

SUMMARY

This summary aims to give you an overview of the information contained in this document. As this is a summary, it does not contain all the information that may be important to you. You should read the entire document carefully before you decide to invest in the [REDACTED]. In particular, we are a biotechnology company seeking a [REDACTED] 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. Moreover, there are risks associated with any investment. Some of the particular risks in investing in the [REDACTED] are set out in the section headed “Risk Factors.” You should read that section carefully.

OVERVIEW

Founded in 2010, we are a biotechnology company dedicated to developing bispecific antibody (BsAb)-based therapies to treat cancer or cancer-associated complications and age-related ophthalmologic diseases. We have designed and developed a pipeline of seven clinical-stage drug candidates, including (i) our Core Product M701, a recombinant BsAb that targets human epithelial cell adhesion molecule (EPCAM)-expressing cancer cells and human cluster of differentiation 3 (CD3)-expressing T cells. We are currently conducting a Phase II clinical trial of M701 in treating malignant ascites (MA) and a Phase Ib/II clinical trial of M701 in treating malignant pleural effusion (MPE), (ii) M802 and Y150, T cell-engaging BsAbs for cancer treatment, (iii) Y101D and Y332, tumor microenvironment (TME)-targeted BsAbs, (iv) Y400, a targeted therapy for the treatment of age-related ophthalmologic diseases, and (v) Y2019, a COVID-19 vaccine. We have strategically developed proprietary technology platforms, including YBODY® platform, Check-BODY platform and Nano-YBODY™ platform to support the R&D of our BsAbs.

WE MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP OR MARKET OUR CORE PRODUCT OR ANY OF OUR PIPELINE PRODUCTS.

Pipeline of Drug Candidates

We have designed and developed a pipeline of seven clinical-stage drug candidates. We carefully select potential targets for our drug candidates, and focus on the therapeutic areas with market potentials where fewer market players have expertise and resources. In particular,



- We have strategically focused on the development of the T cell-engaging BsAbs. We have developed three T cell-engaging BsAbs, namely M701, M802 and Y150;
- We have adopted the therapeutic strategy towards the efficient targeting of tumor microenvironment (TME). TME plays a critical role in tumor initiation, development and progression, and therefore is becoming an emerging treatment target for cancer. We are developing two drug candidates targeting TME, namely Y101D and Y332;
- We are developing Y400, a targeted therapy for the treatment of age-related ophthalmologic diseases.

Our R&D efforts focus on the development of BsAbs. A BsAb is an artificial protein that recognizes and specifically binds two antigens or epitopes. The advantages of BsAbs include the potential effects on various cancers, the application to retarget effector cells of the immune system and stimulate them through the interaction to achieve an efficient lysis of tumor cells. On the other hand, BsAbs also have limitations, including low expression of the target structures, non-human nature, limiting the dosage that can be given to patients. For more details, please refer to the paragraphs headed “Industry Overview – Global and China Antibody Drug Market” in this document.

SUMMARY

The following pipeline chart summarizes the development status of our selected drug candidates:

Candidate ¹	Target	Technology Platform	Type	Regimen	Indication	Pre-clinical	IND	Phase I		Phase II	Phase III/ Pivotal	Commercial Rights	Current Status/ Upcoming Milestone
								Phase Ia	Phase Ib				
★ M701	EPCAM&CD3	YBODY®	BsAb	Mono	Malignant ascites							Global	Phase II commenced in Dec 2021; Expect to initiate Phase III/pivotal trial in Q1 2024 and submit the BLA in Q1 2025
					Malignant pleural effusion						Global	Phase Ib/II commenced in Nov 2022; Expect to initiate Phase III/pivotal trial in Q3 2024 and submit the BLA in Q4 2025	
					Solid tumor					Global	Expect to file IND application in Q1 2024 and initiate Phase III in Q2 2024		
Y101D	PD-L1&TGF-β	Check-BODY	BsAb	Mono	Solid tumors							Global	Phase I commenced in Aug 2021; Expect to complete Phase I in Q4 2023
					Pancreatic cancer						Global	Phase Ib/II commenced in Feb 2023; Expect to complete Phase Ib/II in Q3 2024 and initiate Phase III in Q4 2024	
					Hepatocellular carcinoma and other advanced solid tumors					Global	Phase Ib/II commenced in Mar 2023; Expect to complete Phase Ib/II in Q2 2025		
Y150	CD38&CD3	YBODY®	BsAb	Mono	Small cell lung cancer							Global	Expect to file IND application in Q3 2023; Expect to initiate Phase Ib/II in Q1 2024
					Relapse or refractory multiple myeloma						Global	Phase I commenced in Aug 2021; Expect to complete Phase I in Q2 2024	
					Relapse or refractory multiple myeloma						Global	Expect to file IND application after the completion of the Phase II portion of Phase Ib/III clinical trial of Y150 monotherapy for rMM	
Y2019⁵	SARS-CoV-2 RBD homodimer	UVAX®	Vaccine	Mono	COVID-19							Global	Completed Phase Ia
					HER2-positive solid tumors						Global	Completed Phase I	
Y332	VEGF×TGF-β	Nano-YBODY™	BsAb	Mono	Solid tumors							Global	IND application approved in Apr 2023; Expect to initiate Phase I in Q3 2023
Y400	VEGF×ANG2	Nano-YBODY™	BsAb	Mono	wAMD, DME and other ocular neovascularization related diseases							Global ⁴ CMS Vision	IND application approved in Apr 2023

★ Core Product  Clinical Stage  Pre-clinical Stage

Notes:
 (1) Except for Y2019, all of our drug candidates are in-house developed.
 (2) Specific combination drug(s) of the trial will be decided prior to the commencement of the trial.
 (3) We completed a Phase Ia clinical trial for Y2019 in China in August 2022 which evaluates the safety and tolerability of Y2019 in healthy adults, and obtained ethical committee approval for the Phase Ia clinical trial. Given the evolution of the COVID-19 epidemic and the increasing number of individuals gaining immunity due to COVID-19 infection, there are uncertainties surrounding the market demand for the COVID-19 vaccine, hence we currently have no immediate plans to initiate the Phase Ia clinical trial for Y2019.
 (4) We have transferred all the rights and assets of Y400 to CMS Vision. We are entitled to receive an upfront payment, milestone payments upon the occurrence of certain pre-agreed milestone events, and tiered royalties based on net sales. We have received the full upfront payment of US\$5 million for Y400. We, at our own cost, are responsible for all the pre-clinical studies of Y400 that are necessary for (i) the IND application and (ii) the Phase I clinical trial, if any, in accordance with the standards and requirements set by the CDE. Furthermore, if requested by CMS Vision, we will also be responsible for, at CMS Vision's cost, non-clinical toxicology studies of Y400 that are necessary in the Phase II and Phase III clinical trials and CMC studies in Phase III clinical trials in China. For more details, please refer to the paragraphs headed “Collaboration Agreements – Collaboration with CMS Vision” in this section.
 (5) Some of our drug candidates are not included in the pipeline chart as they are at the early preliminary stage.

Abbreviations: Mono refers to monotherapy; Combo refers combination therapy; EpCAM refers to human epithelial cell adhesion molecule; CD3 refers to cluster of differentiation 3; PD-L1 refers to programmed death ligand 1; TGF-β refers to transforming growth factor-β; CD38 refers to cluster of differentiation 38; COVID-19 refers to coronavirus disease 2019; RBD refers to recombinant receptor-binding domain; HER2 refers to human epidermal growth factor receptor 2; VEGF refers to vascular endothelial growth factor; ANG2 refers to angiopoietin-2; wAMD refers to wet age-related macular degeneration; and DME refers to diabetic macular edema.

SUMMARY

M701 (EpCAM × CD3 BsAb) – Our Core Product

M701 is a recombinant BsAb that targets EpCAM-expressing cancer cells and CD3-expressing T cells. M701 binds to both tumor cells and T cells by using EpCAM as the target on tumor cells and CD3 as the target on T cells, respectively. M701 binds to EpCAM and blocks the downstream signal of EpCAM, and thus can inhibit tumor growth. By binding to T cell surface antigen CD3, M701 promotes T cell activation and proliferation and the release of cytokines to kill tumor cells. M701 also shows cytotoxicity against tumor cells through antibody-dependent cell-mediated cytotoxicity (ADCC), and complement-dependent cytotoxicity (CDC). For more details on the mechanism of action of M701, please refer to the paragraphs headed “Business – Our Drug Candidates – M701 (EpCAM × CD3 BsAb) – Our Core Product – Mechanism of Action” in this document.

