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開拓藥業有限公司*

KINTOR PHARMACEUTICAL LIMITED

(Incorporated in the Cayman Islands with limited liability)

(Stock code: 9939)

ANNUAL RESULTS ANNOUNCEMENT FOR THE YEAR ENDED 31 DECEMBER 2021

The Board of Directors of the Company is pleased to announce the consolidated annual results of the Group for the year ended 31 December 2021, together with comparative figures for the year ended 31 December 2020.

FINANCIAL HIGHLIGHTS

The Group recorded revenue from out-licensing contracts of RMB34.2 million for the Reporting Period, which was generated from the receipt of the upfront payments in connection with the out-licensing of Proxalutamide.

The Group's research and development costs increased from RMB328.8 million for the year ended 31 December 2020 to RMB767.9 million for the year ended 31 December 2021, representing an increase of 133.5%, primarily due to the three MRCTs of Proxalutamide (GT0918) for the indication of COVID-19 which were initiated and conducted by the Group during the Reporting Period.

The Group had cash and cash equivalents and time deposits of RMB1,055.2 million as at 31 December 2021, including utilised bank facilities of RMB154.9 million. In addition, the Group also had unutilised bank facilities of RMB150 million as at 31 December 2021. 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	
	2021	2020
	RMB'000	RMB'000
Revenue from out-licensing contracts	34,231	–
Cost of sales	<u>–</u>	<u>–</u>
Gross profit	34,231	–
Other income	29,311	25,134
Marketing costs	(14,698)	(8,628)
Administrative expenses	(103,255)	(77,063)
Research and development costs	(767,936)	(328,764)
Other losses – net	(17,254)	(115,530)
Operating loss	(839,601)	(504,851)
Finance costs – net	(2,494)	(3,377)
Loss before income tax	(842,095)	(508,228)
Income tax expense	<u>–</u>	<u>(73)</u>
Loss and total comprehensive loss for the year	<u>(842,095)</u>	<u>(508,301)</u>
Added:		
Listing expenses (one-time)	–	20,761
Share-based compensation expenses	37,347	28,159
Adjusted loss and total comprehensive loss for the year	<u>(804,748)</u>	<u>(459,381)</u>
	As of 31 December	
	2021	2020
	RMB'000	RMB'000
Non-current assets	542,094	430,859
Current assets	1,525,895	1,420,616
Cash and cash equivalents and time deposits	1,055,220	1,388,995
Non-current liabilities	193,091	174,208
Current liabilities	219,740	169,333
Total equity	<u>1,655,158</u>	<u>1,507,934</u>

BUSINESS HIGHLIGHTS

In 2021, the COVID-19 pandemic continued to be a threat to the global health. We continued to take active actions to minimise the negative impact of COVID-19 to our business and ensured our research and development plans were carried out as normal. We continued to actively explore Proxalutamide as an effective drug for the treatment of COVID-19 patients with mild to moderate symptoms as well as hospitalised patients. We are actively advancing the self-sponsored studies in the U.S., China and other countries and we have received positive data from the investigator-initiated trials (IIT) of Proxalutamide for the treatment of COVID-19 in Brazil.

Since 1 January 2021, we have been making significant progress with respect to our drug pipeline and business operations, including the following milestones and achievements:

Proxalutamide (GT0918)

Milestones and achievements on self-sponsored studies:

- On 5 March 2021, we announced that we received the approval from the Food and Drug Administration of the U.S. (FDA) for the application of Proxalutamide for the phase III clinical trial in the treatment of male COVID-19 patients with mild or moderate symptoms (NCT04870606).
- On 25 April 2021, we completed the first batch of patients' enrollment and dosing in the U.S. in the phase III clinical trial of Proxalutamide for the treatment of male patients with mild or moderate COVID-19 symptoms (NCT04870606).
- On 18 May 2021, we announced that FDA has greenlighted the phase III clinical trial (NCT05009732) of Proxalutamide for the treatment of hospitalised COVID-19 patients to be conducted, which will recruit both male and female patients. In addition, FDA has agreed to add female patients into phase III clinical trial for treatment of COVID-19 patients with mild or moderate symptoms (NCT04870606).
- On 15 June 2021, we announced that the pivotal study of Proxalutamide for the treatment of COVID-19 outpatients sponsored by the Company (NCT04869228) was approved by the Brazilian Health Regulatory Agency (ANVISA) and the Brazilian National Research and Ethics Committee (CONEP) in Brazil.

- On 14 July 2021, we entered into a licensing agreement with Shanghai Fosun Pharmaceutical Development Ltd. (“**Fosun Pharmaceutical**”) on the commercialisation of Proxalutamide for the treatment of COVID-19 indication in India and 28 African countries (the “**Collaboration Regions**”) and the parties agreed to collaborate on the EUA applications, promotion, and sales of Proxalutamide for the treatment of COVID-19 indication. Pursuant to the agreement, Fosun Pharmaceutical will be granted exclusive rights of registration and commercialisation of Proxalutamide in the Collaboration Regions. The Company will be eligible to receive upfront and milestone payments up to RMB560 million as well as royalty payments that are not less than 50% of the total operating profit in the Collaboration Regions, based on a tiered structure per the amount of net sales as agreed by both parties.
- On 16 July 2021, we announced that the Ministry of Public Health and Social Welfare (MSPBS) of Paraguay recently granted EUA for Proxalutamide for the treatment of hospitalised patients with COVID-19 at the MSPBS hospitals. This was the first EUA we obtained for Proxalutamide globally.
- On 25 August 2021, we entered into a licensing agreement with PT Etana Biotechnologies Indonesia (“**Etana**”), to commercialise Proxalutamide for the treatment of COVID-19 in Indonesia. Pursuant to the agreement, the Company will receive from Etana upfront and milestone payments, in addition to the economic benefit relating to the sales from the launch of Proxalutamide in Indonesia, which is in line with the industry practice.
- On 1 September 2021, we announced that we received the approval from NMPA for two phase III clinical trials of Proxalutamide for the treatment of COVID-19 infections in China. One trial (NCT04869228) will be conducted for the treatment of mild or moderate COVID-19 patients in countries and regions including China, Brazil, Malaysia and the Philippines, while the other trial (NCT05009732) will be conducted for the treatment of hospitalised COVID-19 patients in countries and regions including the U.S., China, South America, Europe and India.
- On 22 September 2021, the phase III clinical trial of Proxalutamide for the treatment of hospitalised COVID-19 patients was conditionally approved by ANVISA, Brazil.
- On 4 October 2021, we announced that the first patient was enrolled and dosed in the phase III clinical trial of Proxalutamide for the treatment of hospitalised COVID-19 patients in the U.S.
- On 27 December 2021, we announced the interim analysis for the phase III study of Proxalutamide for patients with mild to moderate COVID-19 symptoms (NCT04870606). Statistical criteria were not met at the interim analysis of the phase III study. Notwithstanding that, there were no safety concerns and no drug-related serious adverse events (SAEs) reported during the study.
- On 10 February 2022, the first patient was enrolled and dosed in the multi-regional phase III clinical trial of Proxalutamide for the treatment of COVID-19 outpatients (NCT04869228) in China.

