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**3DMed**

**思路迪**

**3D Medicines Inc.**

*(Incorporated in the Cayman Islands with limited liability)*

**(Stock Code: 1244)**

**ANNUAL RESULTS ANNOUNCEMENT  
FOR THE YEAR ENDED DECEMBER 31, 2022**

**FINANCIAL HIGHLIGHTS**

	<b>2022</b>	2021	<b>Changes</b>
	<b>RMB'000</b>	<b>RMB'000</b>	<b>%</b>
Revenue	<b>567,392</b>	60,260	841.6
Cost of sales	<b>(42,215)</b>	(4,277)	887.0
Gross profit	<b>525,177</b>	55,983	838.1
Research and development expenses	<b>(350,864)</b>	(371,162)	(5.5)
Selling and marketing expenses	<b>(357,659)</b>	(42,834)	735.0
Total comprehensive loss for the year	<b>(1,052,030)</b>	(1,461,825)	(28.0)
Adjusted total comprehensive loss for the year (as illustrated under “Non-IFRS Measures”)	<b><u>(253,181)</u></b>	<b><u>(342,420)</u></b>	<b><u>(26.1)</u></b>
	<b>December 31,</b>	December 31,	
	<b>2022</b>	2021	<b>Changes</b>
	<b>RMB'000</b>	<b>RMB'000</b>	<b>%</b>
Cash and cash balances, financial assets at fair value through profit and loss and financial assets measured at amortized costs	<b><u>942,028</u></b>	<b><u>824,484</u></b>	<b><u>14.3</u></b>

## **IFRS Measures:**

### **1. Revenue**

The Group's revenue increased by 841.6% from RMB60.3 million for the year ended December 31, 2021 to RMB567.4 million for the year ended December 31, 2022. The rapid growth in revenue was attributable to the product sales from 恩維達® (Envafolimab, Subcutaneously-Injectable PD-L1) which was approved in November 2021 and commercialized in mainland China market. Benefiting from the differentiated advantages, strategic cooperation with mature sales platforms, and an efficient commercial team, 恩維達® has achieved strong sales performance growth in the fierce market competition.

### **2. Cost of Sales**

The cost of sales increased by 887.0% from RMB4.3 million for the year ended December 31, 2021 to RMB42.2 million for the year ended December 31, 2022. The increase in cost of sales was mainly attributable to the increase in the number of units sold for 恩維達® (Envafolimab, Subcutaneously-Injectable PD-L1).

### **3. Gross Profit and Gross Profit Margin**

The Group's gross profit increased by 838.1% from RMB56.0 million for the year ended December 31, 2021 to RMB525.2 million for the year ended December 31, 2022. It was mainly attributable to the strong increase in revenues. The Group's gross profit margin remained stable at 92.9% and 92.6% in 2021 and 2022, respectively, which shows that our business model has achieved initial success.

### **4. Research and Development Expenses**

The Group's research and development expenses decreased by 5.5% from RMB371.2 million for the year ended December 31, 2021 to RMB350.9 million for the year ended December 31, 2022. The decrease was primarily attributable to (i) the upfront and milestone fee associated with the exclusive development rights in designated regions of our in-licensed drug candidates decreased by RMB55.9 million; and (ii) employee benefit expenses including salaries, social insurance, pension, bonus, and share-based expenses related to our research and development personnel decreased by RMB14.1 million. Such decrease was partially offset by an increase in the third-party contracting expenses paid to service providers of RMB46.1 million.

### **5. Selling and Marketing Expenses**

The Group's selling and marketing expenses increased by 735.0% from RMB42.8 million for the year ended December 31, 2021 to RMB357.7 million for the year ended December 31, 2022. The selling and marketing expenses were mainly attributable to the marketing activities for the approved and commercialized product, 恩維達®. The increase was primarily attributable to the increase in sales of the 恩維達® since December 2021. It is noted that the rate of increase in revenue in 2022 (i.e. 841.6%) is faster than the rate of increase in selling and marketing expenses in 2022 (i.e. 735.0%).

## Non-IFRS Measures

In order to supplement our consolidated statements of profit or loss and other comprehensive income which are presented in accordance with IFRS, we use adjusted loss and total comprehensive loss as an additional financial measure, which is not required by, or presented in accordance with IFRS. Our adjusted loss and total comprehensive loss represents our loss and total comprehensive loss for the year, adjusted to add back fair value losses on preferred shares and share-based payment expenses. We believe that such measure provides investors and other persons with useful information to understand and evaluate our consolidated results of operation in the same manner as it helps our management. However, adjusted net loss presented by us may not be comparable to the similar financial measure presented by other companies. There are limitations to the non-IFRS measure used as an analytical tool, and you should not consider it in isolation or regard it as a substitute for our results of operation or financial position analysis that is presented in accordance with IFRS.

The following table sets forth our loss and total comprehensive loss and adjusted loss and total comprehensive loss for the year, which is adjusted by adding back fair value losses on preferred shares and share-based payment expenses, for the years indicated:

	<b>2022</b> <i>RMB'000</i>	2021 <i>RMB'000</i>	<b>Changes</b> %
Total comprehensive loss for the year	<b>(1,052,030)</b>	(1,461,825)	(28.0)
<i>Add:</i>			
Fair value losses on preferred shares	<b>657,155</b>	954,742	(31.2)
Share-based payment expenses	<b>141,694</b>	164,663	(13.9)
Adjusted total comprehensive loss for the year	<b><u>(253,181)</u></b>	<b><u>(342,420)</u></b>	(26.1)

## **BUSINESS HIGHLIGHTS**

- 1 Product sales exceeded HKD500 million for the first full financial year since commercialization of 恩維達® (Envafolimab, Subcutaneously-Injectable PD-L1)**
- 2 7 indications of 恩維達® were listed in the clinical recommendation guidelines, including six in CSCO Guidelines and one in Chinese Anti-Cancer Association Guideline since 2022**
- 3 恩維達® was selected as the “Top Ten New Drugs in China” of the 14th Health China Forum**
- 4 A supplementary NDA of 恩維達® was approved by NMPA**
- 5 Batiraxcept (3D229) Phase III MRCT in ex-China has been completed for patients enrollment, and Phase I bridge study in China has been completed**
- 6 A peptide cancer vaccine Galinpepimut-S (3D189) obtained IND approval, a Phase III enrollment ongoing ex-China, Phase I in China ongoing**
- 7 3D185 was designated by FDA as an orphan drug for gastric cancer**
- 8 Five INDs approved (including one pivotal study from FDA and targeting global market)**
- 9 Five clinical study results were presented or published in conference or scientific journals**
- 10 Five patent applications were filed, and one Canadian patent for 恩維達® was granted by Canadian Intellectual Property Office**

The Board is pleased to announce the audited consolidated results of the Group for the Reporting Period. The content of this annual results announcement has been prepared in accordance with applicable disclosure requirements under the Listing Rules in relation to preliminary announcements of annual results which is prepared in accordance with the IFRS issued by the IASB, and audited by Ernst & Young, the auditor of the Company. Such annual results have also been reviewed and confirmed by the Board and the Audit Committee. Unless otherwise stated, the financial data of the Company are presented in RMB.

## **MANAGEMENT DISCUSSION AND ANALYSIS**

Founded in 2014, we are a bio-pharmaceutical company focusing on the research and development of oncology therapies for cancer patients, especially those who require long-term care. Our core business model is to develop and commercialize oncology products and drug candidates through a combination of in-house discovery, in-licensing and co-development. We are committed to enhancing our in-house discovery capabilities and continue to conduct clinical trials for more indications and innovative candidates to provide more treatment options for cancer patients and benefiting chronic cancer patients.

We were successfully listed on the main board of the Stock Exchange on December 15, 2022. The Prospectus in relation to the Global Offering was published on the website of the Stock Exchange on November 29, 2022.

### **OUR PIPELINE IS REASONABLE SYNERGY, TWO-THIRDS OF OUR CANDIDATES ARE ALREADY IN CLINICAL STAGE**

As of December 31, 2022, we have built a pipeline consisting of 12 drugs or drug candidates, among which 恩維達® (Envafohimab, Subcutaneously-Injectable PD-L1), as our backbone, was approved in November 2021 and commercialized in China, and seven other drug candidates are in the clinical stage.

### **恩維達®, THE WORLD'S FIRST APPROVED SUBCUTANEOUSLY INJECTABLE PD-L1 ANTIBODY, RECORDED STRONG SALES**

Envafohimab is the world's first approved subcutaneously injectable PD-L1 antibody that has been approved in China for the treatment of previously treated microsatellite instability-high (MSI-H)/ mismatch repair deficiency (dMMR) advanced solid tumors, addressing a huge unmet medical needs for immunotherapy for patients intolerant to intravenous injection. During the Reporting Period, all of our revenue was generated from the sales of 恩維達®, which amounted to RMB567.4 million.

### **EXPEDITING GLOBAL COLLABORATION AND DEVELOPMENT OF TWO FIRST-IN-CLASS PRODUCTS NEAR THE COMMERCIAL STAGE**

The Company has also achieved key milestones in global collaboration. We received IND approval for 3D229 (batiraxcept) and completed this Phase I clinical trial in healthy volunteers in China in May 2022, and its findings were presented at the CSCO conference in September 2022. In April 2022, we obtained IND approval for a Phase Ib clinical trial in patients with NSCLC, RCC and UC. In addition, we obtained IND approval for an on-going Phase III clinical trial in patients with PROC in China in July 2021 to participate in the MRCT, and we initiated this trial in China in February 2022. As of December 31, 2022, twelve patients have been enrolled in this MRCT in China.

We obtained IND approval for 3D189 in China in April 2022 and completed the first patient dosing in the Phase I clinical in China in October 2022 for WT1-positive AML patients in complete remission after completion of at least first-line standard therapy and patients with multiple myeloma, non-Hodgkin's lymphoma, or high-risk group myelodysplastic syndromes who have achieved complete remission or whose best treatment response is partial remission.

