s), the Joint Global Coordinators, the Joint Sponsors, the Joint Bookrunners, the Joint Lead Managers, the Underwriters and any of their respective advisors and agents about you in the same way as it applies to personal data about applicants other than HKSCC Nominees. By applying through **CCASS EIPO** service, you agree to all of the terms of the Personal Information Collection Statement below.

***Personal Information Collection Statement***

This Personal Information Collection Statement informs applicant for, and holder of, the Hong Kong Offer Shares, of the policies and practices of the Company and its H Share Registrar in relation to personal data and the Personal Data (Privacy) Ordinance (Chapter 486 of the Laws of Hong Kong).

***Reasons for the collection of your personal data***

It is necessary for applicants and registered holders of the Hong Kong Offer Shares to supply correct personal data to the Company or its agents and the H Share Registrar when applying for the Hong Kong Offer Shares or transferring the Hong Kong Offer Shares into or out of their names or in procuring the services of the H Share Registrar.

Failure to supply the requested data may result in your application for the Hong Kong Offer Shares being rejected, or in delay or the inability of the Company or its H Share Registrar to effect transfers or otherwise render their services. It may also prevent or delay registration or transfers of the Hong Kong Offer Shares which you have successfully applied for and/or the dispatch of share certificate(s) to which you are entitled.

It is important that the holders of the Hong Kong Offer Shares inform the Company and the H Share Registrar immediately of any inaccuracies in the personal data supplied.



Shanghai Miracogen Inc.- Ex. 2032, Page 000597

***Purposes***

Your personal data may be used, held, processed, and/or stored (by whatever means) for the following purposes:

- processing your application and refund check, where applicable, verification of compliance with the terms and application procedures set out in this prospectus and announcing results of allocation of the Hong Kong Offer Shares;
- compliance with applicable laws and regulations in Hong Kong and elsewhere;
- registering new issues or transfers into or out of the names of the holders of the Company's Shares including, where applicable, HKSCC Nominees;
- maintaining or updating the Company's Register of Members;
- verifying identities of the holders of the Company's Shares;
- establishing benefit entitlements of holders of the Company's Shares, such as dividends, rights issues, bonus issues, etc.;
- distributing communications from the Company and its subsidiaries;
- compiling statistical information and profiles of the holder of the Company's Shares;
- disclosing relevant information to facilitate claims on entitlements; and
- any other incidental or associated purposes relating to the above and/or to enable the Company and the H Share Registrar to discharge their obligations to holders of the Company's Shares and/or regulators and/or any other purposes to which the securities' holders may from time to time agree.

***Transfer of personal data***

Personal data held by the Company and its H Share Registrar relating to the holders of the Hong Kong Offer Shares will be kept confidential but the Company and its H Share Registrar may, to the extent necessary for achieving any of the above purposes, disclose, obtain or transfer (whether within or outside Hong Kong) the personal data to, from or with any of the following:

- the Company's appointed agents such as financial advisors, receiving bankers and overseas principal share registrar;



Shanghai Miracogen Inc.- Ex. 2032, Page 000598

- where applicants for the Hong Kong Offer Shares request a deposit into CCASS, HKSCC or HKSCC Nominees, who will use the personal data for the purposes of operating CCASS;

- any agents, contractors or third-party service providers who offer administrative, telecommunications, computer, payment or other services to the Company or the H Share Registrar in connection with their respective business operation;

- the Hong Kong Stock Exchange, the SFC and any other statutory regulatory or governmental bodies or otherwise as required by laws, rules or regulations; and

- any persons or institutions with which the holders of the Hong Kong Offer Shares have or propose to have dealings, such as their bankers, solicitors, accountants or stockbrokers etc.

***Retention of personal data***

The Company and its H Share Registrar will keep the personal data of the applicants and holders of the Hong Kong Offer Shares for as long as necessary to fulfil the purposes for which the personal data were collected. Personal data which is no longer required will be destroyed or dealt with in accordance with the Personal Data (Privacy) Ordinance.

***Access to and correction of personal data***

Holders of the Hong Kong Offer Shares have the right to ascertain whether the Company or the H Share Registrar hold their personal data, to obtain a copy of that data, and to correct any data that is inaccurate. The Company and the H Share Registrar have the right to charge a reasonable fee for the processing of such requests. All requests for access to data or correction of data should be addressed to the Company, at the Company's registered address disclosed in the section headed "Corporate Information" in this prospectus or as notified from time to time, for the attention of the secretary, or the Company's H Share Registrar for the attention of the privacy compliance officer.

## 7. WARNING FOR ELECTRONIC APPLICATIONS

The application for the Hong Kong Offer Shares by giving **electronic application instructions** to HKSCC is only a facility provided to CCASS Participants. Similarly, the application for Hong Kong Offer Shares through the **White Form eIPO** service is also only a facility provided by the designated **White Form eIPO** Service Provider to public investors. Such facilities are subject to capacity limitations and potential service interruptions and you are advised not to wait until the last application day in making your electronic applications. The Company, the Directors, the Joint Bookrunners, the Joint Sponsors, the Joint Global Coordinators and the Underwriters take no responsibility for such applications and provide no assurance that any CCASS Participant or person applying through the designated **White Form eIPO** Service Provider will be allotted any Hong Kong Offer Shares.



Shanghai Miracogen Inc.- Ex. 2032, Page 000599

To ensure that CCASS Investor Participants can give their **electronic application instructions**, they are advised not to wait until the last minute to input their instructions to the systems. In the event that CCASS Investor Participants have problems in the connection to CCASS Phone System or the CCASS Internet System for submission of **electronic application instructions**, they should go to HKSCC's Customer Service Center to complete an input request form for **electronic application instructions** before 12:00 noon on Tuesday, February 15, 2022, the last application day, or such time as described in the paragraph headed "– 10. Effect of Bad Weather on the Opening and Closing of the Application Lists" in this section.

## 8. HOW MANY APPLICATIONS YOU CAN MAKE

Multiple applications for the Hong Kong Offer Shares are not allowed except by nominees.

All of your applications will be rejected if more than one application through the **CCASS EIPO** service (directly or indirectly through your **broker** or **custodian**) or through the **White Form eIPO** service, is made for your benefit (including the part of the application made by HKSCC Nominees acting on **electronic application instructions**), and the number of Hong Kong Offer Shares applied by HKSCC Nominees will be automatically reduced by the number of Hong Kong Offer Shares for which you have given such instructions and/or for which such instructions have been given for your behalf.

For the avoidance of doubt, giving an **electronic application instruction** under the **White Form eIPO** service more than once and obtaining different application reference numbers without effecting full payment in respect of a particular reference number will not constitute an actual application. However, any **electronic application instructions** to make an application for the Hong Kong Offer Shares given by you or for your benefit to HKSCC will be deemed to be an actual application for the purposes of considering whether multiple applications have been made.

If an application is made by an unlisted company and:

- the principal business of that company is dealing in securities; and
- you exercise statutory control over that company,

then the application will be treated as being made for your benefit.

"Unlisted company" means a company with no equity securities listed on the Stock Exchange.

"Statutory control" means you:

- control the composition of the board of directors of the company;
- control more than half of the voting power of the company; or



Shanghai Miracogen Inc.- Ex. 2032, Page 000600

- hold more than half of the issued share capital of the company (not counting any part of it which carries no right to participate beyond a specified amount in a distribution of either profits or capital).

## 9. HOW MUCH ARE THE HONG KONG OFFER SHARES

The maximum Offer Price is HK$7.38 per Offer Share. You must also pay brokerage of 1.0%, SFC transaction levy of 0.0027%, Hong Kong Stock Exchange trading fee of 0.005% and FRC transaction levy of 0.00015%. This means that for one board lot of 1,000 Hong Kong Offer Shares, you will pay HK$7,454.38.

You must pay the maximum Offer Price, brokerage, SFC transaction levy, the Stock Exchange trading fee and FRC transaction levy in full upon application for the Hong Kong Offer Shares.

You may submit an application through the **White Form eIPO** service or the **CCASS EIPO** service in respect of a minimum of 1,000 Hong Kong Offer Shares. Each application or **electronic application instruction** in respect of more than 1,000 Hong Kong Offer Shares must be in one of the numbers set out in the table in "– 4. Minimum Application Amount and Permitted Numbers", or as otherwise specified on the designated website at **www.eipo.com.hk**.

If your application is successful, brokerage will be paid to the Exchange Participants (as defined in the Listing Rules), and the SFC transaction levy, the Stock Exchange trading fee and the FRC transaction levy are paid to the Stock Exchange (in the case of the SFC transaction levy and the FRC transaction levy, collected by the Stock Exchange on behalf of the SFC and the FRC, respectively).

For further details on the Offer Price, please refer to the paragraph headed "Structure of the Global Offering – Pricing of the Global Offering" in this prospectus.

## 10. EFFECT OF BAD WEATHER ON THE OPENING AND CLOSING OF THE APPLICATION LISTS

The application lists will not open if there is:

- a tropical cyclone warning signal number 8 or above; or
- a "black" rainstorm warning; and/or
- Extreme Conditions,

in force in Hong Kong at any time between 9:00 am and 12:00 noon on Tuesday, February 15, 2022. Instead they will open between 11:45 am and 12:00 noon on the next business day which does not have either of those warnings in Hong Kong in force at any time between 9:00 am and 12:00 noon.



Shanghai Miracogen Inc.- Ex. 2032, Page 000601

If the application lists do not open and close on Tuesday, February 15, 2022 or if there is/are a tropical cyclone warning signal number 8 or above or a "black" rainstorm warning signal and/or Extreme Conditions in force in Hong Kong that may affect the dates mentioned in the section headed "Expected Timetable" in this prospectus, an announcement will be made on our website at **http://www.lepubiopharma.com** and the website of the Stock Exchange at **www.hkexnews.hk**.

## 11. PUBLICATION OF RESULTS

The Company expects to announce the final Offer Price, the level of indication of interest in the International Offering, the level of applications in the Hong Kong Public Offering and the basis of allocation of the Hong Kong Offer Shares on Tuesday, February 22, 2022 on the Company's website at **http://www.lepubiopharma.com** and the website of the Stock Exchange at **www.hkexnews.hk**.

The results of allocations and the Hong Kong identity card/passport/Hong Kong business registration numbers of successful applicants under the Hong Kong Public Offering will be available at the times and dates and in the manner specified below:

- in the announcement to be posted on the Company's website at **http://www.lepubiopharma.com** and the Stock Exchange's website at **www.hkexnews.hk** by no later than 8:00 am on Tuesday, February 22, 2022;

- from the designated results of allocations website at **www.iporesults.com.hk** (alternatively: English **https://www.eipo.com.hk/en/Allotment**; Chinese **https://www.eipo.com.hk/zh-hk/Allotment**) with a "search by ID" function on a 24-hour basis from 8:00 a.m. on Tuesday, February 22, 2022 to 12:00 midnight, on Monday, February 28, 2022; and

- from the allocation results telephone enquiry line by calling +852 2862 8555 between 9:00 a.m. and 6:00 p.m. on Tuesday, February 22, 2022, Wednesday, February 23, 2022, Thursday, February 24, 2022 and Friday, February 25, 2022.

If the Company accepts your offer to purchase (in whole or in part), which it may do by announcing the basis of allocations and/or making available the results of allocations publicly, there will be a binding contract under which you will be required to purchase the Hong Kong Offer Shares if the conditions of the Global Offering are satisfied and the Global Offering is not otherwise terminated. Further details are contained in the section headed "Structure of the Global Offering" in this prospectus.

You will not be entitled to exercise any remedy of rescission for innocent misrepresentation at any time after acceptance of your application. This does not affect any other right you may have.



Shanghai Miracogen Inc.- Ex. 2032, Page 000602

## 12. CIRCUMSTANCES IN WHICH YOU WILL NOT BE ALLOCATED HONG KONG OFFER SHARES

You should note the following situations in which the Hong Kong Offer Shares will not be allotted to you:

### (i) If your application is revoked:

By applying through the **CCASS EIPO** service or through the **White Form eIPO** Service Provider, you agree that your application or application made by HKSCC Nominees on your behalf cannot be revoked on or before the fifth day after the time of the opening of the application lists (excluding for this purpose any day which is Saturday, Sunday or public holiday in Hong Kong). This agreement will take effect as a collateral contract with the Company.

Your application or the application made by HKSCC Nominees on your behalf may only be revoked on or before the fifth day after the time of the opening of the application lists (excluding any days which is a Saturday, Sunday or public holiday in Hong Kong) in the following circumstances:

(a) if a person responsible for this prospectus under Section 40 of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (as applied by Section 342E of the Companies (Winding Up and Miscellaneous Provisions) Ordinance) gives a public notice under that section on or before the fifth day after the time of the opening of the application lists (excluding any days which is a Saturday, Sunday or public holiday in Hong Kong) which excludes or limits that person's responsibility for this prospectus; or

(b) if any supplement to this prospectus is issued, applicants who have already submitted an application will be notified that they are required to confirm their applications. If applicants have been so notified but have not confirmed their applications in accordance with the procedure to be notified, all unconfirmed applications will be deemed revoked.

If your application or the application made by HKSCC Nominees on your behalf has been accepted, it cannot be revoked. For this purpose, acceptance of applications which are not rejected will be constituted by notification in the press of the results of allocation, and where such basis of allocation is subject to certain conditions or provides for allocation by ballot, such acceptance will be subject to the satisfaction of such conditions or results of the ballot respectively.



Shanghai Miracogen Inc.- Ex. 2032, Page 000603

**(ii) If the Company or its agents exercise their discretion to reject your application:**

The Company, the Joint Global Coordinators, the designated **White Form eIPO** Service Provider and their respective agents and nominees have full discretion to reject or accept any application, or to accept only part of any application, without giving any reasons.

**(iii) If the allotment of Hong Kong Offer Shares is void:**

The allotment of Hong Kong Offer Shares will be void if the Listing Committee of the Stock Exchange does not grant permission to list the Shares either:

- within three weeks from the closing date of the application lists; or
- within a longer period of up to six weeks if the Listing Committee notifies the Company of that longer period within three weeks of the closing date of the application lists.

**(iv) If:**

- you make multiple applications or suspected multiple applications;
- you or the person for whose benefit you are applying have applied for or taken up, or indicated an interest for, or have been or will be placed or allocated (including conditionally and/or provisionally) Hong Kong Offer Shares and International Offer Shares;
- your **electronic application instructions** through the **White Form eIPO** service are not completed in accordance with the instructions, terms and conditions on the designated website;
- your payment is not made correctly or the cheque or banker's cashier order paid by you is dishonored upon its first presentation;
- the Underwriting Agreements do not become unconditional or are terminated;
- the Company or the Joint Global Coordinators believe that by accepting your application, it or they would violate applicable securities or other laws, rules or regulations; or
- your application is for more than 50% of the Hong Kong Offer Shares initially offered under the Hong Kong Public Offering.



Shanghai Miracogen Inc.- Ex. 2032, Page 000604

## 13. REFUND OF APPLICATION MONIES

If an application is rejected, not accepted or accepted in part only, or if the Offer Price as finally determined is less than the maximum Offer Price per Offer Share (excluding brokerage, SFC transaction levy, the Stock Exchange trading fee and FRC transaction levy thereon), or if the conditions of the Hong Kong Public Offering are not fulfilled in accordance with the paragraph headed "Structure of the Global Offering – Conditions of the Global Offering" in this prospectus or if any application is revoked, the application monies, or the appropriate portion thereof, together with the related brokerage, SFC transaction levy, the Stock Exchange trading fee and FRC transaction levy, will be refunded, without interest or the cheque or banker's cashier order will not be cleared.

Any refund of your application monies will be made on or before Tuesday, February 22, 2022.

## 14. DESPATCH/COLLECTION OF SHARE CERTIFICATES AND REFUND MONIES

You will receive one share certificate for all Hong Kong Offer Shares allotted to you under the Hong Kong Public Offering (except pursuant to applications made through the **CCASS EIPO** service where the share certificates will be deposited into CCASS as described below).

No temporary document of title will be issued in respect of the Shares. No receipt will be issued for sums paid on application.

Subject to arrangement on dispatch/collection of share certificates and refund monies as mentioned below, any refund cheques and share certificates are expected to be posted on or before Tuesday, February 22, 2022. The right is reserved to retain any share certificate(s) and any surplus application monies pending clearance of cheque(s) or banker's cashier's order(s).

Share certificates will only become valid at 8:00 a.m. on Wednesday, February 23, 2022 provided that the Global Offering has become unconditional and the right of termination described in the section headed "Underwriting" in this prospectus has not been exercised. Investors who trade Shares prior to the receipt of Share certificates or the Share certificates becoming valid do so at their own risk.

### Personal Collection

#### *(i) If you apply through the White Form eIPO service*

If you apply for 1,000,000 Hong Kong Offer Shares or more and your application is wholly or partially successful, you may collect your Share certificate(s) and/or refund cheques (where applicable) from our H Share Registrar, Computershare Hong Kong Investor Services Limited at Shops 1712-1716, 17/F Hopewell Centre, 183 Queen's Road East, Wan Chai, Hong



Shanghai Miracogen Inc.- Ex. 2032, Page 000605

Kong, from 9:00 a.m. to 1:00 p.m. on Tuesday, February 22, 2022, or such other date as notified by the Company in the newspapers as the date of despatch/collection of Share certificates/e-Refund payment instructions/refund cheques.

If you do not collect your Share certificate(s) and/or refund cheques (where applicable) personally within the time specified for collection, they will be sent to the address specified in your application instructions by ordinary post at your own risk.

If you apply for less than 1,000,000 Hong Kong Offer Shares, your Share certificate(s) and/or refund cheques (where applicable) will be sent to the address specified in your application instructions on or before Tuesday, February 22, 2022 by ordinary post at your own risk.

If you apply and pay the application monies from a single bank account, any refund monies will be despatched to that bank account in the form of e-Refund payment instructions. If you apply and pay the application monies from multiple bank accounts, any refund monies will be despatched to the address as specified in your application instructions in the form of refund cheque(s) by ordinary post at your own risk.

***(ii) If you apply through CCASS EIPO service***

*Allocation of Hong Kong Offer Shares*

For the purposes of allocating Hong Kong Offer Shares, HKSCC Nominees will not be treated as an applicant. Instead, each CCASS Participant who gives **electronic application instructions** or each person for whose benefit instructions are given will be treated as an applicant.

*Deposit of Share Certificates into CCASS and Refund of Application Monies*

If your application is wholly or partially successful, your share certificate(s) will be issued in the name of HKSCC Nominees and deposited into CCASS for the credit of your designated CCASS Participant's stock account or your CCASS Investor Participant's stock account on Tuesday, February 22, 2022, or, on any other date determined by HKSCC or HKSCC Nominees.

The Company expects to publish the application results of CCASS Participants (and where the CCASS Participant is a **broker** or **custodian**, the Company will include information relating to the relevant beneficial owner), your Hong Kong identity card number/passport number or other identification code (Hong Kong business registration number for corporations) and the basis of allotment of the Hong Kong Public Offering in the manner specified in the paragraph headed "– 11. Publication of Results" in this section on Tuesday, February 22, 2022. You should check the announcement published by the Company and report any discrepancies to HKSCC before 5:00 p.m. on Tuesday, February 22, 2022 or such other date as determined by HKSCC or HKSCC Nominees.



Shanghai Miracogen Inc.- Ex. 2032, Page 000606

If you have instructed your **broker** or **custodian** to give **electronic application instructions** on your behalf, you can also check the number of Hong Kong Offer Shares allotted to you and the amount of refund monies (if any) payable to you with that **broker** or **custodian**.

If you have applied as a CCASS Investor Participant, you can also check the number of Hong Kong Offer Shares allotted to you and the amount of refund monies (if any) payable to you via the CCASS Phone System and the CCASS Internet System (under the procedures contained in HKSCC's "An Operating Guide for Investor Participants" in effect from time to time) on Tuesday, February 22, 2022. Immediately following the credit of the Hong Kong Offer Shares to your stock account and the credit of refund monies to your bank account, HKSCC will also make available to you an activity statement showing the number of Hong Kong Offer Shares credited to your CCASS Investor Participant stock account and the amount of refund monies (if any) credited to your designated bank account.

Refund of your application monies (if any) in respect of wholly and partially unsuccessful applications and/or difference between the Offer Price and the maximum Offer Price per Offer Share initially paid on application (including brokerage, SFC transaction levy, the Stock Exchange trading fee and FRC transaction levy but without interest) will be credited to your designated bank account or the designated bank account of your **broker** or **custodian** on Tuesday, February 22, 2022.

## 15. ADMISSION OF THE H SHARES INTO CCASS

If the Stock Exchange grants the listing of, and permission to deal in, the H Shares and we comply with the stock admission requirements of HKSCC, the H Shares will be accepted as eligible securities by HKSCC for deposit, clearance and settlement in CCASS with effect from the date of commencement of dealings in the H Shares or any other date HKSCC chooses. Settlement of transactions between Exchange Participants (as defined in the Listing Rules) is required to take place in CCASS on the second settlement day after any trading day.

All activities under CCASS are subject to the General Rules of CCASS and CCASS Operational Procedures in effect from time to time.

Investors should seek the advice of their stockbroker or other professional advisor for details of the settlement arrangement as such arrangements may affect their rights and interests.

All necessary arrangements have been made enabling the H Shares to be admitted into CCASS.



Shanghai Miracogen Inc.- Ex. 2032, Page 000607

*The following is the text of a report set out on pages I-1 to I-3, received from the Company's reporting accountant, PricewaterhouseCoopers, Certified Public Accountants, Hong Kong, for the purpose of incorporation in this prospectus. It is prepared and addressed to the directors of the Company and to the Joint Sponsors pursuant to the requirements of HKSIR 200 Accountants' Reports on Historical Financial Information in Investment Circulars issued by the Hong Kong Institute of Certified Public Accountants.*



羅兵咸永道

**ACCOUNTANT'S REPORT ON HISTORICAL FINANCIAL INFORMATION TO THE DIRECTORS OF LEPU BIOPHARMA CO., LTD. AND CHINA INTERNATIONAL CAPITAL CORPORATION HONG KONG SECURITIES LIMITED AND MORGAN STANLEY ASIA LIMITED**

**Introduction**

We report on the historical financial information of Lepu Biopharma Co., Ltd. (the "Company") and its subsidiaries (together, the "Group") set out on pages I-4 to I-95, which comprises the Company balance sheets as at 31 December 2019 and 2020 and 31 August 2021, the consolidated balance sheets as at 31 December 2019 and 2020 and 31 August 2021, and the consolidated statements of comprehensive loss, the consolidated statements of changes in equity and the consolidated statements of cash flows for each of the years ended 31 December 2019 and 2020 and eight months ended 31 August 2021 (the "Track Record Period") and a summary of significant accounting policies and other explanatory information (together, the "Historical Financial Information"). The Historical Financial Information set out on pages I-4 to I-95 forms an integral part of this report, which has been prepared for inclusion in the prospectus of the Company dated 10 February 2022 (the "Prospectus") in connection with the initial listing of H shares of the Company on the Main Board of The Stock Exchange of Hong Kong Limited.

**Directors' responsibility for the Historical Financial Information**

The directors of the Company are responsible for the preparation of Historical Financial Information that gives a true and fair view in accordance with the basis of preparation set out in Note 2.1 to the Historical Financial Information, and for such internal control as the directors determine is necessary to enable the preparation of Historical Financial Information that is free from material misstatement, whether due to fraud or error.

PricewaterhouseCoopers, 22/F Prince's Building, Central, Hong Kong SAR, China
T: +852 2289 8888, F: +852 2810 9888, www.pwchk.com



Shanghai Miracogen Inc.- Ex. 2032, Page 000608

**Reporting accountant's responsibility**

Our responsibility is to express an opinion on the Historical Financial Information and to report our opinion to you. We conducted our work in accordance with Hong Kong Standard on Investment Circular Reporting Engagements 200, *Accountants' Reports on Historical Financial Information in Investment Circulars* issued by the Hong Kong Institute of Certified Public Accountants ("HKICPA"). This standard requires that we comply with ethical standards and plan and perform our work to obtain reasonable assurance about whether the Historical Financial Information is free from material misstatement.

Our work involved performing procedures to obtain evidence about the amounts and disclosures in the Historical Financial Information. The procedures selected depend on the reporting accountant's judgement, including the assessment of risks of material misstatement of the Historical Financial Information, whether due to fraud or error. In making those risk assessments, the reporting accountant considers internal control relevant to the entity's preparation of Historical Financial Information that gives a true and fair view in accordance with the basis of preparation set out in Note 2.1 to the Historical Financial Information in order to design procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Our work also included evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors, as well as evaluating the overall presentation of the Historical Financial Information.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

**Opinion**

In our opinion, the Historical Financial Information gives, for the purposes of the accountant's report, a true and fair view of the financial position of the Company as at 31 December 2019 and 2020 and 31 August 2021, the consolidated financial position of the Group as at 31 December 2019 and 2020 and 31 August 2021 and of its consolidated financial performance and its consolidated cash flows for the Track Record Period in accordance with the basis of preparation set out in Note 2.1 to the Historical Financial Information.

**Review of stub period comparative financial information**

We have reviewed the stub period comparative financial information of the Group which comprises the consolidated statement of comprehensive loss, the consolidated statement of changes in equity and the consolidated statement of cash flows for the eight months ended 31 August 2020 and other explanatory information (the "Stub Period Comparative Financial Information"). The directors of the Company are responsible for the preparation and presentation of the Stub Period Comparative Financial Information in accordance with the basis of preparation set out in Note 2.1 to the Historical Financial Information. Our responsibility is to express a conclusion on the Stub Period Comparative Financial Information


Shanghai Miracogen Inc.- Ex. 2032, Page 000609

based on our review. We conducted our review in accordance with International Standard on Review Engagements 2410, *Review of Interim Financial Information Performed by the Independent Auditor of the Entity* issued by the International Auditing and Assurance Standards Board ("IAASB"). A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion. Based on our review, nothing has come to our attention that causes us to believe that the Stub Period Comparative Financial Information, for the purposes of the accountant's report, is not prepared, in all material respects, in accordance with the basis of preparation set out in Note 2.1 to the Historical Financial Information.

**Report on matters under the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "Listing Rules") and the Companies (Winding Up and Miscellaneous Provisions) Ordinance**

***Adjustments***

In preparing the Historical Financial Information, no adjustments to the Underlying Financial Statements as defined on page I-4 have been made.

***Dividends***

We refer to note 42 to the Historical Financial Information which states that no dividend has been paid by Lepu Biopharma Co., Ltd. in respect of the Track Record Period.

**PricewaterhouseCoopers**
*Certified Public Accountants*
Hong Kong, 10 February 2022


Shanghai Miracogen Inc.- Ex. 2032, Page 000610

## I HISTORICAL FINANCIAL INFORMATION OF THE GROUP

Set out below is the Historical Financial Information which forms an integral part of this accountant's report. The financial statements of the Group for the Track Record Period, on which the Historical Financial Information is based, were audited by PricewaterhouseCoopers in accordance with International Standards on Auditing issued by the International Auditing and Assurance Standards Board (the "Underlying Financial Statements").

The Historical Financial Information is presented in Renminbi ("RMB") and all values are rounded to the nearest thousand (RMB'000) except when otherwise indicated.



Shanghai Miracogen Inc.- Ex. 2032, Page 000611

## CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

| | Note | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|---|
| | | 2019 | 2020 | 2020 | 2021 |
| | | *RMB'000* | *RMB'000* | *RMB'000* (Unaudited) | *RMB'000* |
| Other income | *6* | 5,553 | 7,964 | 2,656 | 4,601 |
| Other expenses | *7* | (892) | (1,915) | (1,380) | (707) |
| Administrative expenses | *7* | (191,551) | (93,757) | (49,727) | (108,328) |
| Research and development expenses | *7* | (229,197) | (354,427) | (196,273) | (509,483) |
| Fair value changes on financial assets and liabilities at fair value through profit or loss | *9* | (38,312) | (77,991) | (117,497) | (47,434) |
| Other losses, net | *10* | (256) | (225) | (420) | (831) |
| **Operating loss** | | **(454,655)** | **(520,351)** | **(362,641)** | **(662,182)** |
| Finance income | | 397 | 5,306 | 1,019 | 3,267 |
| Finance costs | | (52,559) | (86,319) | (85,144) | (3,027) |
| Finance (costs)/income, net | *11* | (52,162) | (81,013) | (84,125) | 240 |
| Share of loss of investments accounted for using the equity method | *17* | (8,675) | (12,084) | (5,390) | (6,293) |
| **Loss before income tax** | | **(515,492)** | **(613,448)** | **(452,156)** | **(668,235)** |
| Income tax expense | *12* | – | – | – | – |
| **Loss for the year/period** | | **(515,492)** | **(613,448)** | **(452,156)** | **(668,235)** |
| **Loss attributable to:** | | | | | |
| Owners of the Company | | (447,036) | (581,849) | (427,971) | (656,392) |
| Non-controlling interests | | (68,456) | (31,599) | (24,185) | (11,843) |
| | | **(515,492)** | **(613,448)** | **(452,156)** | **(668,235)** |
| **Loss per share for loss attributable to owners of the Company for the year/period (expressed in RMB per share)** | | | | | |
| – Basic and diluted | *13* | (0.69) | (0.51) | (0.45) | (0.43) |
| **Other comprehensive loss** | | | | | |
| *Items that may be subsequently reclassified to profit or loss* | | | | | |
| Currency translation differences | | – | (39) | – | 14 |
| | | **(515,492)** | **(613,487)** | **(452,156)** | **(668,221)** |
| **Total comprehensive loss for the year attributable to:** | | | | | |
| Owners of the Company | | (447,036) | (581,888) | (427,971) | (656,378) |
| Non-controlling interests | | (68,456) | (31,599) | (24,185) | (11,843) |
| | | **(515,492)** | **(613,487)** | **(452,156)** | **(668,221)** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000612

## CONSOLIDATED BALANCE SHEETS

| | Note | As at 31 December 2019 | 2020 | As at 31 August 2021 |
|---|---|---|---|---|
| | | *RMB'000* | *RMB'000* | *RMB'000* |
| **Assets** | | | | |
| **Non-current assets** | | | | |
| Property, plant and equipment | *14* | 331,110 | 606,371 | 725,819 |
| Right-of-use assets | *15* | 130,721 | 163,666 | 149,600 |
| Intangible assets | *16* | 517,333 | 497,922 | 479,662 |
| Investments accounted for using the equity method | *17* | 169,878 | 160,294 | 154,002 |
| Other receivables, prepayments and deposits | *19* | 154,700 | 152,009 | 147,148 |
| **Total non-current assets** | | 1,303,742 | 1,580,262 | 1,656,231 |
| **Current assets** | | | | |
| Inventories | *18* | 8,082 | 19,569 | 24,164 |
| Other receivables, prepayments and deposits | *19* | 24,912 | 70,256 | 82,713 |
| Financial assets at fair value through profit or loss | *20* | – | 330,657 | 132,724 |
| Cash and cash equivalents | *21* | 188,545 | 402,867 | 261,194 |
| Term deposits with initial terms of over three months | *22* | – | 20,000 | 50,000 |
| **Total current assets** | | 221,539 | 843,349 | 550,795 |
| **Total assets** | | **1,525,281** | **2,423,611** | **2,207,026** |
| **Equity** | | | | |
| **Equity attributable to owners of the Company** | | | | |
| Paid-in capital/Share capital | *24, 25* | 1,000,000 | 1,492,693 | 1,531,670 |
| Treasury stock | *26* | (347,454) | – | – |
| Reserves | *26* | (462,631) | 612,260 | 919,773 |
| Accumulated losses | | (542,415) | (631,442) | (1,287,834) |
| | | (352,500) | 1,473,511 | 1,163,609 |
| **Non-controlling interests** | *39* | 166,860 | 28,211 | 16,393 |
| **Total equity** | | **(185,640)** | **1,501,722** | **1,180,002** |
| **Liabilities** | | | | |
| **Non-current liabilities** | | | | |
| Borrowings | *28* | 118,266 | 147,266 | 168,064 |
| Lease liabilities | *15* | 48,251 | 33,534 | 23,259 |
| Deferred government grants | *29* | 12,000 | 12,000 | 12,000 |
| Deferred tax liabilities | *30* | 37,687 | 37,687 | 37,687 |
| Financial liabilities at fair value through profit or loss | *31* | 279,081 | 309,181 | 357,339 |
| Other payables and accruals | *33* | – | – | 150,000 |
| **Total non-current liabilities** | | 495,285 | 539,668 | 748,349 |
| **Current liabilities** | | | | |
| Borrowings | *28* | – | – | 30,000 |
| Trade payables | *32* | 31,684 | 42,448 | 84,560 |
| Other payables and accruals | *33* | 378,278 | 321,307 | 147,927 |
| Lease liabilities | *15* | 27,565 | 18,466 | 16,188 |
| Convertible loans | *34* | 380,620 | – | – |
| Financial instruments with preferred rights at amortised cost | *34* | 397,489 | – | – |
| **Total current liabilities** | | 1,215,636 | 382,221 | 278,675 |
| **Total liabilities** | | **1,710,921** | **921,889** | **1,027,024** |
| **Total equity and liabilities** | | **1,525,281** | **2,423,611** | **2,207,026** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000613

## COMPANY BALANCE SHEETS

| | Note | As at 31 December 2019 | As at 31 December 2020 | As at 31 August 2021 |
|---|---|---|---|---|
| | | *RMB'000* | *RMB'000* | *RMB'000* |
| **Assets** | | | | |
| **Non-current assets** | | | | |
| Property, plant and equipment | *14* | 163,934 | 379,042 | 507,754 |
| Right-of-use assets | *15* | 71,160 | 119,966 | 116,391 |
| Intangible assets | *16* | 27,160 | 25,765 | 24,713 |
| Investments in subsidiaries | *38* | 1,260,737 | 1,938,434 | 1,948,636 |
| Investments accounted for using the equity method | *17* | 164,359 | 155,043 | 150,797 |
| Other receivables, prepayments and deposits | *19* | 104,725 | 75,357 | 75,244 |
| **Total non-current assets** | | 1,792,075 | 2,693,607 | 2,823,535 |
| **Current assets** | | | | |
| Other receivables, prepayments and deposits | *19* | 135,223 | 627,359 | 1,008,401 |
| Financial assets at fair value through profit or loss | *20* | – | 330,657 | 30,058 |
| Cash and cash equivalents | *21* | 172,993 | 232,364 | 207,973 |
| Term deposits with initial terms of over three months | *22* | – | 20,000 | 50,000 |
| **Total current assets** | | 308,216 | 1,210,380 | 1,296,432 |
| **Total assets** | | **2,100,291** | **3,903,987** | **4,119,967** |
| **Equity** | | | | |
| Paid-in capital/Share capital | *24, 25* | 1,000,000 | 1,492,693 | 1,531,670 |
| Treasury stock | *26* | (347,454) | – | – |
| Reserves | *26* | 117,913 | 1,625,182 | 1,932,681 |
| (Accumulated losses)/Retained earnings | | (263,039) | 17,378 | (198,385) |
| **Total equity** | | **507,420** | **3,135,253** | **3,265,966** |
| **Liabilities** | | | | |
| **Non-current liabilities** | | | | |
| Borrowings | *28* | 118,266 | 147,266 | 168,064 |
| Lease liabilities | | 1,720 | 1,217 | 1,229 |
| Deferred government grants | *29* | 12,000 | 12,000 | 12,000 |
| Financial liabilities at fair value through profit or loss | *31* | 279,081 | 309,181 | 357,339 |
| Other payables and accruals | *33* | – | – | 150,000 |
| **Total non-current liabilities** | | 411,067 | 469,664 | 688,632 |
| **Current liabilities** | | | | |
| Borrowings | *28* | – | – | 30,000 |
| Trade payables | *32* | – | 5,435 | 5,148 |
| Other payables and accruals | *33* | 402,797 | 293,054 | 129,064 |
| Lease liabilities | | 898 | 581 | 1,157 |
| Convertible loans | *34* | 380,620 | – | – |
| Financial instruments with preferred rights at amortised cost | *34* | 397,489 | – | – |
| **Total current liabilities** | | 1,181,804 | 299,070 | 165,369 |
| **Total liabilities** | | **1,592,871** | **768,734** | **854,001** |
| **Total equity and liabilities** | | **2,100,291** | **3,903,987** | **4,119,967** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000614

## CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

| | | Attributable to owners of the Company | | | | Non-controlling interests | Total |
|---|---|---|---|---|---|---|---|
| | *Note* | Paid-in capital *RMB'000* | Treasury stock *RMB'000* | Reserves *RMB'000* | Accumulated losses *RMB'000* | *RMB'000* | *RMB'000* |
| **At 31 December 2018** | | 690,400 | – | (36,885) | (62,234) | 189,464 | 780,745 |
| Business combination under common control | *35* | – | – | 70,628 | (33,145) | 32,124 | 69,607 |
| **At 1 January 2019** | | 690,400 | – | 33,743 | (95,379) | 221,588 | 850,352 |
| **Comprehensive loss** | | | | | | | |
| Loss for the year | | – | – | – | (447,036) | (68,456) | (515,492) |
| **Transaction with owners** | | | | | | | |
| Capital contributions from Ningbo Houde Yimin Information Technology Co., Ltd. ("Ningbo Houde Yimin") | *25* | 309,600 | – | – | – | – | 309,600 |
| Capital contributions from shareholders | *35* | – | – | 31,372 | – | 13,936 | 45,308 |
| Recognition of financial instruments with preferred rights at amortised cost | *34.2(a)* | – | (347,454) | – | – | – | (347,454) |
| Share-based payments | *34.2(a)* | – | – | 143,695 | – | – | 143,695 |
| Business combination under common control | *35* | – | – | (112,200) | – | 51,940 | (60,260) |
| Transactions with non-controlling interests | *39* | – | – | (559,241) | – | (52,148) | (611,389) |
| **At 31 December 2019** | | **1,000,000** | **(347,454)** | **(462,631)** | **(542,415)** | **166,860** | **(185,640)** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000615

| | Note | Attributable to owners of the Company | | | | | Non-controlling interests | Total |
|---|---|---|---|---|---|---|---|---|
| | | Paid-in capital | Share capital | Treasury stock | Reserves | Accumulated losses | | |
| | | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* |
| **At 1 January 2020** | | 1,000,000 | – | (347,454) | (462,631) | (542,415) | 166,860 | (185,640) |
| **Comprehensive loss** | | | | | | | | |
| Loss for the year | | – | – | – | – | (581,849) | (31,599) | (613,448) |
| Other comprehensive loss | | – | – | – | (39) | – | – | (39) |
| **Transaction with owners** | | | | | | | | |
| Capital contribution from Lepu Medical Technology (Beijing) Co., Ltd. | *34* | 25,352 | – | – | 64,648 | – | – | 90,000 |
| Capital contribution from non-controlling interests | *39* | – | – | – | – | – | 9,000 | 9,000 |
| Conversion of convertible loans | *34.2(b)* | 101,408 | – | – | 325,876 | – | – | 427,284 |
| Transactions with non-controlling interests | *39* | 138,979 | – | – | (22,927) | – | (116,052) | – |
| Issuance of equity interests to series B investors | *25* | 226,954 | – | – | 1,064,046 | – | – | 1,291,000 |
| Recognition of financial instruments with preferred rights at amortised cost | | | | | | | | |
| – upon conversion of convertible loans | *34.2(b)* | – | – | (328,762) | – | – | – | (328,762) |
| – upon issuance of series B equity interests | *34.2(c)* | – | – | (1,192,480) | – | – | – | (1,192,480) |
| Derecognition of financial instruments with preferred rights at amortised cost | *34.2(d)* | – | – | 1,868,696 | 130,887 | – | – | 1,999,583 |
| Conversion into a joint stock company | *24* | (1,492,693) | 1,492,693 | – | (492,822) | 492,822 | – | – |
| Share-based payments | *27* | – | – | – | 5,222 | – | 2 | 5,224 |
| **At 31 December 2020** | | **–** | **1,492,693** | **–** | **612,260** | **(631,442)** | **28,211** | **1,501,722** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000616

| | Note | Attributable to owners of the Company | | | | | Non-controlling interests | Total |
|---|---|---|---|---|---|---|---|---|
| | | Paid-in capital | Share capital | Treasury stock | Reserves | Accumulated losses | | |
| | | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* |
| **At 1 January 2021** | | – | 1,492,693 | – | 612,260 | (631,442) | 28,211 | 1,501,722 |
| **Comprehensive loss** | | | | | | | | |
| Loss for the period | | – | – | – | – | (656,392) | (11,843) | (668,235) |
| Other comprehensive loss | | – | – | – | 14 | – | – | 14 |
| **Transaction with owners** | | | | | | | | |
| Issuance of shares to series C investors | *24* | – | 38,977 | – | 221,720 | – | – | 260,697 |
| Share-based payments | *27* | – | – | – | 85,779 | – | 25 | 85,804 |
| **At 31 August 2021** | | **–** | **1,531,670** | **–** | **919,773** | **(1,287,834)** | **16,393** | **1,180,002** |
| **At 1 January 2020** | | 1,000,000 | – | (347,454) | (462,631) | (542,415) | 166,860 | (185,640) |
| **Comprehensive loss** | | | | | | | | |
| Loss for the period | | – | – | – | – | (427,971) | (24,185) | (452,156) |
| **Transaction with owners** | | | | | | | | |
| Capital contribution from Lepu Medical Technology (Beijing) Co., Ltd. | *34* | 25,352 | – | – | 64,648 | – | – | 90,000 |
| Conversion of convertible loans | *34.2(b)* | 101,408 | – | – | 325,876 | – | – | 427,284 |
| Transactions with non-controlling interests | *39* | 138,979 | – | – | (22,927) | – | (116,052) | – |
| Issuance of equity interest to series B investors | *25* | 226,954 | – | – | 1,064,046 | – | – | 1,291,000 |
| Recognition of financial instruments with preferred rights at amortised cost | | | | | | | | |
| – upon conversion of convertible loans | *34.2(b)* | – | – | (328,762) | – | – | – | (328,762) |
| – upon issuance of series B equity interests | *34.2(c)* | – | – | (1,192,480) | – | – | – | (1,192,480) |
| Derecognition of financial instruments with preferred rights at amortised cost | *34.2(d)* | – | – | 1,868,696 | 130,887 | – | – | 1,999,583 |
| **At 31 August 2020 (Unaudited)** | | **1,492,693** | **–** | **–** | **1,099,899** | **(970,386)** | **26,623** | **1,648,829** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000617

## CONSOLIDATED STATEMENTS OF CASH FLOWS

| | Note | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|---|
| | | 2019 | 2020 | 2020 | 2021 |
| | | *RMB'000* | *RMB'000* | *RMB'000* (Unaudited) | *RMB'000* |
| **Cash flows from operating activities** | | | | | |
| Cash used in operations | *36* | (234,390) | (427,919) | (212,551) | (421,923) |
| Interest received | | 396 | 5,230 | 1,019 | 3,601 |
| **Net cash used in operating activities** | | **(233,994)** | **(422,689)** | **(211,532)** | **(418,322)** |
| **Cash flows from investing activities** | | | | | |
| Payments for transaction with non-controlling interests | | (50,000) | (50,000) | (50,000) | (50,000) |
| Acquisition of a subsidiary | | – | (19,565) | (19,565) | – |
| Investments in associates | | (10,000) | (25,000) | (25,000) | (1) |
| Purchases of property, plant and equipment | | (318,471) | (239,262) | (93,727) | (134,913) |
| Purchases of land use rights | | – | (54,611) | (54,611) | – |
| Purchases of financial assets at fair value through profit or loss | | (509,500) | (1,657,610) | (735,610) | (944,000) |
| Proceeds from disposal of financial assets at fair value through profit or loss | | 511,535 | 1,332,701 | 231,799 | 1,146,338 |
| Proceeds from disposal of property, plant and equipment | | – | 771 | – | – |
| Purchases of intangible assets | | (45,363) | (9,140) | (9,140) | (943) |
| Placement of term deposits with initial terms of over three months | | – | (20,000) | – | (50,000) |
| Withdrawal of term deposits with initial terms of over three months | | – | – | – | 20,000 |
| Deposits paid for purchase of land use rights | | – | (7,953) | (7,953) | – |
| Repayments of deposits for purchase of land use rights | | 6,481 | – | – | – |
| **Net cash used in investing activities** | | **(415,318)** | **(749,669)** | **(763,807)** | **(13,519)** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000618

| | Note | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|---|
| | | 2019 | 2020 | 2020 | 2021 |
| | | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* |
| **Cash flows from financing activities** | | | | | |
| Capital contributions from shareholders | | – | 1,381,000 | 1,381,000 | 261,120 |
| Capital contributions from Ningbo Houde Yimin | | 309,600 | – | – | – |
| Capital contributions from former shareholder of a subsidiary | | 12,600 | – | – | – |
| Capital contributions from non-controlling interests | | 8,400 | 13,500 | – | – |
| Proceeds from issuance of convertible loans | *34* | 360,000 | – | – | – |
| Proceeds from bank borrowings | | 118,266 | 59,000 | 44,000 | 51,298 |
| Repayments of bank borrowings | | – | (30,000) | – | (500) |
| Proceeds from loans from Ningbo Houde Yimin | | – | 50,000 | 50,000 | – |
| Repayments of loans from Ningbo Houde Yimin | | – | (50,000) | (50,000) | – |
| Repayments of loans from former shareholder of a subsidiary | | (34,210) | – | – | – |
| Payments of issuance costs of convertible loans | *34* | (1,884) | – | – | – |
| Payments of lease liabilities | | | | | |
| – Principal | | (1,685) | (24,126) | (18,230) | (14,150) |
| – Interest | | (122) | (5,262) | (3,736) | (1,277) |
| Payments for listing expenses | | – | – | – | (2,224) |
| Other interests paid | | (571) | (7,433) | (4,222) | (3,127) |
| **Net cash generated from financing activities** | | **770,394** | **1,386,679** | **1,398,812** | **291,140** |
| **Net increase/(decrease) in cash and cash equivalents** | | **121,082** | **214,321** | **423,473** | **(140,701)** |
| Cash and cash equivalents at the beginning of year/period | | 67,462 | 188,545 | 188,545 | 402,867 |
| Effects of exchange rate changes on cash and cash equivalents | | 1 | 1 | – | (972) |
| **Cash and cash equivalents at end of year/period** | *21* | **188,545** | **402,867** | **612,018** | **261,194** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000619

## II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION

### 1 GENERAL INFORMATION

Lepu Biopharma Co., Ltd. (the "Company") was incorporated in Shanghai, the People's Republic of China (the "PRC") on 19 January 2018 as a limited liability company. Upon approval by the shareholders' general meeting held on 10 December 2020, the Company was converted into a joint stock company with limited liability under the Company Law of the PRC.

The Company, together with its subsidiaries (collectively referred to as the "Group"), are principally focus on the discovery, development and commercialization in global of drugs for cancer targeted therapy and immunotherapy.

Upon incorporation of the Company in January 2018, the Company had a registered capital of RMB1,000,000,000 and was owned by Ningbo Houde Yimin Information Technology Co., Ltd. (寧波厚德義民信息科技有限公司) ("Ningbo Houde Yimin") and Lepu Medical Technology (Beijing) Co., Ltd. (樂普(北京)醫療器械股份有限公司) ("Lepu Medical"), as to 80% and 20%, respectively.

Ningbo Houde Yimin was incorporated in the PRC on 29 March 2017 with Dr. Pu Zhongjie being its 100% ultimate controlling shareholder (the "Controlling Shareholder") and Lepu Medical was incorporated in the PRC on 11 June 1999 which listed on the Shenzhen Stock Exchange (stock code: 300003).

### 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The principal accounting policies applied in the preparation of the Historical Financial Information are set out below. These policies have been consistently applied throughout the Track Record Period, unless otherwise stated.

#### 2.1 Basis of preparation

The principal accounting policies applied in the preparation of Historical Financial Information are in accordance with International Financial Reporting Standards ("IFRSs") issued by the International Accounting Standards Board ("IASB").

The Historical Financial Information has been prepared under the historical costs convention, as modified by the revaluation of certain financial assets and financial liabilities measured at fair value.

The preparation of Historical Financial Information in conformity with IFRSs requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the Group's accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the Historical Financial Information are disclosed in Note 4.

The Historical Financial Information has been prepared on a going concern basis. As at 31 December 2019, the Group had net liabilities primarily due to significant amount of financial instruments issued to Series A Investors, (definition refer to Note 34) pursuant to their respective investment agreements, the financial instruments were recognised as liabilities and changes in the carrying amount of the financial instruments were charged to the consolidated statements of comprehensive loss.

On 28 August 2020, Series A Investors and Series B Investors (definition refer to Note 34) agreed to terminated their preferred rights associated with paid-in capital held by the Series A Investors and Series B Investors, therefore, the financial instruments have been re-classified to the equity from liabilities since then, further details of which are set out in Note 34.

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

The IASB has issued a number of new and amended IFRSs. For the purpose of preparing the Historical Financial Information, the Group has adopted all applicable new and amended IFRSs consistently throughout the Track Record Period except for any new or interpretation that are not yet effective.



Shanghai Miracogen Inc.- Ex. 2032, Page 000620

***New/amended standards and interpretations not yet adopted***

The following new/amended standards and annual improvements have been published (which may be applicable to the Group) but not mandatory for reporting periods ended on 31 August 2021 and have not been early adopted by the Group:

| | | **Effective for annual periods beginning on or after** |
|---|---|---|
| Amendment to IAS 16 | Property, Plant and Equipment: Proceeds before Intended Use | 1 January 2022 |
| Amendment to IAS 37 | Onerous Contracts – Cost of Fulfilling a Contract | 1 January 2022 |
| Amendment to IFRS 3 | Update reference to the Conceptual Framework | 1 January 2022 |
| Annual Improvements | Annual Improvements to IFRS Standards 2018-2020 | 1 January 2022 |
| Amendment to IAS 1 | Classification of Liabilities as Current or Non-current | Originally 1 January 2021, but extended to 1 January 2023 |
| IFRS 17 | Insurance contracts | Originally 1 January 2021, but extended to 1 January 2023 |
| Amendments to IAS 1 and IFRS Practice Statement 2 | Disclosure of Accounting Policies | 1 January 2023 |
| Amendments to IAS 8 | Definition of Accounting Estimates | 1 January 2023 |
| Amendments to IFRS 1 and IAS 12 | Deferred Tax related to Assets and Liabilities arising from a Single Transaction | 1 January 2023 |
| Amendments to IFRS 10 and IAS 28 | Sale or contribution of assets between an investor and its associate or joint venture | To be determined |

The Group has already commenced an assessment of the impact of these new/amended standards and annual improvements, and amendments, certain of which are relevant to the Group's operations. According to the preliminary assessment made by the directors, no significant impact on the financial performance and positions of the Group is expected when they become effective.

**2.2 Principles of consolidation and equity accounting**

***2.2.1 Subsidiaries***

Subsidiaries are all entities (including structured entities) over which the Group has control. The Group controls an entity where the Group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power to direct the activities of the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are deconsolidated from the date that control ceases.

The acquisition method of accounting is used to account for business combinations by the Group except for business combination under common control (Note 2.3.1).

Inter-company transactions, balances and unrealised gains on transactions between group companies are eliminated. Unrealised losses are also eliminated unless the transaction provides evidence of an impairment of the transferred asset. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Group.

Non-controlling interests in the results and equity of subsidiaries are shown separately in the consolidated statements of comprehensive loss, statements of changes in equity and balance sheet respectively.



Shanghai Miracogen Inc.- Ex. 2032, Page 000621

*2.2.2 Associates*

Associates are all entities over which the Group has significant influence but not control or joint control. This is generally the case where the Group holds between 20% and 50% of the voting rights. Investments in associates are accounted for using the equity method of accounting (Note 2.2.3), after initially being recognised at cost.

*2.2.3 Equity method*

Under the equity method of accounting, the investments are initially recognised at cost and adjusted thereafter to recognise the Group's share of the post-acquisition profits or losses of the investee in profit or loss, and the Group's share of movements in other comprehensive income of the investee in other comprehensive income. Dividends received or receivable from associates are recognised as a reduction in the carrying amount of the investment.

Where the Group's share of losses in an equity-accounted investment equals or exceeds its interest in the entity, including any other unsecured long-term receivables, the Group does not recognise further losses, unless it has incurred obligations or made payments on behalf of the other entity.

Unrealised gains on transactions between the Group and its associates are eliminated to the extent of the Group's interest in these entities. Unrealised losses are also eliminated unless the transaction provides evidence of an impairment of the asset transferred. Accounting policies of equity-accounted investees have been changed where necessary to ensure consistency with the policies adopted by the Group.

The carrying amount of equity-accounted investments is tested for impairment in accordance with the policy described in Note 2.9.

*2.2.4 Changes in ownership interests*

The Group treats transactions with non-controlling interests that do not result in a loss of control as transactions with equity owners of the Group. A change in ownership interest results in an adjustment between the carrying amounts of the controlling and non-controlling interests to reflect their relative interests in the subsidiary. Any difference between the amount of the adjustment to non-controlling interests and any consideration paid or received is recognised in a separate reserve within equity attributable to owners of the Company.

Contingent consideration is initially measured at fair value and classified either as equity or a financial liability. Amounts classified as a financial liability are subsequently remeasured to fair value with changes in fair value recognised in profit or loss.

**2.3 Business combinations**

*2.3.1 Business combination under common control*

The Historical Financial Information incorporates the financial statements of the consolidating entities or business in which the common control combination occurs as if they had been consolidated from the date when the consolidating entities or business first came under the control of the controlling party.

The net assets of the consolidating entities or business are consolidated using the existing book values from the controlling parties' perspective. No amount is recognised in consideration for goodwill or excess of acquirers' interest in the net fair value of acquiree's identifiable assets, liabilities and contingent liabilities over costs at the time of common control combination, to the extent of the continuation of the controlling party's interest.

The consolidated statements of comprehensive loss include the results of each of the consolidating entities or business from the earliest date presented or since the date when the consolidating entities or business first came under the common control, where there is a shorter period, regardless of the date of the common control combination.



Shanghai Miracogen Inc.- Ex. 2032, Page 000622

A uniform set of accounting policies is adopted by those entities. All intra-group transactions, balances and unrealised gains on transactions between consolidating entities or business are eliminated on consolidation.

***2.3.2 Non-common control business combinations***

The Group applies the acquisition method to account for business combinations except for business combination under common control. The consideration transferred for the acquisition of a subsidiary comprises the:

- fair values of the assets transferred,
- liabilities incurred to the former owners of the acquired business,
- equity interests issued by the Group,
- fair value of any asset or liability resulting from a contingent consideration arrangement, and
- fair value of any pre-existing equity interest in the subsidiary.

Identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are, with limited exceptions, measured initially at their fair values at the acquisition date. The Group recognises any non-controlling interest in the acquired entity on an acquisition-by-acquisition basis either at fair value or at the non-controlling interest's proportionate share of the acquired entity's net identifiable assets.

Acquisition-related costs are expensed as incurred.

The excess of the:

- consideration transferred,
- amount of any non-controlling interest in the acquired entity, and
- acquisition-date fair value of any previous equity interest in the acquired entity

over the fair value of the net identifiable assets acquired is recorded as goodwill. If those amounts are less than the fair value of the net identifiable assets of the business acquired, the difference is recognised directly in profit or loss as a bargain purchase.

Where settlement of any part of cash consideration is deferred, the amounts payable in the future are discounted to their present value as at the date of exchange. The discount rate used is the entity's incremental borrowing rate, being the rate at which a similar borrowing could be obtained from an independent financier under comparable terms and conditions. Contingent consideration is classified either as equity or a financial liability. Amounts classified as a financial liability are subsequently remeasured to fair value with changes in fair value recognised in profit or loss.

If the business combination is achieved in stages, the acquisition date carrying value of the acquirer's previously held equity interest in the acquiree is remeasured to fair value at the acquisition date. Any gains or losses arising from such remeasurement are recognised in profit or loss.

**2.4 Separate financial statements**

Investments in subsidiaries are accounted for at cost less impairment. Costs includes direct attributable costs of investment. The results of subsidiaries are accounted for by the Company on the basis of dividend received and receivable.

Impairment testing of the investments in subsidiaries is required upon receiving a dividend from these investments if the dividend exceeds the total comprehensive income of the subsidiary in the period the dividend is declared or if the carrying amount of the investment in the separate financial statements exceeds the carrying amount in the consolidated financial statements of the investee's net assets including goodwill.



Shanghai Miracogen Inc.- Ex. 2032, Page 000623

**2.5 Segment reporting**

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision maker ("CODM"). The CODM, who is responsible for allocating resources, assessing performance of the operating segments, and has been identified as the executive directors of the Group that make strategic decisions.

**2.6 Foreign currency translation**

***2.6.1 Functional and presentation currency***

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates (the "functional currency"). Since the operations of the Group are located in the PRC, the consolidated financial statements are presented in RMB, which is the Company's primary functional and presentation currency.

***2.6.2 Transactions and balances***

Foreign currency transactions are translated into the functional currency using the exchange rates at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities denominated in foreign currencies at year end exchange rates are generally recognised in profit or loss. They are deferred in equity if they relate to qualifying cash flow hedges and qualifying net investment hedges or are attributable to part of the net investment in a foreign operation. Foreign exchange gains and losses that relate to borrowings are presented in the statement of profit or loss, within finance costs. All other foreign exchange gains and losses are presented in the consolidated statements of comprehensive loss within other (losses)/gain, net.

Non-monetary items that are measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was determined. Translation differences on assets and liabilities carried at fair value are reported as part of the fair value gain or loss. For example, translation differences on non-monetary assets and liabilities such as equities held at financial assets at fair value through profit or loss ("FVPL") are recognised in profit or loss as part of the fair value gain or loss and translation differences on nonmonetary assets such as equities classified as fair value through other comprehensive income ("FVOCI") are recognised in other comprehensive income ("OCI").

***2.6.3 Group companies***

The results and financial position of foreign operations (none of which has the currency of a hyperinflationary economy) that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- assets and liabilities for each balance sheet presented are translated at the closing rate at the date of that balance sheet;
- income and expenses for each statement of comprehensive loss are translated at average exchange rates (unless this is not a reasonable approximation of the cumulative effect of the rates prevailing on the transaction dates, in which case income and expenses are translated at the dates of the transactions); and
- all resulting exchange differences are recognised in other comprehensive loss.

On consolidation, exchange differences arising from the translation of any net investment in foreign entities, and of borrowings and other financial instruments designated as hedges of such investments, are recognised in other comprehensive income. When a foreign operation is sold or any borrowings forming part of the net investment are repaid, the associated exchange differences are reclassified to profit or loss, as part of the gain or loss on sale.


Shanghai Miracogen Inc.- Ex. 2032, Page 000624

**2.7 Property, plant and equipment**

Property, plant and equipment are stated at historical cost less depreciation. Historical costs include expenditure that is directly attributable to the acquisition of the items.

Subsequent costs are included in the asset's carrying amount or recognised as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Group and the costs of the item can be measured reliably. The carrying amount of any component accounted for as a separate asset is derecognised when replaced. All other repairs and maintenance are charged to the consolidated statements of comprehensive loss during the Track Record Period in which they are incurred.