Clinical development status, results and plan

We completed a Phase I clinical trial of M701 in treating MA in January 2022. We have enrolled a total of 35 subjects in this Phase I trial. Of the 35 enrolled patients, 18 of them have completed the 4-week core treatment period in the escalation phase. Reasons for patients not completing the 4-week core treatment period in the escalation phase primarily include patient withdrawal, and secondarily are disease progression, adverse effects (AEs), and recommendation from the investigators. An objective response rate (ORR) of 61.1% and a disease control rate (DCR) of 94.4% were achieved in this trial. The median overall survival (mOS) reached 151.5 days in this clinical trial. Furthermore, 15 out of 35 enrolled subjects did not experience any TRAE, and only 5 patients experienced Grade 3 TRAEs during the trial, indicating the manageable safety profile of M701. The preliminary claim of efficacy of M701 based on the Phase I data only relies on a limited number of patients and may not be indicative of future clinical results.

We are currently conducting a Phase II clinical trial to evaluate the efficacy of M701 monotherapy in combination with systematic treatment (including targeted therapy, immunotherapy or chemotherapy) in MA patients, and expect to complete this clinical trial in the fourth quarter of 2023. After the completion of this Phase II trial, we plan to commence a pivotal/Phase III trial for M701 in treating MA in China in the first quarter of 2024 and file BLA submission in the first quarter of 2025. Furthermore, we are conducting a Phase Ib/II clinical trial of M701 for MPE in China and expect to complete this trial in the third quarter of 2024. Following the completion of this Phase Ib/II trial, we plan to commence a pivotal/Phase III trial for M701 for the treatment of MPE (instead of NSCLC) in China in the third quarter of 2024 and file BLA submission in the fourth quarter of 2025. For more details on the clinical development plan of M701, please refer to the paragraphs headed “Business – Our Drug Candidates – M701 (EpCAM × CD3 BsAb) – Our Core Product – Clinical Development Plan” in this document.

Market opportunities

We are developing M701 primarily for the treatment of MA and MPE, which are severe complications that typically occur in late-stage cancer patients who have widespread metastases to the pleura or peritoneum. These patients represent a subset of the overall cancer population. MA commonly occurs in patients with various types of cancer, including ovarian, gastric, and pancreatic cancers. In patients with ovarian cancer, the incidence of MA is about 45%-50%, in gastric cancer patients, the incidence is approximately 25%, and in pancreatic cancer patients, the incidence is around 21%. MPE often occurs in patients with lung cancer, breast cancer, and lymphoma. In lung cancer patients, the incidence of MPE is about 45%, and in breast cancer patients, the incidence is approximately 11%. Considering the incidence rate of MA and MPE in these types of cancer, the incidence of MA and MPE in China reached 591.8 thousand and 605.6 thousand in 2021, is expected to be approximately 654.0 thousand and approximately 683.1 thousand in 2025, respectively, and approximately 729.8 thousand and 779.1 thousand in 2030, respectively. The China market size of MA therapies is expected to grow from RMB10.7 billion in 2021 to RMB12.4 billion in 2025 and RMB14.7 billion in 2030 while China market size for MPE therapies is expected to grow from RMB11.6 billion in 2021 to RMB13.2 billion in 2025 and RMB15.3 billion in 2030. For more details, please refer to the paragraphs headed “Industry Overview – CD3 Targeted Bispecific Antibody Market – EpCAM x CD3 Targeted BsAb” in this document.

MA and MPE are serious cancer complications that significantly impact the quality of life of patients. MA can lead to abdominal distension, abdominal pain, bowel obstruction, hypokalemia, hyponatremia, hypoalbuminemia, and anemia, leading to poor appetite, electrolyte disorders, systemic edema, and fatigue. This causes patients to be bedridden and require day care, which increases the cost of care, decreases the quality of life of patients, and

SUMMARY

reduces the opportunity for patients to continue systematic treatments, impacting their survival time. MPE can lead to chest pain, chest tightness, difficulty breathing, accompanied by fatigue, poor appetite, and also reduces the opportunity for patients to receive systematic treatments.

Current treatment options for MA and MPE primarily are medical therapies, including paracentesis, diuretics such as spironolactone, hyperthermic intraperitoneal chemotherapy and manual aspiration. Given that MA and MPE are complications of cancer, the current treatment paradigm for MA and MPE do not distinguish between first-line/second-line/later-line therapies. In clinical application, we expect M701 monotherapy could be used in addition to paracentesis to control MA and MPE, with an aim to improve the effectiveness and reduce the side effects of frequent paracentesis.

Competitive landscape

As of the Latest Practicable Date, there were one drug applying for renewal of marketing authorization and six pipelines of innovative therapies under clinical development globally that were specifically developed for the treatment of MA and MPE, including two BsAbs, three cell therapy pipelines and one polypeptide pipeline and one pipeline of other proteins, as illustrated below.

Global Pipeline							
Product	Developer	Highest Clinical Stage	Indication	Region	Drug Type	Target	First Posted Date ⁽¹⁾
Catumaxomab	TRION Pharma GmbH and Neovii Biotech GmbH	Approved in 2009, withdrew from market in 2017, applied for renewal of the marketing authorization in 2022	Cancer, Neoplasms, Carcinoma, MA	France, Germany, Italy, Spain	BsAb	EpCAM, CD3	–
ENDOSTAR™	Jiangsu Simcere Pharmaceutical Co., Ltd.	Phase III	MPE, Malignant Peritoneal Effusion	China	Other Protein	Endostatin	2021/05/27
M701	the Company	Phase II	MA	China	BsAb	EpCAM, CD3	2021/07/23
M701	the Company	Phase Ib/II	MPE	China	BsAb	EpCAM, CD3	2022/08/08
GAIA-102	Gaia BioMedicine Inc; Kyushu University Hospital	Phase II	MA, Stomach Neoplasms, Pancreatic Neoplasms, Carcinoma, NSCLC	Japan	Cell Therapy	–	2021/11/19
RSO-021	RS Oncology LLC	Phase I/II	MPE, Malignant Pleural Mesothelioma, Mesothelioma, Solid Tumor	United Kingdom	Polypeptide	–	2022/02/07
VAK	Wuhan Binhui Biotechnology Co., Ltd.	Phase I	MPE, Malignant Peritoneal Effusion	China	Cell Therapy	–	2022/09/29
IFN-γ and CIK cells, Tem cells or CAR-T cells	Affiliated Hospital of Jiangnan University	Phase I	MPE	China	Cell Therapy	–	2022/03/07

Source: NMPA, CDE, FDA, ClinicalTrials.gov, Frost & Sullivan Analysis

(1) “First Posted Date” in terms of global clinical trials refers to the date when the study corresponding to the global highest clinical phase (except China) was first available on ClinicalTrials.gov after the National Library of Medicine has concluded its quality control review; “First Posted Date” in the context of China clinical trials refers to the date when the study corresponding to the highest clinical phase in China was first available on chinadrugtrials.org.cn after the Center for Drug Evaluation (CDE) has concluded its review. The CDE is an affiliated institution of the NMPA.

Among them, catumaxomab (developed by TRION Pharma GmbH and Neovii Biotech GmbH) is the world’s first marketed BsAb and has two targets identical to M701 which was approved in 2009 for the treatment of MA. Upon the initial commercial launch of catumaxomab in 2009, based on public information, the medical community’s understanding of immunotherapy and BsAb was not fully developed, which limited the comprehension of the mechanism of actions of catumaxomab, resulting in a relatively cautious approach towards the clinical application of the drug. Moreover, based on public information, the developers of catumaxomab fell short in formulating a market-oriented marketing strategy for catumaxomab, which led to poor sales performance after its launch and its subsequent withdrawal from the

SUMMARY

market in 2017. Catumaxomab was marketed in Europe only and the withdrawal of catumaxomab only impacted the Europe market. The withdrawal of catumaxomab was primarily due to timing and sales strategy instead of safety and efficacy concerns. Despite of that, as the world’s first BsAb drug, the withdrawal of catumaxomab did impact the overall perception of BsAbs within the medical community for a period of time. However, this perception has gradually improved with the increase in marketed BsAb drugs and their clinical use. Catumaxomab demonstrated manageable safety and encouraging efficacy during its clinical use. Therefore, the developers of catumaxomab applied for the renewal of the EMA marketing authorization of the drug for the treatment of MA in August 2022, which is currently under review.