## DEVELOPMENT OF PRODUCT PORTFOLIO

The following chart summarizes the development status of our product, clinical-stage drug candidates and selected pre-clinical stage drug candidates as of the date of this announcement:

Candidate	Target / Mechanism	Indications/Study Population	Rights	Preclinical Discovery	IND	Phase I	Phase II	Phase III	NDA	Partner
Envafolelimab	PD-L1	MSI-H/dMMR advanced cancer (mono, 2L+)	Worldwide	China					BLA approved	Alphamab Group, Sincere Group, (China,CSO) TRACON (Sarcoma, North America)
		Advanced BTC (combo with chemo vs. chemo, 1L)		China						
		NSCLC (vs standard treatment, 1L)		China						
		NSCLC (combo with chidamide, 2L+)		China						
		G/GEJ advanced cancer (combo with chemo, 1L)		China	COMPLETED					
		TMB-H advanced cancer (mono, 2L+)		China						
		EC (mono and combo with lenvatinib, 2L+)		China						
		NSCLC, HCC, RCC (combo with lenvatinib)		China						
		HCC, CRC, NSCLC (combo with BD0801)		China						
		Microsatellite stable CRC (combo with cetuximab+/- Fruquintinib, standard treatment failure)		China						
3D189	WT1	Multiple indications AML	Greater China	China					SELLAS	
3D229	GAS6/AXL	Healthy Volunteers	Greater China	China	COMPLETED					Aravive
		NSCLC / RCC / UC PROC (2L)		China						
3D1001	COX-2	Post-surgical dental pain/cancer pain	China	China		US				Haibe Biopharma Group
3D1002	EP-4	Cancer pain / osteoarthritis	China	China		US				
3D185	FGFR1/2/3	Locally advanced or metastatic solid tumors	Worldwide	China/US						Haibe & SIMM
3D011	TKI prodrug	Advanced malignant solid tumors	Worldwide	China						-
3D197	CD47	Multiple indications	Greater China	China						ImmuneOncia
3D057	CD3+PD-L1	Multiple indications	Greater China Worldwide Priority Transfer right	China						Y-Biologics
3D059	WT1	Multiple indications	Greater China	China						SELLAS
3D060	Sema4D	Multiple indications	Worldwide	China/US						-
3D062	KRAS	Multiple indications	Worldwide	China/US						-

 Pivotal Trial

## BUSINESS OVERVIEW

### 1. Our First Commercial Product – 恩維達® (Envafolelimab, Subcutaneously-Injectable PD-L1)

恩維達® (Envafolelimab, Subcutaneously-Injectable PD-L1) is a fusion protein of single domain PD-L1 antibody, which is a subcutaneously-injectable PD-L1 inhibitor for the treatment of tumor-agnostic indications, and it has been approved in China for the treatment of previously treated MSI-H/dMMR advanced solid tumors.

#### – *Successful Business Model Generating Revenue*

For the year ended December 31, 2022, our revenue generated from the sales of envafolelimab in China amounted to RMB567.4 million.

#### – *A sNDA approval from NMPA*

In August 2022, the NMPA approved a supplemental application for “an increased dose of 300 mg administered every two weeks” for envafolelimab. This approval is based on clinical pharmacology data from our sites in China, the United States and Japan. The approval of the increased dosage will significantly reduce the frequency of drug use, improve patient convenience and provide better treatment options for oncology patients.

- ***10 trials are currently being conducted, two new INDs have been approved by NMPA and the US FDA***
- A Phase Ib/II, multi-center, open-label study to evaluate the envafolimab in combination with lenvatinib for the treatment of patients with late-stage solid tumors. The enrollment of last patient in the Ib part has been completed and the study is ongoing as planned.
  - A Phase II study to evaluate envafolimab in combination with lenvatinib for the treatment of patients with late stage non-MSI-H/non-dMMR endometrial cancer who failed at least first line or intolerance to platin treatment. A first patient has been enrolled and the study is ongoing as expected.
  - A Phase II, single-arm, multiple-center, open-label study to evaluate envafolimab for the treatment of patients with tumor mutational burden-high (TMB-H), tissue-agnostic late-stage solid tumors. Interim analysis has been completed and the Independent Data Monitoring Committee recommend to stop the enrollment for patients with TMB<12 and continue to enroll the patients with TMB>12 as planned.
  - A Phase II study to evaluate envafolimab in combination with chidamide for the treatment of patients with NSCLC. The enrollment of last patient has been completed and follow-up is ongoing as planned.
  - A Phase III study to evaluate envafolimab in combination with chemo-therapy as the first line treatment for patients with biliary tract cancer is currently ongoing as planned.
  - A Phase II study to evaluate envafolimab in combination with BD0801 with and without chemotherapy for the treatment of patients with late-stage solid tumor. The study is currently ongoing as expected.
  - In September 2022, we obtained IND approval for a clinical trial, in which envafolimab and cetuximab (Erbix<sup>®</sup>), would be dosed in combination to evaluate the clinical efficacy of this combination in patients with RAS/BRAF wild-type and non-MSI-H/pMMR metastatic colorectal cancer who have failed treatment with fluorouracil, oxaliplatin and irinotecan, and bevacizumab (except for patients with contraindications to bevacizumab, those who are not suitable according to treatment guidelines, and those who cannot be treated with bevacizumab due to financial reasons).
  - In December 2022, we obtained IND approval from FDA to proceed with the Phase II clinical study for the treatment of dMMR advanced solid tumors. This IND is a Phase II, multiregional, multicenter, single-arm study to evaluate the efficacy and safety of envafolimab monotherapy in subjects with dMMR advanced solid tumors. Our Core Product will be administered to the patients subcutaneously every three weeks in this IND study.



## ***Clinical Guideline Recommendations***

恩維達® (Envafolimab, Subcutaneously-Injectable PD-L1) has been well acknowledged by professional bodies since its launch, and has been adopted by six CSCO Guidelines and one Chinese Anti-Cancer Association Guideline since 2022, including:

- 1) CSCO Guidelines for Gastric Cancer 2022 Version (Class I recommendation for dMMR/MSI-H population (regardless of HER2 status) who have not previously used PD-1/PD-L1 monoclonal antibody, Level 2A evidence);
- 2) CSCO Guidelines for Colorectal Cancer 2022 Version (Class II recommendation for MSI-H/dMMR patients with advanced second – and third-line colorectal cancer who have not previously used immune checkpoint inhibitors, Level 2A evidence);
- 3) CSCO Guidelines for Clinical Application of Immune Checkpoint Inhibitors 2022 Version (Class I recommendation for patients with MSI-H/dMMR advanced solid tumors in the second-line or later, Level 2A evidence);
- 4) CSCO Guidelines for Endometrial Cancer 2022 Version (Class II recommendation for second-line biomarker-directed systemic therapy for recurrent and metastatic endometrial cancer);
- 5) CSCO Guidelines for Cervical Cancer 2022 Version (Class II recommendation for second-line treatment of recurrent and metastatic cervical cancer);
- 6) CSCO Guidelines for Ovarian Cancer 2022 Version (Class III recommendation for (i) the evaluation of MSI-H/dMMR platinum-sensitive recurrent ovarian epithelial carcinoma that cannot be surgically resected to achieve satisfactory tumor reduction; and (ii) the evaluation of MSI-H/dMMR platinum-resistant recurrent ovarian epithelial carcinoma that cannot be surgically resected to achieve satisfactory tumor reduction, Level 2B evidence); and
- 7) Chinese Guidelines for the Radiotherapy of Esophageal Cancer 2022 Edition (multiple ongoing II/III clinical studies of PD-1/PD-L1 antibodies, including envafolimab, in combination with concurrent radiotherapy for locally advanced inoperable squamous esophageal cancer with preliminary confirmation of the efficacy and safety of radiotherapy in combination with immunotherapy).

## ***Patent***

One Canadian patent for 恩維達® (Envafolimab, Subcutaneously-Injectable PD-L1) was granted by Canadian Intellectual Property Office on June 14, 2022.

## ***Academic Publications***

Recent academic publications on envafolimab include:

- 1) Markham A. Envafolimab: First Approval. *Drugs*. 2022;82(2):235-240. doi:10.1007/s40265-022-01671-w;



- 2) Shimizu T, Nakajima TE, Yamamoto N, et al. Phase I study of envafolimab (KN035), a novel subcutaneous single-domain anti-PD-L1 monoclonal antibody, in Japanese patients with advanced solid tumors. *Invest New Drugs*. 2022;40(5):1021-1031. doi:10.1007/s10637-022-01287-7;
- 3) Shen L, Li J, Deng Y H, et al. Data update and subgroup analysis of the pivotal phase II study of envelumab for MSI-H/dMMR advanced solid tumors (恩沃利單抗治療 MSI-H/dMMR 晚期實體瘤關鍵性 II 期研究數據更新與亞組分析). 2022 CSCO Annual Academic Conference Paper Collection (2022年CSCO學術年會論文彙編);
- 4) Liu R Y, Yin X L, Deng Y H, et al. Phase II clinical study of envafolimab in combination with FOLFOX in the first-line treatment of advanced gastric/esophagogastric combination adenocarcinoma (恩沃利單抗聯合 FOLFOX 一線治療晚期胃／食管胃結合部腺癌的 II 期臨床研究). *Chinese Journal of New Drugs* (中國新藥雜誌); and
- 5) Xu J, Papadopoulos K P, Shimizu T, et al. Efficacy of Envafolimab, a Novel Subcutaneous Anti-PD-L1 Inhibitor, in patients with advanced solid tumors: Pooled results from three Phase I studies. 2022 CSCO Annual Academic Conference Paper Collection (2022年CSCO學術年會論文彙編).

## 2. **Batiraxcept (3D229)**

Batiraxcept is a high-affinity, soluble Fc-fusion protein designed to bind Growth Arrest Specific 6 (GAS6), intercept the binding of GAS6 to its receptor AXL and block the activation of the GAS6-AXL signaling pathway.