Depreciation is calculated using the straight-line method to allocate their cost or revalued amounts, net of their residual values, over their estimated useful lives or, in the case of leasehold improvement and certain leased plant and equipment, the shorter lease term as follows:

| | |
|---|---|
| – Equipment and instruments | 5-10 years |
| – Office equipment and furniture | 3-5 years |
| – Motor vehicles | 4-10 years |
| – Leasehold improvements | Shorter of remaining lease term or estimated useful life |
| – Antibody purification resin | 3-5 years |

The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at the end of each Track Record Period. An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

Gains and losses on disposals are determined by comparing the proceeds with the carrying amount. These are included in the consolidated statements of comprehensive loss.

Construction-in-progress (the "CIP") represents equipment and decorations under construction, and is stated at costs less accumulated impairment losses, if any. Costs includes the costs of construction and acquisition and capitalised borrowing costs. No provision for depreciation is made on CIP until such time as the relevant assets are completed and ready for intended use. When the assets concerned are available for use, the costs are transferred to leasehold improvements as well as equipment and instruments and depreciated in accordance with the policy as stated above.

**2.8 Intangible assets**

***2.8.1 Goodwill***

Goodwill is measured as described in Note 2.3.2. Goodwill on acquisitions of subsidiaries is included in intangible assets. Goodwill is not amortised, and it is tested for impairment at balance sheet date, or more frequently if events or changes in circumstances indicate that it might be impaired and is carried at cost less accumulated impairment losses. Gains and losses on the disposal of business entity include the carrying amount of goodwill relating to the business sold.

Goodwill is allocated to cash-generating units for the purpose of impairment testing. The allocation is made to those cash-generating units or groups of cash-generating units that are expected to benefit from the business combination in which the goodwill arose. The units or groups of units are identified at the lowest level at which goodwill is monitored for internal management purposes.

***2.8.2 Intellectual properties***

Separately acquired intellectual properties are shown at historical cost. Intellectual properties acquired in a business combination are recognised at fair value at the acquisition date. Intellectual properties have a finite useful life and are amortised using the straight-line method over their estimated useful lives of 14 to 20 years, which are determined based on the shorter of authorised useful lives and the management's estimation of the period of returns on the intellectual properties. Intellectual properties are subsequently carried at cost less accumulated amortisation and impairment losses.



Shanghai Miracogen Inc.- Ex. 2032, Page 000625

The Group might acquire intellectual properties for an initial payment plus contractually agreed additional payments contingent on future events and outcomes occurred. Based on the costs accumulation model chosen by the Group, intellectual properties are recognised at acquisition at the cost paid, and variable payments are not included in the carrying amount of the asset at acquisition. Subsequently the Group capitalises the variable payments as part of the costs of the asset when paid, on the basis that these payments represent the direct costs of acquisition.

***2.8.3 Research and development***

The Group incurs significant costs and efforts on research and development activities. Research expenditures are charged to the profit or loss as an expense in the period the expenditure is incurred. Development costs are recognised as assets if they can be directly attributable to a newly developed product and all the following can be demonstrated:

- The technical feasibility to complete the development project so that it will be available for use or sale;
- The intention to complete the development project to use or sell the product;
- The ability to use or sell the product;
- The manner in which the development project will generate probable future economic benefits for the Group;
- The availability of adequate technical, financial and other resources to complete the development project and use or sell the product; and
- The expenditure attributable to the asset during its development can be reliably measured.

The costs of an internally generated intangible asset is the sum of the expenditure incurred from the date the asset meets the recognition criteria above to the date when it is available for use. The costs capitalised in connection with the intangible asset include costs of materials and services used or consumed, employee costs incurred in the creation of the asset and an appropriate portion of relevant overheads.

Capitalised development costs are amortised using the straight-line method over the life of the related product. Amortisation shall begin when the intangible asset is available for intended use.

Development expenditures not satisfying the above criteria are recognised in the profit or loss as incurred.

During the Track Record Period, there were no internally generated development costs meeting these criteria and capitalised as intangible assets.

**2.9 Impairment of non-financial assets**

Intangible assets that have an indefinite useful life are not subject to amortisation and are tested annually for impairment, or more frequently if events or changes in circumstances indicate that they might be impaired. Other assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognised for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs of disposal and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash inflows which are largely independent of the cash inflows from other assets or groups of assets (cash-generating units). Non-financial assets other than goodwill that suffered an impairment are reviewed for possible reversal of the impairment at the end of each reporting period.


Shanghai Miracogen Inc.- Ex. 2032, Page 000626

**2.10 Investments and other financial assets**

***2.10.1 Classification***

The Group classifies its financial assets in the following measurement categories:

- those to be measured subsequently at fair value (either through other comprehensive income or through profit or loss); and
- those to be measured at amortised cost.

The classification depends on the entity's business model for managing the financial assets and the contractual terms of the cash flows.

For assets measured at fair value, gains and losses will either be recorded in profit or loss or other comprehensive income. For investments in equity instruments that are not held for trading, this will depend on whether the Group has made an irrevocable election at the time of initial recognition to account for the equity investment at FVOCI.

The Group reclassifies debt investments when and only when its business model for managing those assets changes.

***2.10.2 Recognition and derecognition***

Regular way purchases and sales of financial assets are recognised on trade-date, the date on which the Group commits to purchase or sell the asset. Financial assets are derecognised when the rights to receive cash flows from the financial assets have expired or have been transferred and the Group has transferred substantially all the risks and rewards of ownership.

***2.10.3 Measurement***

At initial recognition, the Group measures a financial asset at its fair value plus, in the case of a financial asset not at FVPL, transaction costs that are directly attributable to the acquisition of the financial asset. Transaction costs of financial assets carried at FVPL are expensed in profit or loss.

Financial assets with embedded derivatives are considered in their entirety when determining whether their cash flows are solely payments of principal and interest.

*(a) Debt instruments*

Subsequent measurement of debt instruments depends on the Group's business model for managing the asset and the cash flow characteristics of the asset. There are three measurement categories into which the Group classifies its debt instruments:

- Amortised cost: Assets that are held for collection of contractual cash flows where those cash flows represent solely payments of principal and interest are measured at amortised cost. Interest income from these financial assets is included in finance income using the effective interest rate method. Any gain or loss arising on derecognition is recognised directly in profit or loss and presented in other (losses)/gain, net together with foreign exchange gains and losses.
- FVOCI: Assets that are held for collection of contractual cash flows and for selling the financial assets, where the assets' cash flows represent solely payments of principal and interest, are measured at FVOCI. Movements in the carrying amount are taken through other comprehensive income, except for the recognition of impairment gains or losses, interest income and foreign exchange gains and losses which are recognised in profit or loss. When the financial asset is derecognised, the cumulative gain or loss previously recognised in other comprehensive income is reclassified from equity to profit or loss and recognised in other (losses)/gain, net. Interest income from these financial assets is included in finance income using the effective interest rate method. Foreign exchange gains and losses are presented in other (losses)/gain, net.
- FVPL: Assets that do not meet the criteria for amortised cost or FVOCI are measured at FVPL. A gain or loss on a debt investment that is subsequently measured at FVPL is recognised in profit or loss and presented net within losses, net in the period in which it arises.

During the Track Record Period, no amount is recognised in respect of financial assets at fair value through other comprehensive income.



Shanghai Miracogen Inc.- Ex. 2032, Page 000627

*(b) Equity instruments*

The Group subsequently measures all equity investments at fair value. Where the Group's management has elected to present fair value gains and losses on equity investments in OCI, there is no subsequent reclassification of fair value gains and losses to profit or loss following the derecognition of the investment. Dividends from such investments continue to be recognised in profit or loss as other income when the Group's right to receive payments is established.

Changes in the fair value of financial assets at FVPL are recognised in other (losses)/gain, net in the statements of comprehensive loss as applicable. Impairment losses (and reversal of impairment losses) on equity investments measured at FVOCI are not reported separately from other changes in fair value.

***2.10.4 Impairment***

The Group assesses on a forward-looking basis the expected credit losses associated with its debt instruments carried at amortised cost and FVOCI. The impairment methodology applied depends on whether there has been a significant increase in credit risk.

For other receivables, prepayments and deposits, at each reporting date, the Group shall assess whether the credit risk on a financial instrument has increased significantly since initial recognition.

The measurement of expected credit losses reflects: An unbiased and probability-weighted amount that is determined by evaluating a range of possible outcomes; the time value of money; and reasonable and supportable information that is available without undue costs or effort at the reporting date about past events, current conditions and forecasts of future economic conditions.

**2.11 Offsetting financial instruments**

Financial assets and liabilities are offset and the net amount is reported in the consolidated balance sheets where the Group currently has a legally enforceable right to offset the recognised amounts, and there is an intention to settle on a net basis or realise the asset and settle the liability simultaneously.

**2.12 Financial guarantee contracts**

Financial guarantee contracts are recognised as a financial liability at the time the guarantee is issued. The liability is initially measured at fair value and subsequently at the amount determined in accordance with the expected credit loss model under IFRS 9 *Financial Instruments*.

The fair value of financial guarantees is determined based on the present value of the difference in cash flows between the contractual payments required under the debt instrument and the payments that would be required without the guarantee, or the estimated amount that would be payable to a third party for assuming the obligations.

Where guarantees in relation to loans or other payables of associates are provided for no compensation, the fair values are accounted for as contributions and recognised as part of the costs of the investment.

**2.13 Inventories**

Inventories including raw materials and consumable materials are stated at the lower of costs and net realisable value. Costs are assigned to individual items of inventory on the basis of weighted average costs. Costs of purchased inventory are determined after deducting rebates and discounts. Net realisable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale.

**2.14 Trade and other receivables**

Trade receivables are amounts due from customers for goods sold or services performed in the ordinary course of business. If collection of trade and other receivables is expected in one year or less (or in the normal operating cycle of the business if longer), they are classified as current assets. If not, they are presented as non-current assets.

Trade and other receivables are recognised initially at fair value and subsequently measured at amortised cost using the effective interest method, less allowance for impairment.



Shanghai Miracogen Inc.- Ex. 2032, Page 000628

**2.15 Prepayments**

Prepayments of the Group represent upfront cash payments made to contract research organisations ("CROs"), hospitals and suppliers for equipment.

Prepayments to CROs and hospitals, which are organizations that provide support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis, will be subsequently recorded as research and development expenses in accordance with the applicable performance requirements within one year or less and therefore are all classified as current assets.

Prepayments for equipment which are due for transfer to property, plant and equipment and therefore are classified as non-current assets.

**2.16 Cash and cash equivalents**

For the purpose of presentation in the statement of cash flows, cash and cash equivalents includes cash on hand, deposits held at call with financial institutions, other short-term, highly liquid investments with original maturities of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value, and bank overdrafts. Bank overdrafts are shown within borrowings in current liabilities in the balance sheet.

**2.17 Paid-in Capital/Share Capital**

Ordinary shares are classified as equity. Financial instruments with preferred rights at amortised cost described in Note 34 are classified as liabilities.

Incremental costs directly attributable to the issue of new shares or options are shown in equity as a deduction, net of tax, from the proceeds.

**2.18 Trade and other payables**

These amounts represent liabilities for goods and services provided to the Group prior to the end of financial year which are unpaid. The amounts are unsecured. Trade and other payables are presented as current liabilities unless payments are not due within 12 months after the reporting period. They are recognised initially at their fair value and subsequently measured at amortised cost using the effective interest method.

**2.19 Financial instruments with preferred rights at amortised cost**

A contract that contains an obligation to purchase the Company's equity instruments for cash or another financial asset gives rise to a financial liability for the present value of the redemption amount. Even if the Company's obligations to purchase is conditional on the counterparty exercising a right to redeem, the financial instruments with preferred rights are recognised as financial liability initially at the present value of the redemption amount and subsequently measured at amortised cost with interest charged in finance costs.

The Group derecognises financial liabilities when, and only when, the Group's obligations are discharged, cancelled or have expired. The carrying amount of the financial instruments derecognised was credited into the equity.

**2.20 Borrowings**

Borrowings are initially recognised at fair value, net of transaction costs incurred. Borrowings are subsequently measured at amortised cost. Any difference between the proceeds (net of transaction costs) and the redemption amount is recognised in profit or loss over the period of the borrowings using the effective interest method. Fees paid on the establishment of loan facilities are recognised as transaction costs of the loan to the extent that it is probable that some or all of the facility will be drawn down. In this case, the fee is deferred until the draw-down occurs. To the extent there is no evidence that it is probable that some or all of the facility will be drawn down, the fee is capitalised as a prepayment for liquidity services and amortised over the period of the facility to which it relates.


Shanghai Miracogen Inc.- Ex. 2032, Page 000629

Borrowings are removed from the balance sheet when the obligation specified in the contract is discharged, cancelled or expired. The difference between the carrying amount of a financial liability that has been extinguished or transferred to another party and the consideration paid, including any non-cash assets transferred or liabilities assumed, is recognised in profit or loss as finance costs.

Borrowings are classified as current liabilities unless the Group has an unconditional right to defer settlement of the liability for at least 12 months after the reporting period.

**2.21 Borrowing costs**

General and specific borrowing costs that are directly attributable to the acquisition, construction or production of a qualifying asset are capitalised during the period of time that is required to complete and prepare the asset for its intended use or sale. Qualifying assets are assets that necessarily take a substantial period of time to get ready for their intended use or sale.

Investment income earned on the temporary investment of specific borrowings pending their expenditure on qualifying assets is deducted from the borrowing costs eligible for capitalisation. Other borrowing costs are expensed in the period in which they are incurred.

**2.22 Current and deferred income tax**

The income tax expense or credit for the period is the tax payable on the current period's taxable income based on the applicable income tax rate for each jurisdiction adjusted by changes in deferred tax assets and liabilities attributable to temporary differences and to unused tax losses.

***2.22.1 Current income tax***

The current income tax charge is calculated on the basis of the tax laws enacted or substantively enacted at the end of the reporting period in the countries where the Company and its subsidiaries and associates operate and generate taxable income. Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation. It establishes provisions where appropriate on the basis of amounts expected to be paid to the tax authorities.

***2.22.2 Deferred income tax***

Deferred income tax is provided in full, using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. However, deferred tax liabilities are not recognised if they arise from the initial recognition of goodwill. Deferred income tax is also not accounted for if it arises from initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss. Deferred income tax is determined using tax rates (and laws) that have been enacted or substantively enacted by the end of the reporting period and are expected to apply when the related deferred income tax asset is realised or the deferred income tax liability is settled.

Deferred tax assets are recognised only if it is probable that future taxable amounts will be available to utilise those temporary differences and losses.

Deferred tax liabilities and assets are not recognised for temporary differences between the carrying amount and tax bases of investments in foreign operations where the company is able to control the timing of the reversal of the temporary differences and it is probable that the differences will not reverse in the foreseeable future.

Deferred tax assets and liabilities are offset where there is a legally enforceable right to offset current tax assets and liabilities and where the deferred tax balances relate to the same taxation authority. Current tax assets and tax liabilities are offset where the entity has a legally enforceable right to offset and intends either to settle on a net basis, or to realise the asset and settle the liability simultaneously.

Current and deferred tax is recognised in profit or loss, except to the extent that it relates to items recognised in other comprehensive income or directly in equity. In this case, the tax is also recognised in other comprehensive income or directly in equity, respectively.



Shanghai Miracogen Inc.- Ex. 2032, Page 000630

**2.23 Employee benefits**

*2.23.1 Short-term obligations*

Liabilities for wages and salaries, including non-monetary benefits and accumulating sick leave that are expected to be settled wholly within 12 months after the end of the period in which the employees render the related service are recognised in respect of employees' services up to the end of the reporting period and are measured at the amounts expected to be paid when the liabilities are settled. The liabilities are presented as current employee benefit obligations in the consolidated balance sheets.

*2.23.2 Post-employment obligations*

Employees of the Group are covered by a defined contribution pension plans under which the employees are entitled to a monthly pension based on certain formulas. The relevant government agencies are responsible for the pension liability to these employees when they retire. The Group contributes on a monthly basis to these pension plans for the employees which are determined at a certain percentage of their salaries. Under these plans, the Group has no obligation for post-retirement benefits beyond the contribution made. Contributions to these plans are expensed as incurred and contributions paid to the defined contribution pension plans for a staff are not available to reduce the Group's future obligations to such defined contribution pension plans even if the staff leaves the Group.

*2.23.3 Termination benefits*

Termination benefits are payable when employment is terminated by the Group before the normal retirement date, or when an employee accepts voluntary redundancy in exchange for these benefits. The Group recognises termination benefits at the earlier of the following dates: (a) when the Group can no longer withdraw the offer of those benefits; and (b) when the entity recognises costs for a restructuring and involves the payments of terminations benefits. In the case of an offer made to encourage voluntary redundancy, the termination benefits are measured based on the number of employees expected to accept the offer. Benefits falling due more than 12 months after the end of the reporting period are discounted to present value.

*2.23.4 Housing funds*

The PRC employees of the Group are also entitled to participate in various government-sponsored housing funds. The Group contributes on a monthly basis to those funds based on a certain percentage of the employee's salaries. The Group's liabilities in respect of these funds is limited to the contributions payable in each period and the Group has no further obligation beyond the contributions made. The non-PRC employees are not covered by the housing funds.

**2.24 Share-based payments**

The fair value of awarded shares granted to employees under the Employee Share Ownership Plan (the "ESOP") less amount paid by employees is recognised as an employee benefits expense over the relevant service period, being the vesting period of the shares, and the credit is recognised in equity in the share-based payment reserves. The fair value of the shares is measured at the grant date. The number of shares expected to vest is estimated based on the non-market vesting conditions. The estimates are revised at the end of each reporting period and adjustments are recognised in profit or loss and the share-based payment reserves. Where shares are forfeited due to a failure by the employee to satisfy the service conditions, any expenses previously recognised in relation to such shares are reversed effective at the date of the forfeiture.

**2.25 Government grants**

Grants from the government are recognised at their fair value where there is a reasonable assurance that the grant will be received, and the Group will comply with all attached conditions.

Where the grants related to an expense item, it is recognised as income on a systematic basis over the period that the costs, which it is intended to compensate, are expensed. Where the grants related to an asset, the fair value is credited to a deferred income account and is released to the statement of profit or loss and other comprehensive income over the expected useful life of the relevant asset on straight-line basis or deducted from the carrying amount of the asset and released to the statement of comprehensive income by way of a reduced depreciation charge.



Shanghai Miracogen Inc.- Ex. 2032, Page 000631

**2.26 Interest income**

Interest income from financial assets at FVPL is included in the net fair value gains on these assets.

Interest income is presented as finance income where it is earned from financial assets that are held for cash management purposes.

**2.27 Earnings per share**

To calculate earnings per share, the weighted average number of ordinary shares in issue before the conversion into a joint stock company was determined assuming the paid-in capital had been fully converted into share capital at the same conversion ratio of 1:1 as upon conversion into joint stock company.

*2.27.1 Basic earnings per share*

Basic earnings per share is calculated by dividing:

- The profit attributable to owners of the Company, excluding any costs of servicing equity other than ordinary shares
- By the weighted average number of ordinary shares outstanding during the financial year, adjusted for bonus elements in ordinary shares issued during the year and excluding treasury shares.

*2.27.2 Diluted earnings per share*

Diluted earnings per share adjusts the figures used in the determination of basic earnings per share to take into account:

- The after-income tax effect of interest and other financing costs associated with dilutive potential ordinary shares, and
- The weighted average number of additional ordinary shares that would have been outstanding assuming the conversion of all dilutive potential ordinary shares.

**2.28 Dividend income**

Dividends are received from financial assets measured at fair value through profit or loss (FVPL) and at fair value through other comprehensive income (FVOCI). Dividends are recognised as other income in profit or loss when the right to receive payments is established. This applies even if they are paid out of pre-acquisition profits, unless the dividend clearly represents a recovery of part of the costs of an investment. In this case, the dividend is recognised in OCI if it relates to an investment measured at FVOCI. However, the investment may need to be tested for impairment as a consequence.

**2.29 Leases**

Leases are recognised as a right-of-use asset and a corresponding liability at the date at which the leased asset is available for use by the Group.

Contracts may contain both lease and non-lease components. The Group allocates the consideration in the contract to the lease and non-lease components based on their relative stand-alone prices. However, for leases of real estate for which the Group is a lessee, it has elected not to separate lease and non-lease components and instead accounts for these as a single lease component.

Lease terms are negotiated on an individual basis and contain a wide range of different terms and conditions. The lease agreements do not impose any covenants other than the security interests in the leased assets that are held by the lessor. Leased assets may not be used as security for borrowing purposes.



Shanghai Miracogen Inc.- Ex. 2032, Page 000632

Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of the following lease payments:

- fixed payments (including in-substance fixed payments), less any lease incentives receivable;
- variable lease payments that are based on an index or a rate, initially measured using the index or rate as at the commencement date;
- amounts expected to be payable by the lessee under residual value guarantees;
- the exercise price of a purchase option if the lessee is reasonably certain to exercise that option; and
- payments of penalties for terminating the lease, if the lease term reflects the lessee exercising that option.

Lease payments to be made under reasonably certain extension options are also included in the measurement of the liability.

The lease payments are discounted using the interest rate implicit in the lease. If that rate cannot be readily determined, which is generally the case for leases in the Group, the lessee's incremental borrowing rate is used, being the rate that the individual lessee would have to pay to borrow the funds necessary to obtain an asset of similar value to the right-of-use asset in a similar economic environment with similar terms, security and conditions.

Right-of-use assets are measured at cost comprising the following:

- the amount of the initial measurement of lease liability,
- any lease payments made at or before the commencement date less any lease incentives received,
- any initial direct costs, and
- restoration costs

Right-of-use assets are generally depreciated over the lease term on a straight-line basis. Right-of-use assets are subject to impairment.

Payments associated with short-term leases and leases of low-value assets are recognised on a straight-line basis as an expense in profit or loss. Short-term leases are leases with a lease term of less than 12 months. Low-value assets comprise IT equipment and small items of office furniture.

**2.30 Financial liabilities at fair value through profit or loss**

Financial liabilities are recognised when the entity becomes a party to the contractual provisions of the instrument. At initial recognition, the Group measures a financial liability at its fair value plus or minus, in the case of a financial liability not at fair value through profit or loss, transaction costs that are incremental and directly attributable to the acquisition or issue of the financial liability, such as fees and commissions. Transaction costs of financial liabilities carried at fair value through profit or loss are expensed in the statements of comprehensive loss.

Financial liabilities at fair value through profit or loss includes derivatives and financial liabilities designated as fair value through profit or loss. The Group shall present a gain or loss on those financial liabilities designated as at fair value through profit or loss as follows: the amount of change in the fair value of the financial liability that is attributable to changes in the credit risk of that liability shall be presented in other comprehensive income, and the remaining amount of change in the fair value of the liability shall be presented in profit or loss unless the treatment of the effects of changes in the liability's credit risk would create or enlarge an accounting mismatch in profit or loss.

The financial liability is derecognised when the obligation under the liability is discharged or expires. When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as a derecognition of the original liability and a recognition of a new liability.

During the Track Record Period, no amount is recognised in respect of financial liabilities at fair value through other comprehensive income.


Shanghai Miracogen Inc.- Ex. 2032, Page 000633

## 3 FINANCIAL RISK MANAGEMENT

### 3.1 Financial risk factors

The Group's activities expose it to a variety of financial risks: market risk, credit risk and liquidity risk. The Group's overall risk management programme focuses on the unpredictability of financial markets and seeks to minimise potential adverse effects on the Group's financial performance.

#### *3.1.1 Market risk*

*(a) Foreign exchange risk*

Foreign exchange risk arises when future commercial transactions or recognised assets and liabilities are denominated in a currency that is not the Group entities' functional currency.

The Group manages its foreign exchange risk by performing regular reviews of the Group's net foreign exchange exposures. The Group does not hedge against any fluctuation in foreign currency during the Track Record Period. The Group's subsidiaries in PRC are exposed to foreign exchange risk arising from recognised financial assets and liabilities denominated in United States dollars ("USD").

As at 31 December 2019 and 2020 and 31 August 2021, if the USD strengthened/weakened by 5% against the RMB with all other variables held constant, loss before income tax for the year/period would have been approximately RMB2,000 lower/higher, RMB2,000 lower/higher and RMB6,724,000 lower/higher, respectively.

*(b) Cash flow and fair value interest rate risk*

The Group's main interest rate risk arises from long-term borrowings with variable rates, which expose the Group to cash flow interest rate risk. Generally, the Group enters into long-term borrowings at floating rates and swaps them into fixed rates that are lower than those available if the Group borrowed at fixed rates directly. For the years ended 31 December 2019 and 2020 and eight months ended 31 August 2020 and 2021, the Group has no interest rate swap arrangements.

A 10 basis points increase or decrease represents management's assessment of the reasonably possible change in interest rates. If interest rates had been 10 basis points higher and all other variables were held constant, the Group's loss before income tax would approximately increase by RMB1,000, RMB6,000, RMB4,000 and RMB5,000 for the years ended 31 December 2019 and 2020 and eight months ended 31 August 2020 and 2021, respectively.

#### *3.1.2 Credit risk*

*(a) Risk management*

Credit risk is managed on a group basis.

The Group is exposed to credit risk primarily in relation to its cash and cash equivalents, term deposits with initial terms of over three months, financial assets at FVPL, as well as other receivables and deposits. The carrying amount of each class of the above financial assets represents the Group's maximum exposure to credit risk in relation to the corresponding class of financial assets.

To manage credit risk, cash and cash equivalents and term deposits with initial terms of over three months are mainly placed with state-owned or reputable financial institutions in the PRC and reputable financial institutions outside of the PRC. There has been no recent history of default in relation to these financial institutions. Thus, the directors of the Company were of the view the credit risk related to cash and cash equivalents was insignificant.


Shanghai Miracogen Inc.- Ex. 2032, Page 000634

*(b) Impairment of financial assets*

Other financial assets at amortised cost

Other financial assets at amortised cost mainly include other receivables and deposits. The Group considers the probability of default upon initial recognition of other receivables and whether there has been a significant increase in credit risk on an ongoing basis throughout each reporting period. To assess whether there is a significant increase in credit risk, the Group compares the risk of a default on other receivables as at the reporting date with the risk of default as at the date of initial recognition. It considers available reasonable and supportive forward-looking information. Especially the following indicators are incorporated:

- actual or expected significant adverse changes in business, financial or economic conditions that are expected to cause a significant change to the debtors' ability to meet its obligations;
- actual or expected significant changes in the operating results of the debtors;
- significant increases in credit risk on other financial instruments of the same debtors; or
- significant changes in the expected performance and behaviour of the debtors, including changes in the payments status of debtors, etc.

For the other receivables and deposits, management applies 3-stages model to assess the expected credit loss. Management makes periodic collective assessments as well as individual assessment on the recoverability of other receivables based on historical settlement records and past experience.

In view of the history of cooperation with the debtors and collection from them, the management of the Group believes that the credit risk inherent in the Group's outstanding other receivables is not significant. The expected credit loss rate of other receivables as at the 31 December 2019 and 2020 and 31 August 2021 were 3.08%, 3.96% and 2.51% respectively.

The loss allowance for other financial assets at amortised cost as at 31 December 2019 and 2020 and 31 August 2020 and 2021 reconciles to the opening loss allowance as follows:

| | **Other receivables and deposits** *RMB'000* |
|---|---|
| Opening loss allowance at 1 January 2019 | 80 |
| Increase in the allowance recognised in profit or loss during the year | 372 |
| **Closing loss allowance as at 31 December 2019** | **452** |
| Opening loss allowance as at 1 January 2020 | 452 |
| Increase in the allowance recognised in profit or loss during the year | 212 |
| **Closing loss allowance as at 31 December 2020** | **664** |
| Opening loss allowance as at 1 January 2020 | 452 |
| Decrease in the allowance recognised in profit or loss during the period | 407 |
| **Closing loss allowance as at 31 August 2020 (Unaudited)** | **859** |
| Opening loss allowance as at 1 January 2021 | 664 |
| Decrease in the allowance recognised in profit or loss during the period | (207) |
| **Closing loss allowance as at 31 August 2021** | **457** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000635

*3.1.3 Liquidity Risk*

The Group aims to maintain sufficient cash and cash equivalents to meet operating capital requirements.

The table below analyses the Group's financial liabilities into relevant maturity groupings based on the remaining period at the balance sheet date to the contractual maturity date. The amounts disclosed in the table are the contractual undiscounted cash flows.

| | Less than 1 year | Between 1 and 2 years | Between 2 and 5 years | Over 5 years | Total |
|---|---|---|---|---|---|
| | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* |
| **At 31 December 2019** | | | | | |
| Borrowings | 5,430 | 5,415 | 101,870 | 28,870 | 141,585 |
| Trade payables | 31,684 | – | – | – | 31,684 |
| Other payables and accruals excluding non-financial liabilities | 368,589 | – | – | – | 368,589 |
| Lease liabilities | 28,298 | 17,649 | 37,195 | – | 83,142 |
| | **434,001** | **23,064** | **139,065** | **28,870** | **625,000** |
| **At 31 December 2020** | | | | | |
| Borrowings | 6,679 | 26,420 | 138,479 | – | 171,578 |
| Trade payables | 42,448 | – | – | – | 42,448 |
| Other payables and accruals excluding non-financial liabilities | 301,797 | – | – | – | 301,797 |
| Lease liabilities | 19,022 | 16,206 | 21,099 | – | 56,327 |
| | **369,946** | **42,626** | **159,578** | **–** | **572,150** |
| **At 31 August 2021** | | | | | |
| Borrowings | 44,543 | 32,071 | 154,364 | – | 230,978 |
| Trade payables | 84,560 | – | – | – | 84,560 |
| Other payables and accruals excluding non-financial liabilities | 127,915 | 150,000 | – | – | 277,915 |
| Lease liabilities | 19,257 | 19,019 | 6,566 | – | 44,842 |
| | **276,275** | **201,090** | **160,930** | **–** | **638,295** |

As at 31 December 2019, the convertible loans and the financial instruments with preferred rights at amortised cost as described in Note 34 of approximately RMB380,620,000 and RMB397,489,000 respectively, were not managed by maturing date and were all reclassified to equity in 2020.

Variable consideration as described in Note 31 was recognised as financial liabilities at FVPL which are managed on a fair value basis and no contractual maturity date is applicable.

**3.2 Capital risk management**

The Group monitors capital (including shares, convertible loans and borrowings) by regularly reviewing the capital structure. The Group's objectives when managing capital are to safeguard the Group's ability to continue as a going concern in order to provide returns for shareholders and benefits for other stakeholders and to maintain an optimal capital structure to reduce the costs of capital.

In order to maintain or adjust the capital structure, the Group may issue new shares or sell assets to reduce debt.



Shanghai Miracogen Inc.- Ex. 2032, Page 000636

The Group monitors its capital structure on the basis of liability-to-asset ratio, which is calculated as total liabilities divided by total assets. The liability-to-asset ratio of the Group as at 31 December 2019 and 2020 and 31 August 2021 was as follows:

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| The liability-to-asset ratio | 112% | 38% | 47% |

There were no changes in the Group's approach to capital management during the Track Record Period.

Neither the Company nor any of its subsidiaries are subject to externally imposed capital requirements.

**3.3 Fair value estimation**

This section explains the judgements and estimates made in determining the fair values of the financial instruments that are recognised and measured at fair value in the consolidated financial statements. To provide an indication about the reliability of the inputs used in determining fair value, the Group has classified its financial instruments into the three levels prescribed under the accounting standards.

Level 1: The fair value of financial instruments traded in active markets (such as publicly traded derivatives, and equity securities) is based on quoted market prices at the end of the reporting period. The quoted market price used for financial assets held by the Group is the current bid price. These instruments are included in level 1.

Level 2: The fair value of financial instruments that are not traded in an active market (for example, over-the-counter derivatives) is determined using valuation techniques which maximise the use of observable market data and rely as little as possible on entity-specific estimates. If all significant inputs required to fair value an instrument are observable, the instrument is included in level 2.

Level 3: If one or more of the significant inputs is not based on observable market data, the instrument is included in level 3. This is the case for unlisted equity securities.

Specific valuation techniques used to value financial instruments include:

- the use of quoted market prices or dealer quotes for similar instruments, and
- for other financial instruments – discounted cash flow analysis.

The following table presents the Group's assets and liabilities that were measured at fair value at 31 December 2019 and 2020 and 31 August 2021.

| | Level 1 | Level 2 | Level 3 | Total |
|---|---|---|---|---|
| | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* |
| At 31 December 2019 | | | | |
| **Liabilities** | | | | |
| Financial liabilities at fair value through profit or loss *(Note 31)* | – | – | 279,081 | 279,081 |
| Convertible loans *(Note 34)* | – | – | 380,620 | 380,620 |
| | **–** | **–** | **659,701** | **659,701** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000637

| | Level 1 *RMB'000* | Level 2 *RMB'000* | Level 3 *RMB'000* | Total *RMB'000* |
|---|---|---|---|---|
| At 31 December 2020 | | | | |
| **Assets** | | | | |
| Financial assets at fair value through profit or loss *(Note 20)* | – | – | 330,657 | 330,657 |
| **Liabilities** | | | | |
| Financial liabilities at fair value through profit or loss *(Note 31)* | – | – | 309,181 | 309,181 |
| | **–** | **–** | **639,838** | **639,838** |
| At 31 August 2021 | | | | |
| **Assets** | | | | |
| Financial assets at fair value through profit or loss *(Note 20)* | – | – | 132,724 | 132,724 |
| **Liabilities** | | | | |
| Financial liabilities at fair value through profit or loss *(Note 31)* | – | – | 357,339 | 357,339 |
| | **–** | **–** | **490,063** | **490,063** |

There were no transfers between levels 1, 2 and 3 for recurring fair value measurements during the Track Record Period.

***Financial assets at fair value through profit or loss in Level 3***

| | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|
| | **2019** *RMB'000* | **2020** *RMB'000* | **2020** *RMB'000* (Unaudited) | **2021** *RMB'000* |
| Opening balance | – | – | – | 330,657 |
| Additions | 509,500 | 1,657,610 | 735,610 | 944,000 |
| Settlements | (511,535) | (1,332,701) | (231,799) | (1,146,338) |
| Gains recognised in profit or loss | 2,035 | 5,748 | 1,023 | 4,405 |
| Closing balance | **–** | **330,657** | **504,834** | **132,724** |
| Net unrealized gains for the year | **–** | 657 | 334 | 724 |

The Group entered into contracts in respect of structured deposits from banks with expected but not guaranteed rates of return ranging from 1.6% to 2.85%, from 1.4% to 3.37%, from 1.5% to 3.05% and from 1.1% to 3.40%, respectively per annum for the years ended 31 December 2019 and 2020 and eight months ended 31 August 2020 and 2021. The Group managed and evaluated the performance of these investments on a fair value basis, in accordance with the Group's risk management and investment strategy and hence they are designated as financial assets at fair value through profit or loss. If the expected rate of return of investments in structured deposits held by the Group had been 10% higher/lower as at 31 December 2019, 31 December 2020, 31 August 2020 and 31 August 2021 respectively, loss before tax for the years ended 31 December 2019 and 2020 and eight months ended 31 August 2020 and 2021 would have been nil, approximately RMB45,000 lower/higher, RMB44,000 lower/higher and RMB36,000 lower/higher.



Shanghai Miracogen Inc.- Ex. 2032, Page 000638

***Financial liabilities at fair value through profit or loss in Level 3***

Financial liabilities at fair value through profit or loss including: (i) the variable consideration of acquisition for 40% equity interests of Taizhou Hanzhong Biotechnology Co., Ltd. ("Taizhou Hanzhong") from non-controlling interest; and (ii) the convertible loans issued to the series A investors before it converted into equity in April 2020.

(i) Variable consideration on acquisition of non-controlling interests was valued by the management of the Company with reference to valuation reports carried out by an independent qualified professional valuer. The Company used discounted cash flow method covering the forecasted periods ending 31 December 2029 to determine the fair value of the variable consideration. The management considers the length of forecast period is appropriate because it generally takes longer for the a biopharma company to reach a perpetual growth mode, compared to companies in other industries, especially when recombinant humanized anti-PD-1 monoclonal antibody for injection ("PD-1") products are still under clinical trial and the market of such product is at an early stage of development with substantial growth potential. Hence, the management believes that a forecasted period longer than five years is feasible and consistent with industry practice. Key assumptions of valuation are as follows:

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| The first commercialisation year of PD-1 products | 2022 | 2022 | 2022 |
| Expected revenue growth rate during the forecast period from second year of commercialisation | 390%-6% | 390%-6% | 388%-6% |
| Expected revenue growth rate beyond the forecast period | 3%-0% | 3%-0% | 3%-0% |
| Expected market penetration rate | 0%-19% | 0%-19% | 0%-19% |
| Expected success rate of commercialisation | 14%-64% | 47%-73% | 47%-85% |
| Discount rate | 15.5% | 15.5% | 15.4% |

Should the discount rate used in discounted cash flow method be higher/lower by one point of percentage from management's estimates, the estimated fair value of financial liabilities at fair value through profit or loss as at 31 December 2019 and 2020 and 31 August 2021 would have been approximately RMB28,469,000 lower/RMB33,224,000 higher, RMB29,266,000 lower/RMB33,967,000 higher and RMB32,070,000 lower/RMB37,120,000 higher, respectively.

The changes and valuations of variable consideration on acquisition of non-controlling interests for the years ended 31 December 2019 and 2020 and eight months ended 31 August 2020 and 2021 are presented in Note 31.

(ii) Back-solve method was used to determine the share value of the Company and an equity allocation based on Option Pricing Model ("OPM model") is performed to arrive the fair value of the convertible loans on initial date. The key inputs were as follows:

| | Key assumptions |
|---|---|
| Risk-free interest rate | 2.88% |
| Volatility | 45% |
| Dividend yield | 0% |
| Lack of marketability discount | 10% |

As at 31 December 2019 and 21 April 2020, the date of conversion of the convertible loans, discounted cash flow method was used to determine the share value of the Company, the cash flow forecast of the entire Group covering the periods ending 31 December 2029 and OPM model was further used to determine the fair value of the convertible loans. The management considers the length of forecast period is appropriate because it generally takes longer for the a biopharma company to reach a perpetual growth mode, compared to companies in other industries, especially when its product is still under



Shanghai Miracogen Inc.- Ex. 2032, Page 000639

clinical trial and the market of such product is at an early stage of development with substantial growth potential. Hence, the management believes that a forecasted period longer than five years is feasible and consistent with industry practice. Key valuation assumptions are as follows:

| | As at 31 December 2019 | As at 21 April 2020 |
|---|---|---|
| The first commercialisation year of pipelines of the Group | 2022 | 2022 |
| Expected revenue growth rate during the forecast period from second year of commercialisation | 512%-6% | 506%-6% |
| Expected revenue growth rate beyond the forecast period | 4%-0% | 3%-0% |
| Expected market penetration rate | 0%-19% | 0%-19% |
| Expected success rate of commercialisation | 11%-64% | 11%-73% |
| Discount rate | 13% | 13% |

The Group performed sensitivity test to changes in the above key valuation assumptions in determining the fair value of the convertible loans. When performing the sensitivity test, the management applied an increase or decrease to each key valuation assumptions, which represents the management's assessment of reasonably possible change to these key valuation assumptions, and effect of those changes to the fair value of convertible loans is as below:

| Key valuation assumptions | Relationship of key valuation assumptions to fair value | Effect *RMB'000* |
|---|---|---|
| Expected revenue growth rate during the forecast period from second year of commercialisation | The higher the revenue growth rate, the higher the fair value | 5% increase/decrease change would result in increase/(decrease) in fair value of 52,242/(47,196) and 57,097/(52,074) as at 31 December 2019 and 21 April 2020, respectively |
| Expected market penetration rate | The higher the expected market penetration rate, the higher the fair value | 5% increase/decrease change would result in increase/(decrease) in fair value of 22,582/(22,380) and 24,074/(23,856) as at 31 December 2019 and 21 April 2020, respectively |
| Expected success rate of commercialisation | The higher the expected success rate of commercialisation, the higher the fair value | 5% increase/decrease change would result in increase/(decrease) in fair value of 22,596/(22,380) and 23,562/(24,144) as at 31 December 2019 and 21 April 2020, respectively |
| Discount rate | The higher the discount rate, the lower the fair value | 1% decrease/increase change would result in increase/(decrease) in fair value of 7,410/(7,231) and 7,570/(7,724) as at 31 December 2019 and 21 April 2020, respectively |

The changes and valuations of convertible loans are presented in Note 34.



Shanghai Miracogen Inc.- Ex. 2032, Page 000640

## 4 CRITICAL ACCOUNTING ESTIMATES AND JUDGEMENTS

The preparation of financial statements requires the use of accounting estimates which, by definition, will seldom equal the actual results. Management also need to exercise judgement in applying the Group's accounting policies. Estimates and judgements are continually evaluated. They are based on historical experience and other factors, including expectations of future events that may have a financial impact on the entity and that are believed to be reasonable under the circumstances.

### 4.1 Development expenditures

Development expenditures incurred on the Group's development activities, including conducting clinical trials and other activities related to regulatory filings for the Group's drug candidates, are capitalised as intangible assets only when meet the capitalisation criteria set out in Note 2.8.3. Development expenditures that do not meet these capitalisation principles are recognised as research and development expenses. During the Track Record Period, the Group's development expenditures incurred did not meet these capitalisation principles for any products and were expensed as incurred.

### 4.2 Goodwill impairment

The Group tests whether goodwill has suffered any impairment at balance sheet date. The recoverable amount of a cash-generating unit ("CGU") is determined based on value-in-use calculations which require the use of assumptions. The calculations use cash flow forecasts based on financial budgets approved by management covering the forecast period ended 31 December 2029.

Cash flows beyond the forcast period is extrapolated using the growth rates as estimated by management by reference to certain internal and external market data. Details of key assumptions are disclosed in Note 16.

### 4.3 Fair value of financial liabilities at fair value through profit or loss

The Group has recognised the variable consideration of acquisition for 40% interests of Taizhou Hanzhong from non-controlling interests and convertible loans issued to the Series A Investors during the Track Record Period as financial liabilities at FVPL as set out in Note 31 and Note 34, respectively.

The Group evaluates the fair value of the variable consideration periodically using the discounted cash flow method which key assumptions were adopted to determine the fair value of the variable consideration. Further details are disclosed in Note 3.3(i) and Note 39(a).

The convertible loans issued by the Company exhibits the characteristics of an embedded derivative and the Group has designated the entire instruments as a financial liability at FVPL. The fair value of the convertible loans in which no quoted prices in an active market exist is established by using valuation techniques, which include back-solve method, discounted cash flow method and OPM model. Key assumptions were based on the management's best estimates. Further details are disclosed in Note 3.3(ii).

Management's estimates are reviewed periodically and are adjusted if necessary. Should any of the estimates and assumptions changed, it may lead to a change in the fair value to be recognised in the statements of comprehensive loss.

### 4.4 Current and deferred income taxes

There are many transactions and events for which the ultimate tax determination is uncertain during the ordinary course of business. Significant judgment is required from the Group in determining the provision for income taxes. Where the final tax outcome of these matters is different from the amounts that were initially recorded, such differences will impact the income tax and deferred tax provisions in the period in which such determination is made.

The Group recognises deferred income tax assets based on estimates that it is probable to generate sufficient taxable profits in the foreseeable future against which the deductible losses will be utilised. The recognition of deferred income tax assets mainly involved management's judgments and estimations about the timing and the amount of taxable profits of the companies who had tax losses.


Shanghai Miracogen Inc.- Ex. 2032, Page 000641

**4.5 Fair value of restricted share granted under ESOP**

The Group has adopted the ESOP in 2020. The fair value of the restricted shares granted to employees is determined by using back-solve method from the most recent transaction price of the Company's series B financing and equity allocation based on OPM model. Significant estimates on assumptions, such as risk-free interest rate, volatility, dividend yield and lack of marketability discount are made based on management's best estimates. Further details are included in Note 27.

The Group has to estimate the expected forfeiture rate at the end of vesting periods ("Forfeiture Rate") of the restricted shares granted in order to determine the amount of share-based payment expenses charged to the consolidated comprehensive loss. The Forfeiture Rate of the restricted shares awarded of the Group was assessed to be ranged from 21% to 17% as at 31 December 2020 and 31 August 2021.

## 5 SEGMENT

Management has determined the operating segments based on the reports reviewed by CODM. The CODM, who is responsible for allocating resources and assessing performance of the operating segment, has been identified as the executive directors of the Group.

During the Track Record Period, the Group is principally engaged in the research and development of new drugs. Management reviews the operating results of the business as one operating segment to make decisions about resources to be allocated. Therefore, the CODM of the Company regards that there is only one segment which is used to make strategic decisions.

The major operating entity of the Group is domiciled in the PRC. Accordingly, the Group's results were primarily derived in the PRC during the Track Record Period.

## 6 OTHER INCOME

| | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|
| | **2019** | **2020** | **2020** | **2021** |
| | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* |
| | | | (Unaudited) | |
| Government grants | 2,535 | 774 | 479 | 146 |
| Investment income on financial assets at fair value through profit or loss | 2,035 | 5,091 | 689 | 3,681 |
| Rental and related income | 918 | 1,976 | 1,411 | 734 |
| Others | 65 | 123 | 77 | 40 |
| | **5,553** | **7,964** | **2,656** | **4,601** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000642

## 7 EXPENSES BY NATURE

| | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|
| | 2019 | 2020 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* (Unaudited) | *RMB'000* |
| Employee benefit expenses *(Note 8)* | 184,923 | 81,609 | 42,071 | 165,509 |
| Clinical trial expenses | 117,532 | 146,938 | 82,148 | 249,498 |
| Depreciation and amortisation | 49,266 | 84,114 | 56,580 | 63,736 |
| Pre-clinical study costs | 32,541 | 66,905 | 39,558 | 54,530 |
| Raw material and consumables used | 17,979 | 36,148 | 12,055 | 32,818 |
| Utilities | 3,993 | 7,116 | 1,338 | 5,434 |
| Traveling and transportation expenses | 3,254 | 3,448 | 1,714 | 3,466 |
| Professional services fees | 2,428 | 8,165 | 2,490 | 1,775 |
| Office expenses | 1,785 | 3,385 | 2,104 | 3,519 |
| Listing expenses | – | – | – | 27,573 |
| Auditors' remuneration | | | | |
| – Audit services | 94 | – | – | – |
| – Non-audit service | – | – | – | – |
| Others | 7,845 | 12,271 | 7,322 | 10,660 |
| **Total administrative expenses, research and development expenses and other expenses** | **421,640** | **450,099** | **247,380** | **618,518** |

## 8 EMPLOYEE BENEFIT EXPENSES

| | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|
| | 2019 | 2020 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* (Unaudited) | *RMB'000* |
| Wages, salaries and bonuses | 33,260 | 66,043 | 36,289 | 58,727 |
| Pension costs – defined contribution plans *(a)* | 3,292 | 154 | 462 | 8,089 |
| Other social security costs, housing benefits and other employee benefits | 4,676 | 10,188 | 5,320 | 12,889 |
| Share-based payment expenses | 143,695 | 5,224 | – | 85,804 |
| | **184,923** | **81,609** | **42,071** | **165,509** |

**(a)** The employees of the Group in the PRC are members of state-managed pension scheme operated by the PRC government. The Group is required to contribute a specified percentage of payroll costs as determined by local government authority to the pension obligations to fund the benefits. The only obligation of the Group with respect to the retirement benefits scheme is to make the specified contribution under the scheme. The Group did not have any forfeited contribution for the years ended 31 December 2019 and 2020 and eight months ended 31 August 2020 and 2021 in connection with the defined contribution plan operated by local governments.



Shanghai Miracogen Inc.- Ex. 2032, Page 000643

**(b) Employee benefit expenses by function**

Employee benefit expenses were charged to the followings:

| | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|
| | **2019** | **2020** | **2020** | **2021** |
| | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* |
| | | | (Unaudited) | |
| Research and development expenses | 23,711 | 48,214 | 23,046 | 109,556 |
| Administrative expenses | 161,188 | 33,350 | 18,980 | 55,953 |
| Other expenses | 24 | 45 | 45 | – |
| | **184,923** | **81,609** | **42,071** | **165,509** |

**(c) Five highest paid individuals**

The five individuals whose emoluments were the highest in the Group include nil, 2, 2 and 1 directors for the years ended 31 December 2019 and 2020 and eight months ended 31 August 2020 and 2021 respectively. The emoluments payable to the remaining individuals are as follows:

| | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|
| | **2019** | **2020** | **2020** | **2021** |
| | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* |
| | | | (Unaudited) | |
| Wages, salaries and bonuses | 6,761 | 6,103 | 3,069 | 6,572 |
| Pension costs – defined contribution plans *(i)* | 50 | – | – | – |
| Other social security costs, housing benefits and other employee benefits *(i)* | 50 | – | – | 320 |
| Share-based payment expenses | – | 1,981 | – | 62,327 |
| | **6,861** | **8,084** | **3,069** | **69,219** |

(i) The remaining 3, 3 and 4 highest paid individuals for the year ended 31 December 2020 and eight months ended 31 August 2020 and 2021 were foreign senior managements, who are not entitled to the Group's defined contribution plans as well as other social security costs, housing benefits.



Shanghai Miracogen Inc.- Ex. 2032, Page 000644

The remaining highest paid individuals fell within the following bands:

| | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|
| | 2019 | 2020 | 2020 | 2021 |
| | | | (Unaudited) | |
| **Emolument bands** | | | | |
| HK$1 to HK$1,000,000 | 1 | – | 1 | – |
| HK$1,000,001 – HK$1,500,000 | 1 | – | 2 | – |
| HK$1,500,001 – HK$2,000,000 | 2 | – | – | – |
| HK$2,000,001 – HK$2,500,000 | 1 | – | – | – |
| HK$2,500,001 – HK$3,000,000 | – | 1 | – | – |
| HK$3,000,001 – HK$3,500,000 | – | 1 | – | – |
| HK$3,500,001 – HK$4,000,000 | – | 1 | – | – |
| HK$13,500,001 – HK$14,000,000 | – | – | – | 1 |
| HK$17,500,001 – HK$18,000,000 | – | – | – | 1 |
| HK$24,000,001 – HK$24,500,000 | – | – | – | 1 |
| HK$27,500,001 – HK$28,000,000 | – | – | – | 1 |
| | **5** | **3** | **3** | **4** |

## 9 FAIR VALUE CHANGES ON FINANCIAL ASSETS AND LIABILITIES AT FAIR VALUE THROUGH PROFIT OR LOSS

| | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|
| | 2019 | 2020 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* |
| | | | (Unaudited) | |
| Fair value losses on financial liabilities at fair value through profit or loss | | | | |
| – FVPL *(Note 31)* | (17,692) | (30,100) | (69,283) | (48,158) |
| – Convertible loans *(Note 34)* | (20,620) | (48,548) | (48,548) | – |
| Fair value gains on financial assets at fair value through profit or loss | – | 657 | 334 | 724 |
| | **(38,312)** | **(77,991)** | **(117,497)** | **(47,434)** |

## 10 OTHER LOSSES, NET

| | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|
| | 2019 | 2020 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* |
| | | | (Unaudited) | |
| Net gains on disposal of property, plant and equipment | 70 | – | – | – |
| Expected credit (losses)/gains | (372) | (212) | (407) | 207 |
| Others | 46 | (13) | (13) | (1,038) |
| | **(256)** | **(225)** | **(420)** | **(831)** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000645

## 11 FINANCE (COSTS)/INCOME, NET

| | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|
| | 2019 | 2020 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* (Unaudited) | *RMB'000* |
| **Finance income:** | | | | |
| Bank interest income | 396 | 5,266 | 1,019 | 3,267 |
| Exchange gain | 1 | 40 | – | – |
| | 397 | 5,306 | 1,019 | 3,267 |
| **Finance costs:** | | | | |
| Interest on financial instruments with preferred rights at amortised cost | (50,035) | (80,852) | (80,852) | – |
| Interest on bank borrowings | (571) | (7,046) | (4,478) | (4,422) |
| Interest on lease liabilities *(Note 15(a))* | (2,287) | (3,099) | (2,428) | (1,533) |
| Interest on loan from related party | – | (387) | (387) | – |
| Bank charges | (237) | (1,110) | (1,062) | (432) |
| Exchange loss | – | – | – | (985) |
| | (53,130) | (92,494) | (89,207) | (7,372) |
| Amount capitalised *(a)* | 571 | 6,175 | 4,063 | 4,345 |
| **Finance (costs)/income, net** | **(52,162)** | **(81,013)** | **(84,125)** | **240** |

(a) The capitalisation rate used to determine the amount of borrowing costs to be capitalised is the weighted average interest rate applicable to the Group's borrowings for the years ended 31 December 2019 and 2020 and eight months ended 31 August 2020 and 2021 of 4.54%, 4.50%, 4.52% and 4.46%, respectively.

## 12 INCOME TAX EXPENSE

| | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|
| | 2019 | 2020 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* (Unaudited) | *RMB'000* |
| Current income tax expense | – | – | – | – |
| Deferred income tax expense | – | – | – | – |
| | **–** | **–** | **–** | **–** |

The Group's principal applicable taxes and tax rates are as follows:

Shanghai Miracogen Inc. ("Miracogen Shanghai") was qualified as a High and New Technology Enterprise ("HNTE") under the relevant PRC laws and regulations on 18 November 2020. Accordingly, it was entitled to a preferential corporate income tax rate of 15% on its estimated assessable profits for the years ended 31 December 2020 to 2022.

The Company and the Company's other subsidiaries established and operated in Mainland China are subject to the PRC corporate income tax at the rate of 25%.

According to the relevant laws and regulations promulgated by the State Administration of Taxation of the PRC that has been effective from 2018 onwards, enterprise engaging in research and development activities are entitled to claim 175% of their research and development expenses incurred as tax deductible expenses when determining their assessable profits for that year.



Shanghai Miracogen Inc.- Ex. 2032, Page 000646

A reconciliation of the expected income tax calculated at the applicable corporate income tax rate and loss before income tax, with the actual corporate income tax is as follow:

| | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|
| | 2019 | 2020 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* (Unaudited) | *RMB'000* |
| Loss before income tax | (515,492) | (613,448) | (452,156) | (668,235) |
| Tax calculated at statutory corporate income tax rates of 25% | (128,873) | (153,362) | (113,039) | (167,059) |
| Tax effect of: | | | | |
| Impact of applying preferential tax rate | – | 14,854 | 7,903 | 21,244 |
| Super deduction for research and development expenses | (17,149) | (34,871) | (15,535) | (32,485) |
| Expenses not deductible for tax purpose | 59,658 | 41,429 | 49,779 | 33,730 |
| Impact on investments using equity method | 2,169 | 3,021 | 1,348 | 1,573 |
| Deductible temporary differences not recognised as deferred tax assets | 10,196 | 22,149 | 14,236 | 16,329 |
| Tax losses not recognised as deferred tax assets | 73,999 | 106,780 | 55,308 | 126,688 |
| **Income tax expense** | **–** | **–** | **–** | **–** |

As at 31 December 2019 and 2020 and 31 August 2021, the Group had unused tax losses of approximately RMB513,512,000, RMB1,023,492,000 and RMB1,596,106,000 respectively that can be carried forward against future taxable income. No deferred tax asset has been recognised in respect of such tax losses due to the unpredictability of future taxable income.

The unused tax losses of the Group were mainly from the subsidiaries incorporated in Mainland China, where the accumulated tax losses will normally expire within 5 years. Pursuant to the relevant regulations on extension for expiries of unused tax losses of HNTE and Small and Medium-sized Technological Enterprises issued in August 2018, the accumulated tax losses which did not expire from 2018 will have expiries extending from 5 years to 10 years from then on.

## 13 LOSS PER SHARE

Basic loss per share is calculated by dividing the loss of the Group attributable to owners of the Company by weighted average number of ordinary shares issued during the Track Record Period.

| | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|
| | 2019 | 2020 | 2020 | 2021 |
| | | | (Unaudited) | |
| Loss for the year/period and attributable to owners of the Company (in RMB'000) | (447,036) | (581,849) | (427,971) | (656,392) |
| Weighted average number of ordinary shares in issue (in thousands) *(a)* | 648,899 | 1,134,852 | 955,930 | 1,514,667 |
| Basic and diluted loss per share (in RMB) *(b)* | (0.69) | (0.51) | (0.45) | (0.43) |



Shanghai Miracogen Inc.- Ex. 2032, Page 000647

(a) The weighted average number of ordinary shares in issue before the conversion into a joint stock company was determined assuming the paid-in capital had been fully converted into share capital at the same conversion ratio of 1:1 as upon conversion into joint stock company in December 2020.

(b) Diluted loss per share is calculated by adjusting the weighted average number of ordinary shares outstanding to assume conversion of all dilutive potential ordinary shares. For the years ended 31 December 2019 and 2020 and eight months ended 31 August 2020, the Company had the convertible loans and financial instruments with preferred rights at amortised cost which are potential ordinary shares. As the Group incurred losses for the years ended 31 December 2019 and 2020 and eight months ended 31 August 2020, the potential ordinary shares were not included in the calculation of diluted loss per share as their inclusion would be anti-dilutive. For eight months ended 31 August 2021, the Company had no potential ordinary share. Accordingly, diluted loss per share for the years ended 31 December 2019 and 2020 and eight months ended 31 August 2020 and 2021 are the same as basic loss per share of the respective years.