Milestones and achievements on IITs:

- On 10 January 2021, we released the final results for male patients with mild to moderate symptoms from the clinical trial of Proxalutamide for the treatment of COVID-19 outpatients (NCT04446429), which showed that Proxalutamide could significantly inhibit the transition of condition of male patients infected with COVID-19 from mild or moderate to severe and had good safety for short-term administration (15 days).
- On 10 January 2021, the Company released the interim results for female patients with mild to moderate symptoms from the clinical trial in Brazil of Proxalutamide for the treatment of COVID-19 outpatients as of 7 January 2021, which showed that Proxalutamide could significantly inhibit the transition of condition of female patients infected with COVID-19 from mild or moderate to severe. The hospitalisation rate, percentage of ICU usage, mechanical ventilation usage and death in 30 days in the Proxalutamide Arm was 1.7%, 0%, 0% and 0%, respectively, compared to 17.1%, 8.6%, 5.7% and 2.9% in the Controlled Arm, reducing the risk of hospitalisation by 90%.
- On 28 January 2021, we announced that the clinical trial of Proxalutamide for the treatment of hospitalised COVID-19 patients was approved by the Institutional Review Board (IRB) of Brazil and we have received support from the Brazil government in terms of medical resources allocation. This clinical trial was accepted for accelerated review.
- On 22 February 2021, the clinical trial of Proxalutamide for the treatment of hospitalised COVID-19 patients in Brazil completed the enrollment of approximately 588 patients (actual enrollment of 590 patients).
- On 11 March 2021, we released the results of the clinical trial of Proxalutamide for the treatment of hospitalised COVID-19 patients (NCT04728802), Results of the IIT demonstrated that the trial met the primary endpoint at day 14.

Pyirilutamide (KX-826)

- On 16 April 2021, we completed the first batch of patients enrollment and dosing in China in the Phase I/II clinical trial of Pyirilutamide gel as a treatment for acne vulgaris.
- On 11 July 2021, we announced that FDA has greenlighted the phase II clinical trial of Pyirilutamide for treatment of AGA to be conducted in the U.S.
- On 8 September 2021, we announced that the primary endpoint of phase II clinical trial of Pyirilutamide in China for the treatment of AGA was met, which was statistically significant and clinically meaningful.
- On 12 November 2021, we announced that we had dosed the first patient in the phase II clinical trial of Pyirilutamide in China for the treatment of AGA female patients.

- On 24 November 2021, we announced that the IND application for the pivotal study (phase III clinical trial) of Ppyrilutamide for the treatment of AGA male patients was cleared by NMPA. Ppyrilutamide is the first topical AR antagonist which has entered phase III clinical trial for the treatment of AGA globally.
- On 31 December 2021, we enrolled and dosed the first patient in the phase III clinical trial of Ppyrilutamide for the treatment of male AGA patients in China.
- On 24 January 2022, we enrolled and dosed the first patient in the phase II clinical trial of Ppyrilutamide in China for the treatment of acne vulgaris.
- On 28 February 2022, we enrolled and dosed first patient in the phase II clinical trial of Ppyrilutamide for the treatment of male AGA patients in the U.S.
- On 4 March 2022, we completed the enrollment of 160 patients in the phase II clinical trial of Ppyrilutamide for the treatment of female AGA patients in China.

ALK-1 antibody (GT90001)

- The data collected in the phase II clinical trial of combination therapy of ALK-1 antibody and PD-1 monoclonal antibody Nivolumab (Opdivo) for the second-line therapy of advanced HCC in Taiwan was released at the 2021 American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO-GI). The results showed that among the 20 evaluable patients, eight patients (40.0%) were observed partial remission (PR).
- On February 11, 2021, IND application for a multiregional phase II clinical trial for combination treatment of ALK-1 antibody and Nivolumab for the second-line treatment of advanced HCC was cleared by FDA.
- On 9 October 2021, the clinical trial of ALK-1 antibody and Nivolumab combination therapy for the treatment of patients with advanced hepatocellular carcinoma was approved by NMPA.
- On 2 November 2021, we announced that we had enrolled and dosed the first patient with advanced or refractory solid tumors in the phase Ib/II clinical trial of ALK-1 antibody in combination with KN046 in Taiwan, China.

AR-PROTAC Compound (GT20029)

- On 1 February 2021, we announced that the IND application of GT20029, developed by our PROTAC platform, for AGA and acne vulgaris indications was accepted by the CDE. GT20029 is the first topical PROTAC drug which entered clinical stage around the world.
- On 15 April 2021, we announced that the IND of GT20029 for AGA and acne vulgaris indications were approved by the Center for Drug Evaluation (CDE) of the National Medical Products Administration of China (NMPA).

