

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.

This announcement contains forward-looking statements that involve risks and uncertainties. All statements other than statements of historical fact are forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors, some of which are beyond the Company's control, that may cause the actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. The Company undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.



開拓藥業有限公司*

KINTOR PHARMACEUTICAL LIMITED

(Incorporated in the Cayman Islands with limited liability)

(Stock code: 9939)

**(1) ANNUAL RESULTS ANNOUNCEMENT
FOR THE YEAR ENDED 31 DECEMBER 2022;
(2) PROPOSED AMENDMENTS TO THE
MEMORANDUM AND
ARTICLES OF ASSOCIATION;
AND
(3) PROPOSED INCREASE IN AUTHORISED SHARE CAPITAL**

The Board (the “**Board**”) of Directors (the “**Directors**”) of the Company is pleased to announce the consolidated annual results of the Group for the year ended 31 December 2022, together with comparative figures for the year ended 31 December 2021.

FINANCIAL HIGHLIGHTS

Our R&D costs increased by RMB60.1 million or 7.8% from RMB767.9 million for the year ended 31 December 2021 to RMB828.0 million for the year ended 31 December 2022. Such increased costs were mainly attributable to several ongoing phase III clinical trials, including those of Prixelutamide (GT0918) for the indication of COVID-19 and mCRPC, and Ppyrilutamide (KX-826) for the indication of AGA, during the Reporting Period.

The Group had cash and cash equivalents and time deposits of RMB875.3 million as at 31 December 2022, including utilised bank facilities of RMB276.5 million. In addition, the Group also had unutilised bank facilities of RMB120.0 million as at 31 December 2022. The Group has sufficient cash on hand to support the advancement of the Group's clinical trials and research and development.

	Year ended 31 December	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Revenue from out-licensing contracts	–	34,231
Cost of sales	–	–
Gross profit	–	34,231
Other income	18,612	29,311
Marketing costs	(20,326)	(14,698)
Administrative expenses	(132,249)	(103,255)
Research and development costs	(827,974)	(767,936)
Other gains/(losses) — net	17,408	(17,254)
Operating loss	(944,529)	(839,601)
Finance costs	(8,187)	(2,494)
Share of losses of an associate and a joint venture	(568)	–
Loss before income tax	(953,284)	(842,095)
Income tax expense	(1,085)	–
Loss and total comprehensive loss for the year	<u>(954,369)</u>	<u>(842,095)</u>
	As of 31 December	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Non-current assets	547,267	542,094
Current assets	1,507,869	1,525,895
Cash and cash equivalents and time deposits	875,304	1,055,220
Non-current liabilities	241,821	193,091
Current liabilities	318,127	219,740
Total equity	<u>1,495,188</u>	<u>1,655,158</u>

BUSINESS HIGHLIGHTS

As at the date of this announcement, we have seven innovative potential first-in-class/best-in-class drug candidates at phase I-III clinical stage. Since 2022, we have been making significant progress with respect to our drug pipelines. We have released the positive data of multiple pipelines, such as the data of phase II clinical trials of KX-826 for male and female AGA in China, respectively, and the results of phase I clinical trials of GT20029 for the treatment of AGA and acne in both China and the U.S.. Our phase III clinical trial of Prixelutamide in combination therapy with Abiraterone as a first-line treatment of mCRPC also progressed smoothly, and currently all 718 patients have been enrolled.

KX-826 is currently undergoing phase III trial for male AGA patients in China and we have completed the enrollment of 740 patients. We also plan to initiate phase III trial for female AGA patients in the second or third quarter of 2023. Prior to that, the enrollment of all patients for the male AGA phase II clinical trial in the United States has been completed. The previous results showed that KX-826 demonstrated good safety, and in efficacy as measured by the change of non-vellus TAHC at 24 weeks in comparison with that in the placebo group, the phase II clinical trials for the male and female AGA in China have reached the primary endpoints. In addition, we expect to release the top-line data of KX-826 phase II clinical trial for acne in China in the second quarter of 2023. GT20029 is the first topical AR-PROTAC compound developed by the Company's PROTAC platform. The previously announced data from phase I clinical trial in China and the United States showed that GT20029 demonstrated good safety, tolerability and pharmacokinetic characteristics. As the first topical PROTAC compound in the world which has entered clinical stage, the Company will continue to speed up the research and development process, and is preparing to initiate the phase II clinical trial and complete the first patient enrollment in the second quarter of 2023, and is planning to commence phase II clinical trial in the United States.

Pyrilutamide (KX-826)

AGA Indication

We have completed the phase II clinical trials of Pylrutamide (KX-826) for male AGA and female AGA in China respectively and are conducting phase III clinical trial for male AGA in China and phase II clinical trial for male AGA in the U.S..

- On 28 February 2022, we enrolled and dosed the first patient in the phase II clinical trial of Pylrutamide in the U.S. for the treatment of male AGA. On 1 August 2022, we completed the enrollment of all the patients, which took less than six months amid the ongoing impact of the COVID-19 pandemic.
- On 4 March 2022, we completed the enrollment of 160 patients in the phase II clinical trial of Pylrutamide in China for the treatment of female AGA.
- On 27 August 2022, one of the leading principal investigators of the phase II clinical trial of Pylrutamide in China for the treatment of male AGA, Professor Jianzhong Zhang (張建中) from Peking University People's Hospital, officially released the trial's positive results at the 6th Annual Meeting of Chinese Hair Research Society (第六屆全國毛髮學術會議). The results showed that after 24 weeks of treatment, the 5mg twice daily (BID) group had demonstrated significant improvement in non-vellus target area hair count (TAHC), which as compared with the baseline, increased by 22.73 hairs per cm², $P < 0.001$; and compared with placebo group, increased by 15.34 hairs per cm², $P = 0.024$. No severe adverse event (SAE), serious adverse drug reaction (SADR) or death occurred.
- On 1 December 2022, the primary endpoint of the phase II clinical trial of KX-826 in China for the treatment of adult female AGA was met. KX-826 has demonstrated clinically meaningful and statistically significant improvement in hair growth as measured by non-vellus TAHC with favorable safety profile. The results showed that after 24 weeks of treatment, the non-vellus TAHC of the 5mg (0.5%) once daily (QD) group had increased by 11.39 hair counts per cm² compared with the placebo group from baseline, which was statistically significant ($P = 0.0087$). In addition, KX-826 has demonstrated efficacy as early as at the end of week 12.
- On 28 March 2023, we announced that we have completed the enrollment of all the 740 subjects for the phase III clinical trial of Pylrutamide in China for male AGA. We expect to release the top-line data in the fourth quarter of 2023.

Acne Vulgaris Indication

- Following the preliminary positive safety and tolerability profile demonstrated in the phase I trial of Pyrilutamide, on 24 January 2022, we enrolled and dosed the first patient in the phase II clinical trial of Pyrilutamide in China for the treatment of acne vulgaris, and completed the enrollment of 160 patients on 14 October 2022.

AR-PROTAC Compound (GT20029)

- On 1 February 2022, we enrolled and dosed the first subject in the phase I clinical trial of GT20029 for the treatment of AGA and acne vulgaris in the U.S.. On 25 October 2022, we completed the enrollment and dosing of 123 subjects.
- On 8 August 2022, we completed the enrollment and dosing of 92 subjects for the phase I clinical trial of GT20029 for the treatment of AGA and acne vulgaris in China.
- On 24 November 2022, we announced the top-line results of the phase I clinical trial of GT20029 for the treatment of AGA and acne vulgaris in China. The results showed that GT20029 demonstrated good safety, tolerability and pharmacokinetics in healthy subjects.
- On 10 February 2023, we announced the top-line results of the phase I clinical trial of GT20029 for the treatment of AGA and acne vulgaris in the U.S.. The results showed that GT20029 demonstrated good safety, tolerability and pharmacokinetics following topical single ascending dose (SAD) administration in healthy subjects and multiple ascending dose (MAD) administration in subjects with AGA or acne vulgaris.

Prixelutamide (GT0918)

COVID-19 Indication

- On 6 April 2022, the Company announced the key data of the phase III clinical trial of Prixelutamide in patients with mild to moderate COVID-19 indication. Based on the results, we are seeking the conditional approval or EUA from NMPA and Southeast Asian countries.

mCRPC Indication

- We have initiated the multi-centre, randomised and double blind phase III clinical trial of Prixelutamide in combination therapy with Abiraterone as a first-line combination therapy in China. On 24 February 2022, we completed the enrollment of 718 patients in such clinical trial. We expect to complete the trial in the second half of 2023 or the first half of 2024. In addition, the phase II clinical trial of Prixelutamide as the second-line therapy for the treatment of Enzalutamide or Abiraterone resistant mCRPC patients which is currently underway in the United States is nearly finished. We will continue to focus on the research and development of innovative therapies for the treatment of prostate cancer to provide patients with more treatment options.

GT1708F

- We are currently exploring and developing GT1708F for the treatment of idiopathic pulmonary fibrosis (IPF). Based on the safety profile of GT1708F in blood cancer, we are seeking the approval from NMPA to conduct the IPF phase II clinical trial.
- We have commenced the phase I clinical trial with multiple ascending dose (MAD) administration in patients with blood cancer. Such patients had previously received multiple lines of treatment. GT1708F has been shown to reduce blast counts in three out of thirteen AML patients treated with higher doses and demonstrated favorable pharmacokinetics (PK) and safety profiles in previous studies. Such preclinical data from GT1708F have been shortlisted for presentation at the 2023 American Association of Cancer Research (AACR) Annual Meeting.

For details of any of the foregoing, please refer to the rest of this announcement and, where applicable, the Company's prior announcements published on the websites of the Stock Exchange and the Company.

MANAGEMENT DISCUSSION AND ANALYSIS

OVERVIEW

We are a clinical-stage novel drug developer in China focusing on developing potential first-in-class/best-in-class drugs for unmet clinical needs. We are committed to becoming a leader in the research, development and commercialisation of innovative therapies. Our pipelines cover indications of AGA, acne vulgaris, COVID-19, mCRPC, HCC and other related indications.

During the Reporting Period, the China phase II clinical trials of Ppyrilutamide, our first Core Product, for the treatment of male AGA and female AGA have reached the primary endpoint with positive and safety profile. The detailed data of the two trials have been disclosed. Based on the positive results of the male AGA phase II clinical trial, the Company is conducting the phase III clinical trial for the treatment of male AGA in China and has completed the enrollment of 740 patients. The data readout is expected in the fourth quarter of 2023. Based on the positive results of the female phase II clinical trial, the Company is planning to conduct the phase III clinical trial for the treatment of female AGA in China in the second or third quarter of 2023. Previously, the phase II clinical trial for the treatment of male AGA in the United States has completed subjects enrollment. In addition, it is expected that the top-line data of the phase II trial of KX-826 for the treatment of acne vulgaris in China will be released in the second quarter of 2023.

Meanwhile, the phase I clinical trials of AR-PROTAC compound GT20029, our second Core Product, for the treatment of AGA and acne vulgaris in China and the U.S. have been completed, and we have announced the positive top-line results respectively. Based on such positive safety data, we are preparing to initiate the phase II clinical trial in China and expect to have the first patient enrollment in the second quarter of 2023, and we are planning to commence the phase II clinical trial in the United States. In the meantime, we are actively seeking potential collaboration opportunities for Ppyrilutamide and GT20029 in China and globally to speed up the commercialization.

The phase III trial of Pruxelutamide, our third Core Product, for COVID-19 indication was completed with promising results, and we have announced the top-line results. We are currently seeking the conditional approval or EUA from NMPA and Southeast Asian countries.

