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Keymed Biosciences Inc.
康諾亞生物醫藥科技有限公司
(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 2162)

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

FINANCIAL HIGHLIGHTS

	2022	2021	Changes	Year-on-year changes
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	%
Revenue	100,063	110,269	(10,206)	(9%)
Cost of sales	(2,585)	(17,200)	14,615	(85%)
Gross profits	97,478	93,069	4,409	5%
Research and development expenses	(507,374)	(358,156)	(149,218)	42%
Administrative expenses	(133,912)	(92,454)	(41,458)	45%
Fair value losses on convertible redeemable preferred shares	-	(3,480,294)	3,480,294	(100%)
Total comprehensive loss for the year	(303,596)	(3,892,632)	3,589,036	(92%)
Adjusted total comprehensive loss for the year (as illustrated under “Non-IFRSs Measures”)	(255,029)	(295,515)	40,486	(14%)
	December 31, 2022	December 31, 2021	Changes	Year-on-year changes
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	%
Cash and cash equivalents, time deposits, and financial assets at FVTPL	3,175,326	3,524,579	(349,253)	(10%)

IFRS Measures:

- Revenue amounted to RMB100 million for the year ended December 31, 2022, mainly represented collaboration income from CSPC in respect of granting the relevant license.
- Cost of sales mainly represented R&D costs incurred under the out-licensing arrangement for the year ended December 31, 2022.

- Research and development expenses increased by RMB149 million to RMB507 million for the year ended December 31, 2022. The increase was primarily attributable to the increase of pre-clinical and clinical study expenses.
- Administrative expenses increased by RMB41 million to RMB134 million for the year ended December 31, 2022. The increase was consistent with the expansion of the operation of the Group during the year ended December 31, 2022.
- From 2018 to 2021, the Group issued convertible redeemable preferred shares (“**Preferred Shares**”) for equity financing. These Preferred Shares had been automatically converted to ordinary shares on a 1:1 basis upon the completion of the IPO on July 8, 2021, and the then fair value of financial liabilities had been reclassified as equity accordingly. Accordingly, no fair value changes on the Preferred Shares were recorded during the year ended December 31, 2022.

Non-IFRSs Measures:

To supplement the Group’s consolidated financial statements, which are presented in accordance with IFRSs, we also use the adjusted total comprehensive loss for the year as an additional financial measure, which is not required by, or presented in accordance with IFRSs. We believe that these adjusted measures provide useful information to shareholders and potential investors in understanding and evaluating our consolidated results of operations in turn as they help our management.

Adjusted total comprehensive loss for the year represents the total comprehensive loss for the year excluding the effect of certain non-cash items, namely the fair value loss on convertible redeemable preferred shares and share-based compensation expenses. The term adjusted total comprehensive loss for the year is not defined under IFRSs. The use of this non-IFRSs measure has limitations as an analytical tool, and you should not consider it in isolation from, or as a substitute for analysis of, our results of operations or financial condition as reported under IFRSs. Our presentation of this adjusted figure may not be comparable to similarly titled measures presented by other companies. However, we believe that this non-IFRSs measure reflects our core operating results by eliminating potential impacts of items that our management do not consider to be indicative of our core operating performance, and thus, facilitate comparisons of core operating performance from period to period and company to company to the extent applicable. The table below sets forth a reconciliation of total comprehensive loss to adjusted total comprehensive loss for the years indicated:

	2022	2021	Changes	Year-on-year changes
	RMB’000	RMB’000	RMB’000	%
Total comprehensive loss for the year	(303,596)	(3,892,632)	3,589,036	(92%)
<i>Add:</i>				
Fair value losses on convertible redeemable preferred shares	–	3,480,294	(3,480,294)	(100%)
Share-based payment expenses	48,567	116,823	(68,256)	(58%)
Adjusted total comprehensive loss for the year	(255,029)	(295,515)	40,486	(14%)

BUSINESS HIGHLIGHTS

During the Reporting Period, we have rapidly proceeded with the research and development of our products and made the following milestones and progress with respect to our pipeline under development and business operation:

- **Rapid development of in-house discovered products**

The progress of pipeline products:

CM310 (IL-4R α antibody)

We initiated a randomized, double-blinded, placebo-controlled Phase III clinical study to evaluate the efficacy and safety of CM310 in adult subjects with moderate-to-severe AD in the first quarter of 2022, and the patient enrollment of the Phase III clinical study was completed in November 2022. The Phase III clinical trial is expected to be completed and the NDA is expected to be submitted in 2023.

In June 2022, the CDE granted CM310 breakthrough therapy designation for the treatment of moderate-to-severe AD.

We completed the Phase II clinical trial of CM310 for patients with CRSwNP at the end of the first quarter of 2022. We also completed unblinded data and disclosed the relevant data in March 2022. Based on the positive results from Phase II clinical trial, we initiated a randomized, double-blinded, placebo-controlled Phase III clinical trial to evaluate the efficacy and safety of CM310 in patients with CRSwNP in mid-2022.

In July 2022, the IND for CM310 for the treatment of allergic rhinitis was approved by the NMPA.

In August 2022, the IND for CM310 for the treatment of adults with moderate-to-severe AD was approved by the FDA.

JMT-Bio, a wholly-owned subsidiary of CSPC, holds the exclusive license to develop and commercialize CM310 for the treatment of moderate-to-severe asthma, COPD and other respiratory diseases in China (excluding Hong Kong, Macau, or Taiwan). As of the date of this announcement, CSPC has initiated the critical Phase II/III clinical study for the treatment of moderate-to-severe asthma.

CM326 (TSLP antibody)

We initiated a multi-center, randomized, double-blinded, placebo-controlled Phase Ib/IIa clinical trial to evaluate the safety, tolerability, PK/PD, immunogenicity, and preliminary efficacy of CM326 in subjects with moderate-to-severe AD in the first half of 2022, and simultaneously initiated a randomized, double-blinded, placebo-controlled Phase II clinical study to evaluate efficacy and safety of CM326 in adult subjects with moderate-to-severe AD in the second half of 2022.

We initiated a multi-center, randomized, double-blinded, placebo-controlled Phase Ib/IIa clinical trial to evaluate the safety, tolerability, PK/PD, immunogenicity, and preliminary efficacy of CM326 in subjects with CRSwNP in mid-2022, and we completed the patient enrollment of the Phase Ib/IIa clinical trial in February 2023.

JMT-Bio, a wholly-owned subsidiary of CSPC, has the exclusive license to develop and commercialize CM326 for the treatment of moderate-to-severe asthma, COPD and other respiratory diseases in China (excluding Hong Kong, Macau, or Taiwan).

CMG901 (Claudin 18.2 ADC)

We completed the patient enrollment of the dose-escalation stage of the Phase I clinical trial of CMG901 in subjects with solid tumors in the first half of 2022, and initiated the dose-expansion stage of the Phase I clinical trial of CMG901 in subjects with solid tumors in China in the second quarter of 2022.

In April 2022, CMG901 for the treatment of relapsed/refractory gastric cancer and gastroesophageal junction adenocarcinoma was granted the Fast Track Designation and the Orphan-drug Designation by the FDA.

In September 2022, CDE granted CMG901 a breakthrough therapy designation for the treatment of Claudin 18.2-positive advanced gastric cancer that has failed or cannot be tolerated by first-line or above treatment.

In January 2023, at the 2023 ASCO Gastrointestinal Cancers Symposium, we released the latest data of Phase Ia dose-escalation clinical study of CMG901 for the treatment of advanced solid tumors. The results of the study showed good safety and tolerability for CMG901, and the dose successfully escalated into to 3.4 mg/kg, and the maximum tolerated dose (MTD) had not been reached yet. Only one patient in the 2.2 mg/kg group had dose-limiting toxicity. Among 8 patients with Claudin 18.2-positive gastric cancer or gastroesophageal junction adenocarcinoma treated with CMG901, the objective remission rate was 75%, and the disease control rate was 100%. Among them, the objective remission rate of patients in the 2.6, 3.0 and 3.4 mg/kg cohorts were all 100%. Neither the median progression-free survival (mPFS) nor the median overall survival (mOS) has been reached.

In February 2023, KYM, a 70% non-wholly owned subsidiary of the Group, entered into a global exclusive license agreement with AstraZeneca AB to develop and commercialize CMG901. Subject to the terms of the license agreement, AstraZeneca AB will be granted the exclusive worldwide license for the research, development, registration, production and commercialization of CMG901, and is responsible for all costs and activities related to its further development and commercialization under the license agreement. Pursuant to the license agreement and subject to its terms and conditions, KYM will receive an upfront payment of US\$63 million and additional potential payments of up to US\$1,125 million upon achievement of certain development, regulatory and commercial milestones.

CM313 (CD38 antibody)

We continued proceeding with the dose-escalation stage of the Phase I clinical trial of CM313 for the treatment of patients with MM in 2022. Meanwhile, we initiated a dose-expansion stage of Phase I clinical trial of CM313 for the treatment of patients with MM at the end of the first quarter of 2022.