We received IND approval for Phase I clinical trial in healthy volunteers in China in May 2021 and completed this Phase I clinical trial in May 2022, and its findings were presented at the CSCO conference in September 2022. In April 2022, we obtained IND approval for a Phase Ib/II clinical trial in patients with NSCLC, RCC and UC. In addition, we obtained IND approval for a on-going Phase III clinical trial in patients with PROC in China in July 2021 to participate in the MRCT, and we initiated this trial in China in February 2022. As of Decemeber 31, 2022, twelve patients have been enrolled in this MRCT in China.

In November 2022, our partner Aravive issued an announcement that batiraxcept was granted fast track status by the FDA for the treatment of patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC) who have progressed after prior treatment with first- or second-line systemic therapy. In December 2022, our application of sIND for CMC change was approved by CDE. With this approval, 3D229 samples produced by the new process can be used in clinical studies.

Aravive announced the full enrollment in the registrational Phase III trial of batiraxcept plus paclitaxel for PROC has been achieved.

### **3. Galinpepimut-S (3D189)**

Galipepimut-S is a peptide cancer vaccine that targets the WT1 protein, which is present and over-expressed in an array of hematological malignancies and solid tumors. 3D189 has been granted fast track and orphan drug designations by the FDA for the treatment of AML.

We obtained IND approval for 3D189 in China in April 2022 and completed the first patient dosing in the Phase I clinical study in China in October 2022 for WT1-positive AML patients in complete remission after completion of at least first-line standard therapy and patients with multiple myeloma, non-Hodgkin's lymphoma, or high-risk group myelodysplastic syndromes who have achieved complete remission or whose best treatment response is partial remission.

Our partner SELLAS Group has completed Phase II trial in AML patients in their first complete remission, and the results showed that the median overall survival (OS) was 67.6 months (all ages) for patients in the maintenance setting, which represents a substantial improvement compared to the best standard therapies. The results also showed a trend in improved clinical outcomes in patients who mounted an immune response with galinpepimut-S (GPS) compared to those patients who did not.

We completed the manufacture of the clinical batches in China for 3D189's active pharmaceutical ingredients (API) in October 2022. As of the date of this announcement, 3D189 is being evaluated by SELLAS Group in an ongoing Phase III pivotal trial in the U.S., and Europe for the treatment of AML. We maintain the exclusive rights to develop, manufacture and commercialize 3D189 in Greater China.

### **4. 3D011**

3D011 is an in-house discovered tyrosine kinase inhibitor (TKI) prodrug that will be developed as monotherapy and in combination with other agents for the treatment of solid tumors. We received IND approval from the NMPA in January 2021, and we initiated this Phase I clinical trial in February 2022. On June 7, 2022, a U.S. patent for 3D011 was granted by the United States Patent and Trademark Office. On December 28, 2022, a European patent for 3D011 was granted by European Patent Office. As of the date of this announcement, we are conducting an open-label, single-arm Phase I dose-escalation and dose-expansion clinical trial in patients with advanced solid tumors.

### **5. 3D185**

3D185 is a fibroblast growth factor receptors (FGFR) 1-3 and colony stimulating factor 1 receptor (CSF1R) inhibitor. 3D185 was obtained IND approval from the NMPA in January 2018. We received IND approval from the FDA in September 2019, and completed the Phase I clinical trial in patients with advanced solid tumors in China and the U.S. in August 2021. In October 2022, 3D185 received an orphan-drug designation from the FDA for the treatment of biliary tract cancer. On January 13, 2023, 3D185 was granted the orphan-drug designation by the FDA for the treatment of gastric cancer and gastro-esophageal junction cancer. For exploring and protecting more FGFR inhibitor dosage forms, we submitted one Chinese patent application to the China National Intellectual Property Administration on December 1, 2022. As of the date of this announcement, a new formulation of 3D185 is being studied in a Phase I clinical trial in China and U.S.

## 6. 3D1001

3D1001 is a new-generation cyclooxygenase-2 (COX-2) inhibitor with rapid onset of action and prolonged pain relief to patients with post-surgical dental pain in a clinical study attributable to a favorable PK profile. IND approval was obtained from the NMPA in February 2019. For establishing the IP on compound crystallization, we submitted one Chinese patent application to China National Intellectual Property Administration on December 27, 2022. As of the date of this announcement, we have completed the manufacture of clinical batch Active Pharmaceutical Ingredient (API) for a Phase I/II clinical trial, and 3D1001 is a potential drug for inflammatory pain and will become our next clinical trial candidate and get closer to the commercial stage.

## 7. 3D1002

3D1002 is an E-type prostanoid receptor 4 (EP4) receptor antagonist. IND approval was obtained from the NMPA in July 2018. As of the date of this announcement, we have completed the manufacture of clinical batch Drug Product (DP), and 3D1002 is a potentially effective target candidate for cancer pain and is currently in the advanced stage of clinical trials.

## 8. 3D197

3D197 is a next-generation fully human anti-CD47 IgG4 monoclonal antibody. We obtained IND approval for 3D197 from the NMPA in China in January 2022 to conduct studies to evaluate the efficacy of 3D197 in combination with envafohimab, azacitidine, rituximab and other combination therapies for solid tumors and hematologic malignancies.

## 9. Our Pre-Clinical Stage Drug Candidates

In addition to our clinical-stage drug candidates, we are also evaluating a number of pre-clinical stage drug candidates in our pipeline, including, (a) 3D057, our bispecific antibody drug which targets CD3 receptor of T-cells and PD-L1 of tumor cells, (b) 3D059, our next-generation immunotherapeutic which targets the WT1 protein in hematological malignancies and solid tumors, (c) 3D060, our in-house developed monoclonal antibody which targets Semaphorin 4D (Sema4D) of tumor cells, and (d) 3D062, our in-house developed small molecule for patients with KRAS mutation.

For our in-house developed 3D062, we filed two Chinese patent applications on January 20, 2022 and April 8, 2022, respectively, and one PCT application on December 1, 2022.

**Warning under Rule 18A.08(3) of the Rules Governing the Listing of Securities on the Stock Exchange: There is no assurance that the Company will continuously succeed in commercialization of 恩維達® (Envafohimab, Subcutaneously-Injectable PD-L1). There is no assurance that Batiraxcept (3D229), Galinpepimut-S (3D189), 3D1001, 3D1002, 3D185, 3D011, 3D197, 3D057, 3D059, 3D060, and 3D062 will ultimately be successfully developed and/or marketed by the Company. As of the date of this announcement, no material adverse changes had occurred with respect to the regulatory approvals we had received in relation to our drug candidates.**

## **Continuously Explore Financing Alternatives to Further Strengthen our Capital Reserve**

The Company has been selected and included as an eligible stock in the security list of Shanghai-Hong Kong Stock Connect, with effect from March 13, 2023. On February 23, 2023, the Company has also been selected as a constituent stock of the Hang Seng Composite Index by the Hang Seng Indexes by the Hang Seng Indexes Company Limited, with effect from March 13, 2023. That represents the capital market's recognition of the Group's business performance and growth outlook.

## **Research and Development**

Our management team has extensive industry experience for new drug development including working experience in FDA and global pharmaceutical companies, and has led us to build a proven track record capability from discovery to commercialization.

Our R&D platform has strong molecule screening and design capabilities that increase the possibility of success of moving molecules from pre-clinical studies to market, enable innovative therapeutic approaches and support pipeline assets built around key pathways and targets.

Our R&D centers in Shanghai and Beijing include large and small molecule platforms, cell line screening platforms, compound screening platforms. We believe that R&D is key to maintaining competitiveness in our industry. We have built a platform to enable our R&D in the areas of chronic cancer treatment. Leveraging our proprietary R&D platform, we are able to conduct pre-clinical R&D activities including drug activity screening, studies of cellular functions of drugs, drug biochemical studies and biomolecule detection.

We employ a clinical-demand-oriented and market-driven approach to our clinical research and development efforts. Our clinical development team is composed of scientists and physicians with years of experience in drug development. Our clinical development team carefully customizes clinical development plan for each of our candidate drugs by taking into consideration of scientific rationale, and probability of technical and regulatory success, competition, commercial assessment, expert feedback, timeline and cost.

## **Manufacture**

We have been building our in-house production facilities in Xuzhou, Jiangsu province, with current GMP compliant manufacturing system and facilities throughout the drug development process, including chemical drugs and biologics, to meet stringent global standards. Our GMP-compliant manufacturing facilities are designed and validated according to the FDA, the EMA, and the NMPA regulations, to support the entire drug development process, from drug discovery to process development, GMP-compliant pilots and commercial manufacturing. In anticipation of large needs of our drugs upon commercialization, we purchased the use right of land in Xuzhou with an aggregate area of 65,637.97 square meters. We have obtained the construction permit and started construction of new manufacturing facilities in Xuzhou.

We work with qualified CMOs to manufacture and test drug candidates for pre-clinical and clinical supply. In the near future, we plan to continue outsourcing the manufacturing of our product and drug candidates, including commercial-scale manufacturing of our approved drugs, to qualified CMOs/CDMOs. We have a steady capacity expansion plan to cope with our future clinical development and commercialization demanding.

## **Sales and Marketing**

We are devoted to accelerating the commercialization progress of 恩維達® (Envafolimab, Subcutaneously-Injectable PD-L1) with combining efforts through the marketing strategy targeted at the needs of patients, academic oriented marketing activities were held to highlight the characteristics of product differentiation and improve the quality of life for cancer patients. We have been recommended by some professional clinical guidelines to actively provide necessary assistance to cancer patients and win the recognition of third-party payers to reduce the cost of patients using our products.

We have been establishing our sales and marketing department dedicated to the commercialization of our pipeline products. We have been building our qualified and sales and marketing department in place with rich experience in the commercialization of oncology treatment, and to be mainly responsible for product positioning, market strategy, promotional activity planning and patient assistance.