## 14 PROPERTY, PLANT AND EQUIPMENT

**The Group**

| | Equipment and instruments *RMB'000* | Office equipment and furniture *RMB'000* | Motor vehicles *RMB'000* | Leasehold improvements and antibody purification resin *RMB'000* | Construction-in-progress *RMB'000* | Total *RMB'000* |
|---|---|---|---|---|---|---|
| **At 1 January 2019** | | | | | | |
| Cost | 27,411 | 2,172 | 935 | 5,100 | 39,649 | 75,267 |
| Accumulated depreciation | (1,102) | (33) | (64) | (250) | – | (1,449) |
| **Net book amount** | **26,309** | **2,139** | **871** | **4,850** | **39,649** | **73,818** |
| **Year ended 31 December 2019** | | | | | | |
| Opening net book amount | 26,309 | 2,139 | 871 | 4,850 | 39,649 | 73,818 |
| Additions | 7,082 | 4,766 | 16 | 14,613 | 240,857 | 267,334 |
| Transfer upon completion | 63,456 | – | – | 45,635 | (109,091) | – |
| Disposals | – | (701) | – | – | – | (701) |
| Depreciation charge | (4,549) | (705) | (131) | (3,956) | – | (9,341) |
| **Closing net book amount** | **92,298** | **5,499** | **756** | **61,142** | **171,415** | **331,110** |
| **At 31 December 2019** | | | | | | |
| Cost | 97,949 | 6,187 | 951 | 65,348 | 171,415 | 341,850 |
| Accumulated depreciation | (5,651) | (688) | (195) | (4,206) | – | (10,740) |
| **Net book amount** | **92,298** | **5,499** | **756** | **61,142** | **171,415** | **331,110** |
| **At 1 January 2020** | | | | | | |
| Cost | 97,949 | 6,187 | 951 | 65,348 | 171,415 | 341,850 |
| Accumulated depreciation | (5,651) | (688) | (195) | (4,206) | – | (10,740) |
| **Net book amount** | **92,298** | **5,499** | **756** | **61,142** | **171,415** | **331,110** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000648

| | Equipment and instruments *RMB'000* | Office equipment and furniture *RMB'000* | Motor vehicles *RMB'000* | Leasehold improvements and antibody purification resin *RMB'000* | Construction-in-progress *RMB'000* | Total *RMB'000* |
|---|---|---|---|---|---|---|
| **Year ended 31 December 2020** | | | | | | |
| Opening net book amount | 92,298 | 5,499 | 756 | 61,142 | 171,415 | 331,110 |
| Additions | 11,334 | 11,475 | – | 532 | 287,057 | 310,398 |
| Transfer upon completion | 47,974 | – | – | 23,520 | (71,494) | – |
| Depreciation charge | (11,292) | (2,478) | (135) | (21,232) | – | (35,137) |
| **Closing net book amount** | **140,314** | **14,496** | **621** | **63,962** | **386,978** | **606,371** |
| **At 31 December 2020** | | | | | | |
| Cost | 157,257 | 17,662 | 951 | 89,400 | 386,978 | 652,248 |
| Accumulated depreciation | (16,943) | (3,166) | (330) | (25,438) | – | (45,877) |
| **Net book amount** | **140,314** | **14,496** | **621** | **63,962** | **386,978** | **606,371** |
| **At 1 January 2021** | | | | | | |
| Cost | 157,257 | 17,662 | 951 | 89,400 | 386,978 | 652,248 |
| Accumulated depreciation | (16,943) | (3,166) | (330) | (25,438) | – | (45,877) |
| **Net book amount** | **140,314** | **14,496** | **621** | **63,962** | **386,978** | **606,371** |
| **Eight months ended 31 August 2021** | | | | | | |
| Opening net book amount | 140,314 | 14,496 | 621 | 63,962 | 386,978 | 606,371 |
| Additions | 5,652 | 2,110 | – | 12,037 | 131,701 | 151,500 |
| Transfer upon completion | 9,583 | – | – | 1,118 | (10,701) | – |
| Depreciation charge | (10,987) | (3,072) | (91) | (17,902) | – | (32,052) |
| **Closing net book amount** | **144,562** | **13,534** | **530** | **59,215** | **507,978** | **725,819** |
| **At 31 August 2021** | | | | | | |
| Cost | 172,492 | 19,772 | 951 | 102,555 | 507,978 | 803,748 |
| Accumulated depreciation | (27,930) | (6,238) | (421) | (43,340) | – | (77,929) |
| **Net book amount** | **144,562** | **13,534** | **530** | **59,215** | **507,978** | **725,819** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000649

**The Company**

| | Equipment and instruments *RMB'000* | Office equipment and furniture *RMB'000* | Leasehold improvements and antibody purification resin *RMB'000* | Construction-in-progress *RMB'000* | Total *RMB'000* |
|---|---|---|---|---|---|
| **At 1 January 2019** | | | | | |
| Cost | – | 34 | – | 23,515 | 23,549 |
| Accumulated depreciation | – | (1) | – | – | (1) |
| **Net book amount** | **–** | **33** | **–** | **23,515** | **23,548** |
| **Year ended 31 December 2019** | | | | | |
| Opening net book amount | – | 33 | – | 23,515 | 23,548 |
| Additions | – | 403 | 45 | 140,039 | 140,487 |
| Transfer upon completion | 4,128 | – | – | (4,128) | – |
| Depreciation charge | (33) | (68) | – | – | (101) |
| **Closing net book amount** | **4,095** | **368** | **45** | **159,426** | **163,934** |
| **At 31 December 2019** | | | | | |
| Cost | 4,128 | 437 | 45 | 159,426 | 164,036 |
| Accumulated depreciation | (33) | (69) | – | – | (102) |
| **Net book amount** | **4,095** | **368** | **45** | **159,426** | **163,934** |

| | Equipment and instruments *RMB'000* | Office equipment and furniture *RMB'000* | Leasehold improvements and antibody purification resin *RMB'000* | Construction-in-progress *RMB'000* | Total *RMB'000* |
|---|---|---|---|---|---|
| **At 1 January 2020** | | | | | |
| Cost | 4,128 | 437 | 45 | 159,426 | 164,036 |
| Accumulated depreciation | (33) | (69) | – | – | (102) |
| **Net book amount** | **4,095** | **368** | **45** | **159,426** | **163,934** |
| **Year ended 31 December 2020** | | | | | |
| Opening net book amount | 4,095 | 368 | 45 | 159,426 | 163,934 |
| Additions | – | 260 | 39 | 215,472 | 215,771 |
| Transfer upon completion | 2,778 | – | – | (2,778) | – |
| Depreciation charge | (515) | (121) | (27) | – | (663) |
| **Closing net book amount** | **6,358** | **507** | **57** | **372,120** | **379,042** |
| **At 31 December 2020** | | | | | |
| Cost | 6,906 | 697 | 84 | 372,120 | 379,807 |
| Accumulated depreciation | (548) | (190) | (27) | – | (765) |
| **Net book amount** | **6,358** | **507** | **57** | **372,120** | **379,042** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000650

| | Equipment and instruments *RMB'000* | Office equipment and furniture *RMB'000* | Leasehold improvements and antibody purification resin *RMB'000* | Construction-in-progress *RMB'000* | Total *RMB'000* |
|---|---|---|---|---|---|
| **At 1 January 2021** | | | | | |
| Cost | 6,906 | 697 | 84 | 372,120 | 379,807 |
| Accumulated depreciation | (548) | (190) | (27) | – | (765) |
| **Net book amount** | **6,358** | **507** | **57** | **372,120** | **379,042** |
| **Eight months ended 31 August 2021** | | | | | |
| Opening net book amount | 6,358 | 507 | 57 | 372,120 | 379,042 |
| Additions | – | 517 | 265 | 128,537 | 129,319 |
| Depreciation charge | (438) | (144) | (25) | – | (607) |
| **Closing net book amount** | **5,920** | **880** | **297** | **500,657** | **507,754** |
| **At 31 August 2021** | | | | | |
| Cost | 6,906 | 1,214 | 349 | 500,657 | 509,126 |
| Accumulated depreciation | (986) | (334) | (52) | – | (1,372) |
| **Net book amount** | **5,920** | **880** | **297** | **500,657** | **507,754** |

(a) Depreciation of property, plant and equipment has been charged to the consolidated statements of comprehensive loss as follows:

| | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|
| | 2019 *RMB'000* | 2020 *RMB'000* | 2020 *RMB'000* (Unaudited) | 2021 *RMB'000* |
| Administrative expenses | 4,309 | 21,276 | 15,873 | 8,797 |
| Research and development expenses | 5,032 | 13,861 | 7,685 | 23,255 |
| Total | **9,341** | **35,137** | **23,558** | **32,052** |

(b) The addition in construction-in-progress for the years ended 31 December 2019 and 2020 and eight months ended 31 August 2020 and 2021 included the finance costs capitalised amounted to approximately RMB571,000, RMB6,175,000, RMB4,063,000 and RMB4,345,000, respectively (Note 11).

(c) As at 31 December 2019, certain plant under construction located in Shanghai ("Shanghai Biological Park") with the carrying amounts of approximately RMB158,495,000 were pledged to bank as the security for the long-term bank borrowings of RMB118,266,000 (Note 28).

As at 31 December 2020, Shanghai Biological Park with the carrying amounts of approximately RMB323,768,000 were pledged to bank as the security for the long-term bank borrowings of RMB147,266,000 (Note 28).

As at 31 August 2021, Shanghai Biological Park with the carrying amounts of approximately RMB440,289,000 were pledged to bank as the security for the long-term bank borrowings of RMB178,064,000 (Note 28).



Shanghai Miracogen Inc.- Ex. 2032, Page 000651

**15 LEASES**

**(a) Right-of-use assets**

**The Group**

| | Land use rights *RMB'000* | Leased equipment *RMB'000* | Leased properties *RMB'000* | Total *RMB'000* |
|---|---|---|---|---|
| **At 1 January 2019** | | | | |
| Cost | 74,206 | – | 40,458 | 114,664 |
| Accumulated depreciation | (1,510) | – | (1,530) | (3,040) |
| **Net book amount** | **72,696** | **–** | **38,928** | **111,624** |
| **Year ended 31 December 2019** | | | | |
| Opening net book amount | 72,696 | – | 38,928 | 111,624 |
| Additions | – | 4,402 | 31,541 | 35,943 |
| Depreciation charge | (3,713) | (1,693) | (11,440) | (16,846) |
| **Closing net book amount** | **68,983** | **2,709** | **59,029** | **130,721** |
| **At 31 December 2019** | | | | |
| Cost | 74,206 | 4,402 | 71,999 | 150,607 |
| Accumulated depreciation | (5,223) | (1,693) | (12,970) | (19,886) |
| **Net book amount** | **68,983** | **2,709** | **59,029** | **130,721** |
| **At 1 January 2020** | | | | |
| Cost | 74,206 | 4,402 | 71,999 | 150,607 |
| Accumulated depreciation | (5,223) | (1,693) | (12,970) | (19,886) |
| **Net book amount** | **68,983** | **2,709** | **59,029** | **130,721** |
| **Year ended 31 December 2020** | | | | |
| Opening net book amount | 68,983 | 2,709 | 59,029 | 130,721 |
| Additions | 54,611 | – | 2,473 | 57,084 |
| Depreciation charge | (5,292) | (2,709) | (16,138) | (24,139) |
| **Closing net book amount** | **118,302** | **–** | **45,364** | **163,666** |
| **At 31 December 2020** | | | | |
| Cost | 128,817 | 4,402 | 74,472 | 207,691 |
| Accumulated depreciation | (10,515) | (4,402) | (29,108) | (44,025) |
| **Net book amount** | **118,302** | **–** | **45,364** | **163,666** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000652

| | Land use rights *RMB'000* | Leased equipment *RMB'000* | Leased properties *RMB'000* | Total *RMB'000* |
|---|---|---|---|---|
| **At 1 January 2021** | | | | |
| Cost | 128,817 | 4,402 | 74,472 | 207,691 |
| Accumulated depreciation | (10,515) | (4,402) | (29,108) | (44,025) |
| **Net book amount** | **118,302** | **–** | **45,364** | **163,666** |
| **Eight months ended 31 August 2021** | | | | |
| Opening net book amount | 118,302 | – | 45,364 | 163,666 |
| Additions | – | – | 1,341 | 1,341 |
| Depreciation charge | (4,296) | – | (11,111) | (15,407) |
| **Closing net book amount** | **114,006** | **–** | **35,594** | **149,600** |
| **At 31 August 2021** | | | | |
| Cost | 128,817 | 4,402 | 75,813 | 209,032 |
| Accumulated depreciation | (14,811) | (4,402) | (40,219) | (59,432) |
| **Net book amount** | **114,006** | **–** | **35,594** | **149,600** |

**The Company**

| | Land use rights *RMB'000* | Leased properties *RMB'000* | Total *RMB'000* |
|---|---|---|---|
| **At 1 January 2019** | | | |
| Cost | 74,206 | – | 74,206 |
| Accumulated depreciation | (1,510) | – | (1,510) |
| **Net book amount** | **72,696** | **–** | **72,696** |
| **Year ended 31 December 2019** | | | |
| Opening net book amount | 72,696 | – | 72,696 |
| Additions | – | 2,560 | 2,560 |
| Depreciation charge | (3,713) | (383) | (4,096) |
| **Closing net book amount** | **68,983** | **2,177** | **71,160** |
| **At 31 December 2019** | | | |
| Cost | 74,206 | 2,560 | 76,766 |
| Accumulated depreciation | (5,223) | (383) | (5,606) |
| **Net book amount** | **68,983** | **2,177** | **71,160** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000653

| | Land use rights *RMB'000* | Leased properties *RMB'000* | Total *RMB'000* |
|---|---|---|---|
| **At 1 January 2020** | | | |
| Cost | 74,206 | 2,560 | 76,766 |
| Accumulated depreciation | (5,223) | (383) | (5,606) |
| **Net book amount** | **68,983** | **2,177** | **71,160** |
| **Year ended 31 December 2020** | | | |
| Opening net book amount | 68,983 | 2,177 | 71,160 |
| Additions | 54,611 | – | 54,611 |
| Depreciation charge | (5,292) | (513) | (5,805) |
| **Closing net book amount** | **118,302** | **1,664** | **119,966** |
| **At 31 December 2020** | | | |
| Cost | 128,817 | 2,560 | 131,377 |
| Accumulated depreciation | (10,515) | (896) | (11,411) |
| **Net book amount** | **118,302** | **1,664** | **119,966** |
| **At 1 January 2021** | | | |
| Cost | 128,817 | 2,560 | 131,377 |
| Accumulated depreciation | (10,515) | (896) | (11,411) |
| **Net book amount** | **118,302** | **1,664** | **119,966** |
| **Eight months ended 31 August 2021** | | | |
| Opening net book amount | 118,302 | 1,664 | 119,966 |
| Additions | – | 1,341 | 1,341 |
| Depreciation charge | (4,296) | (620) | (4,916) |
| **Closing net book amount** | **114,006** | **2,385** | **116,391** |
| **At 31 August 2021** | | | |
| Cost | 128,817 | 3,901 | 132,718 |
| Accumulated depreciation | (14,811) | (1,516) | (16,327) |
| **Net book amount** | **114,006** | **2,385** | **116,391** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000654

Depreciation charges have been expensed in the consolidated statements of comprehensive loss as follows:

| | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|
| | **2019** | **2020** | **2020** | **2021** |
| | *RMB'000* | *RMB'000* | *RMB'000* (Unaudited) | *RMB'000* |
| Depreciation charge of right-of-use assets | | | | |
| – Land use rights *(i)* | – | 1,579 | 677 | 1,369 |
| – Leased properties | 11,440 | 16,138 | 12,077 | 11,111 |
| – Leased equipment | 1,693 | 2,709 | 2,709 | – |
| | **13,133** | **20,426** | **15,463** | **12,480** |
| Interest costs included in finance costs *(Note 11)* | 2,287 | 3,099 | 2,428 | 1,533 |
| Expenses relating to short-term leases (included in research and development expenses and administrative expenses) | 432 | 645 | 430 | 731 |
| Expenses relating to leases of low-value assets that are not shown above as short-term leases (included in administrative expenses) | 6 | 4 | 3 | 7 |

(i) For the years ended 31 December 2019 and 2020 and eight months ended 31 August 2020 and 2021, depreciation charge of land use rights approximately RMB3,713,000, RMB3,713,000, RMB2,475,000 and RMB2,927,000, respectively, were capitalised into construction-in-progress.

(ii) For the years ended 31 December 2019 and 2020 and eight months ended 31 August 2020 and 2021, the total cash outflow for leases was approximately RMB1,807,000, RMB29,388,000, RMB23,534,000 and RMB15,428,000, respectively.

**(b)** As at 31 December 2019, land use rights with the carrying amounts of approximately RMB68,983,000 were pledged to bank as the security for the long-term bank borrowings of RMB118,266,000 (Note 28).

As at 31 December 2020, land use rights with the carrying amounts of approximately RMB65,271,000 were pledged to bank as the security for the long-term bank borrowings of RMB147,266,000 (Note 28).

As at 31 August 2021, land use rights with the carrying amounts of approximately RMB62,796,000 were pledged to bank as the security for the long-term bank borrowings of RMB178,064,000 (Note 28).



Shanghai Miracogen Inc.- Ex. 2032, Page 000655

**(c) Lease liabilities**

Lease liabilities recognised in the consolidated balance sheets:

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| Lease liabilities | | | |
| – non-current | 48,251 | 33,534 | 23,259 |
| – current | 27,565 | 18,466 | 16,188 |
| Total | **75,816** | **52,000** | **39,447** |

The table below analyses the Group's lease liabilities into relevant maturity groups based on the remaining period at the balance sheet date to the contractual maturity date. The accounts disclosed in the table are the discounted cash flows.

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| Less than 1 year | 27,565 | 18,466 | 16,188 |
| Between 1 and 2 years | 16,363 | 15,035 | 17,527 |
| Between 2 and 5 years | 31,888 | 18,499 | 5,732 |
| Total | **75,816** | **52,000** | **39,447** |

**16 INTANGIBLE ASSETS**

**The Group**

| | Goodwill | Intellectual properties | Total |
|---|---|---|---|
| | *RMB'000* | *RMB'000* | *RMB'000* |
| **At 1 January 2019** | | | |
| Cost | 52,636 | 325,439 | 378,075 |
| Accumulated amortisation | – | (9,163) | (9,163) |
| **Net book amount** | **52,636** | **316,276** | **368,912** |
| **Year ended 31 December 2019** | | | |
| Opening net book amount | 52,636 | 316,276 | 368,912 |
| Additions | – | 45,363 | 45,363 |
| Business combination under common control *(Note 35)* | – | 129,850 | 129,850 |
| Amortisation charge | – | (26,792) | (26,792) |
| **Closing net book amount** | **52,636** | **464,697** | **517,333** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000656

| | Goodwill | Intellectual properties | Total |
|---|---|---|---|
| | *RMB'000* | *RMB'000* | *RMB'000* |
| **At 31 December 2019** | | | |
| Cost | 52,636 | 500,652 | 553,288 |
| Accumulated amortisation | – | (35,955) | (35,955) |
| **Net book amount** | **52,636** | **464,697** | **517,333** |
| **At 1 January 2020** | | | |
| Cost | 52,636 | 500,652 | 553,288 |
| Accumulated amortisation | – | (35,955) | (35,955) |
| **Net book amount** | **52,636** | **464,697** | **517,333** |
| **Year ended 31 December 2020** | | | |
| Opening net book amount | 52,636 | 464,697 | 517,333 |
| Additions | – | 9,140 | 9,140 |
| Amortisation charge | – | (28,551) | (28,551) |
| **Closing net book amount** | **52,636** | **445,286** | **497,922** |
| **At 31 December 2020** | | | |
| Cost | 52,636 | 509,792 | 562,428 |
| Accumulated amortisation | – | (64,506) | (64,506) |
| **Net book amount** | **52,636** | **445,286** | **497,922** |
| **At 1 January 2021** | | | |
| Cost | 52,636 | 509,792 | 562,428 |
| Accumulated amortisation | – | (64,506) | (64,506) |
| **Net book amount** | **52,636** | **445,286** | **497,922** |
| **Eight months ended 31 August 2021** | | | |
| Opening net book amount | 52,636 | 445,286 | 497,922 |
| Additions | – | 943 | 943 |
| Amortisation charge | – | (19,203) | (19,203) |
| **Closing net book amount** | **52,636** | **427,026** | **479,662** |
| **At 31 August 2021** | | | |
| Cost | 52,636 | 510,735 | 563,371 |
| Accumulated amortisation | – | (83,709) | (83,709) |
| **Net book amount** | **52,636** | **427,026** | **479,662** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000657

**The Company**

| | Intellectual properties *RMB'000* |
|---|---|
| **At 1 January 2019** | |
| Cost | – |
| Accumulated amortisation | – |
| **Net book amount** | **–** |
| **Year ended 31 December 2019** | |
| Opening net book amount | – |
| Additions | 28,526 |
| Amortisation charge | (1,366) |
| **Closing net book amount** | **27,160** |
| **At 31 December 2019** | |
| Cost | 28,526 |
| Accumulated amortisation | (1,366) |
| **Net book amount** | **27,160** |
| **At 1 January 2020** | |
| Cost | 28,526 |
| Accumulated amortisation | (1,366) |
| **Net book amount** | **27,160** |
| **Year ended 31 December 2020** | |
| Opening net book amount | 27,160 |
| Amortisation charge | (1,395) |
| **Closing net book amount** | **25,765** |
| **At 31 December 2020** | |
| Cost | 28,526 |
| Accumulated amortisation | (2,761) |
| **Net book amount** | **25,765** |
| **At 1 January 2021** | |
| Cost | 28,526 |
| Accumulated amortisation | (2,761) |
| **Net book amount** | **25,765** |
| **Eight months ended 31 August 2021** | |
| Opening net book amount | 25,765 |
| Amortisation charge | (1,052) |
| **Closing net book amount** | **24,713** |
| **At 31 August 2021** | |
| Cost | 28,526 |
| Accumulated amortisation | (3,813) |
| **Net book amount** | **24,713** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000658

(a) Amortisation of intangible assets has been charged to the consolidated statements of comprehensive loss as follows:

| | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|
| | 2019 | 2020 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* (Unaudited) | *RMB'000* |
| Research and development expenses | **26,792** | **28,551** | **19,135** | **19,203** |

**(b) Impairment assessment for goodwill**

Goodwill of approximately RMB52,636,000 is resulted from the acquisition of Miracogen Shanghai from a third party during the year of 2018 which is principally engaged in the provision of research and development focusing on antibody drug conjugate ("ADC") related pipelines.

Goodwill is monitored by the management at level of the CGU of Miracogen Shanghai.

The management has involved an independent qualified valuer to perform goodwill impairment assessment to assess the "value-in-use" (determined by management as the recoverable amount) of the CGU as at 31 December 2019 and 2020 and 31 August 2021 by using the discounted cash flow model.

The recoverable amount of the goodwill based on the estimated value-in-use calculations was higher than the carrying amount at 31 December 2019 and 2020 and 31 August 2021. Accordingly, no provision for impairment loss for goodwill is considered necessary.

These calculations use pre-tax cash flow forecast based on financial budgets prepared by management covering the forecast period ending 31 December 2029. The management considers the length of forecast period is appropriate because it generally takes longer for the a biopharma company to reach a perpetual growth mode, compared to companies in other industries, especially when ADC related products are still under clinical trial and the market of such product is at an early stage of development with substantial growth potential. Hence, the management believes that a forecasted period for CGU of Miracogen Shanghai longer than five years is feasible and consistent with industry practice. Key assumptions are disclosed as below:

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| The first commercialisation year of ADC related pipelines | 2023 | 2023 | 2023 |
| Expected revenue growth rate from second commercialisation year during the forecast period | 579%-6% | 1,365%-9% | 1,365%-9% |
| Expected revenue growth rate beyond the forecast period | 3%-0% | 4%-0% | 4%-0% |
| Expected market penetration rate | 0%-18% | 0%-18% | 0%-18% |
| Expected success rate of commercialisation | 11%-12% | 14%-15% | 14%-15% |
| Pre-tax discount rate | 16.9% | 16.8% | 16.9% |

Management has determined the values assigned to certain key assumptions abovementioned as follows:

| Assumption | Approach used to determining values |
|---|---|
| Revenue growth rate | Revenue growth rate covering forecast period ending 31 December 2029 were estimated based on management's expectations of market development and industry data from industry research report issued by a third-party consultation report. |
| Market penetration rate | Based on the expected selling conditions considering the features of marketing and technology development. |
| Success rate of commercialisation | By reference to practices of biopharmaceutical industries, development of technology and related regulations from administrations. |
| Pre-tax discount rate | Reflect specific risks relating to the operation of the business in the PRC. |

Based on the result of the goodwill impairment testing, the estimated recoverable amount of the CGU far exceeded its carrying amount and the headroom was approximately RMB464,206,000, RMB1,577,463,000 and RMB1,914,633,000 as at 31 December 2019 and 2020 and 31 August 2021 respectively.



Shanghai Miracogen Inc.- Ex. 2032, Page 000659

The management performed the sensitivity analysis based on the abovementioned key assumptions have been changed. Had the estimated key assumptions during the forecast period been changed as below, the headroom would be decreased to as below:

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| Expected revenue growth rate from second commercialisation year during the forecast period decreased by 5% | 388,594 | 1,419,463 | 1,745,633 |
| Expected revenue growth rate beyond the forecast period decreased by 3% | 463,576 | 1,573,463 | 1,909,633 |
| Expected market penetration rate decreased by 5% | 419,469 | 1,464,463 | 1,793,633 |
| Expected success rate of commercialisation decreased by 5% | 425,139 | 1,467,463 | 1,793,633 |
| Pre-tax discount rate increased by 1% | 449,713 | 1,548,463 | 1,881,633 |

The management believes that any reasonable possible change in any of the key assumptions would not cause the carrying amounts of the CGU to exceed its recoverable amount.

The management of the Company concluded that no provision for impairment on the goodwill has to be recognised as at 31 December 2019 and 2020 and 31 August 2021.

## 17 INVESTMENTS ACCOUNTED FOR USING THE EQUITY METHOD

**The Group**

| | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|
| | 2019 | 2020 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* |
| | | | (Unaudited) | |
| At beginning of the year/period | 168,553 | 169,878 | 169,878 | 160,294 |
| Additions | 10,000 | 2,500 | 2,500 | 1 |
| Share of loss of investments | (8,675) | (12,084) | (5,390) | (13,587) |
| Dilution of the ownership interest *(Note i)* | – | – | – | 7,294 |
| At ending of the year/period | **169,878** | **160,294** | **166,988** | **154,002** |

**The Company**

| | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|
| | 2019 | 2020 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* |
| | | | (Unaudited) | |
| At beginning of the year/period | 163,723 | 164,359 | 164,359 | 155,043 |
| Additions | 7,500 | – | – | – |
| Share of loss of investments | (6,864) | (9,316) | (2,570) | (11,540) |
| Dilution of the ownership Interest *(Note i)* | – | – | – | 7,294 |
| At ending of the year/period | **164,359** | **155,043** | **161,789** | **150,797** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000660

Set out below are the associates of the Group as at 31 December 2019 and 2020 and 31 August 2021. The associates as listed below are equity/ordinary shares investment, which held directly by the Group. Mainland China is their principal place of business. The proportion of ownership interest is the same as the proportion of voting rights held.

| Name of entity | Place of business/ region of incorporation | % of ownership interest as at 31 December 2019 | 2020 | As at 31 August 2021 | Principal activities |
|---|---|---|---|---|---|
| Wuhan Binhui Biological Technology Co., Ltd. ("Wuhan Binhui") (武漢濱會生物科技股份有限公司) | The PRC | 20.03% | 20.03% | 20.03% | Research and development of biomedicine |
| Hangzhou HealSun Biotechnology Co., Ltd. ("Hangzhou HealSun") (杭州皓陽生物技術有限公司) | The PRC | 30.00% | 30.00% | 26.37% *(Note i)* | Technological development of biotechnology |
| Hangzhou Xiyuan Biotechnology Co., Ltd. (杭州熙源生物技術有限公司) *(Note ii)* | The PRC | 30.00% | 30.00% | 30.00% | Technological development of biotechnology |
| KYM Biosciences Inc. ("KYM") | The United States | N/A | N/A | 30.00% | Technological development of biotechnology |

*Notes:*

(i) During the eight months ended 31 August 2021, Hangzhou HealSun has completed new financing activity by issuing share capital to certain investors, the percentage of share of interests held by the Company in Hangzhou HealSun was diluted from 30.00% to 26.37%. The dilution of the ownership interest in associate resulted in recognition of gain in consolidated statement of comprehensive loss.

(ii) As at 9 October 2021, the Company has entered into an equity transfer agreement with an independent third party (the "Buyer"), pursuant to which the Company has agreed to transfer and the Buyer has agreed to purchase all equity interest of Hangzhou Xiyuan Biotechnology Co., Ltd. ("Hangzhou Xiyuan") held by the Company in a cash consideration of RMB10,000,000. The transaction has been completed at the end of October 2021.

The associates of the Group have been accounted by using the equity method based on the financial information of the associates prepared under the accounting policies consistent with the Group.

All associates are engaged in biotechnology industry and at early stage of development or pre-clinical. Management performed periodically review of their business performance, including development progress of pipelines, the plan of business as well as subsequent financing, and no impairment indicator was noted as at 31 December 2019 and 2020 and 31 August 2021.



Shanghai Miracogen Inc.- Ex. 2032, Page 000661

**Summarised financial information for material associates**

The tables below provide summarised financial information for associates that are material to the Group. The information disclosed reflects the amounts presented in the financial statements of the relevant associates and not the Company's share of those amounts. They have been amended to reflect adjustments made by the entity when using the equity method, including fair value adjustments.

| | Wuhan Binhui | | | Hangzhou HealSun | | |
|---|---|---|---|---|---|---|
| | As at 31 December | | As at 31 August | As at 31 December | | As at 31 August |
| | 2019 | 2020 | 2021 | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* |
| Current assets | 107,963 | 122,679 | 630,557 | 22,986 | 30,908 | 105,582 |
| – Cash and cash equivalents | 26,915 | 53,995 | 90,751 | 12,308 | 8,257 | 29,927 |
| Non-current assets | 385,589 | 363,421 | 367,570 | 94,505 | 93,593 | 109,815 |
| Total assets | **493,552** | **486,100** | **998,127** | **117,491** | **124,501** | **215,397** |
| Current liabilities | 4,156 | 35,029 | 633,663 | 7,979 | 7,652 | 29,519 |
| Non-current liabilities | 12,325 | 12,383 | 688 | 5,100 | 7,091 | 5,697 |
| Total liabilities | **16,481** | **47,412** | **634,351** | **13,079** | **14,743** | **35,216** |
| Non-controlling interests | 204 | 3,220 | 5,889 | – | – | – |
| Equity attribute to owners of the company | 476,867 | 435,468 | 357,887 | 104,412 | 109,758 | 180,181 |
| Total equity | **477,071** | **438,688** | **363,776** | **104,412** | **109,758** | **180,181** |
| Share of net assets | 95,538 | 87,244 | 71,685 | 31,324 | 32,927 | 47,514 |
| Goodwill | 7,165 | 7,165 | 7,165 | 25,082 | 25,082 | 22,051 |
| Others | – | – | – | 5,250 | 2,625 | 2,382 |
| Carrying amount | **102,703** | **94,409** | **78,850** | **61,656** | **60,634** | **71,947** |

| | Wuhan Binhui | | | |
|---|---|---|---|---|
| | Year ended 31 December | | Eight months ended 31 August | |
| | 2019 | 2020 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* (Unaudited) | *RMB'000* |
| Revenue | 80 | 757 | 30 | 652 |
| Cost of sales | – | – | – | – |
| Administrative expenses | (14,021) | (16,955) | (5,614) | (22,463) |
| Research and development expenses | (31,147) | (34,898) | (18,666) | (34,201) |
| Finance (costs)/income, net | (376) | 163 | 126 | (30,777) |
| Other income | 3,310 | 3,185 | 2,060 | 6,093 |
| Other gains, net | 1,372 | 2,199 | 1,124 | 119 |
| Loss for the year/period | **(40,782)** | **(45,549)** | **(20,940)** | **(80,577)** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000662

| | Hangzhou HealSun | | | |
|---|---|---|---|---|
| | Year ended 31 December | | Eight months ended 31 August | |
| | 2019 | 2020 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* (Unaudited) | *RMB'000* |
| Revenue | 40,702 | 46,855 | 28,958 | 68,377 |
| Cost of sales | (14,395) | (28,242) | (15,363) | (35,185) |
| Selling expenses | (987) | (1,660) | (602) | (1,313) |
| Administrative expenses | (6,089) | (7,830) | (8,879) | (5,979) |
| Research and development expenses | (14,486) | (16,783) | (7,838) | (8,283) |
| Finance costs, net | (265) | (214) | (100) | (60) |
| Other gains, net | 46 | 5,172 | 3,831 | 843 |
| Income tax expense | (274) | (703) | (630) | (2,978) |
| Profit/(Loss) for the year/period | **4,252** | **(3,405)** | **(623)** | **15,422** |

## 18 INVENTORIES

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| Raw materials | 8,082 | 19,569 | 24,164 |

## 19 OTHER RECEIVABLES, PREPAYMENTS AND DEPOSITS

**The Group**

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| Value added tax recoverable | 51,627 | 79,566 | 76,881 |
| Deposits | 5,349 | 15,803 | 15,934 |
| Registered capital not received from non-controlling interests | 4,500 | – | – |
| Staff advances | 2,689 | – | 197 |
| Interest receivables | – | 781 | 471 |
| Prepayments for: | | | |
| – property, plant and equipment | 98,444 | 64,330 | 63,003 |
| – clinical trial expenses | 15,305 | 62,267 | 67,875 |
| Prepayments for listing expenses | – | – | 4,384 |
| Others | 2,150 | 182 | 1,573 |
| | 180,064 | 222,929 | 230,318 |
| Less: loss allowance for other receivables and deposits | (452) | (664) | (457) |
| | 179,612 | 222,265 | 229,861 |
| Less: non-current portion *(a)* | (154,700) | (152,009) | (147,148) |
| Current portion | **24,912** | **70,256** | **82,713** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000663

(a) The non-current portion of other receivables, prepayments and deposits include prepayments to suppliers for property, plant and equipment, value added tax recoverable that could not be utilised in the coming 12 months, and deposits as guarantee of land use rights are as follows:

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| Non-current assets | | | |
| Prepayments for property, plant and equipment | 98,444 | 64,330 | 63,003 |
| Value added tax recoverable | 51,627 | 79,566 | 76,881 |
| Deposits | 4,629 | 8,113 | 7,264 |
| | **154,700** | **152,009** | **147,148** |

**The Company**

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| Receivables from subsidiaries | 129,141 | 605,848 | 984,805 |
| Value added tax recoverable | 13,422 | 16,712 | 14,761 |
| Deposits | 4,086 | 12,029 | 12,199 |
| Staff advances | 5 | – | 10 |
| Interest receivables | – | 426 | 471 |
| Prepayments for: | | | |
| – property, plant and equipment | 87,223 | 53,554 | 55,254 |
| – clinical trial expenses | 6,071 | 14,473 | 11,865 |
| Prepayments for listing expenses | – | – | 4,384 |
| | 239,948 | 703,042 | 1,083,749 |
| Less: loss allowance for other receivables and deposits | – | (326) | (104) |
| | 239,948 | 702,716 | 1,083,645 |
| Less: non-current portion *(b)* | (104,725) | (75,357) | (75,244) |
| Current portion | **135,223** | **627,359** | **1,008,401** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000664

(b) The non-current portion of other receivables, prepayments and deposits include prepayments to suppliers for property, plant and equipment, value added tax recoverable that could not be utilised in the coming 12 months, and deposits as guarantee of land use rights are as follows:

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| **Non-current assets** | | | |
| Prepayments for property, plant and equipment | 87,223 | 53,554 | 55,254 |
| Value added tax recoverable | 13,422 | 16,712 | 14,761 |
| Deposits | 4,080 | 5,091 | 5,229 |
| | **104,725** | **75,357** | **75,244** |

## 20 FINANCIAL ASSETS AT FAIR VALUE THROUGH PROFIT OR LOSS

**The Group**

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| Structured deposit from banks | – | 330,657 | 132,724 |

**The Company**

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| Structured deposit from banks | – | 330,657 | 30,058 |

The structured deposit from banks are denominated in RMB, with expected rates of return ranging from 1.6% to 2.85%, from 1.4% to 3.37%, from 1.5% to 3.05% and from 1.1% to 3.40%, respectively per annum for the year ended 31 December 2019 and 2020 and eight months ended 31 August 2020 and 2021. All these structured deposit are purchased from reputable financial institutions in the PRC. The principals of these structured deposit are guaranteed, while the returns are not guaranteed. The contractual cash flows of structured deposit from banks do not qualify for solely payments of principal and interest. Therefore, the structured deposit from banks are measured at fair value through profit or loss. The fair values are based on cash flow discounted using the expected return based on management estimation and are within level 3 of the fair value hierarchy.


Shanghai Miracogen Inc.- Ex. 2032, Page 000665

## 21 CASH AND CASH EQUIVALENTS

**The Group**

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| Cash on hand | | | |
| – RMB | 1 | – | – |
| Cash at banks | | | |
| – RMB | 188,511 | 402,831 | 126,706 |
| – USD | 33 | 36 | 134,488 |
| – HKD | – | – | – |
| | **188,545** | **402,867** | **261,194** |

**The Company**

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| Cash at banks | | | |
| – RMB | 172,993 | 232,364 | 80,243 |
| – USD | – | – | 127,730 |
| | **172,993** | **232,364** | **207,973** |

## 22 TERM DEPOSITS WITH INITIAL TERMS OVER THREE MONTHS

The term deposits are all denominated in RMB.

The carrying amounts of term deposits with initial terms over three months approximated their fair values as at 31 December 2020 and 31 August 2021 due to the short maturity.



Shanghai Miracogen Inc.- Ex. 2032, Page 000666

## 23 FINANCIAL INSTRUMENTS BY CATEGORY

### The Group

The Group held the following financial instruments:

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| **Financial Assets** | | | |
| **Financial assets at amortised cost** | | | |
| – Other receivables, prepayments and deposits excluding non-financial assets | 14,236 | 16,102 | 17,718 |
| – Cash and cash equivalents | 188,545 | 402,867 | 261,194 |
| – Term deposits with the initial terms over three months | – | 20,000 | 50,000 |
| **Financial assets at fair value through profit or loss** | – | 330,657 | 132,724 |
| | **202,781** | **769,626** | **461,636** |
| **Financial Liabilities** | | | |
| **Financial liabilities at amortised cost** | | | |
| – Trade payables | 31,684 | 42,448 | 84,560 |
| – Other payables and accruals excluding non-financial liabilities | 368,589 | 301,797 | 277,915 |
| – Lease liabilities | 75,816 | 52,000 | 39,447 |
| – Financial instruments with preferred rights at amortised cost | 397,489 | – | – |
| – Borrowings | 118,266 | 147,266 | 198,064 |
| **Financial liabilities at fair value through profit or loss** | | | |
| – FVPL | 279,081 | 309,181 | 357,339 |
| – Convertible loans | 380,620 | – | – |
| | **1,651,545** | **852,692** | **957,325** |

### The Company

The Company held the following financial instruments:

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| **Financial Assets** | | | |
| **Financial assets at amortised cost** | | | |
| – Other receivables, prepayments and deposits excluding non-financial assets | 133,232 | 617,977 | 997,381 |
| – Cash and cash equivalents | 172,993 | 232,364 | 207,973 |
| – Term deposits with the initial terms over three months | – | 20,000 | 50,000 |
| **Financial assets at fair value through profit or loss** | – | 330,657 | 30,058 |
| | **306,225** | **1,200,998** | **1,285,412** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000667

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| **Financial Liabilities** | | | |
| **Financial liabilities at amortised cost** | | | |
| – Trade payables | – | 5,435 | 5,148 |
| – Other payables and accruals excluding non-financial liabilities | 399,690 | 286,730 | 271,840 |
| – Lease liabilities | 2,618 | 1,798 | 2,386 |
| – Financial instruments with preferred rights at amortised cost | 397,489 | – | – |
| – Borrowings | 118,266 | 147,266 | 198,064 |
| **Financial liabilities at fair value through profit or loss** | | | |
| – FVPL | 279,081 | 309,181 | 357,339 |
| – Convertible loans | 380,620 | – | – |
| | **1,577,764** | **750,410** | **834,777** |

## 24 SHARE CAPITAL

| | Number of shares | Nominal value of shares *RMB'000* |
|---|---|---|
| **Authorised and issued** | | |
| Ordinary shares upon conversion | 1,492,692,648 | 1,492,693 |
| **At 31 December 2020** | **1,492,692,648** | **1,492,693** |
| **At 1 January 2021** | **1,492,692,648** | **1,492,693** |
| Issue of ordinary shares to series C investors *(b)* | 38,977,190 | 38,977 |
| **At 31 August 2021** | **1,531,669,838** | **1,531,670** |

| | Number of shares | Share capital *RMB'000* |
|---|---|---|
| **Issued and fully paid** | | |
| Issue of ordinary shares upon conversion into a joint stock company *(a)* | 1,492,692,648 | 1,492,693 |
| **At 31 December 2020** | **1,492,692,648** | **1,492,693** |
| At 1 January 2021 | 1,492,692,648 | 1,492,693 |
| Issue of ordinary shares to series C investors *(b)* | 38,977,190 | 38,977 |
| **At 31 August 2021** | **1,531,669,838** | **1,531,670** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000668

(a) In December 2020, the Company converted into a joint stock company with limited liability under the Company Law of the PRC. The net assets of the Company as of the conversion date, including paid-in capital, reserves and accumulated losses, amounting to approximately RMB3,112,653,000 were converted into approximately 1,492,693,000 ordinary shares at RMB1 each. The excess of net assets converted over nominal value of the ordinary shares was credited to the Company's share premium (Note 26).

(b) On 8 April 2021, the Company entered into investment agreement with Vivo Capital Fund IX, L.P. ("Vivo Capital") and Shanghai Biomedical Industrial Equity Investment Fund Partnership (Limited Partnership) ("Shanghai Biomedical"), pursuant to which Vivo Capital and Shanghai Biomedical subscribed 24,360,744 and 14,616,446 shares of the Company respectively, with consideration of RMB163,200,000 and RMB97,920,000, respectively. The insurance cost to be paid is approximately RMB423,000. The par value of the shares under subscription is approximately RMB38,977,000, and the difference with the total consideration after deducting insurance cost of approximately RMB221,720,000 is charged to share premium. The issuance of shares was completed on 17 April 2021.

## 25 PAID-IN CAPITAL

| | **Paid-in capital**<br>*RMB'000* |
|---|---|
| **At 1 January 2019** | 690,400 |
| Capital contribution from Ningbo Houde Yimin *(a)* | 309,600 |
| **At 31 December 2019** | **1,000,000** |
| **At 1 January 2020** | 1,000,000 |
| Capital contribution from Lepu Medical *(b)* | 25,352 |
| Conversion of convertible loans *(c)* | 101,408 |
| Issuance of equity interests to series B investors *(d)* | 226,954 |
| Transactions with non-controlling interests *(Note 39)* | 138,979 |
| Conversion into a joint stock company *(Note 24(a))* | (1,492,693) |
| **At 31 December 2020** | – |
| **At 31 August 2021** | **N/A** |

(a) Pursuant to an equity transfer agreement dated on 12 December 2019 entered into among Ningbo Houde Yimin, Lvyuan (Shanghai) Technology Limited ("Shanghai Lvyuan") ("律元(上海)科技有限公司"), Shanghai Chunruizongheng Technology Partnership (Limited Partnership) ("Shanghai Chunrui") ("上海純瑞縱橫科技合夥企業(有限合夥)"), and Mr. Su Rongyu, Ningbo Houde Yimin transferred the registered capital of RMB240,000,000 in the Company, representing 24% equity interests of the Company to Shanghai Lvyuan, Shanghai Chunrui and Mr. Su Rongyu. Upon completion of the equity transfers, the Company was held as to 56.00%, 20.00%, 10.00%, 9.00% and 5.00% by Ningbo Houde Yimin, Lepu Medical, Mr. Su Rongyu, Shanghai Lvyuan and Shanghai Chunrui, respectively.

The total capital registration of the Company is RMB1,000,000,000. During the year ended 31 December 2018, RMB690,400,000 was paid by the shareholders, representing 69.04% of the total registered capital. During the year ended 31 December 2019, the remaining 30.96% of the total registered capital of approximately RMB309,600,000 was fully paid by the Ningbo Houde Yimin.

(b) On 21 April 2020, Lepu Medical subscribed paid-in capital of RMB25,352,000 with consideration of RMB90,000,000, the difference between total capital contribution and paid-in capital issued amounting to approximately RMB64,648,000 was credited into capital reserves (Note 34).

(c) On 21 April 2020, the convertible loans were converted into equity of the Company, accordingly the Company issued paid-in capital of approximately RMB101,408,000 (Note 34.1).

(d) On 30 July 2020, the Company entered into investment agreement with the series B investors, pursuant to which total capital of RMB1,291,000,000 was to be injected into the Company with approximately RMB226,954,000 and RMB1,064,046,000 credited to the Company's paid-in capital and capital reserves respectively (Note 34).



Shanghai Miracogen Inc.- Ex. 2032, Page 000669

## 26 TREASURY STOCK AND RESERVES

**The Group**

| | | Reserves | | | | |
|---|---|---|---|---|---|---|
| | **Treasury stock** *RMB'000* | **Share premium** *RMB'000* | **Capital reserves** *RMB'000* | **Share-based payment reserves** *RMB'000* | **Other reserves** *RMB'000* | **Total** *RMB'000* |
| **At 31 December 2018** | – | – | – | – | (36,885) | (36,885) |
| Business combination under common control *(Note 35)* | – | – | – | – | 70,628 | 70,628 |
| **At 31 December 2018** | **–** | **–** | **–** | **–** | **33,743** | **33,743** |
| **At 1 January 2019** | – | – | – | – | 33,743 | 33,743 |
| Capital contribution from Ningbo Houde Yimin *(Note 35)* | – | – | 31,372 | – | – | 31,372 |
| Recognition of financial instruments with preferred rights at amortised cost upon issuance of Houde Yimin Loans *(a)* | (347,454) | – | – | – | – | – |
| Share-based payments *(a)* | – | – | – | 143,695 | – | 143,695 |
| Business combination under common control *(Note 35)* | – | – | – | – | (112,200) | (112,200) |
| Transactions with non-controlling interests *(Note 39)* | – | – | – | – | (559,241) | (559,241) |
| **At 31 December 2019** | **(347,454)** | **–** | **31,372** | **143,695** | **(637,698)** | **(462,631)** |
| **At 1 January 2020** | (347,454) | – | 31,372 | 143,695 | (637,698) | (462,631) |
| Capital contribution from Lepu Medical *(Note 25(b))* | – | – | 64,648 | – | – | 64,648 |
| Conversion of convertible loans *(b)* | – | – | 325,876 | – | – | 325,876 |
| Transactions with non-controlling interests *(Note 39)* | – | – | (23,474) | – | 547 | (22,927) |
| Issuance of equity interests to series B investors *(Note 25(d))* | – | – | 1,064,046 | – | – | 1,064,046 |
| Recognition of financial instruments with preferred rights at amortised cost | | | | | | |
| – upon conversion of convertible loans *(b)* | (328,762) | – | – | – | – | – |
| – upon issuance of series B equity interests *(c)* | (1,192,480) | – | – | – | – | – |
| Derecognition of financial instruments with preferred rights at amortised cost | 1,868,696 | – | – | – | 130,887 | 130,887 |
| Conversion into a joint stock company *(Note 24(a))* | – | 1,619,960 | (1,863,982) | (143,695) | (105,105) | (492,822) |
| Share-based payments *(Note 27)* | – | – | – | 5,222 | – | 5,222 |
| Currency translation differences | – | – | – | – | (39) | (39) |
| **At 31 December 2020** | **–** | **1,619,960** | **(401,514)** | **5,222** | **(611,408)** | **612,260** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000670

| | | Reserves | | | | |
|---|---|---|---|---|---|---|
| | Treasury stock *RMB'000* | Share premium *RMB'000* | Capital reserves *RMB'000* | Share-based payment reserves *RMB'000* | Other reserves *RMB'000* | Total *RMB'000* |
| **At 1 January 2020** | (347,454) | – | 31,372 | 143,695 | (637,698) | (462,631) |
| Capital contribution from Lepu Medical *(Note 25(b))* | – | – | 64,648 | – | – | 64,648 |
| Conversion of convertible loans *(b)* | – | – | 325,876 | – | – | 325,876 |
| Transactions with non-controlling interests *(Note 39)* | – | – | (23,474) | – | 547 | (22,927) |
| Issuance of equity interests to series B investors *(Note 25(d))* | – | – | 1,064,046 | – | – | 1,064,046 |
| Recognition of financial instruments with preferred rights at amortised cost | | | | | | |
| – upon conversion of convertible loans *(b)* | (328,762) | – | – | – | – | – |
| – upon issuance of series B equity interests *(c)* | (1,192,480) | – | – | – | – | – |
| Derecognition of financial instruments with preferred rights at amortised cost | 1,868,696 | – | – | – | 130,887 | 130,887 |
| **At 31 August 2020 (Unaudited)** | **–** | **–** | **1,462,468** | **143,695** | **(506,264)** | **1,099,899** |
| **At 1 January 2021** | – | 1,619,960 | (401,514) | 5,222 | (611,408) | 612,260 |
| Issuance of shares to series C investors *(Note 24(b))* | – | 221,720 | – | – | – | 221,720 |
| Share-based payments *(Note 27)* | – | – | – | 85,779 | – | 85,779 |
| Currency translation differences | – | – | – | – | 14 | 14 |
| **At 31 August 2021** | **–** | **1,841,680** | **(401,514)** | **91,001** | **(611,394)** | **919,773** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000671

**The Company**

| | | Reserves | | | | |
|---|---|---|---|---|---|---|
| | **Treasury stock** *RMB'000* | **Share premium** *RMB'000* | **Capital reserves** *RMB'000* | **Share-based payment reserves** *RMB'000* | **Other reserves** *RMB'000* | **Total** *RMB'000* |
| **At 1 January 2019** | | | | | | |
| Recognition of financial instruments with preferred rights at amortised cost upon issuance of Houde Yimin Loans *(a)* | (347,454) | – | – | – | – | – |
| Share-based payments *(a)* | – | – | – | 143,695 | – | 143,695 |
| Business combination under common control | – | – | – | – | (25,782) | (25,782) |
| **At 31 December 2019** | **(347,454)** | **–** | **–** | **143,695** | **(25,782)** | **117,913** |
| **At 1 January 2020** | (347,454) | – | – | 143,695 | (25,782) | 117,913 |
| Capital contribution from Lepu Medical *(Note 25(b))* | – | – | 64,648 | – | – | 64,648 |
| Conversion of convertible loans *(b)* | – | – | 325,876 | – | – | 325,876 |
| Transactions with non-controlling interests *(Note 39)* | – | – | 409,412 | – | – | 409,412 |
| Issuance of equity interests to series B investors *(Note 25(d))* | – | – | 1,064,046 | – | – | 1,064,046 |
| Recognition of financial instruments with preferred rights at amortised cost | | | | | | |
| – upon conversion of convertible loans *(b)* | (328,762) | – | – | – | – | – |
| – upon issuance of series B equity interests *(c)* | (1,192,480) | – | – | – | – | – |
| Derecognition of financial instruments with preferred rights at amortised cost | 1,868,696 | – | – | – | 130,887 | 130,887 |
| Conversion into a joint stock company *(Note 24(a))* | – | 1,619,960 | (1,863,982) | (143,695) | (105,105) | (492,822) |
| Share-based payments *(Note 27)* | – | – | – | 5,222 | – | 5,222 |
| **At 31 December 2020** | **–** | **1,619,960** | **–** | **5,222** | **–** | **1,625,182** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000672

| | | Reserves | | | | |
|---|---|---|---|---|---|---|
| | Treasury stock | Share premium | Capital reserves | Share-based payment reserves | Other reserves | Total |
| | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* |
| **At 1 January 2020** | (347,454) | – | – | 143,695 | (25,782) | 117,913 |
| Capital contribution from Lepu Medical *(Note 25(b))* | – | – | 64,648 | – | – | 64,648 |
| Conversion of convertible loans *(b)* | – | – | 325,876 | – | – | 325,876 |
| Transactions with non-controlling interests *(Note 39)* | – | – | 409,412 | – | – | 409,412 |
| Issuance of equity interests to series B investors *(Note 25(d))* | – | – | 1,064,046 | – | – | 1,064,046 |
| Recognition of financial instruments with preferred rights at amortised cost | | | | | | |
| – upon conversion of convertible loans *(b)* | (328,762) | – | – | – | – | – |
| – upon issuance of series B equity interests *(c)* | (1,192,480) | – | – | – | – | – |
| Derecognition of financial instruments with preferred rights at amortised cost | 1,868,696 | – | – | – | 130,887 | 130,887 |
| **At 31 August 2020 (Unaudited)** | **–** | **–** | **1,863,982** | **143,695** | **105,105** | **2,112,782** |
| **At 1 January 2021** | – | 1,619,960 | – | 5,222 | – | 1,625,182 |
| Issuance of shares to series C investors *(Note 24(b))* | – | 221,720 | – | – | – | 221,720 |
| Share-based payments *(Note 27)* | – | – | – | 85,779 | – | 85,779 |
| **At 31 August 2021** | **–** | **1,841,680** | **–** | **91,001** | **–** | **1,932,681** |

(a) On 4 March 2019, upon issuance of Houde Yimin Loans, the Company recorded treasury stock to reflect the carrying amount of the financial instruments with preferred rights. The difference between issuance price of the Houde Yimin Loans and the fair value of the equity on issuance date was charged to share-based payment reserves. Further details are described in Note 34.2(a).

(b) On 21 April 2020, upon conversion of convertible loans, the Company derecognized the convertible loans, the difference between the fair value of the convertible loans and the paid-in capital issued of approximately RMB325,876,000 was charged to the capital reserves. Meanwhile, the Company recorded treasury stock to reflect the carrying amount of the financial instruments with preferred rights. Further details are described in Note 34.

(c) The Group recorded treasury stock to reflect the carrying amount of the financial instruments with preferred rights at the date of issuance Series B Capital Injection. Further details are described in Note 34.2(c).

(d) On 28 August 2020, upon termination of preferred rights of Houde Yimin Loans, Convertible Loans and Series B Capital Injection, the treasury stocks were derecognised and the difference between the derecognition of the financial instruments with preferred rights and the treasury stocks was charged to the other reserves. Further details are described in Note 34.2.



Shanghai Miracogen Inc.- Ex. 2032, Page 000673

**27 SHARE-BASED PAYMENTS**

Huarui Zongheng (Beijing) Technology Co., Ltd. ("華瑞縱橫(北京)科技有限公司"), Shanghai Zupai Technology Partnership (Limited Partnership) ("上海築湃科技合夥企業(有限合夥)"), Shanghai Zulin Technology Partnership (Limited Partnership) ("上海築麟科技合夥企業(有限合夥)"), Shanghai Renhong Technology Partnership (Limited Partnership) ("上海韌宏科技合夥企業(有限合夥)") and Shanghai Progeun Technology Co., Ltd. ("上海芃槿科技有限責任公司") (collectively referred to as the "Vehicles") were all incorporated in the PRC under the Company Law of the PRC as a vehicle to hold the ordinary shares for the Company's employees under the ESOP of 2020.

As the Company did not have power to govern the relevant activities of the Vehicles nor repurchase or settlement obligations but only derive benefits from the contributions of the eligible employees who are awarded with the shares under the ESOP, the directors of the Company consider not to consolidate the Vehicles. No statutory financial statements had been prepared by the Vehicles during the Track Record Period.

**(a) ESOP**

On 7 December 2020, 151 eligible employees (the "Grantees") were granted 45,149,702 shares of the Company at a consideration of RMB1.00 per share which are vested when Grantees complete a contractual term of service with the authorization from the Board of Directors of the Company to acquire their long-term service in future.

Such plan grants under the plan vest over a period of four years of continuous service, with one-fourth (1/4) vesting upon the first anniversary of the stated vesting commencement date and the remaining vesting rateably over the following 36 months.

Set out below are the movement in the number of awarded restricted shares under the ESOP:

| | |
|---|---|
| At 1 January 2020 | – |
| Granted | 45,149,702 |
| Vested | – |
| Forfeited | – |
| **At 31 December 2020** | **45,149,702** |
| At 1 January 2021 | 45,149,702 |
| Vested | (11,262,500) |
| **At 31 August 2021** | **33,887,202** |

Back-solve method and OPM model were used to determine the underlying equity fair value of the Company and the fair value of the restricted shares granted. The key inputs into the model other than the underlying equity fair value of the Company at the date of grant were as follows:

| | **Key assumptions** |
|---|---|
| Risk-free interest rate | 1.87% |
| Volatility | 40% |
| Dividend yield | 0% |
| Lack of marketability discount | 10% |



Shanghai Miracogen Inc.- Ex. 2032, Page 000674

**(b) Modification of the ESOP**

In April 2021, as a reward for certain senior managements' service, the Group has entered into supplemental agreements with those senior managements to modify key terms under the original ESOP. As a result, the restriction of service conditions of 11,262,500 shares granted to those senior managements on 7 December 2020 were cancelled, and period of continuous service of 3,000,000 shares granted to a certain senior management has been shortened. Expenses related to vesting of restricted share and true up of shortened service condition restriction aforementioned amounted to approximately RMB45,202,000 were recognised immediately upon modification.

**(c) Share-based payment expenses related to Houde Yimin loans**

Share-based payment expenses related to Houde Yimin loans represents the difference between issuance price of such loans and fair value of equity on issue date, further details as described in Note 34.

**(d) Expenses arising from share-based payment transactions**

| | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|
| | **2019** | **2020** | **2020** | **2021** |
| | *RMB'000* | *RMB'000* | *RMB'000* (Unaudited) | *RMB'000* |
| Administrative expenses | 143,695 | 2,481 | – | 26,279 |
| Research and development expenses | – | 2,743 | – | 59,525 |
| | **143,695** | **5,224** | **–** | **85,804** |

**28 BORROWINGS**

**The Group and The Company**

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | **2019** | **2020** | **2021** |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| Current | | | |
| Bank borrowings-non secured | – | – | 20,000 |
| Bank borrowings- secured *(a)* | – | – | 10,000 |
| Non-current | | | |
| Bank borrowings-secured *(a)* | 118,266 | 147,266 | 168,064 |
| | **118,266** | **147,266** | **198,064** |

As at 31 December 2019 and 2020 and 31 August 2021, the Group's borrowings were repayable as follows:

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | **2019** | **2020** | **2021** |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| Within 1 year | – | – | 30,000 |
| Between 1 and 2 years | – | 20,000 | 25,000 |
| Between 2 and 5 years | 90,000 | 127,266 | 143,064 |
| Over 5 years | 28,266 | – | – |
| | **118,266** | **147,266** | **198,064** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000675

(a) The Group has pledged its land use rights and construction-in-progress with carrying amounts of approximately RMB68,983,000 and RMB158,495,000 respectively to bank as the security for the long-term bank borrowings of RMB118,266,000 as at 31 December 2019. The borrowings bear interests at float rate range from 4.50% to 4.60% per annum. Interest is payable quarterly. The principal for the borrowings are payable in batches from 20 June 2022 to 1 September 2025.

The Group has pledged its land use rights and construction-in-progress with carrying amounts of approximately RMB65,271,000 and RMB323,768,000 respectively to bank as the security for the long-term bank borrowings of RMB147,266,000 as at 31 December 2020. The borrowings bear interests at float rate range from 4.20% to 4.60% per annum. Interest is payable quarterly. The principal for the borrowings are payable in batches from 20 June 2022 to 1 September 2025.

The Group has pledged its land use rights and construction-in-progress with carrying amounts of approximately RMB62,796,000 and RMB440,289,000 respectively to bank as the security for the long-term bank borrowings of RMB178,064,000 as at 31 August 2021. The borrowings bear interests at float rate range from 4.20% to 4.60% per annum. Interest is payable quarterly. The principal for the borrowings are payable in batches from 20 June 2022 to 1 September 2025.

Dr. Pu Zhongjie, the Controlling Shareholder, has been the guarantor of the Group's aforementioned secured bank borrowings with irrevocable joint guarantee liabilities. The guarantee period is 2 years from 1 September 2027 to 1 September 2029. Such guarantee was released on 20 April 2021.

The fair value of borrowings approximated their carrying amounts as at 31 December 2019 and 2020 and 31 August 2021 as the borrowings carried interests which were benchmarked against rates announced by the People's Bank of China from time to time.

## 29 DEFERRED GOVERNMENT GRANTS

**The Group and The Company**

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| **Government grants** | | | |
| Asset-related grants *(a)* | 12,000 | 12,000 | 12,000 |
| To be realised after more than 12 months | 12,000 | 12,000 | 12,000 |

(a) The asset-related grants are subsidies received from the government for compensating the Group's project of Shanghai Biological Park for high-efficiency monoclonal antibody drug production. As at 31 December 2019 and 2020 and 31 August 2021, the project is still under construction and was not ready for use.