In April 2022, CM313 was approved for clinical trials for the treatment of indication of systemic lupus erythematosus (SLE). In October 2022, the first patient was dosed with CM313 for the treatment of SLE, which is currently in the stage of the Phase Ib/IIa clinical study.

CM338 (MASP-2 antibody)

In November 2022, we completed a multiple-dose, randomized, double-blinded, placebo-controlled, dose-escalation Phase I clinical study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and immunogenicity of CM338 injection in healthy subjects. In March 2023, we initiated a Phase II clinical study to evaluate the efficacy and safety of CM338 injection in subjects with immunoglobulin A nephropathy (IgAN).

Progress of other pipeline products:

CM355/ICP-B02 (CD20xCD3 bispecific antibody)

In January 2022, the first patient was dosed with CM355, which is currently in the dose-escalation stage of Phase I clinical study. CM355 was jointly developed by us and InnoCare.

CM350 (GPC3xCD3 bispecific antibody)

In May 2022, the first patient was dosed with CM350, which is currently in the dose-escalation stage of the Phase I clinical study.

CM336 (BCMAxCD3 bispecific antibody)

In September 2022, the first patient was dosed with CM336, which is currently in the dose-escalation stage of the Phase I clinical study.

CM369/ICP-B05 (CCR8 antibody)

In August 2022, CM369/ICP-B05 was approved by the NMPA for clinical trials for the treatment of advanced solid tumors. In February 2023, the first patient was dosed with CM369, which is currently in the dose-escalation stage of the Phase I clinical study.

- **Rapid expansion of workforce and production facilities**

As of December 31, 2022, the Company had 613 full-time employees in total, including over 240 employees engaging in clinical development and operations and over 230 employees engaging in manufacturing and quality control. We will continue to recruit talents to meet the growing needs of research and development, clinical, production, operational and product commercialization.

The first phase of a new plant in Chengdu has been completed and put into production at the end of 2022, and has an additional production capacity of 16,000 litres in total. The designs of all facilities are in compliance with the requirements of cGMP of the NMPA and FDA.

- **Other matters**

In March 2022, our Shares have been included as eligible stocks of the Shenzhen-Hong Kong Stock Connect with effect from March 7, 2022.

In August 2022, our Shares have been included as a constituent of FTSE Global Small Cap ex-US Index with effect from September 16, 2022.

In November 2022, our Shares have been included as a constituent of MSCI China Small Cap Index with effect from November 30, 2022.

MANAGEMENT DISCUSSION AND ANALYSIS

OVERVIEW

We are a biotechnology company focused on the in-house discovery and development of innovative biological therapies in the autoimmune and oncology therapeutic areas. We have multiple clinical-stage assets, each of them being a leading contender within its respective competitive landscape.

Based on a solid foundation in biomedical research, we also built in-house drug discovery and development technologies that are complemented by our collaboration with other pharmaceutical and biotechnology companies. These comprise an innovative antibody discovery platform and a proprietary novel T cell engager (nTCE) bispecific antibody platform. As of December 31, 2022, we have nine clinical-stage and IND-enabling drug candidates in our internally-developed pipeline.

To accelerate the efficiency of our research and discovery, we have established a fully-integrated platform encompassing all of the key functions in the biologic drug development. These include target validation, lead molecule discovery and optimization, preclinical evaluation, process development, translational research, clinical development and manufacturing. This integrated platform has enabled us to rapidly and cost-effectively identify, build, expand and advance our diversified pipeline of innovative and differentiated antibody-based therapies, including monoclonal antibodies, antibody drug conjugates (ADCs) and bispecific antibodies.

Product Pipeline

Our proprietary product pipeline reflects our market insights and employs the most recent scientific findings. To complement our in-house research and development efforts, we also collaborate with third parties on the development and commercialization of our drug candidates through joint venture or out-licensing arrangements.

The following chart illustrates our pipeline and summarizes the development status of our clinical-stage drug candidates and selected IND-enabling stage candidates as of the date of the announcement:

Research areas	Drug Candidate	Target (Modality)	Focused Indications	Lead Identification	Pre-Clinical	IND	Ph-I	Ph-II	Ph-III	Partner	Commercial Rights	
Autoimmune	CM310 ★	IL-4R α (mAb)	Moderate-to-severe AD – Adults	BTD granted by CDE								Global
			Moderate-to-severe AD – Children & Adolescents									Global
			CRSwNP									Global
			Moderate-to-severe eosinophilic asthma								石药集团 CSPC	Global ex mainland China
			AR									Global
	CM326 +	TSLP (mAb)	Moderate-to-severe AD									Global
			CRSwNP									Global
Moderate-to-severe asthma										石药集团 CSPC	Global ex mainland China Global ex mainland China	
CM338	MASP-2 (mAb)	IgA nephropathy									Global	
Oncology	CMG901 +	Claudin 18.2 (ADC)	Gastric and Other Solid tumors	FTD & ODD granted by FDA BTD granted by CDE							AstraZeneca 乐器生物 LISHI BIO	Global
	CM313	CD38 (mAb)	RRMM, lymphoma and other hematological malignancies									Global
			SLE									Global
	CM355	CD20 x CD3 (Bispecific)	Lymphoma								INNOCARE	Global
	CM336	BCMA x CD3 (Bispecific)	RRMM									Global
	CM350	GPC3 x CD3 (Bispecific)	Solid tumors									Global
CM369	CCR8 (mAb)	Tumors								INNOCARE	Global	

★ Core Product + Key Product

Abbreviations: 1H = first half; 2H = second half; AD = atopic dermatitis; ADC = antibody drug conjugate; AR = allergic rhinitis; CRS = chronic rhinosinusitis; CRSwNP = chronic rhinosinusitis with nasal polyposis; COPD = chronic obstructive pulmonary disease; GEJ = gastroesophageal junction; mAb = monoclonal antibody; MM = multiple myeloma; Ph = Phase; RRMM = relapsed or refractory multiple myeloma

BUSINESS REVIEW

- CM310 (IL-4R α antibody)**

CM310, our core product as defined under Chapter 18A of the Listing Rules, is a humanized and highly potent antibody against interleukin-4 receptor α -subunit (IL-4R α). It is the first domestically-developed IL-4R α antibody that received IND approval from the NMPA. By targeting IL-4R α , CM310 can lead to dual-blockade of interleukin-4 (IL-4) and interleukin-13 (IL-13) signaling. IL-4 and IL-13 are two critical cytokines for initiating type II inflammation. CM310 can potentially be effective for treating various type II immunological diseases in adults, adolescents and children, such as moderate-to-severe atopic dermatitis (AD), moderate-to-severe asthma, chronic rhinosinusitis with nasal polyposis (CRSwNP), allergic rhinitis, and potentially chronic obstructive pulmonary disease (COPD). It demonstrated favorable safety and encouraging efficacy in Phase Ia, Phase Ib/IIa and Phase IIb clinical trials.

We initiated a randomized, double-blinded, placebo-controlled Phase III clinical study to evaluate the efficacy and safety of CM310 in adult subjects with moderate-to-severe AD in the first quarter of 2022. The Phase III clinical study has been approved by the CDE and plans to include 500 subjects. The co-primary endpoints are the percentage of subjects achieving EASI-75 and the percentage of subjects achieving an IGA score of 0 or 1 with a deduction of ≥ 2 points from the baseline in the 16th week of treatment. The enrollment of subjects for phase III clinical study was completed in November 2022 and the NDA for this indication is expected to be submitted to the NMPA in 2023.

In June 2022, the CDE granted CM310 breakthrough therapy designation for the treatment of moderate-to-severe atopic dermatitis. Drugs that have been granted the breakthrough therapy designation are prioritized by the CDE in communications and exchange, and in receiving guidance to promote the drug development progress.

We completed the Phase II clinical trial of CM310 for patients with CRSwNP by the end of the first quarter of 2022, and the results of primary endpoints of this clinical trial were disclosed in March 2022. 56 subjects were enrolled in this Phase II study, and the co-primary efficacy endpoints were the changes from baseline in bilateral nasal endoscopic polyp score (NPS) and nasal congestion score (NCS) at week 16 during the treatment period. Among others, NPS and NCS at week 16 in CM310 group were reduced by 2.32 and 1.23 from baseline, respectively, which were significantly superior to those in placebo (decreased by 0.19 and 0.30, respectively), with statistically significant differences. Meanwhile, CM310 continued to show a promising safety profile in this study. The incidence of treatment-emergent adverse events (TEAE) in CM310 group was comparable to that of placebo. No Grade 3 and above TEAE occurred and all of TEAEs were transient and the subjects recovered without any medical intervention.