As we already received NDA approval for the treatment of previously treated MSI-H/dMMR advanced solid tumors on November 24, 2021, we sell 恩維達® (i) to pharmacy operating companies and (ii) to distributors cooperating with us directly (for hospital channel). we hire professional employees to negotiate the contracts, manage the distributors and supply chain, provide sufficient products for patients.

In 2022, 恩維達® sales have covered more than 1,000 hospitals and more than 1,000 pharmacies in 30 provinces and over 200 cities, also we have been included in 17 cities as Huimin insurance plan.

For products that are close to commercialization, pre-market preparations are also gradually being carried out.

## **Intellectual Property Rights**

We have an extensive portfolio of patents to protect our product, drug candidates and technologies. As of the date of this announcement, we owned (including co-owned) (i) 10 granted patents in China, (ii) 15 granted patents in other jurisdictions, and (iii) 20 pending patent applications, including 5 Chinese patent applications, one U.S. patent application and 14 patent applications in other jurisdictions, relating to certain of our product, drug candidates and technologies.

## **Impact of the COVID-19 Outbreak**

The outbreak of COVID-19 since December 2019 did not have a material adverse impact on our business, financial condition and results of operations. While we experienced delays in the patient enrollment process and data entry for certain of our clinical trials in China, the outbreak of COVID-19 and its variants, such as the Delta and Omicron variants, did not cause any early termination of our clinical trials or necessitate removal of any patients enrolled in our clinical trials. For our U.S. and Japan trials, we did not experience any material difficulties arising from the outbreak of COVID-19 and its variants in our patient enrollment and trial management, and the progress of those trials is generally in line with our trial development plan despite minor delays. We confirm that the COVID-19 outbreak and its variants have not had any long-term material adverse impact on our business operation and financial performance as of the date of this announcement.



## **Future Development**

We are committed to the discovery, development, and commercialization of safe and effective innovative drugs to help cancer patients who need long-term care globally.

We will continue to carry out additional clinical studies to expand the addressable indications for our 恩維達® (Envafolimab, Subcutaneously-Injectable PD-L1), such as NSCLC, EC, UC and RCC. Furthermore, we plan to continue maximizing the commercial value of 恩維達® by conducting clinical trials both independently and in collaboration with partners outside of China.

We intend to continue advancing the development of our pipeline drug candidates and fully explore the opportunities for combinational use of pipeline assets. For drug candidates at late clinical stage, we will leverage the clinical data from our partners sponsored clinical trials to advance clinical programs and communicate with regulatory authorities to expedite BLA/NDA submission opportunities. For early clinical stage assets, we plan to apply innovative clinical trial designs and efficient clinical strategies to speed up the development process.

We also intend to leverage our experience from the collaboration with reputable partners to further strengthen our R&D capabilities. In addition, we will also continue to invest in pre-clinical R&D to identify pipeline assets that cover a wider spectrum of cancer indications, and actively conduct research to evaluate the combination effects of our pipeline candidates.

We have proved our clinical development and commercialization capabilities through 恩維達® (Envafolimab, Subcutaneously-Injectable PD-L1), and also successfully in our internal research and development capabilities in innovative products. More important, we have demonstrated our scientific judgment, resource integration, and comprehensive capabilities. In line with our Company's vision, we are committed to the discovery, development, and commercialization of safe and effective innovative drugs to help cancer patients who need long-term care, and will further strengthen our positioning in this market.

## **Head Office Address Change**

With effect from 30 March 2023, the address of the head office of the Group in the PRC shall be No. 3 and No. 5, Laiyang Road, Qingdao, Shandong, China. The principal place of business in Hong Kong and the Cayman registered office shall remain unchanged.

## FINANCIAL REVIEW

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
REVENUE	567,392	60,260
Cost of sales	<u>(42,215)</u>	<u>(4,277)</u>
Gross profit	525,177	55,983
Other income and gains	48,945	19,637
Research and development expenses	(350,864)	(371,162)
Administrative expenses	(142,830)	(150,956)
Selling and marketing expenses	(357,659)	(42,834)
Royalty expenses	(59,965)	(7,153)
Other expenses	(53,391)	(8,940)
Finance costs	(3,113)	(1,528)
Fair value losses on preferred shares	(657,155)	(954,742)
Impairment losses on financial assets, net	<u>(1,175)</u>	<u>(130)</u>
LOSS BEFORE TAX	(1,052,030)	(1,461,825)
Income tax expense	<u>—</u>	<u>—</u>
TOTAL COMPREHENSIVE LOSS FOR THE YEAR	<u><u>(1,052,030)</u></u>	<u><u>(1,461,825)</u></u>
Attributable to:		
Owners of the parent	(1,024,350)	(1,434,092)
Non-controlling interests	<u>(27,680)</u>	<u>(27,733)</u>
	<u><u>(1,052,030)</u></u>	<u><u>(1,461,825)</u></u>

### Overview

The following discussion is based on, and should be read in conjunction with, the financial information and the notes included elsewhere in this announcement.

### Revenue

During the Reporting Period, all of our product sales was generated from the sales of commercialized 恩維達® (Envafolimab, Subcutaneously-Injectable PD-L1) to pharmacy operating companies and to distributors cooperating with us directly. In 2021 and 2022, product sales amounted to RMB60.3 million and RMB567.4 million, respectively, increased by 841.6%. The increase was primarily attributable to product sales from 恩維達® which was approved and commercialized in late November 2021. We benefitted from differentiation advantages of the product itself, strategically cooperating with mature sales platform ahead of the launch and highly productive sales force. Thus, our newly approved 恩維達® achieved strong sales results in the fierce market competition.



## **Cost of Sales**

During the Reporting Period, the cost of sales were purchase prices of our 恩維達® we paid to our contract manufacturer for the manufacturing of our 恩維達®. Our cost of sales amounted to RMB4.3 million and RMB42.2 million in 2021 and 2022, respectively, which increased by 887.0%. The increase in cost of sales was mainly attributable to the increase in the number of units sold for 恩維達® (Envafolimab, Subcutaneously-Injectable PD-L1).

## **Gross Profit and Gross Profit Margin**

The Group's gross profit increased by 838.1% from RMB56.0 million for the year ended December 31, 2021 to RMB525.2 million for the year ended December 31, 2022. It was mainly attributable to the strong increase in product sales. Our gross profit margin reached 92.9% and 92.6% in 2021 and 2022, respectively. The stable gross profit rate shows that our business model has achieved initial success.

## **Other Income and Gains**

During the Reporting Period, our other income and gains primarily consisted of (i) foreign exchange gains; (ii) government grants income; and (iii) interest income. For the years ended December 31, 2021 and 2022, we recorded other income and gains of RMB19.6 million and RMB48.9 million, respectively. The increase was primarily attributable to an increase in the foreign exchange gain of RMB34.9 million resulted from the appreciation of the U.S. dollar against RMB, which is our functional and reporting currency.

## **Research and Development Expenses**

During the Reporting Period, our research and development expenses primarily consisted of (i) employee benefit expenses including salaries, social insurance, pension, bonus, and share-based expenses related to our research and development personnel; (ii) third-party contracting expenses paid to service providers; and (iii) upfront and milestone fee associated with the exclusive development rights in designated regions of our in-licensed drug candidates. For the years ended December 31, 2021 and 2022, we recorded research and development expenses of RMB371.2 million and RMB350.9 million, respectively.

The slight decrease is mainly due to the following reasons: (i) the upfront and milestone cost associated with the exclusive development rights in designated regions of our in-licensed drug candidates is reduced by RMB55.9 million; and (ii) employee benefit expenses including salaries, social insurance, pension, bonus, and share-based expenses related to our research and development personnel decreased by RMB14.1 million. Such decrease was partially offset by an increase in the third-party contracting expenses paid to service providers of RMB46.1 million.

## **Administrative Expenses**

During the Reporting Period, our administrative expenses primarily consisted of (i) employee benefit expenses including salaries, social insurance, pension, bonus, and share based expenses related to our administrative personnel; (ii) listing expenses in connection with the Global Offering; and (iii) professional service expenses mainly paid to the third party in relation to operating activities. For the years ended December 31, 2021 and 2022, we recorded administrative expenses of RMB151.0 million and RMB142.8 million, respectively. The decrease was primarily attributable to a decrease of professional service expenses of RMB11.3 million in relation to financing activities and operating activities.

## **Selling and Marketing Expenses**

During the Reporting Period, our selling and marketing expenses mainly represented promoting envafolimab in China in accordance with industry standards for the purpose of increasing its sales. Our selling and marketing expenses increased by 735.0% from RMB42.8 million for the year ended December 31, 2021 to RMB357.7 million for the year ended December 31, 2022. The increase was primarily attributable to the increase in sales of the 恩維達® since December 2021. It is noted that the rate of increase in revenue in 2022 (i.e. 841.6%) is faster than the rate of increase in selling and marketing expenses in 2022 (i.e. 735.0%).

## **Royalty Expenses**

As agreed under the Co-Development Agreements, upon the approval and commercialization of envafolimab, we are entitled to 51% while Alphamab Group is entitled to 49% of the profit before tax generated from the sales of envafolimab globally in the field of oncology therapy.

For the years ended December 31, 2021 and 2022, we recorded royalty expenses of RMB7.2 million and RMB60.0 million, respectively. The increase was primarily attributable to that we only began sales of envafolimab since December 2021.

## **Impairment Losses on Financial Assets, net**

During the Reporting Period, our impairment losses on financial assets represented expected credit losses on our trade receivables and financial assets measured at amortized cost. For the years ended December 31, 2021 and 2022, we recorded impairment losses on financial assets of RMB0.1 million and RMB1.2 million, respectively. The increase was primarily attributable to our trade receivables increased by RMB13.0 million in 2022 and our financial assets measured at amortized cost increased by RMB136.7 million in 2022. The Group conducted an ECL assessment according to forward-looking information and used appropriate models and assumptions in its expected measurement credit losses. These models and assumptions relate to the future macroeconomic conditions and borrower's creditworthiness (e.g., the likelihood of default by borrowers and the corresponding losses).