Moreover, peer products targeting identical molecular targets as M701 are under clinical development. According to public information, besides M701, two BsAb pipelines targeting EpCAM, one CD3-targeted mAb, one CD3-targeted antibody fusion protein and one CAR-T pipeline targeting EpCAM are currently under clinical development globally. As of the Latest Practicable Date, these competitors have not developed their EpCAM × CD3 drug candidates for the treatment of MA/MPE, however we cannot guarantee that these companies will not expand into our target market.

For more details of the competitive landscape of M701, please refer to the paragraphs headed “Business – Our Drug Candidates – M701 (EpCAM × CD3 BsAb) – Our Core Product – Market Opportunities and Competition – Competitive landscape” in this document.

Limitations and imminent risks on the market potential of M701

We face the following limitations and imminent risks on the market potential of M701:

- MA and MPE, the intended indications of M701, are complications of the tumor. The continual refinement of early tumor detection methods, preventive measures, non-drug treatment options, along with the relentless innovation in tumor treatment methodologies, will reduce tumor prevalence and improve early-stage tumor cure rates, subsequently decreases the occurrence of MA and MPE as complications of the tumor.
- Other therapies for primary and metastatic cancers, including but not limited to chemotherapy, targeted therapies, and immunotherapies, while not directly targeting MA and MPE, can help control these complications. Compared to such systematic treatments that have a curative effect on cancer, M701 is primarily used to improve symptoms and complications of cancer, which might be less attractive to doctors and patients. Approximately 10% of patients with mild symptoms of MA and MPE only need these cancer systematic therapies to control their MA and MPE. These therapies for cancer thereby indirectly limit the market size for M701.
- Current medical treatment methods for MA and MPE, including primarily paracentesis, diuretics such as spironolactone, hyperthermic intraperitoneal chemotherapy and manual aspiration, are less costly in nature. Among these current treatment options for MA and MPE, therapeutic paracentesis is recommended by clinical guidelines for controlling MA/MPE which can alleviate symptoms for one to two weeks. In clinical application, we expect M701 monotherapy could be used in addition to paracentesis to control MA and MPE, with an aim to improve the effectiveness and reduce the side effects of frequent paracentesis. However, this method will also be more expensive and may not be affordable by some patients.
- The market size for MA and MPE is relatively limited when compared to the oncology drug market. Comparing with the rapid growth of the oncology drug market in China, the overall growth rate for the China market size of MPE and MA therapies is comparatively stable, which could further limit the market potential of M701.

Y101D (PD-L1 × TGF-β BsAb)

Y101D, a recombinant anti-PD-L1 and anti-TGF-β humanized BsAb, is being developed for the treatment of solid tumors. Y101D is strategically designed to simultaneously inhibit the programmed death 1 (PD-1)/PD-L1 axis and the TGF-β signaling pathways, thus having the potential to unleash a synergistic anti-tumor activity and relieve drug resistance.

SUMMARY

We are currently evaluating Y101D as a monotherapy in a Phase I clinical trial for the treatment of metastatic or locally advanced solid tumors. The interim results of this Phase I clinical study showed an encouraging safety and efficacy profile for Y101D. We commenced a Phase Ib/II clinical trial of Y101D in combination therapy for the treatment of advanced/metastatic pancreatic cancer in February 2023. We commenced a Phase Ib/II clinical trial of Y101D in combination therapy for the treatment of hepatocellular carcinoma (HCC) and other advanced solid tumors in March 2023. In addition, we plan to initiate a Phase Ib/II clinical trial of Y101D in combination with chemotherapy for the treatment of small cell lung cancer (SCLC) in the first quarter of 2024.

The incidence of pancreatic cancer and HCC in China is expected to grow from approximately 115.9 thousand and 388.0 thousand in 2021, respectively, and is expected to increase to approximately 155.8 thousand and 474.2 thousand in 2030, respectively. The addressable late-stage pancreatic cancer and HCC patients of Y101D is estimated to reach 104.7 thousand and 222.9 thousand, respectively, in China in 2030. For more details about the addressable markets of late-stage pancreatic cancer and HCC therapies, please refer to the paragraphs headed “Industry Overview – PD-1/PD-L1 × TGF-β Targeted Drugs Market – China’s Market of PD-1/PD-L1 × TGF-β Targeted Drugs” in this document.

No PD-1/PD-L1 × TGF-β BsAb drug is marketed either globally or in China. There are 16 PD-1/PD-L1 × TGF-β targeted pipelines under clinical trials in China, among which Y101D is the only PD-L1 × TGF-β BsAb and the other 15 pipelines are PD-1/PD-L1 × TGF-β targeted bifunctional antibody receptor fusion proteins, according to the CDE and the ClinicalTrials.gov websites. There is no evidence that BsAbs offer any significant clinical advantages compared to fusion protein antibodies. For a comparative analysis between BsAb and fusion protein antibodies, please refer to the paragraphs headed “Industry Overview – Global and China Antibody Drug Market – Overview” in this document.

For more details of Y101D, please refer to the paragraphs headed “Business – Our Drug Candidates – Y101D (PD-L1 × TGF-β BsAb)” in this document.

Y150 (CD38 × CD3 BsAb)

Y150 is a recombinant anti-CD38 and anti-CD3 humanized BsAb consisting of a fully human anti-CD38 Fab-Fc moiety and a humanized anti-CD3 scFv-Fc moiety. Y150 is well-designed to bind to both CD38 on multiple myeloma (MM) tumor cells and CD3 on T cells, inducing the activation of the T cells, improving the targeting of activated T cells, and allowing the activated T cells to attack the target tumor cells.

We are developing Y150 for the treatment of relapse or refractory multiple myeloma (rrMM) in a Phase I clinical trial. The incidence of MM is expected to increase from approximately 21.7 thousand in 2021 to 27.7 thousand in 2030, and the addressable rrMM patients of Y150 is estimated to reach 60.4 thousand in 2030 in China. For more details about the addressable market of rrMM therapies, please refer to the paragraphs headed “Industry Overview – CD3 Targeted Bispecific Antibody Market – CD38 × CD3 Targeted BsAbs – Multiple Myeloma (MM)” in this document. Current treatment regimens can prolong patient survival only and patients will eventually relapse and succumb to their disease. For most of the patients, MM will eventually develop into rrMM. This makes patients require continuous treatment in order to manage MM as a chronic disease and prefer treatment regimens with convenient administration. Therefore, there remains a need for patients whose disease has relapsed after, or is refractory to, available MM therapies. According to the CDE and the ClinicalTrials.gov websites, there is no CD38 targeted BsAb approved for marketing globally, and Y150 is the only CD38-targeting and T cell-engaging BsAb that has entered into the clinical development in China. As of the Latest Practicable Date, there were 22 and nine CD38 targeted antibody drug candidates or fusion proteins for the treatment of MM under clinical development globally (excluding China) and in China, respectively. Outside of China, there is only one CD38 × CD3 BsAb, namely ISB-1342 of Ichnos Sciences, under development in a Phase I clinical trial. Besides that, SAR442257, an anti-CD38/CD28/CD3 antibody being developed by Sanofi, is also under clinical development, evidencing the therapeutic potentials of the CD38 and CD3 targets. There is no evidence that BsAbs offer any significant clinical advantages compared to fusion protein antibodies. For a comparative analysis of BsAb and fusion protein antibodies, please refer to the paragraphs headed “Industry Overview – Global and China Antibody Drug Market – Overview” in this document.

We are currently evaluating Y150 in a Phase I clinical trial in rrMM in China. The interim results of the Phase I clinical study for Y150 in rrMM in China showed an encouraging safety profile for Y150. We will further explore the clinical efficacy of Y150 monotherapy in treating rrMM patients as well as its potentials in combination therapy. We plan to commence a Phase II/III clinical trial of Y150 monotherapy in China for the treatment of rrMM. We also plan to

SUMMARY

initiate a Phase Ib/II clinical trial for Y150 in combination with lenalidomide as second-line treatment for rrMM after the completion of Phase II portion of Phase II/III clinical trial of Y150 monotherapy for rrMM. For more details of Y150, please refer to the paragraphs headed “Business – Our Drug Candidates – Y150 (CD38 × CD3 BsAb)” in this document.