Based on the above data, we initiated a randomized, double-blinded, placebo-controlled Phase III clinical study to evaluate the efficacy and safety of CM310 in patients with CRSwNP in mid-2022. The Phase III clinical study has been approved by CDE and plans to include 180 subjects. The co-primary efficacy endpoints were the changes from baseline in bilateral nasal endoscopic polyp score (NPS) and nasal congestion score (NCS) at week 16 during the treatment period. The NDA for this indication is expected to be submitted to the NMPA by the first quarter of 2024.

In July 2022, the IND for CM310 for the treatment of allergic rhinitis was approved by the NMPA.

In August 2022, the IND for CM310 for the treatment of adults with moderate-to-severe AD was approved by the FDA.

JMT-Bio, a wholly-owned subsidiary of CSPC, has the exclusive license to develop and commercialize CM310 for the treatment of moderate-to-severe asthma, COPD and other respiratory diseases in China (excluding Hong Kong, Macau, or Taiwan). As of the date of this announcement, CSPC has initiated the critical Phase II/III clinical study for the treatment of moderate-to-severe asthma.

- **CM326 (TSLP antibody)**

CM326 is a humanized and highly potent monoclonal antibody targeting thymic stromal lymphopoietin (TSLP). It is the first domestically-developed TSLP-targeting antibody in China to have received IND approval. TSLP plays a critical role as an upstream cytokine mediating multiple inflammatory pathways. Therefore, blocking its mediated inflammatory response by TSLP antibodies may lead to the treatment of various allergic diseases, including moderate-to-severe asthma and CRSwNP, and COPD. CM326 may also have synergistic effects with CM310.

We initiated a multi-center, randomized, double-blinded, placebo-controlled Phase Ib/IIa clinical trial to evaluate the safety, tolerability, pharmacokinetic/pharmacodynamic (PK/PD), immunogenicity, and preliminary efficacy of CM326 in subjects with moderate-to-severe AD in the first half of 2022, and simultaneously initiated a randomized, double-blinded, placebo-controlled Phase II clinical study to evaluate efficacy and safety of CM326 in adult subjects with moderate-to-severe AD in the second half of 2022.

We initiated a multi-center, randomized, double-blinded, placebo-controlled Phase Ib/IIa clinical trial to evaluate the safety, tolerability, PK/PD, immunogenicity, and preliminary efficacy of CM326 in subjects with CRSwNP in mid-2022, and we completed the patient enrollment of the Phase Ib/IIa clinical trial in February 2023.

JMT-Bio, a wholly-owned subsidiary of CSPC, has the exclusive license to develop and commercialize CM326 for the treatment of moderate-to-severe asthma, COPD and other respiratory diseases in China (excluding Hong Kong, Macau, or Taiwan).

- **CMG901 (Claudin 18.2 ADC)**

CMG901 is a Claudin 18.2-targeting ADC comprising of a Claudin 18.2-specific antibody, a cleavable linker and a toxic payload, monomethyl auristatin E (MMAE). It is the first Claudin 18.2 ADC to have received IND clearance both in China and the U.S.. Claudin 18.2 is selectively and widely expressed in gastric cancer, pancreatic cancer and other solid tumors, which makes it an ideal tumor target for therapeutic development.

We completed the patient enrollment of CMG901 in the dose-escalation phase of the Phase I clinical trial of subjects with solid tumors in June 2022. Furthermore, we also initiated the dose-expansion stage of Phase I clinical trial of CMG901 in subjects with solid tumors in China in the second quarter of 2022, and disclosed the latest results from the Phase Ia dose-escalation trial on January 18, 2023.

In April 2022, CMG901 was granted the Fast Track Designation by the FDA for the treatment of relapsed/refractory gastric cancer and gastroesophageal junction adenocarcinoma. Previously, CMG901 has been granted the Orphan Drug Designation for the same indication.

In September 2022, the CDE granted CMG901 breakthrough therapy designation for the treatment of Claudin 18.2-positive advanced gastric cancer that has failed or cannot be tolerated by first-line treatment or above. The CDE will communicate and exchange resources on the priority allocation of drugs granted breakthrough therapy designation, strengthen guidance and promote the process of drug research and development.

In January 2023, we presented, in a form of wall poster, the latest data from a Phase Ia dose escalation clinical study about CMG901 for the treatment of advanced solid tumors at the 2023 Gastrointestinal Cancers Symposium of the American Society of Clinical Oncology. As of August 4, 2022, a total of 27 patients (13 with gastric cancer or gastroesophageal junction adenocarcinoma and 14 with pancreatic cancer) were enrolled in the CMG901 Phase Ia clinical study. The study results showed that CMG901 had a good safety and tolerability, with 3/27 (11.1%) patients experiencing grade 3 drug-related adverse events and no grade 4 or above drug-related adverse events. The dose was successfully increased to 3.4 mg/kg and the maximum tolerated dose (MTD) was not reached. Only one patient in the 2.2 mg/kg group had dose-limiting toxicity. In terms of efficacy, 8 patients with Claudin 18.2-positive gastric cancer or gastroesophageal junction adenocarcinoma treated with CMG901 had an objective response rate of 75% and a disease control rate of 100%. Objective response rates were 100% for patients in the 2.6, 3.0 and 3.4 mg/kg cohorts. Median progression-free survival (mPFS) and median overall survival (mOS) were not reached.

In February 2023, KYM, a non-wholly-owned subsidiary in which the Group has a 70% interest, and AstraZeneca AB (“**AstraZeneca**”, a global pharmaceutical company which, to the best of the Company’s knowledge and belief, is an Independent Third Party) have entered into a global exclusive license agreement. AstraZeneca will be granted a worldwide exclusive license to research, develop, register, manufacture and commercialize CMG901 and will be responsible for all costs and activities associated with its further development and commercialization under the license agreement. According to the license agreement and subject to its terms and conditions, KYM will receive an upfront payment of US\$63 million and additional potential payments of up to US\$1,125 million upon completion of certain development, regulation and commercial milestones. KYM is also entitled to collect tiered royalties from AstraZeneca on net sales. KYM has a responsibility to provide assistance and personnel to facilitate the transfer of technology and expertise. Unless otherwise agreed, AstraZeneca will be responsible for all costs of development and regulatory affairs activities related to the ongoing experiments with respect to CMG901. The license agreement is subject to customary closing conditions, including the completion of antitrust regulatory reviews.

- **CM313 (CD38 antibody)**

CM313 is a humanized monoclonal antibody that targets CD38. CM313 is the first domestically-developed CD38 antibody with IND approval by the NMPA in China. Given the encouraging efficacy in pre-clinical studies, we believe CM313 has the potential to become an innovative treatment option for relapsed or refractory multiple myeloma (RRMM), lymphoma and other hematological malignancies. In the first half of 2022, we continued proceeding with a multi-center, open-label Phase I clinical trial to evaluate the safety, tolerability, pharmacokinetics, immunogenicity, and preliminary efficacy of CM313 monotherapy in hematological malignancies including multiple myeloma and lymphoma. Meanwhile, we initiated a dose-expansion stage of Phase I trial of CM313 for the treatment of multiple myeloma (MM) in China at the end of the first quarter of 2022.

In addition, given the observed outstanding clearance effect of CM313 on plasma cells, we believe CM313 has the potential to become an innovative treatment option for systemic lupus erythematosus (SLE). In January 2022, we submitted IND approval to the NMPA for the indication of CM313 in the treatment of SLE, and the clinical trial was approved to conduct in April 2022. In October 2022, we completed the first patient dosing of CM313 for the treatment of SLE, which is currently in the dose-escalation stage of Phase Ib/IIa clinical study.

- **CM338 (MASP-2 antibody)**

CM338 is a humanized, highly potent antagonist antibody against mannose-binding lectin-associated serine protease-2 (MASP-2).

In November 2022, we completed a multiple-dose, randomized, double-blinded, placebo-controlled, dose-escalation Phase I clinical study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and immunogenicity of CM338 injection in healthy subjects. In March 2023, we initiated a Phase II clinical study to evaluate the efficacy and safety of CM338 injection in subjects with immunoglobulin A nephropathy (IgAN).

- **CM355/ICP-B02 (CD20xCD3 bispecific antibody)**

CM355 is a CD20xCD3 bispecific antibody for the treatment of relapsed or refractory non-Hodgkin's lymphoma (NHL). In preclinical studies, CM355 demonstrated stronger T-cell directed cellular cytotoxicity (TDCC) activities and less cytokine release as compared to its leading competitors.

We collaborate with InnoCare for the development of CM355. The Phase I trial first patient for the treatment of lymphoma was dosed in January 2022 and Phase I dose escalation is progressing with the fourth cohort being completed in January 2023. So far, the almost complete B-cell depletion was observed in patients treated with low dose of CM355.

- **CM336 (BCMAxCD3 bispecific antibody)**

CM336 is a BCMAxCD3 bispecific antibody for the treatment of multiple myeloma. BCMA is an attractive target for multiple myeloma immunotherapy due to its high expression on malignant plasma cells in multiple myeloma patients and normal expression restricted to plasma cells in healthy individuals. CM336 is designed to target BCMA on BCMA-positive tumor cells and the CD3 receptor on the surface of T cells, bridging them together and activating T cells to kill the cancer cells.