## **Other Expenses**

During the Reporting Period, our other expenses primarily consisted of donations. For the years ended December 31, 2021 and 2022, we recorded other expenses of RMB8.9 million and RMB53.4 million, respectively. The increase was primarily attributable to an increase in donations of RMB51.9 million worth of 恩維達® and cash we made to a non-profit charity organization, which supports cancer patients for public welfare purposes.

The foreign exchange losses arose from the fluctuations in exchange rate between RMB, our functional currency, and U.S. dollar.

The Group manages its foreign exchange risk by closely monitoring the movement of the foreign currency rates, the Group did not commit to any financial instruments to hedge its exposure to foreign currency risk.

## Finance Costs

During the Reporting Period, our finance costs consisted of (i) interest on bank loans; and (ii) interest on lease liabilities. For the years ended December 31, 2021 and 2022, we recorded finance costs of RMB1.5 million and RMB3.1 million, respectively. The increase was primarily attributable to the increase of interest expenses related to the leased properties and the interest expense associated with the bank loans.

## Non-IFRS Measures

In order to supplement our consolidated statements of profit or loss and other comprehensive income which are presented in accordance with IFRS, we use adjusted loss and total comprehensive loss as an additional financial measure, which is not required by, or presented in accordance with IFRS. Our adjusted loss and total comprehensive loss represents our loss and total comprehensive loss for the year, adjusted to add back fair value losses on preferred shares and share-based payment expenses. We believe that such measure provides investors and other persons with useful information to understand and evaluate our consolidated results of operation in the same manner as it helps our management. However, adjusted net loss presented by us may not be comparable to the similar financial measure presented by other companies. There are limitations to the non-IFRS measure used as an analytical tool, and you should not consider it in isolation or regard it as a substitute for our results of operation or financial position analysis that is presented in accordance with IFRS.

The following table sets forth our loss and total comprehensive loss and adjusted loss and total comprehensive loss for the year, which is adjusted by adding back fair value losses on preferred shares and share-based payment expenses, for the years indicated:

	<b>2022</b>	2021	<b>Changes</b>
	<b>RMB'000</b>	RMB'000	%
Total comprehensive loss for the year	<b>(1,052,030)</b>	(1,461,825)	(28.0)
<i>Add:</i>			
Fair value losses on preferred shares	<b>657,155</b>	954,742	(31.2)
Share-based payment expenses	<b>141,694</b>	164,663	(13.9)
Adjusted total comprehensive loss for the year	<b><u>(253,181)</u></b>	<b><u>(342,420)</u></b>	(26.1)

## Selected Data from Consolidated Statement of Financial Position

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Total non-current assets	189,005	141,066
Total current assets	<u>1,143,058</u>	<u>919,227</u>
<b>Total assets</b>	<b><u>1,332,063</u></b>	<b><u>1,060,293</u></b>
Total non-current liabilities	60,400	84,810
Total current liabilities	<u>376,249</u>	<u>3,248,045</u>
<b>Total liabilities</b>	<b><u>436,649</u></b>	<b><u>3,332,855</u></b>

### Liquidity and Capital Resources

Since our inception, we have incurred net losses and negative cash flows from our operations. Our primary uses of cash are to fund the research and development of our drug pipeline, our clinical trials, administrative expenses and other recurring expenses.

Our net cash used in operating activities amounted to RMB377.1 million and RMB278.8 million for the years ended December 31, 2021 and 2022, respectively. As our business develops and expands, we expect to generate cash from our operating activities mainly through sales of our products. We shall continue to advance our late stage clinical assets into NDA stage and commercialization which will bring incremental cash flow to fund our operations in the foreseeable future.

For the year ended December 31, 2022, our net cash flows used in investing activities was RMB242.1 million, primarily as a result of (i) purchase of items of property, plant and equipment of RMB54.0 million; (ii) purchase of financial assets at FVTPL of RMB322.4 million, partially offset by proceeds from disposal of financial assets at FVTPL of RMB265.8 million; and (iii) purchase of financial assets measured at amortised cost of RMB 137.5 million.

For the year ended December 31, 2022, our net cash flows from financing activities was RMB408.4 million, primarily as a result of (i) proceeds from issue of ordinary shares of RMB313.5 million; and (ii) new bank loans and other borrowings of RMB149.0 million and partially offset by repayment of bank loans and other borrowings of RMB19.1 million.

As of December 31, 2022, our cash and bank balances is RMB696.7 million, meanwhile our liquidity can be further improved with financial assets at fair value through profit or loss of RMB108.6 million and financial assets measured at amortised cost of RMB136.7 million.

### Capital Expenditure

Our capital expenditures primarily consist of expenditures to expand our operations and optimize our operating efficiency in order to enhance our development capabilities and expand our business operations, including the construction of our facility in Xuzhou city. Our capital expenditures decreased from RMB55.4 million in 2021 to RMB54.0 million in 2022.

## **Borrowings and Gearing Ratio**

As at December 31, 2022, the Group aggregated interest-bearing bank borrowings of RMB131.0 million. Among the total borrowings, RMB104.0 million will be due within one year and RMB27.0 million will be due after one year.

As at December 31, 2022, the gearing ratio, calculated as total liabilities over total assets, was 33%, as compared with 314% as at December 31, 2021. The improvement is mainly due to the decrease of preferred shares related liabilities as a result of company public listing in December 2022.

## **Contingent Liabilities**

As at December 31, 2022, the Group did not have any material contingent liabilities.

## **Foreign Exchange Exposure**

During the Reporting Period, the Group mainly operated in China and a majority of its transactions were settled in Renminbi, the functional currency of the Company's primary subsidiaries. The Group is exposed to foreign currency risk as a result of certain cash and bank balances and time deposits, and redeemable and convertible preferred shares denominated in non-functional currency. We currently do not have a foreign currency hedging policy. However, our management monitors foreign exchange exposure and will consider hedging significant foreign currency exposure should the need arise.

## **Significant Investments, Material Acquisitions and Disposals**

The Group did not have material acquisitions or disposals of subsidiaries, associates and joint ventures during the Reporting Period.

## **Future Investment Plans and Expected Funding**

The Group had no material capital expenditure plan as of the date of this announcement.

## **Employees and Remuneration**

As of December 31, 2022, the Group had 245 full-time employees, who were based in Shanghai and Beijing, other cities of China and U.S. The total employee benefits expenses of our Group, which consist of (i) wages, salaries and bonuses, (ii) social security costs, (iii) employee welfare and (iv) equity-settled share awards, for the year ended December 31, 2022, were approximately RMB277.9 million.

We recruit our employees based on a number of factors, including work experience, educational background and the requirements of a relevant vacancy etc.. We invest in continuing education and training programs for our management staff and other employees to upgrade their skills and knowledge continuously. We provide our employees with regular feedback as well as internal and external training in various areas, such as product knowledge, project development and team building. We also assess our employees based on their performance to determine their salary, promotion and career development.

In compliance with the relevant PRC labor laws, we enter into individual employment contracts with our employees covering matters such as terms, wages, employee benefits, workplace safety, confidentiality obligations, non-competition and grounds for termination. In addition, we are required under PRC laws to make contributions to statutory employee benefit plans (including pension plans, medical insurance, work-related injury insurance, unemployment insurance, maternity insurance and housing funds) at a certain percentage of our employees' salaries, up to a maximum amount specified by local governments.

## **SIGNIFICANT EVENTS AFTER THE END OF THE REPORTING PERIOD**

On January 6, 2023, the Over-allotment Option as stated in the Prospectus was partially exercised by the Joint Representatives on behalf of the International Underwriters in respect of an aggregate of 415,000 Shares. For details of the partial exercise of the Over-allotment Option, please refer to the announcement of the Company published on January 9, 2023.

Save as disclosed above, there is no material subsequent event undertaken by the Company or the Group after the Reporting Period and up to the date of this announcement.

## **USE OF NET PROCEEDS FROM LISTING**

The 255,642,000 Shares were listed on the Main Board of the Stock Exchange by way of Global Offering on December 15, 2022, and the total net proceeds received by the Company from the Global Offering (excluding the proceeds from the partial exercise of the Over-allotment Option) amounted to approximately HK\$251.1 million after deducting professional fees, underwriting commissions and other related listing expenses.

The 415,000 Shares in connection with the partial exercise of the Over-allotment Option were listed on the Main Board of the Stock Exchange on January 11, 2023, and the additional net proceeds (together with the total net proceeds from the Global Offering, the "Net Proceeds") received by the Company amounted to approximately HK\$10.4 million after deducting professional fees, underwriting commissions and other related listing expenses.

The intended uses and the balance of the total net proceeds from the Global Offering (excluding the proceeds from the partial exercise of the Over-allotment Option) as at December 31, 2022 are set out below:

Intended use of proceeds as stated in the Prospectus	Percentage to total amount %	Total net proceeds from the Global Offering (excluding the proceeds from the partial exercise of the Over-allotment Option) RMB'000	Utilised amount as at December 31, 2022 RMB'000	Unutilised amount as at December 31, 2022 RMB'000
(a) Research and development, regulatory filings and commercialization of our product and drug candidates:	90	201,515.3	11,902.9	189,612.4
(i) 恩維達® envafolimab	55	123,148.2	11,279.0	111,869.2
(ii) other drug candidates	25	55,976.5	623.9	55,352.6
(iii) the construction of our in- house production facilities in Xuzhou, Jiangsu province and procurement of new machineries, instruments and equipment	10	22,390.6	-	22,390.6
(b) General corporate and working capital purposes	10	22,390.6	1,300.4	21,090.2
Total	<u>100</u>	<u>223,905.9</u>	<u>13,203.3</u>	<u>210,702.6</u>

The Group will utilize the Net Proceeds in accordance with the intended purposes as set out in the Prospectus. The Board is not aware of any material change to the planned use of the Net Proceeds as at the date of this announcement.