In the capital market, the stock of the Company has been included in the MSCI China Index and Shanghai-Hong Kong Stock Connect, and we completed two placings in 2022 to raise approximately USD100 million, which will further enhance the stock's liquidity and provide financial support to move forward our R&D.

Product Pipeline

Our pipeline includes a risk-balanced and diversified portfolio of drug candidates. The Company strategically targets AGA, ance, COVID-19, mCRPC and other indications with substantial market potential and unmet medical needs. The following chart sets forth a summary of our drug candidates as well as their respective mechanism, indications and development progresses:

	Drug Candidate	Target / Mechanism	Indication	Country/Region	Pre-Clinical	IND Filing (Filed) (Accepted)	Phase I	Phase II	Phase III	NDA	
Clinical stages	Dermatology	Pyrilutamide (KX-826)	AR antagonist (for external use)	Androgenetic alopecia (Male)	China	Completed	patients enrollment in Mar 2023				
				Androgenetic alopecia (Female)	China		Data readout on Dec 1, 2022				
				Androgenetic alopecia (Male)	US	Completed	patients enrollment on Aug 1, 2022				
				Acne vulgaris	China	Completed	patients enrollment on Oct 14, 2022				
				Acne vulgaris	US						
	Dermatology	AR-PROTAC (GT20029)	AR-PROTAC compound	Androgenetic alopecia	China		Expect FPI in 2Q 2023				
				Acne vulgaris	China		Positive top-line data released on Nov 24, 2022				
				Androgenetic alopecia	US		Positive top-line data released on Feb 10, 2023				
	Non-dermatology	Pruxelutamide (GT0918)	Second generation AR antagonist	COVID-19	Intl						
				Combination therapy with Abiraterone for mCRPC	China	Completed	patients enrollment on Feb 24, 2022				
		GT1708F ¹	Hedgehog/SMO inhibitor	mCRPC	US		Expected to release data in 2Q/3Q 2023				
				Combination therapy with Exemestane, Letrozole and Fulvestrant for metastatic breast cancer	China	Completed	patients enrollment on Aug 25, 2021				
Idiopathic pulmonary fibrosis (IPF) ²				China							
Detorsertib (GT0486)	mTOR kinase inhibitor	Metastatic solid tumours	China	Completed	FPI on Feb 18, 2021						
Biologics	ALK-1 (GT90001)	Angiogenesis inhibitor	Combination therapy with a PD-1 for metastatic HCC (2L)	Taiwan		Last patient last visit completed on Jul 7, 2022					
			Combination therapy with a PD-1 for metastatic HCC (2L)	US & Intl	Completed	FPI on May 2, 2022					
	GT90008	PD-L1 / TGF- β dual targeting antibody	Multiple types of solid tumours	China		IND was approved on Oct 11, 2021					
Pre-clinical		c-Myc inhibitor & molecular glue	Blood cancer and solid tumors								
					PROTAC compounds	External therapy					
					ALK-1/VEGF bispecific antibody	Solid tumours					

Note: 1. In addition, IND for basal-cell carcinoma indication has been cleared by FDA in the U.S.; 2. Will conduct phase II clinical trial directly due to good safety, and the protocol is under preparation

BUSINESS REVIEW

As at the date of this announcement, we have developed a pipeline of seven clinical-stage drug candidates, for which we had obtained approvals to commence clinical trials in China (including Taiwan), the U.S. and other countries and regions. These clinical-stage drug candidates include Pylilutamide, AR-PROTAC, Pruxelutamide, Hedgehog/SMO inhibitor, mTOR kinase inhibitor, ALK-1 antibody and PD-L1/TGF- β dual targeting antibody, the details of which are set out as follows:

Main Products

- *Pyrilutamide (KX-826)*

Pyrilutamide (KX-826) is a topical treatment to locally block the androgen mediated signaling instead of reducing androgen level systematically, and its metabolite has substantially reduced AR agonist activity in vivo, thereby reducing its side effects.

We are currently developing Pyrilutamide in tincture and gel as a potential first-in-class topical drug for the treatment of AGA and acne vulgaris. Its patent is valid until 8 September 2030.

- i. AGA Indication*

Data from the National Health Commission (國家衛生健康委員會) showed that, by the end of 2020, the number of people suffering from hair loss in China had exceeded 252 million, and AGA was the most common type of hair loss. According to a paper published in 2022, the prevalence of AGA in China is approximately 27.5% in males and 8.1% in females.

- Mechanism*

Where AGA occurs, the androgen binds to the AR in the hair follicle cells, and the AR undergoes a complex enzymatic reaction and forms an AR complex. The AR complex enters the nucleus, binds to a specific hormone-responsive element of the gene locus, induces or inhibits the transcription of the target gene, and synthesises specific messenger RNA (mRNA) and corresponding proteins, such as different kinds of cytokines. This regulates cell proliferation and differentiation, which causes the hair to prematurely enter into a resting period and shrinks hair follicles. The hair in the growing period gradually becomes thinner and hair follicles shrink and disappear, resulting in AGA. Abnormal changes in systemic and local androgen metabolism are important factors in the pathogenesis of AGA, and dihydrotestosterone (“DHT”) catalysed by androgen by 5 α -reductase is an important molecule leading to AGA. AR is recognised as a risk factor for AGA. Pyrilutamide (KX-826) is for topical application to locally block the androgen mediated signaling by competing androgen to bind to AR in the targeted tissues.

Previous Clinical Trials

On 27 August 2022, Professor Jianzhong Zhang from Peking University People's Hospital, one of the leading principal investigators of the phase II clinical trial of Pyrilutamide in China for the treatment of male AGA patients, officially released the positive results of the trial at the 6th Annual Meeting of Chinese Hair Research Society (第六屆全國毛髮學術會議).

A total of 120 male AGA patients who have met Hamilton-Norwood Scale IIIv to V were enrolled in the trial. Among them, 90 patients were randomly assigned to three treatment groups, including KX-826 2.5mg (0.25%) BID, KX-826 5mg (0.5%) QD and KX-826 5mg (0.5%) BID; and the remaining 30 patients were randomly assigned to placebo groups (QD or BID). The primary endpoint for the trial is the change from baseline in non-vellus TAHC after 24 weeks of treatment in comparison to placebo.

- For efficacy, after 24 weeks of treatment, the KX-826 (0.5%) 5mg BID group demonstrated significant improvement in non-vellus TAHC, which increased by 22.73 hairs per cm², $P < 0.001$ as compared with the baseline, and 15.34 hairs per cm², $P = 0.024$ as compared with the placebo group. KX-826 (0.5%) 5 mg BID was recommended and determined as the male AGA phase III dose.
- The overall safety profile of KX-826 was good and manageable. No SAE, adverse drug reaction (ADR), nor death occurred. After 14 days of topical application, the systemic exposure of KX-826 and its metabolites in vivo reached a steady state, and the drug concentration in blood in each dose group was low.

On 1 December 2022, we announced that the primary endpoint of the phase II clinical trial of KX-826 in China for the treatment of adult female AGA was met. A total of 160 female AGA patients who have met Savin Scale D3-D6 were enrolled in the trial. Among them, 119 patients were randomly assigned to four treatment groups, including KX-826 2.5mg (0.25%) QD, KX-826 2.5mg (0.25%) BID, KX-826 5mg (0.5%) QD and KX-826 5mg (0.5%) BID; and the remaining 41 patients were randomly assigned to placebo groups (QD and BID). The primary endpoint for the trial is the change from baseline in non-vellus TAHC after 24 weeks of treatment in comparison to placebo.

- For efficacy, the results showed that after 24 weeks of treatment, the non-vellus TAHC of the 5mg (0.5%) QD group had increased by 11.39 hair counts per cm² compared with the placebo group from baseline, which was statistically significant ($P=0.0087$). In addition, KX-826 has demonstrated efficacy as early as week 12.
- For safety, the overall profile of KX-826 was favorable. The majority of treatment-emergent adverse events (“TEAE”) were mild and similar to those of placebo. No TEAE resulting in patient withdrawal or death from the trial was reported.

Ongoing or Planned Clinical Trials

Previously, the phase II clinical trial for the treatment of male AGA in the United States has completed subjects enrollment, and we expect to release the top-line data in the second quarter of 2023.

Pyrilutamide is the first topical AR antagonist which has entered phase III clinical trial of AGA globally. On 24 November 2021, we announced that the pivotal study (phase III clinical trial) of Pylrutamide for the treatment of male AGA patients was granted clearance by NMPA. The phase III clinical trial is a randomized, double-blind, placebo-controlled, multi-centre study designed to evaluate the efficacy and safety of KX-826 for treating male AGA subjects in China. The primary endpoint for the trial is the change from baseline in non-vellus TAHC after 24 weeks of treatment in comparison to placebo. As at the date of this announcement, we have completed the enrollment of total 740 patients.

Meanwhile, we are planning to conduct phase III clinical trial for the treatment of female AGA patients in China in the second or third quarter of 2023 based on the positive data from previous clinical trials.

ii. Acne vulgaris indication

Acne vulgaris is the eighth most prevalent disease in the world which is particularly common among adolescents and young adults. Acne vulgaris affects more than 9.4% of the global population. The pathogenesis of acne vulgaris is complicated. The influence of androgen and its receptor signaling pathway on sebaceous glands and sebum secretion is one of the important factors causing acne vulgaris. The U.S. FDA approved the first androgen receptor (AR) antagonist over the past 40 years for the treatment of acne in August 2020, which had paved the way for our ongoing clinical trials in China. To date, there has been significant unmet medical needs as no effective topical AR antagonist was approved for the acne vulgaris treatment in China.

Pyrilutamide is a well-targeted topical AR antagonist, which competitively inhibits the combination of androgen with the AR in the skin tissue and is able to topically control the activation of the AR signal pathway caused by the excessive level of androgen without affecting the activity of the AR signal pathway in human body. Through external application, Pyrilutamide is able to inhibit the combination of AR with androgen in hair follicle sebaceous glands for the treatment of acne vulgaris.

The phase I trial of Pyrilutamide as treatment for the acne vulgaris was commenced in China on 16 April 2021, which has demonstrated a preliminary positive safety and tolerability profile in terms of dose-escalation and dosing frequency. On 14 October 2022, we completed the enrollment of 160 patients for the phase II clinical trial of Pyrilutamide in China for the treatment of acne vulgaris. Data readout of this trial is expected in the first half year of 2023.

- ***AR-PROTAC Compound (GT20029)***

GT20029 has the potential to become a new generation of treatment for AGA and acne vulgaris. GT20029 is a topical AR-PROTAC compound developed by the Group's in-house PROTAC platform. It is also the first topical PROTAC compound in the world which has entered clinical stage, and completed phase I clinical trial in both China and the U.S.. By degrading AR protein, GT20029 can block the shrinkage and miniaturization of hair follicles caused by the activation of AR signaling pathway. As a result, it prevents hair from thinning, softening and falling out. GT20029 can also effectively inhibit sebaceous gland development and sebum secretion. It has a topical curative effect and can avoid systemic exposure by limiting skin penetration, and thus achieving good safety profile. The repeated pharmacodynamics studies in DHT-induced mouse model showed that GT20029 significantly promotes hair growth with statistical difference. The study of testosterone propionate (“**TP**”)-induced skin hamster flank organ acne model showed that GT20029 significantly inhibited the enlargement of the flank organ, with statistical difference.