- On 13 July 2021, we announced that we received IND clearance by FDA for GT20029 for the treatment of AGA and acne vulgaris in the U.S.
- On 28 July 2021, we announced that the first batch of subjects have been enrolled and dosed in the phase I clinical trial of GT20029 for treating AGA and acne vulgaris in China.
- On 1 February 2022, the first subject was enrolled and dosed in the phase I clinical trial of GT20029 for the treatment of AGA and acne vulgaris in the U.S..

PD-L1/TGF- β (GT90008)

- On 21 October 2021, the clinical trial of PD-L1/TGF- β dual-targeting antibody (GT90008) for the treatment of advanced solid tumours was approved by NMPA.

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 focused on the unmet clinical needs. We are committed to becoming a leader in the research, development and commercialisation of innovative therapies.

Product Pipeline

Our pipeline of drug candidates includes a risk-balanced and diversified portfolio of products that strategically targets COVID-19 and major cancer types and other AR-related indications

with substantial market potential. The following chart sets forth a summary of our drug candidates as well as their respective mechanism, indications and development progress:

Products Pipeline

Drug Candidate	Target / Mechanism	Indication	Country / Region	Pre-Clinical	IND Filing (Filed)/(Accepted)	Phase I	Phase II	Phase III	NDA
Proxalutamide (GT0918)	Second generation AR antagonist	COVID-19 (Outpatients)	US & Intl		Completed patients enrollment on Dec 23, 2021				
		COVID-19 (Inpatients)	US, China & Intl		Completed FPI on Oct 1, 2021				
		COVID-19 (Outpatients)	China, Brazil & Intl		Completed FPI on Feb 10, 2022 in China				
		mCRPC	China		Expected to submit NDA in 2022				
		Combination therapy with Abiraterone for mCRPC	China		Completed patients enrollment on Feb 24, 2022				
		mCRPC	US		Expected to complete phase II in 2022				
		Metastatic breast cancer	China						
		Combination therapy with Exemestane, Letrozole and Fulvestrant for metastatic breast cancer	China		Completed patients enrollment on Aug 25, 2021				
		Androgenetic alopecia (Male)	China		Completed FPI on Dec 31, 2021				
		Androgenetic alopecia (Female)	China		Completed patients enrollment on Mar 4, 2022				
Pyrilutamide (KX-826)	AR antagonist (for external use)	Androgenetic alopecia (Male)	US		Completed FPI on Feb 28, 2022				
		Acne vulgaris	China		Completed FPI of phase II on Jan 24, 2022				
		Acne vulgaris	US						
		Combination therapy with a PD-1 for metastatic HCC (2L)	Taiwan		Interim data was released at ASCO GI in Jan 2021				
ALK-1 (GT90001)	Angiogenesis inhibitor	Combination therapy with a PD-1 for metastatic HCC (2L)	US & Intl		IND was cleared on Feb 18, 2021				
		Combination therapy with a PD-1 for metastatic HCC	China		IND was approved on Oct 11, 2021				
		Combination therapy with a PD-1 for metastatic HCC	Taiwan		Completed FPI on Nov 2, 2021				
		Combination therapy with KNO46 (PD-L1/CTLA-4) for HCC, GC, GEJ adenocarcinoma, UC, ESCC	China		First batch of subjects were dosed on Jul 28, 2021				
GT20029	AR-PROTAC compound	AGA and acne vulgaris	China		First subject was dosed on Feb 1, 2022				
		AGA and acne vulgaris	US						
GT90008	PD-L1 / TGF-β dual targeting antibody	Multiple types of solid tumours	China		IND was approved on Oct 21, 2021				
		Metastatic solid tumours	China		Completed FPI on Feb 18, 2021				
Detorsertib (GT0486)	mTOR kinase inhibitor	Blood Cancer	China						
		Basal-cell carcinoma	US						
GT11708F	Other AR-PROTAC compounds	Blood Cancer	China						
		Basal-cell carcinoma	US						
		Multiple indications							
		c-Myc inhibitor							
Pre-Clinical	ALK-1/VEGF bispecific antibody	Blood cancer							
		Solid tumours							
		Trials initiated by Kintor							

Legend: Trials initiated by Kintor (Blue bar), Trials initiated by Kintor and partners (Green bar)

Abbreviations: FPI = First patient in, HCC = hepatocellular carcinoma, GC = gastric carcinoma, GEJ = gastroesophageal junction, UC = urothelial carcinoma, ESCC = esophageal squamous cell carcinoma



BUSINESS REVIEW

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

Core Products

- ***Proxalutamide (GT0918)***

Proxalutamide (GT0918) (普克魯胺) is a second generation AR antagonist and also an ACE2 and TMPRSS2 degrader with the potential to be a best-in-class drug. We are currently developing Proxalutamide for the treatment of COVID-19, mCRPC and AR+ metastatic breast cancer.

Indication of COVID-19

Proxalutamide has a mechanism of effectively lowering the expression of the proteins ACE2 and TMPRSS2, which the SARS-CoV-2 uses to invade host cells. Thus, Proxalutamide prevents the virus from infecting normal host cells, and viral replication and reproduction, and thus can treat novel coronavirus infections effectively. In addition, Proxalutamide also promotes the clearance of pathogens and decreases inflammation by activating the Nrf2 pathway, which activates several antioxidative genes and proteins and reduces the intensity of the cytokine response, which is of clinical benefit to the most seriously ill COVID-19 patients.

So far, the in vitro studies in the P3 laboratory have demonstrated that Proxalutamide can effectively inhibit infections caused by the Alpha and Delta variants. The outcome of genome sequencing on COVID-19 inpatients in Brazil has shown that Proxalutamide has effectively treated inpatients infected by Gamma variant.

- ***Phase III Clinical Trials Sponsored by Kintor***

- (a) *The US and International Registration Phase III Clinical Trial for Outpatients (NCT04870606)*

The study is a randomised, double-blind, placebo-controlled phase III MRCT. Its primary endpoint is the percentage of hospitalisation events (including death) by Day 28 and the secondary endpoints include but not limited to proportion of mortality by Day 28, percentage of subjects achieving each clinical status on Days 7, 14 and 28, respectively, using National Institute of Allergy and Infectious Diseases (NIAID*) 8-point scoring scale.