Shanghai Miracogen Inc.- Ex. 2032, Page 000676

**30 DEFERRED INCOME TAX**

Deferred income taxes are calculated in full on temporary differences under the liability method using the tax rates at which are expected to be applied at the time of reversal of the temporary differences.

The deferred income tax assets and liabilities are mainly due from acquisition of subsidiaries, and the amount of offsetting deferred income tax assets and liabilities is RMB30,476,000, RMB27,760,000 and RMB25,950,000 as at 31 December 2019 and 2020 and 31 August 2021, respectively. The analysis of deferred income tax assets and liabilities before offsetting is as follows:

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| **Deferred income tax assets:** | | | |
| – Deferred income tax assets to be recovered after more than 12 months | 27,760 | 25,046 | 23,238 |
| – Deferred income tax assets to be recovered within 12 months | 2,716 | 2,714 | 2,712 |
| | 30,476 | 27,760 | 25,950 |
| **Deferred income tax liabilities:** | | | |
| – Deferred income tax liabilities to be settled after more than 12 months | (65,447) | (62,733) | (60,925) |
| – Deferred income tax liabilities to be settled within 12 months | (2,716) | (2,714) | (2,712) |
| | (68,163) | (65,447) | (63,637) |
| **Deferred income tax liabilities – net** | **(37,687)** | **(37,687)** | **(37,687)** |

**Deferred tax assets**

| | Tax losses |
|---|---|
| | *RMB'000* |
| At 1 January 2019 | 35,002 |
| Charged to consolidated statements of comprehensive loss | (4,526) |
| **At 31 December 2019** | **30,476** |
| At 1 January 2020 | 30,476 |
| Charged to consolidated statements of comprehensive loss | (2,716) |
| **At 31 December 2020** | **27,760** |
| At 1 January 2021 | 27,760 |
| Charged to consolidated statements of comprehensive loss | (1,810) |
| **At 31 August 2021** | **25,950** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000677

**Deferred tax liabilities**

| | Property, plant and equipment acquired in business combination *RMB'000* | Intangible assets acquired in business combination *RMB'000* | Total *RMB'000* |
|---|---|---|---|
| At 1 January 2019 | (220) | (72,469) | (72,689) |
| Credited to consolidated statements of comprehensive loss | 32 | 4,494 | 4,526 |
| **At 31 December 2019** | **(188)** | **(67,975)** | **(68,163)** |
| At 1 January 2020 | (188) | (67,975) | (68,163) |
| Credited to consolidated statements of comprehensive loss | 19 | 2,697 | 2,716 |
| **At 31 December 2020** | **(169)** | **(65,278)** | **(65,447)** |
| At 1 January 2021 | (169) | (65,278) | (65,447) |
| Credited to consolidated statements of comprehensive loss | 13 | 1,797 | 1,810 |
| **At 31 August 2021** | **(156)** | **(63,481)** | **(63,637)** |

## 31 FINANCIAL LIABILITIES AT FAIR VALUE THROUGH PROFIT OR LOSS

**The Group and The Company**

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 *RMB'000* | 2020 *RMB'000* | 2021 *RMB'000* |
| Variable consideration for transactions with non-controlling interests *(Note 39)* | 279,081 | 309,181 | 357,339 |

As described in Note 39(a), the fair value of variable consideration payable as at 31 December 2019 and 2020 and 31 August 2021 was determined by an independent qualified valuer (Note 3.3(i)). And the changes in fair value was recognised in the consolidated statements of comprehensive loss.

The movements of financial liabilities at fair value through profit or loss for the years ended 31 December 2019 and 2020 and eight months ended 31 August 2020 and 2021 are set out below:

| | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|
| | 2019 *RMB'000* | 2020 *RMB'000* | 2020 *RMB'000* (Unaudited) | 2021 *RMB'000* |
| Opening balance | – | 279,081 | 279,081 | 309,181 |
| Additions | 261,389 | – | – | – |
| Change in fair value *(Note 9)* | 17,692 | 30,100 | 69,283 | 48,158 |
| Closing balance | 279,081 | 309,181 | 348,364 | 357,339 |



Shanghai Miracogen Inc.- Ex. 2032, Page 000678

## 32 TRADE PAYABLES

The ageing analysis of the trade payables based on their respective invoice and issue dates are as follows:

**The Group**

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| Less than 1 year | 31,648 | 40,785 | 84,166 |
| Between 1 and 2 years | 36 | 1,663 | 394 |
| | **31,684** | **42,448** | **84,560** |

**The Company**

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| Less than 1 year | **–** | **5,435** | **5,148** |

Trade payables are unsecured and are usually paid within 30 days from the date of initial recognition.

The carrying amounts of trade payables are considered to be the same as their fair values, due to their short-term nature.

The trade payables are all denominated in RMB.

## 33 OTHER PAYABLES AND ACCRUALS

**The Group**

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| Payables for acquisitions/investments *(a)* | 342,065 | 250,000 | 200,000 |
| Payables for purchase of property, plant and equipment | 16,828 | 42,100 | 50,039 |
| Payroll and welfare payables | 9,267 | 18,600 | 18,980 |
| Leases payables | 2,837 | 3,813 | 2,416 |
| Deferred government grants | 2,000 | 2,000 | 4,000 |
| Payables for professional fees | 387 | 1,882 | 375 |
| Payables for listing expenses | – | – | 17,850 |
| Other taxes and surcharges payables | 422 | 910 | 1,032 |
| Deposits from suppliers | 200 | 500 | 1,161 |
| Payables for interests | 163 | 165 | 1,460 |
| Others | 4,109 | 1,337 | 614 |
| | 378,278 | 321,307 | 297,927 |
| Less: non-current portion *(a(i))* | – | – | (150,000) |
| Current portion | **378,278** | **321,307** | **147,927** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000679

**The Company**

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| Payables for acquisition/investments *(a)* | 342,065 | 250,000 | 200,000 |
| Payables for related party in group | 56,728 | 2,113 | 4,850 |
| Payables for purchase of property, plant and equipment | 308 | 32,473 | 45,962 |
| Payroll and welfare payables | 3,055 | 6,014 | 6,570 |
| Leases payables | 8 | 51 | 193 |
| Payables for professional fees | 387 | 1,628 | 375 |
| Payables for listing expenses | – | – | 17,850 |
| Other taxes and surcharges payables | 52 | 310 | 654 |
| Deposits from suppliers | – | 300 | 1,150 |
| Payables for interests | 163 | 165 | 1,460 |
| Others | 31 | – | – |
| | 402,797 | 293,054 | 279,064 |
| Less: non-current portion *(a(i))* | – | – | (150,000) |
| Current portion | **402,797** | **293,054** | **129,064** |

(a) Payables for acquisitions as at 31 December 2019 and 2020 and 31 August 2021 consists of the following:

(i) As mentioned in Note 39(a), the unpaid fixed consideration for acquisition of 40% equity interests of Taizhou Hanzhong as at 31 December 2019 and 2020 and 31 August 2021 were RMB300,000,000, RMB250,000,000 and RMB200,000,000, respectively. The Group makes the payment based on the pre-determined payment milestone in the acquisition contracts. In August 2021, the Company has agreed with HanX to specify the payment schedule of unpaid amounts. Accordingly, the Company has or will pay RMB50,000,000, RMB75,000,000 and RMB75,000,000 to HanX in October 2021, November and December 2022, respectively. As a result, as at 31 August 2021, the outstanding payable of RMB150,000,000 which would be settled beyond 12 months were reclassified to non-current portion of other payables and accruals.

(ii) On 4 July 2018, the Group, Miracogen HK and Dr. Hu Chaohong, the controlling person of Miracogen HK, entered into an equity transfer agreement, pursuant to which: (i) the Group has conditionally agreed to acquire 59.49% equity interests of Miracogen Shanghai through capital injection of approximately RMB330,435,000 (the "Capital Injection"); (ii) upon 6 months after the completion of the Capital Injection, the Group agreed to acquire 3.52% equity interests of Miracogen Shanghai from Miracogen HK at a cash consideration of approximately RMB19,565,000.

On 26 December 2018, the Group, Miracogen HK and Dr. Hu Chaohong entered into a supplemental agreement, pursuant to which the time to acquire 3.52% equity interests of Miracogen Shanghai has been extended to 22 months after the completion of the Capital injection. As at 31 December 2019, the unpaid consideration for acquisition of Miracogen Shanghai was approximately RMB19,565,000.

On 12 March 2020, the aforementioned total consideration to acquire Miracogen Shanghai is fully paid.

(iii) On 30 July 2018, the Group entered into an investment agreement between Ningbo Mingxi Equity Investment Partnership (Limited Partnership) ("寧波明浠股權投資合夥企業(有限合夥)") and Ningbo Junfeng Equity Investment Partnership (Limited Partnership) ("Ningbo Junfeng") ("寧波濬豐股權投資合夥企業(有限合夥)"), pursuant to which the Group acquired 30% equity interests of Hangzhou Healsun that held by Ningbo Junfeng at a consideration of RMB45,000,000 and then injected capital of RMB15,000,000 into Hangzhou Healsun after acquisition.

As at 31 December 2019, the Group has paid 50% of the consideration amounting to RMB22,500,000 and has injected capital of RMB12,500,000, the remaining consideration to be paid was RMB22,500,000. In August 2020, the remaining consideration of RMB22,500,000 was fully paid and capital of RMB2,500,000 was fully injected by the Group.



Shanghai Miracogen Inc.- Ex. 2032, Page 000680

## 34 CONVERTIBLE LOANS/FINANCIAL INSTRUMENTS WITH PREFERRED RIGHTS AT AMORTISED COST

**Series A financing**

On 4 March 2019, the Company, Ningbo Houde Yimin, Lepu Medical and the Controlling Shareholder entered into investment agreements (the "Series A Investment Agreement"), with Suzhou Danqing II Innovation Pharmaceutical Industry Investment Partnership (Limited Partnership) ("蘇州丹青二期創新醫藥產業投資合夥企業(有限合夥)"), Jiaxing Danqing Investment Partnership (Limited Partnership) ("嘉興丹青投資合夥企業(有限合夥)"), Suzhou Private Capital Investment Holding Co., Ltd. ("蘇州民營資本投資控股有限公司"), Suzhou Industrial Park Guochuang Kaiyuan II Investment Centre (Limited Partnership) ("蘇州工業園區國創開元二期投資中心(有限合夥)"), Kington Capital No. 1 Equity Investment Partnership (Limited Partnership) ("蘇州翼樸一號股權投資合夥企業(有限合夥)"), Suzhou Suzi Investment Limited Partnership ("蘇州蘇梓投資合夥企業(有限合夥)"), Suzhou Xinrui Qiyuan Investment Center (Limited Partnership) ("蘇州新銳啟源投資中心(有限合夥)") and Linzhi Lecheng Medical Industry Development Co., Ltd. ("林芝樂成醫療產業發展有限公司") (collectively referred to the "Series A Investors"), pursuant to the Series A Investment Agreement, 1) the Company agreed to issue convertible loans to Series A Investors of RMB360,000,000 (the "Convertible Loans"), 2) Ningbo Houde Yimin agreed to issue exchangeable loans to the Series A Investors of RMB450,000,000 (the "Houde Yimin Loans") and 3) Lepu Medical agreed to subscribe additional paid-in capital of RMB25,352,113 with consideration of RMB90,000,000. The Convertible Loans and Houde Yimin Loans were repayable within 12 months from issuance of the loans, bearing nil of interests. The Series A Investors were eligible to 1) convert the Convertible Loans into the Company's paid-in capital of RMB101,408,452, as capital injection to the Company and 2) exchange the Houde Yimin Loans to paid-in capital of the Company held by Ningbo Houde Yimin of RMB126,760,564, as share transferred from Ningbo Houde Yimin to the Series A Investors. The exercise of the abovementioned conversion/exchange right was solely at discretion of the Series A Investors within the period of such loans.

On 21 April 2020, abovementioned counterparties and other shareholders of the Company entered into a supplementary agreement (the "Series A Supplement Agreement"), pursuant to which the Series A Investors exercised the conversion/exchange right, thereafter, the Convertible Loans was converted into the Company's paid-in capital of RMB101,408,452, and Ningbo Houde Yimin has transferred the Company's paid-in capital of RMB126,760,564 to Series A Investors (collectively refer as "Series A Conversion"). Concurrently, Lepu Medical has subscribed additional paid-in capital of RMB25,352,113 with consideration of RMB90,000,000.

**Series B financing**

On 30 July 2020, the Company entered into investment agreement (the "Series B Investment Agreement"), with Tianjin PingAn Consumption Technology Investment Partnership (Limited Partnership) ("天津市平安消費科技投資合夥企業(有限合夥)"), Sunshine Life Insurance Company Limited ("陽光人壽保險股份有限公司"), Haitong Innovation Securities Investment Co., Ltd. ("海通創新證券投資有限公司"), Beijing Ronghui Sunshine Xinxing Industry Investment Management Center (Limited Partnership) ("北京融匯陽光新興產業投資管理中心(有限合夥)"), China Reform Guangzhou Investment Fund (Limited Partnership) ("國新央企運營(廣州)投資基金(有限合夥)"), SDIC Unity Capital Investment Fund (Limited Partnership) ("國投創合國家新興產業創業投資引導基金(有限合夥)"), Qingdao Minxin Qiyuan Investment Center (Limited Partnership) ("青島民芯啟元投資中心(有限合夥)"), Shenzhen Haihui Quanxing Investment Consultation Limited Partnership (Limited Partnership) ("深圳市海匯全興投資諮詢合夥企業(有限合夥)"), Xinye (Guangzhou) Equity Investment Limited Partnership (Limited Partnership) ("新業(廣州)股權投資合夥企業(有限合夥)"), Mr. Tongjun Guo, Mr. Lei Wang, Mr. Xinglin Wang, Ms. Xia Zhang, Ms. Yong Wang, Ms. Juan Chen, Mr. Zhanjiang Wei and Mr. Yi Lin (collectively referred to as the "Series B Investors"), pursuant to which total capital of RMB1,291,000,000 was to be injected into the Company, the Company has then issued paid-in capital of RMB226,953,977 to the Series B Investors (collectively refer as "Series B Capital Injection").

In accordance with the Series A Investment Agreement and Series B Investment Agreement, Series A Investors and Series B Investors have been granted certain preferred rights upon issuance of the Convertible Loans and Houde Yimin Loans and Series B Capital Injection, the preferred rights were mainly as followings:



Shanghai Miracogen Inc.- Ex. 2032, Page 000681

***Redemption right***

Series A Investors and Series B Investors have a right to require the Company to redeem their investments if (i) The Company failed to qualified initial public offering ("IPO") before 31 December 2022; (ii) During the period from the issuance date to before the Company's qualified IPO, the Company and its ultimate controlling shareholder or existing shareholders has committed a major criminal violation.

The redemption amount of Series A is the sum amount of: (i) the original investment principal from the Series A Investors, plus an annual simple rate of 12% of the original investment principle for a period of time commencing from the delivery date to the actual payments date of the settlement (calculated as 360 days in a calendar year); (ii) the retained earnings of the Company upon the date of settlement; minus any dividends or profits distributed to Series A Investors.

The redemption amount of Series B is the original investment principal from the Series B Investors, plus an annual simple rate of 12% of the original investment principle for a period of time commencing from the delivery date to the actual payments date of the settlement (calculated as 360 days in a calendar year) and any declared but unpaid dividends or profits thereon up to the date of the settlement, meanwhile, minus any dividends or profits distributed to Series B Investors.

***Anti-dilution right***

If the Company increases its paid-in capital at a price lower than the price paid by Series A Investors and Series B Investors on a per paid-in capital basis, the Series A Investors and Series B Investors have a right to require the Company to issue new paid-in capital for nil consideration (or nominal consideration) to the Series A Investors and Series B Investors, so that the total amount paid by the investors divided by the total amount of paid-in capital obtained is equal to the price per paid-in capital in the new issuance.

If the Company increases its paid-in capital at a price lower than the price paid by Series A Investors and Series B Investors on a per paid-in capital basis, the Series A Investors and Series B Investors have a right to require : (1) the Company to issue new paid-in capital for nil consideration (or nominal consideration) to the Series A Investors and Series B Investors; (2) Controlling Shareholder to transfer the equity interests of the Company directly or indirectly held to the Series A Investors and Series B Investors at the lowest price allowed by the law; (3) Controlling Shareholder to settle the difference in cash and (4) other arrangements allowed by the law, so that the total amount paid by the investors divided by the total amount of paid-in capital obtained is equal to the price per paid-in capital in the new issuance.

***Liquidation preferences***

In the event of any liquidation, dissolution or winding up of the Company, either voluntarily or involuntarily, the Series A Investors and Series B Investors shall be entitled to receive the liquidation preference amount, prior and in preference to any distribution of any of the assets or surplus funds of the Company to the holders of ordinary shares.

The liquidation preference amount of Series A Investors is calculated whichever higher of: (i) the distributable assets of the Company for Series A Investors based on their shareholding ratio and (ii) the original investment principle from the Series A Investors, plus an annual simple rate of 10% of the original investment principle for a period of time commencing from the delivery date to the actual payments date of the settlement (calculated as 360 days in a calendar year) and any declared but unpaid dividends or profits thereon up to the date of the settlement, meanwhile, minus any dividends or profits already distributed.

The liquidation preference amount of Series B Investors is calculated whichever higher of: (i) the distributable assets of the Company for Series B Investors based on their shareholding ratio. If the amount of distributable assets is not enough to cover the amount calculated based on the method described in (ii) below, the difference should be paid by the original shareholder and the Controlling Shareholder. (iii) the original investment principle from the Series B Investors, plus an annual simple rate of 10% of the original investment principle for a period of time commencing from the delivery date to the actual payments date of the settlement (calculated as 360 days in a calendar year) and any declared but unpaid dividends or profits thereon up to the date of the settlement, meanwhile, minus any dividends or profits already distributed.

A liquidation event means (i) any sale, lease, disposition or conveyance by the Company of all or substantially all of its assets (including the exclusive licensing of all or substantially all the intellectual property assets of the Company); (ii) any merger, consolidation or other transactions resulting in the Company acquired by other entity or after which change the substantial control of the Company; (iii) any transactions after which change the substantial control of the ultimate controller of the Company; (iv) any liquidation, dissolution or winding up, either voluntarily or involuntarily, of the Company; (v) any transaction similar with above (i) to (v).



Shanghai Miracogen Inc.- Ex. 2032, Page 000682

***Withdrawal Rights under Acquisition***

If any third party proposes to acquire all or most of the equity interests of the Company or a merger transaction, the consideration should refer to the market price. If ultimate controlling shareholder, existing shareholders and related parties propose to acquire all or most of the equity interests of the Company or a merger transaction, the transaction must obtain pre-approvals from Series A Investors and Series B Investors and Series A Investors and Series B Investors are guaranteed that the expected annual rate of return is no lower than 25%. Otherwise, the Company, ultimate controlling shareholder and the existing shareholders are obligated to bear related responsibility. The rights aforementioned are not applicable under the circumstances that the Company's equity interests held by the ultimate controlling shareholder were acquired by Lepu Medical after the Company's qualified IPO.

On 28 August 2020, the Series A Investors and Series B Investors agreed to terminate abovementioned preferred rights.

**34.1 Convertible Loans**

**The Group and The Company**

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| Convertible loans | 380,620 | – | – |

(a) In March and June 2019, the Convertible Loans were issued according to the Series A Investment Agreement and were initially recognised as convertible loans at fair value of RMB360,000,000 in accordance with IFRS 9. The management of the Company has involved an independent qualified valuer to determine the fair value of convertible loans by using the back-solve method and OPM model upon initial recognition (Note 3.3(ii)).

The convertible loans were subsequently measured at fair value. As at 31 December 2019, the fair value of convertible loans amounted to approximately RMB380,620,000, which was determined by an independent qualified valuer using discounted cash flow method and OPM model (Note 3.3(ii)). Changes in fair value was recognised in the consolidated statements of comprehensive loss.

On 21 April 2020, upon completion of Series A Conversion, the convertible loans at fair value of approximately RMB429,168,000 was derecognised and the paid-in capital was accordingly increased by approximately RMB101,408,000 in accordance with the conversion arrangement of the Series A Investment Agreement. The difference between the fair value of the convertible loans and the paid-in capital was charged to the capital reserves.

(b) The movements of convertible loans for the years ended 31 December 2019 and 2020 and eight months ended 31 August 2020 and 2021 are set out below:

| | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|
| | 2019 | 2020 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* (Unaudited) | *RMB'000* |
| Opening balance | – | 380,620 | 380,620 | – |
| Additions | 360,000 | – | – | – |
| Change in fair value *(Note 9)* | 20,620 | 48,548 | 48,548 | – |
| Converted into financial instruments with preferred rights at amortised cost *(Note 34.2)* | – | (429,168) | (429,168) | – |
| Closing balance | **380,620** | **–** | **–** | **–** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000683

**34.2 Financial Instruments with Preferred Rights at Amortised Cost**

**The Group and The Company**

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| Financial instruments with preferred rights | 397,489 | – | – |

The financial instruments with preferred rights represented the paid-in capital of the Company with preferred rights held by certain investors. The Group recognised the financial instruments with preferred rights as financial liabilities due to that all triggering events as abovementioned of key preferred rights to Series A Investors and Series B Investors, are out of control of the Company and these financial instruments does not meet the definition of equity for the Company. The financial liabilities are initially measured at present value and subsequently measured at amortised cost. The present value is the amount expected to be paid to the investors upon redemption which is assumed to be at the dates of issuance of the financial instruments. Interests from the financial instruments are charged in finance cost.

***(a) Houde Yimin Loans***

In accordance with the Series A Investment, Series A Investors have been granted redemption rights upon issuance of Houde Yimin Loans. Series A Investors have a right to require the Company to redeem their investments. Therefore, the Company has undertaken the obligation to redeem the Houde Yimin Loans and then the paid-in capital converted by Houde Yimin Loans.

Therefore, on 4 March 2019, the abovementioned Houde Yimin Loans were initially recognised as financial instruments with preferred rights at amortised cost. The Company applied a redemption discount rate of 18.02%, to arrive the present value of the financial instruments issued to investors. Accordingly, the Group recorded treasury stock of approximately RMB347,454,000 to reflect the carrying amount of the financial instruments with preferred rights. The difference between issuance price of the Houde Yimin Loans and the fair value of the equity on issuance date, amounted to approximately RMB143,695,000 was recognised as the share-based compensation to reflect the benefit received by the Ningbo Houde Yimin in accordance with IFRS 2 *Share-based Payment*.

On 28 August 2020, as the abovementioned preferred rights granted upon issuance of Houde Yimin Loans were terminated. The financial instruments with preferred rights at amortised cost of approximately RMB444,115,000 and the treasury stock of approximately RMB347,454,000 was derecognised, and the difference was charged to the other reserves, which was approximately RMB96,661,000.

***(b) Convertible Loans***

On 21 April 2020, upon completion of Series A Conversion, the convertible loans were derecognised and credited to equity and were further recognised as financial instruments with preferred rights at amortised cost. The Group applied a redemption discount rate of 18.81%, to arrive the present value of the financial instruments issued to investors. Accordingly, the Group recorded treasury stock of approximately RMB328,762,000 to reflect the carrying amount of the financial instruments with preferred rights at amortised cost.

On 28 August 2020, as the abovementioned preferred rights granted upon issuance of Convertible Loans were terminated. The financial instruments with preferred rights at amortised cost of approximately RMB349,706,000 and the treasury stock of approximately RMB328,762,000 were derecognised, and the difference was charged to the other reserves, which was approximately RMB20,944,000.



Shanghai Miracogen Inc.- Ex. 2032, Page 000684

*(c) Series B Capital Injection*

In August 2020, upon completion of Series B Capital Injection, the Company issued paid-in capital of approximately RMB226,954,000, the difference between capital contribution received from Series B Investors of RMB1,291,000,000 and paid-in capital issued was recorded as reserve. The Company further recognised the financial instruments with preferred rights at amortised cost of approximately of RMB1,192,480,000 which is the present value of the financial instruments with preferred rights issued to Series B Investors. The Company applied a redemption discount rate of 14.74%, to arrive the present value of the financial instruments issued to investors.

On 28 August 2020, as the abovementioned preferred rights granted upon issuance of Series B Capital Injection were terminated. The financial instruments with preferred rights at amortised cost of approximately RMB1,205,762,000 and the treasury stock of approximately RMB1,192,480,000 were derecognised, and the difference was charged to the other reserves, which was approximately RMB13,282,000.

*(d)* The movements of financial instruments with preferred rights at amortised cost for the years ended 31 December 2019 and 2020 and eight months ended 31 August 2020 and 2021 are set out below:

**Group and Company**

| | **Financial instruments with preferred rights** *RMB'000* |
|---|---|
| As at 1 January 2019 | – |
| Recognition of Houde Yimin Loans | 347,454 |
| Charged to finance costs | 50,035 |
| **As at 31 December 2019** | **397,489** |
| As at 1 January 2020 | 397,489 |
| Recognition of Series B Preferred Rights | 1,192,480 |
| Conversion of Convertible Loans | 328,762 |
| Charged to finance costs | 80,852 |
| Derecognition | (1,999,583) |
| **As at 31 December 2020** | **–** |
| As at 1 January 2021 | – |
| **As at 31 August 2021** | **–** |
| As at 1 January 2020 | 397,489 |
| Recognition of Series B Preferred Rights | 1,192,480 |
| Conversion of Convertible Loans | 328,762 |
| Charged to finance costs | 80,852 |
| Derecognition | (1,999,583) |
| **As at 31 August 2020 (Unaudited)** | **–** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000685

## 35 BUSINESS COMBINATION UNDER COMMON CONTROL

On 8 September 2017, in order to support research and development strategy and expand the business, Ningbo Houde Yimin entered into an investment agreement (the "Hanzhong Investment Agreement") with Hangzhou HanX Biomedical Co., Ltd. ("HanX") to acquire the 60% equity interests of Taizhou Hanzhong, pursuant to which: (i) Ningbo Houde Yimin agreed to acquire 38.46% equity interests of Taizhou Hanzhong from HanX; (ii) Ningbo Houde Yimin agreed to inject capital of RMB70,000,000 into Taizhou Hanzhong; (iii) HanX and its related parties agreed to transfer the rights and interests of PD-1 to Taizhou Hanzhong (the "PD-1 Transition"), which will constitute the significant assets of Taizhou Hanzhong.

The total consideration of the above transactions was RMB120,000,000 and was paid based on the payment ratios of 20%, 30%, 20% and 30% on 21 September 2017, 29 December 2017, 18 September 2018, and 29 January 2019, respectively as predetermined in the Hanzhong Investment Agreement by Ningbo Houde Yimin.

On 7 June 2018, the Company entered into an equity transfer agreement (the "Equity Transfer Agreement") with Ningbo Houde Yimin, pursuant to which the Company has conditionally agreed to acquire and Ningbo Houde Yimin has conditionally agreed to sell 51% equity interests of Taizhou Hanzhong at a consideration of RMB112,200,000 subject to the aforementioned PD-1 Transition. The consideration was fully paid on 12 July 2018.

On 19 February 2019, the PD-1 Transition was completed with the recognition of intangible assets of approximately RMB129,850,000 in Taizhou Hanzhong, which also met the precondition agreed in the Equity Transfer Agreement. Accordingly, Taizhou Hanzhong has become a subsidiary of the Company and the other reserves amounting to RMB112,200,000 were offset by the consideration paid.

As the Company and Taizhou Hanzhong are ultimately controlled by Ningbo Houde Yimin before and after the acquisitions, and the control is not temporary simultaneously, the acquisition is accounted for business combination under common control using predecessor method. The consolidated financial statements have been restated to give effect to the acquisition with Track Record Period presented as if the business of Taizhou Hanzhong had always been carried out by the Group. Accordingly, the adjusted other reserves were increased by approximately RMB70,628,000, accumulated losses were increased by approximately RMB33,145,000 and the non-controlling interests was increased by RMB32,124,000 as at 1 January 2019.

On 29 January 2019, according to the payments scheduled as pre-determined in the Hanzhong Investment Agreement, approximately RMB45,308,000 was paid by Ningbo Houde Yimin and non-controlling shareholder, of which approximately RMB31,372,000 was charged to the capital reserve and RMB13,936,000 was attributed to the remaining 9% non-controlling interests.



Shanghai Miracogen Inc.- Ex. 2032, Page 000686

**36 CASH USED IN OPERATIONS**

| | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|
| | **2019** | **2020** | **2020** | **2021** |
| | *RMB'000* | *RMB'000* | *RMB'000* (Unaudited) | *RMB'000* |
| **Cash flows from operating activities** | | | | |
| Loss before income tax | (515,492) | (613,448) | (452,156) | (668,235) |
| Adjustments for: | | | | |
| – Impairment loss on financial assets | 372 | 212 | 406 | (207) |
| – Depreciation of property, plant and equipment | 9,341 | 35,137 | 23,558 | 32,052 |
| – Amortisation of intangible assets | 26,792 | 28,551 | 19,135 | 19,203 |
| – Depreciation of right-of-use assets | 13,133 | 20,426 | 13,887 | 12,481 |
| – Share-based payments | 143,695 | 5,224 | – | 85,805 |
| – Gain on disposal of property, plant and equipment | (70) | – | – | – |
| – Change in fair value of financial liabilities at fair value through profit or loss | 38,312 | 78,648 | 117,831 | 48,158 |
| – Change in fair value of financial assets at fair value through profit or loss | – | (657) | (334) | (724) |
| – Finance costs/(income), net | 51,925 | 79,903 | 83,063 | (672) |
| – Investment income on financial assets at fair value through profit or loss | (2,035) | (5,091) | (689) | (3,681) |
| – Share of loss/(profit) of investments accounted for using the equity method | 8,675 | 12,084 | 5,390 | 6,293 |
| Operating cash flows before movements in working capital | **(225,352)** | **(359,011)** | **(189,909)** | **(469,527)** |
| Increase in deferred government grants | 12,000 | – | – | – |
| Increase in inventories | (8,082) | (11,487) | (8,058) | (4,595) |
| Increase in other receivables, prepayments and deposits | (46,358) | (76,146) | (32,338) | (4,846) |
| Increase in trade payables and other payables and accruals | 33,402 | 18,725 | 17,754 | 57,045 |
| **Cash used in operations** | **(234,390)** | **(427,919)** | **(212,551)** | **(421,923)** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000687

**Non-cash investing and financing activities**

Non-cash investing and financing activities disclosed in other notes are:

- Capitalisation of depreciation charge of land use rights – Note 15(a)
- Dilution of the ownership interest – Note 17
- Recognition of financial instruments with preferred rights at amortised cost upon issuance of Houde Yimin Loans – Note 34.2(a)
- Conversion of Convertible Loans – Note 34.2(b)
- Acquisition of 36.99% equity interests of Miracogen Shanghai – Note 39(b)
- Derecognition of financial instruments with preferred rights at amortised cost – Note 34.2(d).

**Net Debt Reconciliation**

This section sets out an analysis of net debt and the movements in net debt for each of the periods presented.

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | **2019** | **2020** | **2021** |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| Cash and cash equivalents | 188,545 | 402,867 | 261,194 |
| Term deposits with initial terms over three months | – | 20,000 | 50,000 |
| Financial assets at fair value through profit or loss | – | 330,657 | 132,724 |
| Financial liabilities at fair value through profit or loss | (279,081) | (309,181) | (357,339) |
| Convertible loans | (380,620) | – | – |
| Financial instruments with preferred rights at amortised cost | (397,489) | – | – |
| Borrowing | (118,266) | (147,266) | (198,064) |
| Lease liabilities | (75,816) | (52,000) | (39,447) |
| **Net debt** | **(1,062,727)** | **245,077** | **(150,932)** |
| Cash and liquid investments | 188,545 | 753,524 | 443,918 |
| Gross debt – fixed interest rates | (473,305) | (52,000) | (39,447) |
| Gross debt – variable interest rates | (777,967) | (456,447) | (555,403) |
| **Net debt** | **(1,062,727)** | **245,077** | **(150,932)** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000688

| | Cash and cash equivalents | Bank deposits with the initial maturity over three months | Financial assets at fair value through profit or loss | Financial liabilities at fair value through profit or loss | Convertible loans | Financial instruments with preferred rights at amortised cost | Borrowings | Lease liabilities | Total |
|---|---|---|---|---|---|---|---|---|---|
| | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* |
| **Net debt as at 1 January 2019** | 67,462 | – | – | – | – | – | – | (39,393) | 28,069 |
| Cash flows | 121,083 | – | – | – | (360,000) | – | (118,266) | 1,807 | (355,376) |
| Addition-leases | – | – | – | – | – | – | – | (35,943) | (35,943) |
| Non-cash movements | – | – | – | (279,081) | (20,620) | (397,489) | – | (2,287) | (699,477) |
| **Net debt as at 31 December 2019** | **188,545** | **–** | **–** | **(279,081)** | **(380,620)** | **(397,489)** | **(118,266)** | **(75,816)** | **(1,062,727)** |
| Cash flows | 214,322 | 20,000 | 330,657 | – | – | – | (29,000) | 29,388 | 565,367 |
| Addition-leases | – | – | – | – | – | – | – | (2,473) | (2,473) |
| Non-cash movements | – | – | – | (30,100) | 380,620 | 397,489 | – | (3,099) | 744,910 |
| **Net debt as at 31 December 2020** | **402,867** | **20,000** | **330,657** | **(309,181)** | **–** | **–** | **(147,266)** | **(52,000)** | **245,077** |
| Cash flows | (140,701) | 30,000 | (198,657) | – | – | – | (50,798) | 15,427 | (344,729) |
| Addition-leases | – | – | – | – | – | – | – | (1,341) | (1,341) |
| Non-cash movements | (972) | – | 724 | (48,158) | – | – | – | (1,533) | (49,939) |
| **Net debt as at 31 August 2021** | **261,194** | **50,000** | **132,724** | **(357,339)** | **–** | **–** | **(198,064)** | **(39,447)** | **(150,932)** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000689

## 37 COMMITMENTS

### (a) Capital commitments

Capital expenditure contracted for at end of year but not yet incurred is as follows:

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| Property, plant and equipment | 418,482 | 309,104 | 204,665 |
| Intangible assets | 9,124 | – | – |
| | **427,606** | **309,104** | **204,665** |

The Group entered into licensing agreements with certain collaboration parties. As at 31 December 2019 and 2020 and 31 August 2021, the possible contractual milestone obligation payments is approximately RMB537,567,000, RMB498,126,000 and RMB493,290,000, such possible obligation will be confirmed only by the occurrence of specific uncertain future events during the Group's long-term collaboration with such collaboration parties.

### (b) Operating lease commitments

The following is the details of operating lease commitments for short-term and low value leases.

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| **No Later than 1 year** | 649 | 652 | 838 |

## 38 SUBSIDIARIES

The Group's principal subsidiaries during the Track Record Period are set out below. Unless otherwise stated, the Group's subsidiaries have share capital consisting solely of ordinary shares that are held directly by the Group, and the proportion of ownership interests held equals the voting rights held by the Group. The country of incorporation or registration is also their principal place of business.

| | | | | Ownership interest held by the Group | | | Ownership interest held by non-controlling interests | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Name of subsidiaries | Place and date of incorporation | Registered/ Issued share capital | Principal business activities | As at 31 December 2019 | 2020 | As at 31 August 2021 | As at 31 December 2019 | 2020 | As at 31 August 2021 | Statutory Auditors |
| Miracogen Shanghai | the PRC, 27 January 2014 | RMB49,371,981 | Research and development focusing on ADC related pipelines | 63.01% | 100% | 100% | 36.99% | – | – | Note ii & v |
| Taizhou Hanzhong | the PRC, 25 November 2016 | RMB7,692,308 | Research and development focusing on PD-1 related pipelines | 91% | 91% | 91% | 9% | 9% | 9% | Note i & iv |



Shanghai Miracogen Inc.- Ex. 2032, Page 000690

| Name of subsidiaries | Place and date of incorporation | Registered/ Issued share capital | Principal business activities | Ownership interest held by the Group | | | Ownership interest held by non-controlling interests | | | Statutory Auditors |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | As at 31 December | | As at 31 August | As at 31 December | | As at 31 August | |
| | | | | 2019 | 2020 | 2021 | 2019 | 2020 | 2021 | |
| Taizhou Houde Aoke Technology Co., Ltd. ("Taizhou Aoke") | the PRC, 23 March 2018 | RMB262,000,000 | Research and development focusing on PD-L1 related pipelines | 70% | 70% | 70% | 30% | 30% | 30% | Note i & iv |
| CtM Bio Co., Ltd. ("CtM Bio") | the PRC, 26 March 2020 | RMB30,000,000 | Discovery of new drug candidates | N.A. | 70% | 70% | N.A. | 30% | 30% | Note i & iv |
| Lepu (Beijing) Biopharma Co., Ltd. ("Lepu Beijing") | the PRC, 30 July 2018 | RMB100,000,000 | Operation of manufacturing site in Beijing | 100% | 100% | 100% | – | – | – | Note ii & iv |
| Innocube Limited | the British Virgin Islands, 30 July 2020 | USD50,000 | Platform for clinical development overseas | N.A. | 100% | 100% | N.A. | – | – | Note i & iv |
| Shanghai Lepu Biopharma Investment Co., Ltd. ("Lepu Shanghai") | the PRC, 30 May 2018 | RMB50,000,000 | Investment | 100% | 100% | 100% | – | – | – | Note i & iv |
| Lepu Hangjia (Shanghai) Venture Capital Co., Ltd. ("Lepu Hangjia") | the PRC, 4 July 2018 | RMB50,000,000 | Business incubator management | 100% | 100% | 100% | – | – | – | Note ii & iv |
| Innocube Biosciences Inc. | the United States, 12 March 2021 | USD1,600,000 | Platform for clinical development overseas | N.A. | N.A. | 100% | N.A. | N.A. | – | Note i & iv |

*Notes:*

(i) No audited financial statements have been prepared for these companies for the year ended 31 December 2019, as they are newly incorporated or not required to issue audited financial statements under statutory requirements of their respective places of incorporation.

(ii) The statutory financial statements of these companies for the year ended 31 December 2019 were audited by BDO China Shu Lun Pan Certified Public Accountants LLP (立信會計師事務所(特殊普通合夥)).

(iii) The statutory financial statements of the Company for the year ended 31 December 2019 were audited by BDO China Shu Lun Pan Certified Public Accountants LLP (立信會計師事務所(特殊普通合夥)).

(iv) No audited financial statements have been prepared for these companies for the year ended 31 December 2020, as they are not required to issue audited financial statements under statutory requirements of their respective places of incorporation.

(v) The statutory financial statements of these companies for the year ended 31 December 2020 were audited by Shanghai Rongshen Certified Public Accountants Co., Ltd. (上海榮審會計師事務所有限責任公司).



Shanghai Miracogen Inc.- Ex. 2032, Page 000691

**(a) Non-controlling interests ("NCI")**

Set out below is summarised financial information for each subsidiary that has non-controlling interests ("NCI") that are material to the Group. The balances/amounts disclosed for each subsidiary are before inter-company balances/transactions eliminations.

***Summarised balance sheet***

| | Miracogen Shanghai | | | Taizhou Hanzhong | | | Taizhou Aoke | | |
|---|---|---|---|---|---|---|---|---|---|
| | As at 31 December | | As at 31 August | As at 31 December | | As at 31 August | As at 31 December | | As at 31 August |
| | 2019 | 2020 | 2021 | 2019 | 2020 | 2021 | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000 (Note)* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* |
| Current assets | 51,762 | NA | NA | 11,152 | 27,471 | 27,244 | 24,788 | 120,874 | 109,855 |
| Current liabilities | (16,538) | NA | NA | (71,656) | (200,548) | (309,104) | (21,771) | (44,127) | (56,954) |
| **Net current assets/(liabilities)** | **35,224** | **NA** | **NA** | **(60,504)** | **(173,077)** | **(281,860)** | **3,017** | **76,747** | **52,901** |
| Non-current assets | 378,422 | NA | NA | 129,840 | 125,124 | 122,412 | 4,334 | 2,723 | 1,743 |
| Non-current liabilities | (70,541) | NA | NA | – | – | – | – | – | – |
| **Net non-current assets** | **307,881** | **NA** | **NA** | **129,840** | **125,124** | **122,412** | **4,334** | **2,723** | **1,743** |
| **Net Assets/(liabilities)** | **343,105** | **NA** | **NA** | **69,336** | **(47,953)** | **(159,448)** | **7,351** | **79,470** | **54,644** |
| Accumulated NCI | 126,915 | NA | NA | 6,240 | – | – | 33,705 | 23,841 | 16,393 |

***Summarised statement of comprehensive loss***

| | Miracogen Shanghai | | | | Taizhou Hanzhong | | | | Taizhou Aoke | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Year ended 31 December | | Eight months ended 31 August | | Year ended 31 December | | Eight months ended 31 August | | Year ended 31 December | | Eight months ended 31 August | |
| | 2019 | 2020 | 2020 | 2021 | 2019 | 2020 | 2020 | 2021 | 2019 | 2020 | 2020 | 2021 |
| | *RMB'000* | *RMB'000 (Note)* | *RMB'000 (Unaudited)* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000 (Unaudited)* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000 (Unaudited)* | *RMB'000* |
| Other income | 600 | 1,052 | 1,052 | NA | 2,000 | 1 | 1 | 1 | 272 | 81 | 31 | 773 |
| **Loss for the year/period** | **(91,642)** | **(30,844)** | **(30,844)** | **NA** | **(95,695)** | **(110,016)** | **(65,312)** | **(111,591)** | **(29,368)** | **(32,880)** | **(20,438)** | **(24,826)** |
| Other comprehensive loss | – | – | – | NA | – | – | – | – | – | – | – | – |
| **Total comprehensive loss** | **(91,642)** | **(30,844)** | **(30,844)** | **NA** | **(95,695)** | **(110,016)** | **(65,312)** | **(111,591)** | **(29,368)** | **(32,880)** | **(20,438)** | **(24,826)** |
| Loss allocated to NCI | (33,899) | (11,409) | (11,409) | NA | (25,747) | (6,241) | (5,878) | (9) | (8,810) | (9,864) | (6,131) | (7,448) |



Shanghai Miracogen Inc.- Ex. 2032, Page 000692

***Summarised statements of cash flows***

| | Miracogen Shanghai | | | | Taizhou Hanzhong | | | | Taizhou Aoke | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Year ended 31 December | | Eight months ended 31 August | | Year ended 31 December | | Eight months ended 31 August | | Year ended 31 December | | Eight months ended 31 August | |
| | 2019 | 2020 | 2020 | 2021 | 2019 | 2020 | 2020 | 2021 | 2019 | 2020 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* |
| | | *(Note)* | *(Unaudited)* | | | | *(Unaudited)* | | | | *(Unaudited)* | |
| Cash flows used in operating activities | (63,941) | (28,116) | (28,116) | NA | (94,233) | (105,546) | (53,060) | (91,250) | (14,005) | (13,066) | (5,131) | (12,063) |
| Cash flows (used in)/generated from investing activities | (25,747) | (8,349) | (8,349) | NA | (1,658) | (1,717) | (17) | – | 233 | 17 | (4,503) | (100,996) |
| Cash flows generated from/(used in) financing activities | 99,000 | 33,599 | 33,599 | NA | 80,830 | 116,587 | 53,120 | 86,042 | (23,000) | 128,648 | 110,700 | – |
| **Net increase/(decrease) in cash and cash equivalents** | **9,312** | **(2,866)** | **(2,866)** | **NA** | **(15,061)** | **9,324** | **43** | **(5,208)** | **(36,772)** | **115,599** | **101,066** | **(113,059)** |

*Note:* Miracogen Shanghai has become a wholly-owned subsidiary of the Group on 29 May 2020 since the Group has completed the acquisition of remaining equity interests of Miracogen Shanghai. See Note 39(b) for further details.

## 39 TRANSACTIONS WITH NON-CONTROLLING INTERESTS

| | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|
| | 2019 | 2020 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* (Unaudited) | *RMB'000* |
| Acquisition of 40% equity interests of Taizhou Hanzhong *(a)* | 559,241 | – | – | – |
| Acquisition of 36.99% equity interests of Miracogen Shanghai *(b)* | – | 23,474 | 23,474 | – |
| Disposal of 30% equity interests of CtM Bio *(c)* | – | (547) | (547) | – |
| | **559,241** | **22,927** | **22,927** | **–** |

**(a) Acquisition of 40% equity interests of Taizhou Hanzhong**

| | *RMB'000* |
|---|---|
| Consideration recognised in the transactions with non-controlling interests: | |
| Fixed consideration | 350,000 |
| Variable consideration | 261,389 |
| Total consideration | 611,389 |
| Carrying amount of non-controlling interests acquired | (52,148) |
| **Acquisition of 40% equity interests of Taizhou Hanzhong** | 559,241 |



Shanghai Miracogen Inc.- Ex. 2032, Page 000693

On 29 September 2019, the Group entered into an equity purchase agreement with HanX to acquire 40% equity interests of Taizhou Hanzhong held by HanX at (i) the fixed consideration of RMB350,000,000 which is settled in cash; and (ii) the variable consideration of 4.375% of the annual net sales revenue of PD-1 products which will be settled annually after the PD-1 products launched into the market. The payment of aforementioned fixed consideration and the transfer of Taizhou Hanzhong's share are non-cancellable and to be settled in stages.

Considering the uncertainty for the annual sales revenue of PD-1 products, the Group recognised the variable consideration payables as financial liabilities at fair value through profit or loss. The variable consideration payables were initially recognised at fair value and the management has involved an independent qualified valuer to determine the fair value of variable consideration by using the discounted cash flow model. Key valuation assumptions are as follows:

| | **29 September 2019** |
|---|---|
| The first commercialisation year of PD-1 products | 2022 |
| Expected revenue growth rate from second year of commercialisation during the forecast period | 389%-6% |
| Expected revenue growth rate beyond the forecast period | 3%-0% |
| Expected market penetration rate | 0%-19% |
| Expected success rate of commercialisation | 14%-64% |
| Discount rate | 15.5% |

Upon completion of the transaction, the non-controlling interests were derecognised by approximately RMB52,148,000. The difference between total consideration and non-controlling interests are charged to other reserve amounted to RMB559,241,000.

**(b) Acquisition of 36.99% equity interests of Miracogen Shanghai**

| | *RMB'000* |
|---|---|
| Consideration recognised in the transactions with non-controlling interests: | |
| Total consideration | 138,979 |
| Carrying amount of non-controlling interests acquired | (115,505) |
| **Acquisition of 36.99% equity interests of Miracogen Shanghai** | **23,474** |

On 16 May 2020, the Group and Miracogen HK has entered into an equity transfer agreement, pursuant to which the Company has agreed to acquire and Miracogen HK has agreed to sell 36.99% equity interests of Miracogen Shanghai for a consideration of 10.98% equity interests of the Company. After the exchange of equity, the total paid-in capital of the Company was increased by approximately RMB138,979,000 and the non-controlling interests was derecognised by RMB115,505,000. The difference between such paid-in capital and non-controlling interests are charged into capital reserve amounted to approximately RMB23,474,000.

On 29 May 2020, the transaction was completed and Miracogen Shanghai has become a wholly owned subsidiary of the Group.

**(c) Disposal of 30% equity interests of CtM Bio**

| | *RMB'000* |
|---|---|
| Consideration recognised in the transactions with non-controlling interests: | |
| Total consideration | – |
| Carrying amount of equity interests disposed | (547) |
| **Disposal of 30% equity interests of CtM Bio** | **(547)** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000694

On 1 June 2020, the Group and Dr. Fang Lei, the research and development vice present of the Group and general manager of CtM Bio, have entered into an equity transfer agreement, pursuant to which the Group have agreed to sell and Dr. Fang Lei has agreed to acquire 30% equity interests of CtM Bio at a consideration of nil.

On 29 July 2020, the transaction was completed and approximately RMB547,000 attributed to non-controlling shareholders' interests was charged to the other reserve.

## 40 RELATED PARTY TRANSACTIONS

Parties are considered to be related if one party has the ability, directly or indirectly, to control the other party or exercise significant influence over the other party in making financial and operating decisions. Parties are also considered to be related because they are subject to common control, common significant influence or joint control in the controlling shareholder's families. Members of key management and their close family member of the Group are also considered as related parties.

The Group is controlled by the following entity for the Track Record Period.

| | | | Ownership interests in the Company | | |
|---|---|---|---|---|---|
| **Name** | **Type** | **Place of incorporation** | **As at 31 December 2019** | **2020** | **As at 31 August 2021** |
| Ningbo Houde Yimin | Immediate parent entity | Ningbo, the PRC | 56.00% | 29.02% | 28.29% |

The Company was ultimately controlled by Dr. Pu Zhongjie.

The directors are of the view that the following parties are other related parties exclude subsidiaries and associates that had transactions or balances with the Group:

| **Name** | **Relationship with the Group** |
|---|---|
| Beijing Zhongjie Tiangong Medical Technology Co., Ltd. ("北京中傑天工醫療科技有限公司") | Subsidiary of an entity which the director is a close family member of Dr. Pu Zhongjie |
| Beijing Pufeng Medical Management Co., Ltd. ("北京普峰醫療管理有限公司") | Subsidiary of an entity which the director is a close family member of Dr. Pu Zhongjie |
| Beijing Volt Technology Co., Ltd. ("北京伏爾特技術有限公司") | Subsidiary of an entity which the director is a close family member of Dr. Pu Zhongjie |
| Beijing Highthink Pharmaceutical Technology Service Co., Ltd. ("北京海金格醫藥科技股份有限公司") | Entity which the director is Dr. Pu Zhongjie |
| Lepu Pharmaceutical Co., Ltd. ("樂普藥業股份有限公司") | Controlled by Controlling Shareholder |
| Shanghai Shape Memory Alloy Material Co., Ltd. ("上海形狀記憶合金材料有限公司") | Controlled by Controlling Shareholder |
| Beijing Lepu Hushengtang Network Technology Co., Ltd. ("北京樂普護生堂網絡科技有限公司") | Controlled by Controlling Shareholder |
| Lepu Zhixin (Tianjin) Medical Devices Co., Ltd. ("樂普智芯(天津)醫療器械有限公司") | Controlled by Controlling Shareholder |
| Shanghai Youjiali Health Management Co., Ltd. ("上海優加利健康管理有限公司") | Controlled by Controlling Shareholder |
| Shenzhen Keruikang Industrial Co., Ltd. ("深圳市科瑞康實業有限公司") | Controlled by Controlling Shareholder |


Shanghai Miracogen Inc.- Ex. 2032, Page 000695

| Name | Relationship with the Group |
|---|---|
| Beijing Lejian Dongwai Clinic Co., Ltd. ("北京樂健東外門診部有限公司") | Controlled by Controlling Shareholder |
| Beijing Aipuyi Medical Testing Center Co., Ltd. ("北京愛普益醫學檢驗中心有限公司") | Controlled by Controlling Shareholder |
| Dr. Fang Lei | A senior management of the Group |
| CG Oncology, Inc. | Entity which the director is Ms. Pu Jue, who is director of the Company |

The following significant transactions were carried out between the Group and its related parties during the Track Record Period. In the opinion of the directors of the Company, the related party transactions were carried out in the normal course of business and at terms negotiated between the Group and the respective related parties.

**40.1 Transactions with other related parties**

(a) Purchase and sale of raw materials and various services

| | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|
| | 2019 | 2020 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* (Unaudited) | *RMB'000* |
| Purchase of equipment from Lepu Pharmaceutical Co., Ltd. | – | 31,858 | – | – |
| Licensing-in of intellectual property from CG Oncology, Inc. | 28,525 | – | – | – |
| Leasing from: | | | | |
| – Beijing Zhongjie Tiangong Medical Technology Co., Ltd. | – | 17,573 | 15,044 | 185 |
| – Lepu Pharmaceutical Co., Ltd. | – | 4,602 | 2,832 | – |
| – Shanghai Shape Memory Alloy Material Co., Ltd. | – | 739 | – | 3,106 |
| – Beijing Pufeng Medical Management Co., Ltd. | – | – | – | 6,932 |
| Purchase of technical development services from: | | | | |
| – Beijing Highthink Pharmaceutical Technology Service Co., Ltd. | 7,730 | 9,654 | 4,276 | 34,876 |
| – associates | 2,736 | 4,111 | 180 | 21,069 |
| – other related parties | 2,194 | 2,741 | 1,148 | 4,368 |
| Purchase of professional services from CG Oncology, Inc. | 614 | 1,841 | 1,493 | 932 |
| Purchase of raw materials from other related parties | 2,269 | 1,030 | 545 | 241 |
| Rental services provided to associates | 778 | 1,556 | 1,037 | 734 |



Shanghai Miracogen Inc.- Ex. 2032, Page 000696

(b) Loans from Ningbo Houde Yimin

| | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|
| | 2019 | 2020 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* (Unaudited) | *RMB'000* |
| Beginning of the year | – | – | – | – |
| Loans advanced | – | 50,000 | – | – |
| Loans repayments received | – | (50,000) | – | – |
| Interest charged | – | 387 | – | – |
| Interest paid | – | (387) | – | – |
| End of the year | – | – | – | – |

(c) Transaction with Non-controlling interest

| | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|
| | 2019 | 2020 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* (Unaudited) | *RMB'000* |
| Disposal of 30% equity interests of CtM Bio *(Note 39(c))* | Not applicable | 547 | Not applicable | Not applicable |

(d) Guarantee from related parties

The following balances are guaranteed by related parties for the Group's bank borrowings:

| | Guaranteed by | Guaranteed credit line *RMB'000* | Guarantees start date | Guarantees end date | Guarantees due or not |
|---|---|---|---|---|---|
| Bank A *(Note 28(a))* | Dr. Pu Zhongjie | 350,000 | 02/09/2019 | 25/04/2021 | Due |
| Convertible loans | Ningbo Houde Yimin and Dr. Pu Zhongjie | 360,000 | 04/03/2019 | 03/03/2020 | Due |

All guarantees provided by the related parties have been released before 31 August 2021.

(e) Guarantee to related parties

The following balances are guaranteed to related parties for the related parties' borrowings:

| | Guaranteed to | Guaranteed credit line *RMB'000* | Guarantees start date | Guarantees end date | Guarantees due or not |
|---|---|---|---|---|---|
| Houde Yimin Loans | Ningbo Houde Yimin | 450,000 | 04/03/2019 | 03/03/2020 | Due |

The guarantee provided to the related party has been released before 31 August 2021.



Shanghai Miracogen Inc.- Ex. 2032, Page 000697

**40.2 Balances with related parties**

| | As at 31 December | | As at 31 August |
|---|---|---|---|
| | 2019 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* |
| **Balances due from related parties** | | | |
| Other receivables from associates | 833 | – | – |
| Prepayment to: | | | |
| – associates | 113 | 2,171 | – |
| – Beijing Zhongjie Tiangong Medical Technology Co., Ltd. | – | 1,560 | – |
| – Beijing Pufeng Medical Management Co., Ltd. | – | – | 1,440 |
| – other related parties | 137 | – | – |
| | **1,083** | **3,731** | **1,440** |
| **Balances due to related parties** | | | |
| Trade payables to: | | | |
| – Beijing Highthink Pharmaceutical Technology Service Co., Ltd. | 2,866 | 7,968 | 23,437 |
| – other related parties | 466 | 878 | – |
| – associates | – | 27 | 4,987 |
| Other payables and accruals to: | | | |
| – Beijing Zhongjie Tiangong Medical Technology Co., Ltd. | 4,355 | 1,358 | – |
| – Beijing Pufeng Medical Management Co., Ltd. | – | 1,518 | 1,287 |
| – other related parties | 761 | 1,569 | 471 |
| | **8,448** | **13,318** | **30,182** |

As at 31 December 2019 and 2020 and 31 August 2021, there was no any non-trade nature balance with related parties, all balances with related parties were non-interest bearing and trade in nature, and their fair values approximated their carrying amounts due to their short maturities.

**40.3 Key management compensation**

Key management includes executive directors, supervisors and senior managements. The compensation paid or payable to key management personnel other than Directors and supervisors disclosed in Note 41 is shown as below:

| | Year ended 31 December | | Eight months ended 31 August | |
|---|---|---|---|---|
| | 2019 | 2020 | 2020 | 2021 |
| | *RMB'000* | *RMB'000* | *RMB'000* (Unaudited) | *RMB'000* |
| Salaries, bonus and other allowances | 6,009 | 8,727 | 3,490 | 8,416 |
| Pension costs – defined contribution plans | – | – | – | 74 |
| Other social security costs, housing benefits, and other employee benefits | – | 48 | 16 | 411 |
| Share-based payment expenses | – | 2,713 | – | 65,501 |
| | **6,009** | **11,488** | **3,506** | **74,402** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000698

## 41 BENEFITS AND INTERESTS OF DIRECTORS

### (a) Directors and supervisors

Details of the emoluments paid or payable to the directors and supervisors for the Track Record Period are set out as follows:

| | Fees | Salaries | Bonus and other allowances | Share-based payments | Defined contribution plans | Total |
|---|---|---|---|---|---|---|
| | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* |
| **Year ended 31 December 2019** | | | | | | |
| Name of director: | | | | | | |
| Dr. Pu Zhongjie *(i)* | – | – | – | – | – | – |
| | **–** | **–** | **–** | **–** | **–** | **–** |
| Name of supervisor: | | | | | | |
| Ms. Wang Yong *(ii)* | – | – | – | – | – | – |
| | **–** | **–** | **–** | **–** | **–** | **–** |

| | Fees | Salaries | Bonus and other allowances | Share-based payments | Defined contribution plans | Total |
|---|---|---|---|---|---|---|
| | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* |
| **Year ended 31 December 2020** | | | | | | |
| Name of directors: | | | | | | |
| Dr. Pu Zhongjie *(i)* | – | – | – | – | – | – |
| Dr. Sui Ziye *(iii)* | – | 1,032 | 309 | 522 | 57 | 1,920 |
| Dr. Hu Chaohong *(iv)* | – | 2,270 | 469 | 522 | – | 3,261 |
| Ms. Pu Jue *(v)* | – | – | – | – | – | – |
| Mr. Yang Hongbing *(vi)* | – | – | – | – | – | – |
| Mr. Lin Xianghong *(vii)* | – | – | – | – | – | – |
| | **–** | **3,302** | **778** | **1,044** | **57** | **5,181** |
| Name of independent non-executive directors: | | | | | | |
| Mr. Zhou Demin *(viii)* | 15 | – | – | – | – | 15 |
| Mr. Yang Haifeng *(ix)* | 15 | – | – | – | – | 15 |
| Ms. Li Lan *(x)* | 15 | – | – | – | – | 15 |
| | **45** | **–** | **–** | **–** | **–** | **45** |
| Name of supervisor: | | | | | | |
| Ms. Wang Yong *(ii)* | – | – | – | – | – | – |
| Mr. Xu Yang *(xi)* | 15 | – | – | – | – | 15 |
| Mr. Yang Ming *(xii)* | – | – | – | – | – | – |
| Mr. Wang Jiwei *(xiii)* | – | 93 | 29 | – | 11 | 133 |
| | **15** | **93** | **29** | **–** | **11** | **148** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000699

| | Fees | Salaries | Bonus and other allowances | Share-based payments | Defined contribution plans | Total |
|---|---|---|---|---|---|---|
| | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* |
| **Eight months ended 31 August 2020** | | | | | | |
| Name of directors: | | | | | | |
| Dr. Pu Zhongjie *(i)* | – | – | – | – | – | – |
| Dr. Sui Ziye *(iii)* | – | 677 | – | – | 32 | 709 |
| Dr. Hu Chaohong *(iv)* | – | 1,169 | – | – | – | 1,169 |
| Ms. Pu Jue *(v)* | – | – | – | – | – | – |
| Mr. Yang Hongbing *(vi)* | – | – | – | – | – | – |
| Mr. Lin Xianghong *(vii)* | – | – | – | – | – | – |
| | **–** | **1,846** | **–** | **–** | **32** | **1,878** |
| Name of independent non-executive directors: | | | | | | |
| Mr. Zhou Demin *(viii)* | – | – | – | – | – | – |
| Mr. Yang Haifeng *(ix)* | – | – | – | – | – | – |
| Ms. Li Lan *(x)* | – | – | – | – | – | – |
| | **–** | **–** | **–** | **–** | **–** | **–** |
| Name of supervisor: | | | | | | |
| Ms. Wang Yong *(ii)* | – | – | – | – | – | – |
| Mr. Xu Yang *(xi)* | – | – | – | – | – | – |
| Mr. Yang Ming *(xii)* | – | – | – | – | – | – |
| Mr. Wang Jiwei *(xiii)* | – | – | – | – | – | – |
| | **–** | **–** | **–** | **–** | **–** | **–** |



Shanghai Miracogen Inc.- Ex. 2032, Page 000700

| | Fees | Salaries | Bonus and other allowances | Share-based payments | Defined contribution plans | Total |
|---|---|---|---|---|---|---|
| | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* | *RMB'000* |
| **Eight months ended 31 August 2021** | | | | | | |
| Name of directors: | | | | | | |
| Dr. Pu Zhongjie *(i)* | – | – | – | – | – | – |
| Dr. Sui Ziye *(iii)* | – | 1,384 | – | 5,290 | 87 | 6,761 |
| Dr. Hu Chaohong *(iv)* | – | 1,653 | – | 5,290 | – | 6,943 |
| Ms. Pu Jue *(v)* | – | – | – | – | – | – |
| Mr. Yang Hongbing *(vi)* | – | – | – | – | – | – |
| Mr. Lin Xianghong *(vii)* | – | – | – | – | – | – |
| | **–** | **3,037** | **–** | **10,580** | **87** | **13,704** |
| Name of independent non-executive directors: | | | | | | |
| Mr. Zhou Demin *(viii)* | 168 | – | – | – | – | 168 |
| Mr. Yang Haifeng *(ix)* | 168 | – | – | – | – | 168 |
| Ms. Li Lan *(x)* | 168 | – | – | – | – | 168 |
| Mr. Li Yipeng *(xiv)* | 97 | – | – | – | – | 97 |
| | **601** | **–** | **–** | **–** | **–** | **601** |
| Name of supervisor: | | | | | | |
| Ms. Wang Yong *(ii)* | – | – | – | – | – | – |
| Mr. Xu Yang *(xi)* | 168 | – | – | – | – | 168 |
| Mr. Yang Ming *(xii)* | – | – | – | – | – | – |
| Mr. Wang Jiwei *(xiii)* | – | 74 | – | – | 24 | 98 |
| | **168** | **74** | **–** | **–** | **24** | **266** |

(i) Dr. Pu Zhongjie was designated as the director of the Company on 19 January 2018. For other benefit from the Controlling Shareholder Loans, please refer to Note 34.