In September 2022, we completed the first patient dosing of CM336 for the treatment of multiple myeloma. The dose-escalation stage of the Phase I clinical study of CM336 is currently ongoing.

- **CM350 (GPC3xCD3 bispecific antibody)**

CM350 is a GPC3xCD3 bispecific antibody for the treatment of solid tumors, especially for hepatocellular carcinoma (HCC). CM350 is designed to target GPC3 on GPC3-positive tumor cells and the CD3 receptor on the surface of T cells, bridging them together and activating T cells to kill the cancer cells. The dual targeting of GPC3 and CD3 activates and redirects T cells to engage and eliminate target tumor cells.

In January 2022, we received the IND approval from the NMPA to carry out the clinical trial of solid tumors. In May 2022, we completed the first patient dosing of CM350 for the treatment of hepatocellular carcinoma, which is currently in the dose-escalation stage of Phase I clinical study.

- **CM369/ICP-B05 (CCR8 antibody)**

CM369 is an anti-CC chemokine receptor 8 (“**CCR8**”) monoclonal antibody, a potential first-in-class drug co-developed by us and InnoCare as a monotherapy or in combination with other therapies for the treatment of various cancers. CCR8 has been shown to be selectively overexpressed on immunosuppressive regulatory T cells (“**Tregs**”) in the tumor microenvironment (“**TME**”). CM369 binds to CCR8 on Tregs and eradicates immunosuppressive Tregs through antibody-dependent cell-mediated cytotoxicity (ADCC) to augment the anti-tumor immunity in TME while preserving peripheral homeostasis. CM369 has the potential to deliver optimal tumor targeted Treg depletion and be more specific in anti-tumor activity than other immunotherapies.

We collaborate with InnoCare for the development of CM369. In August 2022, the CM369 was approved by NMPA for clinical trials for the treatment of advanced solid tumors. In February 2023, we completed the first patient dosing of CM369. The product is currently in the dose-escalation stage of Phase I clinical study.

Cautionary Statement required by Rule 18A.08(3) of the Listing Rules: The Company may not be able to ultimately develop and market CM310, CM326, CMG901, CM313, CM338, CM355, CM336, CM350, and CM369 successfully. As at 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.

Our R&D and Manufacturing

Leveraging the expertise of our clinical development team, we are able to efficiently design and execute our clinical trials and demonstrate the advantages of our innovative drugs through outstanding clinical results. Our clinical development team achieves this goal through well-designed trial protocols and excellent trial execution. The team coordinates clinical development strategies and trial protocols for our drug candidates, and manages the trial implementation with the assistance of reputable CROs in a cost-effective manner. Our medical and translational research staff identify and validate biomarkers, direct patient selection, and analyze clinical data to guide clinical studies and preclinical evaluations. As our clinical-stage drug candidates are each among the first three domestically-developed for its target or in its class to have obtained IND approval in China and/or the U.S., we have attracted numerous first-tier hospitals and leading principal investigators (PIs) to join our clinical trials. We believe the long-term relationships with these medical collaborators will bring us tremendous benefits.

To ensure production and supply of high-quality and affordable antibody drugs, we have always been committed to enhancing our in-house manufacturing capabilities. We have internally developed high-expressing cell lines to ensure high yield and low costs for our antibody manufacturing. Our first cGMP-compliant manufacturing facility with a capacity of 1,600 litres was built in Chengdu in 2019, which internally manufactured antibody continuously and successfully for preclinical and clinical studies. In addition, the first phase of construction of the new plant in Chengdu was completed and put into production at the end of 2022, with an additional production capacity of 16,000 litres in total. The designs of all facilities are in compliance with the requirements of cGMP of the NMPA and FDA.

R&D Platforms

We have built fully-integrated platforms to enable our in-depth R&D in the areas of immunology and oncology. Our platforms are integrated seamlessly to support key drug development functionalities, including antibody screening, functional evaluation, in vivo preclinical studies and biomarker identification. We have the expertise and capability to independently complete the entire drug development process from drug discovery to pre-clinical research to clinical development and to NDA/BLA application. Our core platforms are as follows:

- **Novel T Cell Engager (nTCE) Platform**

Our nTCE platform enables us to develop bispecific T cell engagers that are potent and highly tumor specific. In recent years, T cell engaging bispecific antibodies have attracted particular interest as a promising class of immunotherapies for the treatment of non-immunogenic tumors. Our technology is designed to maximize T cell-mediated cell killing effects with minimal cytokine release syndrome, and high stability and productivity.

Leveraging the nTCE platform, we are developing multiple T-cell engaging bispecific antibodies, including CM355, CM336 and CM350 which have obtained IND approvals as of the date of this announcement. In preclinical studies, these drug candidates have demonstrated encouraging T cell-mediated cell killing effects with low possibility of cytokine release syndrome.

- **Innovative antibody discovery platform**

Our innovative antibody discovery platform is a versatile platform for the discovery and evaluation of antibody drugs. This platform includes the following main functionalities: antibody screening, engineering and optimization. With these functions and technologies, we are able to develop antibody-based therapies with new modalities and new mechanisms of action, which potentially increase the efficacy and specificity of the therapies. Based on this platform, we have developed multiple drug candidates with different modalities in our pipeline, including bispecific antibodies, ADCs and fragment crystallisable region (Fc) engineered antibodies. This platform is also empowered by enhanced automatic antibody screening and discovery techniques, leading to cost-efficient discovery of drug candidates with high affinity, cross-species activity and improved developability.

- **Bio-evaluation Platform**

Our bio-evaluation platform is responsible for effective assessment of antibody drug candidates. We have developed multiple cell-based assays using engineered reporter cells, which enable us to quickly screen and select highly potent antibodies with desired biological activities. Building on our experience and expertise, we are also able to establish a variety of immunoassays to facilitate our immunology and oncology pipeline development. To further evaluate the efficacies of antibody drugs in vivo, we have developed a number of animal models in different species in collaboration with CROs to support our target validation and lead molecule selection.

- **High-Throughput Screening Platform for High Yield Antibody-Expressing Cells**

Leveraging the experience and know-how of our chemistry, manufacturing and controls (CMC) and manufacturing team, we have developed our high-throughput screening platform to identify high-yielding cell lines that have desirable characteristics for further cost-efficient development. With this platform, we have successfully identified the cell lines to produce drug candidates as fast as three months. This allows us to rapidly advance our assets to the preclinical and clinical evaluation stage and accelerate the drug development process.

Impact of the COVID-19 Outbreak

The resurgence of COVID-19 since the beginning of 2022 did not have a material adverse impact on our business, financial position and results of operations. Although we experienced minor delays in the patient enrollment process and data entry for certain of our clinical trials in China as a result of COVID-19 pandemic control policies, the situation has improved subsequently. As of December 31, 2022, we had resumed normal patient enrollment and data entry for our clinical trials, and had not encountered any material adverse effects on our collaboration with third-party service providers, including our cooperative CROs, for our clinical development. Furthermore, since the outbreak of the COVID-19 and as of the end of the Reporting Period, we had not experienced any material production suspension and decrease in production volume of our manufacturing facilities. We had not experienced any material difficulties in procuring our major raw materials, and our supply chain had not experienced any material disruption since the outbreak of COVID-19 and as of the date of this announcement.

Other Corporate Development

Our Shares have been included as eligible stocks of the Shenzhen-Hong Kong Stock Connect with effect from March 7, 2022. In August 2022, the Company has been included as a constituent of FTSE Global Small Cap ex-US Index with effect from September 16, 2022. In November 2022, the Company has been included as a constituent of MSCI China Small Cap Index with effect from November 30, 2022.

We believe that the inclusion of our Shares as eligible stocks of the Shenzhen-Hong Kong Stock Connect and constituent of the above-mentioned international stock index will allow us to access a broader investor base in global financial markets and further increase the trading liquidity of our Shares, which would result in realization of the value of the investment in the Company.

Future Development

We will continue to rapidly advance both ongoing and planned clinical programs for our pipeline products in China and globally, including in the U.S., and prepare for the commercialization of our late-stage pipeline products. In the meantime, to expedite the commercialization of our drug candidates and maximize the commercial value, we will actively build strategic partnerships such as co-development, collaboration and licensing in China and globally.

In anticipation of increased production demands for our drug candidates, we plan to further expand our cGMP-compliant manufacturing capacity to improve the cost-effectiveness of our production. We are very pleased to see the rapid progress we achieved so far and the detailed development plan ahead of us. In line with our Company's vision, we are committed to developing, manufacturing and commercializing innovative biological therapies for patients worldwide.