## **DIVIDEND**

The Board did not recommend the payment of a final dividend for the year ended December 31, 2022.



## **CLOSURE OF THE REGISTER OF MEMBERS**

The Company will hold the AGM on Monday, June 26, 2023. The register of members of the Company will be closed from Tuesday, June 20, 2023 to Monday, June 26, 2023, both days inclusive, in order to determine the identity of the Shareholders who are entitled to attend the AGM, during which period no share transfers will be registered. To be eligible to attend the AGM, all properly completed transfer forms accompanied by the relevant share certificates must be lodged for registration with the Company's branch share registrar in Hong Kong, Tricor Investor Services Limited, at 17/F, Far East Finance Centre, 16 Harcourt Road, Hong Kong no later than 4:30 p.m. on Monday, June 19, 2023.

## **CORPORATE GOVERNANCE**

The Group is committed to maintaining high standards of corporate governance to safeguard the interests of the Shareholders and to enhance corporate value and accountability. The Company has adopted the CG Code as set out in Appendix 14 of the Listing Rules on the Stock Exchange as its own code of corporate governance. The Company has complied with all applicable code provisions of the CG Code during the Reporting Period, save for the deviations from the code provisions C.2.1, C.5.1, D.3.3 and F.1.1 as explained below. The Company will continue to review and monitor its corporate governance practices to ensure compliance with the CG Code.

Code provision C.2.1 of the CG Code stipulates that the roles of chairman and chief executive should be segregated and should not be performed by the same individual. According to the current structure of the Board, the positions of the Chairman and Chief Executive Officer of the Company are held by Dr. Gong Zhaolong.

The Board believes that this structure will not impair the balance of power and authority between the Board and the management of the Company, given that: (i) decision to be made by the Board requires approval by at least a majority of the Directors and that the Board comprises three independent nonexecutive Directors out of seven Directors, and the Board believes there is sufficient check and balance on the Board, (ii) Dr. Gong Zhaolong and the other Directors are aware of and undertake to fulfil their fiduciary duties as Directors, which require, among other things, that they act for the benefit and in the best interests of the Company and will make decisions of the Group accordingly, and (iii) the balance of power and authority is ensured by the operations of the Board which comprises experienced and high caliber individuals who meet regularly to discuss issues affecting the operations of the Group. Moreover, the overall strategic and other key business, financial and operational policies of the Group are made collectively after thorough discussion at both the Board and senior management levels. Finally, as Dr. Gong Zhaolong is our principal founder, the Board believes that vesting the roles of both chairman and chief executive officer in the same person has the benefit of ensuring consistent leadership within the Group and enables more effective and efficient overall strategic planning for the Group. The Board will continue to review the effectiveness of the corporate governance structure of the Group in order to assess whether separation of the roles of chairman and chief executive officer is necessary.

Code provision C.5.1 of the CG Code provides that Board meetings should be held at least four times a year at approximately quarterly intervals with active participation of the majority of the Directors, either in person or through electronic means of communication. As the Company was only listed on the Stock Exchange on December 15, 2022, no Board meetings were held during the period from the Listing Date to December 31, 2022. The Company expects to continue to convene at least four regular meetings in each financial year at approximately quarterly intervals in accordance with code provision C.5.1 of the CG Code.

Code provision D.3.3 of the CG Code provides that members of the Audit Committee should liaise with the Board and senior management and the committee must meet, at least twice a year, with the auditors. As the Company was only listed on the Stock Exchange on December 15, 2022, only one Audit Committee meeting was held during the period from the Listing Date to December 31, 2022. The Company expects to continue to convene at least two regular meetings in each financial year at approximately semi-annually intervals in accordance with code provision D.3.3 of the CG Code.

Code provision F.1.1 of the CG Code provides that the issuer should have a policy on payment of dividends. As the Company expects to retain all future earnings for use in the operation and expansion of the business and does not have any dividend policy to declare or pay any dividends in the near future. The Board will review the Company's status periodically and consider adopting a dividend policy if and when appropriate.

A detailed Corporate Governance Report setting out the Group's framework of governance and explanations about how the provisions of the CG Code have been applied will be included in the Company's 2022 Annual Report to be published.

## **MODEL CODE FOR SECURITIES TRANSACTIONS**

The Company has adopted the Model Code as set out in Appendix 10 of the Listing Rules as its own code of conduct regarding directors' securities transactions. Having made specific enquiries of all Directors, each of the Directors has confirmed that he/she has complied with the required standards as set out in the Model Code during the Reporting Period.

## **PURCHASE, SALE OR REDEMPTION OF LISTED SECURITIES**

During the Reporting Period, except for the Global Offering in connection with the Listing, neither the Company nor any of its subsidiaries or consolidated affiliated entities has purchased, sold or redeemed any of the Company's listed securities.

## **AUDIT COMMITTEE**

The Company has established an Audit Committee with written terms of reference in compliance with Rule 3.21 of the Listing Rules and paragraph A.2 and paragraph D.3 of the CG Code. The primary duties of the Audit Committee are to assist the Board by providing an independent view of the effectiveness of the financial reporting process, internal control and risk management systems of the Group, overseeing the audit process and performing other duties and responsibilities as assigned by the Board. The Audit Committee consists of two independent non-executive Directors being Dr. Lin Tat Pang, Dr. Li Jin and non-executive Director Mr. Zhu Pai. The chairman of the Audit Committee is Dr. Lin Tat Pang. Dr. Lin holds the appropriate professional qualifications as required under Rules 3.10(2) and 3.21 of the Listing rules. The Audit Committee had reviewed together with the management the accounting principles and policies adopted by the Group and discussed internal controls and financial reporting matters including a review of the consolidated financial statements and annual results of the Group for the year ended December 31, 2022.

## **PUBLICATION OF THE ANNUAL RESULTS AND 2022 ANNUAL REPORT ON THE WEBSITES OF THE STOCK EXCHANGE AND THE COMPANY**

This annual results announcement is published on the websites of the Stock Exchange ([www.hkexnews.hk](http://www.hkexnews.hk)) and the Company ([www.3d-medicines.com](http://www.3d-medicines.com)), and the 2022 Annual Report containing all the information required by the Listing Rules will be dispatched to the Shareholders and published on the respective websites of the Stock Exchange and the Company in due course.

## CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

Year ended December 31, 2022

	<i>Notes</i>	<b>2022</b> <b>RMB'000</b>	2021 <i>RMB'000</i>
REVENUE	4	567,392	60,260
Cost of sales		<u>(42,215)</u>	<u>(4,277)</u>
Gross profit		525,177	55,983
Other income and gains	4	48,945	19,637
Research and development expenses		(350,864)	(371,162)
Administrative expenses		(142,830)	(150,956)
Selling and marketing expenses		(357,659)	(42,834)
Royalty expenses		(59,965)	(7,153)
Other expenses	5	(53,391)	(8,940)
Finance costs	6	(3,113)	(1,528)
Fair value losses on preferred shares		(657,155)	(954,742)
Impairment losses on financial assets, net		<u>(1,175)</u>	<u>(130)</u>
LOSS BEFORE TAX	7	(1,052,030)	(1,461,825)
Income tax expense	8	<u>—</u>	<u>—</u>
TOTAL COMPREHENSIVE LOSS FOR THE YEAR		<u><b>(1,052,030)</b></u>	<u><b>(1,461,825)</b></u>
Attributable to:			
Owners of the parent		(1,024,350)	(1,434,092)
Non-controlling interests		<u>(27,680)</u>	<u>(27,733)</u>
		<u><b>(1,052,030)</b></u>	<u><b>(1,461,825)</b></u>
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted (RMB)	10	<u><b>(22.52)</b></u>	<u><b>(36.72)</b></u>

## CONSOLIDATED STATEMENT OF FINANCIAL POSITION

As at December 31, 2022

	<i>Notes</i>	<b>2022</b> <b>RMB'000</b>	2021 <i>RMB'000</i>
<b>NON-CURRENT ASSETS</b>			
Property, plant and equipment		<b>126,822</b>	52,246
Intangible assets		<b>828</b>	929
Right-of-use assets		<b>51,021</b>	66,293
Other non-current assets		<b>8,263</b>	18,384
Amounts due from related parties		<b>2,071</b>	3,214
		<hr/>	<hr/>
Total non-current assets		<b>189,005</b>	141,066
<b>CURRENT ASSETS</b>			
Inventories		<b>1,196</b>	13
Trade receivables	<i>11</i>	<b>78,041</b>	65,004
Prepayments, other receivables and other assets		<b>120,552</b>	29,654
Amounts due from related parties		<b>1,241</b>	–
Financial assets at fair value through profit or loss (“FVTPL”)		<b>108,604</b>	50,178
Financial assets measured at amortised cost		<b>136,684</b>	–
Restricted bank balances		<b>–</b>	72
Cash and bank balances		<b>696,740</b>	774,306
		<hr/>	<hr/>
Total current assets		<b>1,143,058</b>	919,227
<b>CURRENT LIABILITIES</b>			
Trade payables	<i>12</i>	<b>15,880</b>	3,742
Other payables and accruals		<b>245,068</b>	137,431
Interest-bearing bank borrowings		<b>103,993</b>	–
Amounts due to related parties		<b>–</b>	150
Preferred shares		<b>–</b>	3,093,968
Lease liabilities		<b>11,308</b>	12,754
		<hr/>	<hr/>
Total current liabilities		<b>376,249</b>	3,248,045
<b>NET CURRENT ASSETS/(LIABILITIES)</b>		<b>766,809</b>	<b>(2,328,818)</b>
		<hr/>	<hr/>
<b>TOTAL ASSETS LESS CURRENT LIABILITIES</b>		<b>955,814</b>	<b>(2,187,752)</b>

continued/

## CONSOLIDATED STATEMENT OF FINANCIAL POSITION (continued)

As at December 31, 2022

	<i>Notes</i>	<b>2022</b> <b>RMB'000</b>	2021 <i>RMB'000</i>
<b>NON-CURRENT LIABILITIES</b>			
Lease liabilities		<b>33,400</b>	45,987
Preferred shares		–	38,823
Interest-bearing bank borrowings		<b>27,000</b>	–
		<hr/>	<hr/>
Total non-current liabilities		<b>60,400</b>	84,810
		<hr/>	<hr/>
<b>NET ASSETS/(LIABILITIES)</b>		<b>895,414</b>	<b>(2,272,562)</b>
		<hr/> <hr/>	<hr/> <hr/>
<b>EQUITY/(DEFICIENCY IN EQUITY)</b>			
Equity attributable to owners of the parent			
Share capital		<b>223</b>	57
Treasury shares		<b>(26)</b>	(27)
Reserves/(deficits)		<b>942,804</b>	<b>(2,238,041)</b>
		<hr/>	<hr/>
		<b>943,001</b>	<b>(2,238,011)</b>
		<hr/>	<hr/>
Non-controlling interests		<b>(47,587)</b>	<b>(34,551)</b>
		<hr/>	<hr/>
<b>TOTAL EQUITY/(DEFICITS)</b>		<b>895,414</b>	<b>(2,272,562)</b>
		<hr/> <hr/>	<hr/> <hr/>