(ii) Ms. Wang Yong was appointed as a supervisor on 19 January 2018 and resigned on 10 December 2020.

(iii) Dr. Sui Ziye was appointed as an executive director on 22 April 2020.

(iv) Dr. Hu Chaohong was appointed as an executive director on 16 May 2020.

(v) Ms. Pu Jue was appointed as a non-executive director on 22 April 2020.

(vi) Mr. Yang Hongbing was appointed as a non-executive director on 22 April 2020.

(vii) Mr. Lin Xianghong was appointed as a non-executive director on 22 April 2020.

(viii) Mr. Zhou Demin was appointed as an independent non-executive director on 10 December 2020.

(ix) Mr. Yang Haifeng was appointed as an independent non-executive director on 10 December 2020.

(x) Ms. Li Lan was appointed as an independent non-executive director on 10 December 2020 and resigned on 14 April 2021.



Shanghai Miracogen Inc.- Ex. 2032, Page 000701

(xi) Mr. Xu Yang was appointed as a supervisor on 10 December 2020.

(xii) Mr. Yang Ming was appointed as a supervisor on 10 December 2020.

(xiii) Mr. Wang Jiwei was appointed as a supervisor on 10 December 2020.

(xiv) Mr. Li Yipeng was appointed as an independent non-executive director on 14 April 2021.

No directors or supervisors waived or agreed to waive any emoluments during the Track Record Period. No emoluments were paid to directors or supervisors as an inducement to join or upon joining the Group or as compensation for loss of office during the Track Record Period.

**(b) Directors and supervisors' retirement benefits**

None of the directors or supervisors received or will receive any retirement benefits during the Track Record Period.

**(c) Directors and supervisors' termination benefits**

None of the directors or supervisors received or will receive any termination benefits during the Track Record Period.

**(d) Information about loans, quasi-loans and other dealings in favour of directors, supervisors and bodies corporate controlled by or entities connected with directors**

Other than disclosed in Note 40, there were no loans, quasi-loans and other dealings in favour of directors, supervisors or controlled bodies corporate by and connected entities with such directors or supervisors during the Track Record Period.

**(e) Directors and supervisors' material interests in transactions, arrangements or contracts**

Other than disclosed in Note 40, there were no other significant transactions, arrangements and contracts in relation to the Group's business to which the Group was a party and in which a director or supervisor of the Company had a material interest, whether directly or indirectly, subsisted at the end of the year/period or at any time during the Track Record Period.

**42 DIVIDEND**

No dividend has been paid or declared by the Company or companies comprising the Group during the Track Record Period.

**43 CONTINGENCIES**

As at 31 December 2019 and 2020 and 31 August 2021, there were no significant contingencies items for the Group and the Company.

**44 SUBSEQUENT EVENTS**

Other than the event as disclosed in Note 17, there is no other significant event occurred after the balance sheet date.

## III. SUBSEQUENT FINANCIAL STATEMENTS

No audited financial statements have been prepared for the Company or any of the companies now comprising the Group in respect of any period subsequent to 31 August 2021 and up to the date of this report. No dividend or distribution have been declared, made or paid by the Company or any of the companies now comprising the Group in respect of any period subsequent to 31 August 2021.



Shanghai Miracogen Inc.- Ex. 2032, Page 000702

*The following information set forth does not form part of the "Accountant's Report" from the PricewaterhouseCoopers, Certified Public Accountants, Hong Kong, the Company's reporting accountant, as set forth in Appendix I to this prospectus, and is included herein for illustrative purpose only. The unaudited pro forma financial information should be read in conjunction with the sections headed "Financial Information" in this document and the Accountant's Report set out in Appendix I to this document.*

## A. UNAUDITED PRO FORMA STATEMENT OF ADJUSTED CONSOLIDATED NET TANGIBLE ASSETS

The following is an illustrative unaudited pro forma statement of adjusted consolidated net tangible assets which has been prepared in accordance with Rule 4.29 of the Listing Rules for the purpose of illustrating the effect of the Global Offering as if it had taken place on 31 August 2021 and based on the consolidated net tangible assets attributable to the owners of the Company as at 31 August 2021 as shown in the Accountant's Report, the text of which is set out in Appendix I to this prospectus, and adjusted as described below.

This unaudited pro forma statement of adjusted consolidated net tangible assets has been prepared for illustrative purposes only and, because of its hypothetical nature, it may not give a true picture of the consolidated net tangible assets of the Group had the Global Offering been completed as at 31 August 2021 or at any future date.

| | **Audited consolidated net tangible assets attributable to the owners of the Company as at 31 August 2021** | **Estimated net proceeds from the Global Offering** | **Unaudited pro forma adjusted consolidated net tangible assets attributable to the owners of the Company** | **Unaudited pro forma adjusted consolidated net tangible assets per share** | |
|---|---|---|---|---|---|
| | *Note 1* | *Note 2* | | *Note 3* | *Note 4* |
| | *RMB'000* | *RMB'000* | *RMB'000* | *RMB* | *HK$* |
| Based on the Offer Price of HK$6.87 per share | 683,947 | 659,711 | 1,343,658 | 0.81 | 0.99 |
| Based on the Offer Price of HK$7.38 per share | 683,947 | 710,535 | 1,394,482 | 0.84 | 1.03 |



Shanghai Miracogen Inc.- Ex. 2032, Page 000703

*Notes:*

(1) The audited consolidated net tangible assets attributable to the owners of the Company as at 31 August 2021 is extracted from the Accountant's Report set forth in Appendix I to the prospectus, which is based on the audited consolidated net assets attributable to the owners of the Company as at 31 August 2021 of RMB1,163,609,000 with an adjustment for the intangible assets attributable to the owners of the Company as at 31 August 2021 of RMB479,662,000.

(2) The estimated net proceeds from the Global Offering are based on the indicative Offer Price of HK$6.87 and HK$7.38 per share after deduction of the estimated underwriting fees and other related expenses payable by the Company (excluding RMB27,573,000 which had been charged to the consolidated statements of comprehensive loss up to 31 August 2021) and takes no account of any shares which may be issued upon the exercise of the Over-allotment Option.

(3) The unaudited pro forma adjusted consolidated net tangible assets per share are determined after the adjustments as described in note (2) above and on the basis that 1,658,545,838 shares are in issue, assuming the Global Offering had been completed on 31 August 2021 but takes no account of any shares which may fall to be issued upon the exercise of the Over-Allotment Option.

(4) For the purpose of this unaudited pro forma adjusted net tangible assets, the balance stated in Renminbi is converted into Hong Kong dollars at a rate of HK$1.00 to RMB0.81824. No representation is made that Renminbi amounts have been, could have been or may be converted to Hong Kong dollars, or vice versa, at that rate.

(5) No adjustments have been made to the unaudited pro forma adjusted consolidated net tangible assets to reflect any trading results or other transactions of the Group entered into subsequent to 31 August 2021.



Shanghai Miracogen Inc.- Ex. 2032, Page 000704

## B. REPORT ON UNAUDITED PRO FORMA FINANCIAL INFORMATION

*The following is the text of a report received from PricewaterhouseCoopers, Certified Public Accountants, Hong Kong, for the purpose of incorporation in this prospectus.*



羅兵咸永道

### INDEPENDENT REPORTING ACCOUNTANT'S ASSURANCE REPORT ON THE COMPILATION OF UNAUDITED PRO FORMA FINANCIAL INFORMATION

To the Directors of Lepu Biopharma Co., Ltd.

We have completed our assurance engagement to report on the compilation of unaudited pro forma financial information of Lepu Biopharma Co., Ltd. (the "Company") and its subsidiaries (collectively the "Group") by the directors of the Company (the "Directors") for illustrative purposes only. The unaudited pro forma financial information consists of the unaudited pro forma statement of adjusted consolidated net tangible assets of the Group as at 31 August 2021, and related notes (the "Unaudited Pro Forma Financial Information") as set out on pages II-1 to II-2 of the Company's prospectus dated 10 February 2022, in connection with the proposed initial public offering of the shares of the Company, (the "Prospectus"). The applicable criteria on the basis of which the Directors have compiled the Unaudited Pro Forma Financial Information are described on pages II-1 to II-2 of the Prospectus.

The Unaudited Pro Forma Financial Information has been compiled by the Directors to illustrate the impact of the proposed initial public offering on the Group's financial position as at 31 August 2021 as if the proposed initial public offering had taken place at 31 August 2021. As part of this process, information about the Group's financial position has been extracted by the Directors from the Group's financial information for the eight months ended 31 August 2021, on which an accountant's report has been published.

**Directors' Responsibility for the Unaudited Pro Forma Financial Information**

The Directors are responsible for compiling the Unaudited Pro Forma Financial Information in accordance with paragraph 4.29 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "Listing Rules") and with reference to Accounting Guideline 7 *Preparation of Pro Forma Financial Information for Inclusion in Investment Circulars* ("AG 7") issued by the Hong Kong Institute of Certified Public Accountants ("HKICPA").

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Shanghai Miracogen Inc.- Ex. 2032, Page 000705

**Our Independence and Quality Control**

We have complied with the independence and other ethical requirements of the Code of Ethics for Professional Accountants issued by the HKICPA, which is founded on fundamental principles of integrity, objectivity, professional competence and due care, confidentiality and professional behaviour.

Our firm applies Hong Kong Standard on Quality Control 1 issued by the HKICPA and accordingly maintains a comprehensive system of quality control including documented policies and procedures regarding compliance with ethical requirements, professional standards and applicable legal and regulatory requirements.

**Reporting Accountant's Responsibilities**

Our responsibility is to express an opinion, as required by paragraph 4.29(7) of the Listing Rules, on the Unaudited Pro Forma Financial Information and to report our opinion to you. We do not accept any responsibility for any reports previously given by us on any financial information used in the compilation of the Unaudited Pro Forma Financial Information beyond that owed to those to whom those reports were addressed by us at the dates of their issue.

We conducted our engagement in accordance with Hong Kong Standard on Assurance Engagements 3420 *Assurance Engagements to Report on the Compilation of Pro Forma Financial Information Included in a Prospectus*, issued by the HKICPA. This standard requires that the reporting accountant plans and performs procedures to obtain reasonable assurance about whether the Directors have compiled the Unaudited Pro Forma Financial Information in accordance with paragraph 4.29 of the Listing Rules and with reference to AG 7 issued by the HKICPA.

For purposes of this engagement, we are not responsible for updating or reissuing any reports or opinions on any historical financial information used in compiling the Unaudited Pro Forma Financial Information, nor have we, in the course of this engagement, performed an audit or review of the financial information used in compiling the Unaudited Pro Forma Financial Information.

The purpose of unaudited pro forma financial information included in a prospectus is solely to illustrate the impact of a significant event or transaction on unadjusted financial information of the entity as if the event had occurred or the transaction had been undertaken at an earlier date selected for purposes of the illustration. Accordingly, we do not provide any assurance that the actual outcome of the proposed initial public offering at 31 August 2021 would have been as presented.



Shanghai Miracogen Inc.- Ex. 2032, Page 000706

A reasonable assurance engagement to report on whether the unaudited pro forma financial information has been properly compiled on the basis of the applicable criteria involves performing procedures to assess whether the applicable criteria used by the directors in the compilation of the unaudited pro forma financial information provide a reasonable basis for presenting the significant effects directly attributable to the event or transaction, and to obtain sufficient appropriate evidence about whether:

- The related pro forma adjustments give appropriate effect to those criteria; and
- The unaudited pro forma financial information reflects the proper application of those adjustments to the unadjusted financial information.

The procedures selected depend on the reporting accountant's judgment, having regard to the reporting accountant's understanding of the nature of the company, the event or transaction in respect of which the unaudited pro forma financial information has been compiled, and other relevant engagement circumstances.

The engagement also involves evaluating the overall presentation of the unaudited pro forma financial information.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Our work has not been carried out in accordance with auditing standards or other standards and practices generally accepted in the United States of America or auditing standards of the Public Company Accounting Oversight Board (United States) or standards and practices of any professional body in any other overseas jurisdiction and accordingly should not be relied upon as if it had been carried out in accordance with those standards and practices.

**Opinion**

In our opinion:

- the Unaudited Pro Forma Financial Information has been properly compiled by the Directors on the basis stated;
- such basis is consistent with the accounting policies of the Group; and
- the adjustments are appropriate for the purposes of the Unaudited Pro Forma Financial Information as disclosed pursuant to paragraph 4.29(1) of the Listing Rules.

**PricewaterhouseCoopers**
*Certified Public Accountants*
Hong Kong, 10 February 2022


Shanghai Miracogen Inc.- Ex. 2032, Page 000707

*Our estimate of the consolidated loss for the year ended 31 December 2021 is set out in "Financial information – Loss estimate for the year ended 31 December 2021" of this prospectus.*

## A. BASES

Our Directors have prepared the estimate of the consolidated loss attributable to owners of the Company for the year ended 31 December 2021 (the "Loss Estimate") based on the audited consolidated results of our Group for the eight months ended 31 August 2021 and the unaudited consolidated results based on the management accounts of our Group for four months ended 31 December 2021. The Loss Estimate has been prepared on the basis of the accounting policies consistent in all material aspects with those currently adopted by our Group as summarized in the Accountant's Report, the text of which is set out in Appendix I to this prospectus.

## B. LOSS ESTIMATE FOR THE YEAR ENDED 31 DECEMBER 2021

On the basis set out in Appendix III to this prospectus, and in the absence of unforeseen circumstances, we estimate that our unaudited consolidated loss attributable to the owners of the Company are as follows:

| | |
|---|---|
| **Estimated consolidated loss attributable to owners of the Company for the year ended 31 December 2021** | **Not more than RMB1,023 million (approximately HK$1,250 million)** *(Note)* |

*Note:* For the purpose of this estimated consolidated loss attributable to owners of the Company, the amounts stated in Renminbi are converted into Hong Kong dollars at a rate of HK$1.00 to RMB0.81824. No representation is made that Renminbi amounts have been, could have been or may be converted to Hong Kong dollars, or vice versa, at that rate.



Shanghai Miracogen Inc.- Ex. 2032, Page 000708

## C. LETTER FROM THE REPORTING ACCOUNTANT

*The following is the text of a letter received from PricewaterhouseCoopers, Certified Public Accountants, Hong Kong, for the purpose of incorporation in this prospectus.*



羅兵咸永道

The Board of Directors
Lepu Biopharma Co., Ltd.

China International Capital Corporation Hong Kong Securities Limited
Morgan Stanley Asia Limited

10 February 2022

Dear Sirs,
Lepu Biopharma Co., Ltd. (the "Company")

**Loss Estimate for Year Ended 31 December 2021**

We refer to the estimate of the consolidated loss attributable to owners of the Company for the year ended 31 December 2021 (the "Loss Estimate") set forth in the section headed "Loss Estimate for the Year Ended 31 December 2021" in the prospectus of the Company dated 10 February 2022 (the "Prospectus").

**Directors' Responsibilities**

The Loss Estimate has been prepared by the directors of the Company based on the audited consolidated results of the Company and its subsidiaries (collectively referred to as the "Group") for the eight months ended 31 August 2021 and the unaudited consolidated results based on the management accounts of the Group for the four months ended 31 December 2021.

The Company's directors are solely responsible for the Loss Estimate.

PricewaterhouseCoopers, 22/F Prince's Building, Central, Hong Kong SAR, China
T: +852 2289 8888, F: +852 2810 9888, www.pwchk.com



Shanghai Miracogen Inc.- Ex. 2032, Page 000709

**Our Independence and Quality Control**

We have complied with the independence and other ethical requirements of the *Code of Ethics for Professional Accountants* issued by the Hong Kong Institute of Certified Public Accountants ("HKICPA"), which is founded on fundamental principles of integrity, objectivity, professional competence and due care, confidentiality and professional behavior.

Our firm applies Hong Kong Standard on Quality Control ("HKSQC") 1, *Quality Control for Firms that Perform Audits and Reviews of Financial Statements, and Other Assurance and Related Services Engagements* issued by the HKICPA, and accordingly maintains a comprehensive system of quality control including documented policies and procedures regarding compliance with ethical requirements, professional standards and applicable legal and regulatory requirements.

**Reporting Accountant's Responsibilities**

Our responsibility is to express an opinion on the accounting policies and calculations of the Loss Estimate based on our procedures.

We conducted our engagement in accordance with Hong Kong Standard on Investment Circular Reporting Engagements 500, *Reporting on Profit Forecasts, Statements of Sufficiency of Working Capital and Statements of Indebtedness,* and with reference to Hong Kong Standard on Assurance Engagements 3000 (Revised), *Assurance Engagements Other Than Audits or Reviews of Historical Financial Information*, issued by the HKICPA. Those standards require that we plan and perform our work to obtain reasonable assurance as to whether, so far as the accounting policies and calculations are concerned, the Company's directors have properly compiled the Loss Estimate in accordance with the bases adopted by the directors and as to whether the Loss Estimate is presented on a basis consistent in all material respects with the accounting policies normally adopted by the Group. Our work is substantially less in scope than an audit conducted in accordance with Hong Kong Standards on Auditing issued by the HKICPA. Accordingly, we do not express an audit opinion.

**Opinion**

In our opinion, so far as the accounting policies and calculations are concerned, the Loss Estimate has been properly compiled in accordance with the bases adopted by the directors as set out in Appendix III of the Prospectus and is presented on a basis consistent in all material respects with the accounting policies normally adopted by the Group as set out in our accountant's report dated 10 February 2022, the text of which is set out in Appendix I of the Prospectus.

Yours faithfully,

**PricewaterhouseCoopers**
*Certified Public Accountants*
Hong Kong


Shanghai Miracogen Inc.- Ex. 2032, Page 000710

## D. LETTER FROM THE JOINT SPONSORS ON LOSS ESTIMATE

*The following is the text of a letter, prepared for inclusion in this prospectus, received by our Directors from the Joint Sponsors, in connection with the estimate of the consolidated profit attributable to owners of our Company for the year ended 31 December 2021.*

CICC 中金公司 Morgan Stanley

February 10, 2022

The Board of Directors
Lepu Biopharma Co., Ltd.

Dear Sirs,

We refer to the estimate of the consolidated loss attributable to owners of Lepu Biopharma Co., Ltd. (the "Company") and its subsidiaries (hereinafter collectively referred to as the "Group") for the year ended 31 December 2021 (the "Loss Estimate"), as set out in the section headed "Financial Information" of the prospectus issued by the Company dated February 10, 2022.

The Loss Estimate, for which you, as the directors of the Company are solely responsible, has been prepared by you based on (i) the audited consolidated results of the Group for the eight months ended 31 August 2021, and (ii) the unaudited consolidated results of the Group based on its management accounts for the four months ended 31 December 2021.

We have discussed with you the bases and assumptions upon which the Loss Estimate has been made, we have also considered the letter dated February 10, 2022 addressed to you and us from PricewaterhouseCoopers, the reporting accountant of the Company, regarding the accounting policies and calculations upon which the Loss Estimate has been made.

On the basis of the information comprising the Loss Estimate and on the basis of the accounting policies and calculations adopted by you and reviewed by PricewaterhouseCoopers, we are of the opinion that the Loss Estimate, for which you as directors of the Company are solely responsible for, has been made after due and careful enquiry.

Yours faithfully
For and on behalf of

**China International Capital Corporation Hong Kong Securities Limited**
**YAO Xudong**
*Managing Director*

**Morgan Stanley Asia Limited**
**Robin ZHAO**
*Managing Director*


Shanghai Miracogen Inc.- Ex. 2032, Page 000711

*The following is the text of a letter and a valuation certificate prepared for the purpose of incorporation in this prospectus received from AVISTA Valuation Advisory Limited, an independent valuer, in connection with its valuation as at 31 December 2021 of the property interests held by the Company.*

AVISTA Valuation Advisory
艾華迪評估諮詢

23rd Floor, Siu On Centre, No. 188 Lockhart Road,
Wan Chai, Hong Kong

TEL : (852) 3702 7338 FAX : (852) 3914 6388
info@avaval.com
www.avaval.com

10 February 2022

The Board of Directors
**Lepu Biopharma Co., Ltd. (樂普生物科技股份有限公司)**
Room C280, Building 1
No. 1628 Suzhao Road
Minhang District, Shanghai
People's Republic of China

Dear Sirs/Madams,

## INSTRUCTIONS

In accordance with the instructions of Lepu Biopharma Co., Ltd. (樂普生物科技股份有限公司) (the "Company") for us to carry out the valuation of the property interests located in the People's Republic of China (the "PRC") held by the Company (the "Property"). We confirm that we have carried out inspection, made relevant enquiries and searches and obtained such further information as we consider necessary for the purpose of providing you with our opinion of the market value of the property interests as at 31 December 2021 (the "Valuation Date").

## VALUATION STANDARDS

In valuing the property interests, we have complied with all the requirements set out in Chapter 5 and Practice Note 12 of the Rules Governing the Listing of Securities issued by The Stock Exchange of Hong Kong Limited (the "Listing Rules"), the RICS Valuation – Global Standards 2020 published by the Royal Institution of Chartered Surveyors ("RICS") and the International Valuation Standards published from time to time by the International Valuation Standards Council.


Shanghai Miracogen Inc.- Ex. 2032, Page 000712

## BASIS OF VALUATION

Our valuation is carried out on a market value basis, which is defined by the Royal Institution of Chartered Surveyors as "*the estimated amount for which an asset or liability should exchange on the valuation date between a willing buyer and a willing seller in an arm's length transaction, after proper marketing and where the parties had each acted knowledgeably, prudently and without compulsion*".

## VALUATION ASSUMPTIONS

Our valuation of the Property excludes an estimated price inflated or deflated by special terms or circumstances such as atypical financing, sale and leaseback arrangement, special considerations or concessions granted by anyone associated with the sale, or any element of special value or costs of sale and purchase or offset for any associated taxes.

No allowance has been made in our report for any charges, mortgages or amounts owing on any of the property interests valued nor for any expenses or taxation which may be incurred in effecting a sale. Unless otherwise stated, it is assumed that the Property are free from encumbrances, restrictions and outgoings of an onerous nature, which could affect its value.

In the course of our valuation of the Property in the PRC, we have assumed that transferable land use rights in respect of the Property for a specific term at nominal annual land use fees have been granted and that any premium has already been fully settled. We have relied on the advice given by the Company and its legal adviser, being Zhong Lun Law Firm (中倫律師事務所) (the "PRC Legal Adviser"), regarding the title to the Property.

In valuing the Property, we have relied on a legal opinion regarding the property interests provided by the PRC Legal Adviser dated 8 February 2022, (the "PRC Legal Opinion") which states the Company has legally obtained the land use rights of the Property. The grantees or the users of the Property have free and uninterrupted rights to use or to assign the Property for the whole of the unexpired term as granted.

Unless noted in the report, vacant possession is assumed for the Property concerned.

Moreover, we have assumed that the design and construction of the Property are/will be in compliance with the local planning regulations and requirements and had been/would have been duly examined and approved by the relevant authorities.

Continued uses assumes the Property will be used for the purposes for which the Property are designed and built, or to which it is currently adapted. The valuation on the Property in continued uses does not represent the amount that might be realised from piecemeal disposition of the Property in the open market.


Shanghai Miracogen Inc.- Ex. 2032, Page 000713

No environmental impact study has been ordered or made. Full compliance with applicable national, provincial and local environmental regulations and laws is assumed. Moreover, it is assumed that all required licences, consents or other legislative or administrative authority from any local, provincial or national government or private entity or organisation either have been or can be obtained or renewed for any use which the report covers.

It is also assumed that all applicable zoning and use regulations and restrictions have been complied with unless nonconformity has been stated, defined and considered in the valuation report. In addition, it is assumed that the utilisation of the land and improvements are within the boundaries of the Property described and that no encroachment or trespass exists, unless noted in the report.

We have further assumed that the Property was not transferred or involved in any contentious or non-contentious dispute as at the Valuation Date. We have also assumed that there was not any material change of the Property in between dates of our inspection and the Valuation Date.

**VALUATION METHODOLOGY**

In the course of our valuation, unless otherwise stated, we have valued the Property in its designated uses with the understanding that the Property will be used as such (hereafter referred to as "Continued Uses").

In valuing the property interests, which was/were under construction as at the Valuation Date, we have assumed that it/they will be developed and completed in accordance with the latest development proposals provided to us by the Company. We have assumed that approvals for the proposals have been obtained. In arriving at our opinion of values, we have adopted the comparison approach by making reference to land comparable sales evidence as available in the relevant market and have also taken into account the accrued construction cost and professional fees relevant to the stage of construction as at the Valuation Date and the remainder of the cost and fees expected to be incurred for completing the developments. We have relied on the accrued construction cost and professional fees information provided by the Company according to the different stages of construction of the Property as at the Valuation Date, and we did not find any material inconsistency from those of other similar developments.



Shanghai Miracogen Inc.- Ex. 2032, Page 000714

## TITLE INVESTIGATION

We have been provided with copies of documents in relation to the title of the property interests in the PRC. Where possible, we have examined the original documents to verify the existing title to the property interests in the PRC and any material encumbrance that might be attached to the property interests or any tenancy amendment. All documents have been used for reference only and all dimensions, measurements and areas are approximate. In the course of our valuation, we have relied considerably on the PRC Legal Opinion given by the PRC Legal Adviser, concerning the validity of title of the property interests in the PRC.

## SITE INVESTIGATION

We have inspected the exteriors and, where possible, the interior of the Property. The site inspection was carried out on 2 March 2021 by Leo Shen (Valuer). However, we have not carried out an investigation on site to determine the suitability of ground conditions and services for any development thereon. Our valuation has been prepared on the assumption that these aspects are satisfactory. We have further assumed that there is no significant pollution or contamination in the locality which may affect any future developments.

## SOURCE OF INFORMATION

Unless otherwise stated, we shall rely to a considerable extent on the information provided to us by the Company or the PRC Legal Adviser or other professional advisers on such matters as statutory notices, planning approvals, zoning, easements, tenures, completion date of buildings, development proposal, identification of Property, particulars of occupation, site areas, floor areas, matters relating to tenure, tenancies and all other relevant matters.

We have had no reason to doubt the truth and accuracy of the information provided to us by the Company. We have also sought confirmation from the Company that no material factors have been omitted from the information supplied. We consider that we have been provided with sufficient information to reach an informed view and we have no reason to suspect that any material information has been withheld.

We have not carried out detailed measurements to verify the correctness of the areas in respect of the Property but have assumed that the areas shown on the title documents and official site plans handed to us are correct. All documents and contracts have been used as reference only and all dimensions, measurements and areas are approximations. No on-site measurement has been taken.

## LIMITING CONDITION

Wherever the content of this report is extracted and translated from the relevant documents supplied in Chinese context and there are discrepancies in wordings, those parts of the original documents will take prevalent.



Shanghai Miracogen Inc.- Ex. 2032, Page 000715

**CURRENCY**

Unless otherwise stated, all monetary amounts stated in this report are in Renminbi (RMB).

Our valuation certificate is attached below.

Yours faithfully,
For and on behalf of
**AVISTA Valuation Advisory Limited**
**Vincent C B Pang**
*MRICS CFA FCPA FCPA Australia*
*RICS Registered Valuer*
*Managing Director*

*Notes:* Mr. Vincent C B Pang is a member of Royal Institution of Chartered Surveyors (RICS) and a registered valuer of RICS. He has over 10 years' experience in the valuation of properties including Hong Kong, the PRC, the U.S., Canada, East and Southeast Asia including Singapore, Japan and Korea.


Shanghai Miracogen Inc.- Ex. 2032, Page 000716

## Property interests held by the Company under development in the PRC

## VALUATION CERTIFICATE

| Property | Description and tenure | Particulars of occupancy | Market value in existing state as at 31 December 2021<br>*RMB* |
|---|---|---|---|
| Industrial properties located at the corner of Wanfang Road and Lianhang Road, Pujiang Town, Minhang District, Shanghai City, the PRC<br><br>(中國上海市閔行區浦江鎮萬芳路與聯航路交界的工業物業) | The property comprises two parcels of land with a total site area of approximately 93,242.70 sq.m. and various industrial buildings which are currently being constructed thereon.<br><br>The phase 1 development is scheduled to be completed in June 2022. Upon completion, the development will have a total gross floor area of approximately 108,550.33 sq.m..<br><br>As advised by the Company, the total construction cost of phase 1 development is estimated to be approximately RMB705,500,000 of which RMB562,200,000 had been paid as at the Valuation Date.<br><br>The phase 2 development is scheduled to be completed in December 2023. Upon completion, the development will have a total gross floor area of approximately 101,663.78 sq.m..<br><br>As advised by the Company, the total construction cost of phase 2 development is estimated to be approximately RMB411,600,000 of which RMB6,500,000 had been paid as at the Valuation Date.<br><br>The property is located in Shanghai City, near the Pujiang Intelligence Valley, with approximately 4km to Lianhang Road Station and 40km to Shanghai Pudong International Airport.<br><br>The land use rights of phase 1 development of the property have been granted for a term expiring on 19 August 2038 for industrial use and the land use rights of phase 2 development of the property have granted for a term expiring on 14 June 2040 for industrial use. | The property is currently under construction as at the Valuation Date. | 698,700,000 |



Shanghai Miracogen Inc.- Ex. 2032, Page 000717

*Notes:*

1. Pursuant to two State-owned Land Use Rights Grant Contracts issued by the Planning and Land Resources Administration Bureau of Minhang District of Shanghai City (上海市閔行區規劃和土地管理局) and Planning and Natural Resources Bureau of Minhang District of Shanghai City (上海市閔行區規劃和自然資源局) respectively, the land use rights of the property with a total site area of 93,242.70 sq.m. have been granted to the Company for a land use right term of 20 years for industrial use at a total land premium of approximately RMB125,030,000 with details as follows: –

| No. | State-owned Land Use Grant Contract No. | Date of Contract | Land Premium *(RMB)* | Site Area *(sq.m.)* | Maximum Plot Ratio | Permitted Upper Ground Accountable Gross Floor Area *(sq.m.)* |
|---|---|---|---|---|---|---|
| i | Hu Min Gui Tu (2018) Chu Rang He Tong Di No. 35 | 8 August 2018 | 72,010,000 | 47,813.10 | 1.94 | 92,774.35 |
| ii | Hu Min Gui Hua Zi Yuan (2020) Chu Rang He Tong Di No. 32 | 14 May 2020 | 53,020,000 | 45,429.60 | 2.00 | 90,409.69 |

2. Pursuant to two Real Estate Ownership Certificates issued by Natural Resources Ownership Registry Bureau of Shanghai City (上海市自然資源確權登記局), the land use rights of the property with a total site area of approximately 93,242.70 sq.m. have been vested to the Company for a land use right term of 20 years for industrial use with details shown as follows: –

| No. | Real Estate Ownership Certificate No. | Date of Expiry | Site Area *(sq.m.)* |
|---|---|---|---|
| i | Hu (2021) Min Zi Bu Dong Chan Quan Di No. 045624 | 19 August 2038 | 47,813.10 |
| ii | Hu (2020) Min Zi Bu Dong Chan Quan Di No. 051045 | 14 June 2040 | 45,429.60 |

3. Pursuant to two Construction Land Planning Permits issued by the Planning and Land Resources Administration Bureau of Minhang District of Shanghai City (上海市閔行區規劃和土地管理局) and Planning and Natural Resources Bureau of Minhang District of Shanghai City (上海市閔行區規劃和自然資源局) respectively, in favour of the Company, permission towards the planning of the two parcels of land with a total site area of approximately 93,242.70 sq.m. is obtained with details shown as follows: –

| No. | Construction Land Planning Permit No. | Date of Issuance | Site Area *(sq.m.)* | Proposed Gross Floor Area *(sq.m.)* |
|---|---|---|---|---|
| i | Hu Min Di (2018) No. EA31011220186053 | 31 August 2018 | 47,813.10 | – |
| ii | Hu Min Di (2020) No. EA310112202000339 | 9 July 2020 | 45,429.60 | 95,241.11 |

4. Pursuant to two Construction Works Planning Permits – (i) Hu Min Jian (2018) No. FA31011220187664 dated 30 September 2018, and (ii) Hu Min Jian (2019) No. FA31011220196534 dated 15 January 2019 issued by the Planning and Land Resources Administration Bureau of Minhang District of Shanghai City (上海市閔行區規劃和土地管理局) in favour of the Company, the development has been approved for the construction of the phase 1 development.

5. Pursuant to a Construction Works Planning Permit – Hu Min Jian (2021) No. FA310112202101143 dated 1 November 2021 issued by the Planning and Natural Resources Bureau of Minhang District of Shanghai City (上海市閔行區規劃和自然資源局) in favour of the Company, the development has been approved for the construction of the phase 2 development.



Shanghai Miracogen Inc.- Ex. 2032, Page 000718

6. Pursuant to two Construction Works Commencement Permits – (i) No. 1802MH0382D01 dated 9 October 2018, and (ii) No. 1802MH0382D02 dated 21 January 2019 issued by Construction and Management Committee of Minhang District of Shanghai City (上海市閔行區建設和管理委員會) in favour of the Company, permissions have been given to commence the construction work with a total gross floor area of approximately 108,550.33 sq.m. for the development foundation and buildings of the phase 1 development.

7. Pursuant to two Construction Works Commencement Permits – (i) No. 310112202106250101 dated 25 June 2021, and (ii) No. 310112202112090401 dated 9 December 2021 issued by Construction and Management Committee of Minhang District of Shanghai City (上海市閔行區建設和管理委員會) in favour of the Company, permissions have been given to commence the construction work with a total gross floor area of approximately 101,663.78 sq.m. for the development foundation and buildings of the phase 2 development.

8. We have been provided with the PRC Legal Opinion, which contains, *inter alia*, the following: –

   a. The Company has legally and validly obtained the land use rights of the property under the terms of the Real Estate Ownership Certificates;

   b. The Company has the rights to use the land use rights legally for the whole of the unexpired term as granted and the land use rights is not subject to any encumbrances;

   c. The land use rights and the construction-in-progress of the phase 1 development of the property was pledged; and

   d. The Company has legally and validly obtained the permissions and approvals in relation to the construction of the phase 1 and phase 2 development of the property.

9. In our valuation, we have made reference to four transaction price references of land comparables in the subject and nearby development. We have adopted the range of unit rates between RMB600 to RMB900 per sq.m.. The unit rates assumed by us are consistent with the said price reference. Due adjustments to the unit rates of those price reference have been made to reflect factors including but not limited to time, location, and size in arriving at the key assumptions.

10. A summary of major certificates/licenses/documents is shown as follows: –

| | | |
|---|---|---|
| a. | Real Estate Ownership Certificates | Yes |
| b. | Construction Land Planning Permits | Yes |
| c. | Construction Works Planning Permits | Yes |
| d. | Construction Works Commencement Permits | Yes |



Shanghai Miracogen Inc.- Ex. 2032, Page 000719

## TAXATION OF EQUITY HOLDERS

The following is a summary of certain PRC and Hong Kong tax consequences of the ownership of H Shares by an investor who purchases such H Shares in the Global Offering and holds the H Shares as capital assets. This summary does not purport to address all material tax consequences of the ownership of H Shares, and does not take into account the specific circumstances of any particular investor, some of which may be subject to special provisions, and is not intended to be and should not be taken on constitute legal or tax advice. This summary is based upon laws and relevant interpretations in effect as of the Latest Practicable Date, all of which are subject to change and may have retroactive effect.

This section does not address any aspects of PRC or Hong Kong taxation other than income tax, capital gains tax, value-added tax, stamp duty and estate duty. Prospective investors are advised to consult their financial advisors regarding the tax consequences of owning and disposing of H Shares. Neither the Company nor any of the Relevant Persons assumes any responsibility for any tax consequences or liabilities that may arise from the subscription for, holding or disposal of the H shares.

The taxation of the Company and that of the Shareholders is described below. Where Hong Kong and PRC tax laws are discussed, these are merely an outline of the implications of such laws. Such laws and regulations may be interpreted differently. It should not be assumed that the relevant tax authorities or the Hong Kong or PRC courts will accept or agree with the explanations or conclusions that are set out below.

## PRINCIPAL TAXATION OF OUR COMPANY BY THE PRC

### Enterprise Income Tax

According to the Enterprise Income Tax Law of PRC (《中華人民共和國企業所得税法》), which was promulgated by the NPC on March 16, 2007, implemented on January 1, 2008, and subsequently revised on February 24, 2017 and December 29, 2018 respectively, and the Implementation Rules for the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得税法實施條例》) enacted on December 6, 2007 by the State Council and became effective on January 1, 2008, and amended on April 23, 2019 (collectively, the "**EIT Law**"), a resident enterprise shall pay EIT on its income derived from both inside and outside PRC at an EIT rate of 25%. Foreign invested enterprises in the PRC falls into the category of resident enterprises, which shall pay EIT for the income originated from domestic and overseas sources at an EIT rate of 25%. For a non-resident enterprise having no office or establishment inside China, or for a non-resident enterprise whose incomes have no actual connection to its office or establishment inside China, it shall pay enterprise income tax on the incomes derived from China. The enterprise income tax rate shall be 10%.


Shanghai Miracogen Inc.- Ex. 2032, Page 000720

According to the Administrative Measures for Determination of High and New Tech Enterprises (《高新技術企業認定管理辦法》), which was adopted by the Ministry of Science and Technology, the MOF and the SAT on January 29, 2016, and took effect from January 1, 2016, an enterprise which is determined as a high and new tech enterprise may apply for a preferential enterprise income tax rate of 15% pursuant to the EIT Law. Pursuant to the Notice on Promoting Nationwide the Enterprise Income Tax Policies for Advanced Technology Service Enterprises Across the country (《關於將技術先進型服務企業所得稅政策推廣至全國實施的通知》) promulgated by the MOF, the SAT, the MOFCOM, the Ministry of Science and Technology and the NDRC on November 2, 2017, with effect from January 1, 2017, the enterprise income tax shall be levied on certified advanced technology service enterprises at a reduced tax rate of 15% nationwide. The portion of the employee educational expenses of a certified advanced technology service enterprise not exceeding 8% of its total salaries and wages shall be allowed to be deducted in calculating its taxable income; and the excessive portion shall be allowed to be carried forward to the subsequent tax years for deduction.

**Value-added Tax**

According to the Interim Regulations of the PRC on Value-Added Tax (《中華人民共和國增值稅暫行條例》), which was promulgated by the State Council on December 13, 1993, and subsequently amended on November 5, 2008, February 6, 2016 and November 19, 2017 respectively, and the Detailed Rules for the Implementation of the Provisional Regulations of the PRC on Value-added Tax (《中華人民共和國增值稅暫行條例實施細則》), which was promulgated by the Ministry of Finance on December 25, 1993 and subsequently amended on December 15, 2008 and October 28, 2011 (collectively, the "**VAT Law**"), all enterprises and individuals that engage in the sale of goods, the provision of processing, repair and replacement services, sales of service, intangible assets and real estate and the importation of goods within the territory of the PRC shall pay value-added tax at the rate of 0%, 6%, 11% and 17% for the different goods it sells and different services it provides, except when specified otherwise.

In accordance with the Circular on Comprehensively Promoting the Pilot Program of the Collection of Value-added Tax in Lieu of Business Tax (《關於全面推開營業稅改徵增值稅試點的通知》), which was promulgated on March 23, 2016 and came into effect on May 1, 2016, upon approval of the State Council, the pilot program of the collection of VAT in lieu of business tax shall be promoted nationwide in a comprehensive manner starting from May 1, 2016.

The Notice on the Adjustment to VAT Rates (《關於調整增值稅稅率的通知》), promulgated by the MOF and the SAT on April 4, 2018 and took effect as of May 1, 2018, the VAT rates of 17% and 11% applicable to the taxpayers who have VAT taxable sales activities or imported goods are adjusted to 16% and 10%, respectively.

According to the Announcement on Relevant Policies for Deepening Value-Added Tax Reform (《關於深化增值稅改革有關政策的公告》) promulgated by the MOF, the SAT and General Administration of Customs on March 20, 2019 and became effective on April 1, 2019, the VAT rates of 16% and 10% applicable to the taxpayers who have VAT taxable sales activities or imported goods are adjusted to 13% and 9%, respectively.


Shanghai Miracogen Inc.- Ex. 2032, Page 000721

## THE PRC TAXATION

### Taxation on Dividends

***Enterprise Investors***

In accordance with the EIT Law, a non-resident enterprise is generally subject to a 10% enterprise income tax on PRC-sourced income (including dividends received from a PRC resident enterprise that issues shares in Hong Kong), if such non-resident enterprise does not have an establishment or place in the PRC or has an establishment or place in the PRC but its PRC-sourced income is not connected with such establishment or place in the PRC. The withholding tax may be reduced pursuant to applicable treaties for the avoidance of double taxation. Such withholding tax for non-resident enterprises are deducted at source, where the payer of the income is required to withhold the income tax from the amount to be paid to the non-resident enterprise when such payment is made or due.

The Circular on Issues Relating to the Withholding of Enterprise Income Tax by PRC Resident Enterprises on Dividends Paid to Overseas Non-Resident Enterprise Shareholders of H Shares (《關於中國居民企業向境外H股非居民企業股東派發股息代扣代繳企業所得稅有關問題的通知》, which was issued by the SAT on November 6, 2008 and came into effect on the same date, further clarified that a PRC-resident enterprise must withhold corporate income tax at a rate of 10% on the dividends of 2008 and onwards that it distributes to non-PRC resident enterprise shareholders of H Shares. In addition, the Response to Questions on Levying Corporate Income Tax on Dividends Derived by Non-resident Enterprise from Holding Stock such as B Shares (《關於非居民企業取得B股等股票股息徵收企業所得稅問題的批覆》), which was issued by the SAT and came into effect on July 24, 2009, further provides that any PRC-resident enterprise that is listed on overseas stock exchanges must withhold enterprise income tax at a rate of 10% on dividends of 2008 and onwards that it distributes to non-resident enterprises. Such tax rates may be further modified pursuant to the tax treaty or agreement that China has concluded with a relevant jurisdiction, where applicable.

Pursuant to the Arrangement between the Mainland and the Hong Kong Special Administrative Region on the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Incomes (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》), issued on August 21, 2006, the PRC Government may levy taxes on the dividends paid by a PRC company to Hong Kong residents (including natural persons and legal entities) in an amount not exceeding 10% of the total dividends payable by the PRC company. If a Hong Kong resident directly holds 25% or more of the equity interest in a PRC company, then such tax shall not exceed 5% of the total dividends payable by the PRC company. Pursuant to the Fourth Protocol of the Arrangement between the Mainland of China and the Hong Kong Special Administrative Region on the Avoidance of Double Taxation and the Prevention of Fiscal Evasion issued by the State Administration of Taxation (《國家稅務總局關於<內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排>第四議定書》), which came into effect on December 29, 2015, the abovementioned provisions are not applicable to any arrangement which is primarily made for the purpose of obtaining the above taxation benefits. The application of the dividend clause of tax agreements is subject to the requirements of PRC tax law documents, such as the Notice of the State Administration of Taxation on the Issues Concerning the Application of the Dividend Clauses of Tax Agreements (《國家稅務總局關於執行稅收協定股息條款有關問題的通知》).



Shanghai Miracogen Inc.- Ex. 2032, Page 000722

***Individual Investor***

Pursuant to the Individual Income Tax Law of the PRC (《中華人民共和國個人所得税法》), which was last amended on August 31, 2018 and came into effect on January 1, 2019 and the Implementation Provisions of the Individual Income Tax Law of the PRC (《中華人民共和國個人所得税法實施條例》), which was last amended on December 18, 2018 and came into effect on January 1, 2019 (collectively, the "**IIT Law**"), dividends distributed by PRC enterprises are subject to individual income tax levied at a flat rate of 20%. According to the Notice on Issues concerning the Implementation of Differential Individual Income Tax Policies on Dividends and Bonuses of Listed Companies (《關於上市公司股息紅利差別化個人所得税政策有關問題的通知》) issued by the MOF on September 7, 2015, where an individual acquires the stocks of a listed company from public offering of the company or from the stock market, if the stock holding period is more than one year, the income from dividends shall be exempted from personal income tax for the time being. Where an individual acquires the stocks of a listed company in a public offering of the company or from the stock market, if the stock holding period is one month or less, the income from dividends shall be included into the taxable incomes in full amount; if the stock holding period is more than one month and up to one year, only 50% of the income from dividends shall be included into the taxable incomes of the individual. Individual income taxes on the aforesaid incomes shall be collected at the uniform rate of 20%. For a foreign individual who is not a resident of the PRC, the receipt of dividends from an enterprise in the PRC is normally subject to individual income tax of 20% unless a reduction is approved by the MOF or exempted by an international convention or agreement to which the PRC government is a party.

Pursuant to the Circular on Certain Policy Questions Concerning Individual Income Tax (《關於個人所得税若干政策問題的通知》), which was issued by the MOF and the SAT on May 13, 1994 and came into effect on the same date, overseas individuals are exempted from the individual income tax for dividends or bonuses received from foreign-invested enterprises.

***Tax Treaties***

Investors who are not PRC residents and reside in countries and regions which have entered into avoidance of double taxation treaties with the PRC are entitled to a reduction of the withholding taxes imposed on the dividends received from PRC companies. The PRC currently has entered into Avoidance of Double Taxation Treaties/Arrangements with a number of countries and regions including Hong Kong, Macau, Australia, Canada, France, Germany, Japan, Malaysia, the Netherlands, Singapore, the United Kingdom and the United States. Non-PRC resident enterprises entitled to preferential tax rates in accordance with the relevant income tax treaties or arrangements are required to apply to the PRC tax authorities for a refund of the withholding tax in excess of the agreed tax rate, and the refund payment is subject to approval by the PRC tax authorities.


Shanghai Miracogen Inc.- Ex. 2032, Page 000723

**Taxation on Share Transfer**

***Enterprise Investors***

In accordance with the EIT Law, a non-resident enterprise is generally subject to a 10% enterprise income tax on PRC-sourced income, including gains derived from the disposal of equity interests in a PRC resident enterprise, if it does not have an establishment or place in the PRC or has an establishment or place in the PRC but its PRC-sourced income is not connected with such establishment or place. Such income tax payable for non-resident enterprises are deducted at source, where the payer of the income is required to withhold the income tax from the amount to be paid to the non-resident enterprise when such payment is made or due. The withholding tax may be reduced or eliminated pursuant to applicable treaties or agreements on avoidance of double taxation.

***Individual Investors***

According to the IIT Law, gains realized on the sale of equity interests in the PRC resident enterprises are subject to individual income tax at a rate of 20%.

Under the Circular of Declaring that Individual Income Tax Continues to be Exempted over Income of Individuals from the Transfer of Shares (《關於個人轉讓股票所得繼續暫免徵收個人所得税的通知》) issued by the MOF and the SAT on January 1, 1997, effective as of March 30, 1998, gains of individuals from the transfer of shares of listed enterprises continues to be exempted from individual income tax. On December 31, 2009, the MOF, the SAT and the CSRC jointly issued the Circular on Related Issues on Levying Individual Income Tax over the Income Received by Individuals from the Transfer of Listed Shares Subject to Sales Limitation (《關於個人轉讓上市公司限售股所得徵收個人所得税有關問題的通知》), which provides that individuals' income from the transfer of listed shares on certain domestic exchanges shall continue to be exempted from individual income tax, except for certain shares which are subject to sales restriction as defined in the Supplementary Notice on Issues Concerning the Levy of Individual Income Tax on Individuals' Income from the Transfer of Restricted Stocks of Listed Companies (《關於個人轉讓上市公司限售股所得徵收個人所得税有關問題的補充通知》).

As of the Latest Practicable Date, the aforesaid provision has not expressly provided that whether individual income tax shall be levied from non-Chinese resident individuals on the transfer of shares in PRC resident enterprises listed on overseas stock exchanges. To our knowledge, in practice, no such individual income tax was levied by PRC tax authorities. However, there is no assurance that the PRC tax authorities will not change these practices which could result in levying income tax on non-PRC resident individuals on gains from the sale of H shares.



Shanghai Miracogen Inc.- Ex. 2032, Page 000724

**Stamp Duty**

Pursuant to the Provisional Regulations of the PRC on Stamp Duty (《中華人民共和國印花稅暫行條例》), which was issued on August 6, 1988, came into effect on October 1, 1988 and amended on January 8, 2011, and the Implementation Provisions of Provisional Regulations of the PRC on Stamp Duty (《中華人民共和國印花稅暫行條例施行細則》), which came into effect on October 1, 1988, PRC stamp duty only applies to specific proof executed or received within the PRC, having legally binding force in the PRC and protected under the PRC laws, thus the requirements of the stamp duty imposed on the transfer of shares of PRC listed companies shall not apply to the acquisition and disposal of H Shares by non-PRC investors outside of the PRC.

**Estate Duty**

The PRC currently does not impose any estate duty.

**TAXATION IN HONG KONG**

**Tax on Dividends**

Under the current practice of the Inland Revenue Department of Hong Kong, no tax is payable in Hong Kong in respect of dividends paid by us.

**Capital Gains and Profit Tax**

No tax is imposed in Hong Kong in respect of capital gains from the sale of H Shares. However, trading gains from the sale of the H Shares by persons carrying on a trade, profession or business in Hong Kong, where such gains are derived from or arise in Hong Kong from such trade, profession or business will be subject to Hong Kong profits tax, which is currently imposed at the maximum rate of 16.5% on corporations and at the maximum rate of 15% on unincorporated businesses. Certain categories of taxpayers (for example, financial institutions, insurance companies and securities dealers) are likely to be regarded as deriving trading gains rather than capital gains unless these taxpayers can prove that the investment securities are held for long-term investment purposes. Trading gains from sales of H Shares effected on the Hong Kong Stock Exchange will be considered to be derived from or arise in Hong Kong. Liability for Hong Kong profits tax would thus arise in respect of trading gains from sales of H Shares effected on the Hong Kong Stock Exchange realized by persons carrying on a business of trading or dealing in securities in Hong Kong.


Shanghai Miracogen Inc.- Ex. 2032, Page 000725

**Stamp Duty**

Hong Kong stamp duty, currently charged at the ad valorem rate of 0.13% on the higher of the consideration for or the market value of the H Shares, will be payable by the purchaser on every purchase and by the seller on every sale of Hong Kong securities, including H Shares (in other words, a total of 0.26% is currently payable on a typical sale and purchase transaction involving H Shares). In addition, a fixed duty of HK$5.00 is currently payable on any instrument of transfer of H Shares. Where one of the parties is a resident outside Hong Kong and does not pay the ad valorem duty due by it, the duty not paid will be assessed on the instrument of transfer (if any) and will be payable by the transferee. If no stamp duty is paid on or before the due date, a penalty of up to ten times the duty payable may be imposed.

**Estate Duty**

The Revenue (Abolition of Estate Duty) Ordinance 2005 came into effect on February 11, 2006 in Hong Kong, pursuant to which no Hong Kong estate duty is payable and no estate duty clearance papers are needed for an application of a grant of representation in respect of holders of H Shares whose deaths occur on or after February 11, 2006.

**FOREIGN EXCHANGE**

The lawful currency of the PRC is Renminbi, which is currently subject to foreign exchange control and is be freely convertible into foreign exchange. The SAFE, under the authorization of the PBOC, is empowered with the functions of administering all matters relating to foreign exchange, including the enforcement of foreign exchange control regulations.

On January 29, 1996, the State Council promulgated the Regulations of the PRC on Foreign Exchange Control (《中華人民共和國外匯管理條例》) (the "**Foreign Exchange Control Regulations**") which became effective on April 1, 1996. The Foreign Exchange Control Regulations classifies all international payments and transfers into current account items and capital account items. Most of the current account items are no longer subject to the SAFE's approval, while capital account items are still subject to such approval. The Foreign Exchange Control Regulations were subsequently amended on January 14, 1997 and August 5, 2008. The latest amendment to the Foreign Exchange Control Regulations clearly states that PRC will not impose any restriction on international payments and transfers under the current account items.

On June 20, 1996, PBOC promulgated the Provisional Regulations for the Administration of Settlement, Sale and Payment of Foreign Exchange (《結匯、售匯及付匯管理規定》) (the "**Settlement Regulations**"), which became effective on July 1, 1996. The Settlement Regulations abolished all other restrictions on convertibility of foreign exchange under current account items, while retaining the existing restrictions on foreign exchange transactions under capital account items.



Shanghai Miracogen Inc.- Ex. 2032, Page 000726

According to the relevant laws and regulations in the PRC, PRC enterprises (including foreign investment enterprises) which need foreign exchange for transactions relating to current accounts item may, without the approval of the foreign exchange administrative authorities, effect payment through foreign exchange accounts opened at financial institutions that carries foreign exchange business or operating institutions that carries settlement and sale business, on the strength of valid receipts and proof. Foreign investment enterprises which need foreign exchange for the distribution of profits to their shareholders and PRC enterprises which, in accordance with regulations, are required to pay dividends to their shareholders in foreign exchange (such as the Company) may, on the strength of resolutions of the board of directors or the shareholders' meeting on the distribution of profits, effect payment from foreign exchange accounts opened at financial institutions that carries foreign exchange business or institutions that carries settlement and sale business, or effect exchange and payment at financial institutions that carries foreign exchange business or institutions that carries settlement and sale business.

On December 26, 2014, the SAFE issued the Notice of the State Administration of Foreign Exchange on Issues Concerning the Foreign Exchange Administration of Overseas Listing (《國家外匯管理局關於境外上市外匯管理有關問題的通知》), pursuant to which a domestic company shall, within 15 business days of the completion of its overseas listing issuance, register the overseas listing with the Administration of Foreign Exchange at the place of its establishment; the proceeds from an overseas listing of a domestic company may be remitted to the domestic special account or deposited in an overseas special account, but the use of the proceeds shall be consistent with the content of the prospectus and other disclosure documents. A domestic company (except for bank financial institutions) shall present its certificate of overseas listing to open a special account at a local bank for its initial public offering (or follow-on offering) and repurchase business to handle the exchange, remittance and transfer of funds for the business concerned.

On February 13, 2015, the SAFE issued the Notice of the State Administration of Foreign Exchange on Further Simplifying and Improving Policies for the Foreign Exchange Administration of Direct Investment (《國家外匯管理局關於進一步簡化和改進直接投資外匯管理政策的通知》), which came into effect on June 1, 2015. The notice canceled two of the administrative examination and approval items, being the confirmation of foreign exchange registration under domestic direct investment and the confirmation of foreign exchange registration under overseas direct investment, instead, banks shall directly examine and handle foreign exchange registration under domestic direct investment and foreign exchange registration under overseas direct investment, and the SAFE and its branch offices shall indirectly regulate the foreign exchange registration of direct investment through banks.


Shanghai Miracogen Inc.- Ex. 2032, Page 000727

According to the Notice of the State Administration of Foreign Exchange of the PRC on Revolutionize and Regulate Capital Account Settlement Management Policies (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》) issued by the SAFE and came into effect on June 9, 2016, foreign currency earnings in capital account that relevant policies of willingness exchange settlement have been clearly implemented on (including the recalling of raised capital by overseas listing) may undertake foreign exchange settlement in the banks according to actual business needs of the domestic institutions. The tentative percentage of foreign exchange settlement for foreign currency earnings in capital account of domestic institutions is 100%, subject to adjustment of the SAFE in due time in accordance with international revenue and expenditure situations.

On January 26, 2017, Notice of the State Administration of Foreign Exchange on Further Promoting the Reform of Foreign Exchange Administration and Improving the Examination of Authenticity and Compliance (《國家外匯管理局關於進一步推進外匯管理改革完善真實合規性審核的通知》) was issued by SAFE to further expand the scope of settlement for domestic foreign exchange loans, allow settlement for domestic foreign exchange loans with export background under goods trading, allow repatriation of funds under domestic guaranteed foreign loans for domestic utilization, allow settlement for domestic foreign exchange accounts of foreign institutions operating in the Free Trade Pilot Zones, and adopt the model of full-coverage RMB and foreign currency overseas lending management, where a domestic institution engages in overseas lending, the sum of its outstanding overseas lending in RMB and outstanding overseas lending in foreign currencies shall not exceed 30% of its owner's equity in the audited financial statements of the preceding year.