* NIAID 8-point scoring scale: By National Institute of Allergy and Infectious Diseases, 1) Death; 2) Hospitalised, on invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO); 3) Hospitalised, on non-invasive ventilation or high flow oxygen devices; 4) Hospitalised, requiring supplemental oxygen; 5) Hospitalised, not requiring supplemental oxygen – requiring ongoing medical care (COVID-19 related or otherwise); 6) Hospitalised, not requiring supplemental oxygen – no longer requires ongoing medical care; 7) Not hospitalised, limitation on activities and/or requiring home oxygen; 8) Not hospitalised, no limitations on activities.

On 5 March 2021 and 18 May 2021, we announced that we received the greenlight from FDA for the application of Proxalutamide for phase III clinical trial in the treatment of male and female COVID-19 patients with mild or moderate symptoms respectively. On 25 April 2021, we announced that first patient enrollment and dosing was completed in the U.S.. On 19 July 2021, the study was further approved by ANVISA. As at 23 December 2021, we have completed the enrollment of 736 patients for this study. More than 95% of the enrolled patients were from the United States. On 27 December 2021, we announced the interim analysis did not meet the statistical significance, but there were no safety concerns of Proxalutamide nor drug-related serious adverse events (SAEs) reported during the study. The study is ongoing as per the original protocol, and the top-line results for the final analysis is going to release soon.

(b) *The U.S., China and International Registration Phase III Clinical Trial for Inpatients (NCT05009732)*

The study is a randomised, double-blind, placebo-controlled phase III MRCT being conducted in various countries and regions including U.S., South America, Asia (including China) and Europe.

On 18 May 2021, we announced that FDA has greenlighted the phase III clinical trial of Proxalutamide for the treatment of hospitalised COVID-19 patients to be conducted, which would recruit both male and female patients. On 1 September 2021, we announced that the clinical trial received the approval from NMPA of China. On 22 September 2021, the study was conditionally approved by ANVISA. As at the date of this announcement, the clinical trial is ongoing in United States, the Philippines and South Africa, and the patients enrollment centre in China has been launched. Subsequently, more countries and centres will participate in this global multi-centre clinical trial. The primary endpoint was the need for intensive care unit (ICU) admission or invasive mechanical ventilation/ECMO or all-cause mortality within 30 days of randomisation.

(c) *The China, Brazil and International Phase III Clinical Trial for Outpatients (NCT04869228)*

On 15 June 2021, we announced that the phase III clinical trial in the treatment of patients with mild to moderate COVID-19 symptoms had been officially approved by the Brazilian National Research and Ethics Committee (CONEP) on 27 May 2021 and by ANVISA on 11 June 2021. On 1 September 2021, we announced that we received approval from NMPA of China. The study is a randomised, double-blind, placebo-controlled, phase III MRCT to be conducted in various countries and regions, including China, Brazil, Malaysia and the Philippines. Currently, we have completed the amendment to the protocol of the trial based on certain study data of NCT04870606, with the enrollment criterion changed to include high risk population. The protocol amendment has been cleared by NMPA of China.

Please refer to the announcements of the Company dated 5 March 2021, 18 May 2021, 15 June 2021, 1 September 2021, 26 September 2021, 4 October 2021, 27 December 2021 and 11 February 2022, respectively, for further information.

- ***Commercialisation of Proxalutamide as a Treatment for COVID-19***

On 14 July 2021, Suzhou Kintor entered into a Proxalutamide licensing agreement with Fosun Pharmaceutical, a wholly-owned subsidiary of Shanghai Fosun Pharmaceutical (Group) Co., Ltd. (Stock Code (Shanghai Stock Exchange): 600196, Stock Code (the Stock Exchange): 02196) on the commercialisation of Proxalutamide for the treatment of COVID-19 in India and 28 African countries and the parties agreed to collaborate on EUA applications, promotion, and sales of Proxalutamide. Pursuant to the agreement, Fosun Pharmaceutical will be granted exclusive rights of registration and commercialisation of Proxalutamide in the Collaboration Regions. The Company will be eligible to receive upfront and milestone payments up to RMB560 million as well as royalty payments that are not less than 50% of the total operating profit in the Collaboration Regions, based on a tiered structure per the amount of net sales as agreed by both parties.

On 25 August 2021, the Company entered into a licensing agreement with Etana in relation to the commercialisation of Proxalutamide for the treatment of COVID-19 in Indonesia and the parties agreed that the Company will receive from Etana upfront and milestone payments and economic benefit relating to the sales from the launch of Proxalutamide in Indonesia.

On 16 July 2021, we announced that the Ministry of Public Health and Social Welfare (“MSPBS”) of Paraguay granted an EUA for Proxalutamide for the treatment of inpatients with COVID-19 at the MSPBS hospitals. It was the first EUA obtained for Proxalutamide globally. The first hospital to use Proxalutamide under the EUA, Hospital Barrio Obrero, part of the MSPBS network, has reported promising initial results. Among the 25 patients, the admission baseline of 18 (72%) patients scored 5 while 7 patients (28%) scored 6. Following 14 days of dosing, 22 patients showed remission and 1 patient died with a mortality rate of 4%, which was significantly lower than the average mortality rate of inpatients in Paraguay.

Please refer to the announcements of the Company dated 15 July 2021, 16 July 2021 and 25 August 2021 for further information.

Indication of mCRPC and AR+ metastatic breast cancer

Our pre-clinical and clinical research on Proxalutamide 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 commenced pre-clinical research of Proxalutamide in April 2010. We received approval from NMPA in 2015 to conduct phase I to phase III clinical trials for Proxalutamide for mCRPC in China, and Proxalutamide was classified as a key designated project and a key category of drug subject to a special accelerated review process by the CDE. We completed phase I and phase II clinical trials for Proxalutamide for mCRPC in China in 2016 and 2017, respectively. We commenced phase III clinical trials of Proxalutamide for mCRPC in China in May 2018. As of 4 August 2020, the

Group completed patients enrollment under the final trial protocol for Proxalutamide's phase III clinical trial for mCRPC in China and plan to submit the NDA to NMPA for Proxalutamide in 2022 based on the final analysis of primary endpoint of overall survival (OS).