Y2019 (RBD-dimer Subunit SARS-CoV-2 Vaccine)

Y2019 is a recombinant RBD-dimer subunit SARS-CoV-2 vaccine candidate for COVID-19. We have taken a collaborative approach to develop Y2019.

We completed a Phase Ia clinical trial for Y2019 in China in August 2022 which evaluated the safety and tolerability of Y2019 in healthy adults aged 18 years or older, and have obtained satisfactory 7-day and 90-day safety data post immunization. Given the evolution of the COVID-19 epidemic and the increasing number of individuals gaining immunity due to COVID-19 infection, there are uncertainties surrounding the market demand for the COVID-19 vaccine, hence we currently have no immediate plans to initiate the Phase IIa clinical trial for Y2019.

M802 (HER2 × CD3 BsAb)

M802 is an anti-human epidermal growth factor receptor 2 (HER2) and anti-CD3 humanized BsAb consisting of a monovalent unit that specifically binds to HER2 and a single chain unit that binds to CD3.

We are developing M802 for the treatment of HER2-positive solid tumors. HER2 is highly expressive in many types of cancers, including breast cancer, gastric cancer and ovarian cancer. The addressable late-stage HER2-positive gastric cancer and late-stage HER2-positive breast cancer patients of M802 is estimated to reach 39.4 thousand and 13.6 thousand, respectively, in China in 2030. For more details about the addressable market of HER2-positive cancer therapies, please refer to the paragraphs headed “Industry Overview – CD3 Targeted Bispecific Antibody Market – HER2 × CD3 Targeted BsAb – Market of HER2 Targeted BsAb” in this document. As of the Latest Practicable Date, there were ten HER2-targeted BsAb pipelines under clinical development globally (excluding China), and 13 HER2-targeted BsAb pipelines in China. The development of HER2 × CD3 BsAbs represents an emerging trend. As of the Latest Practicable Date, there were four HER2 × CD3 BsAbs under clinical development globally, including M802, RG6194, EX 101 Injection and AMX 818.

We have completed a Phase I clinical trial for M802 in China. Data obtained from the Phase I clinical trial of M802 also indicates that M802 has a favorable safety profile. We will consider exploring potential out-licensing opportunities of M802 in the global market. For more details of M802, please refer to the paragraphs headed “Business – Our Drug Candidates – M802 (HER2 × CD3 BsAb)” in this document.

Y332 (VEGF × TGF-β BsAb)

Y332, a recombinant anti-vascular endothelial growth factor (VEGF) and anti-TGF-β BsAb, is being developed for the treatment of a variety of solid tumors. In pre-clinical studies, Y332 showed high affinity to both VEGF and TGF-β, and demonstrated encouraging anti-tumor effects. Y332 can also be used in combination with immune checkpoint inhibitors to deliver an enhanced anti-tumor effect. According to the CDE website, there is currently only one VEGF × TGF-β BsAb, namely ZGGS18, that has entered into clinical development in China. We are conducting chemistry, manufacturing, and controls (CMC) studies for Y332 and have filed an IND application with the NMPA in January 2023. We received IND approval for Y332 in April 2023. For more details of Y332, please refer to the paragraphs headed “Business – Our Drug Candidates – Y332 (VEGF × TGF-β BsAb)” in this document.

Y400 (VEGF × ANG2 BsAb)

Y400 is a recombinant anti-vascular endothelial growth factor (VEGF) and anti-angiopoietin-2 (ANG2) BsAb for the treatment of wAMD and DME. The addressable wAMD and DME patients of Y400 is estimated to reach 3.4 million and 2.7 million, respectively, in 2030 in China. For more details about the addressable markets of wAMD and DME therapies, please refer to the paragraphs headed “Industry Overview – VEGF × ANG2 Targeted Bispecific Antibody Market – China’s Market of wAMD and DME Treatment” in this document. The CMC studies for Y400 have been completed and the CDE approved the IND application for Y400 in April 2023. As a testament to our strong R&D capability, we have transferred all the rights and assets of Y400 to CMS Vision. We are entitled to receive an upfront payment, milestone payments upon the occurrence of certain pre-agreed milestone events, as well as tiered royalties based on net sales. We have received the full upfront payment of US\$5 million for Y400. For more details of Y400, please refer to the paragraphs headed “Business – Our Drug Candidates – Y400 (VEGF × ANG2 BsAb)” in this document.

SUMMARY

Our Research and Development

We have built an integrated research and development platform that encompasses three main functions: drug discovery and pre-clinical development function, CMC function and clinical development function. With collaboration among such functional groups, we are able to bring our strong pipeline from inception through development, manufacturing and commercialization. As of the Latest Practicable Date, our research and development team consisted of 99 employees, 46.5% of which have a master’s degree or higher. Our research and development team members have extensive pre-clinical and clinical development experience, focusing on oncology and immunology. Our key R&D staff have an average of 12 years of relevant experience working in the biopharmaceutical industry. In 2021 and 2022, our total research and development expenses were RMB112.9 million and RMB157.3 million, respectively, and the research and development expenses attributable to our Core Product, M701, amounted to RMB9.9 million and RMB23.5 million, representing approximately 8.7% and 15.0% of the total research and development expenses for the same years, respectively. In 2021 and 2022, our total research and development expenses accounted for approximately 78.2% and 88.5% of our operating expenses (being the research and development expenses and administrative expenses) for the same years, respectively. For details about our research and development capability, please refer to the paragraphs headed “Business – Our R&D Platform” in this document.

Our Platforms

Equipped with our platform technologies, we stand at the forefront in discovering and developing drug candidates for the treatment of cancer and age-related ophthalmologic diseases. We have strategically developed four innovative platforms, including the self-developed YBODY[®] platform, Check-BODY platform and Nano-YBODY[™] platform, and UVAX platform developed in collaboration with WIV.

- Our YBODY[®] platform is a BsAb platform that focuses on the development of asymmetric human immunoglobulin G (IgG)-like BsAbs with the structure of single-chain variable fragment – antigen-binding fragment – crystallizable fragment (scFv-Fab-Fc structure). The BsAbs with scFv-Fab-Fc structure developed by the YBODY[®] platform have unique features, including (i) favorable safety profile with low cytokine release syndrome-related toxicity due to their reduced affinity to human immune cells, (ii) high drug product purity of 99%, (iii) minimized mispairing between the heavy chains and light chains of BsAbs, (iv) favorable pharmacokinetics (PK) and pharmacodynamics (PD) profile, and (v) high stability. We can achieve 99% product purity of the YBODY[®] molecules by (a) achieving over 90% accurate pairing of heavy chains based on the technologies of the YBODY[®] platform and (b) eliminating those less than 10% mismatches in heavy chains by applying the traditional protein purification process techniques. Based on YBODY[®] platform, we have developed three T cell-engaging BsAbs, namely M701, M802 and Y150.
- Our Check-BODY platform is designed to develop symmetric tetravalent BsAbs. Both Fab and Fv fragments of a Check-BODY molecule show high affinity to the targets. Due to the symmetric structure of these molecules, the purification process of Check-BODY molecules is similar to that of IgG-like monoclonal antibodies (mAbs) and therefore is easier to achieve. We are able to develop Check-BODY molecules with consistent high quality in multiple batches, and can easily scale up the production of Check-BODY molecules. We have discovered and developed Y101D, an anti-programmed death ligand 1 (PD-L1) and anti-transforming growth factor β (TGF- β) BsAb, based on the technologies of our Check-BODY platform.
- Our Nano-YBODY[™] platform is designed to develop symmetric tetravalent BsAbs based on single-domain antibodies. The well-designed structure enables Nano-YBODY[™] molecules to achieve higher binding affinity, better stability, lower immunogenicity and higher production yield than other BsAbs. We have discovered and developed Y400 and Y332 based on the technologies of Nano-YBODY[™] platform. As a testament to our strong R&D capability, we have transferred all the rights and assets of Y400 to CMS Vision. We are entitled to receive an upfront payment, milestone payments upon the occurrence of certain pre-agreed milestone events, and tiered royalties based on net sales. For more details, please refer to the paragraphs headed “Business – Collaboration Agreements – Collaboration with CMS Vision” in this document. We have received the full upfront payment of US\$5 million for Y400.