Shanghai Miracogen Inc.- Ex. 2032, Page 000728

This Appendix contains a summary of laws and regulations on companies and securities in the PRC, certain major differences between the PRC Company Law and Companies (Winding Up and Miscellaneous Provisions) Ordinance and the Companies Ordinance as well as the additional regulatory provisions of the Stock Exchange on joint stock limited companies of the PRC. The principal objective of this summary is to provide potential investors with an overview of the principal laws and regulations applicable to us. This summary is with no intention to include all the information which may be important to the potential investors. For discussion of laws and regulations specifically governing the business of the Company, please see "Regulatory Overview" in this Prospectus.

## PRC LAWS AND REGULATIONS

### The PRC Legal System

The PRC legal system is based on the PRC Constitution (《中華人民共和國憲法》, the "**Constitution**"), which was adopted on December 4, 1982 and amended five times on April 12, 1988, March 29, 1993, March 15, 1999, March 14, 2004 and March 11, 2018. The PRC legal system is made up of written laws, administrative regulations, local regulations, autonomous regulations, separate regulations, rules and regulations of State Council departments, rules and regulations of local governments, laws of special administrative regions and international treaties of which the PRC government is a signatory and other regulatory documents. Court judgments do not constitute legally binding precedents, although they are used for the purposes of judicial reference and guidance.

The National People's Congress (the "**NPC**") and its Standing Committee are empowered to exercise the legislative power of the State in accordance with the Constitution and the PRC Legislation Law (《中華人民共和國立法法》, the "**Legislation Law**"), which was adopted on July 1, 2000 and amended on March 15, 2015. The NPC has the power to formulate and amend basic laws governing state organs, civil, criminal and other matters. The Standing Committee of the NPC formulates and amends laws other than those required to be enacted by the NPC and to interpret, supplement and amend parts of the laws enacted by the NPC during the adjournment of the NPC, provided that such supplements and amendments are not in conflict with the basic principles of such laws.

The State Council is the highest organ of state administration and has the power to formulate administrative regulations based on the Constitution and laws.

The people's congresses of the provinces, autonomous regions and municipalities and their respective standing committees may formulate local regulations based on the specific circumstances and actual needs of their respective administrative areas, provided that such local regulations do not contravene any provision of the Constitution, laws or administrative regulations.


Shanghai Miracogen Inc.- Ex. 2032, Page 000729

The people's congresses of cities divided into districts and their respective standing committees may formulate local regulations on aspects such as urban and rural construction and management, environmental protection and historical and cultural protection based on the specific circumstances and actual needs of such cities, provided that such local regulations do not contravene any provision of the Constitution, laws, administrative regulations and local regulations of their respective provinces or autonomous regions. If the law provides otherwise on the matters concerning formulation of local regulations by cities divided into districts, those provisions shall prevail. Such local regulations will become enforceable after being reported to and approved by the standing committees of the people's congresses of the relevant provinces or autonomous regions. The standing committees of the people's congresses of the provinces or autonomous regions examine the legality of local regulations submitted for approval, and such approval should be granted within four months if they are not in conflict with the Constitution, laws, administrative regulations and local regulations of such provinces or autonomous regions. Where, during the examination for approval of local regulations of cities divided into districts by the standing committees of the people's congresses of the provinces or autonomous regions, conflicts are identified with the rules and regulations of the people's governments of the provinces or autonomous regions concerned, a decision should be made by the standing committees of the people's congresses of provinces or autonomous regions to resolve the issue. People's congresses of national autonomous areas have the power to enact autonomous regulations and separate regulations in light of the political, economic and cultural characteristics of the ethnic groups in the areas concerned. The people's congresses or their standing committees of the provinces and cities where special economic zones are located may, upon authorization by the National People's Congress, formulate regulations and enforce them within the special economic zones.

The ministries and commissions of the State Council, People's Bank of China, the State Audit Administration and the subordinate institutions with administrative functions directly under the State Council may, in accordance with the laws and the administrative regulations, decisions and orders of the State Council and within the limits of their power, formulate rules. Provisions of departmental rules should be the matters related to the enforcement of the laws and administrative regulations, and the decisions and orders of the State Council. The people's governments of the provinces, autonomous regions, municipalities and cities or autonomous prefectures divided into districts may formulate rules and regulations based on the laws, administrative regulations and local regulations of such provinces, autonomous regions and municipalities.

According to the Constitution, the power to interpret laws is vested in the Standing Committee of the NPC. Pursuant to the Resolution of the Standing Committee of the NPC Providing an Improved Interpretation of the Law (《全國人民代表大會常務委員會關於加強法律解釋工作的決議》) implemented on June 10, 1981, issues related to the application of laws in a court trial should be interpreted by the Supreme People's Court, issues related to the application of laws in a prosecution process of a procuratorate should be interpreted by the Supreme People's Procuratorate. If there is any disagreement in principle between Supreme People's Court's interpretations & Supreme People's Procuratorate's interpretations, such


Shanghai Miracogen Inc.- Ex. 2032, Page 000730

issues shall be reported to the Standing Committee of the NPC for interpretation or judgment. The other issues related to laws other than the abovementioned should be interpreted by the State Council and the competent authorities. The State Council and its ministries and commissions are also vested with the power to give interpretations of the administrative regulations and departmental rules which they have promulgated. At the regional level, the power to interpret regional laws and regulations as well as administrative rules is vested in the regional legislative and administrative authorities which promulgate such laws, regulations and rules.

**The PRC Judicial System**

Under the Constitution and the Law of Organization of the People's Courts of the PRC (《中華人民共和國人民法院組織法》), which is adopted on January 1, 1980 and amended three times on September 2, 1983, December 2, 1986, October 31, 2006 and October 26, 2018, the PRC judicial system is made up of the Supreme People's Court, the local people's courts, the military courts and other special people's courts. The local people's courts are divided into three levels, namely, the basic people's courts, the intermediate people's courts and the higher people's courts. The basic people's courts may set up civil, criminal and economic divisions, and certain people's courts based on the facts of the region, population and cases. The intermediate people's courts have divisions similar to those of the basic people's courts and may set up other special divisions, such as the intellectual property division, if needed. These two levels of people's courts are subject to supervision by people's courts at higher levels. The Supreme People's Court is the highest judicial authority in the PRC. It supervises the administration of justice by the people's courts at all levels and special people's courts. The Supreme People's Procuratorate is authorized to supervise the judgment and ruling of the people's courts at all levels which have been legally effective, and the people's procuratorate at a higher level is authorized to supervise the judgment and ruling of a people's court at lower levels which have been legally effective.

A people's court takes the rule of the second instance as the final rule, that is, the judgments or rulings of the second instance at a people's court are final. A party may appeal against the judgment or ruling of the first instance of a local people's court. The people's procuratorate may present a protest to the people's court at the next higher level in accordance with the procedures stipulated by the laws. In the absence of any appeal by the parties and any protest by the people's procuratorate within the stipulated period, the judgments or rulings of the people's court are final. Judgments or rulings of the second instance of the intermediate people's courts, the higher people's courts and the Supreme People's Court, and judgments or rulings of the first instance of the Supreme People's Court are final. However, if the Supreme People's Court finds some definite errors in a legally effective judgment, ruling or conciliation statement of the people's court at any level, or if the people's court at a higher level finds such errors in a legally effective judgment, ruling or conciliation statement of the people's court at a lower level, it has the authority to review the case itself or to direct the lower-level people's court to conduct a retrial. If the chief judge of all levels of people's courts finds some definite


Shanghai Miracogen Inc.- Ex. 2032, Page 000731

errors in a legally effective judgment, ruling or conciliation statement, and considers a retrial is preferred, such case shall be submitted to the judicial committee of the people's court at the same level for discussion and decision.

The Civil Procedure Law of the PRC (《中華人民共和國民事訴訟法》, the "**PRC Civil Procedure Law**") adopted on April 9, 1991 and amended three times on October 28, 2007, August 31, 2012 and June 27, 2017 prescribes the conditions for instituting a civil action, the jurisdiction of the people's courts, the procedures for conducting a civil action, and the procedures for enforcement of a civil judgment or ruling. All parties to a civil action conducted within the PRC must abide by the PRC Civil Procedure Law. A civil case is generally heard by the court located in the defendant's place of domicile. The court of jurisdiction in respect of a civil action may also be chosen by explicit agreement among the parties to a contract, provided that the people's court having jurisdiction should be located at places substantially connected with the disputes, such as the plaintiff's or the defendant's place of domicile, the place where the contract is executed or signed or the place where the object of the action is located. However, such choice shall not in any circumstances contravene the regulations of differential jurisdiction and exclusive jurisdiction.

A foreign individual, a person without nationality, a foreign enterprise or a foreign organization is given the same litigation rights and obligations as a citizen, a legal person or other organizations of the PRC when initiating actions or defending against litigations at a PRC court. Should a foreign court limit the litigation rights of PRC citizens or enterprises, the PRC court may apply the same limitations to the citizens and enterprises of such foreign country. A foreign individual, a person without nationality, a foreign enterprise or a foreign organization must engage a PRC lawyer in case he or it needs to engage a lawyer for the purpose of initiating actions or defending against litigations at a PRC court. In accordance with the international treaties to which the PRC is a signatory or participant or according to the principle of reciprocity, a people's court and a foreign court may request each other to serve documents, conduct investigation and collect evidence and conduct other actions on its behalf. A PRC court shall not accommodate any request made by a foreign court which will result in the violation of sovereignty, security or public interests of the PRC.

All parties to a civil action shall perform the legally effective judgments and rulings. If any party to a civil action refuses to abide by a judgment or ruling made by a people's court or an award made by an arbitration tribunal in the PRC, the other party may apply to the people's court for the enforcement of the same within two years subject to application for postponed enforcement or revocation. If a party fails to satisfy within the stipulated period a judgment which the court has granted an enforcement approval, the court may, upon the application of the other party, mandatorily enforce the judgment on the party.


Shanghai Miracogen Inc.- Ex. 2032, Page 000732

A party seeking to enforce a judgment or ruling of a people's court against a party who is not personally or whose property is not within the PRC may apply to a foreign court with jurisdiction over the case for recognition and enforcement of the judgment or ruling. A foreign judgment or ruling may also be recognized and enforced by the people's court according to PRC enforcement procedures if the PRC has entered into or acceded to an international treaty with the relevant foreign country, which provides for such recognition and enforcement, or if the judgment or ruling satisfies the court's examination according to the principle of reciprocity, unless the people's court finds that the recognition or enforcement of such judgment or ruling will result in a violation of the basic legal principles of the PRC, its sovereignty or security or against social and public interest.

**The PRC Company Law, Special Regulations, the Mandatory Provisions and Official Reply**

The PRC Company Law (《中華人民共和國公司法》) was adopted by the 5th meeting of the Standing Committee of the 8th National People's Congress Session on December 29, 1993 and came into effect on July 1, 1994. It was amended on December 25, 1999, August 28, 2004, October 27, 2005, December 28, 2013, and October 26, 2018. The latest revised PRC Company Law was implemented on October 26, 2018.

The Special Regulations was passed at the 22nd Standing Committee Meeting of the State Council on July 4, 1994 and promulgated and implemented on August 4, 1994. The Special Regulations include provisions in respect of the overseas share offering and listing of joint stock limited companies.

The Mandatory Provisions jointly promulgated by the former Securities Commission of the State Council and the former State Commission for Restructuring the Economic System and implemented on August 27, 1994 and effective as of December 19, 1994 prescribe that the provisions should be incorporated in the articles of association of joint stock limited companies to be listed in overseas stock exchanges. Accordingly, the contents required by the Mandatory Provisions have been incorporated in the Articles of Association. References to a "company" made in this Appendix are to a joint stock limited company established under the PRC Company Law with overseas-listed foreign invested shares to be issued.

According to the Official Reply, promulgated by the State Council on October 17, 2019, the notice period for a shareholders' meeting, the shareholder proposal right, and the procedures for convening a shareholders' meeting, for those joint stock companies established within the territory of China but listed outside the territory of China, should be governed by the PRC Company Law, and the Special Regulations will no longer apply to the aforesaid matters.

Set out below is a summary of the major provisions of the PRC Company Law, the Special Regulations, the Mandatory Provisions and Official Reply.


Shanghai Miracogen Inc.- Ex. 2032, Page 000733

***General***

A "joint stock limited company" ("company") refers to a corporate legal person incorporated in China under the PRC Company Law with independent legal person properties and entitlements to such legal person properties and with its registered capital divided into shares of equal par value. The liability of the company for its own debts is limited to all the properties it owns and the liability of its shareholders for the company is limited to the extent of the shares they subscribe for.

***Incorporation***

A company may be established by promotion or subscription. A company shall have a minimum of two but no more than 200 people as its promoters, and over half of the promoters must be resident within the PRC. Companies established by promotion are companies of which the registered capital is the total share capital subscribed for by all the promoters registered with the company's registration authorities. No share offering shall be made before the shares subscribed for by the promoters are fully paid up. For companies established by subscription, the registered capital is the total paid-up share capital as registered with the company's registration authorities. If laws, administrative regulations and State Council decisions provide otherwise on paid-in registered capital and the minimum registered capital, the company should follow such provisions.

For companies incorporated by way of promotion, the promoters shall subscribe in writing for the shares required to be subscribed for by them and pay up their capital contributions under the articles of association. Procedures relating to the transfer of titles to non-monetary assets shall be duly completed if such assets are to be contributed as capital. Promoters who fail to pay up their capital contributions in accordance with the foregoing provisions shall assume default liabilities in accordance with the covenants set out in the promoters' agreement. After the promoters have subscribed for the capital contribution under the articles of association, a board of directors and a supervisory board shall be elected and the board of directors shall apply for registration of establishment by filing the articles of association with relevant administration for industry and commerce, and other documents as required by the law or administrative regulations.

Where companies are incorporated by subscription, not less than 35% of their total number of shares must be subscribed for by the promoters, unless otherwise provided by the laws or administrative regulations. A promoter who offers shares to the public must announce a share offering prospectus and prepare a share subscription form to be completed, signed and sealed by subscribers, specifying the number and amount of shares to be subscribed for and the subscribers' addresses. The subscribers shall pay up monies for the shares they subscribe for. Where a promoter is offering shares to the public, such offer shall be underwritten by security companies established under PRC law, and underwriting agreements shall be entered into. A promoter offering shares to the public shall also enter into agreements with banks in relation to the receipt of subscription monies. The receiving banks shall receive and keep in custody the


Shanghai Miracogen Inc.- Ex. 2032, Page 000734

subscription monies, issue receipts to subscribers who have paid the subscription monies and is obliged to furnish evidence of receipt of those subscription monies to relevant authorities. After the subscription monies for the share issue have been paid in full, a capital verification institution established under PRC law must be engaged to conduct a capital verification and furnish a certificate thereof. The promoters shall preside over and convene an inauguration meeting within 30 days from the date of the full payment of subscription monies. The inauguration meeting shall be formed by the promoters and subscribers. Where the shares issued remain under subscribed by the cut-off date stipulated in the share offering prospectus, or where the promoter fails to convene an inauguration meeting within 30 days of the subscription monies for the shares issued being fully paid up, the subscribers may demand that the promoters refund the subscription monies so paid together with the interest at bank rates of a deposit for the same period. Within 30 days of the conclusion of the inauguration meeting, the board of directors shall apply to the company registration authority for registration of the establishment of the company. A company is formally established and has the capacity of a legal person after approval of registration has been given by the relevant administration for industry and commerce and a business license has been issued.

A company's promoter shall be liable for the followings:

(1) the debts and expenses incurred in the establishment process jointly and severally if the company cannot be incorporated;

(2) the refund of subscription monies paid by the subscribers together with interest at bank rates of deposit for the same period jointly and severally if the company cannot be incorporated; and

(3) the compensation of any damages suffered by the company as a result of the promoters' fault in the course of its establishment.

***Share Capital***

The promoters may make a capital contribution in currencies, or non-monetary assets such as in kind or intellectual property rights or land use rights which can be appraised with monetary value and transferred lawfully, except for assets which are prohibited from being contributed as capital by the laws or administrative regulations. If a capital contribution is made in non-monetary assets, a valuation and verification of the fair value of the assets contributed must be carried out.

The issuance of shares shall be conducted in a fair and equitable manner. The same class of shares must carry equal rights. For shares issued at the same time and within the same class, the conditions and price per share must be the same. The share offering price may be equal to or greater than the nominal value of the share, but may not be less than the nominal value.


Shanghai Miracogen Inc.- Ex. 2032, Page 000735

A company must obtain the approval of CSRC to offer its shares to the overseas public. According to the Special Regulations and the Mandatory Provisions, the shares issued to foreign investors and listed overseas by a company shall be in registered form, denominated in Renminbi and subscribed for in foreign currency. Shares issued to foreign investors and listed overseas are classified as overseas-listed foreign shares, and those shares issued to investors within the PRC, are known as domestic shares. Qualified foreign institutional investors approved by CSRC may hold domestic listed shares. Under the Special Regulations, upon approval of CSRC, a company may agree, in the underwriting agreement in respect of an issue of overseas-listed foreign shares, to retain not more than 15% of the aggregate number of such overseas-listed foreign invested shares proposed to be issued in addition to the number of underwritten shares. The issuance of the retained shares is deemed to be a part of this issuance.

Under the PRC Company Law, a company issuing registered share certificates shall maintain a shareholder registry which sets forth the following matters:

(1) the name and domicile of each shareholder;

(2) the number of shares held by each shareholder;

(3) the serial numbers of shares held by each shareholder; and

(4) the date on which each shareholder acquired the shares.

***Increase in Share Capital***

Under the PRC Company Law, where a company is issuing new shares, resolutions shall be passed at shareholder's general meeting in accordance with the articles of association in respect of the class and amount of the new shares, the issue price of the new shares, the commencement and end dates for the issue of the new shares and the class and amount of the new shares proposed to be issued to existing shareholders.

When a company launches a public issue of new shares upon the approval by CSRC, a new share offering prospectus and financial accounting report must be published and a subscription form must be prepared. After the issue of new share the company has been paid up, the change must be registered with the relevant company registration authorities and a public announcement must be made accordingly. Where an increase in registered capital of a company is made by means of an issue of new shares, the subscription of new shares by shareholders shall be made in accordance with the relevant provisions on the payment of subscription monies for the establishment of a company.


Shanghai Miracogen Inc.- Ex. 2032, Page 000736

***Reduction of Share Capital***

A company may reduce its registered capital in accordance with the following procedures prescribed by the PRC Company Law:

(1) the company shall prepare a balance sheet and an inventory of assets;

(2) the reduction of registered capital must be approved by shareholders at general meeting;

(3) the company shall notify its creditors of the reduction in share capital within 10 days and publish the relevant announcement in newspapers within 30 days of the resolution approving the reduction being passed;

(4) the creditors of the company may require the company to repay its debts or provide guarantees for covering the debts within 30 days of receipt of the notification or within 45 days of the date of the announcement if he/she/it has not received any notification; and

(5) the company must apply to the relevant administration bureau for industry and commerce for registration of the change on the reduction of registered capital.

***Repurchase of Shares***

A company shall not purchase its own shares except under any of the following circumstances:

(1) Reducing the registered capital of the company.

(2) Merging with another company that holds its shares.

(3) Using shares for employee stock ownership plan or equity incentives.

(4) A shareholder requesting the company to purchase the shares held by him since he objects to a resolution of the shareholders' meeting on the combination or division of the company.

(5) Using shares for converting convertible corporate bonds issued by the listed company.

(6) It is necessary for a listed company to protect the corporate value and the rights and interests of shareholders.



Shanghai Miracogen Inc.- Ex. 2032, Page 000737

A company purchasing its own shares under any of the circumstances set forth in items (1) and (2) of the preceding paragraph shall be subject to a resolution of the shareholders' meeting; and a company purchasing its own shares under any of the circumstances set forth in items (3), (5) and (6) of the preceding paragraph may, pursuant to the bylaws or the authorization of the shareholders' meeting, be subject to a resolution of a meeting of the board of directors at which more than two-thirds of directors are present.

After purchasing its own shares pursuant to the provisions of the first paragraph of this article, a company shall, under the circumstance set forth in item (1), cancel them within 10 days after the purchase; while under the circumstance set forth in either item (2) or (4), transfer or cancel them within six months; and while under the circumstance set forth in item (3), (5) or (6), aggregately hold not more than 10% of the total shares that have been issued by the company, and transfer or cancel them within three years.

A listed company purchasing its own shares shall perform the obligation of information disclosure according to the Securities Law of the People's Republic of China. A listed company purchasing its own shares under any of the circumstances set forth in items (3), (5) and (6) of paragraph 1 of this article shall carry out trading in a public and centralized manner.

A company shall not accept its own shares as the subject matter of pledge.

***Transfer of Shares***

Shares held by shareholders may be transferred legally. Under the PRC Company Law, a shareholder should effect a transfer of his shares on a stock exchange established in accordance with laws or by any other means as required by the State Council. Registered shares may be transferred after the shareholders endorse the back of the share certificates or in any other manner specified by the laws or administrative regulations. Following the transfer, the company shall enter the names and domiciles of the transferees into its share register. No changes of registration in the share register described above shall be effected during a period of 20 days prior to convening a shareholders' general meeting or 5 days prior to the record date for the purpose of determining entitlements to dividend distributions, unless otherwise stipulated by laws on the registration of changes in the share register of listed companies. The transfer of bearer share certificates shall become effective upon the delivery of the certificates to the transferee by the shareholder. The Mandatory Provision provides that changes due to share transfer should not be made to shareholder registry within 30 days before a shareholders' general meeting or within 5 days before the record date for the purpose of determining entitlements to dividend distributions.

Under the PRC Company Law, shares held by promoters may not be transferred within one year of the establishment of the company. Shares of the company issued prior to the public issuance of shares may not be transferred within one year of the date of the company's listing on a stock exchange. Directors, supervisors and the senior management of a company shall declare to the company their shareholdings in it and any changes in such shareholdings. During


Shanghai Miracogen Inc.- Ex. 2032, Page 000738

their terms of office, they may transfer no more than 25% of the total number of shares they hold in the company every year. They shall not transfer the shares they hold within one year of the date of the company's listing on a stock exchange, nor within six months after they leave their positions in the company. The articles of association may set out other restrictive provisions in respect of the transfer of shares in the company held by its directors, supervisors and the senior management.

***Shareholders***

Under the PRC Company Law, the rights of holders of ordinary shares of a company include:

(1) to receive dividends and profit distributions in any other form in proportion to the shares they hold;

(2) to lawfully require, convene, preside over or attend general meetings either in person or by proxy and exercise the corresponding voting right;

(3) to supervise, present suggestions on or make inquiries about the operations of the Company;

(4) to transfer, gift or pledge their shares in accordance with the laws, administrative regulations, departmental rules, normative documents and the listing rules of the stock exchange in the place where the stocks of the company are listed, and the articles of association;

(5) to acquire relevant information according to the provisions of the articles of association, including the duplicate of the articles of association, share register, counterfoil of company debentures, minutes of shareholders' general meetings, audited financial statements of the company, reports of directors, accounting firms and the Supervisory Committee;

(6) in the event of the termination or liquidation of the company, to participate in the distribution of the remaining property of the company in proportion to the shares held by them;

(7) to require the company to buy their shares in the event of their objection to resolutions of the general meeting concerning merger or division of the company; and

(8) any other shareholders' rights provided for in laws, administrative regulations, other regulatory documents and the articles of association.


Shanghai Miracogen Inc.- Ex. 2032, Page 000739

The obligations of shareholders include the obligation to abide by the company's articles of association, to pay the subscription monies in respect of the shares subscribed for, to be liable for the company's debts and liabilities to the extent of the amount of his or her subscribed shares and any other shareholder obligation specified in the articles of association.

***Shareholders' General Meetings***

The general meeting is the organ of authority of the company, which exercises its powers in accordance with the PRC Company Law. The general meeting may exercise its powers:

(1) to decide on the company's operational objectives and investment plans;

(2) to elect and dismiss the directors and supervisors (not being representative(s) of employees) and to decide on the matters relating to the remuneration of directors and supervisors;

(3) to review and approve the reports of the board of directors;

(4) to review and approve the reports of the supervisory board;

(5) to review and approve the company's annual financial budgets and final accounts;

(6) to review and approve the company's profit distribution proposals and loss recovery proposals;

(7) to decide on any increase or reduction of the company's registered capital;

(8) to decide on the issue of corporate bonds;

(9) to decide on merger, division, dissolution and liquidation of the company or change of its corporate form;

(10) to amend the company's articles of association; and

(11) to exercise any other authority stipulated in the articles of association.

A shareholders' general meeting is required to be held once every year. An extraordinary general meeting is required to be held within two months of the occurrence of any of the following:

(1) the number of directors is less than the number stipulated by the PRC Company Law or less than two-thirds of the number specified in the articles of association;


Shanghai Miracogen Inc.- Ex. 2032, Page 000740

(2) the outstanding losses of the company amounted to one-third of the company's total paid-in share capital;

(3) shareholders individually or in aggregate holding 10% or more of the company's shares request the convening of an extraordinary general meeting;

(4) the board deems necessary;

(5) the supervisory board proposes to hold; or

(6) any other circumstances as provided for in the articles of association.

A shareholders' general meeting shall be convened by the board of directors, and presided over by the chairman of the board of directors. In the event that the chairman is incapable of performing or is not performing his duties, the meeting shall be presided over by the vice chairman. In the event that the vice chairman is incapable of performing or is not performing his duties, a director nominated by half or more of the directors shall preside over the meeting. Where the board of directors is incapable of performing or is not performing its duties to convene the general meeting, the supervisory board shall convene and preside over shareholders' general meeting in a timely manner. If the supervisory board fails to convene and preside over shareholders' general meeting, shareholders individually or in aggregate holding 10% or more of the company's shares for 90 days or more consecutively may unilaterally convene and preside over shareholders' general meeting.

In accordance with the PRC Company Law, a notice of the general meeting stating the date and venue of the meeting and the matters to be considered at the meeting shall be given to all shareholders 20 days before the meeting. A notice of extraordinary general meeting shall be given to all shareholders 15 days prior to the meeting. For the issuance of bearer share certificates, the time and venue of and matters to be considered at the meeting shall be announced 30 days before the meeting. A single shareholder who holds, or several shareholders who jointly hold, three percent or more of the shares of the company may submit an interim proposal in writing to the board of directors ten days before the general meeting is held. The board of directors shall notify other shareholders within two days upon receipt of the proposal, and submit the said interim proposal to the general meeting for deliberation. The contents of the interim proposal shall fall within the scope of powers of the general meeting, and the proposal shall have a clear agenda and specific matters on which resolutions are to be made. The general meeting shall not make any resolution in respect of any matter not set out in the above-mentioned two types of notices. Holders of bearer share certificates who wish to attend a general meeting shall deposit their share certificates with the company five days before the meeting and till the conclusion of the meeting.

There is no specific provision in the PRC Company Law regarding the number of shareholders constituting a quorum in a shareholders' general meeting.


Shanghai Miracogen Inc.- Ex. 2032, Page 000741

Under the PRC Company Law, shareholders present at a shareholders' general meeting have one vote for each share they hold, save that the company's shares held by the company are not entitled to any voting rights.

An accumulative voting system may be adopted for the election of directors and supervisors at the general meeting pursuant to the provisions of the articles of association or a resolution of the general meeting. Under the accumulative voting system, each share shall be entitled to the number of votes equivalent to the number of directors or supervisors to be elected at the general meeting, and shareholders may consolidate their votes for one or more directors or supervisors when casting a vote.

Under the PRC Company Law, resolutions of the general meeting must be passed by more than half of the voting rights held by shareholders present in person (including those represented by proxies) at the meeting, with the exception of matters relating to merger, division or dissolution of the company, increase or reduction of registered share capital, change of corporate form or amendments to the articles of association, which in each case must be passed by at least two-thirds of the voting rights held by the shareholders present at the meeting. Where the PRC Company Law and the articles of association provide that the transfer or acquisition of significant assets or the provision of external guarantees by the company and the other matters must be approved by way of resolution of the general meeting, the directors shall convene a shareholders' general meeting promptly to vote on such matters by shareholders' general meeting.

Minutes shall be prepared in respect of matters considered at the general meeting and the chairperson and directors attending the meeting shall endorse such minutes by signature. The minutes shall be kept together with the shareholders' attendance register and the proxy forms.

According to the Mandatory Provisions, the increase or reduction of share capital, the issuance of shares of any class, warrants or other similar securities and bonds, the division, merger, dissolution and liquidation of the company, the amendments to the articles of association and any other matters, which, as resolved by way of an ordinary resolution of the general meeting, may have a material impact on the company and require adoption by way of a special resolution, must be approved through special resolutions by no less than two-thirds of the voting rights held by shareholders (including proxies thereof) present at the meeting.

The Mandatory Provisions require a special resolution to be passed at the general meeting and a class meeting to be held in the event of a variation or derogation of the class rights of a shareholder class. For this purpose, holders of domestic shares and H shares are deemed to be shareholders of different classes.


Shanghai Miracogen Inc.- Ex. 2032, Page 000742

***Board***

A company shall have a board, which shall consist of 5 to 19 members. Members of the board may include staff representatives, who shall be democratically elected by the company's staff at a staff representative assembly, general staff meeting or otherwise. The term of a director shall be stipulated in the articles of association, provided that no term of office shall last for more than three years. A director may serve consecutive terms if re-elected. A director shall continue to perform his/her duties as a director in accordance with the laws, administrative regulations and the articles of association until a duly reelected director takes office, if re-election is not conducted in a timely manner upon the expiry of his/her term of office or if the resignation of directors results in the number of directors being less than the quorum.

Under the PRC Company Law, the board of directors may exercise its powers:

(1) to convene shareholders' general meetings and report on its work to the shareholders' general meetings;

(2) to implement the resolutions passed by the shareholders at the shareholders' general meetings;

(3) to decide on the company's operational plans and investment proposals;

(4) to formulate proposal for the company's annual financial budgets and final accounts;

(5) to formulate the company's profit distribution proposals and loss recovery proposals;

(6) to formulate proposals for the increase or reduction of the company's registered capital and the issue of corporate bonds;

(7) to formulate proposals for the merger, division or dissolution of the company or change of corporate form;

(8) to decide on the setup of the company's internal management organs;

(9) to appoint or dismiss the company's manager and decide on his/her remuneration and, based on the manager's recommendation, to appoint or dismiss any deputy general manager and financial officer of the company and to decide on their remunerations;

(10) to formulate the company's basic management system; and

(11) to exercise any other authority stipulated in the articles of association.



Shanghai Miracogen Inc.- Ex. 2032, Page 000743

In addition, the Mandatory Provisions provide that the board of directors is also responsible for formulating the proposals for amendment of the articles of association of a company.

Meetings of the board of directors shall be convened at least twice each year. Notices of meeting shall be given to all directors and supervisors 10 days before the meeting. Interim board meetings may be proposed to be convened by shareholders representing more than 10% of the voting rights, more than one-third of the directors or the supervisory board. The chairman shall convene the meeting within 10 days of receiving such proposal, and preside over the meeting. The board may otherwise determine the means and the period of notice for convening an interim board meeting. Meetings of the board of directors shall be held only if more than half of the directors are present. Resolutions of the board shall be passed by more than half of all directors. Each director shall have one vote for a resolution to be approved by the board. Directors shall attend board meetings in person. If a director is unable to attend for any reason, he/she may appoint another director to attend the meeting on his/her behalf by a written power of attorney specifying the scope of authorization.

If a resolution of the board of directors violates the laws, administrative regulations or the articles of association or resolutions of the general meeting, and as a result of which the company sustains serious losses, the directors participating in the resolution are liable to compensate the company. However, if it can be proved that a director expressly objected to the resolution when the resolution was voted on, and that such objection was recorded in the minutes of the meeting, such director shall be relieved from that liability.

Under the PRC Company Law, the following person may not serve as a director in a company:

(1) a person who is unable or has limited ability to undertake any civil liabilities;

(2) a person who has been convicted of an offense of corruption, bribery, embezzlement, misappropriation of property or destruction of the socialist market economic order, or who has been deprived of his political rights due to his crimes, in each case where less than five years have elapsed since the date of completion of the sentence;

(3) a person who has been a former director, factory manager or manager of a company or an enterprise that has entered into insolvent liquidation and who was personally liable for the insolvency of such company or enterprise, where less than three years have elapsed since the date of the completion of the bankruptcy and liquidation of the company or enterprise;

(4) a person who has been a legal representative of a company or an enterprise that has had its business license revoked due to violations of the law or has been ordered to close down by law and the person was personally responsible, where less than three years have elapsed since the date of such revocation; and

(5) a person who is liable for a relatively large amount of debts that are overdue.


Shanghai Miracogen Inc.- Ex. 2032, Page 000744

Where a company elects or appoints a director to which any of the above circumstances applies, such election or appointment shall be null and void. A director to which any of the above circumstances applies during his/her term of office shall be released of his/her duties by the company.

Other circumstances under which a person is disqualified from acting as a director of a company are set out in the Mandatory Provisions.

Under the PRC Company Law, the board shall appoint a chairman and may appoint a vice chairman.

The chairman and the vice chairman shall be elected with approval of more than half of all the directors. The chairman shall convene and preside over board meetings and review the implementation of board resolutions. The vice chairman shall assist the chairman to perform his/her duties. Where the chairman is incapable of performing or is not performing his/her duties, the duties shall be performed by the vice chairman. Where the vice chairman is incapable of performing or is not performing his/her duties, a director nominated by more than half of the directors shall perform his/her duties.

The legal representative of a company, in accordance with the company's articles of association, may be the chairman, any executive director or the manager. The Special Regulations provide that a company's directors, supervisors, managers and other officers bear fiduciary duties and the duty to act diligently. They are required to faithfully perform their duties, protect the interests of the company and not to use their positions for their own benefit.

***Supervisory Board***

A company shall have a supervisory board composed of not less than three members. The supervisory board shall consist of representatives of the shareholders and an appropriate proportion of representatives of the company's staff, of which the proportion of representatives of the company's staff shall not be less than one-third, and the actual proportion shall be determined in the articles of association. Representatives of the company's staff at the supervisory board shall be democratically elected by the company's staff at the staff representative assembly, general staff meeting or otherwise. Directors and senior management shall not act concurrently as supervisors.

Each term of office of a supervisor is three years and he/she may serve consecutive terms if reelected. A supervisor shall continue to perform his/her duties as a supervisor in accordance with the laws, administrative regulations and the articles of association until a duly re-elected supervisor takes office, if re-election is not conducted in a timely manner upon the expiry of his/her term of office or if the resignation of supervisors results in the number of supervisors being less than the quorum.


Shanghai Miracogen Inc.- Ex. 2032, Page 000745

The supervisory board may exercise its powers:

(1) to review the company's financial position;

(2) to supervise the directors and senior management in their performance of their duties and to propose the removal of directors and senior management who have violated laws, regulations, the articles of association or the resolutions of shareholders' meeting;

(3) when the acts of directors and senior management are harmful to the company's interests, to require correction of those acts;

(4) to propose the convening of extraordinary shareholders' general meetings and to convene and preside over shareholders' general meetings when the board of directors fails to perform the duty of convening and presiding over shareholders' general meeting under this law;

(5) to initiate proposals for resolutions to shareholders' general meeting;

(6) to initiate proceedings against directors and senior management;

(7) to exercise any other authority stipulated in the articles of association.

Supervisors may be present at board meetings and make inquiries or proposals in respect of the resolutions of the board. The supervisory board may investigate any irregularities identified in the operation of the company and, when necessary, may engage an accounting firm to assist its work at the cost of the company.

The supervisory board shall appoint a chairman and may appoint a vice chairman. The chairman and the vice chairman of the supervisory board shall be elected by more than half of the supervisors. According to the Reply of the Overseas Listing Department of CSRC and the Production System Department of the State Commission for Restructuring the Economic System on Opinions Concerning the Supplement and Amendment to Articles of Association by Companies to Be Listed in Hong Kong (《中國證監會海外上市部、國家體改委生產體制司關於到香港上市公司對公司章程作補充修改的意見的函》), which is promulgated and implemented on April 3, 1995, the chairman of the supervisory board shall be selected by more than two-thirds of the supervisors.

The chairman of the supervisory board shall convene and preside over supervisory board meetings. Where the chairman of the supervisory board is incapable of performing or is not performing his/her duties, the vice chairman of the supervisory board shall convene and preside over supervisory board meetings. Where the vice chairman of the supervisory board is incapable of performing or is not performing his/her duties, a supervisor recommended by more than half of the supervisors shall convene and preside over supervisory board meetings.


Shanghai Miracogen Inc.- Ex. 2032, Page 000746

***Manager and Senior Management***

Under the PRC Company Law, a company shall have a manager who shall be appointed or removed by the board of directors. The manager shall report to the board of directors and may exercise the following powers:

(1) to manage the production and operation and administration of the company and arrange for the implementation of the resolutions of the board of directors;

(2) to arrange for the implementation of the company's annual operation plans and investment proposals;

(3) to formulate proposals for the establishment of the company's internal management organs;

(4) to formulate the fundamental management system of the company;

(5) to formulate the company's specific rules and regulations;

(6) to recommend the appointment or dismissal of any deputy manager and any financial officer of the company;

(7) to appoint or dismiss management personnel (other than those required to be appointed or dismissed by the board of directors); and

(8) to exercise any other authority granted by the board of directors.

Other provisions in the articles of association on the manager's powers shall also be complied with. The manager shall be present at meetings of the board of directors. However, the manager shall have no voting rights at meetings of the board of directors unless he/she concurrently serves as a director.

According to the PRC Company Law, senior management shall mean the manager, deputy manager(s), person-in-charge of finance, secretary to the board of a listed company and other personnel as stipulated in the articles of association.

***Duties of Directors, Supervisors and Senior Management***

Directors, supervisors and senior management of the company are required under the PRC Company Law to comply with the relevant laws, administrative regulations and the articles of association, and carry out their duties of loyalty and diligence.


Shanghai Miracogen Inc.- Ex. 2032, Page 000747

Directors, supervisors and senior management are prohibited from abusing their authority in accepting bribes or other unlawful income and from misappropriating the company's property.

Directors and senior management are prohibited from:

(1) misappropriating company funds;

(2) depositing company funds into accounts under their own names or the names of other individuals to deposit;

(3) loaning company funds to others or providing guarantees in favor of others supported by company's property in violation of the articles of association or without approval of the general meeting or the board of directors;

(4) entering into contracts or transactions with the company in violation of the articles of association or without approval of the general meeting;

(5) using their position to procure business opportunities for themselves or others that should have otherwise been available to the company or operating businesses similar to that of the company for their own benefits or on behalf of others without approval of the general meeting;

(6) accepting commissions paid by a third party for transactions conducted with the company;

(7) unauthorized divulgence of confidential information of the company; and

(8) other acts in violation of their duty of loyalty to the company.

Income generated by directors or senior management in violation of aforementioned shall be returned to the company.

A director, supervisor or senior management who contravenes any law, administrative regulation or articles of association in the performance of his/her duties resulting in any loss to the company shall be liable to the company.

Where a director, supervisor or senior management is required to attend a shareholders' general meeting, such director, supervisor or senior management shall attend the meeting and answer the inquiries from shareholders. Directors and senior management shall furnish all true information and data to the supervisory board, without impeding the discharge of duties by the supervisory board or supervisors.


Shanghai Miracogen Inc.- Ex. 2032, Page 000748

Where a director or senior management contravenes law, administrative regulation or articles of association in the performance of his/her duties resulting in any loss to the company, shareholder(s) holding individually or in aggregate no less than 1% of the company's shares consecutively for at least 180 days may request in writing that the supervisory board institute litigation at a people's court on its behalf. Where the supervisory violates the laws or administrative regulations or the articles of association in the discharge of its duties resulting in any loss to the company, such shareholder(s) may request in writing that the board of directors institute litigation at a people's court on its behalf. If the supervisory board or the board of directors refuses to institute litigation after receiving this written request from the shareholder(s), or fails to institute litigation within 30 days of the date of receiving the request, or in case of emergency where failure to institute litigation immediately will result in irrecoverable damage to the company's interests, such shareholder(s) shall have the power to institute litigation directly at a people's court in its own name for the company's benefit. For other parties who infringe the lawful interests of the company resulting in loss to the company, such shareholder(s) may institute litigation at a people's court in accordance with the procedure described above. Where a director or senior management contravenes any laws, administrative regulations or the articles of association in infringement of shareholders' interests, a shareholder may also institute litigation at a people's court.

The Special Regulations and the Mandatory Provisions provide that a company's directors, supervisors, manager and other senior management shall have duty of loyalty to the company. They are required to faithfully perform their duties, to protect the interests of the company and not to use their positions in the company for their own benefits. The Mandatory Provisions contain detailed stipulations on these duties.

***Finance and Accounting***

Under the PRC Company Law, a company shall establish its own financial and accounting systems according to the laws, administrative regulations and the regulations of the competent financial departments of the State Council. At the end of each financial year, a company shall prepare a financial report which shall be audited by an accounting firm in accordance with the laws. The financial and accounting reports shall be prepared in accordance with the laws, administrative regulations and the regulations of the financial departments of the State Council.

The company's financial reports shall be made available for shareholders' inspection at the company 20 days before the convening of an annual general meeting. A joint stock limited company that makes public stock offerings shall publish its financial reports.

When distributing each year's profits after taxation, the company shall set aside 10% of its profits after taxation for the company's statutory common reserve fund until the fund has reached 50% or more of the company's registered capital. When the company's statutory common reserve fund is not sufficient to make up for the company's losses for the previous years, the current year's profits shall first be used to make good the losses before any allocation is set aside for the statutory common reserve fund. After the company has made allocations to


Shanghai Miracogen Inc.- Ex. 2032, Page 000749

the statutory common reserve fund from its profits after taxation, it may, upon passing a resolution at a shareholders' general meeting, make further allocations from its profits after taxation to the discretionary common reserve fund. After the company has made good its losses and made allocations to its discretionary common reserve fund, the remaining profits after taxation shall be distributed in proportion to the number of shares held by the shareholders, except for those which are not distributed in a proportionate manner as provided by the articles of association.

Profits distributed to shareholders by a resolution of a shareholders' general meeting or the board of directors before losses have been made good and allocations have been made to the statutory common reserve fund in violation of the requirements described above must be returned to the company. The company shall not be entitled to any distribution of profits in respect of shares held by it.

The premium over the nominal value of the shares of the company earned from the issue of share and other income as required by CSRC to be treated as the capital reserve fund shall be accounted for as the capital reserve fund. The common reserve fund of a company shall be applied to make good the company's losses, expand its business operations or increase its capital. The capital reserve fund, however, shall not be used to make good the company's losses. Upon the transfer of the statutory common reserve fund into capital, the balance of the fund shall not be less than 25% of the registered capital of the company before such transfer.

The company shall have no accounting books except the statutory books. Its assets shall not be deposited in any account opened under the name of an individual.

***Appointment and Retirement of Auditors***

Pursuant to the PRC Company Law, the appointment or dismissal of an accounting firm responsible for the company's auditing shall be determined by a shareholders' general meeting or the board of directors in accordance with the articles of association. The accounting firm should be allowed to make representations when the general meeting or the board of directors conducts a vote on the dismissal of the accounting firm. The company should provide true and complete accounting evidence, accounting books, financial and accounting reports and other accounting information to the engaged accounting firm without any refusal or withholding or falsification of information.

The Special Regulations require a company to engage an independent qualified accounting firm to audit the company's annual reports and to review and check other financial reports of the company. The accounting firm's term of office shall commence from the end of the shareholders' annual general meeting to the end of the next shareholders' annual general meeting.


Shanghai Miracogen Inc.- Ex. 2032, Page 000750

***Profit Distribution***

According to the PRC Company Law, a company shall not distribute profits before losses are covered and the statutory common reserve fund is provided. The Special Regulations require that any dividend and other distribution to shareholders of overseas-listed foreign shares shall be declared and calculated in RMB and paid in foreign currency.

Under the Mandatory Provisions, a company shall make foreign currency payments to shareholders through receiving agents.

***Amendments to the Articles of Association***

Pursuant to PRC Company Law, the resolution of a shareholders' general meeting regarding any amendment to a company's articles of association requires affirmative votes by at least two-thirds of the votes held by shareholders attending the meeting. Pursuant to the Mandatory Provisions, the company may amend its articles of association according to the laws, administrative regulations and the articles of association. The amendment to articles of association involving content of the Mandatory Provisions will only be effective upon approval of the department in charge of company examination and approval and the securities regulatory department of the State Council authorized by the State Council, while the amendment to articles of association involving matters of company registration must be registered with the relevant authority in accordance with applicable laws.

***Dissolution and Liquidation***

Under the PRC Company Law, a company shall be dissolved for any of the following reasons:

(1) the term of its operation set out in the articles of association has expired or other events of dissolution specified in the articles of association have occurred;

(2) the shareholders have resolved at a shareholders' general meeting to dissolve the company;

(3) the company is dissolved by reason of its merger or division;

(4) the business license of the company is revoked or the company is ordered to close down or to be dissolved in accordance with the laws; or

(5) the company is dissolved by a people's court in response to the request of shareholders holding shares that represent more than 10% of the voting rights of all shareholders of the company, on the grounds that the operation and management of the company has suffered serious difficulties that cannot be resolved through other means, rendering ongoing existence of the company a cause for significant losses to the shareholders.



Shanghai Miracogen Inc.- Ex. 2032, Page 000751

In the event of paragraph 1 above, the company may carry on its existence by amending its articles of association. The amendments to the articles of association in accordance with the provisions described above shall require the approval of more than two-thirds of voting rights of shareholders attending a shareholders' general meeting.

Where the company is dissolved under the circumstances set forth in paragraph 1, 2, 4 or 5 above, it should establish a liquidation committee within 15 days of the date on which the dissolution matter occurs. The liquidation committee shall be composed of directors or any other person determined by a shareholders' general meeting. If a liquidation committee is not established within the prescribed period, the company's creditors may file an application with a people's court to appoint relevant personnel to form a liquidation committee to administer the liquidation. The people's court should accept such application and form a liquidation committee to conduct liquidation in a timely manner.

The liquidation committee may exercise following powers during the liquidation:

(1) to sort out the company's assets and to prepare a balance sheet and an inventory of assets;

(2) to notify the company's creditors or publish announcements;

(3) to deal with any outstanding business related to the liquidation;

(4) to pay any overdue tax together with any tax arising during the liquidation process;

(5) to settle the company's claims and liabilities;

(6) to handle the company's remaining assets after its debts have been paid off; and

(7) to represent the company in any civil procedures.

The liquidation committee shall notify the company's creditors within 10 days of its establishment, and publish an announcement in newspapers within 60 days.

A creditor shall lodge his claim with the liquidation committee within 30 days of receipt of the notification or within 45 days of the date of the announcement if he has not received any notification. A creditor shall report all matters relevant to his claimed creditor's rights and furnish relevant evidence. The liquidation committee shall register such creditor's rights. The liquidation committee shall not make any settlement to creditors during the period of the claim.


Shanghai Miracogen Inc.- Ex. 2032, Page 000752

Upon disposal of the company's property and preparation of the required balance sheet and inventory of assets, the liquidation committee shall draw up a liquidation plan and submit this plan to a shareholders' general meeting or a people's court for endorsement. The remaining part of the company's assets, after payment of liquidation expenses, employee wages, social insurance expenses and statutory compensation, outstanding taxes and the company's debts, shall be distributed to shareholders in proportion to shares held by them. The company shall continue to exist during the liquidation period, although it cannot conduct operating activities that are not related to the liquidation. The company's property shall not be distributed to shareholders before repayments are made in accordance with the requirements described above.

Upon liquidation of the company's property and preparation of the required balance sheet and inventory of assets, if the liquidation committee becomes aware that the company does not have sufficient assets to meet its liabilities, it must apply to a people's court for a declaration of bankruptcy in accordance with the laws. Following such declaration by the people's court, the liquidation committee shall hand over the administration of the liquidation to the people's court.

Upon completion of the liquidation, the liquidation committee shall prepare a liquidation report and submit it to the shareholders' general meeting or a people's court for confirmation of its completion. Following such confirmation, the report shall be submitted to the company registration authority to cancel the company's registration, and an announcement of its termination shall be published. Members of the liquidation committee are required to discharge their duties in good faith and perform their obligation in compliance with laws. Members of the liquidation committee shall be prohibited from abusing their authority in accepting bribes or other unlawful income and from misappropriating the company's properties. Members of the liquidation committee are liable to indemnify the company and its creditors in respect of any loss arising from their willful or material default.

Liquidation of a company declared bankrupt according to laws shall be processed in accordance with the laws on corporate bankruptcy.

***Overseas Listing***

Pursuant to the Special Regulations, the shares of a company shall only be listed overseas after obtaining approval from CSRC and the listing must be arranged in accordance with the procedures specified by the State Council.

According to Rule 2(6) of the Regulatory Guidelines for the Application Documents and Examination Procedures for the Overseas Share Issuance and Listing by Joint Stock Companies (《關於股份公司境外發行股票和上市申報文件及審核程序的監管指引》) promulgated by CSRC (effective from January 1, 2013), the approval documents for overseas stock issuance and listing by the company granted by CSRC shall be valid for a period of 12 months.


Shanghai Miracogen Inc.- Ex. 2032, Page 000753

*Loss of Share Certificates*

If a registered share certificate is lost, stolen or destroyed, the relevant shareholder may apply, in accordance with the relevant provisions set out in the Civil Procedure Law, to a people's court to declare such certificate invalid. After the people's court declares the invalidity of such certificate, the shareholder may apply to the company for a replacement share certificate. A separate procedure regarding the loss of overseas listed and foreign invested share certificates is provided for in the Mandatory Provisions.

*Merger and Division*

A merger agreement shall be signed by merging companies and the involved companies shall prepare respective balance sheets and inventory of assets. The companies shall within 10 days of the date of passing the resolution approving the merger notify their respective creditors and publicly announce the merger in newspapers within 30 days. A creditor may, within 30 days of receipt of the notification, or within 45 days of the date of the announcement if he has not received the notification, request the company to settle any outstanding debts or provide relevant guarantees. In case of a merger, the credits and debts of the merging parties shall be assumed by the surviving or the new company.

In case of a division, the company's assets shall be divided and a balance sheet and an inventory of assets shall be prepared. When a resolution regarding the company's division is approved, the company should notify all its creditors within 10 days of the date of passing such resolution and publicly announce the division in newspapers within 30 days. Unless an agreement in writing is reached with creditors before the company's division in respect of the settlement of debts, the liabilities of the company which have accrued prior to the division shall be jointly borne by the divided companies.

Changes in the business registration of the companies as a result of the merger or division shall be registered with the relevant administration authority for industry and commerce.

In accordance with the laws, cancelation of a company shall be registered when a company is dissolved and incorporation of a company shall be registered when a new company is incorporated.

**The PRC Securities Laws, Regulations**

The PRC has promulgated a number of regulations that relate to the issue and trading of the Shares and disclosure of information of companies. In October 1992, the State Council established the Securities Committee and CSRC. The Securities Committee is responsible for coordinating the drafting of securities regulations, formulating securities-related policies, planning the development of securities markets, directing, coordinating and supervising all securities-related institutions in the PRC and administering CSRC. CSRC is the regulatory arm of the Securities Committee and is responsible for the drafting of regulatory provisions


Shanghai Miracogen Inc.- Ex. 2032, Page 000754

governing securities markets, supervising securities companies, regulating public offerings of securities by PRC companies in the PRC or overseas, regulating the trading of securities, compiling securities-related statistics and undertaking relevant research and analysis. In April 1998, the State Council consolidated the Securities Committee and CSRC and reformed CSRC.

On April 22, 1993, the State Council promulgated the Provisional Regulations Concerning the Issue and Trading of Shares (《股票發行與交易管理暫行條例》) governing the application and approval procedures for public offerings of shares, issuance of and trading in shares, the acquisition of listed companies, deposit, clearing and transfer of shares, the disclosure of information, investigation, penalties and dispute resolutions with respect to a listed company.

On December 25, 1995, the State Council promulgated the Regulations of the State Council Concerning Domestic Listed Foreign Shares of Joint Stock Limited Companies (《國務院關於股份有限公司境內上市外資股的規定》). These regulations principally govern the issue, subscription, trading and declaration of dividends and other distributions of domestic listed foreign shares and disclosure of information of joint stock limited companies having domestic listed foreign shares.

The Securities Law of the PRC (《中華人民共和國證券法》, the "PRC Securities Law") took effect on July 1, 1999 and was revised as of August 28, 2004, October 27, 2005, June 29, 2013, August 31, 2014 and December 28, 2019, respectively. It was the first national securities law in the PRC, and is divided into 14 chapters and 226 articles comprehensively regulating activities in the PRC securities market, including the issue and trading of securities, takeovers by listed companies, securities exchanges, securities companies and the duties and responsibilities of the State Council's securities regulatory authorities. Article 224 of the PRC Securities Law provides that domestic enterprises which, directly or indirectly, issue securities or list and trade their securities outside the PRC shall comply with the relevant regulations of the State Council. Currently, the issue and trading of foreign issued securities (including shares) are principally governed by the regulations and rules promulgated by the State Council and CSRC.

**Arbitration and Enforcement of Arbitral Awards**

The Arbitration Law of the PRC (《中華人民共和國仲裁法) (the "Arbitration Law") was passed by the Standing Committee of the NPC on August 31, 1994, became effective on September 1, 1995 and was amended on August 27, 2009 and September 1, 2017. Under the Arbitration Law, an arbitration committee may, before the promulgation by the PRC Arbitration Association of arbitration regulations, formulate interim arbitration rules in accordance with the Arbitration Law and the Civil Procedure Law. Where the parties have by agreement provided arbitration as the method for dispute resolution, the people's court will refuse to handle the case except when the arbitration agreement is declared invalid.


Shanghai Miracogen Inc.- Ex. 2032, Page 000755

The Mandatory Provisions require an arbitration clause to be included in the articles of association of an issuer. Matters in arbitration include any disputes or claims in relation to the issuer's affairs or as a result of any rights or obligations arising under its articles of association, the PRC Company Law or other relevant laws and administrative regulations.

Where a dispute or claim of rights referred to in the preceding paragraph is referred to arbitration, the entire claim or dispute must be referred to arbitration, and all persons who have a cause of action based on the same facts giving rise to the dispute or claim or whose participation is necessary for the resolution of such dispute or claim, must comply with the arbitration. Disputes in respect of the definition of shareholder and disputes in relation to the issuer's register of shareholders need not be resolved by arbitration.

A claimant may elect for arbitration to be carried out at either the China International Economic and Trade Arbitration Commission (中國國際經濟貿易仲裁委員會) ("CIETAC") in accordance with its rules or the Hong Kong International Arbitration center ("HKIAC") in accordance with its Securities Arbitration Rules (the "Securities Arbitration Rules"). Once a claimant refers a dispute or claim to arbitration, the other party shall submit to the arbitral body elected by the claimant. If the claimant elects for arbitration to be carried out at the HKIAC, any party to the dispute or claim may apply for a hearing to take place in Shenzhen in accordance with the Securities Arbitration Rules. In accordance with the Arbitration Regulations of CIETAC (《中國國際經濟貿易仲裁委員會仲裁規則》) which was amended on November 4, 2014 and will be implemented on January 1, 2015, CIETAC shall deal with economic and trading disputes over contractual or non-contractual transactions, including disputes involving Hong Kong based on the agreement of the parties. The arbitration commission is established in Beijing and its branches and centers have been set up in Shenzhen, Shanghai, Tianjin and Chongqing.

Under the Arbitration Law and the Civil Procedure Law, an arbitral award is final and binding on the parties. If a party fails to comply with an award, the other party to the award may apply to the people's court for enforcement. A people's court may refuse to enforce an arbitral award made by an arbitration commission if there is any irregularity on the procedures or composition of arbitrators specified by law or the award exceeds the scope of the arbitration agreement or is outside the jurisdiction of the arbitration commission.

A party seeking to enforce an arbitral award of PRC arbitration panel against a party who, or whose property, is not within the PRC, may apply to a foreign court with jurisdiction over the case for enforcement. Similarly, an arbitral award made by a foreign arbitration body may be recognized and enforced by the PRC courts in accordance with the principles of reciprocity or any international treaty concluded or acceded to by the PRC. The PRC acceded to the Convention on the Recognition and Enforcement of Foreign Arbitral Awards (the "New York Convention") adopted on June 10, 1958 pursuant to a resolution of the Standing Committee of the NPC passed on December 2, 1986. The New York Convention provides that all arbitral awards made in a state which is a party to the New York Convention shall be recognized and enforced by all other parties to the New York Convention, subject to their right to refuse enforcement under certain circumstances, including where the enforcement of the arbitral award is against the public policy of the state to which the application for enforcement is made.


Shanghai Miracogen Inc.- Ex. 2032, Page 000756

It was declared by the Standing Committee of the NPC simultaneously with the accession of the PRC that (i) the PRC will only recognize and enforce foreign arbitral awards on the principle of reciprocity and (ii) the PRC will only apply the New York Convention in disputes considered under PRC laws to arise from contractual and non-contractual mercantile legal relations.

An arrangement was reached between Hong Kong and the Supreme People's Court for the mutual enforcement of arbitral awards. On June 18, 1999, the Supreme People's Court adopted the Arrangement on Mutual Enforcement of Arbitral Awards between Mainland China and Hong Kong (《關於內地與香港特別行政區相互執行仲裁裁決的安排》), which became effective on February 1, 2000 and was further supplemented on November 26, 2020. In accordance with this arrangement, awards made by PRC arbitral authorities under the Arbitration Law can be enforced in Hong Kong, and Hong Kong arbitration awards are also enforceable in the PRC.

**Judicial judgement and its enforcement**

According to the Arrangement on Mutual Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland China and of the Hong Kong Special Administrative Region Pursuant to Agreed Jurisdiction by Parties Concerned (《最高人民法院關於內地與香港特別行政區法院相互認可執行當事人協議管轄的民事案件判決的安排》) promulgated by the Supreme People's Court on July 3, 2008 and implemented on August 1, 2008, in the case of final judgment, defined with payment amount and enforcement power, made between the court of China and the court of the Hong Kong Special Administrative Region in a civil and commercial case with written jurisdiction agreement, any party concerned may apply to the People's Court of China or the court of the Hong Kong Special Administrative Region for recognition and enforcement based on this arrangement. "Choice of court agreement in written" refers to a written agreement defining the exclusive jurisdiction of either the People's Court of China or the court of the Hong Kong Special Administrative Region in order to resolve dispute with particular legal relation occurred or likely to occur by the party concerned. Therefore, the party concerned may apply to the Court of China or the court of the Hong Kong Special Administrative Region to recognize and enforce the final judgment made in China or Hong Kong that meet certain conditions of the aforementioned regulations.

## MATERIAL DIFFERENCES BETWEEN CERTAIN ASPECTS OF CORPORATION LAW IN THE PRC AND HONG KONG

Hong Kong company law is primarily set out in the Companies Ordinance and the Companies (Winding Up and Miscellaneous Provisions) Ordinance, supplemented by common law and rules of equity that apply to Hong Kong. As a joint stock limited company incorporated in the PRC that is seeking a listing of shares on the Hong Kong Stock Exchange, we are governed by the PRC Company Law and all other rules and regulations promulgated pursuant to the PRC Company Law. Set out below is a summary of certain material differences between Hong Kong company law and the PRC Company Law. This summary is, however, not intended to be an exhaustive comparison.