## NOTES TO FINANCIAL STATEMENTS

As at December 31, 2022

### 1. CORPORATE INFORMATION

3D Medicines Inc. (the “**Company**”) was incorporated in the Cayman Islands (“Cayman”) on January 30, 2018 as a limited liability company. The registered office address of the Company is Cricket Square, Hutchins Drive, P.O. Box 2681, Grand Cayman KY1-1111, Cayman Islands.

The Company is an investing holding company. The Company and its subsidiaries (collectively referred to as the “**Group**”) are principally engaged in the research, development and commercialisation of pharmaceutical products.

### 2 BASIS OF PREPARATION

These financial statements have been prepared in accordance with International Financial Reporting Standards (“IFRSs”), which include all standards and interpretations approved by the International Accounting Standards Board (“IASB”), accounting principles generally accepted in Hong Kong and the disclosure requirements of the Hong Kong Companies Ordinance. They have been prepared under the historical cost convention, except for wealth management products which have been measured at fair value. These financial statements are presented in RMB and all values are rounded to the nearest thousand (RMB’000) except when otherwise indicated.

### 3. OPERATING SEGMENT INFORMATION

#### Operating segment information

The Group is engaged in biopharmaceutical research and development, which is regarded as a single reportable segment in a manner consistent with the way in which information is reported internally to the Group’s senior management for purposes of resource allocation and performance assessment. Therefore, no further operating segment analysis thereof is presented.

#### Geographical information

During the reporting period, all of the Group’s revenues were derived from customers located in Mainland China and almost all of the Group’s non-current assets were located in Mainland China, and therefore no geographical information is presented in accordance with IFRS 8 Operating Segments.

#### Information about major customers

Revenue from each major customer (including sales to a group of entities which are known to be under common control with that customer) which accounted for 10% or more of the Group’s revenue during the reporting period is set out below:

	Year ended December 31,	
	2022	2021
	<i>RMB’000</i>	<i>RMB’000</i>
Customer A	<b>234,018</b>	21,789
Customer B	<b>73,543</b>	8,399
Customer C	<b>61,050</b>	–

#### 4. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Revenue from contracts with customers		
Sales of products	<u>567,392</u>	<u>60,260</u>

#### Revenue from contracts with customers

##### (a) *Disaggregated revenue information*

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
<b>Geographical market</b>		
Mainland China	<u>567,392</u>	<u>60,260</u>
<b>Timing of revenue recognition</b>		
Goods transferred at a point in time	<u>567,392</u>	<u>60,260</u>

There was no revenue recognised during the reporting period that was included in the contract liabilities at the beginning of the reporting period and recognised from performance obligations satisfied in previous periods.

##### (b) *Performance obligations*

Information about the Group's performance obligations is summarised below:

###### *Sales of products*

The performance obligation is satisfied upon delivery of the products and acceptance by the customers. During the year ended December 31, 2022, for customers obtained through Jiangsu Simcere's distribution network, Jiangsu Simcere reconciles the payments received from the customers with the Group on monthly basis, and the credit term given to Jiangsu Simcere is usually 70 days, while customer developed by the Group usually have a credit term of 45 to 60 days.



An analysis of other income and gains is as follows:

	<b>2022</b>	2021
	<b><i>RMB'000</i></b>	<i>RMB'000</i>
Other income		
Government grants income*	<b>4,811</b>	8,423
Interest income	<b>7,210</b>	5,502
Investment income on other investments classified as financial assets at FVTPL	<b>1,595</b>	424
Investment income on other investments classified as financial assets at amortised cost	<b>314</b>	–
Contract research income	<b>–</b>	5,110
	<b>13,930</b>	19,459
Other Gains		
Foreign exchange gains, net	<b>34,860</b>	–
Fair value gains on other investments classified as financial assets at FVTPL	<b>155</b>	178
	<b>35,015</b>	178
	<b>48,945</b>	19,637

\* The government grants mainly represent subsidies received from the local governments for the purpose of compensation of expenses spent on research, clinical trial activities and allowances for new drug development. There were no unfulfilled conditions or contingencies relating to the grants.

## 5. OTHER EXPENSES

	<b>2022</b>	2021
	<b><i>RMB'000</i></b>	<i>RMB'000</i>
Donations*	<b>53,340</b>	1,424
Foreign exchange losses, net	–	3,699
Research service cost	–	2,538
Loss on disposal of property, plant and equipment	–	959
Others	<b>51</b>	320
	<b>53,391</b>	8,940

\* Donations represented the expenditures incurred in relation to a drug donation program hosted by a charity organization.

## 6. FINANCE COSTS

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Interest on lease liabilities	1,910	1,482
Interest on bank borrowings	1,203	46
	<u>3,113</u>	<u>1,528</u>

## 7. LOSS BEFORE TAX

The Group's loss before tax is arrived at after charging/(crediting):

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Fair value losses on preferred shares	657,155	954,742
Marketing service fees*	326,213	38,281
Royalty expenses**	59,965	7,153
Donations	53,340	1,424
Cost of inventories sold	42,215	4,277
Listing expenses	29,192	25,565
Depreciation of right-of-use assets	13,627	8,757
Depreciation of property, plant and equipment	7,872	3,750
Auditor's remuneration	2,990	23
Impairment losses on financial assets measured at amortised cost	1,149	–
Lease payments in respect of short-term leases	440	1,263
Amortisation of intangible assets	101	84
Impairment losses on trade receivables	26	130
Loss on disposal of property, plant and equipment	–	959
Fair value gains on other investments classified as financial assets at FVTPL	(155)	(178)
Employee benefit expenses (excluding directors' and chief executive's remuneration)		
Wages and salaries	119,451	103,682
Equity-settled share-based payment expenses	39,157	87,686
Pension scheme contributions***	11,708	7,153
Staff welfare expenses	3,206	2,272
	<u>173,522</u>	<u>200,793</u>

\* Pursuant to the marketing and promotion agreement with Jiangsu Simcere, the Group needs to pay Jiangsu Simcere marketing service fees for the marketing and promotion services performed by Jiangsu Simcere for the Group's sales of envafolimab. The marketing service fees are recognised in selling and marketing expenses at the time when the Group is obligated to pay and the amounts are determinable.

\*\* Pursuant to the co-development agreement with Alphamab, the Group needs to pay Alphamab royalty fees on profit-sharing basis as part of the consideration for the exclusive rights acquired from Alphamab to conduct clinical trials and commercialize envafohimab worldwide. The royalty expenses are recognised at the time when the Group is obligated to pay and the amounts are determinable.

\*\*\* There are no forfeited contributions that may be used by the Group as the employer to reduce the existing level of contributions.

## 8. INCOME TAX

We did not recognize any income tax expense for the Reporting Period.

## 9. DIVIDENDS

No dividends have been declared and paid by the Company during the year (2021: Nil).

## 10. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

The calculation of the basic loss per share amount is based on the loss attributable to ordinary equity holders of the parent and the weighted average number of ordinary shares in issue (excluding shares reserved for share incentive scheme) during the reporting period. The weighted average number of ordinary shares has been retrospectively adjusted for the effect of the implemented share subdivision.

No adjustment has been made to the basic loss per share amounts presented for the reporting period in respect of a dilution as the impact of the preferred shares and restricted share units had an anti-dilutive effect on the basic loss per share amounts presented.

The calculation of the basic and diluted loss are based on:

	2022	2021
<b>Loss for the year</b>		
Loss for the year attributable to ordinary equity holders of the parent, used in the basic loss per share calculation (RMB'000)	<u><u>(1,024,350)</u></u>	<u><u>(1,434,092)</u></u>
<b>Number of shares</b>		
Weighted average number of ordinary shares in issue during the year, used in the basic loss per share calculation ('000)	<u><u>45,488</u></u>	<u><u>39,051</u></u>
<b>Loss per share (basic and diluted)</b>		
RMB per share	<u><u>(22.52)</u></u>	<u><u>(36.72)</u></u>

## 11. TRADE RECEIVABLES

	<b>2022</b> <i>RMB'000</i>	2021 <i>RMB'000</i>
Trade receivables	<b>78,197</b>	65,134
Impairment	<b>(156)</b>	(130)
	<b>78,041</b>	65,004

The Group's trade terms with Jiangsu Simcere and the distributors are payment on credit. The credit period is generally 70 days for Jiangsu Simcere and 45 to 60 days for the distributors. The Group seeks to maintain strict control over its outstanding receivables and has a credit control department to minimise credit risk. Overdue balances are reviewed regularly by senior management. The Group does not hold any collateral or other credit enhancements over its trade receivable balances. Trade receivables are non-interest-bearing. The Group has a concentration of credit risk as 96% (2021: 100%) of trade receivables were due from Jiangsu Simcere, a service provider of the Group, at the end of the year.