SUMMARY

- Our UVAX[®] platform is a unique immunogen preparation platform for the development of recombinant protein vaccines, which is designed leveraging our proprietary BsAb engineering technologies. We utilize our UVAX[®] platform to form subunit dimers of coronavirus efficiently and produce immunogens of the vaccine through reliable, safe and high-yield Chinese hamster ovary (CHO) expression and antibody-like purification systems. We have discovered and developed Y2019, based on the technologies of the UVAX[®] platform.

These platforms serve as an engine for our continuous endeavor to deliver new drug candidates, including potential drug candidates we may develop in the future utilizing the molecular structures and CMC processes of the platforms. To protect our proprietary technologies and maintain our competitive advantages, we have built a comprehensive patent portfolio for our platforms. Leveraging our platform technologies, we are able to design and generate different antibody structures, and therefore can quickly expand our pipeline to include additional BsAbs that direct toward a wide range of targets and signaling pathways.

For more details, please refer to the paragraphs headed “Business – Our R&D Platform – Drug Discovery and Pre-clinical Development – Our Proprietary Technology Platforms” in this document.

Our Business Model

Our core business model is to in-house discover, develop and commercialize BsAb-based therapies to treat cancer or cancer-associated complications and age-related ophthalmologic diseases. All of our drug candidates and platform technologies are in-house developed, except for Y2019 and UVAX[®] platform which we develop in collaboration with Wuhan Institute of Virology, Chinese Academy of Sciences (WIV).

We have been dedicated to developing BsAb-based therapies since our inception in 2010. As of the Latest Practicable Date, five of our seven pipeline drug candidates were BsAbs designed for the treatment of some of the most significant cancer types as well as cancer-associated complications such as MA and MPE. In particular, we have been focusing on the development of the T cell-engaging BsAbs, including M701, M802 and Y150, and the development of the tumor microenvironment (TME)-targeted BsAbs, including Y101D and Y332. During the Track Record Period, we have invested a significant portion of our efforts and financial resources in the development of BsAbs designed for cancer treatment. In 2021 and 2022, the R&D expenses attributable to the five BsAbs for the treatment of cancer and its complications in our pipeline amounted to RMB58.2 million and RMB80.4 million, respectively. For details about our key development milestones for BsAbs for cancer treatment, please refer to the paragraphs headed “History, Development and Corporate Structure – Milestones” in this document.

Our ability to design and develop BsAbs is largely driven by our solid core technology platforms, namely YBODY[®], Check-BODY and Nano-YBODY[™]. M701, Y150 and M802 were designed and generated by YBODY[®], Y101D was designed and generated by Check-BODY, while Y332 and Y400 were generated by Nano-YBODY[™]. Leveraging our advanced platform technologies, we are able to design and generate different antibody structures. For more details about our R&D capability and technology platforms, please refer to the paragraphs headed “Business – Our R&D Platform” in this document.

We are committed to the continuous development and commercialization of BsAb-based therapies. We will continue to advance the development of our drug candidates for cancer treatment and invest more resources in the clinical development and pre-clinical studies of these drug candidates. Particularly, we plan to use a significant portion of our [REDACTED] from the [REDACTED] for ongoing and planned clinical trials, preparation for registration filings, and planned commercial launch (including sales and marketing activities) of drug candidates for treatment of cancer and its complications. For more details, please refer to the section headed “Future Plans and [REDACTED]” in this document.

To complement our internal efforts, we have entered into collaboration arrangements with third parties in relation to the development of certain of our drug candidates. For details, please refer to the paragraphs headed “– Collaboration Agreements” in this section. In the future, we will continue to seek strategic collaborations with resourceful partners and form additional strategic alliances or other collaborations, and we currently do not intend to out-license or seek collaboration with third parties in relation to our Core Product.

SUMMARY

We face pricing pressure for our BsAb drug candidates due to fierce competition in the market. Current medical treatment methods for MA and MPE, primarily paracentesis, diuretics such as spironolactone, hyperthermic intraperitoneal chemotherapy and manual aspiration, are less costly in nature. To maximize the market potential of M701 after its commercialization, we will adopt a more flexible pricing strategy for M701 with an aim to provide affordable drugs to patients and to benefit the patients. We will take into consideration clinical demands by MA and MPE patients, clinical value of M701, our market share, the competitive landscape and the price level of other available treatment options for MA or MPE in the relevant market. Furthermore, we may also face pricing pressure for our BsAb drug candidates to be included in the National Reimbursement Drug List (NRDL) in China due to their high costs of development and manufacturing. In China, prices of pharmaceutical products are currently determined mainly by market competition. However, for a pharmaceutical product to be included on the NRDL, a ceiling of such product’s reimbursable amount under the national medical insurance will be determined, based on negotiation with the government. In addition, we may face competition from international and Chinese biopharmaceutical conglomerates who may operate on lower margins based on their economies of scale.

To navigate through such pricing pressure and competition, we (i) develop our Core Product, M701, with differentiated market positioning for the treatment of MA and MPE, (ii) develop stable, high-yield processes under our proprietary technology platforms, including YBODY[®], Check-BODY and Nano-YBODY[™], to produce high-purity BsAb, (iii) maintain clinical dosages of our drug candidates at the microgram or milligram level with our high-yield CMC process, ensuring that each treatment course requires minimal medication quantities, thus lowering costs of treatment of our drug candidates and balancing patient affordability with our profitability, and (iv) seek strategic collaborations and contract part of our manufacturing process to CMOs/CDMOs to reduce upfront investment costs.

For more details about our business model, please refer to the paragraphs headed “Business – Overview – Our Business Model” in this document.

OUR STRENGTHS

We believe the following competitive strengths have contributed to our success and differentiate us from our competitors:

- A pioneer standing at the forefront of the development of BsAbs in China;
- Advanced technology platforms fueling the research and development of drug candidates;
- A strong pipeline of drug candidates with market potential leveraging our differentiated clinical development strategies;
- A robust and GMP-compliant CMC platform; and
- Visionary, seasoned and execution-driven management and R&D teams with a proven track record.

For more details, please refer to the paragraphs headed “Business – Our Strengths” in this document.

OUR STRATEGIES

We intend to pursue the following strategies to further our business growth.

- Accelerate the development of our drug candidates;
- Continue to expand our pipeline through in-house R&D efforts and collaborations;
- Continue to enhance our manufacturing capabilities;
- Continue to build our commercialization capabilities; and
- Continue to attract, nurture and retain skilled talent.

For more details, please refer to the paragraphs headed “Business – Our Strategies” in this document.

SUMMARY

OUR MAJOR SUPPLIERS

During the Track Record Period, our purchases mainly included third-party contracting services for preclinical evaluation and clinical trials of our drug candidates, raw materials, consumables, machines, and equipment. Our major suppliers primarily consist of CROs, CDMOs, CMOs, and suppliers of equipment, devices, and consumable items located in China.

For the years ended December 31, 2022 and 2021, the aggregate purchases attributable to our five largest suppliers in each year were RMB68.0 million and RMB24.5 million, respectively, representing 48.4% and 37.7% of our total purchases for the same years, respectively. Purchases attributable to our single largest supplier in each year were RMB50.0 million and RMB9.0 million, accounting for 35.3% and 13.8% of our total purchases for the same years, respectively. We believe that we maintain strong and stable relationships with our major suppliers.

COLLABORATION AGREEMENTS

Collaboration with CMS Vision

On July 26, 2022 (the “Effective Date”), we entered into an asset transfer agreement (the “CMS Agreement”) with Shenzhen Kangzhe Vision Pharmaceutical Development Co., Ltd. (深圳市康哲維盛醫藥發展有限責任公司) (formerly known as Kangzhe Pharmaceutical Research and Development (Shenzhen) Limited (深圳康哲醫藥發展有限公司)) (“CMS Vision”), a wholly-owned subsidiary of China Medical System Holdings Limited (0867.HK) (together with its subsidiaries, the “CMS Group”), to transfer all of the rights and assets relating to Y400 to CMS Vision.