Financial Review

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Revenue	100,063	110,269
Cost of sales	<u>(2,585)</u>	<u>(17,200)</u>
GROSS PROFIT	<u>97,478</u>	<u>93,069</u>
Other income and gains	259,002	52,667
Research and development expenses	(507,374)	(358,156)
Administrative expenses	(133,912)	(92,454)
Listing expenses	–	(37,932)
Fair value losses on convertible redeemable preferred shares	–	(3,480,294)
Other expenses	(683)	(57,680)
Finance costs	(8,397)	(11,133)
Share of losses of a joint venture	<u>(9,711)</u>	<u>(719)</u>
LOSS BEFORE TAX	(303,597)	(3,892,632)
Income tax expense	<u>–</u>	<u>–</u>
TOTAL LOSS FOR THE YEAR	<u>(303,597)</u>	<u>(3,892,632)</u>
Attributable to:		
Owners of the parent	(308,115)	(3,887,309)
Non-controlling interests	<u>4,518</u>	<u>(5,323)</u>
	<u>(303,597)</u>	<u>(3,892,632)</u>
OTHER COMPREHENSIVE INCOME FOR THE YEAR, NET OF TAX	<u>1</u>	<u>–</u>
TOTAL COMPREHENSIVE LOSS FOR THE YEAR	<u>(303,596)</u>	<u>(3,892,632)</u>
Attributable to:		
Owners of the parent	(308,114)	(3,887,309)
Non-controlling interests	<u>4,518</u>	<u>(5,323)</u>
	<u>(303,596)</u>	<u>(3,892,632)</u>

1. Revenue and Cost of Sales

During the Reporting Period, the Group's revenue primarily consists of collaboration income from CSPC in respect of granting the relevant license. Cost of sales mainly represented R&D costs incurred under the out-licensing arrangement for the year ended December 31, 2022.

2. Other Income and Gains

During the Reporting Period, the Group's other income and gains primarily consisted of government grants income, interest income and gain on exchange difference. For the year ended December 31, 2022, the other income and gains of the Group increased by RMB206 million to RMB259 million. The increase was primarily attributable to the increase of government grants income, interest income and gain on exchange difference by RMB226 million to RMB257 million.

3. Research and Development expenses

During the Reporting Period, the Group's R&D expenses primarily consisted of (i) expenses incurred in connection with pre-clinical and clinical studies, including third-party contracting costs with respect to the engagement of CROs, clinical trial sites and other service providers in connection with our R&D activities; (ii) employee compensation for our R&D employees; (iii) expenses for procuring raw materials and consumables used in the R&D of our drug candidates; and (iv) depreciation and amortization of property, plant and equipment and other intangible assets related to R&D activities. For the year ended December 31, 2022, the R&D expenses of the Group increased by RMB149 million to RMB507 million. The increase was primarily attributable to the increase of clinical trial and pre-clinical study expenses by RMB114 million. Such increase was consistent with the expansion of our R&D team and the ramp up of the scale of our R&D plans during the Reporting Period.

4. Administrative expenses

During the Reporting Period, the Group's administrative expenses primarily consisted of (i) employee compensation for our administrative employees; (ii) depreciation and amortization expenses for operating activities; (iii) depreciation and amortization of property, plant and equipment and other intangible assets related to administrative activities; (iv) professional services fees paid to legal counsel, agents, auditor, and other professional service providers, incurred in connection with business operations; and (v) travelling expenses of our administrative employees. For the year ended December 31, 2022, the administrative expenses of the Group increased by RMB41 million to RMB134 million. The increase was primarily attributable to the increase of employee compensation and professional services fees by RMB28 million and RMB3 million, respectively.

5. Fair Value Losses on Convertible Redeemable Preferred Shares

For the year ended December 31, 2021, the Group recorded fair value loss on convertible redeemable preferred shares of RMB3,480 million. These preferred shares had been automatically converted to ordinary shares on a 1:1 basis upon the completion of the IPO on July 8, 2021, and the then fair value of financial liabilities had been reclassified to equity accordingly. No fair value changes on the preferred shares had been recorded accordingly during the Reporting Period.

6. Other Expenses

During the Reporting Period, the Group's other expenses primarily consisted of exchange loss on foreign currencies. For the Reporting Period, the other expenses of the Group decreased by RMB57 million to RMB1 million. The decrease was primarily attributable to the decrease of exchange loss.

7. Finance Costs

During the Reporting Period, the Group's finance costs primarily consisted of implicit interest on other financial liabilities and interest on lease liabilities and bank borrowings. For the Reporting Period, the finance costs of the Group decreased by RMB3 million to RMB8 million. The decrease was primarily attributable to the decrease of the implicit interest on other financial liabilities by RMB5 million, and partially offset by the increase of the interest on bank borrowings by RMB2 million.

8. Share of loss of a joint venture

During the Reporting Period, our shared loss from the 50%-owned joint venture, Beijing Tiannuo Pharma Tech Co., Ltd., amounted to RMB10 million. The increase was primarily attributable to the increase of clinical trial expenses incurred by the joint venture during the Reporting Period.

9. Income tax expense

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

10. Selected Data from Consolidated Statement of Financial Position

	As at December 31, 2022 <i>RMB'000</i>	As at December 31, 2021 <i>RMB'000</i>
Total current assets	3,309,974	3,581,949
Total non-current assets	622,342	352,506
Total assets	3,932,316	3,934,455
Total current liabilities	379,699	112,075
Total non-current liabilities	213,399	176,998
Total liabilities	593,098	289,073
Net current assets	2,930,275	3,469,874

11. Liquidity and Capital Resources

As at December 31, 2022, our cash and bank balances, time deposits and bank wealth management products decreased by RMB349 million to RMB3,175 million from RMB3,524 million as at December 31, 2021. The decrease was primarily attributable to the cash used in our daily business operation during the Reporting Period.

As at December 31, 2022, the current assets of the Group were RMB3,310 million, including cash and bank balances of RMB604 million, time deposits of RMB2,339 million, bank wealth management products of RMB232 million and other current assets of RMB135 million. As at December 31, 2022, the current liabilities of the Group were RMB380 million, including trade payables of RMB15 million, other payables and accruals of RMB146 million, other financial liabilities of RMB146 million, interest-bearing bank borrowings of RMB61 million, lease liabilities of RMB11 million and other current liabilities of RMB1 million.

For the year ended December 31, 2022, our net cash used in operating activities increased by RMB187 million to RMB402 million from RMB215 million for the year ended December 31, 2021. The increase was primarily attributable to our business expansion as well as the progress advancement of our clinical trials.

For the year ended December 31, 2022, our net cash used in investing activities decreased by RMB1,390 million to RMB646 million from RMB2,036 million for the year ended December 31, 2021. The decrease was primarily attributable to the significant increase in the withdrawal of time deposits.

For the year ended December 31, 2022, our net cash flows used in financing activities amounted to RMB8 million while the net cash flows from financing activities amounted to RMB3,638 million for the year ended December 31, 2021. The significant decrease was primarily attributable to proceeds received by the Company from issuance of series C preferred shares and the IPO in 2021 while nil in 2022.

As part of our treasury management, we invest in certain wealth management products to better utilize excess cash when our cash sufficiently covers our ordinary course of business. We have implemented a series of internal control policies and rules setting forth overall principles as well as detailed approval process of our investment activities. Under our investment policy, we generally limit our purchases to low-risk, short-term products from reputable commercial banks which must not interfere with our daily operation and business prospects.

We recorded other investments classified as financial assets at FVTPL of RMB232 million as of December 31, 2022. We manage and evaluate the performance of these investments on a fair value basis in accordance with our risk management and investment strategy. Therefore, these investments in wealth management products were designated as financial assets at FVTPL as of December 31, 2022.

12. *Indebtedness*

As at December 31, 2022, our interest-bearing bank borrowings amounted to RMB90 million and unutilized credit facilities amounted to RMB570 million. Of the borrowings, RMB50 million are borrowed at fixed interest rate.

As at December 31, 2022, the lease liabilities decreased by RMB7 million to RMB32 million as the result of the increase of lease payments.

As at December 31, 2022, the other financial liabilities increased by RMB5 million to RMB146 million as the result of the recognition of the implicit interest expenses.

The gearing ratio (calculated by total liabilities divided by total assets) of the Group as of December 31, 2022 was 15%, representing an increase of 8% from the gearing ratio of 7% as at December 31, 2021.

13. *Significant Investment, Material Acquisitions and Disposals*

The Group did not have significant investment, material acquisitions or disposals of subsidiaries, associates and joint ventures for the year ended December 31, 2022.

14. *Contingent Liabilities*

As of December 31, 2022, we did not have any contingent liabilities. The Company confirms that as of the date of this announcement, there had been no material changes or arrangements to our contingent liabilities.

15. *Capital Commitments*

As of December 31, 2022, we had capital commitments contracted, but not yet provided, of RMB1 million, which were related to the purchase of property, plant and equipment for the Group's production plant. We intend to fund the commitments with proceeds from the Company's prior fundraising activities.