On 24 November 2022, we announced the top-line results of the phase I clinical trial of GT20029 for the treatment of AGA and acne vulgaris in China. The results showed that GT20029 demonstrated good safety, tolerability and pharmacokinetics in healthy subjects. Following a single dose administration, all subjects had no detectable drug concentrations (below lower limit of quantification (“**LLOQ**”), 0.001ng/mL) at all dose levels. Following multiple-doses topical administration, the mean maximum drug concentrations of all cohorts were lower than 0.05ng/mL. All treatment related adverse events (“**TRAE**”) were grade 1.

On 10 February 2023, we announced the top-line results of the phase I clinical trial of GT20029 for the treatment of AGA and acne vulgaris in the U.S.. The results showed that GT20029 demonstrated good safety, tolerability and pharmacokinetics following topical single ascending dose (“**SAD**”) administration in healthy subjects and multiple ascending dose (“**MAD**”) administration in subjects with AGA or acne vulgaris. In the SAD stage, subjects had no systemic exposure at all dose levels, and all sample concentrations were below the LLOQ (0.003 ng/mL). In the MAD stage, after 14 days of continuous administration in subjects with AGA or acne vulgaris, the systemic exposure was limited and the mean maximum observed concentration (C_{max}) of all dose levels fluctuated near the LLOQ, with the highest not exceeding 0.015 ng/mL. No TEAE relating to GT20029 in the SAD stage was reported. Most of the TEAEs in the MAD stage were mild, including dryness, itching, burning and pain at application sites. No SAE, severe TEAE (Grade ≥3), subject withdrawal or death caused by TEAE were reported. We are preparing to initiate the phase II clinical trial and expect to complete first patient enrollment in the second quarter of 2023.

- ***Prixelutamide (GT0918)***

Prixelutamide is a second-generation AR antagonist as well as an ACE2 and TMPRSS2 degrader with the potential to be a best-in-class drug. We are currently developing Prixelutamide for the treatment of COVID-19, mCRPC and AR+ metastatic breast cancer. Its patent is valid until 8 March 2032.

- i. Indication of COVID-19*

On 6 April 2022, the Company announced the top-line results of phase III clinical trial of Prixelutamide in patients with mild to moderate COVID-19 indication. Based on the results, we are seeking the conditional approval or EUA from NMPA and Southeast Asian countries.

As the COVID-19 pandemic has alleviated since early 2023, the prevention and control measures are gradually loosened worldwide and there is lower expectation of another wave in the short period of time. In addition, the competition in the COVID-19 oral small molecule drug market is fierce, and many new COVID-19 small molecule drugs have obtained marketing approvals globally and in China. Considering the Company’s current financial situation, we have decided to reduce the expenditure in the COVID-19 clinical trials of Prixelutamide.

ii. Indication of mCRPC and AR+ metastatic breast cancer

Prixelutamide is a potential best-in-class small molecule AR antagonist based on well-researched mechanism. Prixelutamide has a novel chemical structure and constitutes a dual-action mechanism which not only inhibits androgen from binding to AR, but also reduces AR expression. We developed Prixelutamide for the treatment of mCRPC and AR+ metastatic breast cancer.

Our pre-clinical and clinical research on Prixelutamide for prostate cancer and AR+ breast cancer were recognised as a Science and Technology Major Project for “Major New Drugs Innovation and Development” (“重大新藥創製” 科技重大專項) in 2011 and 2017, respectively.

We are conducting a multi-centre, randomised, double-blind phase III clinical trial for Prixelutamide in combination therapy with Abiraterone for mCRPC as a first-line combination therapy, and the phase III clinical trial has completed 718 patients enrollment on 24 February 2022. We expect to finish the clinical stage work by the second half of 2023 or the first half year of 2024. The phase II clinical trial of Prixelutamide as second-line therapy for the treatment of Enzalutamide or Abiraterone resistant mCRPC patients which is currently underway in the United States is nearly finished.

We are carrying out an open and multi-centre phase Ic clinical trial to evaluate the safety, pharmacokinetic characteristics and initial efficacy of Prixelutamide in combination with Exemestane, Letrozole and Fulvestrant in patients with AR+ metastatic breast cancer. The trial has completed patients enrollment on 25 August 2021, and we are conducting data analysis for the publication or presentation at a medical conference in the future.

- *GT1708F (Hedgehog/SMO Inhibitor)*

GT1708F is an inhibitor of the hedgehog signal transduction pathway. We are currently developing GT1708F primarily for the treatment of IPF and blood cancer.

i. IPF Indication

The global incidence rate of IPF reaches 14 to 43 per 100,000 people. The incidence rate in China reaches 2 to 29 per 100,000 people, which means around 28 to 406 thousand patients in total. GT1708F affects the activity of Hh pathway and expression of the relevant downstream proteins by inhibiting the activity of SMO protein. Reactivation of the Hh signaling pathway is a feature of fibrotic lung tissue in IPF which inhibits the increase in fibroblast migration and proliferation. Many nonclinical studies have shown that the Hh signaling pathway

plays a crucial role in IPF. According to reports, in IPF tissue, the expression of genes or proteins such as SMO and Gli1 is higher than that in normal lung tissue, and after stimulating Hh in pulmonary fibrosis cells isolated from lung tissue of patients suffering from IPF, the expression of SMO and Gli1 proteins and genes is increased. In-vitro study showed that GT1708F could significantly decrease the expression of Gli1, Gli2 and pulmonary fibrosis related α -SMA protein .

The results of the bleomycin-induced pulmonary fibrosis model on Sprague–Dawley(SD) rats showed that after GT1708F treatment, the damage of the terminal bronchial wall and pulmonary arteriole wall and inflammatory cell infiltration (in the lesion and on the edge of the lesion) were effectively improved. Compared with the active comparator nintedanib, different doses of GT1708F have similar improvement effects on lung damage and inflammatory cell infiltration. In addition, GT1708F can significantly improve the degree of pulmonary fibrosis ($P<0.001$).

We expect to enter into phase II clinical trial for GT1708F for treatment of IPF after the clearance of NMPA.

ii. Blood Cancer Indication

We have obtained IND approval for GT1708F for the treatment of blood cancer from NMPA and are conducting phase I clinical trial which contains single dose and multiple dose escalation stages.

GT1708F was studied in a phase I clinical trial of acute myeloid leukemia (AML) patients with previous multiple lines of regimens. GT1708F has been shown to reduce blast counts in three of 13 AML patients treated with higher doses and demonstrated favorable pharmacokinetics (PK) and safety profiles. The latest preclinical data from GT1708F have been shortlisted for presentation at the 2023 American Association of Cancer Research Annual Meeting to be held on 14 to 19 April 2023.

- ***ALK-1 Antibody (GT90001)***

ALK-1 antibody is a fully human IgG2 neutralising monoclonal antibody that inhibits ALK-1/TGF- β signal transduction and tumor angiogenesis and a potential first-in-class antibody for which the Company obtained an exclusive global license of ALK-1 for all the oncological areas from Pfizer in February 2018. ALK-1 antibody has the potential to become the first fully human monoclonal antibody therapeutic drug for ALK-1 target, which can potentially be used in combination with PD-1 inhibitors or VEGF inhibitors for the treatment of a variety of solid tumours.

In Taiwan, China, our phase II clinical trial of ALK-1 antibody and Nivolumab combination therapy for the treatment of advanced HCC has completed the last patient last visit on 7 July 2022. Previously, the preliminary data were released at the 2021 American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO-GI). The results showed that among the 20 evaluable patients, 8 patients (40.0%) were observed partial remission (PR).

In the U.S., we obtained IND approval for the combination therapy of ALK-1 antibody and Nivolumab for a global multi-center phase II clinical trial for the second-line treatment of advanced HCC and completed the first patient dosing. In China, we also obtained approval for the clinical trial of combination therapy of ALK-1 antibody and Nivolumab for the treatment of advanced HCC.

Other Clinical Stage Products

Detorsertib (GT0486) is an inhibitor of the PI3K/mTOR signaling pathway and a second generation mTOR inhibitor. We are currently developing GT0486 primarily for the treatment of metastatic solid tumours such as breast cancer, prostate cancer and HCC. We received the IND approval from NMPA for Detorsertib and the phase I clinical trial is currently at the dose escalation stage.

PD-L1/TGF- β (GT90008) is a dual-targeting antibody licensed from Gensun Biopharma Inc. (“**Gensun**”) which is composed of an antagonist antibody of PD-L1 and the extracellular domain of TGF- β with high activity in inhibiting PD-L1 and TGF- β simultaneously. The compound has the potential in the treatment of a variety of solid tumours, including non-small cell lung cancer, biliary tract cancer, triple negative breast cancer and HPV-associated tumours such as cervical cancer and has the potential to become a best-in-class drug. On 21 October 2021, the clinical trial of GT90008 for the treatment of advanced solid tumours was approved by NMPA.

Pre-Clinical Stage Products

In addition to the drug candidates described above, we are also at the discovery stage for the development of other potential drug candidates, including c-Myc inhibitor, compound of other targets (such as c-Myc) out of PROTAC platform and ALK-1/VEGF bispecific antibody for the treatment of multiple indications such as blood cancer and solid tumours, respectively.

WARNING UNDER RULE 18A.08(3) OF THE LISTING RULES: WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR DRUG CANDIDATES (INCLUDING OUR CORE PRODUCTS) SUCCESSFULLY

RESEARCH AND DEVELOPMENT

We have established an integrated R&D platform to support our drug development programmes from discovery to clinical stage. We conduct proprietary laboratory research to identify and select new compounds as our potential drug candidates, and we manage our drug development process primarily using our internal R&D resources to ensure that the quality standards we have set internally will be met.

Through the development of Prixelutamide and Ppyrilutamide, we have accumulated significant expertise in AR-related know-how and have developed a leading AR technology platform. We believe that we have accumulated industry-leading expertise in the field of AR signaling pathway, molecule design and PK/PD modelling. Leveraging our AR technology platform, we have successfully progressed Prixelutamide to phase III clinical trials in China, the U.S. and global, and have also developed Ppyrilutamide for AGA and acne vulgaris. As at the date of this announcement, we have successfully progressed Ppyrilutamide to phase III clinical trial for the treatment of male AGA patients for which we have completed 740 subjects enrollment, phase II clinical trial for the treatment of female AGA patients which have reached the primary endpoint and positive data of which have been released, and phase II clinical trial for the treatment of acne vulgaris for which we have completed subject enrollment in China.

PROTAC is a novel drug discovery technology platform for targeting and/or degrading undruggable and oncogene mutant drivers that drive the resistance to the targeted therapies. We are currently employing the PROTAC technology with an aim to develop the compounds targeting AR and other targets for patients with unmet medical needs globally. We have developed AR-PROTAC for AGA and acne vulgaris and have released its phase I results of its clinical trials in China and the US.

By in-licensing and developing ALK-1 antibody, we have gradually established and expanded our R&D capabilities in the field of biological drugs. We have carried forward ALK-1 antibody to phase II clinical trial. In addition, we also introduced the second biological drug, PD-L1/TGF- β dual-targeting antibody, for the treatment of multiple solid tumors. We expanded our geographical presence to the Zhuhai International Health Port through our Zhuhai subsidiary, which will focus on tumor immunity and promote the clinical R&D, production and commercialization of the Group's biological drugs. This is a step forward in our strategy to enrich our drug pipeline.

Our R&D work is led by Dr. TONG, and several experienced returnee scientists who have accumulated decades of pharmaceutical R&D and entrepreneurship experience in reputable pharma and biotech companies in the U.S. and together provide us with integrated expertise covering small molecule, biologics, and compound design. As part of our global expansion strategy, our various products have been granted IND approvals in multiple countries and regions and our in-house R&D team has collaborated with local and overseas CROs to conduct MRCTs of drug candidates.

For the years ended 31 December 2021 and 2022, our research and development expenses were approximately RMB767.9 million and RMB828.0 million, respectively.