We received approval from the CDE in 2018 to conduct phase III clinical trial for Proxalutamide in combination therapy with Abiraterone for mCRPC as a first-line combination therapy, the phase III clinical trial has completed 718 patients enrollment on 24 February 2022.

The U.S. phase I clinical trial of Proxalutamide were completed in May 2019. The results showed that Proxalutamide was generally well tolerated in mCRPC patients progressed after the treatment with existing drugs such as Enzalutamide and Abiraterone. As at 16 July 2020, the Group had completed the protocol defined patients enrollment for Proxalutamide phase II clinical trial for mCRPC in the U.S..

We are carrying out an open and multi-centre phase Ic clinical trial to evaluate the safety, pharmacokinetic characteristics and initial efficacy of Proxalutamide in combination with Exemestane, Letrozole and Fulvestrant in patients with AR+ metastatic breast cancer. The trial has completed patients enrollment for phase Ic on 25 August 2021.

- ***Pyrilutamide (KX-826)***

Pyrilutamide (KX-826) (福瑞他恩) is an AR antagonist. We commenced pre-clinical research of Pyrilutamide in July 2011 and are currently developing Pyrilutamide as a potential first-in-class topical drug for the treatment of AGA and acne vulgaris.

Indication of AGA

We received IND approval for Pyrilutamide for AGA in China and the U.S. in April 2018 and June 2018, respectively. We commenced relevant phase I clinical trials in China and the U.S. in December 2018 and January 2019, respectively.

On 29 December 2020, we completed the enrollment of 120 patients for the phase II clinical trial of Pyrilutamide for male AGA patients in China. On 8 September 2021, we announced that the primary endpoint of phase II clinical trial of Pyrilutamide in China for the treatment of male AGA patients was met, which was statistically significant and clinically meaning. Results have shown that the use of Pyrilutamide in the treatment of AGA has a good safety profile, and that the majority of adverse events observed were mild, and no serious adverse event occurred. On 24 November 2021, we announced that the IND application for the pivotal study (phase III clinical trial) of Pyrilutamide for the treatment of AGA male patients was cleared by NMPA. Pyrilutamide is the first topical AR antagonist which has entered the phase III clinical trial of AGA globally. As at the date of this announcement, we have completed the enrollment and dosing of patients in the phase II clinical trial for the treatment of AGA female patients and the enrollment and dosing of the first patient of the phase III clinical trial for the treatment of male AGA patients, respectively, in China.

On 3 August 2020, we completed the phase Ib clinical trial of Ppyrilutamide in the U.S.. On 11 July 2021, we announced that FDA has greenlighted Ppyrilutamide's phase II clinical trial for AGA to be conducted in the U.S.

On 28 February 2022, we enrolled and dosed first patient in the phase II clinical trial of Ppyrilutamide for the treatment of male AGA patients in the U.S.

Please refer to the announcements of the Company dated 11 July 2021, 8 September 2021, 12 November 2021, 24 November 2021, 2 January 2022, 1 March 2022 and 6 March 2022, respectively, for further information on the latest research developments on Ppyrilutamide for the indication of AGA.

Indication of acne vulgaris

On 17 September 2020, we obtained the approval for the IND of Ppyrilutamide (KX-826) gel formula for the indication of acne vulgaris from NMPA. On 16 April 2021, the phase I/II clinical trial of Ppyrilutamide gel as a treatment for the acne vulgaris completed the first batch of patients enrollment and successfully dosed in China. The phase I clinical trial of KX-826 for the treatment of acne vulgaris has demonstrated a preliminary positive safety and tolerability profile in terms of dose-escalation and dosing frequency. On 24 January 2022, we enrolled and dosed the first patient in the phase II clinical trial of Ppyrilutamide gel as a treatment for acne vulgaris in China.

Please refer to the announcements of the Company dated 16 April 2021 and 24 January 2022, respectively, for further information on the latest research developments on Ppyrilutamide for the indication of acne vulgaris.

- ***ALK-1 antibody (GT90001)***

ALK-1 antibody is a new antiangiogenesis inhibitor and ALK-1 is a new biological target spot globally. In 2018, we obtained an exclusive global licence from Pfizer to develop and commercialise ALK-1 antibody for the treatment of metastatic HCC and other oncological indications.

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.

Pfizer completed two phase I clinical trials for ALK-1 antibody for advanced solid tumours, including HCC, as a monotherapy in the U.S. and Italy, as well as in South Korea and Japan. Our phase II clinical trials for ALK-1 antibody as a combination therapy with PD-1 monoclonal antibody Nivolumab (Opdivo), for metastatic HCC in Taiwan for patients who failed the first-line treatment of Sorafenib or Lenvatinib. The data collected were released at the 2021 American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO-GI). The results showed that among the 20 evaluable patients, eight patients (40.0%) were observed partial remission (PR). We expect the last patient out in June 2022 for this phase II trial.

On 30 July 2020, we entered into a partnership agreement with Jiangsu Alphamab Biopharmaceuticals Co., Ltd., a wholly-owned subsidiary of Alphamab Oncology (stock code: 9966), to jointly develop the combination therapy of PD-L1/CTLA-4 bispecific antibody KN046 and ALK-1 monoclonal antibody globally. We have commenced the enrollment and dosing of patients with advanced or refractory solid tumors in a phase Ib/II clinical trial of ALK-1 antibody in combination with KN046 in Taiwan, China.

On 18 February 2021, we announced that the IND application of the combination therapy of ALK-1 monoclonal antibody ALK-1 antibody and Nivolumab for a global multi-centre phase II clinical trial for the second-line treatment of advanced HCC had been greenlighted by FDA. On 9 October 2021, the clinical trial of combination therapy of ALK-1 antibody and Nivolumab for the treatment of advanced HCC was approved by NMPA.