16. Pledge of Assets

As of December 31, 2022, the Group committed to pledge a total of RMB430 million equipment to secure its bank borrowings within six months upon receiving the loan.

17. 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's borrowing is made in Renminbi, while cash and cash equivalents are primarily held in Renminbi, Hong Kong dollars and US dollars. The Group is exposed to foreign currency risk as a result of certain cash and bank balances, time deposits and financial assets at FVTPL 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.

HUMAN RESOURCES

As of December 31, 2022, we had 613 full-time employees in total, including 5 employees who are employed overseas and the remaining in China. In strict compliance with the relevant labor laws, we enter into individual employment contracts with our employees covering matters such as terms, wages, bonuses, employee benefits, workplace safety, confidentiality obligations and grounds for termination.

To remain competitive in the labor market, we provide various incentives and benefits to our employees. We invest in continuing education and training programs, including internal and external training, for our management staff and other employees to upgrade their skills and knowledge. We also provide competitive salaries and the opportunity to participate in share incentive schemes to our employees. We believe our benefits, working environment and development opportunities for our employees have contributed to good employee relations.

Our Company has adopted the 2021 RSU Scheme on April 5, 2021 (further details of which are set forth in our Prospectus) and the 2022 RSU Scheme on January 21, 2022 (further details of which are set forth in the Company's announcements dated January 21, 2022 and January 28, 2022). During the Reporting Period, restricted share units underlying 2,747,021 Shares have been awarded under the 2021 RSU Scheme.

SIGNIFICANT EVENTS AFTER THE END OF THE REPORTING PERIOD

In January 2023, Chengdu Kangnuoxing Biopharma, Inc.* (成都康諾行生物醫藥科技有限公司), a non-wholly owned subsidiary of the Company, entered into an asset transfer agreement with Chengdu Bio-Town Construction Co., Ltd.* (成都生物城建設有限公司) for the sale and purchase of a parcel of land located in Songbai Community No. 1 in Chengdu, consisting of three near-completed buildings situated on the parcel of land, which the Company proposes to use as its new headquarters and a manufacturing plant for its pipeline drug products. Please refer to the announcement of the Company dated January 18, 2023 for further information.

In February 2023, KYM entered into a global exclusive out-license agreement with AstraZeneca AB to develop and commercialize CMG901. Please refer to the section “Management Discussion and Analysis – Business Review – CMG901 (Claudin 18.2 ADC)” and the announcement of the Company dated February 23, 2023 for further information.

FINAL DIVIDEND

The Board has resolved not to recommend a final dividend for the year ended December 31, 2022.

ANNUAL GENERAL MEETING

The AGM will be held on June 27, 2023. Notice of the AGM and all other relevant documents will be published and despatched to Shareholders in due course.

CLOSURE OF REGISTER OF MEMBERS

In order to determine the entitlement to attend and vote at the AGM, the register of members of the Company will be closed from June 21, 2023 to June 27, 2023, both days inclusive, during which period no transfer of shares will be registered. Shareholders whose names appear on the register of shares of the Company on June 27, 2023 will be entitled to attend and vote at the AGM. All transfer documents of the Company accompanied by the relevant share certificates must be lodged with the branch share registrar of the Company in Hong Kong, Computershare Hong Kong Investor Services Limited at Shops 1712-1716, 17th Floor, Hopewell Centre, 183 Queen’s Road East, Wan Chai, Hong Kong, for registration not later than 4:30 p.m. on June 20, 2023.

CORPORATE GOVERNANCE PRACTICES

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 contained in Appendix 14 to the Listing Rules as its own code of corporate governance.

Under the code provision C.2.1 of Part 2 of the CG Code, the roles of chairman and chief executive should be separate and should not be performed by the same individual. Dr. Chen is the chairman of the Board and the chief executive officer of the Company. With extensive experience in the pharmaceutical industry and having served in the Company since its establishment, Dr. Chen is in charge of overall strategic planning, business direction and operational management of the Group. The Board considers that vesting the roles of the chairman of the Board and the chief executive officer in the same person is beneficial to the management of the Group. The balance of power and authority is ensured by the operation of the Board and our senior management, which comprises experienced and diverse individuals. The Board currently comprises three executive Directors (including Dr. Chen), three non-executive Directors and four independent non-executive Directors, and therefore has a strong independence element in its composition.

Save as disclosed above, in the opinion of the Directors, the Company has complied with the relevant code provisions contained in the CG Code during the Reporting Period.

Code provision F.2.2 of Part 2 of the CG Code provides that the chairman of the Board should attend the annual general meeting and that the chairmen of the audit, remuneration, nomination and any other committees should be invited to attend the annual general meeting. In their absence, the chairman of the board should invite other members of the committee or other duly appointed delegate to attend. Dr. Chen (being the chairman of the Board and the chairperson of the nomination committee), Mr. Qi CHEN (being a member of the audit committee) and Dr. Changyu WANG (being a member of the remuneration committee) attended the Company's annual general meeting on June 28, 2022.

The Board will continue to review and monitor the practices of the Company with an aim of maintaining a high standard of corporate governance.

MODEL CODE FOR SECURITIES TRANSACTIONS

The Company has adopted the Model Code as its own code of conduct regarding dealings in the securities of the Company by the Directors and the Company's senior management who, because of his/her office or employment, is likely to possess inside information in relation to the Company's securities.

Upon specific enquiry, all Directors confirmed that they have complied with the Model Code during the Reporting Period. In addition, the Company is not aware of any non-compliance of the Model Code by the senior management of the Group during the Reporting Period.

REVIEW OF ANNUAL RESULTS BY THE AUDIT COMMITTEE

The Board has established the Audit Committee which comprises two independent non-executive Directors and one non-executive Director, namely Mr. Cheuk Kin Stephen LAW (Chairperson), Prof. Linqing LIU and Mr. Qi CHEN. The primary duties of the Audit Committee are to review and supervise the Company's financial reporting process and internal controls.

The Audit Committee has reviewed the Group's audited consolidated financial statements for the year ended December 31, 2022 and confirmed that it has complied with all applicable accounting principles, standards and requirements, and made sufficient disclosures. The Audit Committee has also discussed the matters of audit and financial reporting.

PURCHASE, SALE OR REDEMPTION OF THE COMPANY'S LISTED SECURITIES

Neither the Company nor any of its subsidiaries have purchased, sold or redeemed any of the Company's listed securities during the Reporting Period.

USE OF PROCEEDS FROM GLOBAL OFFERING

In connection with the Global Offering, 67,004,000 Shares were issued at a price of HK\$53.3 per share for a total cash consideration, after deduction of the underwriting fees and expenses, of approximately RMB2,841 million. Dealings in the shares of the Company on the Stock Exchange commenced on July 8, 2021. The Group will apply such proceeds in a manner consistent with the intended use of proceeds as set out in the Prospectus.

The table below sets forth the utilisation of the net proceeds from the Global Offering and the unused amount as at December 31, 2022:

Business objective as stated in the Prospectus	Planned applications <i>RMB million</i>	Balance as at December 31, 2021 <i>RMB million</i>	Actual utilisation during the Reporting period <i>RMB million</i>	Balance as at December 31, 2022 <i>RMB million</i>	Expected timeline for unutilized amount
R&D and commercialization of the Company's core product and key drug candidates	1,705	1,621	345	1,276	By the end of 2025
Preclinical evaluation and clinical development of the Company's other pipeline products	426	378	136	242	By the end of 2024
Payment of lease for the Company's new manufacturing and R&D facilities and procurement of machinery and equipment	426	264	240	24	By the end of 2023
General corporate and working capital purposes	284	227	80	147	By the end of 2024
Total	<u>2,841</u>	<u>2,490</u>	<u>801</u>	<u>1,689</u>	

PUBLICATION OF RESULTS ANNOUNCEMENT AND ANNUAL REPORT

This announcement is published on the website of the Stock Exchange (www.hkexnews.hk) and the Company's website (www.keymedbio.com). The annual report of the Company for the Reporting Period containing all the information required by the Listing Rules will be dispatched to Shareholders and published on the above websites in due course.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS*Year ended 31 December 2022*

	<i>Notes</i>	2022 RMB'000	2021 RMB'000
Revenue	4	100,063	110,269
Cost of sales		(2,585)	(17,200)
GROSS PROFIT		97,478	93,069
Other income and gains	5	259,002	52,667
Research and development expenses		(507,374)	(358,156)
Administrative expenses		(133,912)	(92,454)
Listing expenses		–	(37,932)
Fair value losses on convertible redeemable preferred shares		–	(3,480,294)
Other expenses	6	(683)	(57,680)
Finance costs	7	(8,397)	(11,133)
Share of losses of a joint venture		(9,711)	(719)
LOSS BEFORE TAX	8	(303,597)	(3,892,632)
Income tax expense	9	–	–
TOTAL LOSS FOR THE YEAR		(303,597)	(3,892,632)
Attributable to:			
Owners of the parent		(308,115)	(3,887,309)
Non-controlling interests		4,518	(5,323)
		(303,597)	(3,892,632)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT		–	–
Basic and diluted	11	(RMB1.18)	(RMB24.17)