MANUFACTURING AND COMMERCIALISATION

We plan to use our in-house production and R&D base in Suzhou and Pinghu in China for the manufacture of APIs and products for Prixelutamide and Ppyrilutamide. On 28 August 2020, our manufacturing and R&D facility in Suzhou commenced operations in preparation for the production of Prixelutamide. In November 2020, our Suzhou production and R&D base was granted the Pharmaceutical Production License issued by Jiangsu Medical Products Administration. In July 2022, the Pinghu industrial base held its foundation stone laying ceremony, which marked the official start of construction.

As at the date of this announcement, we had not commercialised any of our drug candidates. We plan to prepare the commercialization of our products through both distribution and license-out partnerships.

FINANCIAL REVIEW

Overview

We currently have no drugs approved for commercial sale and have not generated any revenue from drug sales for the year ended 31 December 2022. We have never generated any profit since our inception. Our loss and total comprehensive loss were RMB842.1 million and RMB954.4 million for the years ended 31 December 2021 and 2022, respectively. Our operating losses mainly resulted from R&D costs (primarily consisting of clinical research expenses) and administrative expenses.

Cost of Sales

We did not record any cost of sales for the years ended 31 December 2022 and 2021.

Other Income

Our other income primarily consisted of government grants and interest income from bank balances. Our other income decreased by RMB10.7 million or 36.5% from RMB29.3 million for the year ended 31 December 2021 to RMB18.6 million for the year ended 31 December 2022, which was mainly attributable to (i) a RMB4.9 million decrease in government grants which we have received to compensate for the expenses of our Group's research and development; (ii) a RMB3.0 million decrease in interest income from time deposits as a result of our decreased bank balances in time deposit account during the Reporting Period; and (iii) a RMB2.1 million decrease in interest income from bank balances primarily as a result of the decrease of our bank balances.

Marketing Costs

Our marketing costs primarily consisted of (i) salaries and other benefits of our sales and marketing team; and (ii) administrative expenses including business trip expenses and other business development expenses. Our marketing costs increased from RMB14.7 million for the year ended 31 December 2021 to RMB20.3 million for the year ended 31 December 2022, which was mainly attributable to (i) an increase of RMB2.4 million in salary of our sales and marketing team in preparation for commercialisation of the Company's drug candidates; and (ii) an increase of RMB3.2 million in RSU expenses partially offset by a decrease of RMB0.8 million of administrative costs which includes business development expenses, traveling expenses, office expenses and other expenses incurred by marketing staff for marketing and business development purposes.

Administrative Expenses

Our administrative expenses during the Reporting Period primarily consisted of (i) employee benefit expenses, which primarily comprised compensation for management and executives (including share-based compensation expenses relating to the Employee Incentive Scheme); (ii) utilities and office expenses; (iii) depreciation and amortization, which primarily comprised depreciation of right-of-use assets and property, plant and equipment in relation to properties for administrative use; and (iv) other miscellaneous administrative expenses such as repair and maintenance expenses, professional advisory expenses, and materials and consumables expenses.

The following table sets forth a breakdown of our administrative expenses, by amount and as a percentage of our total administrative expenses, for the years indicated:

	For the year ended			
	2022		2021	
	<i>RMB'000</i>	<i>%</i>	<i>RMB'000</i>	<i>%</i>
Employee benefit expenses	50,114	37.9	40,535	39.3
Add: share-based compensation expenses	29,789	22.5	11,949	11.6
Employee benefit expenses (including share-based compensation expenses)	79,903	60.4	52,484	50.9
Utilities and office expenses ^(Note)	19,328	14.6	21,033	20.4
Depreciation and amortization	8,878	6.7	5,778	5.6
Others	24,140	18.3	23,960	23.1
Total	<u>132,249</u>	<u>100.0</u>	<u>103,255</u>	<u>100.0</u>

Note: The line item “utilities and office expenses” included short-term and low-value lease rental expenses incurred by the Group.

Our administrative expenses increased by RMB29.0 million or 28.1% from RMB103.3 million for the year ended 31 December 2021 to RMB132.2 million for the year ended 31 December 2022, which was mainly attributable to (i) a RMB27.4 million increase in employee benefit expenses primarily resulting from new recruitments and annual adjustment of remuneration for all employees and the grant of RSUs to qualified senior management employees according to the Employee Incentive Scheme on 8 October 2022; (ii) a RMB3.1 million increase in depreciation and amortisation; and (iii) a RMB0.2 million increase in other administrative expenses primarily relating to the increase in the repair and maintenance expenses incurred for our self-owned properties, and the increase in our professional advisory expenses such as compliance consulting fees, legal consulting fees and construction and environment consulting fees, as well as the increase in our materials and consumables expenses in line with the fast-paced development of our business, partially offset by a RMB1.7 million decrease in utilities and office expenses, which relates to a decrease in recruitment, travel and supplies expenses.

R&D Costs

Our R&D costs during the Reporting Period primarily consisted of (i) clinical research expenses, which primarily consisted of fees paid to CROs for clinical trials and the hospitals in which we conducted our clinical trials; (ii) materials and consumables expenses in connection with our R&D; (iii) write-down of inventories to net realisable value; (iv) employee benefit expenses, which primarily consisted of compensation to R&D personnel (including the share-based compensation expenses for the Employee Incentive Scheme); (v) third-party contracting fees, which primarily consisted of fees paid to CROs and CMOs for purposes of preclinical trials; and (vi) other R&D costs, which primarily consisted of utilities and office expenses in relation to R&D use, depreciation of right-of-use assets in relation to our leased properties for R&D use and depreciation of our laboratory equipment. The following table sets forth a breakdown of our R&D costs, by amount and as a percentage of our total R&D costs, for the periods indicated:

	For the year ended			
	2022		2021	
	<i>RMB'000</i>	<i>%</i>	<i>RMB'000</i>	<i>%</i>
Clinical research expenses	410,028	49.5	448,870	58.4
Materials and consumables expenses	109,766	13.3	146,433	19.1
Write-down of inventories to net realisable value	92,986	11.2	—	0.0
Employee benefit expenses	98,848	11.9	76,659	10.0
Add: share-based compensation expenses	57,229	7.0	19,929	2.6
Employee benefit expenses (including share-based compensation expenses)	156,077	18.9	96,588	12.6
Third party contracting fees	35,787	4.3	59,419	7.7
Others	23,330	2.8	16,626	2.2
Total	827,974	100.0	767,936	100.0

Our R&D costs increased by RMB60.1 million or 7.8% from RMB767.9 million for the year ended 31 December 2021 to RMB828.0 million for the year ended 31 December 2022, which was mainly attributable to (i) an increase of RMB93.0 million in write-down of inventories to net realisable value; and (ii) an increase of RMB59.5 million in R&D employee benefit expenses primarily due to the expansion of our R&D personnel and the grant of RSUs to certain of our R&D employees under the Employee Incentive Scheme, partially offset by (i) a decrease of RMB23.6 million for third party contracting fees primarily consisting of fees paid to CROs and CMOs for preclinical trials; (ii) a decrease of RMB38.8 million in clinical research expenses primarily paid to hospitals and CROs in relation to clinical trials for Proxelutamide for the COVID-19 indication, and (iii) a decrease of RMB36.7 million in materials and consumables used for R&D purposes.

Other Gains/Losses — Net

We had other gains of RMB17.4 million for the year ended 31 December 2022 primarily as a result of net foreign exchange gains due to exchange rates movement. We had other losses of RMB17.3 million for the year ended 31 December 2021.

Finance Costs

Our finance costs during the Reporting Period primarily consisted of interest expense from bank borrowings. Our finance costs increased by RMB5.7 million or 228.0% from RMB2.5 million for the year ended 31 December 2021 to RMB8.2 million for the year ended 31 December 2022, which was mainly attributable to the increase in interest expense from borrowings.

Income Tax Expenses

We did not have any income tax expenses for the year ended 31 December 2021 as we incurred a net loss. Our income tax expenses for the year ended 31 December 2022 were RMB1.1 million, which consisted of income tax expense paid for service fee received by Kintor Pharmaceuticals Inc., a wholly-owned subsidiary of the Company, from the Company for the purpose of general R&D activities in the US which was recognised as revenue, and income tax paid for the government grants received by a subsidiary of our Company.

Net Loss for the Reporting Period

Our net loss increased by RMB112.3 million or 13.3% from RMB842.1 million for the year ended 31 December 2021 to RMB954.4 million for the year ended 31 December 2022.

Non-IFRS Measure

To supplement the Group's consolidated financial statements, which are presented in accordance with the IFRS, the Company also uses adjusted loss and total comprehensive loss for the Reporting Period and other adjusted figures as additional financial measures, which are not required by, or presented in accordance with, the IFRS. The Company believes that these adjusted measures provide useful information to Shareholders and potential investors in understanding and evaluating the Group's consolidated results of operations in the same manner as they help the Company's management.

Adjusted loss and total comprehensive loss for the Reporting Period represents the loss and total comprehensive loss for the Reporting Period excluding the effect of certain non-cash items, namely the share-based compensation expenses. The term adjusted loss and total comprehensive loss for the Reporting Period is not defined under the IFRS. The use of this non-IFRS measure has limitations as an analytical tool, and it should not be considered in isolation from, or as substitute for analysis of, the Group's results of operations or financial condition as reported under IFRS. The Company's presentation of such adjusted figure may not be comparable to a similarly titled measure presented by other companies. However, the Company believes that this and other non-IFRS measures reflect the Group's normal operating results by eliminating impacts of items that the management do not consider to be indicative of the Group's operating performance, and thus facilitate comparison of operating performance from period to period and company to company to the extent applicable.

The table below sets forth a reconciliation of the loss and total comprehensive loss for the year to adjusted loss and total comprehensive loss for the years indicated:

	Year ended 31 December	
	2022	2021
	RMB'000	RMB'000
Loss and total comprehensive loss for the year	(954,369)	(842,095)
Added:		
<i>Share-based compensation expenses</i>	<u>95,636</u>	<u>37,347</u>
Adjusted loss and total comprehensive loss for the year	<u><u>(858,733)</u></u>	<u><u>(804,748)</u></u>

Employees and Remuneration Policies

The following table sets forth a breakdown of our employees by function:

	As of 31 December 2022	
	Number of employees	As a percentage of total
Core management	9	3.0%
Clinical	63	20.9%
R&D	92	30.6%
Manufacturing	63	20.9%
Commercial	14	4.7%
Project management	14	4.7%
Others	46	15.2%
Total	301	100.0%

As at 31 December 2022, the Group had a total of 301 full time employees, among whom, the total staff with clinical and R&D mission accounted for over 51.5%. We generally formulate our employees' remuneration package to include basic salary, position-specific salary, performance-based bonus, project-based bonus and various allowances. We conduct periodic performance reviews for our employees. We have also adopted the Employee Incentive Scheme to retain and incentivise our key management and staff.

Contingent Liabilities

The Group did not have any material contingent liabilities as at 31 December 2022 and 2021.

Liquidity and Capital Resources

Our cash and cash equivalents and time deposits consisted of deposits with banks and cash on hand. As at 31 December 2022, cash and cash equivalents and time deposits decreased by RMB179.9 million or 17.0% from RMB1,055.2 million as at 31 December 2021 to RMB875.3 million. The change in our cash and cash equivalents for the Reporting Period was mainly attributable to the net proceeds from the Top-up Placing 2022 I and Top-up Placing 2022 II amounting to approximately RMB697.8 million, partially offset by the cash we used in (i) purchasing raw materials for COVID-19 related products; and (ii) R&D activities.