The parties shall establish a joint steering committee (“JSC”) with an equal number of representatives from each party. All decisions of the JSC shall be made by unanimous vote with each party’s representatives collectively having one vote. In case of any disagreement that cannot be resolved by negotiations, CMS Vision shall have the final decision-making authority over all matters relating to the development, manufacturing and commercialization of Y400 in the Territory (as defined below).

Pursuant to the CMS Agreement, we agree to, subject to certain special arrangement with respect to the United States, Europe and Japan, transfer all of the rights and assets relating to Y400 for any indication worldwide (the “Territory”) to CMS Vision, including but not limited to: (i) all of the rights, proprietary technologies, regulatory approvals and assets (tangible and intangible) that are necessary to use, develop, register, make, have made, sell, distribute, promote and commercialize Y400; (ii) all of the intellectual property rights (including trademarks, patents, know-how and applications thereof) relating to Y400; and (iii) all of the cell bank, data, materials, information, filings and records relating to Y400, as well as all of the rights obtained or otherwise generated from all the pre-clinical and clinical studies and experiments conducted for the purpose of applying and receiving regulatory approvals and intellectual property rights for Y400, that are currently owned or controlled by, or will be owned or controlled by, us and our affiliates. We also agree to grant a non-exclusive sublicense to CMS Vision with respect to an upstream cell line which we have sublicensed from a third party relating to Y400.

We, at our own cost, are responsible for all the pre-clinical studies of Y400 that are necessary for (a) the IND application and (b) the Phase I clinical trial, if any, in accordance with the standards and requirements by the CDE. CMS Vision, at its own cost, is responsible for the IND applications, clinical development, regulatory activities and commercialization of Y400 in the Territory, and we provide all necessary support and assistance. CMS Vision is entitled to manufacture Y400 for clinical use, use in regulatory approval or in commercial sales by itself or engage us/a CMO.

We are entitled to receive an upfront payment, milestone payments upon the occurrence of certain pre-agreed milestone events, as well as tiered royalties based on net sales. We have received the full upfront payment of US\$5 million from CMS Vision.

For more details, please refer to the paragraphs headed “Business – Collaboration Agreements – Collaboration with CMS Vision” in this document.

SUMMARY

Collaboration with WIV

In July 2020, we entered into an agreement with Wuhan Institute of Virology, Chinese Academy of Sciences (WIV), for our collaboration in the research and development of Y2019.

Pursuant to our agreement with WIV, we are responsible for leading the clinical trials of Y2019 and the filing of IND and NDA submissions under the names of both parties. Upon mutual agreement by the parties, WIV will conduct the antibody activity assay and animal studies during the clinical development of Y2019, and we will provide reimbursements for such activities.

Pursuant to our agreement with WIV, we and WIV shall jointly own intellectual property rights of Y2019 arising from our collaboration. Upon the commercialization of Y2019, WIV is entitled to 4% of annual sales revenue.

For more details, please refer to the paragraphs headed “Business – Collaboration Agreements – Collaboration with WIV” in this document.

COLLABORATION WITH CROS, SMOS, CMOS/CDMOS, AND OTHER THIRD PARTIES

In line with the practice in the pharmaceutical industry, we use CROs, SMOs, CMOs/CDMOs, and third-party research centers to conduct and support our preclinical studies and clinical trials. We closely supervise the activities of these third party collaborators. We have selected these institutions weighing various factors, such as their qualifications, expertise, experience, reputation and costs.

For more details, please refer to the paragraphs headed “Business – Our R&D Platform – Clinical Development – Collaboration with CROs, SMOs, CMOs/CDMOs and Other Third Parties” in this document.

INTELLECTUAL PROPERTY

As of the Latest Practicable Date, we owned (i) 21 issued patents in the PRC, (ii) eight issued patents in the United States, (iii) four issued patents in other jurisdictions, and (iv) 45 patent applications, including 15 pending PRC patent applications, five pending U.S. patent applications, five pending PCT patent applications which have not entered into national phases, and 20 pending applications in other jurisdictions. As of the Latest Practicable Date, we self-owned all of our material patents as well as patent applications. We owned two PCT applications in relation to M701, including one PCT application that is generally applicable to our YBODY[®] molecules, including M701 and M802, and one PCT application specifically relating to M701. One PCT application had entered into national phase in major markets, including five granted patents in China, Canada, the U.S. and Japan, and one pending patent applications in China; and the other PCT application was published. For more details, please refer to the paragraphs headed “Business – Intellectual Property” in this document.

DATA PRIVACY AND PROTECTION

We routinely receive, collect, generate, store, process, transmit and maintain medical data treatment records and other personal details of the subjects enrolled in our clinical trials, along with other personal or sensitive information. As such, we are subject to the relevant local, state, national and international data protection and privacy laws, directives regulations and standards. We have established procedures to protect the confidentiality of patients’ data. We also require external parties and internal employees involved in clinical trials to comply with confidentiality requirements.

For more details, please refer to the paragraphs headed “Business – Data Privacy and Protection” in this document.

SUMMARY OF HISTORICAL FINANCIAL INFORMATION

The following tables set forth summary financial data from our consolidated financial information for the Track Record Period, extracted from the Accountants’ Report set out in Appendix I to this document. The summary consolidated financial data set forth below should be read together with, and is qualified in its entirety by reference to, the consolidated financial statements in this document, including the related notes. Our consolidated financial information was prepared in accordance with the International Financial Reporting Standards (“IFRSs”).

SUMMARY

Summary of Consolidated Statements of Profit or Loss and Other Comprehensive Expenses

The table below sets out our consolidated statements of profit or loss and other comprehensive expenses for the years indicated derived from the Accountants’ Report included in Appendix I to this document.

	Year ended December 31,	
	2021	2022
	<i>(RMB in thousands)</i>	
Other income	12,798	2,560
Other gains and losses	716	671
Research and development expenses	(112,893)	(157,329)
Administrative expenses	(31,497)	(20,525)
[REDACTED] expenses	[REDACTED]	[REDACTED]
Finance costs	(14,972)	(2,468)
Loss before tax	(148,518)	(188,866)
Loss and total comprehensive expenses for the year	(148,518)	(188,866)

Our loss and total comprehensive expenses increased from RMB148.5 million in 2021, to RMB188.9 million in 2022, mainly due to the increase of our research and development expenses.

Our research and development expenses increased from RMB112.9 million for the year ended December 31, 2021 to RMB157.3 million for the year ended December 31, 2022. The increase was primarily due to (i) the expenses incurred from the technical service for Phase I clinical trials of Y150, Y101D and Y2019, and the Phase II clinical trial of M701; (ii) the increase in our purchases of raw materials as a result of increased production of stock solutions and reagents for Y332 and Y400; and (iii) the increased cost of Y332 and Y400 in relation to their pharmacodynamic research and preclinical safety evaluation. Such increase was partially offset by the decrease in employee benefits expenses as we did not grant share-based payments for research and development employees in 2022.

For more details, please refer to the paragraphs headed “Financial Information – Description of Selected Components of Consolidated Statements of Profit or Loss and Other Comprehensive Expenses” and “Financial Information – Period to Period Comparison of Results of Operations” in this document.

Summary of Consolidated Statements of Financial Position

The table below sets out selected information from our consolidated statements of financial position as of the dates indicated, which has been extracted from the Accountants’ Report included in Appendix I to this document.

	As of December 31,	
	2021	2022
	<i>(RMB in thousands)</i>	
Total non-current assets	74,517	63,885
Total current assets	125,638	238,957
Total assets	200,155	302,842
Total current liabilities	56,908	146,960
Net current assets	68,730	91,997
Total non-current liabilities	83	–
Total liabilities	56,991	146,960
Net assets	143,164	155,882

SUMMARY

Our net current assets increased from RMB68.7 million as of December 31, 2021 to RMB92.0 million as of December 31, 2022, primarily due to the combined effects of (i) an increase in cash and cash equivalents as a result of the completion of the Series C Financing in October 2022; (ii) an increase in financial assets at FVTPL reflecting our investment in certain structured deposits and wealth management; (iii) an increase in bank borrowings; and (iv) an increase in advance from the CMS Agreement as a result of the fixed upfront fee, which will be required to refund upon certain conditions.