Shanghai Miracogen Inc.- Ex. 2032, Page 000757

**Corporate Existence**

Under Hong Kong company law, a company with share capital is incorporated by the Registrar of Companies in Hong Kong, which issues a certificate of incorporation to the Company upon its incorporation, and the company will acquire an independent corporate existence henceforth. A company may be incorporated as a public company or a private company. Pursuant to the Companies Ordinance, the articles of association of a private company incorporated in Hong Kong shall contain certain pre-emptive provisions. A public company's articles of association do not contain such pre-emptive provisions.

Under the PRC Company Law, a joint stock limited company may be incorporated by promotion or public subscription.

**Share Capital**

Under Hong Kong law, the directors of a Hong Kong company may, with the prior approval of the shareholders if required, issue new shares of the company. The PRC Company Law does not provide for authorized share capital. The Company's registered capital is the amount of its issued share capital. Any increase in the Company's registered capital must be approved by our Shareholders' general meeting and shall be approved by/filed with the relevant PRC governmental and regulatory authorities (if applicable).

Under the Securities Law, a company which is authorized by the relevant securities regulatory authority to list its shares on a stock exchange must have a total registered capital of not less than RMB30 million. The Companies Ordinance does not prescribe any minimum capital requirement for companies incorporated in Hong Kong.

Under the PRC Company Law, the shares may be subscribed for in the form of money or non-monetary assets (other than assets not entitled to be used as capital contributions under relevant laws or administrative regulations). For non-monetary assets to be used as capital contributions, appraisals must be carried out to ensure there is no overvaluation or undervaluation of the assets. There is no such restriction on a company incorporated in Hong Kong.

**Restrictions on Shareholding and Transfer of Shares**

Generally, A Shares of the Company, which are denominated and subscribed for in Renminbi, can be subscribed for and traded by PRC investors, qualified overseas institutional investors or qualified overseas strategic investors. Overseas listed shares, which are denominated in Renminbi and subscribed for in a currency other than Renminbi, may only be subscribed for, and traded by, investors from Hong Kong, Macau and Taiwan or any country and territory outside the PRC, or qualified domestic institutional investors.


Shanghai Miracogen Inc.- Ex. 2032, Page 000758

Under the PRC Company Law, a promoter of a joint stock limited company is not allowed to transfer the shares it holds for a period of one year after the date of establishment of the company. Shares in issue prior to a public offering of the company cannot be transferred within one year from the listing date of the shares on a stock exchange. Shares in a joint stock limited liability company held by its directors, supervisors and senior management and transferred each year during their term of office shall not exceed 25% of the total shares they held in a company, and the shares they held in a company cannot be transferred within one year from the listing date of the shares, and also cannot be transferred within half a year after the said personnel has left office. The articles of association may set other restrictive requirements on the transfer of a company's shares held by its directors, supervisors and senior management. There are no restrictions on shareholdings and transfers of shares under Hong Kong law apart from (i) the restriction on the Company to issue additional Shares within six months, and (ii) 12-month lockup on the Controlling Shareholders' disposal of Shares, after the Global Offering.

**Financial Assistance for Acquisition of Shares**

The PRC Company Law does not prohibit or restrict a joint stock limited company or its subsidiaries from providing financial assistance for the purpose of an acquisition of its own or its holding company's shares. However, the Mandatory Provisions contain certain restrictions on a company and its subsidiaries on providing such financial assistance similar to those under Hong Kong company law.

**Notice of Shareholders' Meetings**

Under the PRC Company Law, notice of a shareholder's annual general meeting must be given not less than 20 days before the meeting. Whereas notice of an extraordinary general meeting must be given not less than 15 days before the meeting. If a company issues bearer shares, notice of a shareholder's general meeting must be given at least 30 days prior to the meeting.

For a company incorporated in Hong Kong with limited liability, the minimum period of notice of a general meeting is 14 days. Further, where a meeting involves consideration of a resolution requiring special notice, the company must also give its shareholders notice of the resolution at least 14 days before the meeting. The notice period for the annual shareholders' general meeting is 21 days.

**Quorum for Shareholders' Meetings**

The PRC Company Law does not specify any quorum requirement for a shareholders' general meeting. Under Hong Kong law, the quorum for a shareholders' meeting is two members, unless the articles of association of a company specifies otherwise or the company has only one member, in which case the quorum is one.


Shanghai Miracogen Inc.- Ex. 2032, Page 000759

**Voting at Shareholders' Meetings**

Under the PRC Company Law, the passing of any resolution requires more than one-half of the affirmative votes held by our shareholders present in person or by proxy at a shareholders' meeting except in cases such as proposed amendments to our Articles of Association, increase or decrease of registered capital, merger, division, dissolution or transformation, which require two-thirds of the affirmative votes cast by shareholders present in person or by proxy at a shareholders' general meeting.

Under Hong Kong law, an ordinary resolution is passed by a simple majority of affirmative votes cast by shareholders present in person, or by proxy, at a general meeting, and a special resolution is passed by not less than three-fourths of affirmative votes casted by shareholders present in person, or by proxy, at a general meeting.

**Variation of Class Rights**

The PRC Company Law makes no specific provision relating to variation of class rights. However, the PRC Company Law states that the State Council can promulgate requirements relating to other kinds of shares. The Mandatory Provisions contain detailed provisions relating to the circumstances which are deemed to be variations of class rights and the approval procedures required to be followed in respect thereof. These provisions have been incorporated in the Articles of Association, which are summarized in "Appendix VII – Summary of the Articles of Association" to this prospectus.

Under the Companies Ordinance, no rights attached to any class of shares can be varied except (i) with the passing of a special resolution by the shareholders of the relevant class at a separate meeting sanctioning the variation, (ii) with the written consent of shareholders representing at least three-fourths of the total voting rights of shareholders of the relevant class, or (iii) if there are provisions in the articles of association relating to the variation of those rights, then in accordance with those provisions.

As required by the Listing Rules and the Mandatory Provisions, we have adopted in the Articles of Association provisions protecting class rights in a similar manner to those found in Hong Kong law. Holders of overseas listed shares and domestic listed shares are defined in the Articles of Association as different classes. The special procedures for voting by a class of Shareholders shall not apply in the following circumstances: (i) where we issue, either separately or concurrently in any 12-month period, upon approval by special resolutions passed at a general meeting, A shares and H shares not more than 20% of each of the existing issued A shares and H shares, respectively; (ii) where the plan for the issue of A shares and H shares upon our establishment is implemented within 15 months following the date of approval or within the valid period of the approval by the securities regulatory authorities under the State Council or within the stated period as stipulated by applicable requirements.


Shanghai Miracogen Inc.- Ex. 2032, Page 000760

**Derivative Action by Minority Shareholders**

Under Hong Kong company law, a shareholder may, with the leave of the Court, start a derivative action on behalf of a company for any misconduct committed by its directors against the company. For example, leave may be granted where the directors control a majority of votes at a general meeting, and could thereby prevent the company from suing the directors in its own name.

Pursuant to the PRC Company Law, in the event where the directors and senior management of a joint stock limited company violate laws, administrative regulations or its articles of association, resulting in losses to the company, the shareholders individually or jointly holding over 1% of the shares in the company for more than 180 consecutive days may request in writing the board of supervisors to initiate proceedings in the people's court. In the event that the supervisors violates as such, the above said shareholders may send written request to the board of directors to initiate proceedings in the people's court. Upon receipt of such written request from the shareholders, if the board of supervisors or the board of directors refuses to initiate such proceedings, or has not initiated proceedings within 30 days upon receipt of the request, or if under urgent situations, failure of initiating immediate proceeding may cause irremediable damages to the company, the above said shareholders shall, for the benefit of the company's interests, have the right to initiate proceedings directly to the court in their own name.

In addition, the Mandatory Provisions provide us with certain remedies against the Directors, Supervisors and senior management who breach their duties to the Company. In addition, as a condition to the listing of overseas listed foreign Shares on the Hong Kong Stock Exchange, each director and supervisor of a joint stock limited company is required to give an undertaking to observe the articles of association in favor of the company. This allows minority Shareholders to take action against our Directors and Supervisors in default.

**Minority Shareholder Protection**

Under the Companies Ordinance, a shareholder who alleges that the affairs of a company are conducted in a manner unfairly prejudicial to his interests may petition to the Court to make an appropriate order to give relief to the unfairly prejudicial conduct. Alternatively, pursuant to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, a shareholder may seek to wind up the company on the just and equitable ground. In addition, on the application of a specified number of members, the Financial Secretary may appoint inspectors who are given extensive statutory powers to investigate the affairs of a company incorporated or registered in Hong Kong. The PRC Company Law provides that any shareholders holding 10% or above of voting rights of all issued shares of company may request a People's Court to dissolve the company to the extent that the operation or management of the company experiences any serious difficulties and its continuous existence would cause serious losses to them, and no other alternatives can resolve such difficulties.


Shanghai Miracogen Inc.- Ex. 2032, Page 000761

The Company, as required by the Mandatory Provisions, has adopted in its Articles of Association minority Shareholder protection provisions similar to (though not as comprehensive as) those available under the Hong Kong law. These provisions state that a controlling shareholder may not exercise its voting rights in a manner prejudicial to the interests of other shareholders, may not relieve a director or supervisor of his duty to act honestly in our best interests or may not approve the expropriation by a director or supervisor of our assets or the individual rights of other shareholders.

**Directors**

The PRC Company Law, unlike Hong Kong company law, does not contain any requirements relating to the declaration of directors' interests in material contracts, restrictions on directors' authority in making major dispositions, restrictions on companies providing certain benefits to directors and indemnification in respect of directors' liability and prohibitions against compensation for loss of office without shareholders' approval. The Mandatory Provisions, however, contain certain requirements and restrictions on major disposals and specify the circumstances under which a director may receive compensation for loss of office.

**Board of Supervisors**

Under the PRC Company Law, a joint stock limited company's directors and senior management are subject to the supervision of a board of supervisors. There is no mandatory requirement for the establishment of a board of supervisors for a company incorporated in Hong Kong. The Mandatory Provisions provide that each supervisor owes a duty, in the exercise of his powers, to act in good faith and honestly in what he considers to be in the best interests of the Company and to exercise the care, diligence and skill that a reasonably prudent person would exercise in comparable circumstances.

**Fiduciary Duties**

In Hong Kong, directors owe fiduciary duties to the company, including the duty not to act in conflict with the company's interests. Furthermore, the Companies Ordinance has codified the directors' statutory duty of care. Under the Special Regulations, directors, supervisors, managers and other members of senior management of the company shall honestly and diligently perform their duties for the company.

**Financial Disclosure**

Under the PRC Company Law, a joint stock limited company is required to make available at the company for inspection by shareholders its financial report 20 days before its annual general meeting. In addition, a joint stock limited company of which the shares are publicly offered must publish its financial report.


Shanghai Miracogen Inc.- Ex. 2032, Page 000762

The Companies Ordinance requires a company incorporated in Hong Kong to send to every shareholder a copy of its financial statements, auditors' report and directors' report, which are to be presented before the company in its annual general meeting, not less than 21 days before such meeting. According to the PRC laws, a company shall prepare its financial accounting reports as at the end of each accounting year, and submit the same to accounting firms for auditing as required by law. The Mandatory Provisions require that a company must, in addition to preparing financial statements according to the Chinese accounting standards and regulations, have its financial statements prepared and audited in accordance with international or Hong Kong accounting standards and its financial statements must also contain a statement of the financial effect of the material differences (if any) from the financial statements prepared in accordance with the Chinese accounting standards.

The Special Regulations require that there should not be any inconsistency between the information disclosed within and outside the PRC and that, to the extent that there are differences in the information disclosed in accordance with the relevant PRC and overseas laws, regulations and requirements of the relevant stock exchanges, such differences should also be disclosed simultaneously.

**Information on Directors and Shareholders**

The PRC Company Law gives shareholders the right to inspect the company's articles of association, minutes of the general meetings and financial and accounting reports. Under the articles of association, shareholders have the right to inspect and copy (at reasonable charges) certain information on shareholders and on directors which is similar to the rights of shareholders of Hong Kong companies under the Companies Ordinance.

**Receiving Agent**

Under both the PRC and Hong Kong law, dividends once declared will become debts payable to shareholders. The limitation period for debt recovery action under Hong Kong law is six years, while under the PRC law this limitation period is two years. The Mandatory Provisions require that the relevant company shall appoint a receiving agent for shareholders who hold overseas listed foreign shares, and the receiving agent shall receive on behalf of such holders of shares dividends declared and other monies owed by the company in respect of its overseas listed foreign shares.


Shanghai Miracogen Inc.- Ex. 2032, Page 000763

**Corporate Reorganization**

Corporate reorganization involving a company incorporated in Hong Kong may be effected in a number of ways, such as a transfer of the whole or part of the business or property of the company in the course of voluntary winding up to another company pursuant to Section 237 of the Companies (Winding Up and Miscellaneous Provisions) Ordinance or a compromise or arrangement between the company and its creditors or between the company and its members pursuant to Section 673 and Division 2 of Part 13 of the Companies Ordinance, which requires the sanction of the court. In addition, subject to the shareholders' approval, an intra-group wholly-owned subsidiary company may also be amalgamated horizontally or vertically under the Companies Ordinance. Under PRC law, merger, division, dissolution of the company or the conversion of the corporate form has to be approved by shareholders in general meeting.

**Mandatory Transfers**

Under the PRC Company Law, a company is required to make transfers equivalent to certain prescribed percentages of its after tax profit to the statutory common reserve fund. There are no corresponding provisions under Hong Kong law.

**Arbitration of Disputes**

In Hong Kong, disputes between shareholders and a company or its directors, managers and other senior management may be resolved through the courts. The Mandatory Provisions provides that disputes between a holder of H shares and the Company, a holder of H shares and directors, supervisors, managers and other members of senior management of the Company or a holder of H shares and a holder of domestic listed shares, arising from the Articles of Association, the PRC Company Law or other relevant laws and administrative regulations which concerns the affairs of the Company should, with certain exceptions, be referred to arbitration at either the HKIAC or the China International Economic and Trade Arbitration Commission, at the claimant's choice. Such arbitration is final and conclusive.

The Securities Arbitration Rules of the HKIAC contain provisions allowing, upon application by any party, an arbitral tribunal to conduct a hearing in Shenzhen for cases involving the affairs of companies incorporated in the PRC and listed on the Stock Exchange so that PRC parties and witnesses may attend. Where any party applies for a hearing to take place in Shenzhen, the tribunal shall, where satisfied that such application is based on bona fide grounds, order the hearing to take place in Shenzhen conditional upon all parties, including witnesses and arbitrators, being permitted to enter Shenzhen for the purpose of the hearing. Where a party, other than a PRC party or any of its witnesses or any arbitrator, is not permitted to enter Shenzhen, then the tribunal shall order that the hearing be conducted in any practicable manner, including the use of electronic media. For the purpose of the Securities Arbitration Rules of the HKIAC, a PRC party means a party domiciled in the PRC other than the territories of Hong Kong, Macau and Taiwan.


Shanghai Miracogen Inc.- Ex. 2032, Page 000764

**Remedies of a Company**

Under the PRC Company Law, if a director, supervisor or senior management person in carrying out his duties infringes any law, administrative regulation or the articles of association of a company, which results in damage to the company, that director, supervisor or manager should be responsible to the company for such damages. In addition, in compliance with the Listing Rules and the Mandatory Provisions, remedies of the company similar to those available under Hong Kong law (including rescission of the relevant contract and recovery of profits from a director, supervisor or senior management) have been set out in the Articles of Association.

**Dividends**

Pursuant to relevant PRC laws and regulations, the company in certain circumstances shall withhold, and pay to the relevant tax authorities, any tax payable under PRC law on any dividends or other distributions payable to a shareholder. Under Hong Kong law, the limitation period for an action to recover a debt (including the recovery of declared dividends) is six years, whereas under PRC laws, the relevant limitation period is two years. The company must not exercise its powers to forfeit any unclaimed dividend in respect of shares until after the expiry of the applicable limitation period.

**Closure of Register of Shareholders**

The Companies Ordinance requires that the register of shareholders of a company must not be closed for the registration of transfers of shares for more than thirty days (extendable to sixty days in certain circumstances) in a year, whereas, as required by the Mandatory Provisions, share transfers shall not be registered within thirty days before the date of convening a general meeting or within five days before the base date of distribution of dividends.



Shanghai Miracogen Inc.- Ex. 2032, Page 000765

This appendix contains the summary of the principal provisions of the Articles of Association adopted by our Company on April 18, 2021 and shall take effect on the date of the H-Shares being listed on the Hong Kong Stock Exchange. The main purpose of this appendix is to provide an overview of the Company's Articles of Association for potential investors, so it may not contain all the information that is important to potential investors.

## I. SHARES AND REGISTERED CAPITAL

The Company shall issue ordinary shares at all times. With the approval from authorities authorized by the State Council, the Company may issue other classes of shares when needed.

All the shares issued by the Company shall have a nominal value, each share having a nominal value of RMB1.00.

The Company shall issue shares in an open, fair and just manner, and each share of the same class shall have equal rights.

All shares of the same class issued at the same time shall be issued under the same conditions and at the same price; the same price shall be paid for each share subscribed by any entities or individuals.

The domestic shares/domestic unlisted shares and overseas listed shares issued by the company enjoy the same rights to distribution of dividends and distribution in any other form. The Company shall not exercise any rights to freeze or otherwise prejudice any rights attached to the shares held by any person who directly or indirectly has interest in the Company solely for the reason that such person fails to disclose to the Company any such interests.

## II. SHARES AND REGISTERED CAPITAL

### Increase of Capital

The Company may, based on its business and development needs and in accordance with the requirements of laws, regulations and Articles of Association, increase its registered capital in the following manners:

(1) by issuing new shares to public;

(2) by issuing new shares to private;

(3) by placing new shares to its existing Shareholders;

(4) by distributing new shares to its existing Shareholders;

(5) by capitalizing its capital reserves;

(6) by other ways permitted by the laws, administrative regulations and pertinent regulatory authorities.



Shanghai Miracogen Inc.- Ex. 2032, Page 000766

The Company's increase of capital by issuing new shares shall, after being approved in accordance with the provisions of the Articles of Association, be conducted in accordance with the procedures stipulated in the relevant laws and administrative regulations and the stock listing rules of the stock exchange in which Company's shares are listed.

**Decrease of Capital**

Our Company may reduce our registered capital according to the Articles of Association and shall be conducted by accordance with the procedures stipulated in the PRC Company Law, other relevant regulations and the Articles of Association.

In the event of reduction of registered capital, the Company shall prepare a balance sheet and a list of assets.

The company shall notify its creditors within ten days from the date of resolution on reduction in registered capital and publish an announcement on the newspapers within 30 days. The creditors may demand, within 30 days from receipt of the notice (or within 45 days for those creditors who did not receive the notice), that the company settles the debts or provide the corresponding guarantee.

**Repurchase of Shares**

The Company may, according to the requirements of the laws, administrative regulations, departmental rules and, stock listing rules of the stock exchange in which Company's shares are listed and the Articles of Association, repurchase its shares under the following circumstances:

(1) cancelling shares for reducing the Company's registered capital;

(2) merging with other companies which hold shares in the Company;

(3) awarding shares for employee stock ownership plan or share incentive plan;

(4) acquiring shares held by Shareholders, who vote against any resolution proposed in any general meeting on the merger or division of the Company, upon their request;

(5) other circumstances as permitted by laws, administrative regulations and regulatory authorities.

After repurchasing the shares issued by itself in accordance with the laws, the company shall cancel repurchased shares and file an application with the competent authority for the change of the registered capital.

The amount of our registered share capital shall be reduced by the aggregate nominal value of those cancelled shares.



Shanghai Miracogen Inc.- Ex. 2032, Page 000767

Unless the Company is under liquidation, it shall comply with the following provisions regarding the repurchase of its outstanding shares:

(1) where the Company repurchases its shares at nominal value, the amount thereof shall be deducted from the book balance of the distributable profits of the Company and from the proceeds of the new issue of shares made for the repurchase of shares;

(2) where the Company repurchases its shares at a price higher than nominal value, the portion corresponding to the nominal value shall be deducted from the book balance of the distributable profits of the Company and from the proceeds of the new issue of shares made for the repurchase of shares. The portion in excess of the nominal value shall be handled as follows:

    1. if the shares repurchased were issued at nominal value, payment shall be deducted from the book balance of the distributable profits of the Company;

    2. if the shares repurchased were issued at a price higher than their nominal value, payment shall be deducted from the book balance of the distributable profits of the Company and from the proceeds of a new issue of shares made for the repurchase of shares, provided that the amount deducted from the proceeds of the new issue of shares shall not be more than the aggregate of premiums received by the Company at the time of the issue of the shares repurchased nor shall it be more than the amount of the Company's share premium account or capital common reserve account (including the premiums on the new issue of shares) at the time of such repurchase;

(3) payment by the Company for the following purposes shall be paid out of the Company's distributable profits:

    1. acquisition of rights to repurchase shares of the Company;

    2. modification of any agreement for repurchasing shares of the Company;

    3. release the Company's obligations under any agreement for repurchasing its shares.

(4) after the aggregate nominal value of the cancelled shares has been deducted from the registered capital of the Company in accordance with the relevant requirements, the amount deducted from the distributable profits for payment for repurchasing shares at their nominal value shall be accounted for in the Company's share premium account or capital common reserve account.


Shanghai Miracogen Inc.- Ex. 2032, Page 000768

## III. TRANSFER OF SHARES

The shares of the Company held by the promoters shall not be transferred within one year after the incorporation of the Company.

The directors, supervisors and senior management of the Company shall report to the Company their shareholdings and changes thereof and shall not transfer more than 25 percent of the total number of their shares in the Company per annum during their terms of office. The aforesaid persons shall not transfer their shares in the Company within half a year after they terminate service with the Company.

## IV. FINANCIAL ASSISTANCE FOR PURCHASE OF THE COMPANY'S OR ANY OF ITS SUBSIDIARIES' SHARES

According to the requirements of Articles of Association, the Company or any of its Subsidiaries shall not, by any means and at any time, provide any financial assistance to purchasers or potential purchasers of the Company's shares. The aforesaid purchasers of the Company's shares include persons directly or indirectly undertaking obligations due to purchase of the Company's shares.

The Company or its subsidiaries shall not, by any means and at any time, provide any financial assistance to the aforesaid obligors for the purpose of reducing or discharging their obligations.

In respect of the foresaid rules, "Financial assistance" includes (but not limited to) the following ways:

(1) gift;

(2) guarantee (including the undertaking of liability or provisions of property by the guarantor in order to guarantee the performance of the obligation by the obligor), indemnity (excluding, however, indemnity arising from the Company's own fault) and termination or waiver of rights;

(3) providing of a loan or signing of a contract under which the obligations of the Company are to be fulfilled prior to the fulfillment of the obligations of the other party to the contract, and a change in the party to such loan or agreement as well as the assignment of rights under such loan or contract;

(4) financial assistance provided in any other form when the Company is insolvent or has no net assets or when such assistance would lead to a significant reduction in the Company's net assets.



Shanghai Miracogen Inc.- Ex. 2032, Page 000769

The term "undertake obligations" shall include the undertaking of an obligation by the obligor by entering into a contract or making an arrangement (whether or not such contract or arrangement is enforceable and whether or not such obligation is assumed by the obligor individually or jointly with any other person), or by changing its financial position in any other way.

The following acts shall not be prohibited:

(1) the Company provides the relevant financial assistance in the interests of the Company in good faith, and the primary purpose of the said financial assistance is not to purchase the Company's shares, or the said financial assistance is part of a master plan of the Company;

(2) the Company distributes its assets as dividends in accordance with the laws;

(3) the Company distributes dividends in the form of shares;

(4) the Company reduces its registered capital, repurchases its shares and adjusts the equity structure in accordance with the Articles of Association;

(5) the Company provides a loan for its normal business operations within its business scope (provided that such financial assistance shall not result in a reduction in the net assets of the Company, or in the event of such reduction, such financial assistance is provided out of the distributable profits of the Company);

(6) the Company provides the funding for employee stock ownership plan (provided that such financial assistance shall not result in a reduction in the net assets of the Company, or in the event of such reduction, such financial assistance is provided out of the distributable profits of the Company).

## V. SHARE CERTIFICATES AND REGISTER OF SHAREHOLDERS

### (1) Share Certificates

The share certificates of the Company shall be in registered form.

Matters needed to be specified in Company shares shall pursuant to the PRC Company Law and to the rules of the stock exchange in which Company's shares are listed.

The share certificates shall be signed by the Chairman of the Board. Where the signatures of other senior management of the Company are required by the stock exchange where the Company's shares are listed, the share certificates shall also be signed by such other senior management. The share certificates shall become valid after the Company seal is affixed


Shanghai Miracogen Inc.- Ex. 2032, Page 000770

thereto or imprinted thereon. The affixing or imprinting of the Company seal to the share certificates shall be authorized by the Board. The signature of the Chairman of the Board or such other senior management of the Company on the share certificates may also be in printed form.

In case of paperless issuance and trading of the shares of the Company, provisions otherwise provided by the securities regulatory authorities, the stock exchange in the place where the Company's shares are listed shall apply.

**(2) Register of Shareholders**

The Company shall establish a register of shareholders and shall register therein the following particulars:

(1) the name (title), address (domicile), occupation or nature of each Shareholder;

(2) the class and number of shares held by each Shareholder;

(3) the amount paid or payable for the shares held by each Shareholder;

(4) the serial number of the share certificate held by each Shareholder;

(5) the date on which each shareholder is registered as a Shareholder;

(6) the date on which each shareholder ceases to be a Shareholder.

The shareholders' register is a sufficient evidence of the Shareholders' shareholdings in the Company unless there is evidence to the contrary.

The Company may keep overseas the register of shareholders of overseas listed shares and entrust the administration thereof to an overseas agent in accordance with the understanding and agreement reached between the Securities Regulatory Authorities of the State Council and the overseas Securities Regulatory Authorities. The original register of holders of overseas listed shares listed on the Hong Kong Stock Exchange shall be kept in Hong Kong.

The Company shall keep at its domicile a copy of the register of shareholders of overseas listed shares. The entrusted overseas agent shall always ensure that the original and copies of the register of holders of overseas listed shares are consistent.

Where the original and copies of the register of shareholders of overseas listed shares are inconsistent, the original shall prevail.


Shanghai Miracogen Inc.- Ex. 2032, Page 000771

The Company shall keep a complete shareholders' register, which shall include the following parts:

(1) the register(s) of shareholders kept at the Company's domicile other than those specified in items (2) and (3);

(2) the register(s) of shareholders of overseas listed shares kept in the place(s) of the overseas stock exchange(s) where the shares are listed;

(3) the register(s) of shareholders kept in other places as the Board may decide and consider necessary for listing purposes.

The various parts of the register of shareholders shall not overlap with each another. The transfer of shares registered in a certain part of the register of shareholders shall not, during the continuance of the registration of such shares, be registered in any other part of the register of shareholders.

Changes and corrections to each part of the register of shareholders shall be carried out in accordance with the laws of the places where each part is kept.

When the Company convenes a general meeting, distributes dividends, commences liquidation or participates in other activities requiring the recognition of shareholdings; the Board shall designate a certain date as the record date, at the end of which the shareholders in the register shall be shareholders of the Company.

If any person objects to the register of shareholders and requests to have his/her name (title) recorded in or deleted from the register of shareholders, the said person may apply to the court with jurisdiction to correct the register of shareholders.

If any Shareholder in the register of shareholders or any person requesting to have his/her name (title) recorded in the register of shareholders loses his/her original share certificates, the said Shareholder or person may apply to the Company to issue replacement certificates in respect of the said shares.

The Company shall not be liable for any damages suffered by any person arising from the cancellation of the original share certificates or the issuance of a new replacement share certificate, unless the claimant can prove that the Company has committed a fraudulent act.

## VI. RIGHTS AND OBLIGATIONS OF SHAREHOLDERS

### (1) Shareholders

A Shareholder is a person who lawfully holds shares of the Company and has his/her name (title) recorded in the register of shareholders.



Shanghai Miracogen Inc.- Ex. 2032, Page 000772

**(2) Rights and Obligations of Shareholders**

A Shareholder shall enjoy the relevant rights and assume the relevant obligations in accordance with the class and amount of shares he/she holds. Shareholders holding the same class of shares shall enjoy the same rights and assume the same obligations.

Shareholders of all classes of the Company have equal rights in any distribution made by dividends or other forms.

If the Shareholder is a legal entity, the rights shall be enforced by its legal representative or a proxy of such legal representative (if the Shareholder is a recognized clearing house as defined in the relevant Ordinance as amended from time to time in accordance with the laws of Hong Kong or its agent) or the representative or consignor of the recognized clearing house (or its agent).

The ordinary Shareholders shall enjoy the following rights:

(1) the right to receive dividends and other profit distributions in proportion to their shareholdings;

(2) the right to request, convene, preside, attend or appoint proxies to attend general meetings lawfully and to exercise the voting rights in proportion to their shareholdings;

(3) the right to supervise and manage the Company's business activities, to present proposals or to raise enquires;

(4) the right to transfer, gift or pledge shares in accordance with laws, administrative regulations and provisions of the Articles of Association;

(5) the right to obtain relevant information in accordance with the provisions of the Articles of Association, including:

    1. the right to obtain a copy of the Articles of Association, subject to payment of reasonable cost;

    2. the right to inspect and copy, subject to payment of a reasonable charge:

        i. the copies of register of all the Shareholders;

        ii. personal particulars of each of the Company's Directors, Supervisors, CEO and other senior management members, including:

            (a) present and former name and alias;

            (b) principal address (domicile);



Shanghai Miracogen Inc.- Ex. 2032, Page 000773

(c) nationality;

(d) primary and all other part-time occupations and duties;

(e) identification documents and the numbers thereof.

iii. reports showing the status of the Company's share capital;

iv. special resolutions of the general meeting of shareholders of the Company;

v. reports showing the aggregate nominal value, quantity, maximum and minimum prices paid in respect of each class of shares repurchased by the Company since the end of the last financial year and the aggregate amount incurred by the Company for this purpose;

vi. minutes of general meetings;

vii. the latest audited financial and accounting report;

viii. a copy of the latest annual return that has been filed with the Administration for Industry and Commerce or other competent authorities.

(6) in the event of the termination or liquidation of the Company, to participate in the distribution of remaining assets of the Company in accordance with the shareholdings;

(7) the right to request the Company to purchase the shares held by shareholders who vote against the Company's merger or division resolution adopted by the shareholders' meeting;

(8) other rights under laws, administrative regulations, departmental rules or the Articles of Association.

The ordinary Shareholders of the Company shall have the following obligations:

(1) to abide by laws, administrative regulations and the Articles of Association;

(2) to pay capital contribution for the shares subscribed for in the prescribed method of subscription;

(3) to fulfill other obligations as stipulated by laws, administrative regulations and the Articles of Association.

Shareholders shall not be liable for further contribution to share capital other than the conditions agreed to as a subscriber of the shares at the time of subscription.



Shanghai Miracogen Inc.- Ex. 2032, Page 000774

## VII. RESTRICTIONS ON THE CONTROLLING SHAREHOLDERS' RIGHTS

Except for the obligations required by the laws, administrative regulations or the listing rules of the stock exchanges in which the Company's shares are listed, the Controlling Shareholder shall not exercise its voting rights on the following issues to the detriment of all or part of the Shareholders:

(1) Exempting Directors and Supervisors from acting in good faith with the best interests of the Company;

(2) Approving Directors and Supervisors (for the benefit of themselves or others) to deprive the Company's property in any form, including (but not limited to) any opportunity that is beneficial to the Company;

(3) Approving Directors and Supervisors (for the benefit of themselves or others) to deprive other Shareholders' own rights, including (but not limited to) any distribution rights and voting rights, but does not include the reorganization of the Company approved by the shareholders' general meeting in accordance with the Company's Articles of Association.

## VIII. SHAREHOLDERS' GENERAL MEETING

### (1) General rules for the Shareholders' General Meeting

The general meeting is the authority of power of the Company, and shall exercise the following duties and powers in accordance with the law:

(1) to decide the Company's operational policies and investment plans;

(2) to elect and change the Directors and Supervisors who are not representatives of the employees and decide on the remunerations of Directors and Supervisors;

(3) to examine and approve reports of the Board of Directors;

(4) to examine and approve reports of the Supervisory Committee;

(5) to examine and approve the proposed annual financial budgets, final accounts of the Company;

(6) to examine and approve the profit distribution plans and loss recovery plans of the Company;

(7) to make resolutions on the increase or reduction of the registered capital of the Company and the issuance of any kinds of stocks, warrants and other similar securities;



Shanghai Miracogen Inc.- Ex. 2032, Page 000775

(8) to make resolutions on the issuance of corporate bonds;

(9) to make resolutions on the merger, division, dissolution, liquidation or change in the form of the Company;

(10) to amend the Articles of Association;

(11) to examine and approve the purchase or sale of major assets or the investment of more than 30% of the Company's total audited assets in the latest period within one year;

(12) to examine and approve the guarantee matters and transaction matters prescribed in Article 67 and Article 68 of the Articles of Association;

(13) to make resolutions on the engagement, renewal, or discontinuance of engagement of accounting firms by the Company;

(14) to examine and approve changes in the purposes of the raised funds;

(15) to examine and approve equity incentive plans;

(16) in addition to the guarantee provided by the Company, the Company's affiliated transactions with more than 30 million RMB and accounting for more than 1% of the Company's total audited assets or market value in the latest period;

(17) other matters required by laws, administrative regulations, the listing rules of the place where the Company's shares are listed and the Articles of Association.

The Company shall not enter into contracts with a party (other than a Director, Supervisor, the CEO and other senior management members) in relation to handover of the administration of all business or the important business of the Company to that party without the pre-approval of the general meeting.

The general meetings consist of annual general meetings and extraordinary general meetings. The general meetings shall be convened by the Board of Directors. The annual general meeting shall hold once every year within six months from the end of the previous accounting year.

The extraordinary general meeting shall be convened as and when necessary. In the occurrence of any of the following events, the Board of Directors shall convene an extraordinary general meeting within two months:

(1) when the number of directors is less than the number stipulated in the PRC Company Law or two-thirds of the number specified in the Articles of Association;



Shanghai Miracogen Inc.- Ex. 2032, Page 000776

(2) when the unrecovered losses of the Company amount to one-third of the total amount of its paid-up share capital;

(3) when Shareholder(s) individually or jointly holding 10 percent or more of the Company's issued shares request(s) in writing to convene an extraordinary general meeting;

(4) when deemed necessary by the Board or when proposed by the Supervisory Committee;

(5) when proposed by two or more independent non-executive directors;

(6) any other circumstances stipulated by laws, administrative regulations, departmental regulations, the listing rules of the stock exchange where the Company's shares are listed or the Articles of Association.

The number of shares held referred to in item (3) of this Article shall be calculated on the date when the shareholders put forward a written request.

**(2) Proposals of the Shareholders' General Meeting**

When a general meeting is convened by the Company, Shareholders who individually or jointly hold three percent or more of the shares of the Company carrying voting right, shall be entitled to make proposals in writing to the Company and the convener ten days before the convening of the general meeting. The content of the proposal shall fall within the scope of duties and powers of the general meeting of shareholders, with clear issues and specific resolutions, and comply with the relevant provisions of laws and regulations and the Company's Articles of Association. The Company shall make the matters within the scope of duties and powers of the general meeting listed in the agenda of this meeting and submit the matters to the general meeting for consideration.

Except as stipulated in the above paragraph, the convener, after issuing the notice of the general meeting, shall neither modify the proposals stated in the notice of general meetings nor add new proposals.

The proposals which do not set out in the notice of shareholders' general meeting or do not comply with the provisions of the Articles of Association, any Shareholder shall neither vote at the general meeting nor make resolution.


Shanghai Miracogen Inc.- Ex. 2032, Page 000777

**(3) Notices of the Shareholders' General Meeting**

In order to hold a shareholders' general meeting, notice in writing shall be given to all Shareholders registered 20 days in advance and 15 days in advance in case of extraordinary Shareholders' general meetings, the matters to be discussed and the venue, date of the meeting shall be included in that notice. For the notice given in these rules, the date of issue is the date on which the Company or the Company's share registration office has served the notice to the postal service.

The notice of the shareholders' general meeting issued to the Shareholders of overseas listed shares may be published on the designated website of the stock exchange where the Company's shares are listed and the website of the Company. Once announced, all overseas listed Shareholders shall be deemed to have received the relevant notice of the general meeting.

Except as stipulated in the Articles of Association, the notice of the general meeting shall be served on the Shareholders (whether or not such Shareholder is entitled to vote at the general meeting) by hand or postage prepaid mail. The address of the recipient shall be the registered address as shown in the register of shareholders. For holders of domestic shares/domestic unlisted shares, the notice of the general meeting may also be given by way of announcement. The announcement referred above shall be published in one or more newspapers designated by the Securities Regulatory Authorities of the State Council 20 days prior to the convening of the Shareholders' annual general meetings, 15 days prior to the convening of extraordinary Shareholders' general meetings. Once such an announcement is made, all holders of the domestic shares/domestic unlisted shares shall be deemed to have received the relevant notice of the general meeting. Notice of a general meeting shall satisfy the following requirements:

(1) be in writing;

(2) specific venue, date and time of the meeting;

(3) matters to be considered at the meeting;

(4) any information and explanations necessary to be made available to the Shareholders for such Shareholders to make sound decisions about the matters to be discussed. This principle includes (but not limited to) the provision of the specific terms and contract(s), if any, of the proposed transaction(s) and serious explanations about the reasons and effects when the Company proposes mergers, repurchase of shares, equity restructuring or other restructuring;

(5) in the event that any of the Directors, Supervisors, CEO and other senior management has material interests in matters to be discussed, the nature and extent of the interests shall be disclosed. If the matters to be discussed affect any Director, Supervisor, CEO and other senior management as a Shareholder in a manner different from the manner they affect other Shareholders of the same class, the difference shall be explained;



Shanghai Miracogen Inc.- Ex. 2032, Page 000778

(6) the full text of any special resolution to be proposed for approval at the meeting;

(7) a prominent statement that all Shareholders are eligible for attending the general meeting and are entitled to appoint one or more proxies to attend and vote at such meeting on his/her behalf, and that such proxy does not need to be a Shareholders of the Company;

(8) the time and venue for lodging a proxy form for the meeting.

**(4) Convening of Shareholders' General Meeting**

Any Shareholder entitled to attend and vote at the general meeting shall have the right to appoint one or several persons (who may not be Shareholders) to act as his or her proxy to attend and vote at the meeting on his or her behalf. The proxy(ies) so appointed by the Shareholder(s) may, pursuant to the instructions of the Shareholder(s), exercise the following rights:

(1) the Shareholders' right to speak at the general meeting;

(2) the right to demand a poll by himself/herself or jointly with others;

(3) the right to exercise voting rights by a show of hands or by a poll, provided that where more than one proxy is appointed, the proxies may only exercise such voting rights by a poll.

The appointment of a proxy shall be in writing and signed by the appointing Shareholder or his/her attorney duly authorized in writing; where the appointing Shareholder is a legal person, such appointment shall be affixed with its seal or signed by its Director or attorney duly authorized.

The proxy statement shall be placed in the Company's domicile or in other places designated by the meeting notice at least 24 hours prior to the relevant meeting in which the power of vote is entrusted, or 24 hours prior to the designated voting time.

The general meeting shall be convened by the Chairman of the Board, who shall also act as the chairman of the meeting. If the Chairman is unable to perform his/her duties, a director appointed by more than half of the board of directors shall perform the duties. In the event that no chairman is appointed, the attending Shareholders shall elect one person to act as the chairman of the meeting; if, for any reason, the Shareholders fail to elect a chairman of the general meeting, the Shareholder (including his/her proxy) holding the largest number of voting shares among the attending Shareholders shall be the chairman of the general meeting.


Shanghai Miracogen Inc.- Ex. 2032, Page 000779

**(5) Resolutions of Shareholders' General Meetings**

Resolutions of the general meeting include ordinary resolutions and special resolutions.

Ordinary resolution at a general meeting shall be adopted by more than one half of the voting rights held by Shareholders (including their proxies) attending the general meeting.

Special resolution at a general meeting shall be adopted by two-thirds or more of the voting rights held by Shareholders (including their proxies) attending the general meeting.

Shareholders (including their proxies) who vote at a general meeting shall exercise their voting rights according to the number of voting shares they represent, with one vote for each share. However, shares in the Company which are held by the Company do not carry any voting rights and shall not be counted in the total number of voting shares represented by Shareholders present at a general meeting.

Voting at general meetings shall be conducted by a show of hands, only when the chairman of the meeting make the decision on the principle of good faith, and on purely procedural or administrative matters. Other matters shall be voted by way of polls.

When voting by a show of hands, the chairman of the meeting shall announce the result of voting by a show of hands on proposals, and shall record the result in the minutes as final evidence, without specifying the number or percentage of in favor of or against the resolutions approved at the meeting.

The demand for a poll can be withdrawn by the proposer.

If the matter required to be voted by way of a poll relates to election of chairman or adjournment of meeting, a poll shall be conducted immediately; in respect of other matters required to be voted by way of a poll, the chairman may decide the time of a poll, and the meeting may proceed to consider other matters. The voting results shall still be deemed as resolutions passed at the said meeting.

When voting by a poll, Shareholders (including their proxies) entitled to two or more votes need not cast all their votes for, against or abstaining in the same way.

When the number of votes against and in favor are equal, the chairman of the meeting shall be entitled to an additional vote.

The following matters shall be resolved by way of ordinary resolutions at a general meeting:

(1) work reports of the Board and the Supervisory Committee;

(2) profit distribution plan and loss recovery plan formulated by the Board;



Shanghai Miracogen Inc.- Ex. 2032, Page 000780

(3) dismissal of the members of the Board and Supervisory Committee, and remuneration and payment methods thereof (except for employee representative Supervisors);

(4) annual budget plan and final account plan of the Company;

(5) decide to engagement, renewal, or discontinuance of engagement of accounting firms by the Company;

(6) other major matters beyond the power of the Board to make investment and decision-making as stipulated in Article 149 of the Articles of Association;

(7) matters other than those requiring approval by special resolutions in accordance with laws, administrative regulations, the listing rules of the place where the Company's shares are listed or the Articles of Association.

The following matters shall be resolved by way of special resolutions at a general meeting:

(1) increase or reduction of registered capital of the Company and issuance of stocks, share warrants and other similar securities of any kind;

(2) issuance of corporate bonds;

(3) division, merger, dissolution, liquidation or change in the form of the Company;

(4) purchase or sale of material assets within one year exceeds 30% of the Company's total audited assets in the latest period;

(5) examining the guarantee items where the amount of guarantee of the Company for 12 consecutive months exceeds 30% of the Company's total audited assets in the latest period;

(6) amendments to the Articles of Association;

(7) equity incentive plan;

(8) other matters stipulated by laws, administrative regulations, the listing rules of the place where the Company's shares are listed, or the Company's Articles of Association, and the general meeting of shareholders adopting ordinary resolutions that are considered to have a significant impact on the Company, requiring approval by special resolutions.


Shanghai Miracogen Inc.- Ex. 2032, Page 000781

**(6) Special Procedures for Voting of Class Shareholders**

Shareholders holding different classes of shares shall be class Shareholders.

Class Shareholders shall enjoy the rights and assume the obligations in accordance with laws, administrative regulations, and the Articles of Association.

The Company shall not proceed to change or abrogate the rights of class Shareholders unless such proposed change or abrogation has been approved by way of a special resolution at a general meeting and by a separate shareholder meeting convened by the class Shareholders so affected in accordance with the Articles of Association.

Except as stipulated by laws, administrative regulations or the Company's Articles of Association, the following circumstances shall be deemed as change or abrogation of the rights of a certain class shareholder:

(1) to increase or decrease the number of shares of such class, or to increase or decrease the number of shares of a class' voting rights, distribution rights or other privileges equal or superior to those of the shares of such class;

(2) to change all or part of the shares of such class into shares of another class or to change all or part of the shares of another class into shares of that class or to grant relevant conversion rights;

(3) to cancel or reduce rights to accrued dividends or cumulative dividends attached to shares of the said class;

(4) to reduce or cancel rights attached to the shares of the said class to preferentially receive dividends or to receive distributions of assets in a liquidation of the Company;

(5) to add, cancel or reduce share conversion rights, options, voting rights, transfer rights, pre-emptive placing rights, or rights to acquire securities of the Company attached to the shares of the said class;

(6) to cancel or reduce rights to receive Company payables in a particular currency attached to the shares of the said class;

(7) to create a new class of shares with voting rights, distribution rights or other privileges equal or superior to those of the shares of the said class;

(8) to restrict the transfer or ownership of the shares of the said class or to impose additional restrictions;



Shanghai Miracogen Inc.- Ex. 2032, Page 000782

(9) to issue rights to subscribe for, or to convert into, shares of the said class or another class;

(10) to increase the rights and privileges of the shares of another class;

(11) to restructure the Company in such a way to cause Shareholders of different classes to undertake liabilities disproportionately during the restructuring;

(12) to amend or cancel provisions in this chapter.

Shareholders of the affected class, whether or not with the rights to vote at general meetings originally, shall have the right to vote at shareholders' class meetings in respect of matters referred to in items (2) to (8) and (11) to (12) above, except that interested Shareholders shall not vote at such shareholders' class meetings.

The term "interested shareholders" in the preceding paragraph shall mean:

(1) in case of a buy-back of shares by the Company by way of a general offer to all Shareholders in equal proportion or by way of open market transactions on a stock exchange where our shares are listed in accordance with the Articles of Association, the controlling shareholders as defined in the Articles of Association shall be the "interested shareholders";

(2) in case of a buy-back of shares by the Company by an off market agreement outside the stock exchange where our shares are listed in accordance with the Articles of Association, holders of shares in relation to such agreement shall be the "interested shareholders";

(3) in case of a proposed restructuring of the Company, Shareholders who assume a relatively lower proportion of obligation than the obligations imposed on the other Shareholders of that class or who have an interest in the proposed restructuring that is different from the general interests in such proposed restructuring of the other Shareholders of that class shall be the "interested shareholders".

Resolution of a shareholders' class meeting shall be passed only by two-thirds or more of the total voting rights being held by the Shareholders of that class, who are entitled to do so, present and vote at the shareholders' class meeting in accordance with the Articles of Association.

The notice of a shareholders' class meeting shall be sent to the Shareholders entitled to vote at such meeting only.


Shanghai Miracogen Inc.- Ex. 2032, Page 000783

The procedure of a shareholders' class meeting shall, to the extent possible, be identical with the procedure of a general meeting. Provisions of the Articles of Association relevant to procedure for the holding of a general meeting shall be applicable to a shareholders' class meeting.

Except for other classes of Shareholders, holders of the domestic shares/domestic unlisted shares and shareholders of overseas listed shares are treated as different classes of shareholders. In the following circumstances, the special procedures for voting by class shareholders shall not apply:

(1) with the approval by a special resolution at the general meeting, the Company issues domestic shares/domestic unlisted shares or overseas listed shares alone or at the same time at each interval of 12 months and the number of the proposed domestic shares/domestic unlisted shares and overseas listed shares does not exceed 20 percent of the respective outstanding shares of such class;

(2) the Company has made the plans to issue domestic shares/domestic unlisted shares or overseas listed shares at the time of incorporation and the implementation of such plan has been completed within 15 months from the date of approval by the securities regulatory authorities of the State Council;

(3) with the approval of the securities regulatory authorities of the State Council, holders of the domestic shares/domestic unlisted shares of the Company transfers all or part of the shares held by it to overseas investors and is listed on the overseas stock exchanges or the Company converts all or part of the already issued but unlisted shares into overseas listed shares.

## IX. DIRECTORS AND BOARD OF DIRECTORS

### (1) Directors

The directors shall be elected or replaced at the general meeting for a term of three years. A Director may serve consecutive terms if re-elected upon the expiry of his/her term. Under the premise of complying with the relevant laws and administrative regulations, the general meeting may, in the ordinary resolution, remove any director whose term of office has not expired (but the damage claims of the director based on any contract is not affected by this rule).

The term of office of the directors shall be counted from the date of appointment until the expiration of the term of the current Board of Directors. When the directors' term expires and re-election not be held in time, the original directors shall still perform their duties as directors in accordance with laws, administrative regulations, departmental rules and the Company's Articles of Association before the re-elected directors take office.

Neither a Director nor an alternate Director is required to hold any shares in the Company by way of qualification. Further, there are no provisions in the Articles relating to retirement of Directors upon reaching any age limit.


Shanghai Miracogen Inc.- Ex. 2032, Page 000784

**(2) Board of Directors**

The Company shall have a Board of directors which consists of 9 directors. The Board of Directors has one chairman and 3 independent non-executive directors.

The Board of Directors shall be accountable to the general meeting and exercise the following powers and duties:

(1) to convene a general meeting and submit a work report to such meeting;

(2) to implement the resolutions of a general meeting;

(3) to decide on the operation plan and investment scheme of the Company;

(4) to prepare the draft annual budget and final accounts of the Company;

(5) to prepare the profit distribution plan and loss recovery plan of the Company;

(6) to prepare the plan for the Company to increase or reduce its registered capital and issuance of bonds;

(7) to prepare plans of the merger, divisions, dissolution and changes of the form of the Company;

(8) to decide on the establishment of the internal management organizations of the Company;

(9) to appoint or remove the CEO and Secretary of the Board; to appoint or remove the Co-CEO, vice presidents (including senior vice presidents), chief medical officers, chief financial officer and other senior managerial personnel of the Company, and to decide on matters concerning remuneration, rewards and punishments thereof;

(10) to decide on the establishment of the Company's internal management structure;

(11) to decide on the composition of the special committees of the Board of Directors and the chairmen (convenors) of each special committee;

(12) to establish a basic management system of the Company;

(13) to prepare plans to amend the Articles of Association;

(14) to file a bankruptcy application on behalf of the Company;

(15) to draw up plans for major matters in relation to investment, acquisition or disposal of assets, financing and connected transactions;



Shanghai Miracogen Inc.- Ex. 2032, Page 000785

(16) to examine and approve the listing of the unlisted shares held by the shareholders of the Company on foreign stock exchanges;

(17) to decide on other connected transactions of the Company except for those as required by the PRC Company Law and the provisions of the Articles of Association to be passed by resolutions at the general meetings;

(18) within the scope authorized by the shareholders' general meeting, to decide on matters of the Company's overseas investment, purchase and sale of assets, asset mortgage, guarantee, entrusted financial management, connected transactions, etc.;

(19) to manage the information disclosure matters of the Company;

(20) to propose to the shareholders' meeting for the appointment or replacement of an accounting firm for auditing the Company;

(21) to hear the work report of the CEO of the Company and inspect his work;

(22) to exercise other powers and duties conferred by relevant laws, administrative regulations, the listing rules of the stock exchange where our shares are listed, the Articles of Association or the general meetings.

Resolutions relating to the above, with the exception of items (6), (7) and (13) which shall be approved by not less than two-thirds of the Directors, shall be approved by not less than half of the Directors.

The board meeting can be held only when there are more than one half of the directors (including entrusted directors) attending the meeting.

Each director enjoys only one voting right. The resolution of the Board of Directors shall be passed by more than a half of all directors, except as otherwise stipulated by laws, administrative regulations and Articles of Association. When the number of votes against and in favor are equal, the chairman of the Board of Directors shall be entitled to an additional vote.

When a director has a material interest in a resolution of a board meeting, has a related relationship with the company involved, or has other circumstances that specified by laws and regulations, he may not exercise voting rights on the resolution or act as an agent for other directors to exercise voting rights. The above directors shall not be counted in the quorum of the relevant board meeting. The board meeting can be held by more than a half of the unrelated directors. The resolutions of the board meeting shall be passed by more than a half of the unrelated directors. If the number of unrelated directors attending is less than three, the matter shall be submitted to the general meeting for consideration.



Shanghai Miracogen Inc.- Ex. 2032, Page 000786

**(3) Borrowing Powers**

The Articles of Association do not contain any special provision in respect of the manner in which borrowing powers may be exercised by the Directors, other than provisions which (a) give the Board the power to formulate proposals for the issuance of corporate bonds by the Company; and (b) require the issuance of corporate bonds to be approved by the Shareholders in general meeting by way of a special resolution.

**(4) Remuneration and Compensation for Loss of Office**

The Company shall enter into written contracts with the Directors and the Supervisors regarding remuneration which are subject to the prior approval from the Shareholders' general meeting. The aforementioned "remunerations" include:

(a) remuneration for the Directors, Supervisors or senior management personnel of the Company;

(b) remuneration for the Directors, Supervisors or senior management personnel of the subsidiaries of the Company;

(c) remuneration for those providing other services for managing the Company and its subsidiaries; and

(d) compensation to Directors or Supervisors for loss of office or upon retirement.

Except for the contracts aforementioned, the Directors and Supervisors shall not initiate litigation against the Company and claim benefits due to them for the foregoing matters.

The remuneration contracts between the Company and its Directors or Supervisors shall stipulate that if the Company is to be acquired, the Directors and Supervisors of the Company shall, subject to prior approval from the Shareholders' general meeting, be entitled to compensation or other funds for loss of their positions or upon retirement. The "acquisition of the Company" mentioned in this paragraph refers to one of the following circumstances:

(a) a takeover offer made by any person to all Shareholders; and

(b) a takeover offer made by any person with the intent of becoming a "Controlling Shareholder". See the definition of "Controlling Shareholder" in Article 271 of our Articles.

If Directors and Supervisors do not comply with the proceeding provisions, any funds received by them shall go to the persons who have accepted the offer mentioned above and sell their Shares. The Directors and Supervisors shall bear the expenses arising form the proportional distribution of such amounts, and such expenses shall not be deducted from the amounts.



Shanghai Miracogen Inc.- Ex. 2032, Page 000787

## X. BOARD SECRETARY

The Company has one secretary of the Board, which is considered as the senior management of the Company. The secretary of the Board shall be a natural person with necessary professional knowledge and experience, nominated by the chairman of the Board of Directors, appointed or dismissed by the Board of Directors.

The accountant of the accounting firm engaged by the Company and the management personnel of the controlling shareholder shall not concurrently serve as the secretary of the Board of the Company.

## XI. CEO

The Company has one CEO, which is nominated by the chairman of the Board of Directors, appointed or removed by the Board of Directors. The Company has a number of vice presidents, who are nominated by the CEO and appointed or dismissed by the Board of Directors. Directors may concurrently serve as CEO, vice president or other senior management.

The CEO is accountable to the Board of Directors and shall exercise the following powers and duties:

(1) being in charge of managing the Company's production and operation, and report work to the Board of Directors;

(2) organizing the implementation of resolutions of the Board of Directors, annual operating plans and investment programs of the Company;

(3) making basic management system and inner management organization establishment plan;

(4) formulating detailed rules and regulations of the Company;

(5) recommending to the Board of Directors for appointment or removal of Co-CEO, vice presidents (including senior vice presidents), chief medical officers, chief financial officer and other senior management personnel;

(6) deciding to appoint or remove officers of the Company other than those to be appointed or removed by the Board of Directors;

(7) proposing to hold an interim meeting of the Board of Directors;

(8) the functions and powers stipulated in the work rules of the CEO;

(9) other powers and duties prescribed by the Articles of Association and delegated by the Board of Directors.



Shanghai Miracogen Inc.- Ex. 2032, Page 000788

## XII. SUPERVISORY COMMITTEE

Our Company shall establish a Supervisory Committee.

The Supervisory Committee consists of 3 members and one of them should be the chairman. The term of office of a Supervisor is three years and the Supervisors can be re-elected and re-appointed.

The Supervisory Committee shall be composed of the Shareholders' representative(s) and representative(s) of the workers of the Company in an appropriate ratio. In particular, the ratio of the employee representative Supervisor(s) shall no less than one third. The employee representative Supervisor(s) shall be elected by the staff and workers congress, the representative staff and workers congress or other forms of democratic election.

The Supervisory Committee shall be accountable to the general meeting, and exercise the following duties and powers:

(1) to review the financial position of the Company;

(2) to supervise the performance of directors, CEO and senior management members if they violate laws, administrative regulations or the Articles of Association in fulfilling their duties to the Company, and propose dismissal of Directors and senior management members that have violated laws, administrative regulations, the Articles of Association or resolutions of the general meeting;

(3) to demand rectification by Directors and senior management members of the Company when the acts of such persons are prejudicial to the Company's interest;

(4) to review financial information such as financial reports, business reports, and profit distribution plans as proposed by the Board to the general meetings, and to engage certified public accountants and practicing auditors to assist with further examination in the name of the Company if there are any queries;

(5) to propose the convening of an extraordinary general meeting, and to convene and preside over the general meeting when the Board fails to perform such duties;

(6) to put forward proposals to general meetings;

(7) to negotiate with Directors on behalf of the Company or initiate litigations against Directors;

(8) to propose the convening of extraordinary general meetings of the Board of Directors;



Shanghai Miracogen Inc.- Ex. 2032, Page 000789

(9) to initiate litigations against Directors and senior management members pursuant to the PRC Company Law;

(10) other duties and powers conferred by laws, administrative regulations and the Articles of Association.

Supervisors may present at meetings of the Board of Directors.

## XIII. FINANCE AND ACCOUNTING SYSTEM

The Company shall establish its financial and accounting system in accordance with relevant laws and administrative regulations, and PRC accounting standards formulated by the competent financial authorities under the State Council.

The Company shall adopt RMB as its accounts keeping unit.

The Company shall prepare a financial report at the end of each financial year, and such financial report shall be audited in compliance with laws.

Any financial report shall be prepared in accordance with the PRC accounting standards and regulations, and also in accordance with either international accounting standards or those of the place outside the PRC where the Company's shares are listed. If there are significant discrepancies in the above two standards financial reports, the notes shall be added in the financial report that in accordance with either international accounting standards or those of the place outside the PRC where the Company's shares are listed.

The financial report of the Company shall be kept at the Company and shall be made available to the Shareholders twenty days before the annual general meeting is held. Each Shareholder shall have the right to obtain the financial report mentioned in this chapter.

The Company shall send the report mentioned above to each holder of overseas listed shares by hand or prepaid mail at least twenty-one days before the convening of the annual general meeting of shareholders. The address of the recipient shall be the registered address as shown on the register of shareholders. Under the premise of complying with the relevant laws, administrative regulations, departmental regulations, the relevant rules of the securities regulatory authorities where the Company's shares are listed, the Company may adopt announcement (including make announcement on the Company's website).

The Company shall publish two financial reports in each financial year; the interim financial report shall be published within sixty days after the end of the first six months of a fiscal year; the annual financial report shall be published within one hundred and twenty days after the end of the financial year. If provisions otherwise provided by the stock exchange in the place where the Company's shares are listed, these provisions shall apply.



Shanghai Miracogen Inc.- Ex. 2032, Page 000790

## XIV. PROFIT DISTRIBUTION

The Company shall, when distributing its after-tax profits of the year, withdraw ten percent of the profits into the Company's statutory reserve fund. The Company may not withdraw a statutory reserve fund if the cumulative amount has reached fifty percent or more of the Company's registered capital.

If the Company's statutory reserve fund could not cover the losses of the preceding year, profit of the year shall be used to cover the losses before withdrawing, according to the foregoing provision, the statutory reserve fund.