For further details on the latest research developments on ALK-1 antibody, please refer to the announcements published by the Company on 18 February 2021, 11 October 2021 and 2 November 2021, respectively.

Other Clinical Stage Products

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

GT20029 is considered a natural progression from AR inhibitors such as Proxalutamide, and has the potential to become a new generation of treatment for AGA and acne vulgaris. GT20029 is a topical AR-PROTAC compound developed by using the Group's in-house PROTAC platform.

On 14 April 2021, the IND applications of GT20029 for AGA and acne vulgaris indications were approved by CDE. GT20029 is the first topical PROTAC drug which entered clinical stage around the world. On 28 July 2021, the first batch of subjects have been enrolled and dosed in the clinical trial.

On 13 July 2021, we announced that IND clearance has been received from FDA for GT20029 for the treatment of AGA and acne vulgaris in the U.S. On 1 February 2022, the first subject has been enrolled and dosed in this clinical trial.

Please refer to the announcements of the Company dated 1 February 2021, 15 April 2021, 13 July 2021, 28 July 2021 and 3 February 2022, respectively, for further information.

- ***PD-L1/TGF – β (GT90008)***

On 20 August 2020, we entered into an exclusive license agreement with Gensun Biopharma Inc. (“**Gensun**”), pursuant to which we obtained from Gensun, among others, an exclusive license to conduct research, development, clinical trials, registration, manufacture and commercialisation of PD-L1/TGF – β dual-targeting antibody (the “**Compound**”) in Greater China. The Compound is a dual-targeting antibody 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. Please refer to the announcement of the Company dated 20 August 2020 for further information.

On 21 October 2021, the clinical trial of PD L1/TGF- β dual-targeting antibody for the treatment of advanced solid tumours was approved by NMPA.

- ***Detorsertib (GT0486)***

Detorsertib (GT0486) (迪拓賽替) is an inhibitor of the PI3K/mTOR signalling 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 in August 2019 and recorded the first patient enrollment on 18 February 2021.

- ***Hedgehog/SMO Inhibitor (GT1708F)***

Hedgehog/SMO Inhibitor (GT1708F) is an inhibitor of the hedgehog signal transduction pathway. We are currently developing GT1708F primarily for the treatment of leukaemia and BCC. We obtained IND approval for GT1708F from NMPA in February 2020 and recorded the first patients enrollment on 27 November 2020. We also obtained IND approval for GT1708F in the U.S. on 23 November 2020.

Pre-Clinical Stage Products

In addition to the drug candidates described above, we are also in the discovery phase 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.

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 drug discovery to clinical trials. 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 process meets the quality standards we have set internally.

Through the development of two of our Core Products, being Proxalutamide and Ppyrilutamide, we have accumulated significant expertise in AR-related know-how and have developed a leading AR technology platform. We believe we have accumulated industry-leading expertise in the field of AR signalling pathway, molecule design and PK/PD modelling. Leveraging our AR technology platform, we have successfully progressed Proxalutamide to phase III clinical trials in China and the U.S., expanded the indication of Proxalutamide to COVID-19, and have also developed Ppyrilutamide and AR-PROTAC for AGA and acne vulgaris. As at the date of this announcement, we have successfully progressed Ppyrilutamide to phase III clinical trials for the treatment of male AGA patients and phase II clinical trials for the treatment of AGA female patients and Ppyrilutamide gel to phase II clinical trial for treatment for acne vulgaris 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.

By in-licensing and developing our Core Product ALK-1, we have gradually established and expanded our R&D capabilities in the field of biological drug. We have carried forward ALK-1 to phase II, and explored the combination therapy with KN046 and other drugs. As at the date of this announcement, we have commenced the enrollment and dosing of patients with advanced or refractory solid tumors in a phase Ib/II clinical trial of combination therapy with KN046. In addition, we also introduced the second biological drug PD-L1/TGF- β dual-targeting antibody for the treatments of multiple solid tumors.

Our R&D work is led by senior scientists, including Dr. TONG, supported by seven other returnee scientists who have accumulated decades of pharmaceutical R&D and entrepreneurship experience in reputable pharma and biotech companies in the U.S. and who together provide us with combined expertise covering small molecule, biologics, compound design.

For the years ended 31 December 2020 and 2021, our research and development expenses were approximately RMB328.8 million and RMB767.9 million, respectively.

COMMERCIALISATION AND MANUFACTURING

As of the date of this announcement, we had not commercialised any of our drug candidates. We plan to conduct the sales and marketing and subsequent commercialisation preparation work in relation to our Core Products primarily by license-out in several countries around the world and building sales and marketing team. As of 31 December 2021, we had built a sales and marketing team of 13 members. In addition, we appointed Dr. Qun LU as our chief technology officer and appointed Dr. Jiawen HAN as our vice president of business development on 10 May 2021. Dr. LU has over 20 years of experience in the biopharmaceutical industry with a proven track record of successfully leading the CMC development at various pharmaceutical corporations. Dr. HAN has over 25 years of experience in drug development and business operations in the pharmaceuticals industry. The participation of Dr. LU and Dr. HAN will certainly further accelerate the pace of product commercialisation of the Company.

We plan to use our own manufacturing facilities in Suzhou and Pinghu in China for the manufacture of APIs and final products for Proxalutamide and Ppyrilutamide. We also expanded the production capacity of Proxalutamide through cooperation with CDMO companies. On 28 August 2020, our manufacturing and R&D facility in Suzhou commenced operations in preparation for the production of Proxalutamide. In November 2020, our Suzhou facility was granted the Pharmaceutical Production License issued by Jiangsu Medical Products Administration. In April 2021, we entered into a strategic cooperation agreement with a CDMO company, namely Hainan Visum Pharmaceutical Limited (海南華益泰康藥業有限公司), relating to expansion of production capacity of Proxalutamide. Our manufacturing facilities in Pinghu are currently in the project design stage. The construction of our manufacturing facilities in Pinghu is in the preparatory stage and is expected to commence in the second quarter of 2022. On 30 April 2021, we expanded our geographical presence to the Zhuhai International Health Port. The Zhuhai office 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.