The current ratio (total current assets as a percentage of total current liabilities) of the Group decreased from 694.4% as at 31 December 2021 to 474.0% as at 31 December 2022, mainly due to the decrease in cash and cash equivalents and time deposits and the increase in borrowings and trade and other payables during the Reporting Period.

As at 31 December 2022, we had utilised bank facilities of RMB276.5 million and unutilised bank facilities of RMB120.0 million.

Significant Investments, Material Acquisitions or Disposals

As of 31 December 2022, there was no significant investments held by the Company nor any material acquisitions or disposals of subsidiaries, associates and joint ventures during the Reporting Period.

Cash Flow

The following table sets forth a summary of our consolidated statements of cash flows for the years indicated:

	Year ended 31 December	
	2022	2021
	RMB'000	RMB'000
Cash used in operations	(960,267)	(1,049,673)
Income tax paid	(905)	(809)
Net interest paid	(88)	(881)
	<hr/>	<hr/>
Net cash used in operating activities	(961,260)	(1,051,363)
Net cash generated from investing activities	67,195	92,005
Net cash generated from financing activities	815,750	857,418
	<hr/>	<hr/>
Net decrease in cash and cash equivalents	(78,315)	(101,940)
Cash and cash equivalent at the beginning of the year	926,331	1,064,689
Exchange gains/(losses) on cash and cash equivalents	16,454	(36,418)
	<hr/>	<hr/>
Cash and cash equivalent at the end of the year	<u>864,470</u>	<u>926,331</u>

Net Cash Used in Operating Activities

During the Reporting Period, we derived our cash inflows primarily from government grants. Our net cash used in operating activities mainly consisted of R&D expenses and administrative expenses.

During the year ended 31 December 2022, our net cash used in operating activities was RMB961.3 million, consisting of RMB960.3 million of cash used in operations, interest paid on borrowings of RMB10.0 million, interest received on bank balances of RMB9.9 million and income tax paid of RMB0.9 million.

During the year ended 31 December 2021, our net cash used in operating activities was RMB1,051.4 million, consisting of RMB1,049.7 million of cash used in operations, interest paid on borrowings of RMB6.8 million, interest received on bank balances of RMB5.9 million and income tax paid of RMB0.8 million.

Net Cash Generated from Investing Activities

During the Reporting Period, our cash flows relating to investing activities primarily reflected purchases of equipment and purchase of financial products.

During the year ended 31 December 2022, our net cash generated from investing activities was RMB67.2 million, which primarily consisted of proceeds received upon maturity of certain time deposits with maturities of over three months and disposal of financial assets at fair value through profit or loss of RMB337.8 million, partially offset by (i) purchase of equipment of RMB27.5 million for our Suzhou plant to expand its capacity; (ii) purchase of time deposits with maturities of over three months and financial assets at fair value through profit or loss of RMB220.7 million; (iii) purchase of intangible assets of RMB0.2 million resulting from payments for the new modules of the enterprise resource planning (ERP) software; (iv) payments for restricted cash of RMB4.0 million resulting from payments of deposits for our financial products; and (v) investment in a joint venture and an associate of RMB18.5 million.

During the year ended 31 December 2021, our net cash generated from investing activities was RMB92.0 million, which primarily consisted of proceeds received upon maturity of certain time deposits with maturities of over three months and disposal of financial assets at fair value through profit or loss of RMB714.8 million, partially offset by (i) purchase of equipment of RMB76.2 million for our Suzhou plant to expand its capacity; (ii) purchase of time deposits with maturities of over three months and financial assets at fair value through profit or loss of RMB515.4 million; (iii) purchase of intangible assets of RMB29.5 million resulting from milestone payments of PDLI/TGF- β ; and (iv) payments for restricted cash of RMB1.7 million resulting from payments of deposits for our financial products.

Net Cash Generated from Financing Activities

During the Reporting Period, our cash flows relating to financing activities primarily reflected proceeds from issue of Shares of the Company and bank borrowings.

During the year ended 31 December 2022, our net cash generated from financing activities was RMB815.8 million, which primarily consisted of (i) proceeds from the Top-up Placing 2022-I and Top-up Placing 2022-II of RMB697.8 million; (ii) proceeds from borrowings of RMB170.0 million; and (iii) proceeds from Shares vested under the Employee Incentive Scheme and transferred to the grantees of RMB1.0 million, partially offset by (i) repayment of borrowings of RMB48.4 million; and (ii) payment of lease liabilities of RMB4.6 million.

During the year ended 31 December 2021, our net cash generated from financing activities was RMB857.4 million, which primarily consisted of (i) proceeds from the Top-up Placing 2021 of RMB952.0 million; and (ii) proceeds from borrowings of RMB20.0 million, partially offset by (i) repayment of borrowings of RMB83.6 million; (ii) payment of lease liabilities of RMB28.9 million; and (iii) payment of listing expenses of RMB2.0 million.

Financial Position

Our net current assets decreased from RMB1,306.2 million as at 31 December 2021 to RMB1,189.7 million as at 31 December 2022, primarily due to a an increase in current liabilities, which was mainly attributable to the increase in borrowings and trade and other payables. Current assets decreased from RMB1,525.9 million as at 31 December 2021 to RMB1,507.9 million as at 31 December 2022, primarily due to the decrease of cash and cash equivalents.

Significant Change in Accounting Policy

There was no significant change in accounting policy during the Reporting Period.

Indebtedness

As at 31 December 2022, the balance of our bank borrowings consisted of long-term bank borrowings of RMB91.5 million which were secured by certain land use right, buildings and construction in progress, unsecured long-term bank borrowings of RMB145.0 million, and short-term bank borrowings of RMB58.9 million. In the balance of our bank borrowings, RMB98.9 million is repayable within one year or on demand.

As of 31 December 2021, the balance of our bank borrowings consisted of long-term bank borrowings of RMB96.5 million which were secured by certain land use right, buildings and construction in progress and unsecured long-term bank borrowings of RMB58.4 million. In the balance of our bank borrowings, RMB7.4 million is repayable within one year or on demand.

As at 31 December 2022, cash and cash equivalents are more than total borrowings of the Group, therefore, the gearing ratio is not applicable.

Financial Risks

The Group is exposed to various types of financial risks: market risks (including foreign exchange risk, cash flow and fair value interest rate risk), credit risk and liquidity risk. The Group's overall risk management programme focuses on the unpredictability of financial markets and seeks to minimise potential adverse effects on the Group's financial performance.

Foreign Exchange Risk

The Group mainly operates in the PRC with most of the transactions settled in RMB. The Group currently does not have a foreign currency hedging policy. However, management of the Group monitors foreign exchange exposure and will consider hedging significant foreign currency exposure should the need arise.

The Group is not exposed to foreign exchange risk as there are no significant financial assets or liabilities of the Group denominated in the currencies other than the functional currency, except for cash and cash equivalents, restricted cash and time deposits at bank in USD and HKD which were primarily received from the investors as capital contributions.

Cash Flow and Fair Value Interest Rate Risk

Our income and operating cash flows are substantially independent of changes in market interest rates. We have no significant interest-bearing assets and liabilities, except for lease liabilities, cash and cash equivalents, restricted cash, time deposits and borrowings. Those carried at floating rates expose us to cash flow interest rate risk whereas those carried at fixed rates expose us to fair value interest rate risk.

Our interest rate risk mainly arises from borrowings. Borrowings obtained at fixed rates expose us to fair value interest rate risk. As at 31 December 2022, our borrowings carried at fixed rates, which exposed the Group to fair value interest rate risk.

Our management does not anticipate significant impact on interest-bearing assets resulting from the changes in interest rates, because the interest rates of bank deposits are not expected to change significantly.

Credit Risk

The Group is exposed to credit risk in relation to receivables, cash and cash equivalents, restricted cash, time deposits and wealth management products. The carrying amounts of receivables, cash and cash equivalents, restricted cash, time deposits and wealth management products represent our maximum exposure to credit risk in relation to financial assets.

The Group expects that there is no significant credit risk associated with cash and cash equivalents, restricted cash, time deposits, and wealth management products since they are substantially deposited at or purchased from state-owned banks and other medium or large-sized foreign banks. Management does not expect that there will be any significant losses from non-performance by these counterparties and the loss allowance provision is considered immaterial.

Management has assessed that during the Reporting Period, other receivables have not had a significant increase in credit risk since their initial recognition. Therefore, a 12-month expected credit loss approach that results from possible default event within 12 months of each reporting date is adopted by management. As at 31 December 2022, other receivables mainly comprise deposits to lessors in respect of the Group's leased properties.

Management expects that there is no significant credit risk associated with other receivables since the counterparties have no history of default. Accordingly, the expected credit loss of other receivables is considered immaterial.

Liquidity Risk

The Group finances its working capital requirements through the issue of new shares, borrowings and government grants. Management monitors rolling forecasts of the Group's liquidity reserve on the basis of expected cash flow.

Prudent liquidity risk management includes maintaining sufficient cash and cash equivalents and the ability to apply for credit facilities if necessary. We had net current assets of RMB1,189.7 million as at 31 December 2022. We are able to meet our financial obligations and fund our R&D activities through our cash on hand and consecutive capital raising activities.

FINANCIAL INFORMATION

The Board announces the consolidated annual results of the Group for the year ended 31 December 2022, with comparative figures for the previous year as follows:

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

	<i>Note</i>	Year ended 31 December	
		2022	2021
		RMB'000	RMB'000
Revenue from out-licensing contracts	3	–	34,231
Cost of sales		–	–
Gross profit		–	34,231
Other income		18,612	29,311
Marketing costs	4	(20,326)	(14,698)
Administrative expenses	4	(132,249)	(103,255)
Research and development costs	4	(827,974)	(767,936)
Other gains/(losses) — net	5	17,408	(17,254)
Operating loss		(944,529)	(839,601)
Finance costs		(8,187)	(2,494)
Share of losses of an associate and a joint venture		(568)	–
Loss before income tax		(953,284)	(842,095)
Income tax expense	6	(1,085)	–
Loss and total comprehensive loss for the year attributable to the equity holders of the Company		<u>(954,369)</u>	<u>(842,095)</u>
Basic and diluted loss per share for loss attributable to the equity holders of the Company (in RMB)	8	<u>(2.53)</u>	<u>(2.36)</u>

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	<i>Note</i>	As at 31 December	
		2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Assets			
Non-current assets			
Property, plant and equipment		240,250	223,686
Intangible assets		235,648	235,621
Investment in an associate		17,432	–
Investment in a joint venture		513	–
Right-of-use assets		42,227	38,614
Other non-current assets		11,197	44,173
		547,267	542,094
Current assets			
Inventories	9	603,503	351,362
Other receivables, deposits and prepayments	10	23,421	117,655
Time deposits		10,223	125,071
Restricted cash		5,641	1,658
Cash and cash equivalents		865,081	930,149
		1,507,869	1,525,895
Total assets		2,055,136	2,067,989
Liabilities			
Non-current liabilities			
Borrowings		177,600	147,500
Lease liabilities		5,451	2,764
Deferred income tax liabilities		38,818	38,818
Deferred income		19,952	4,009
		241,821	193,091

		As at 31 December	
	<i>Note</i>	2022	2021
		<i>RMB'000</i>	<i>RMB'000</i>
Current liabilities			
Trade and other payables	<i>11</i>	214,534	209,863
Borrowings		98,900	7,400
Lease liabilities		4,435	2,069
Amounts due to related parties		258	408
		<u>318,127</u>	<u>219,740</u>
Total liabilities		<u>559,948</u>	<u>412,831</u>
Equity			
Equity attributable to the equity holders of the Company			
Share capital		315	273
Shares held for the Employee Incentive Scheme		(14)	(17)
Reserves		1,494,887	1,654,902
		<u>1,495,188</u>	<u>1,655,158</u>
Total equity		<u>1,495,188</u>	<u>1,655,158</u>
Total equity and liabilities		<u>2,055,136</u>	<u>2,067,989</u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENT

1 GENERAL INFORMATION

1.1 General information

Kintor Pharmaceutical Limited (the “**Company**”) was incorporated on 16 May 2018 in the Cayman Islands as an exempted company with limited liability under the Companies Law of the Cayman Islands. The address of its registered office is Cricket Square, Hutchins Drive, PO Box 2681, Grand Cayman, KY1-1111, Cayman Islands.