After the Company has withdrawn the statutory reserve fund from the after-tax profits, the Company may also withdraw discretionary reserve fund from the after-tax profits upon the approval of the general meeting.

After losses have been covered and the statutory reserve fund has been allocated, any remaining after-tax profits shall be the profits available to Shareholders, which shall be distributed to the Shareholders in proportion to their shareholdings according to resolutions of the general meeting.

Where the general meeting distributes profits to Shareholders before losses have been covered and the statutory reserve fund has been allocated, which is in violation of the foregoing provision, the Shareholders concerned shall refund to the Company the profits distributed in violation of the foregoing provision.

The shares of the Company held by the Company shall not be subject to profit distribution.

The Company shall appoint collection agents in Hong Kong for holders of overseas listed shares. The collection agents shall, on behalf of the related Shareholders, collect and safekeeping distributed dividends and other payables by the Company for the overseas listed shares so as to make a payment for related Shareholders.

The collection agents appointed by the Company shall be in compliance with the requirements of the laws or the rules of local stock exchange at the place where the shares of the Company are listed.

The collection agents appointed by the Company for holders of overseas listed shares, shall be trust companies registered pursuant to Hong Kong Trustee Ordinance.

As for unclaimed dividends, in compliance with the laws, regulations of PRC, the Company may exercise the right of confiscation, but it shall not be exercised until the expiry of the six-year period after the date of the dividend announcement.



Shanghai Miracogen Inc.- Ex. 2032, Page 000791

The Company may exercise the power to cease sending dividend warrants to holders of overseas listed shares by post if such warrants have been left uncashed for two consecutive times. Nevertheless, the Company may exercise such power after the first occasion on which such undelivered warrants are returned.

The Company may sell the shares held by a holder of overseas listed shares who is untraceable in such ways as the Board of Directors thinks fit, provided that the following conditions shall be complied with:

(1) at least three dividends have been distributed in respect of such shares during the period of twelve years, and no dividend has been claimed by the Shareholder during that period; and

(2) upon the expiry of the 12 year period, the Company shall make announcement in one or more newspapers at the place where the shares of the Company are listed stating the Company's intention to sell the shares, and notify the Stock Exchange where the shares of the Company are listed of such intention.

## XV. DISSOLUTION AND LIQUIDATION

The Company shall be dissolved and liquidated according to laws in any of the following circumstances:

(1) the special resolution of general meeting has resolved to dissolve the Company;

(2) merger or division of the Company requires a dissolution;

(3) the business license is revoked in accordance with the law, or the Company is ordered to close or is cancelled;

(4) if the Company gets into serious trouble in operations and management and continuation may incur material losses of the interests of the Shareholders, and no solution can be found through any other means, the Shareholders holding ten percent or more of the total voting rights of the Company may request the People's Court to dissolve the Company;

(5) the Company is declared bankrupt in accordance with the law because it is unable to pay its debts as they fall due;

(6) the term of its operations specified in the Articles of Association has expired and other circumstance for dissolution specified in the Articles of Association has occurred.


Shanghai Miracogen Inc.- Ex. 2032, Page 000792

Where the Company is dissolved under the circumstances set out in items (1), (3), (4) and (6), the Company shall establish a liquidation committee to start liquidation within fifteen days from the date the cause of dissolution occurred. The composition of the liquidation committee shall be determined by ordinary resolution at the general meeting. If a liquidation group fails to be established within the limited time for liquidation, the creditor may apply to the People's Court for appointing relevant personnel to form a liquidation group for liquidation.

Where the Board resolves to liquidate the Company for any reason other than bankruptcy, the Board shall include a statement in its notice convening a general meeting to the effect that, after making full inquiry into the affairs of the Company, the Board is of the opinion that the Company shall be able to pay its debts in full within twelve months from the commencement of the liquidation.

The Board shall lose its powers immediately after the resolution for liquidation is passed at the general meeting.

The liquidation committee shall act in accordance with instructions of the general meeting and make a report at least once every year to the general meeting on the committee's income and expenses, the business of the Company and the progress of the liquidation; and present a final report to the general meeting upon completion of the liquidation.

The liquidation committee shall notify all creditors within ten days after its establishment and shall publish announcements in newspapers within sixty days. The creditors shall declare their rights to the liquidation committee within thirty days after receipt of the notice or within 45 days after the announcement if the creditors have not received the notice.

When submitting their claims, creditors shall explain matters relating to their rights and provide evidential documents. The liquidation committee shall register the creditor's rights.

During the period of declaration of claims, the liquidation committee shall not liquidate the creditors.

During the liquidation period, the Company shall not commence any new business activity.

After the liquidation committee has examined and taken possession of the assets of the Company and prepared a balance sheet and a property inventory, if it discovers that the Company's assets are insufficient to repay its debts in full, it shall immediately apply to the People's Court to declare the Company bankrupt.

Following a ruling by the People's Court that the Company is declared bankrupt, the liquidation committee shall hand over all matters relating to the liquidation to the People's Court.



Shanghai Miracogen Inc.- Ex. 2032, Page 000793

After completion of liquidation of the Company, the liquidation committee shall prepare a liquidation report, a statement of revenue and expenditure and financial account books in respect of the liquidation period and, after verification thereof by an accountant registered in China, submit the same to the general meeting or the People's Court. Within thirty days from the date of confirmation of the aforementioned documents by the general meeting or the People's Court, the liquidation committee shall deliver the same to the Company registration authority, apply for cancellation of the Company's registration and publicly announce the Company's dissolution.

## XVI. AMENDMENTS TO THE ARTICLES OF ASSOCIATION

The Company may amend the Articles of Association pursuant to laws, administrative regulations, and the Articles of Association.

The amendment of the Company's Articles of Association shall take effect on the date when it passed by the special resolution of the general meeting; If such amendments adopted by the resolution of the general meeting of shareholders is subject to be approved by the competent administrative department, the amendment shall be submitted to the authorities in charge for approval; If such amendments involve any registered particulars of the Company, application shall be made for change of registration in accordance with laws.



Shanghai Miracogen Inc.- Ex. 2032, Page 000794

## 1. FURTHER INFORMATION ABOUT OUR COMPANY

### A. Incorporation

On January 19, 2018, the predecessor of our Company, Lepu Biopharma Co., Ltd. (樂普生物科技有限公司), was established as a limited liability company in Shanghai, the PRC, with a registered capital of RMB1,000,000,000. On December 16, 2020, our Company was converted into a joint stock company with limited liability and renamed as Lepu Biopharma Co., Ltd. (樂普生物科技股份有限公司), with the promoters being Ningbo Houde Yimin, Miracogen HK, Mr. Su Rongyu, Shanghai Lvyuan, Shanghai Chunrui, Series A Investors and Series B Investors.

We have established a place of business in Hong Kong at Level 54, Hopewell Centre, 183 Queen's Road East, Wanchai, Hong Kong, and have been registered as a non-Hong Kong company in Hong Kong under Part 16 of the Companies Ordinance on March 19, 2021. Ms. Lai Siu Kuen (黎少娟) has been appointed as our agent for the acceptance of services of process and notices on behalf of our Company in Hong Kong.

As we are incorporated in the PRC, we are subject to the relevant laws and regulations of the PRC. A summary of the relevant aspects of laws and regulations of the PRC and our Articles of Association is set out in "Regulatory Overview" of this Prospectus and Appendix VI to this Prospectus.

### B. Changes in the Share Capital of our Company

On April 30, 2020, the registered capital of our Company was increased from RMB1,000,000,000 to RMB1,126,760,565.

On May 29, 2020, the registered capital of our Company was increased from RMB1,126,760,565 to RMB1,265,738,671.

On August 6, 2020, the registered capital of our Company was increased from RMB1,265,738,671 to RMB1,492,692,648.

On December 16, 2020, our Company was converted into a joint stock company with limited liability, and our registered share capital was RMB1,492,692,648, consisting of 1,492,692,648 Shares with a nominal value of RMB1.00 each.

On April 14, 2021, the registered capital of our Company was increased from RMB1,492,692,648 to RMB1,531,669,838.


Shanghai Miracogen Inc.- Ex. 2032, Page 000795

Upon completion of the Global Offering, without taking into account any H Shares which may be issued pursuant to the Over-allotment Option, our registered share capital will be increased to RMB1,658,545,838, comprising 54,268,364 Domestic Shares and 1,604,277,474 H Shares to be issued and sold under the Global Offering, representing 3.27%, and 96.73% of our registered capital, respectively.

Save as disclosed above, there has been no alteration in the share capital of our Company during the two years immediately preceding the date of this Prospectus.

## C. Resolutions of the Shareholders of our Company dated April 18, 2021

On April 18, 2021, the shareholders of our Company passed, among other things, the following resolutions:

(a) the issue by the Company of H Shares of nominal value of RMB1.00 each. The amount of the H Shares is no more than 25% of the total share capital as enlarged immediately following the Global Offering (before the exercise of the Over-allotment Option);

(b) the granting of the Over-allotment Option in respect of no more than 15% of the number of H Shares issued as mentioned above;

(c) the granting to our Directors of general mandate to separately or concurrently allot, issue and deal with additional Domestic Shares and H Shares, and the number of such Domestic Shares or H Shares shall not exceed 20% of Domestic Shares in issue and H Shares in issue (as the case may be) as of the Listing Date.

(d) subject to the completion of the Global Offering, the Articles of Association have been approved and adopted, which shall only become effective from the Listing Date, and the Board has been authorized to amend the Articles of Association in accordance with any comments from the Stock Exchange and the relevant PRC regulatory authorities; and

(e) approving the Board to handle all matters relating to, among other things, the issuer of H Shares and the Listing of H Shares on the Stock Exchange.

## D. Conversion

In preparation of the Global Offering, we underwent the Conversion, details of which are set out in "History, Development and Corporate Structure" in this Prospectus. Our PRC legal adviser, Zhong Lun Law Firm, has confirmed that the Conversion was legally and duly completed, and that we have obtained all necessary approvals from relevant PRC regulatory authorities required for the Conversion.


Shanghai Miracogen Inc.- Ex. 2032, Page 000796

## E. Subsidiaries of Our Company

### *(a) Subsidiaries*

Certain details of our principal subsidiaries are set forth in the Accountant's Report in Appendix I to this Prospectus.

### *(b) Changes in the share capital of principal subsidiaries*

The following changes in the share capital of our subsidiaries took place during the two years immediately preceding the date of this Prospectus:

*Taizhou Aoke*

On March 1, 2019, the registered capital of Taizhou Aoke was increased from RMB112,000,000 to RMB412,000,000.

On November 1, 2020, the registered capital of Taizhou Aoke was decreased from RMB412,000,000 to RMB262,000,000.

*Miracogen Shanghai*

On November 1, 2021, the registered capital of Miracogen Shanghai was increased from RMB49,371,981 to RMB99,371,981.

Save as disclosed above, there has been no alteration in the share capital of any of the subsidiaries of the Company within the two years immediately preceding the date of this Prospectus.

Save for the subsidiaries mentioned in the Accountant's Report set out in Appendix I to this Prospectus, the Company has no other subsidiaries.

## 2. FURTHER INFORMATION ABOUT OUR BUSINESS

## A. Summary of Our Material Contracts

We have entered into the following material contracts (not being contracts entered into in the ordinary course of business) within two years preceding the date of this Prospectus and a copy of each has been delivered to the Registrar of Companies in Hong Kong for registration:

(a) the supplemental investment agreement dated April 21, 2020 entered into among our Company, Ningbo Houde Yimin, Lepu Medical, Shanghai Lvyuan, Shanghai Chunrui, Mr. Su Rongyu (蘇榮譽), Suzhou Danqing, Jiaxing Danqing, Suzhou Private Capital Investment, Kaiyuan Guochuang, Kington Capital, Suzhou Suzi, Suzhou Xinrui, Linzhi Lecheng, Dr. Pu Zhongjie, Ms. Pu Jue (蒲珏), Oceancere



Shanghai Miracogen Inc.- Ex. 2032, Page 000797

Limited and Evercare Inc. (the "Parties"), pursuant to which the Parties agreed to (i) proceed with the listing of our Company, rather than Evercare Inc., on certain approved stock exchanges; (ii) waive our Company from conducting offshore reorganization and each of Linzhi Lecheng, Jiaxing Danqing, Suzhou Private Capital Investment, Kaiyuan Guochuang, Kington Capital, Suzhou Suzi and Suzhou Xinrui (collectively, the "Lenders") from making offshore investments; (iii) terminate the warrant and the call option agreement entered into among Evercare Inc. and the Lenders; (iv) terminate the rights and obligations of Oceancere Limited and Evercare Inc. under the investment agreement dated March 4, 2019 entered into among our Company, Ningbo Houde Yimin, Lepu Medical, Dr. Pu Zhongjie, Ms. Pu Jue, Oceancere Limited, Evercare Inc. and the Lenders (the "Investment Agreement"), the clauses related to the offshore entities, the offshore agreement and other offshore matters thereunder; (v) waive the progress of the conversion of debt to equity as stipulated in clause 3.7 under the Investment Agreement; (vi) terminate the Lenders' special rights under clauses 1 to 9 of schedule 4 to the Investment Agreement from the date of conversion of our Company into a joint stock company with limited liability; and (vii) exercise the conversion rights in accordance with clause 3.7 of the Investment Agreement in exchange for direct equity interest of our Company, as a result of which the Lenders subscribed for 9% of the equity interest of our Company at the consideration of RMB360 million and acquired 11.25% of the equity interest of our Company through transfer at a consideration of RMB450 million, and Lepu Medical further subscribed for 2.25% of the equity interest of our Company at the consideration of RMB90 million;

(b) the equity transfer agreement dated May 7, 2020 among Miracogen HK, Miracogen Shanghai and our Company, pursuant to which Miracogen HK agreed to transfer 36.99% equity interest of Miracogen Shanghai to our Company in consideration for 10.98% equity interest of our Company;

(c) the capital increase agreement dated May 16, 2020 between Miracogen HK and our Company, pursuant to which Miracogen HK agreed to subscribe 10.98% equity interest of our Company in consideration for Miracogen HK transferring to our Company 36.99% equity interest of Miracogen Shanghai;



Shanghai Miracogen Inc.- Ex. 2032, Page 000798

(d) the investment agreement dated July 30, 2020 entered into among Sunshine Insurance, Ronghui Sunshine, Tianjin Pingan, Haitong Capital, China Reform, SDIC Unity Capital, Minxin Qiyuan, Haihui Quanxing, Xinye Guangzhou, Guo Tongjun (郭同軍), Wang Lei (王磊), Wang Xinglin (王興林), Zhang Xia (張霞), Wang Yong (王泳), Chen Juan (陳娟), Wei Zhanjiang (魏戰江), Lin Yi (林儀), Ningbo Houde Yimin and Dr. Pu Zhongjie (collectively, the "Subscribers") and our Company, pursuant to which, the Subscribers agreed to subscribe for an aggregate of 15.2044% of the equity interest in our Company at a total consideration of RMB1,291 million;

(e) the promoters agreement dated December 9, 2020 entered into among Ningbo Houde Yimin, Lepu Medical, Miracogen HK, Mr. Su Rongyu (蘇榮譽), Shanghai Lvyuan, Suzhou Danqing, Shanghai Chunrui, Tianjin Pingan, Haitong Capital, Sunshine Insurance, Kaiyuan Guochuang, SDIC Unity Capital, China Reform, Ronghui Sunshine, Kington Capital, Suzhou Suzi, Minxin Qiyuan, Suzhou Xinrui, Jiaxing Danqing, Linzhi Lecheng, Haihui Quanxing, Xinye Guangzhou, Guo Tongjun (郭同軍), Wang Lei (王磊), Wang Xinglin (王興林), Wei Zhanjiang (魏戰江), Wang Yong (王泳), Zhang Xia (張霞), Chen Juan (陳娟) and Lin Yi (林儀), pursuant to which it was agreed that our Company shall be converted into a joint stock company with limited liability;

(f) the investment agreement dated April 8, 2021 entered into among our Company, Vivo Capital, SHC, Lepu Medical, Ningbo Houde Yimin, Dr. Pu Zhongjie, Miracogen Shanghai, Taizhou Hanzhong, Taizhou Aoke, Lepu Shanghai, Lepu Hangjia, CtM Bio and Lepu Beijing, pursuant to which Vivo Capital and SHC agreed to subscribe for 1.5905% and 0.9543% equity interest of our Company at the consideration of RMB163.2 million and RMB97.92 million, respectively;

(g) the equity transfer agreement dated October 9, 2021 entered into among Lepu Shanghai, Xiyuan Anjian Medical (Shanghai) Co., Ltd. (熙源安健醫藥(上海)有限公司) and Hangzhou Xiyuan Biotechnology Co., Ltd. (杭州熙源生物技術有限公司), pursuant to which Xiyuan Anjian Medical (Shanghai) Co., Ltd. agreed to acquire 30% of the equity interest in Hangzhou Xiyuan Biotechnology Co., Ltd. from Lepu Shanghai at the cash consideration of RMB10 million;

(h) the cornerstone investment agreement dated February 5, 2022 entered into among the Company, Vivo Capital Fund IX, L.P., China International Capital Corporation Hong Kong Securities Limited and Morgan Stanley Asia Limited, pursuant to which Vivo Capital agreed to subscribe for such number of H Shares at the Offer Price in an aggregate maximum investment amount of US$30,000,000 (excluding the brokerage fee, SFC transaction levy, Stock Exchange trading fee and FRC transaction levy in respect of such number of H Shares);


Shanghai Miracogen Inc.- Ex. 2032, Page 000799

(i) the cornerstone investment agreement dated February 5, 2022 entered into among the Company, King Star Med LP, China International Capital Corporation Hong Kong Securities Limited and Morgan Stanley Asia Limited, pursuant to which King Star Med LP agreed to subscribe for such number of H Shares at the Offer Price in an aggregate maximum investment amount of US$20,000,000 (excluding the brokerage fee, SFC transaction levy, Stock Exchange trading fee and FRC transaction levy in respect of such number of H Shares); and

(j) the Hong Kong Underwriting Agreement.

## B. Intellectual Property Rights

### *(a) Patents*

For details of owned and in-licensed patent portfolios that we consider to be or may be material to our business, see "Business – Intellectual property rights".

### *(b) Trademarks*

As of the Latest Practicable Date, the following trademarks have been registered in the name of the relevant member of our Group which are considered by us to be or may be material to our business:

| No. | Trademark Registrant | Trademark | Registration Number | Place of Registration | Class | Valid Period |
|---|---|---|---|---|---|---|
| 1 | Miracogen Shanghai | MIRACOGEN | 16754858 | China | 42 | June 14, 2016 to June 13, 2026 |
| 2 | Miracogen Shanghai | MIRACOGEN | 16754768 | China | 35 | June 14, 2016 to June 13, 2026 |
| 3 | Miracogen Shanghai | MIRACOGEN | 16754749 | China | 5 | June 14, 2016 to June 13, 2026 |
| 4 | Miracogen Shanghai |  | 16754659 | China | 5 | June 14, 2016 to June 13, 2026 |
| 5 | Miracogen Shanghai |  | 16754564 | China | 35 | September 21, 2016 to September 20, 2026 |
| 6 | Miracogen Shanghai |  | 16754330 | China | 42 | June 7, 2016 to June 6, 2026 |



Shanghai Miracogen Inc.- Ex. 2032, Page 000800

| No. | Trademark Registrant | Trademark | Registration Number | Place of Registration | Class | Valid Period |
|---|---|---|---|---|---|---|
| 7 | Miracogen Shanghai | 美雅珂 | 16754324 | China | 42 | June 7, 2016 to June 6, 2026 |
| 8 | Miracogen Shanghai | 美雅珂 | 16754142 | China | 35 | June 21, 2016 to June 20, 2026 |
| 9 | Miracogen Shanghai | 美雅珂 | 16753840 | China | 5 | September 28, 2016 to September 27, 2026 |
| 10 | Taizhou Hanzhong | 普佑恒 | 46980020 | China | 5 | February 7, 2021 to February 6, 2031 |
| 11 | Taizhou Hanzhong | 乐佑舒 | 45896796 | China | 5 | December 28, 2020 to December 27, 2030 |
| 12 | Taizhou Hanzhong | 乐月恒 | 45864387 | China | 5 | December 28, 2020 to December 27, 2030 |
| 13 | CtM Bio | 樂普創一 | 51159008 | China | 5 | August 21, 2021 to August 20, 2031 |
| 14 | CtM Bio | 樂普創一 | 51138653 | China | 9 | August 14, 2021 to August 13, 2031 |
| 15 | CtM Bio | 樂普創一 | 51144185 | China | 10 | August 21, 2021 to August 20, 2031 |
| 16 | CtM Bio | 樂普創一 | 51140263 | China | 35 | August 21, 2021 to August 20, 2031 |
| 17 | CtM Bio | 樂普創一 | 51156327 | China | 40 | August 14, 2021 to August 13, 2031 |
| 18 | CtM Bio | 樂普創一 | 51150343 | China | 42 | August 7, 2021 to August 6, 2031 |


Shanghai Miracogen Inc.- Ex. 2032, Page 000801

| No. | Trademark Registrant | Trademark | Registration Number | Place of Registration | Class | Valid Period |
|---|---|---|---|---|---|---|
| 19 | CtM Bio | 樂普創一 | 51161647 | China | 44 | August 7, 2021 to August 6, 2031 |
| 20 | Company | 乐普生物 LEPU BIOPHARMA | 305527260 | China | 5 | February 4, 2021 to February 3, 2031 |
| 21 | Company | 乐普生物 LEPU BIOPHARMA | 305527260 | China | 9 | February 4, 2021 to February 3, 2031 |
| 22 | Company | 乐普生物 LEPU BIOPHARMA | 305527260 | China | 10 | February 4, 2021 to February 3, 2031 |
| 23 | Company | 乐普生物 LEPU BIOPHARMA | 305527260 | China | 16 | February 4, 2021 to February 3, 2031 |
| 24 | Company | 乐普生物 LEPU BIOPHARMA | 305527260 | China | 35 | February 4, 2021 to February 3, 2031 |
| 25 | Company | 乐普生物 LEPU BIOPHARMA | 305527260 | China | 41 | February 4, 2021 to February 3, 2031 |
| 26 | Company | 乐普生物 LEPU BIOPHARMA | 305527260 | China | 42 | February 4, 2021 to February 3, 2031 |
| 27 | Company | 乐普生物 LEPU BIOPHARMA | 305527260 | China | 44 | February 4, 2021 to February 3, 2031 |
| 28 | CtM Bio | CTMBio concept to medicine | 53117147 | China | 9 | December 14, 2021 to December 13, 2031 |

The class number represents the specifications of products or services which have already been applied for or registered. Detailed specifications of the products or services represented by that class number are set out in the relevant application forms or registration certificates.



Shanghai Miracogen Inc.- Ex. 2032, Page 000802

*(c) Domain Name*

As of the Latest Practicable Date, the following domain names have been registered in the name of the relevant member of our Group which are considered by us to be or may be material to our business:

| No. | Domain Name | Registered Owner | Effective Period |
|---|---|---|---|
| 1 | lepubiotech.com | Company | January 5, 2018 to January 5, 2029 |
| 2 | lepubio.com | Company | January 5, 2018 to January 5, 2029 |
| 3 | lepubiotech.com.cn | Company | January 5, 2018 to January 5, 2029 |
| 4 | lepubiotech.net | Company | November 5, 2018 to November 5, 2028 |
| 5 | lepubiotech.cn | Company | January 5, 2018 to January 5, 2029 |
| 6 | lepubio.cn | Company | January 5, 2018 to January 5, 2029 |
| 7 | lepubio.com.cn | Company | January 5, 2018 to January 5, 2029 |
| 8 | lepubiopharma.com | Lepu Beijing | March 18, 2020 to March 18, 2030 |
| 9 | lepu-bio.com | Lepu Beijing | March 18, 2020 to March 18, 2030 |
| 10 | lepu-bio.com.cn | Lepu Beijing | March 18, 2020 to March 18, 2030 |
| 11 | lepu-bio.cn | Lepu Beijing | March 18, 2020 to March 18, 2030 |
| 12 | miracogen.com.cn | Miracogen Shanghai | March 31, 2014 to March 31, 2022 |
| 13 | ctm-bio.com | CtM Bio | March 18, 2020 to March 18, 2030 |
| 14 | ctmbiotech.com | CtM Bio | April 9, 2020 to April 9, 2030 |
| 15 | ctm-biotech.com | CtM Bio | April 9, 2020 to April 9, 2030 |
| 16 | ctm-bio.cn | CtM Bio | March 18, 2020 to March 18, 2030 |
| 17 | ctm-bio.com.cn | CtM Bio | March 18, 2020 to March 18, 2030 |
| 18 | hj-biomed.com | Lepu Hangjia | December 4, 2019 to December 4, 2029 |
| 19 | lepubiopharma.cn | Company | July 8, 2021 to July 8, 2022[1] |
| 20 | lepubiopharma.com.cn | Company | July 8, 2021 to July 8, 2022[1] |

*Note 1:* Before the expiration of the domain name, the Company will pay the renewal fee to the relevant domain name registry to extend the effective period.



Shanghai Miracogen Inc.- Ex. 2032, Page 000803

## 3. FURTHER INFORMATION ABOUT OUR DIRECTORS AND SUPERVISORS

### A. Particulars of Directors and Supervisors' Contracts

Each of our executive Directors, independent non-executive Directors and Supervisors entered into a service contract with our Company on February 9, 2022, with a term of three years commencing from the Listing Date. The service contract may be renewed in accordance with our Articles of Association and the applicable laws, rules and regulations.

Pursuant to Rules 19A.54 and 19A.55 of the Listing Rules, each of our Directors and Supervisors entered into a contract with our Company on the Listing Date in respect of, among other things, (i) the compliance of relevant laws and regulations, (ii) compliance with the Articles of Association, and (iii) the provision on arbitration.

Save as disclosed above, none of our Directors or Supervisors has or is proposed to have a service contract with any of our Group (other than contracts expiring or determinable by the relevant employer within one year without the payment of compensation (other than statutory compensation)).

### B. Directors and Supervisors' Remuneration

The aggregate amount of remuneration paid to our Directors and Supervisors (including salaries, remuneration, pension, discretionary bonus, share-based compensation and other welfares) for the years ended December 31, 2019 and 2020, and the eight months ended August 31, 2021 were approximately nil, RMB5,375,000 and RMB14,571,000, respectively.

For each of the years ended December 31, 2019 and 2020, and the eight months ended August 31, 2021, the aggregate amount of fees, salaries, allowances, discretionary bonus, pension schemes contribution and other benefits in kind (if applicable) paid to the five highest-paid individuals of our Group were approximately RMB6,861,000, RMB13,266,000 and RMB76,162,000, respectively.

It is estimated that under the arrangements currently in force, the aggregate amounts of remuneration payable by our Company to our Directors and Supervisors for the year ending December 31, 2022 is approximately RMB13,567,862 (excluding any discretionary bonus).

There is no arrangement under which any Director or Supervisor has waived or agreed to waive any remuneration of benefits in kind during the Track Record Period.



Shanghai Miracogen Inc.- Ex. 2032, Page 000804

## 4. DISCLOSURE OF INTERESTS

### A. Substantial Shareholders

For information on the persons (other than our Directors, Supervisors and chief executive of the Company) who will, immediately following the completion of the Global Offering, have interests or short positions in our Shares or underlying Shares which would be required to be disclosed to us and the Hong Kong Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO, or, directly or indirectly, be interested in 10% or more of the nominal value of any class of share capital carrying the rights to vote in all circumstances at general meetings of our Company, please see below:

| | | | As of the Latest Practicable Date | | Immediately following the completion of the Global Offering (assuming the Over-Allotment Option is not exercised) | | |
|---|---|---|---|---|---|---|---|
| Name of Substantial Shareholder | Class of Shares to be held after the Global Offering | Nature of Interest | Number of Shares | Approximate percentage in the Company | Number of Shares | Approximate percentage in the relevant class of Shares of the Company | Approximate percentage of shareholding in the total issued Share capital of our Company |
| Ningbo Houde Yimin | H Shares | Beneficial interest | 433,239,436 | 28.2855% | 433,239,436 | 27.0053% | 26.1216% |
| Beijing Houde Yimin | H Shares | Interest in controlled corporation | 433,239,436 | 28.2855% | 433,239,436 | 27.0053% | 26.1216% |
| Lepu Medical | H Shares | Beneficial interest | 225,352,113 | 14.7128% | 225,352,113 | 14.0470% | 13.5873% |
| Dr. Pu Zhongjie | H Shares | Interest in controlled corporation | 658,591,549 | 42.9983% | 658,591,549 | 41.0522% | 39.7090% |
| Miracogen HK | H Shares | Beneficial interest | 138,978,106 | 9.0736% | 138,978,106 | 8.6630% | 8.3795% |
| Miracogen Inc. | H Shares | Interest in controlled corporation | 138,978,106 | 9.0736% | 138,978,106 | 8.6630% | 8.3795% |
| Dr. Hu Chaohong | H Shares | Interest in controlled corporation | 138,978,106 | 9.0736% | 138,978,106 | 8.6630% | 8.3795% |
| Mr. Su Rongyu | H Shares | Beneficial interest | 100,000,000 | 6.5288% | 100,000,000 | 6.2333% | 6.0294% |
| Shanghai Lvyuan | H Shares | Beneficial interest | 90,000,000 | 5.8759% | 90,000,000 | 5.6100% | 5.4264% |
| Cereblue Limited | H Shares | Interest in controlled corporation | 90,000,000 | 5.8759% | 90,000,000 | 5.6100% | 5.4264% |
| Ms. Pu Jue | H Shares | Interest in controlled corporation | 90,000,000 | 5.8759% | 90,000,000 | 5.6100% | 5.4264% |
| Kington Capital | H Shares | Beneficial interest | 39,436,621 | 2.5747% | 39,436,621 | 2.4582% | 2.3778% |
| | Domestic Shares | Beneficial interest | 39,436,620 | 2.5747% | 39,436,620 | 72.6696% | 2.3778% |



Shanghai Miracogen Inc.- Ex. 2032, Page 000805

| Name of Substantial Shareholder | Class of Shares to be held after the Global Offering | Nature of Interest | As of the Latest Practicable Date | | Immediately following the completion of the Global Offering (assuming the Over-Allotment Option is not exercised) | | |
|---|---|---|---|---|---|---|---|
| | | | Number of Shares | Approximate percentage in the Company | Number of Shares | Approximate percentage in the relevant class of Shares of the Company | Approximate percentage of shareholding in the total issued Share capital of our Company |
| Suzhou Yipu No. 1 Chuangzhe Management Consultation Limited Partnership (蘇州翼樸一號創喆管理諮詢合夥企業(有限合夥))[1] | H Shares | Interest in controlled corporation | 39,436,621 | 2.5747% | 39,436,621 | 2.4582% | 2.3778% |
| | Domestic Shares | Interest in controlled corporation | 39,436,620 | 2.5747% | 39,436,620 | 72.6696% | 2.3778% |
| Suzhou Suzi | H Shares | Beneficial interest | 9,859,155 | 0.6437% | 9,859,155 | 0.6146% | 0.5944% |
| | Domestic Shares | Beneficial interest | 9,859,155 | 0.6437% | 9,859,155 | 18.1674% | 0.5944% |
| Suzhou Zisu Investment Consultation Limited Partnership (蘇州梓蘇投資諮詢合夥企業(有限合夥))[2] | H Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 0.6146% | 0.5944% |
| | Domestic Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 18.1674% | 0.5944% |
| Suzhou Kington Equity Investment Fund Management Co., Ltd. (蘇州翼樸股權投資基金管理有限公司)[2] | H Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 0.6146% | 0.5944% |
| | Domestic Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 18.1674% | 0.5944% |
| Shanghai Qianyu Equity Investment Fund Management Co., Ltd. (上海前宇股權投資基金管理有限公司)[2] | H Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 0.6146% | 0.5944% |
| | Domestic Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 18.1674% | 0.5944% |



Shanghai Miracogen Inc.- Ex. 2032, Page 000806

| Name of Substantial Shareholder | Class of Shares to be held after the Global Offering | Nature of Interest | As of the Latest Practicable Date | | Immediately following the completion of the Global Offering (assuming the Over-Allotment Option is not exercised) | | |
|---|---|---|---|---|---|---|---|
| | | | Number of Shares | Approximate percentage in the Company | Number of Shares | Approximate percentage in the relevant class of Shares of the Company | Approximate percentage of shareholding in the total issued Share capital of our Company |
| Suzhou Yumeng Investment Management Co., Ltd. (蘇州宇夢投資管理有限公司)[2] | H Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 0.6146% | 0.5944% |
| | Domestic Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 18.1674% | 0.5944% |
| Qian Xin (錢鑫)[2] | H Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 0.6146% | 0.5944% |
| | Domestic Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 18.1674% | 0.5944% |
| Yinhua Changan Capital Management (Beijing) Co., Ltd. (銀華長安資本管理(北京)有限公司)[2] | H Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 0.6146% | 0.5944% |
| | Domestic Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 18.1674% | 0.5944% |
| Yinhua Fund Management Co., Ltd. (銀華基金管理股份有限公司)[2] | H Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 0.6146% | 0.5944% |
| | Domestic Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 18.1674% | 0.5944% |
| Southwest Securities Co., Ltd. (西南證券有限責任公司)[2] | H Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 0.6146% | 0.5944% |
| | Domestic Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 18.1674% | 0.5944% |
| Chongqing Yufu Capital Management Group Co., Ltd. (重慶渝富資本運營集團有限公司)[2] | H Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 0.6146% | 0.5944% |
| | Domestic Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 18.1674% | 0.5944% |



Shanghai Miracogen Inc.- Ex. 2032, Page 000807

| Name of Substantial Shareholder | Class of Shares to be held after the Global Offering | Nature of Interest | As of the Latest Practicable Date | | Immediately following the completion of the Global Offering (assuming the Over-Allotment Option is not exercised) | | |
|---|---|---|---|---|---|---|---|
| | | | Number of Shares | Approximate percentage in the Company | Number of Shares | Approximate percentage in the relevant class of Shares of the Company | Approximate percentage of shareholding in the total issued Share capital of our Company |
| Chongqing Yufu Holding Group Co., Ltd. (重慶渝富控股集團有限公司)[2] | H Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 0.6146% | 0.5944% |
| | Domestic Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 18.1674% | 0.5944% |
| State-Owned Assets Supervision and Administration Commission of Chongqing Municipal Government[2] | H Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 0.6146% | 0.5944% |
| | Domestic Shares | Interest in controlled corporation | 9,859,155 | 0.6437% | 9,859,155 | 18.1674% | 0.5944% |
| Suzhou Kington Equity Investment Fund Management Co., Ltd. (蘇州翼樸股權投資基金管理有限公司)[3] | H Shares | Interest in controlled corporation | 49,295,776 | 3.2184% | 49,295,776 | 3.0728% | 2.9722% |
| | Domestic Shares | Interest in controlled corporation | 49,295,775 | 3.2184% | 49,295,775 | 90.8370% | 2.9722% |
| Suzhou Private Capital Investment[4] | H Shares | Interest in controlled corporation | 49,295,776 | 3.2184% | 49,295,776 | 3.0728% | 2.9722% |
| | Domestic Shares | Interest in controlled corporation | 49,295,775 | 3.2184% | 49,295,775 | 90.8370% | 2.9722% |

*Notes:*

(1) Suzhou Yipu No. 1 Chuangzhe Management Consultation Limited Partnership is the general manager of Kington Capital and therefore is deemed to be interested in our Shares held by Kington Capital.

(2) Suzhou Zisu Investment Consultation Limited Partnership is the general partner of Suzhou Suzi, with Suzhou Kington Equity Investment Fund Management Co., Ltd. being its general partner and Shanghai Qianyu Equity Investment Fund Management Co., Ltd. being its limited partners holding 50% partnership interest. Suzhou Kington Equity Investment Fund Management Co., Ltd. is wholly owned by Suzhou Private Capital Investment. Shanghai Qianyu Equity Investment Fund Management Co., Ltd. is owned as to 40% by Suzhou Yumeng Investment Management Co., Ltd., a company owned by Qian Xin as to 99.50%.



Shanghai Miracogen Inc.- Ex. 2032, Page 000808

Yinhua Changan Capital Management (Beijing) Co., Ltd. is the limited partner of Suzhou Suzi holding 69.47% partnership interest, which in turn is wholly owned by Yinhua Fund Management Co., Ltd. Southwest Securities Co., Ltd. owns 49% equity interest in Yinhua Fund Management Co., Ltd. and is owned by Chongqing Yufu Capital Management Group Co., Ltd. as to 56.63%. Chongqing Yufu Capital Management Group Co., Ltd. is a wholly owned subsidiary of Chongqing Yufu Holding Group Co., Ltd., a company wholly owned by the State-Owned Assets Supervision and Administration Commission of Chongqing Municipal Government.

Therefore, each of Suzhou Zisu Investment Consultation Limited Partnership, Suzhou Kington Equity Investment Fund Management Co., Ltd., Shanghai Qianyu Equity Investment Fund Management Co., Ltd., Suzhou Yumeng Investment Management Co., Ltd., Qian Xin, Yinhua Changan Capital Management (Beijing) Co., Ltd., Yinhua Fund Management Co., Ltd., Southwest Securities Co., Ltd., Chongqing Yufu Capital Management Group Co., Ltd., Chongqing Yufu Holding Group Co., Ltd. and the State-Owned Assets Supervision and Administration Commission of Chongqing Municipal Government is deemed to be interested in our Shares held by Suzhou Suzi.

(3) Suzhou Kington Equity Investment Fund Management Co., Ltd. is the general partner of Suzhou Yipu No. 1 Chuangzhe Management Consultation Limited Partnership and Suzhou Zisu Investment Consultation Limited Partnership, and is therefore deemed to be interested in our Shares held by Kington Capital and Suzhou Suzi.

(4) Suzhou Private Capital Investment holds 100% equity interest in Suzhou Kington Equity Investment Fund Management Co., Ltd. and is therefore deemed to be interested in our Shares held by Kington Capital and Suzhou Suzi.

Save as disclosed above, so far as our Directors, Supervisors, and chief executives of our Company are not aware of any person, not being a Director, Supervisor, and chief executive of our Company, who has an interest or short position in the Shares and underlying Shares of Our Group which, once our H Shares are listed, would have to be disclosed to us under the provisions of Division 2 and 3 of Part XV of the SFO, or who is, directly or indirectly, interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of our Group.

**B. Directors, Supervisors or Chief Executives**

Save as disclosed above in "– 4. Disclosure of Interests – A. Substantial Shareholders" in this section, immediately following completion of the Global Offering (and assuming the Over-allotment Option is not exercised), none of our Directors, Supervisors or chief executive of the Company has any interest and/or short position in the Shares, underlying Shares and debentures of the Company or any of its associated corporations (within the meaning of Part XV of the SFO), which will have to be notified to us and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions which has been taken or is deemed to have under such provisions of the SFO) or which will be required, pursuant to section 352 of the SFO, to be entered in the register referred to therein, or will be required, pursuant to the Model Code for Securities Transactions by Directors of Listed Issuers to be notified to the Company and the Stock Exchange (for this purpose, the relevant provisions of the SFO will be interpreted as if they applied to the Supervisors).


Shanghai Miracogen Inc.- Ex. 2032, Page 000809

## C. Disclaimers

Save as disclosed in this Prospectus:

(a) none of our Directors, Supervisors or chief executive of Our Company has any interests and short positions in the shares, underlying shares and debentures of Our Company or any associated corporation (within the meaning of Part XV of the SFO) which will have to be notified to us and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions which he is taken or deemed to have under such provisions of SFO) or which will be required, pursuant to section 352 of the SFO, to be entered in the register referred to therein, or will be required, pursuant to the Model Code for Securities Transactions by Directors of Listed Companies to be notified to us and the Stock Exchange, in each case once our Shares are listed. For this purpose, the relevant provisions of the SFO will be interpreted as if they applied to the Supervisors;

(b) none of our Directors or Supervisors is a director or employee of a company which is expected to have an interest in the Shares falling to be disclosed to the Company and the Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO once our Shares are listed on the Stock Exchange;

(c) none of our Directors or Supervisor nor any of the parties listed in "– 6. Other Information – G. Qualification of Experts" of this Appendix is materially interested in any contract or arrangement subsisting at the date of this Prospectus which is significant in relation to our business;

(d) none of our Directors or Supervisor nor any of the parties listed in "– 6. Other Information – G. Qualification of Experts" of this Appendix is interested in our promotion, or in any assets which have, within two years immediately preceding the issue of this Prospectus, been acquired or disposed of by or leased to us, or are proposed to be acquired or disposed of by or leased to our Company;

(e) none of the parties listed in the paragraph headed "– 6. Other Information – G. Qualification of Experts" of this Appendix: (i) is interested legally or beneficially in any of our Shares or any shares in any of our subsidiaries; or (ii) has any right (whether legally enforceable or not) to subscribe for or to nominate persons to subscribe for our securities; and

(f) none of our Directors or Supervisors or their respective associates or any Shareholders of our Company (who to the knowledge of our Directors owns more than 5% of our issued share capital) has any interest in our five largest suppliers or our five largest customers.



Shanghai Miracogen Inc.- Ex. 2032, Page 000810

## 5. EMPLOYEE SHARE OWNERSHIP PLAN

We have established an Employee Share Ownership Plan in December 2020 to attract and retain the talents and to provide incentives that align the interests of shareholders, the Company and employees, for long-term development of the Company. The ESOP was approved and adopted pursuant to the Board resolution dated December 7, 2020. The terms of the ESOP are not subject to the provisions of Chapter 17 of the Listing Rules.

### (a) ESOP Platform

We have incorporated Shanghai Chunrui, a limited partnership, on December 12, 2019 as an employee share ownership platform for the ESOP and the general partner of Shanghai Chunrui is Huarui Zongheng (Beijing) Technology Co., Ltd. (華瑞縱橫(北京)科技有限公司) ("Huarui Zongheng"), a limited liability company incorporated in the PRC and wholly owned by Dr. Pu Zhongjie. Huarui Zongheng holds 9.70% partnership interest in Shanghai Chunrui. The limited partners of Shanghai Chunrui are Shanghai Pengjin Technology Co., Ltd. (上海芃槿科技有限公司) ("Pengjin"), Shanghai Zhupai Technology Limited Partnership (上海築湃科技合夥企業(有限合夥)) ("Zhupai"), Shanghai Renhong Technology Limited Partnership (上海韌宏科技合夥企業(有限合夥)) ("Renhong"), and Shanghai Zhulin Technology Limited Partnership (上海築麟科技合夥企業(有限合夥)) ("Zhulin"), which hold 55.92%, 20.26%, 8.19% and 5.93% of the partnership interests of Shanghai Chunrui, respectively. All matters of Shanghai Chunrui shall be approved by the majority of the partners, including the general partner and limited partners, with each partner holding one vote.

Set out below is the holding structure of the limited partners of Shanghai Chunrui as of the Latest Practicable Date:

- ***Pengjin***: Pengjin is a limited liability company incorporated in the PRC on November 26, 2020 and is an incentive platform for foreign employees of our Group who hold equity interest in Pengjin through Shanghai Pengshan Technology Co., Ltd. (上海芃杉科技有限公司) ("Shanghai Pengshan"), the parent company of Pengjin. Shanghai Pengshan is held by Dr. Hu Chaohong, our executive Director, as to 17.88%, and the remaining 82.12% equity interest in Shanghai Pengshan is held by four members of the senior management of the Company with none of them individually holding more than one-third of the equity interest of Shanghai Pengshan.

- ***Zhupai***: Zhupai is a limited partnership incorporated in the PRC on October 22, 2020 and is an incentive platform for Chinese employees of our Group. The general partner of Zhupai is Dr. Sui Ziye, our executive Director, who holds 49.37% partnership interest in Zhupai, and the rest of the 50.63% partnership interests in Zhupai are held by 49 limited partners who were granted partnership interest for their contribution as senior management and employees of the Group, with none of them individually holding more than one-third of the partnership interest in Zhupai.


Shanghai Miracogen Inc.- Ex. 2032, Page 000811

- ***Renhong***: Renhong is a limited partnership incorporated in the PRC on October 22, 2020 and is an incentive platform for Chinese employees of our Group. A senior management member of our Group is the general partner of Renhong and holds 0.24% partnership interests in Renhong. None of the 46 limited partners of Renhong, who were granted partnership interest for their contribution as senior management and employees of the Group, individually holds more than one-third of the partnership interest of Renhong.

- ***Zhulin***: Zhulin is a limited partnership incorporated in the PRC on October 22, 2020 and is an incentive platform for Chinese employees. Save for Ms. Li Yunyi, a senior management member of the Company, who is the general partner of Zhulin and holds 33.40% of the partnership interest of Zhulin, none of the 49 limited partners of Zhulin, who were granted partnership interest for their contribution as senior management and employees of the Group, individually holds more than one-third of the partnership interest of Zhulin.

**(b) Administration**

The Board is responsible for reviewing and approving the ESOP together with its amendment and termination. The chairman of the Board is responsible for drafting and amending the ESOP and determining the participants to be enrolled under the ESOP. The board of supervisors oversees the implementation of the ESOP and reviews the participants list proposed by the chairman of the Board. Participants shall hold the shares granted under the ESOP through indirectly holding partnership interest in Shanghai Chunrui, the shareholding platform of the ESOP.

**(c) Qualification of Participants under the ESOP**

To be qualified under the ESOP, the participants shall:

(i) pass the performance review as set out by the chairman of the Board; and

(ii) serve as a director, senior management, middle-level management or core technical/business employees of the Company or its subsidiaries;

and shall not:

(iii) serve as an independent non-executive director or supervisor of the Company or its subsidiaries;

(iv) have been denounced publicly or announced as an inappropriate candidate by a stock exchange in the past three years;


Shanghai Miracogen Inc.- Ex. 2032, Page 000812

(v) have been subject to administrative punishment imposed by the relevant authorities for his or her material breach of laws, rules or regulations during the past three years;

(vi) have other circumstances provided under the PRC Company Law that disqualifies a person to be a director, supervisor or senior management of a company; or

(vii) have other circumstances that the chairman of the Board believes to be a material breach of the Company's rules and regulations.

**(d) Term**

The ESOP commenced on December 7, 2020 and shall continue to be effective so long as Shanghai Chunrui holds Shares of the Company, subject to termination by the Company for development concerns or pursuant to applicable laws and regulations.

**(e) Shares and Share Price Granted under the ESOP**

On December 7, 2020, 151 eligible employees were granted 45,149,702 shares of the Company, 33,887,202 shares of which are vested over a four-year contractual term of service while the remaining 11,262,500 shares, held by certain senior management, were vested immediately pursuant to the supplementary agreements entered into in April 2021. The price per Share granted to each participant under the ESOP is RMB1.00 and the participants shall pay the relevant price to Shanghai Chunrui within ten business days from the grant date. Other than the 45,149,702 shares granted, we do not expect to grant additional share awards under the ESOP. Immediately following completion of the Global Offering, the aggregate number of shares of the Company underlying the ESOP will be 45,149,702, all of which will be held by Shanghai Chunrui. As a result, the ESOP will not cause any dilution of the shareholding of our Shareholders immediately after the Global Offering. For further details on the interest of our connected persons and employees granted under the ESOP, please refer to the partnership interest of Shanghai Chunrui in the section headed "5. Employee Share Ownership Plan – (a) ESOP Platform".


Shanghai Miracogen Inc.- Ex. 2032, Page 000813

**(f) Repurchase of Shares Granted**

Under the following circumstances, the Shares granted under the ESOP may be repurchased at the grant price of RMB1.00 per Share, subject to adjustment if there is any capital increase, conversion of capital reserve into capital or bonus share issuance at Company level after the grant:

(i) termination of the participant's employment relationship with the Company or any of its subsidiaries (each an "ESOP Employer"), as applicable, for the following reasons:

- the participant's material breach of the employment contract or other rules set by the ESOP Employer;
- the participant enters into employment relationship with other employers which adversely affect his or her work at the ESOP Employer or the participant refuses to terminate employment relationship with other employers;
- the participant's negligence or malpractice resulting in material damage to the ESOP Employer;
- the participant engages in business that competes with the ESOP Employer;
- the employment contract was concluded or amended as a result of fraudulence, coercion or taking advantage of the ESOP employer;
- the participant is subject to criminal sanctions;
- the ESOP's interest or reputation is jeopardized as a result of the participant's violation of law, professional ethics, confidential information leakage or other malpractices;
- the participant is not competent for the job and after training and reallocation of work, still cannot achieve satisfactory results;
- the participant's absence without approval of the ESOP Employer;
- the participant resigns or is not willing to extend employment contract with the ESOP Employer;
- any other circumstances that results in the termination of employment contract except internal job transfer between the Company and its subsidiaries; and
- disability of the participant as a result of non-occupational injuries.


Shanghai Miracogen Inc.- Ex. 2032, Page 000814

(ii) the participant has been disqualified due to the following circumstances after being granted the incentive Shares:

- the participant has been denounced publicly or announced as an inappropriate candidate by a stock exchange in the past three years;
- the participant has been subject to administrative punishment imposed by the relevant authorities for his or her material breach of laws, rules or regulations during the past three years; and
- any other circumstances provided under the PRC Company Law that disqualifies a person to be a director, supervisor or senior management of a company.

(iii) other circumstances as determined by the chairman of the Board.

If the participant retires at statutory retirement age, terminates employment contract with the ESOP Employer as a result of occupational injury, or is dead, the Shares granted under the ESOP shall not be affected. In the case that the participant is dead, the participant's designated beneficiary or other legitimate heir may succeed the Shares granted to such participant.

**(g) Selling Shares**

After listing of the Company, the participants are entitled to sell, once a year, all or partial of the incentive Shares under the organization of the general partner of Shanghai Chunrui or other parties designated by the general partner of Shanghai Chunrui, subject to a four-year contractual term of service arrangement. The tax applicable to such sell-out shall be borne by the participants.

**(h) Restrictions of Transfer**

Prior to the listing of the Company, the participants shall not transfer the Shares granted under the ESOP unless approved by the chairman of the Board and to below transferees at a price negotiated between the parties, with applicable tax borne by the transferring participant:

(i) general partner of Shanghai Chunrui;

(ii) participants under the ESOP; and

(iii) other employees approved by the chairman of the Board.

The transfer of the Shares by the participants are also subject to the relevant undertakings given by such participants under the applicable laws, rules, regulations, securities regulations or stock exchanges.



Shanghai Miracogen Inc.- Ex. 2032, Page 000815

## 6. OTHER INFORMATION

### A. Estate Duty

We have been advised that no material liability for estate duty under the PRC law is likely to fall upon our Company or any member of our Group.

### B. Litigation

As of the Latest Practicable Date, save as disclosed in this Prospectus, we were not involved in any material litigation, arbitration or administrative proceedings, and so far as our Directors are aware, no such material litigation, arbitration or administrative proceedings are pending or threatened against any member of our Group.

### C. Joint Sponsors

Each of the Joint Sponsors has declared its independence pursuant to Rule 3A.07 of the Listing Rules.

The Joint Sponsors have made an application on our behalf to the Listing Committee for listing of, and permission to deal in, our H Shares, including any Offer Shares which may be issued pursuant to the exercise of the Over-allotment Option. All necessary arrangements have been made to enable the H Shares to be admitted into CCASS.

We have entered into an engagement agreement with the Joint Sponsors, pursuant to which we agreed to pay a total amount of US$800,000 to the Joint Sponsors to act as our sponsors to our Company in the Global Offering.

### D. Compliance Adviser

We have appointed Maxa Capital Limited as our compliance adviser in compliance with Rule 3A.19 of the Listing Rules.

### E. Preliminary Expenses

As of the Latest Practicable Date, our Company has not incurred material preliminary expenses.



Shanghai Miracogen Inc.- Ex. 2032, Page 000816

## F. Promoters

The promoters of our Company are Ningbo Houde Yimin, Miracogen HK, Mr. Su Rongyu, Shanghai Lvyuan, Shanghai Chunrui, certain of the Series A Investors and the Series B Investors. For details of our promoters, please see "History, Development and Corporate Structure – Corporate Development – Subsequent Capital Increase and Equity Transfer – Conversion."

Save as disclosed in this Prospectus, within the two years immediately preceding the date of this Prospectus, no cash, securities or other interest have been paid, allotted or given to the above promoters in connection with the Global Offering or related transactions in this Prospectus.

## G. Qualification of Experts

The qualifications of the experts, as defined under the Listing Rules, who have given their opinions or advice in the Prospectus, are as follows:

| Name | Qualification |
|---|---|
| China International Capital Corporation Hong Kong Securities Limited | A licensed corporation to conduct Type 1 (dealing in securities), Type 2 (dealing in futures contracts), Type 4 (advising on securities), Type 5 (advising on futures contracts) and Type 6 (advising on corporate finance) of the regulated activities under the SFO |
| Morgan Stanley Asia Limited | A licensed corporation under the SFO to carry on type 1 (dealing in securities), type 4 (advising on securities), type 5 (advising on futures contracts), type 6 (advising on corporate finance) and type 9 (asset management) regulated activities |
| PricewaterhouseCoopers | Certified Public Accountants under Professional Accountants Ordinance (Cap. 50 of the Laws of Hong Kong)<br><br>Registered Public Interest Entity Auditor under Financial Reporting Council Ordinance (Cap. 588 of the Laws of Hong Kong) |
| Zhong Lun Law Firm | PRC legal adviser |
| Frost & Sullivan (Beijing) Inc., Shanghai Branch Co. | Independent industry consultant |
| Avista Valuation Advisory Limited | Property Valuer |



Shanghai Miracogen Inc.- Ex. 2032, Page 000817

## H. Consents of Experts

Each of the experts as referred to in "– 6. Other Information – G. Qualification of Experts" of this Appendix has given, and has not withdrawn, its respective written consents to the issue of this Prospectus with the inclusion of its reports and/or letter and/or opinion and/or the references to its name included herein in the form and context in which it is respectively included.

As of the Latest Practicable Date, none of the experts named above has any shareholding interests in any member of our Group or the right (other than the penal provisions) of sections 44A of the Companies (Winding Up and Miscellaneous Provisions) Ordinance so far as applicable.

## I. Taxation of Holders of H Shares

The sale, purchase and transfer of H shares are subject to Hong Kong stamp duty if such sale, purchase and transfer are effected on the H share register of members of our Company, including in circumstances where such transaction is effected on the Stock Exchange. The current rate of Hong Kong stamp duty for such sale, purchase and transfer is a total of HK$2.60 for every HK$1,000 (or part thereof) of the consideration or, if higher, the fair value of the H shares being sold or transferred. For further information in relation to taxation, see "Appendix V – Taxation and Foreign Exchange" in this Prospectus.

## J. No Material Adverse Change

Save as disclosed in this Prospectus, our Directors confirm that there has been no material adverse change in our financial or operational position since August 31, 2021 and up to the Latest Practicable Date.

## K. Binding effect

This Prospectus shall have the effect, if an application is made in pursuance hereof, of rendering all persons concerned bound by all the provisions (other than the penal provisions) of sections 44A and 44B of the Companies (Winding Up and Miscellaneous Provisions) Ordinance so far as applicable.

## L. Related Party Transactions

Within the two years immediately preceding the date of this Prospectus, we have entered into the related party transactions as described in Note 40 to the financial information in the Accountant's Report set out in Appendix I.


Shanghai Miracogen Inc.- Ex. 2032, Page 000818

## M. Agency Fees or Commissions Paid or Payable

Save as disclosed in this Prospectus, no commissions, discounts, brokerages or other special terms have been granted in connection with the issue or sale of any capital of any member of our Group within the two years preceding the date of this Prospectus.

## N. Miscellaneous

Save as disclosed in this Prospectus:

(a) within the two years immediately preceding the date of this Prospectus, we have not issued or agreed to issue any share or loan capital fully or partly paid either for cash or for a consideration other than cash;

(b) no share or loan capital of our Group, if any, is under option or is agreed conditionally or unconditionally to be put under option;

(c) we have not issued or agreed to issue any founder shares, management shares or deferred shares;

(d) our Company has no outstanding convertible debt securities or debentures;

(e) there are no restrictions affecting the remittance of profits or repatriation of capital by us into Hong Kong from outside Hong Kong;

(f) within the two years immediately preceding the date of this Prospectus, no commission, discount, brokerage or other special term has been granted in connection with the issue or sale of any capital of our Company;

(g) there is no arrangement under which future dividends are waived or agreed to be waived;

(h) there has been no interruption in our business which may have or have had a significant effect on the financial position in the last 12 months; and

(i) none of the equity and debt securities of our Company, if any, is listed or dealt with in any other stock exchange nor is any listing or permission to deal being or proposed to be sought.

## O. Bilingual Prospectus

The English language and Chinese language versions of this Prospectus are being published separately, in reliance upon the exemption provided by section 4 of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong).



Shanghai Miracogen Inc.- Ex. 2032, Page 000819

## DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES IN HONG KONG

The documents attached to the copy of this prospectus delivered to the Registrar of Companies in Hong Kong for registration were, among other documents:

(a) copies of the **GREEN** Application Form;

(b) the written consents referred to under the paragraph headed "Statutory and General Information – 6. Other Information – H. Consents of Experts" in Appendix VIII to this prospectus; and

(c) copies of the material contracts referred to in the paragraph headed "Statutory and General Information – 2. Further Information about Our Business – A. Summary of Our Material Contracts" in Appendix VIII to this prospectus.

## DOCUMENTS AVAILABLE ON DISPLAY

Copies of the following documents will be published on the Stock Exchange's website (www.hkexnews.hk) and the Company's own website (www.lepubiopharma.com) for a period of time for 14 days from the date of this prospectus:

(a) the Articles of Association;

(b) the Accountant's Report from PricewaterhouseCoopers, the text of which is set out in Appendix I to this prospectus;

(c) the report on the unaudited pro forma financial information of our Group from PricewaterhouseCoopers, the text of which is set out in Appendix II to this prospectus;

(d) the letters from PricewaterhouseCoopers and the Joint Sponsors relating to the loss estimate, the texts of which are set out in Appendix III to this prospectus;

(e) the audited consolidated financial statements of our Group for the years ended December 31, 2019 and 2020 and the eight months ended August 31, 2021;

(f) the legal opinions issued by Zhong Lun Law Firm, our PRC Legal Advisor, in respect of the general matters and property interests of our Group;

(g) the PRC Company Law, the Mandatory Provisions and the Special Regulations together with their unofficial translation;



Shanghai Miracogen Inc.- Ex. 2032, Page 000820

(h) the written consents referred to under the paragraph headed "Statutory and General Information – 6. Other Information – H. Consents of Experts" in Appendix VIII to this prospectus;

(i) the material contracts referred to in "Statutory and General Information – 2. Further Information about Our Business – A. Summary of Our Material Contracts" in Appendix VIII to this prospectus;

(j) the service contracts and the letters of appointment with our Directors referred to in "Statutory and General Information – 3. Further Information about our Directors and Supervisors – A. Particulars of Directors' and Supervisor's Contracts" in Appendix VIII to this prospectus;

(k) the industry report issued by Frost & Sullivan, the summary of which is set forth in the section headed "Industry Overview" in this prospectus; and

(l) the valuation report relating to certain property interest of our Company prepared by AVISTA Valuation Advisory Limited, the text of which is set out in Appendix IV to this prospectus.



Shanghai Miracogen Inc.- Ex. 2032, Page 000821

乐普生物
LEPU BIOPHARMA