IMPACT OF COVID-19

We are conducting a number of global multi-centre clinical trials for our drug candidates in the PRC (including Taiwan), the U.S. and other countries and regions. We have employed various measures to mitigate the impact of the COVID-19 outbreak on our ongoing clinical trials, including supplying enrolled patients with study medication through courier and arranging for enrolled patients to conduct check-ups at alternative medical centres if the ones they generally visit become unavailable. We currently do not anticipate any material deviation from our drug development, manufacturing and commercialisation plans, and the expected development progress of our Core Products has taken into account the temporary delays and disruptions on our ongoing clinical trials as a result of the COVID-19 outbreak. However, the COVID-19 pandemic is with limited precedent, and it is therefore not possible to predict the impact that it will ultimately have on our business or our industry. There is also no assurance that the COVID-19 outbreak will not further escalate or have a material adverse effect on our results of operations.

The Directors confirm that, save as disclosed above, there has been no material adverse change in our financial, operational or trading positions or prospects during the Reporting Period.

Besides, following the outbreak of COVID-19, the Company has found that one of the Core Products, Proxalutamide, could treat COVID-19 and we have been conducting various clinical trials of Proxalutamide for the treatment of COVID-19. As of the date of this announcement, Proxalutamide had been administered with an EUA in certain hospitals in Paraguay for treatment of hospitalised COVID-19 patients, where promising initial results had been observed. The Group will continue to advance clinical trials and EUA applications for Proxalutamide to be used for the purposes of treating COVID-19 patients in other countries and regions to drive the sales and the progress of commercialisation of Proxalutamide.

FINANCIAL REVIEW

Overview

We currently have no drugs approved for commercial sale for the year ended 31 December 2021. We have never been profitable and have incurred operating losses in each year since our inception. For the year ended 31 December 2021, we generated revenue from out-licensing contracts of RMB34.2 million as compared to nil for the year ended 31 December 2020. We recorded other income of RMB29.3 million, representing an increase of 16.7% as compared with RMB25.1 million for the year ended 31 December 2020. Our loss and total comprehensive loss were RMB508.3 million and RMB842.1 million for the years ended 31 December 2020 and 2021, respectively. Our adjusted loss and total comprehensive loss for the same period after adding back the Listing expenses and share-based compensation expenses for the Employee Incentive Scheme were RMB459.4 million and RMB804.7 million, respectively. Our marketing costs were RMB8.6 million and RMB14.7 million for the years ended 31 December 2020 and 2021, respectively. Our administrative expenses were RMB77.1 million and RMB103.3 million for the years ended 31 December 2020 and 2021, respectively. Our R&D costs were RMB328.8 million and RMB767.9 million for the years ended 31 December 2020 and 2021, respectively. Our other losses were RMB115.5 million and RMB17.3 million for the years ended 31 December 2020 and 2021, respectively. Our finance costs were RMB3.4 million and RMB2.5 million for the years ended 31 December 2020 and 2021, respectively.

Revenue from out-licensing contracts

For the year ended 31 December 2021, we recorded revenue from out-licensing contracts of RMB34.2 million (2020: nil), which was generated from the receipt of the upfront payments in connection with the out-licensing of Proxalutamide.

Other Income

Our other income primarily consisted of interest income from bank balances and government grants. Our other income increased by RMB4.2 million or 16.7% from RMB25.1 million for the year ended 31 December 2020 to RMB29.3 million for the year ended 31 December 2021, which was mainly attributable to (i) a RMB0.7 million increase in interest income from bank balances primarily due to the increase of our bank balances resulting from the proceeds from the Global Offering and the Top-up Placing; (ii) a RMB1.8 million increase in government grants; (iii) a RMB1.0 million increase in interest income from time deposits primarily as a result of the increase of our time deposits for the unused proceeds from the Global Offering and the Top-up Placing; and (iv) other income of RMB0.7 million.

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 RMB8.6 million for the year ended 31 December 2020 to RMB14.7 million for the year ended 31 December 2021, which was mainly attributable to the increase in share-based compensation expense for key team members; and the organisation of more academic and conference activities.

Administrative Expenses

Our administrative expenses during the Reporting Period primarily consisted of (i) employee benefit expenses, which primarily consisted of compensation for management and administrative personnel (including share-based compensation expenses relating to the Employee Incentive Scheme); (ii) utilities and office expenses for our offices and laboratories; (iii) depreciation and amortization, which primarily consisted of depreciation of right-of-use assets in relation to our leased properties for administrative use and amortization of computer software; and (iv) other miscellaneous administrative expenses such as professional advisory expenses, recruitment related activities expenses, bank charges, rental expenses for our other leased offices not accounted for as right-of-use assets and other general administrative 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			
	2021		2020	
	<i>RMB'000</i>	%	<i>RMB'000</i>	%
Employee benefit expenses	40,535	39.3	24,035	31.2
Add: share-based compensation expenses	<u>11,949</u>	<u>11.6</u>	<u>7,832</u>	<u>10.2</u>
Employee benefit expenses (including share-based compensation expenses)	52,484	50.9	31,867	41.4
Utilities and office expenses	21,033	20.4	10,318	13.4
Depreciation and amortization	5,778	5.6	3,259	4.2
Listing expenses	–	–	20,761	26.9
Others	<u>23,960</u>	<u>23.1</u>	<u>10,858</u>	<u>14.1</u>
Total	<u><u>103,255</u></u>	<u><u>100.0</u></u>	<u><u>77,063</u></u>	<u><u>100.0</u></u>

Our administrative expenses increased by RMB26.2 million or 34.0% from RMB77.1 million for the year ended 31 December 2020 to RMB103.3 million for the year ended 31 December 2021, which was mainly attributable to (i) an RMB20.6 million increase in employee benefit expenses primarily resulting from new recruitments and hiring of senior management in line with the fast development of our business and the grant of RSUs to senior management and employees with administrative functions on 31 March 2021 and 30 September 2021 (ii) an RMB10.7 million increase in utilities and office expenses in line with the expansion of our operations; and (iii) an RMB13.1 million increase in other administrative expenses primarily relating to the increase of our recruitment related activities expenses and professional advisory expenses such as compliance consulting fees, legal consulting fees, taxation, intangible property valuation and intellectual property maintenance.