The Company is an investment holding company. The Company and its subsidiaries (collectively, “**the Group**”) are principally engaged in research and development of innovative medicine products.

The Company’s shares have been listed on the Main Board of The Stock Exchange of Hong Kong Limited since 22 May 2020.

The consolidated financial statements are presented in Renminbi (“**RMB**”) thousands, unless otherwise stated.

2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The principal accounting policies applied in the preparation of the consolidated financial statements are set out below. These policies have been consistently applied to both the years presented, unless otherwise stated.

2.1 Basis of preparation

The consolidated financial statements of the Group have been prepared in accordance with International Financial Reporting Standards (“**IFRSs**”) and the disclosure requirements of the Hong Kong Companies Ordinance Cap. 622. The consolidated financial statements have been prepared under the historical cost convention, as modified by the revaluation of financial assets at fair value through profit or loss (FVPL) which are carried at fair value.

The preparation of consolidated financial statements in conformity with IFRSs requires the use of certain critical accounting estimates. It also requires management to exercise judgment in the process of applying the accounting policies.

(a) Amendments to standards adopted by the Group

The following amendments to standards have been adopted by the Group for the first time for the financial year beginning on 1 January 2022:

Standards	Key requirements	Effective for accounting periods beginning on or after
Amendments to IAS 16	Property, Plant and Equipment: Proceeds before intended use	1 January 2022
Amendments to IAS 37	Onerous Contracts — Cost of Fulfilling a Contract	1 January 2022
Amendments to IFRS 3	Reference to the Conceptual Framework	1 January 2022
Amendments to IFRS 1, IFRS 9, IAS 41 and IFRS 16	2018–2020 Annual Improvement Cycle	1 January 2022

These new standards and interpretations did not have material impact on the financial performance and position of the Group and did not require retrospective adjustments.

(b) New standards and interpretations not yet adopted

The following new standards and amendments to standards have not come into effect for the financial year beginning on 1 January 2022 and have not been early adopted by the Group in preparing the consolidated financial statements. None of these is expected to have a significant effect on the consolidated financial statements of the Group:

Standards	Key requirements	Effective for accounting periods beginning on or after
IFRS 17	Insurance Contracts	1 January 2023
Amendments to IFRS 10 and IAS 28	Sale or contribution of assets between an investor and its associate or joint venture	To be determined
Amendments to IAS 1	Classification of liabilities as current or non-current	1 January 2024
Amendments to IAS 1	Non current liabilities with covenants	1 January 2024
Amendments to IAS 1 and IFRS Practice Statement 2	Disclosure of Accounting Policies	1 January 2023
Amendments to IAS 8	Definition of Accounting Estimates	1 January 2023
Amendments to IAS 12	Deferred Tax related to Assets and Liabilities arising from a Single Transaction	1 January 2023
Amendments to IFRS 16	Leases on sale and leaseback	1 January 2024

The Group has already commenced an assessment of the impact of these new or revised standards and amendments, certain of which are relevant to the Group's operations. According to the preliminary assessment made by the directors, no significant impact on the financial performance and positions of the Group is expected when they become effective.

3 SEGMENT AND REVENUE INFORMATION

(a) Description of segments and principal activities

The Group is principally engaged in the research and development of new drug. The outcome of the Group's research and development activities will be given preference to be used by the Group for its own commercialization. There is one team managing and operating all revenue streams. Accordingly, management considers there is only one segment and hence no segment information is presented.

(b) License agreement with customers

In July 2021, the Group entered into an agreement with a pharmaceutical company (customer A) for out-licensing one of its bio-pharmaceutical license to customer A for development and commercialization for a period of 10 years. The agreement includes non-refundable upfront payment, development milestone payments, commercial milestone payments and sales-based royalty upon commercialization. As at 31 December 2021, the Group has fulfilled the performance obligation at a point of time and therefore, the upfront payment of RMB30,189,000 received was recognised as revenue during the year ended 31 December 2021. During the year ended 31 December 2022, the Group did not receive any payment under the agreement.

In August 2021, the Group entered into an agreement with another pharmaceutical company (customer B) for out-licensing one of its bio-pharmaceutical license to customer B for development and commercialization. The agreement includes non-refundable upfront payment, development milestone payments and commercial milestone payments upon commercialization. As at 31 December 2021, the Group has fulfilled the performance obligation at a point of time and therefore, the upfront payment of RMB4,042,000 received was recognised as revenue during the year ended 31 December 2021. During the year ended 31 December 2022, the Group did not receive any payment under the agreement.

(c) Disaggregated revenue information is as follows:

	Year ended 31 December	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Timing of revenue recognition:		
At a point in time		
— Revenue from out-licensing contracts	<u>—</u>	<u>34,231</u>

(d) Unfulfilled long-term contracts

The out-licensing contract with customer A includes upfront fee of RMB32,000,000 (including tax), development milestone payments of RMB78,000,000 (including tax) in aggregate. The contract also includes commercial milestone payments and sales-based royalty. Upfront fee was recognised as revenue for the year ended 31 December 2021. The remaining milestones and sales-based royalty are not included in the transaction price based on the most likely amount and the application of the variable consideration constraint. As a result, as at 31 December 2021, there is no transaction price that would be allocated to unsatisfied performance obligations after considering the constraint.

The out-licensing contract with customer B includes upfront fee of USD500,000 (approximately RMB3,188,000, exclusive of all applicable tax), development milestone payments of USD1,000,000 (approximately RMB6,376,000, exclusive of all applicable tax) in aggregate. The contract also includes commercial milestone payments. Upfront fee was recognised as revenue for the year ended 31 December 2021. The remaining milestone payments are not included in the transaction price based on the most likely amount and the application of the variable consideration constraint. As a result, as at 31 December 2021, there is no transaction price that would be allocated to unsatisfied performance obligations after considering the constraint.

(e) Geographical information

Geographical information of revenue by location of customers for the years ended 31 December 2022 and 2021 is as follows:

	Year ended 31 December	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
China	–	30,189
Others	–	4,042
	–	34,231
	<u>–</u>	<u>34,231</u>

(f) Information about major customers

The major customers which contributed more than 10% of the total revenue of the Group for the years ended 31 December 2022 and 2021 are listed as below:

	Year ended 31 December	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Customer A	–	30,189
Customer B	–	4,042
	–	34,231
	<u>–</u>	<u>34,231</u>

4 EXPENSES BY NATURE

	Year ended 31 December	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Clinical research expenses	410,028	448,870
Employee benefit expenses	252,225	159,748
Materials and consumables used	113,102	147,916
Write-down of inventories to net realisable value	92,986	–
Outsourced research and development costs	35,787	59,419
Utilities and office expenses	33,251	35,856
Professional fees	9,232	9,200
Depreciation of property, plant and equipment	12,678	6,729
Depreciation of right-of-use assets	5,604	3,837
Less: amounts capitalised in property, plant and equipment	(45)	(199)
	5,559	3,638
Auditors' remuneration	3,400	3,356
Rental expenses	1,217	1,365
Bank charges	421	190
Amortisation of intangible assets	151	143
Others	10,512	9,459
	<u>980,549</u>	<u>885,889</u>

5 OTHER GAINS/(LOSSES) — NET

	Year ended 31 December	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Gains on disposal of financial assets at fair value through profit or loss	2,004	777
Net foreign exchange gains/(losses)	16,329	(17,625)
Losses on disposal of property, plant and equipment	(620)	(106)
Others	(305)	(300)
	<u>17,408</u>	<u>(17,254)</u>

6 INCOME TAX EXPENSE

	Year ended 31 December	
	2022	2021
	RMB'000	RMB'000
Current income tax expense		
— Current tax on profits for the year	1,077	—
— Underprovision in prior year	8	—
Deferred income tax expense	—	—
	<u>1,085</u>	<u>—</u>

(i) Income tax expense

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

Under the current laws of the Cayman Islands, the Company is not subject to tax on income or capital gains.

Hong Kong

Kintor Science Limited, Koshine Pharmaceuticals Limited and Kintor Pharmaceuticals Hong Kong Limited were incorporated in Hong Kong in 2018 and are subject to Hong Kong profits tax at the rate of 16.5% (2021: 16.5%). Since these companies did not have assessable profits during the years ended 31 December 2022 and 2021, no Hong Kong profits tax has been provided.

United States of America

Kintor Pharmaceuticals Inc. was incorporated in the United States of America and is subject to federal and state income tax rate of 23.5% (2021: 23.5%).

Ireland

Kintor Pharmaceutical Ireland Limited was incorporated in the Ireland in 2021 and is subject to corporate income tax rate of 12.5% (2021: 12.5%). Since Kintor Pharmaceutical Ireland Limited did not have assessable profit during the year ended 31 December 2022 and 2021, no corporate income tax has been provided.

The Mainland of China

Pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the “**CIT Law**”), the subsidiaries which operate in the Mainland of China are subject to CIT at a rate of 25% (2021: 25%) on the taxable income.

7 DIVIDEND

No dividend has been paid or declared by the Company during the years ended 31 December 2022 and 2021.

8 LOSS PER SHARE

Basic loss per share

Basic loss per share is calculated by dividing the loss attributable to owners of the Company by the weighted average number of ordinary shares outstanding during the year ended 31 December 2022 and 2021 excluding 20,119,665 shares (2021: 23,613,590 shares) held for the employee incentive scheme (including 18,107,699 shares (2021: 21,252,231 shares) arising from the relevant capitalisation issue of initial public offering).

	Year ended 31 December	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Loss for the year	(954,369)	(842,095)
Weighted average number of ordinary shares in issue (in thousand)	<u>376,566</u>	<u>356,393</u>
Basic loss per share (in RMB)	<u><u>(2.53)</u></u>	<u><u>(2.36)</u></u>

Diluted loss per share

Diluted loss per share is same as basic loss per share as there is no dilutive potential ordinary shares during the years ended 31 December 2022 and 2021.

9 INVENTORIES

	As at 31 December	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Raw materials	603,503	346,285
Work in progress	<u>–</u>	<u>5,077</u>
	<u><u>603,503</u></u>	<u><u>351,362</u></u>

Write-downs of inventories to net realisable value amounted to 92,986,000 (2021: nil). These were recognised as an expense during the year ended 31 December 2022 and included in ‘Research and development costs’ in the consolidated statement of comprehensive income.

10 OTHER RECEIVABLES, DEPOSITS AND PREPAYMENTS

	As at 31 December	
	2022	2021
	RMB'000	RMB'000
Prepayments to suppliers	19,814	115,026
Deposits	1,652	1,509
Advances to employees	24	428
Others	1,931	692
	<u>23,421</u>	<u>117,655</u>

As at 31 December 2022 and 2021, the carrying amounts of other receivables and deposits were denominated in RMB and approximated their fair values.