Our net assets increased from RMB143.2 million as of December 31, 2021 to RMB155.9 million as of December 31, 2022, mainly due to the combined effects of (i) an increase in share capital of RMB14.0 million and an increase of share premium of RMB186.0 million, as our Company issued 14,000,000 ordinary shares at the consideration of RMB200.0 million to investors in October 2022, (ii) an increase in equity-settled share-based payments of RMB1.6 million recognized for the same period, and (iii) an increase in loss and total comprehensive expense of RMB188.9 million in 2022.

For more details, please refer to the paragraphs headed “Financial Information – Discussion of Certain Selected Items from the Consolidated Statements of Financial Position” in this document.

Summary of Consolidated Statement of Cash Flows

The following table sets forth a summary of our cash flows for the years indicated.

	Year Ended December 31,	
	2021	2022
	<i>(RMB in thousands)</i>	
Net cash used in operating activities	(98,710)	(176,703)
Net cash (used in) from investing activities	(19,933)	5,804
Net cash from financing activities	81,034	241,334
Net (decrease) increase in cash and cash equivalents	(37,609)	70,435
Cash and cash equivalents at beginning of the year	120,694	83,085
Cash and cash equivalents at the end of the year	83,085	153,520

During the Track Record Period, we incurred net operating cash outflows primarily in relation to our research and development expenses, and administrative expenses. For more details, please refer to the paragraphs headed “Financial Information – Liquidity and Capital Resources – Cash Flows – Operating Activities.”

Our Directors are of the opinion that, taking into account the financial resources available, including cash and bank balances and the estimated [REDACTED] from the [REDACTED], as well as our cash burn rate, we have sufficient working capital to cover at least 125% of our costs, including research and development expenses, general and administrative expenses and other operating expenses for at least the next 12 months from the date of this document.

SUMMARY

Our cash burn rate refers to the average monthly aggregate amount of (i) net cash used in operating activities, including clinical development and business development activities; (ii) purchase of property and equipment; (iii) interest paid; (iv) interest paid on lease liabilities; and (v) payments of lease liabilities. We had cash and cash equivalents of RMB104.7 million as of April 30, 2023. Assuming an average cash burn rate going forward of 1.0 times of the level in 2022, we estimate that our cash and cash equivalents and financial assets at fair value through profit or loss as of April 30, 2023 will be able to maintain our financial viability for 16 months taking into account the estimated [REDACTED] from the [REDACTED] (based on the low-end of the indicative [REDACTED] range stated in this document). Our Directors and management team will continue to monitor our working capital, cash flows, and our business development progress. We monitor our cash flows from operations closely and expect to raise our next round of financing, if needed, with a minimum buffer of 12 months. In the event our business operations experience any material and adverse impact, we will proactively manage our cash flows and control our costs and expenses; on the other hand, in the event we identify any additional promising research and development projects, or identify any suitable target for investment or acquisition, we may adjust our financing plans to take advantage of such opportunities. We may also diversify our source of funding to further support the development of our product candidates going forward.

Key Financial Ratios

The following table sets forth certain of our key financial ratios for the years indicated.

	As of December 31,	
	2021	2022
Current ratio ⁽¹⁾	2.2	1.6

(1) Current ratio is calculated by current assets divided by current liabilities as of the same date.

For more details, please refer to the paragraphs headed “Financial Information – Key Financial Ratios” in this document.

OUR SINGLE LARGEST SHAREHOLDER GROUP

Pursuant to a concert party agreement dated June 30, 2018, and supplemental concert party agreements dated October 26, 2020 and June 2, 2023 entered into by Yuan Qian, Dr. Zhou Hongfeng, Dr. Zhou Pengfei and Wuhan Caizhi (each an “AIC Party”, collectively, “AIC Parties”), the AIC Parties agreed (i) to act in concert by way of reaching consensus on proposals related to the Group’s daily management and operation presented to all general meetings and Board meetings of the Company; and (ii) that when no consensus can be reached, the AIC Parties shall vote in concurrence with Yuan Qian on the proposals, or, in the event of Yuan Qian’s absence from voting, the AIC Parties shall vote in concurrence with the AIC Party with the highest shareholding percentage among the AIC Parties who votes at the meetings. As of the Latest Practicable Date, the AIC Parties, being our single largest shareholder group, were in aggregate entitled to exercise approximately 29.81% (slightly lower than 30%) of the voting rights in our Company, which have only been diluted upon the completion of the Series C Financing in October 2022 prior to our submission of the [REDACTED] form to the Stock Exchange. Upon completion of the [REDACTED] (assuming that the [REDACTED] is not exercised), the AIC Parties will hold approximately [REDACTED]% of our total issued share capital. For more details, please refer to the paragraphs headed “History, Development and Corporate Structure – Concert Party Arrangement” in this document.

SUMMARY

[REDACTED] INVESTMENTS

We have attracted certain investors to raise funds for the development of our business. As of the Latest Practicable Date, we have completed six rounds of [REDACTED] investments, including: (i) Series Pre-A Financing; (ii) Series A Financing; (iii) Series B Financing; (iv) Series B+ Financing; (v) Series B++ Financing; and (vi) Series C Financing. The equity interests held by Series Pre-A Financing investors were all subsequently transferred to other Shareholders. Our Group raised a total of approximately RMB712.2 million through the [REDACTED] investments (including the Additional Consideration (as defined in “History, Development and Corporate Structure”). Our [REDACTED] Investors include Sophisticated Investors, such as CSPC-NBP, who has made meaningful investment in the Company at least six months before the [REDACTED] and will hold approximately [REDACTED]% of the total issued share capital of the Company upon the completion of the [REDACTED] (assuming the [REDACTED] is not exercised). For more details of the identity and background of the [REDACTED] Investors, please refer to the section headed “History, Development and Corporate Structure” in this document.

DIVIDEND

We did not declare or pay any dividend during the Track Record Period. We currently intend to retain all available funds and earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Investors should not purchase our ordinary shares with the expectation of receiving cash dividends. Any future determination to pay dividends will be made at the discretion of our Directors and may be based on a number of factors, including our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that our Directors may deem relevant. Regulations in the PRC currently permit payment of dividends of a PRC company only out of accumulated distributable after-tax profits less any recovery of accumulated losses and appropriations to statutory and other reserves that we are required to make, as determined in accordance with its articles of association and the accounting standards and regulations in China. As a result, we may not have sufficient or any distributable profits to make dividend contributions to our Shareholders, even if we become profitable.

USE OF [REDACTED]

We estimate that the aggregate [REDACTED] to our Company from the [REDACTED] (after deducting [REDACTED] and other estimated expenses in connection with the [REDACTED] paid and payable by us taking into account any additional discretionary [REDACTED] and assuming that the [REDACTED] is not exercised and an [REDACTED] of HK\$[REDACTED] per [REDACTED], being the mid-point of the indicative [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per [REDACTED]) will be approximately HK\$[REDACTED].

We intend to use the [REDACTED] as follows (based on the mid-point of the [REDACTED] range stated in this document):

- (i) approximately [REDACTED]%, or HK\$[REDACTED], will be used for ongoing and planned clinical trials, preparation for registration filings, and planned commercial launch (including sales and marketing activities) of M701, our Core Product;
- (ii) approximately [REDACTED]%, or HK\$[REDACTED], will be used for ongoing and planned clinical trials of Y101D; and
- (iii) approximately [REDACTED]%, or HK\$[REDACTED], will be used for working capital and general corporate purposes.

For more details, please refer to the section headed “Future Plans and Use of [REDACTED]” in this document.