An ageing analysis of the trade receivables as at the end of the reporting period, based on the invoice date and net of loss allowance, is as follows:

	<b>2022</b> <i>RMB'000</i>	2021 <i>RMB'000</i>
Within 3 months	<b>78,041</b>	65,004

The movements in the loss allowance for impairment of trade receivables are as follows:

	<b>2022</b> <i>RMB'000</i>	2021 <i>RMB'000</i>
At beginning of year	<b>130</b>	–
Impairment losses	<b>26</b>	130
At end of year	<b>156</b>	130

The Group performed an impairment analysis during the reporting periods by considering the probability of default of the debtors or comparable companies with published credit ratings. Set out below is the information about the credit risk exposure on the Group's trade receivables using a provision matrix:

	<b>2022</b> <i>Current</i>	2021 <i>Current</i>
Expected credit loss rate	<b>0.2%</b>	0.2%
Gross carrying amount (RMB'000)	<b>78,197</b>	65,134
Expected credit losses (RMB'000)	<b>156</b>	130

## 12. TRADE PAYABLES

An ageing analysis of the trade payables as at the end of the reporting periods, based on the invoice date, is as follows:

	<b>2022</b> <i>RMB'000</i>	2021 <i>RMB'000</i>
Within 3 months	<b>11,346</b>	3,732
3 to 6 months	<b>255</b>	–
6 months to 1 year	<b>4,279</b>	10
	<b>15,880</b>	3,742

The trade payables are non-interest-bearing and payable on demand, which are normally settled on terms of 1 to 3 months.

## DEFINITIONS AND GLOSSARY

In this annual results announcement, unless the context otherwise requires, the following expressions shall have the following meanings.

“恩維達®”	envafolimab (brand name: ENWEIDA, 恩維達®), a subcutaneously-injectable PD-L1 inhibitor for the treatment of tumor-agnostic indications
“AGM”	the annual general meeting of the Company to be held on Monday, June 26, 2023
“Alphamab Group”	Alphamab Oncology (康寧傑瑞生物製藥), an exempted company with limited liability incorporated under the laws of the Cayman Islands on March 28, 2018 and listed on the Stock Exchange (stock code: 9966), and its subsidiaries, each of which is an Independent Third Party
“AML”	acute myeloid leukemia, a type of cancer that progresses rapidly and aggressively, and affects the bone marrow and blood
“Aravive”	Aravive Inc., a clinical-stage oncology company incorporated in the U.S. on December 10, 2008 and listed on the Nasdaq Stock Market (stock code: ARAV), which is an Independent Third Party
“Audit Committee”	the audit committee of the Board
“AXL”	AXL is a receptor tyrosine kinase that transduces signals from the extracellular matrix into the cytoplasm <sup>28</sup> and regulates many physiological processes, including cell survival, proliferation, differentiation and immune responses

“BLA”	biologic license application
“Board of Directors” or “Board”	the board of Directors
“CD3”	cluster of differentiation 3, a protein complex (enzyme) and T-cell co-receptor that is involved in activating both the cytotoxic T-cell and T helper cells
“CD47”	cluster of differentiation 4, a glycoprotein found on the surface of immune cells such as T helper cells
“CDE”	center for drug evaluation
“CG Code”	the “Corporate Governance Code” as contained in Appendix 14 to the Listing Rules
“China” or “PRC”	the People’s Republic of China, which, for the purpose of this interim results announcement and for geographical reference only, excludes Hong Kong, Macau and Taiwan
“CMO(s)”	a contract manufacturing organization, which provides support to the pharmaceutical industry in the form of manufacturing services outsourced on a contract basis
“Co-Development Agreements”	the co-development agreement and the subsequent amendments and supplemental agreements thereto entered into by our Company with Alphamab Group for envafolimab
“Company” or “our Company”	3D Medicines Inc., an exempted company with limited liability incorporated under the laws of the Cayman Islands on January 30, 2018
“CRO”	contract research organization, a company provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research and development services outsourced on a contract basis
“CSCO”	the Chinese Society of Clinical Oncology
“Director(s)”	the director(s) of the Company or any one of them
“EC”	Endometrial cancer
“EMA”	European Medicines Agency
“FDA”	the United States Food and Drug Administration
“Frost and Sullivan”	Frost & Sullivan (Beijing) Inc., Shanghai Branch Co., an independent market research and consulting company
“Global Offering	the Hong Kong Public Offering and the International Offering

"GMP"	good manufacturing practice, guidelines and regulations issued from time to time pursuant to the PRC Law on the Administration of Pharmaceuticals (《中華人民共和國藥品管理法》) as part of quality assurance which ensures that pharmaceutical products subject to these guidelines and regulations are consistently produced and controlled in conformity to the quality and standards appropriate for their intended use
"Group", "our Group", "our", "we", or "us"	the Company and all of its subsidiaries, or any one of them as the context may require or, where the context refers to any time prior to its incorporation, the business which its predecessors or the predecessors of its present subsidiaries, or any one of them as the context may require, were or was engaged in and which were subsequently assumed by it
"Hong Kong"	the Hong Kong Special Administrative Region of the PRC
"Hong Kong dollars" or "HK dollars" or "HK\$"	Hong Kong dollars and cents respectively, the lawful currency of Hong Kong
"IFRS"	International Financial Reporting Standards, as issued from time to time by the International Accounting Standards Board
"IND"	investigational new drug or investigational new drug application, also known as clinical trial application in China
"Independent Third Party" or "Independent Third Parties"	a person or entity who is not a connected person of the Company under the Listing Rules
"International Underwriters"	the group of international underwriters, led by the Joint Representatives, that entered into the International Underwriting Agreement to underwrite the International Offering
"International Underwriting Agreement"	the underwriting agreement entered into on December 8, 2022 by our Company, our Single Largest Shareholder Group, the Joint Representatives, the Joint Global Coordinators and the International Underwriters in respect of the International Offering
"Jiangsu Simcere"	Jiangsu Simcere Pharmaceutical Co. Ltd., the subsidiary of Simcere Pharmaceutical Group Limited (先聲藥業集團有限公司), a private company limited by shares incorporated under the laws of Hong Kong on November 30, 2015 and listed on the Stock Exchange (stock code: 2096), an Independent Third Party
"Joint Representatives"	the joint representatives as named in the section headed "Directors and Parties Involved in the Global Offering" of the Prospectus



“KRAS”	Kirsten rat sarcoma virus, a gene that provides instructions for making a protein called K-Ras, a part of the RAS/MAPK pathway
“Listing”	the listing of the Shares on the Main Board of the Stock Exchange
“Listing Rules”	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (as amended, supplemented or otherwise modified from time to time)
“Model Code”	the “Model Code for Securities Transactions by Directors of Listed Issuers” set out in Appendix 10 to the Listing Rules
"MRCT"	multi-regional clinical trial
“NDA”	new drug application
“NMPA”	the National Medical Product Administration of the PRC (國家藥品監督管理局), successor to the China Food and Drug Administration or CFDA (國家食品藥品監督管理總局)
“NSCLC”	non-small cell lung cancer
“Over-allotment Option”	the option exercised by the Joint Representatives on behalf of the International Underwriters under the International Underwriting Agreement in respect of an aggregate of 415,000 Shares on January 6, 2023
“PD-1”	programmed cell death protein 1, an immune checkpoint receptor expressed on T cells, B cells and macrophages. The normal function of PD-1 is to turn off the T cell mediated immune response as part of the process that stops a healthy immune system from attacking other pathogenic cells in the body. When PD-1 on the surface of a T cell attaches to certain proteins on the surface of a normal cell or a cancer cell, the T cell turns off its ability to kill the cell
“PD-L1”	PD-1 ligand 1, which is a protein on the surface of a normal cell or a cancer cell that attaches to certain proteins on the surface of the T cell that causes the T cell to turn off its ability to kill the cancer cell
"PROC"	platinum resistant ovarian cancer
“Prospectus”	the prospectus of the Company dated November 29, 2022
“R&D”	research and development
“RCC”	renal cell carcinoma

“Reporting Period”	for the year ended December 31, 2022
“RMB”	Renminbi, the lawful currency of the PRC
“SELLAS Group”	SELLAS Life Sciences Group, Inc., a late-stage clinical biopharmaceutical company incorporated in the U.S. on April 3, 2006 and listed on the Nasdaq Stock Market (stock code: SLS), and its subsidiaries, each of which is an Independent Third Party
“Share(s)”	ordinary share(s) with nominal value of HK\$0.001 each in the share capital of the Company
“Shareholder(s)”	holder(s) of the Share(s)
“Single Largest Shareholder Group”	Dr. Gong Zhaolong, Dragon Prosper Holdings Limited, Immunal Medixin US Limited, Immunal Medixin Cino L. Limited and Immunal Medixin Cino Limited
“Stock Exchange”	The Stock Exchange of Hong Kong Limited
“TRACON”	TRACON Pharmaceuticals, Inc., a leading biopharmaceutical company incorporated in the U.S. on October 28, 2004 and listed on the Nasdaq Stock Market (stock code: TCON), which is an Independent Third Party
“UC”	urothelial carcinoma
“United States” or “U.S.”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
"WT1"	Wilms Tumor 1, a protein that in humans is encoded by the WT1 gene on chromosome 11p
%	per cent

By order of the Board  
**3D Medicines Inc.**  
**Dr. Gong Zhaolong**  
*Chairman of the Board and Executive Director*

Hong Kong, March 30, 2023

*As at the date of this announcement, the Board of Directors of the Company comprises Dr. GONG Zhaolong as executive Director, Mr. ZHU Pai, Mr. ZHOU Feng and Ms. CHEN Yawen as non-executive Directors, and Dr. LI Jin, Dr. LIN Tat Pang and Mr. LIU Xinguang as independent non-executive Directors.*