11 TRADE AND OTHER PAYABLES

	As at 31 December	
	2022	2021
	RMB'000	RMB'000
Payables for materials and consumables (<i>Note (a)</i>)	101,948	128,256
Payables for service suppliers (<i>Note (a)</i>)	78,453	44,700
Salary and staff welfare payables	16,131	21,905
Payables for property, plant and equipment	4,810	7,223
Payables for audit services	3,400	3,000
Payables for individual income tax and other taxes	1,899	2,097
Payables for interest expenses	361	213
Others	7,532	2,469
	<u>214,534</u>	<u>209,863</u>

As at 31 December 2022 and 2021, all trade and other payables of the Group were non-interest bearing, and their fair value approximated their carrying amounts due to their short maturities.

- (a) As at 31 December 2022 and 2021, the ageing analysis of payables for materials and consumables and payables for service suppliers based on invoice date are as follows:

	As at 31 December	
	2022	2021
	RMB'000	RMB'000
— Within 1 year	<u>180,401</u>	<u>172,956</u>

FUTURE AND OUTLOOK

Our vision focuses on developing potential “best-in-class” and “first-in-class” novel drugs and commercialisation platform in order to address the unmet medical needs for dermatology indications such as AGA and acne vulgaris; and to explore innovative treatment for non-dermatology indications such as COVID-19, prostate cancer, idiopathic pulmonary fibrosis (IPF). We also plan to develop biological drugs for the treatment of liver cancer and various solid tumours in order to expand the variety of treatment in the biologics field.

Based on our R&D experience on AR, we have created an advantageous position and laid a solid foundation in the field of dermatological drugs. By leveraging our strength on R&D regarding AR, we will continue our clinical development of KX-826 for the treatment of AGA and acne vulgaris in China and the United States. The previous results have showed that KX-826 demonstrated safety and efficacy, and it could be used on both men and women in the treatment of AGA and acne vulgaris. In addition, we plan to further leverage our PROTAC platform to develop small molecule drugs. We will be in the process of launching phase II clinical trial of GT20029 in China, which is the first topical PROTAC compound that has entered clinical stage around the world. The previously announced data from phase I clinical trials in China and the United States showed that GT20029 demonstrated good safety, tolerability and pharmacokinetic characteristics. KX-826 and GT20029 are targeting for China and the global markets, and they are expected to address the inelastic demand of the AGA and acne vulgaris patients.

In order to support our continuous growth, we plan to continue our investment in R&D infrastructure and talent to advance the clinical development of our clinical-stage drug candidates as well as the pre-clinical development of our existing and future drug candidates. We also plan to seek collaboration opportunities in various aspects of our drug development process, including pre-clinical technology, clinical combination therapies and commercialisation.

COMPLIANCE WITH THE CG CODE

The Company has applied the principles and code provisions as set out in the CG Code. During the year ended 31 December 2022, the Board is of the opinion that the Company has complied with all the code provisions under the CG Code apart from the deviation stated below.

Under code provision C.2.1 of the CG Code, the responsibilities between the chairman and chief executive officer should be separate and should not be performed by the same individual. We do not have a separate chairman and chief executive officer and Dr. TONG currently performs these two roles. The Board believes that vesting the roles of both chairman and chief executive officer in Dr. TONG has the benefit of ensuring consistent leadership within our Group and enables more effective and efficient overall strategic planning for our Group, given that: (i) decision to be made by our Board requires approval by at least a majority of our Directors and that our Board comprises three independent non-executive Directors out of eight Directors, and we believe there is sufficient check and balance in our Board; (ii) Dr. TONG and other Directors are aware of and undertake to fulfill their fiduciary duties as Directors, which require, among other things, that they act for the benefit and in the best interests of our Company and will make decisions for our Group accordingly; and (iii) the balance of power and authority is ensured by the operations of our Board which comprises experienced and high caliber individuals who meet regularly to discuss issues affecting the operations of our Company. Moreover, the overall strategic and other key business, financial and operational policies of our Group are made collectively after thorough discussion at both our Board and senior management levels. Finally, our 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 our Group and enables more effective and efficient overall strategic planning for and communication within our Group. Our Board will continue to review the effectiveness of the corporate governance structure of our Group in order to assess whether separation of the roles of chairman and chief executive officer is necessary.

COMPLIANCE WITH MODEL CODE FOR SECURITIES TRANSACTIONS BY DIRECTORS OF LISTED ISSUERS

The Group has adopted the Model Code for securities transactions by Directors as its own code of conduct.

Specific enquiries have been made of all the Directors and they have confirmed that they have complied with the Model Code throughout the Reporting Period.

The Group's employees, who are likely to be in possession of inside information of the Group, are subject to the Model Code. No incident of non-compliance of the Model Code by the relevant employees was noted by the Company throughout the Reporting Period.

USE OF PROCEEDS

Global Offering

With the Shares listed on the Stock Exchange on 22 May 2020, the net proceeds from the Global Offering were approximately HK\$1,717.3 million (the “**IPO proceeds**”). As at 31 December 2022, the IPO proceeds have been fully utilised following the proposed use of proceeds as set out in the Prospectus.

As at 31 December 2022, details of the application of net proceeds are set out as follows:

	Approximate % of total net proceeds %	Planned use of actual net proceeds HKD'million	Utilised net proceeds up to 31 December 2022 HKD'million
Development and commercialisation of Prixelutamide	42.0	721.3	721.3
Development and commercialisation of Ppyrilutamide	28.0	480.8	480.8
Our ongoing and planned clinical trials for our other clinical-stage drug candidates	14.0	240.4	240.4
The R&D of pre-clinical stage drug candidates	6.0	103.1	103.1
Working capital and general corporate purposes	10.0	171.7	171.7
Total	100.0	1,717.3	1,717.3

Top-up Placing 2021

Completion of the subscription under the Top-up Placing 2021 took place on 2 June 2021. The Top-up Placing 2021 was for the purposes of supplementing the Group's long-term funding of its expansion plan and growth strategies, and to raise further capital for the Company whilst broadening the shareholder base and the capital base of the Company. The net proceeds received by the Company are approximately HK\$1.16 billion, net of professional fees and out-of-pocket expenses. As at 31 December 2022, the Company has used all of the net proceeds for development and commercialisation of Prixelutamide and working capital for general corporate purpose.

The following table sets out a breakdown of the use of net proceeds as at 31 December 2022:

	Approximate % of total net proceeds %	Planned use of actual net proceeds HKD'million	Utilised net proceeds up to 31 December 2022 HKD'million
Phase III multi-regional clinical trials (MRCT) of Prixelutamide in the U.S., Brazil, China and a few other countries	60	696.0	696.0
Procurement of study material and active pharmaceutical ingredient (API) in preparation for the commercialisation of Prixelutamide	33	382.8	382.8
Working capital for general corporate purpose	7	81.2	81.2
	-----	-----	-----
Total	<u>100</u>	<u>1,160</u>	<u>1,160</u>

During the Reporting Period, the Group had followed the proposed use of proceeds as set out in the announcement of the Company dated 26 May 2021.

Top-up Placing in 2022

During the Reporting Period, Top-up Placing 2022-I and Top-up Placing 2022-II were conducted by the Company for the purpose of supplementing the Group's long-term funding of its expansion plan and growth strategies, as well as providing an opportunity to raise further capital for the Company whilst broadening the shareholder base and the capital base of the Company.

Top-up Placing 2022-I

The completion of the subscription under the Top-up Placing 2022-I took place on 7 September 2022. The proceeds received by the Company was approximately HK\$273.0 million, net of professional fees and out-of-pocket expenses.

The following table sets out a breakdown of the use of net proceeds as at 31 December 2022:

	Approximate % of total net proceeds %	Planned use of actual net proceeds HKD'million	Utilised net proceeds up to 31 December 2022 HKD'million	Proceeds unused HKD'million	Expected timeline for utilizing the remaining balance of net proceeds from the Top-up Placing
Clinical development and preparation for the commercialisation of Prixelutamide	75	204.8	204.8	-	-
Clinical development of Ppyrilutamide	25	68.3	36.0	32.3	Expected to be fully utilised by December 2023
Total	100	273.0	240.8	32.3	

Top-up Placing 2022-II

Completion of the subscription under the Top-up Placing 2022-II took place on 16 December 2022. The proceeds received by the Company was approximately HK\$509.1 million, net of professional fees and out-of-pocket expenses (the “**Net Proceeds**”).

As disclosed in the Company’s announcement dated 28 March 2023, the Company received the Net Proceeds on 16 December 2022, and the Net Proceeds remained unutilised (the “**Unutilised Proceeds**”) as at 31 December 2022 due to the short time interval.

In light of the alleviation of the COVID-19 pandemic and fierce competition in the COVID-19 oral small molecule drug market, the Board has resolved to reallocate the use of the Unutilised Proceeds to optimise the utilisation of the Unutilised Proceeds and generate better investment returns in the long run. Details of the original allocation and utilisation of the revised allocation of Unutilised Proceeds are set out below.

	Original use of Unutilised Proceeds		Revised allocation of Unutilised Proceeds		Expected timeline for utilising the Unutilised Proceeds
	%	HK\$' million	%	HK\$' million	HK\$' million
Clinical development and preparation for the commercialisation of prixelutamide for the treatment of COVID-19	70	356.4	15	76.4	Expected to be fully utilised by December 2023
Clinical development of pyrilutamide for the treatment of AGA and acne vulgaris	25	127.3	49	249.5	Expected to be fully utilised by June 2024
Clinical development of GT20029 for the treatment of AGA and acne vulgaris	5	25.4	27	137.5	Expected to be fully utilised by June 2024
General working capital	–	–	9	45.8	Expected to be fully utilised by June 2024
Total	100	509.1	100	509.1	

For further information on the change in allocation of the Unutilised Proceeds, please refer to the announcement of the Company dated 28 March 2023.

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

During the financial year ended 31 December 2022, neither the Company nor any of its subsidiaries has purchased, sold or redeemed any of the Company's listed securities.

CHARGE ON GROUP'S ASSETS

As at 31 December 2022, certain land use right, buildings and construction in progress were pledged for the Group's borrowings amounting to RMB91,500,000 (31 December 2021: RMB96,500,000).

SUBSEQUENT EVENTS

On 28 March 2023, we announced that the analysis results of the multi-centre, randomised, double-blind, placebo-controlled phase III clinical trial of Prixelutamide for the treatment of mCRPC in China showed that it failed to reach statistical significance differences at the overall survival time primary endpoint, but some sub-groups observed positive effects of Prixelutamide and showed good safety and tolerability. For further details, please refer to the Company's announcement dated 28 March 2023.

Save as disclosed above, there are no important events affecting the Group which have occurred since the end of the Reporting Period.

AUDIT COMMITTEE

The Audit Committee comprises two independent non-executive Directors, namely, Mr. Wallace Wai Yim YEUNG and Dr. Michael Min XU and one non-executive Director, namely, Mr. Chengwei LIU. The chairman of the Audit Committee is Mr. Wallace Wai Yim YEUNG. The Audit Committee has reviewed the audited consolidated financial statements of the Group for the year ended 31 December 2022. The Audit Committee has also discussed with the management and the independent auditors of the Company the accounting principles and policies adopted by the Company and discussed internal control and financial reporting matters (including the review of annual results for the year ended 31 December 2022) of the Group. The Audit Committee considered that the annual results are in compliance with the applicable accounting standards, laws and regulations, and the Company has made appropriate disclosures thereof.