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

Year ended 31 December 2022

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
TOTAL LOSS FOR THE YEAR	<u>(303,597)</u>	<u>(3,892,632)</u>
OTHER COMPREHENSIVE INCOME		
Other comprehensive income that will not be reclassified to profit or loss in subsequent periods:		
Equity investments designated at fair value through other comprehensive income:		
Changes in fair value	1	–
OTHER COMPREHENSIVE INCOME FOR THE YEAR, NET OF TAX	1	–
TOTAL COMPREHENSIVE LOSS FOR THE YEAR	(303,596)	(3,892,632)
Attributable to:		
Owners of the parent	(308,114)	(3,887,309)
Non-controlling interests	<u>4,518</u>	<u>(5,323)</u>
	<u>(303,596)</u>	<u>(3,892,632)</u>

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

31 December 2022

	<i>Notes</i>	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
NON-CURRENT ASSETS			
Property, plant and equipment		553,556	139,419
Right-of-use assets		30,878	38,111
Other intangible assets		1,496	1,104
Prepayments, other receivables and other assets		15,841	153,591
Equity investments designated at fair value through other comprehensive income (“FVTOCI”)		10,001	–
Investment in a joint venture		10,570	20,281
Total non-current assets		<u>622,342</u>	<u>352,506</u>
CURRENT ASSETS			
Inventories		44,495	16,393
Contract assets		–	3,980
Prepayments, other receivables and other assets		90,153	36,997
Financial assets at fair value through profit or loss (“FVTPL”)		232,188	53,401
Time deposits		2,339,068	1,950,559
Cash and cash equivalents		604,070	1,520,619
Total current assets		<u>3,309,974</u>	<u>3,581,949</u>
CURRENT LIABILITIES			
Trade payables	12	14,913	2,784
Other payables and accruals		146,208	95,402
Amounts due to related parties		225	553
Deferred income		–	1,612
Other financial liabilities		146,112	–
Interest-bearing bank borrowings		61,163	–
Lease liabilities, current		11,078	11,724
Total current liabilities		<u>379,699</u>	<u>112,075</u>
NET CURRENT ASSETS		<u>2,930,275</u>	<u>3,469,874</u>
TOTAL ASSETS LESS CURRENT LIABILITIES		<u>3,552,617</u>	<u>3,822,380</u>

CONSOLIDATED STATEMENT OF FINANCIAL POSITION (continued)*31 December 2022*

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
NON-CURRENT LIABILITIES		
Deferred income, non-current	163,671	8,719
Lease liabilities	20,928	26,985
Interest-bearing bank borrowings	28,800	–
Other financial liabilities	–	141,294
	<hr/>	<hr/>
Total non-current liabilities	213,399	176,998
	<hr/>	<hr/>
NET ASSETS	3,339,218	3,645,382
	<hr/>	<hr/>
EQUITY		
Equity attributable to owners of the parent		
Ordinary share capital	170	171
Treasury shares	1	–
Reserves	3,340,117	3,650,799
	<hr/>	<hr/>
	3,340,288	3,650,970
Non-controlling interests	(1,070)	(5,588)
	<hr/>	<hr/>
TOTAL EQUITY	3,339,218	3,645,382
	<hr/> <hr/>	<hr/> <hr/>

NOTES TO FINANCIAL STATEMENTS

31 December 2022

1. CORPORATE INFORMATION

Keymed Biosciences Inc. (the “Company”) was incorporated in the Cayman Islands (“Cayman”) on April 23, 2018 as a limited liability company. The registered office of the Company is located at the offices of 4th Floor, Willow House, Cricket Square, Grand Cayman KY1-9010, Cayman Islands.

The shares of the Company have been listed on The Stock Exchange of Hong Kong Limited (the “Stock Exchange”) with effect from July 8, 2021.

During the year ended December 31, 2022, the Group was involved in the research and development of pharmaceutical products.

2. BASIS OF PREPARATION AND ACCOUNTING POLICIES

These financial statements have been prepared in accordance with International Financial Reporting Standards (“IFRSs”), which comprise all standards and interpretations approved by the International Accounting Standards Board (“IASB”) and the disclosure requirements of the Hong Kong Companies Ordinance. All IFRSs effective for the accounting period commencing from 1 January 2022, together with the relevant transitional provisions, have been early adopted by the Group in the preparation of the financial statements throughout the year ended December 31, 2022.

These financial statements have been prepared under the historical cost convention, except for certain financial instruments which have been measured at fair value at the end of the reporting period. They are presented in Renminbi (“RMB”) and all values are rounded to the nearest thousand (RMB’000) except when otherwise indicated.

The Group has adopted the following revised IFRSs for the first time for the current year’s financial statements.

Amendments to IFRS 3	Reference to the Conceptual Framework
Amendment to IFRS 16	Covid-19-Related Rent Concessions beyond 30 June 2021
Amendments to IAS 16	Property, Plant and Equipment: Proceeds before Intended Use
Amendments to IAS 37	Onerous Contracts – Cost of Fulfilling a Contract
Annual Improvements to IFRSs 2018-2020	Amendments to IFRS 1, IFRS 9, Illustrative Examples accompanying IFRS 16, and IAS 41

The new or amended IFRSs that are effective from 1 January 2022 did not have any significant impact on the Group’s accounting policies.

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 year ended December 31, 2022, the Group generated all revenue from Mainland China.

Majority of the Group's non-current assets were located in Mainland China as at December 31, 2022, geographical segment information in accordance with IFRS 8 Operation Segments is presented.

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Hong Kong	141	703
Mainland China	<u>622,201</u>	<u>351,803</u>
	<u><u>622,342</u></u>	<u><u>352,506</u></u>

Information about major customers

Revenue of approximately RMB100,000,000 (2021: RMB110,000,000) was derived from collaborations with a pharmaceutical companies.

4. REVENUE

An analysis of revenue is as follows:

Revenue from contracts with customers

(a) *Disaggregated revenue information*

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Type of services		
Collaboration revenue	<u>100,063</u>	<u>110,269</u>
Timing of revenue recognition		
Transferred at a point in time	<u>100,063</u>	<u>110,269</u>

The following table shows the amount of revenue recognised in the current reporting period that was included in the contract liabilities at the beginning of the reporting period and recognised from performance obligations satisfied in current periods:

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Revenue recognised that was included in contract liabilities at the beginning of the reporting period:		
Collaboration revenue	<u>-</u>	<u>8,000</u>

(b) Performance obligations

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

Licensing of Intellectual Property

The performance obligation is satisfied at a point in time when the customer obtains the rights to use the underlying intellectual property under the corresponding license.

In November 2021, the Group entered into an exclusive license agreement (the "Agreement") with JMT-Bio Technology Co., Ltd. ("JMT-Bio"), to develop, use, sell, contract and commercialize CM326 (the "Product"), an TSLP antibody, for the treatment of moderate and severe asthma, COPD and other respiratory diseases (the "Field") in Mainland China (excluding Hong Kong, Macau or Taiwan) (the "Territory"). Pursuant to the Agreement, JMT-Bio will be responsible for the clinical development, regulatory activities and commercialisation of CM326 in the Field and the Territory at its own costs and expenses. JMT-Bio will be the market authorisation holder of CM326 in the Field and in the Territory, once approved. Pursuant to the Agreement, the Group is entitled to receive upfront payment, milestone payment and royalty payment. In January 2022, JMT-Bio paid the Group a one-time and non-refundable upfront payment of RMB100 million. The Group recognised revenue of RMB100 million when the Group had completed the grant of an exclusive and royalty-bearing licence covering the know-how and patents related to the Product in the Field and the Territory to JMT-Bio accordingly during the year ended December 31, 2022.

5. OTHER INCOME AND GAINS

An analysis of other income and gains is as follows:

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Other income		
Government grants income	65,544	24,154
Contract development and manufacturing service ("CDM service") income (note (i))	–	21,500
Interest income on other investments classified as financial assets at FVTPL	2,277	1,049
Interest income	52,039	5,964
Others	79	–
	<u>119,939</u>	<u>52,667</u>
Gains		
Gain on exchange differences, net	139,030	–
Others	33	–
	<u>139,063</u>	<u>–</u>
	<u><u>259,002</u></u>	<u><u>52,667</u></u>

- (i) CDM service income is one-off and non-recurring services rendered to a third party during the year ended December 31, 2021.