SUMMARY

RISK FACTORS

Investing in the [REDACTED] involves certain risks as set out in the section headed “Risk Factors” in this document. Some of the major risks we are exposed to are as follows:

- 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 their clinical development, obtain their regulatory approvals and achieve their commercialization, or if we experience significant delays in doing any of the foregoing, our business will be materially harmed;
- We face substantial competition and our competitors may discover, develop or commercialize competing drugs faster or more successfully than we do. For instance, our Core Product, M701, faces competition from current medical treatment methods for MA and MPE which are less costly in nature, and competition from multiple peer products under development for the treatment of MA and MPE and peer products targeting identical molecular targets as M701. Furthermore, we face indirect competition from other therapies for primary and metastatic cancers that do not directly target MA and MPE but can help control these complications;
- The development of BsAbs is a nascent field and faces many imminent risks and challenges. The development of BsAbs involved more difficulties and risks due to the complex molecular design and mechanisms of action, and typically incur higher production costs. BsAbs cannot be administered orally, thus the less convenient administration methods of BsAbs increase treatment costs and safety risks associated with infusions. BsAbs face intense competition from mAbs, antibody-drug conjugates, multi-specific antibodies and fusion protein antibodies, which may surpass BsAbs in terms of cost, R&D difficulty, success rate and market acceptance;
- Clinical drug development involves a lengthy and expensive process with uncertain outcomes, and we may encounter unexpected difficulties executing our clinical trials and commercializing our drug candidates on a timely basis;
- 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;
- All material aspects of the research, development and commercialization of pharmaceutical products are heavily regulated. 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;
- We have limited experience in the commercialization of drugs. If we are unable to build and manage sales network, or maintain sufficient sales and marketing capabilities, either by ourselves or through third parties, we may not be able to successfully create or increase market awareness of our products or sell our products, which will materially affect our ability to generate product sales revenue; and
- We have incurred net losses since inception. We expect to continue to incur net losses for the foreseeable future and may not be able to generate sufficient revenue to achieve or maintain profitability.

For more details, please refer to the section headed “Risk Factors” in this document.

SUMMARY

[REDACTED]

[REDACTED] EXPENSES

[REDACTED] expenses to be borne by us are estimated to be approximately RMB[REDACTED] (including [REDACTED]), based on the mid-point of our indicative [REDACTED] for the [REDACTED]), assuming no Shares are [REDACTED] pursuant to the [REDACTED]. During the Track Record Period, we incurred [REDACTED] expenses of approximately RMB [REDACTED], among which RMB[REDACTED] was recognized in our consolidated statements of profit or loss and other comprehensive income, and approximately RMB[REDACTED] ([REDACTED] expenses directly attributable to the [REDACTED] of Shares) will be deducted from equity upon [REDACTED]. After December 31, 2022, approximately RMB[REDACTED] is expected to be charged to our consolidated statements of profit or loss, and approximately RMB[REDACTED] is expected to be charged against equity upon the [REDACTED]. The [REDACTED] expenses above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

The [REDACTED] expenses are expected to represent approximately [REDACTED]% of the [REDACTED] of the [REDACTED], assuming an [REDACTED] of HK\$[REDACTED] per [REDACTED] (being the mid-point of the indicative [REDACTED] range) and that the [REDACTED] is not exercised. The [REDACTED] expenses are comprised of: (i) [REDACTED] expenses of RMB[REDACTED]; and (ii) [REDACTED] expenses of [REDACTED], which can be further broken down into: (A) fees and expenses of legal advisors and accountants of RMB[REDACTED]; and (B) other fees and expenses of RMB[REDACTED].

SUMMARY

RECENT DEVELOPMENT

In January 2023, the IND applications were successfully filed with the NMPA for Y332 and Y400.

In February 2023, we commenced the Phase Ib/II clinical trial of Y101D in combination therapy for the treatment of advanced/metastatic pancreatic cancer.

In April 2023, we received the IND approval for Y332 for metastatic or locally advanced solid tumors and the CDE approved the IND application for Y400.

We expect an increase in forecast loss in the year ended December 31, 2023, primarily because we expect to incur increasing R&D expenses and administrative expenses as we continue to carry out and expand our clinical development programs and advance the research and development of pre-clinical assets.

IMPACT OF THE COVID-19 OUTBREAK

Since late 2019, COVID-19 has spread rapidly globally. Since the beginning of 2022, there have been a number of regional resurgences of COVID-19 cases in several parts of China due to the spread of the Omicron variant. We have employed various measures to mitigate any impact the COVID-19 pandemic may have on our operations, including offering personal protection equipment such as masks to our employees, regularly checking the body temperature of our employees and closely monitoring their health conditions.

The COVID-19 outbreak and resurgences in China and the quarantine measures taken by the PRC government had only limited impact on us. From early 2020 to December 2022, we experienced increased difficulties in patient enrollment for the Phase I and Phase II clinical trials of M701 for the treatment of MA. Specifically, for the Phase II clinical trial of M701 for the treatment of MA, we originally planned to have the first patient in October 2021 and expected to enroll eight to ten patients per month. However, due to the lockdown measures implemented by local governments where our research institutions are located, we did not have our first patient in until December 2021 and the number of patients enrolled in the Phase II clinical trial of M701 for the treatment of MA was approximately six per month from December 2021 to April 2022, lower than what we originally expected. The above disruptions in combined, lead to certain delays in advancing the clinical development of M701 and relatively lower R&D expenses for M701 during the Track Record Period. We also experienced temporary delays in subject enrollment for our clinical trials in certain regions, such as Beijing, Shanghai and Henan province, for one to three months in 2022. Nevertheless, we resumed the normal patient enrollment for these clinical trials later, and the resurgences and quarantine measures did not cause any material impact on our clinical trials, including any early termination of our clinical trials or necessitated removal of any patients enrolled in our clinical trials. We employed various measures to mitigate any impact the COVID-19 outbreak and resurgences may have on our ongoing clinical trials in China, including providing alternative methods for safety and efficacy assessment, continuing patient visit through remote access, and engaging necessary communications with our investigators to identify and address any issues that may arise. The expected development progress of our drug candidates has taken into account the temporary delays and disruptions on our ongoing clinical trials caused by the COVID-19 resurgences. With regard to the impact of the resurgence of COVID-19 outbreak since December 2022, most of our employees were infected with the COVID-19, and then recovered within a short period of time. Our operations for clinical trials experienced disruptions, however, such delays were temporary and we resumed the normal patient enrollment since January 2023. For example, the number of patients we enrolled for all of our ongoing clinical trials increased from eight in January 2023 to eleven in February 2023, and further to 16 patients in March 2023, among which we enrolled three, seven and ten patients for clinical trials of M701 in January, February and March 2023, respectively. In addition, as such resurgence was less severe because of lower mortality rate and higher curability rate than that of the initial COVID-19 outbreak in early 2020, and taking into account that the COVID-19 related governmental measures have been gradually lifted in China (such as the government's releasing measures to lift up quarantine measures and travel restrictions to accelerate the economic recovery and resume normal operations of the society), our Directors were not aware of any material adverse impact of such resurgence on our operations and financial performance.

SUMMARY

Although the COVID-19 related restrictive measures adopted by the Chinese government has been lifted in various regions in China since December 2022, it is still uncertain whether the continuance or future recurrence of the COVID-19 outbreak in China will have a material adverse effect on our business, results of operations, financial position or prospects. The recent COVID-19 outbreaks in China, and future resurgences, if any, may adversely affect our operations if any of our employees or employees of our suppliers and other business partners are suspected of contracting or contracted COVID-19, as we, our suppliers or our business partners may arrange such employees to work remotely at home or disinfect the operating facilities. The ongoing clinical trials and the commencement of new clinical trials for our drug candidates could also be delayed if, due to the COVID-19 outbreak and resurgences in China, there is any delay or failure in subject recruitment or enrollment and/or any diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials from the conduct of clinical trials.

In view of the above situation, our Directors confirm that the COVID-19 outbreak did not have a material adverse impact on our business operations and financial performance as of the Latest Practicable Date, as (i) there had been no material disruption of our ongoing clinical trials or research and development efforts; and (ii) we had not encountered any material supply chain disruption and had not experienced any material difficulties in procuring major raw materials.

The extent to which the COVID-19 outbreak impacts on our business, results of operations and financial condition will depend on many factors beyond our control, including the extent of resurgences of the disease and its variants, vaccine distribution and other actions in response to the virus or to contain its impact. We cannot foresee whether COVID-19 will have a material and adverse impact on our business going forward. For more details, please refer to the paragraphs headed “Risk Factors – Risks Relating to Our Operations – We face risks related to health epidemics and other outbreaks of contagious diseases, including the COVID-19 outbreak” in this document. We will closely monitor and evaluate any impact of the COVID-19 outbreak and resurgences on us and adjust our precautionary measures according to its developments.

NO MATERIAL ADVERSE CHANGE

Our Directors confirm that, as of the date of this document, there has been no material adverse change in our financial or trading position, indebtedness, contingent liabilities or prospects of our Group since December 31, 2022, the end of the period reported on in the Accountants’ Report set out in Appendix I to this document, and there is no event since December 31, 2022 that would materially affect the information contained in the Accountants’ Report set out in Appendix I to this document.