SCOPE OF WORK OF AUDITOR

The figures in respect of the Group's consolidated statement of comprehensive income and consolidated statement of financial position and the related notes thereto for the year ended 31 December 2022 as set out in this announcement have been agreed by the Group's auditor, PricewaterhouseCoopers, to the amounts set out in the Group's audited consolidated financial statements for the year. The work performed by PricewaterhouseCoopers in this respect did not constitute an assurance engagement in accordance with Hong Kong Standards on Auditing, Hong Kong Standards on Review Engagements or Hong Kong Standards on Assurance Engagements issued by the Hong Kong Institute of Certified Public Accountants and consequently no assurance has been expressed by PricewaterhouseCoopers on this announcement.

FINAL DIVIDEND

The Board does not recommend any payment of final dividend for the year ended 31 December 2022 (2021 : Nil).

PUBLICATION OF THE ANNUAL RESULTS AND ANNUAL REPORT

This results announcement is published on the website of the Stock Exchange (www.hkexnews.hk) and the Company's website (www.kintor.com.cn). The annual report for the year ended 31 December 2022 containing all the information in accordance with the requirements under the Listing Rules will be despatched to the Shareholders and published on the respective websites of the Stock Exchange and the Company in April 2023.

PROPOSED AMENDMENTS TO THE MEMORANDUM AND ARTICLES OF ASSOCIATION

The Board further proposes to amend the existing amended and restated memorandum and articles of association of the Company (the “**Existing Memorandum and Articles of Association**”), among others, (i) to conform to the amended Appendix 3 to the Listing Rules which took effect on 1 January 2022 and applicable laws of the Cayman Islands; (ii) to reflect the proposed Increase in Authorised Share Capital (as defined below); and (iii) to make other house-keeping amendments for the purpose of clarifying existing practices and making consequential amendments in line with the proposed amendments (collectively, the “**Amendments**”). The Board proposes that the Company adopts a new set of amended and restated memorandum and articles of association (the “**Second Amended Memorandum and Amended Articles of Association**”) in substitution for, and to the exclusion of, the Existing Memorandum and Articles of Association.

The proposed adoption of the Second Amended Memorandum and Articles of Association is subject to the approval of the Shareholders by way of a special resolution at the forthcoming annual general meeting of the Company to be held in due course (the “AGM”) and shall take effect on the date the relevant special resolution is approved at the AGM.

PROPOSED INCREASE IN AUTHORISED SHARE CAPITAL

The Board proposes to increase the authorised share capital of the Company.

The existing authorised share capital of the Company is USD50,000 divided into 500,000,000 ordinary shares of nominal value of USD0.0001 each, of which 447,499,600 Shares are in issue.

In order to provide the Company with sufficient share capital to support the Company’s business development whereby promoting future business growth, the Board proposes to increase the authorised share capital of the Company to USD70,000 divided into 700,000,000 Shares by the creation of additional 200,000,000 new Shares (the “**Increase in Authorised Share Capital**”). Such new Shares, upon issue, shall rank *pari passu* in all respects with the existing Shares.

The proposed Increase in Authorised Share Capital is subject to the approval of the Shareholders by way of passing an ordinary resolution at the AGM.

A circular containing, among other things, details of the proposed Amendments and Increase in Authorised Share Capital, and a notice of the AGM will be despatched to the Shareholders in due course.

APPRECIATION

The Board would like to express its sincere gratitude to the Shareholders, management team, employees, business partners and customers of the Group for their continuous support and contribution to the Group.

DEFINITIONS

In this announcement, unless the context otherwise require, the following expressions shall have the following meaning:

“Abiraterone”	a synthetic, steroidal CYP17A1 inhibitor and the active metabolite of abiraterone acetate, an ester and prodrug of abiraterone that is used in the treatment of prostate cancer
“ACE2”	angiotensin converting enzyme-2, a protein on the surface of many cell types, which has been identified as the receptor for the SARS-CoV-2 viral entry
“AGA”	androgenetic alopecia
“ALK-1”	activin receptor-like kinase-1, an antagonistic mediator of lateral transforming growth factor-beta/ALK-5 signaling, also known as GT90001
“ALK-5”	the transforming growth factor-beta type I receptor kinase, an attractive target for intervention in transforming growth factor-beta signaling due to its druggability as well as its centrality and specificity in the pathway
“API”	Active Pharmaceutical Ingredient
“AR”	androgen receptor
“AR+”	androgen receptro positive
“Audit Committee”	the audit committee of the Board
“Board” or “Board of Directors”	the board of directors of the Company
“c-Myc”	MYC proto-oncogene, bHLH transcription factor, a protein that codes for transcription factors

“CG Code”	the Corporate Governance Code as set out in Appendix 14 to the Listing Rules
“China” or “PRC”	The People’s Republic of China, for the purpose of this announcement only, excluding Hong Kong, Macao and Taiwan
“CMO(s)”	a company that offers manufacturing services, with volume capabilities ranging from small amounts for preclinical R&D to larger volumes necessary for clinical trials purposes and commercialisation
“Company”	Kintor Pharmaceutical Limited, formerly known as KTKM Holdings Inc., an exempted company with limited liability incorporated in the Cayman Islands on 16 May 2018 whose Shares are listed on the Main Board of the Stock Exchange with stock code 9939
“Core Products”	has the meaning ascribed to it in Chapter 18A of the Listing Rules; for purposes of this announcement, our Core Products consist of Ppyrilutamide (KX-826), AR-PROTAC Compound (GT20029), Pruxelutamide (GT0918)
“COVID-19”	coronavirus disease 2019
“CRO(s)”	contract research organisation(s), a company hired by another company or research centre to take over certain parts of running a clinical trial. The company may design, manage, and monitor the trial, and analyse the results
“CTLA-4”	a protein receptor that functions as an immune checkpoint and downregulates immune responses
“Detorsertib” or “GT0486”	an inhibitor of the PI3K/mTOR signaling pathway and a second generation mTOR inhibitor under development by our Group primarily for the treatment of metastatic solid tumours such as breast cancer, prostate cancer and liver cancer

“Director(s)”	director(s) of the Company
“Dr. TONG”	Dr. Youzhi TONG, one of the co-founders, as executive Director, chairman and chief executive officer of the Company
“Employee Incentive Scheme”	the employee incentive scheme of our Company approved and adopted by our Board on 31 March 2020
“EUA”	emergency use authorization
“Global Offering”	has the meaning ascribed to it under the Prospectus
“Group”	the Company and its subsidiaries (or our Company and any one or more of its subsidiaries, as the context may require)
“hedgehog”	one of the anticancer targets, when hedgehog is not turned off during adulthood, it promotes the growth of cancer cells
“HCC”	hepatocellular carcinoma, a common type of liver cancer
“HKD” or “HK\$”	Hong Kong dollar, the lawful currency of Hong Kong
“Hong Kong” or “HK”	the Hong Kong Special Administrative Region of the PRC
“IFRS”	International Financial Reporting Standards as issued by the International Accounting Standards Board
“IND”	investigational new drug
“IPF”	idiopathic pulmonary fibrosis
“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, as amended or supplemented from time to time

“mCRPC”	metastatic castration-resistant prostate cancer
“Model Code”	the Model Code for Securities Transactions by Directors of Listed issuers as set out in Appendix 10 to the Listing Rules
“MRCT”	multi-regional clinical trial
“mTOR”	mammalian target of rapamycin, a critical effector in cell-signaling pathways commonly deregulated in human cancers
“NDA”	new drug application
“Nivolumab”	a human immunoglobulin G4 (IgG4) monoclonal antibody, which targets the negative immunoregulatory human cell surface receptor programmed death-1 (PD1, PCD-1,) with immune checkpoint inhibitory and antineoplastic activities
“NMPA”	the National Medical Products Administration of the PRC (國家藥品監督管理局), successor to the China Food and Drug Administration according to the Institutional Reform Plan of the State Council
“PD”	Pharmacodynamics
“PD-1” or “PCD-1”	programmed cell death protein 1, a protein in humans is encoded by the programmed cell death 1 (PDCD1) gene
“PD-L1”	programmed cell death-ligand 1, part of an immune checkpoint system that is essential for preventing autoimmunity and cancer
“Pfizer”	Pfizer, Inc., a corporation organised and existing under the laws of the State of Delaware, U.S., and a research-based global biopharmaceutical company

“PI3K”	the acronym of Phosphoinositide 3-kinase, a family of enzymes involved in cellular functions such as cell growth, proliferation, differentiation, motility, survival, and intracellular trafficking, which in turn are involved in cancer
“PK”	Pharmacokinetics
“Prospectus”	the prospectus of the Company dated 12 May 2020
“PROTAC”	proteolysis targeting chimera, a small molecule composed of (i) a recruiting element for a protein of interest; (ii) an E3 ubiquitin ligase recruiting element; and (iii) a linker bounding (i) and (ii)
“Prixelutamide” or “GT0918”	formerly known as “Proxalutamide”, a small molecule second generation AR antagonist under development by our Group for the treatment of mCRPC and AR+ metastatic breast cancer
“Pyrilutamide” or “KX-826”	an AR antagonist under development by our Group as a topical drug for the treatment of AGA and acne vulgaris
“R&D”	research and development
“Reporting Period”	the year ended 31 December 2022
“Restricted Share(s)”	share(s) granted to a participant under the Employee Incentive Scheme that are subject to such vesting and transfer requirements as the Board shall determine, and such other conditions as set forth in the rules of the Employee Incentive Scheme
“RMB”	Renminbi yuan, the lawful currency of the PRC
“RSU”	a restricted share unit award granted to a participant under the Employee Incentive Scheme that is subject to such terms and conditions as set forth in the rules of the Employee Incentive Scheme, and each restricted share unit represents one underlying Share
“SARS-CoV-2”	severe acute respiratory syndrome coronavirus 2

“Share(s)”	ordinary share(s) in the share capital of the Company, currently of nominal value USD0.0001 each
“Shareholder(s)”	holder(s) of the Shares
“SMO”	smoothed, a Class Frizzled G protein-coupled receptor that is a component of the hedgehog signaling pathway
“Stock Exchange”	The Stock Exchange of Hong Kong Limited
“TGF- β ”	a regulatory cytokine that has multifunctional properties that can enhance or inhibit many cellular functions, including interfering with the production of other cytokines and enhancing collagen deposition
“TAHC”	target area hair counts
“Top-up Placing 2021”	the top-up placing conducted by the Company pursuant to a placing agreement and a subscription agreement, both dated 26 May 2021. Please refer to the announcement of the Company dated 26 May 2021 for further information
“Top-up Placing 2022-I”	the top-up placing conducted by the Company pursuant to a placing and subscription agreement dated 31 August 2022. Please refer to the announcement of the Company dated 31 August 2022 for further information
“Top-up Placing 2022-II”	the top-up placing conducted by the Company pursuant to a placing and subscription agreement dated 9 December 2022. Please refer to the announcement of the Company dated 11 December 2022 for further information
“U.S.” or “US” or “United States”	the United States of America
“USD”	U.S. dollars, the lawful currency of the U.S.
“U.S. FDA”	Food and Drug Administration of the U.S.

“VEGF” vasoactive endothelial growth factor, a potent angiogenic factor and was first described as an essential growth factor for vascular endothelial cells

“we”, “us” or “our” the Company and, unless the context indicates otherwise, its subsidiaries

By order of the Board
KINTOR PHARMACEUTICAL LIMITED
Dr. Youzhi Tong
Chairman, Executive Director and Chief Executive Officer

Hong Kong, 30 March 2023

As at the date of this announcement, the executive Directors are Dr. Youzhi Tong and Ms. Yan Lu; the non-executive Directors are Mr. Weipeng Gao, Ms. Geqi Wei and Mr. Chengwei Liu; and the independent non-executive Directors are Dr. Michael Min Xu, Mr. Wallace Wai Yim Yeung and Prof. Liang Tong.

* *For identification purpose only*