6. OTHER EXPENSES

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Exchange loss, net	–	54,721
Contract development and manufacturing service costs	–	1,756
Others	683	1,203
	683	57,680

7. FINANCE COSTS

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Implicit interest on other financial liabilities	4,818	9,658
Interest on lease liabilities	1,535	1,475
Interest expense on bank borrowings	1,866	–
Others	178	–
	8,397	11,133

8. 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>
Depreciation of property, plant and equipment	22,274	12,804
Depreciation of right-of-use assets	13,513	8,138
Amortisation of other intangible assets	336	77
Listing expenses	–	37,932
Lease payments not included in the measurement of lease liabilities	1,887	2,486
Government grants income	(65,544)	(24,154)
Auditors' remuneration	2,830	2,800
Interest income from financial assets at FVTPL	(2,277)	(1,049)
Interest income	(52,039)	(5,964)
Finance costs	8,397	11,133
Foreign exchange (gains)/losses, net	(139,030)	54,721
Fair value losses on convertible redeemable preferred shares	–	3,480,294
Employee benefit expenses (excluding directors' and chief executive's remuneration)		
– Wages and salaries	136,415	77,671
– Pension scheme contributions	25,351	6,933
– Staff welfare expenses	4,454	992
– Share-based payments expense	48,567	116,823
	214,787	202,419

9. INCOME TAX

The Group is subject to income tax on an entity basis on profits arising in or derived from the jurisdictions in which members of the Group are domiciled and operate.

Cayman Islands

Pursuant to the rules and regulations of the Cayman Islands, the Group is not subject to any income tax.

British Virgin Islands

Pursuant to the rules and regulations of the British Virgin Islands (“BVI”), the subsidiaries incorporated in the BVI are not subject to any income tax.

United States of America

Subsidiaries incorporated in Delaware, the USA, are subject to the statutory federal corporate income tax at a rate of 21% during the year ended December 31, 2022.

Hong Kong

The subsidiaries incorporated in Hong Kong are subject to Hong Kong profits tax at the statutory rate of 16.5% on any estimated assessable profits arising in Hong Kong during the year ended December 31, 2022. No provision for Hong Kong profits tax has been made as the Group had no assessable profits derived from or earned in Hong Kong during the year ended December 31, 2022.

Mainland China

Most subsidiaries incorporated in Mainland China are subject to the statutory rate of 25% on the taxable profits determined in accordance with the PRC Corporate Income Tax Law which became effective on January 1, 2008. Chengdu Kangnuo Xing Biosciences Co., Ltd., a subsidiary of the Group, is subject to the statutory rate of 15% as it obtained the Certificate of High-tech Enterprise in 2022.

The Group had no taxable income during the year ended December 31, 2022.

10. DIVIDENDS

No dividends have been declared and paid by the Company during the year ended December 31, 2022.

11. 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 for the year attributable to ordinary equity holders of the parent and the weighted average number of ordinary shares in issue (excluding treasury shares reserved under the restricted share units scheme) during each reporting period.

The computation of diluted loss per share for the year ended 31 December 2022 and 31 December 2021 was made without the assumption of the exercise of restricted share units in 2022 and 2021 and conversion of the convertible redeemable preferred shares in 2021 since their assumed exercise or conversion of such shares would result in a decrease in loss per share.

The calculation of the basic and diluted loss per share attributable to ordinary equity holders of the parent is based on the following data:

	2022	2021
<u>Loss for the year</u>		
Loss for the year attributable to ordinary equity holders of the parent (RMB'000)	<u><u>(308,115)</u></u>	<u><u>(3,887,309)</u></u>
<u>Number of shares</u>		
Weighted average number of ordinary shares for the purpose of basic and diluted loss per share	<u><u>261,126,555</u></u>	<u><u>160,849,076</u></u>
<u>Loss per share (basic and diluted)</u>		
RMB per share	<u><u>(1.18)</u></u>	<u><u>(24.17)</u></u>

12. TRADE PAYABLES

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

	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Within 3 months	4,995	271
3 to 6 months	4,358	1,958
6 months to 1 year	5,495	392
Over 1 year	<u>65</u>	<u>163</u>
	<u><u>14,913</u></u>	<u><u>2,784</u></u>

Trade payables are non-interest-bearing and unsecured.

DEFINITIONS

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

“AGM”	the 2022 annual general meeting of the Company to be held on June 27, 2023
“Audit Committee”	the audit committee of the Board
“BLA”	biologics license application
“Board of Directors” or “Board”	the board of Directors
“CDE”	Center for Drug Evaluation of the NMPA
“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 annual results announcement and for geographical reference only, excludes Hong Kong, the Macau Special Administrative Region of the People’s Republic of China and Taiwan
“cGMP” or “Current Good Manufacturing Practice”	cGMP refers to the Current Good Manufacturing Practice regulations enforced by the FDA. cGMPs provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities. Adherence to the cGMP regulations assures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations. This includes establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories
“Company” or “our Company”	Keymed Biosciences Inc. (formerly known as 2Health Biosciences, Inc.), an exempted company with limited liability incorporated in the Cayman Islands on April 23, 2018
“Core Product”	CM310, the designated “core product” as defined under Chapter 18A of the Listing Rules
“CRO(s)”	contract research organization, a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis
“CSPC”	CSPC Pharmaceutical Group Limited, a company listed on the Stock Exchange (stock code: 1093), and its affiliates

“Director(s)”	the director(s) of the Company or any one of them
“Dr. Chen”	Dr. Bo CHEN, the chairman of our Board, an executive Director and the chief executive officer of our Company
“EASI”	the Eczema Area and Severity Index is a validated scoring system that grades the physical signs of AD. An area score of 0-6 is assigned for each body region (total of four), depending on the percentage of AD-affected skin in that area: 0 (none), 1 (1% to 9%), 2 (10% to 29%), 3 (30% to 49%), 4 (50% to 69%), 5 (70% to 89%), or 6 (90% to 100%). The composite score, on a scale from 0 to 72, determines the severity of the signs of AD and the extent to which a patient is affected. EASI-75 indicates $\geq 75\%$ improvement from baseline
“FDA”	the Food and Drug Administration of the United States
“FVTPL”	fair value through profit and loss
“Global Offering”	the global offering of the Shares, details of which are set forth in the Prospectus
“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
“IFRSs”	International Financial Reporting Standards, as issued from time to time by the International Accounting Standards Board
“IGA”	Investigator’s Global Assessment scale, a five-point scale that provides a global clinical assessment of AD severity ranging from 0 to 4, where 0 indicates clear, 2 is mild, 3 is moderate and 4 indicates severe AD
“IND”	investigational new drug or investigational new drug application, also known as clinical trial application in China or the U.S.
“Independent Third Party” or “Independent Third Parties”	a person or entity who is not a connected person of the Company under the Listing Rules
“InnoCare”	Beijing InnoCare Pharma Tech Co., Ltd. (北京諾誠健華醫藥科技有限公司), a limited liability company incorporated under the laws of PRC on December 13, 2013, a subsidiary of InnoCare Pharma Limited (Stock Code: 9969), and an Independent Third Party

“IPO”	the initial public offering of the Shares on the Main Board of the Stock Exchange on July 8, 2021
“JMT-Bio”	Shanghai JMT-Bio Technology Co., Ltd. (上海津曼特生物科技有限公司), a wholly-owned subsidiary of CSPC
“KYM”	KYM Biosciences Inc., a 70% non-wholly owned subsidiary of the Company
“Listing Date”	July 8, 2021, on which the Shares were listed and from which dealings therein were permitted to take place on 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
“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)
“Prospectus”	the prospectus of the Company dated June 25, 2021
“R&D”	research and development
“Reporting Period”	the year ended December 31, 2022
“RMB”	Renminbi, the lawful currency of the PRC
“RSU(s)”	restricted share unit(s), being a conditional right when an award under the 2021 RSU Scheme or 2022 RSU Scheme vests whereby the grantee shall be entitled to obtain either Shares or an equivalent value in cash with reference to the market value of the Shares on or about the date of vesting
“Share(s)”	ordinary share(s) with nominal value of US\$0.0001 each in the share capital of the Company
“Shareholder(s)”	holder(s) of the Share(s)

“Stock Exchange”	The Stock Exchange of Hong Kong Limited
“United States” or “U.S.”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“US\$”	United States dollars, the lawful currency of the U.S.
“2021 RSU Scheme”	the restricted share unit scheme adopted by the Board on April 5, 2021
“2022 RSU Scheme”	the restricted share unit scheme adopted by the Board on January 21, 2022
“%”	per cent

By order of the Board
Keymed Biosciences Inc.
Dr. Bo CHEN
Chairman

Hong Kong, March 17, 2023

As at the date of this announcement, the Board of Directors of the Company comprises Dr. Bo CHEN, Dr. Changyu WANG and Dr. Gang XU as executive Directors; Mr. Qi CHEN, Dr. Min Chuan WANG and Mr. Yilun LIU as non-executive Directors; Prof. Xiao-Fan WANG, Prof. Yang KE, Mr. Cheuk Kin Stephen LAW and Prof. Linqing LIU as independent non-executive Directors.