Research and Development 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) employee benefit expenses, which primarily consisted of compensation to R&D personnel (including the share-based compensation expenses for the Employee Incentive Scheme); (iv) third party contracting fees, which primarily consisted of fees paid to CROs and CMOs for purpose of preclinical trials; and (v) 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 years indicated:

	For the year ended			
	2021		2020	
	<i>RMB'000</i>	%	<i>RMB'000</i>	%
Employee benefit expenses	76,659	10.0	48,440	14.7
Add: share-based compensation expenses	<u>19,929</u>	<u>2.6</u>	<u>20,327</u>	<u>6.2</u>
Employee benefit expenses (including share-based compensation expenses)	96,588	12.6	68,767	20.9
Clinical research expenses	448,870	58.4	104,702	31.8
Materials and consumables expenses	<u>146,433</u>	<u>19.1</u>	<u>88,223</u>	<u>26.8</u>
Third party contracting fees	59,419	7.7	59,267	18.0
Others	<u>16,626</u>	<u>2.2</u>	<u>7,805</u>	<u>2.5</u>
Total	<u><u>767,936</u></u>	<u><u>100.0</u></u>	<u><u>328,764</u></u>	<u><u>100.0</u></u>

Our R&D costs for Proxalutamide were RMB165.2 million and RMB537.3 million for the year ended 31 December 2020 and 2021, respectively, and our R&D costs for Pylutamide were RMB34.8 million and RMB45.7 million in 2020 and 2021, respectively (excluding ancillary R&D costs which are not product-specific).

Our R&D costs increased by RMB439.1 million or 133.5% from RMB328.8 million for the year ended 31 December 2020 to RMB767.9 million for the year ended 31 December 2021, which was mainly attributable to (i) an RMB344.2 million increase in clinical research expenses primarily paid to CROs for clinical trials and hospitals where we conducted clinical trials; (ii) an RMB58.2 million increase in materials and consumables expenses primarily resulting from (1) the purchases of active pharmaceutical ingredients (APIs) for the production of Proxalutamide and Pylutamide used in our clinical trials; (2) the purchase of branded Abiraterone for our Proxalutamide phase III clinical trials (combination therapy with Abiraterone for mCRPC) in China; and (iii) an RMB27.8 million increase 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.

Other Losses – Net

We had other losses of RMB17.3 million for the year ended 31 December 2021 primarily as a result of net foreign exchange losses due to exchange rates movement. We had other losses of RMB115.5 million for the year ended 31 December 2020.

Finance Costs – Net

Our finance costs during the Reporting Period primarily consisted of interest expense from bank borrowings. Our finance costs decreased by RMB0.9 million or 26.5% from RMB3.4 million for the year ended 31 December 2020 to RMB2.5 million for the year ended 31 December 2021, which was mainly attributable to the decrease in interest expense from borrowings.

Income Tax Expenses

We recorded income tax expenses of RMB73,000 for the year ended 31 December 2020, primarily due to the US\$0.1 million service fee received by Kintor US from Suzhou Kintor for the purpose of general R&D was recognised as revenue. We did not record any income tax expense for the Reporting Period as we incurred a net loss.

Net Loss for the Reporting Period

Our net loss increased by RMB333.8 million or 65.7% from RMB508.3 million for the year ended 31 December 2020 to RMB842.1 million for the year ended 31 December 2021.

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 and one-time events, namely the share-based compensation expenses and the Listing 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 form 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	
	2021	2020
	RMB'000	RMB'000
Loss and total comprehensive loss for the year	(842,095)	(508,301)
Added:		
<i>Listing expenses (one-time)</i>	–	20,761
<i>Share-based compensation expenses</i>	37,347	28,159
	<u>(804,748)</u>	<u>(459,381)</u>
Adjusted loss and total comprehensive loss for the year	<u>(804,748)</u>	<u>(459,381)</u>

Employees and Remuneration Policies

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

	As of 31 December 2021	
	Number of employees	As a percentage of total
Core management	11	3.5%
Clinical	64	20.3%
R&D	93	29.4%
Manufacturing	67	21.2%
Commercial	13	4.1%
Project management	19	6.0%
Others	49	15.5%
Total	<u>316</u>	<u>100.0%</u>

As at 31 December 2021, the Group had a total of 316 full time employees, among whom, 305 were based in China, 7 were based in the U.S., and 4 was based in Hong Kong. We generally formulate our employees' remuneration package to include basic salary, position-specific salary, performance-based remuneration, project-based remuneration 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.

Liquidity and Capital Resources

Our cash and cash equivalents and time deposits primarily consisted of deposits with banks and cash on hand. As of 31 December 2021, cash and cash equivalents and time deposits decreased by RMB333.8 million from RMB1,389.0 million as of 31 December 2020 to RMB1,055.2 million. The decrease was primarily resulted from usage for various operating activities including R&D, purchase of assets, staff wages and benefits and other various management expenses. The current ratio (total current assets as a percentage of total current liabilities) of the Group decreased from 838.9% as of 31 December 2020 to 694.4% as of 31 December 2021, mainly due to the increase in trade and other payables resulting from the increased business activities during the Reporting Period.

As of 31 December 2021, we had utilised bank facilities of RMB154.9 million and unutilised bank facilities of RMB150 million.

Significant Investments, Material Acquisitions or Disposals

As of 31 December 2021, there were 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	
	2021	2020
	RMB'000	RMB'000
Cash used in operations before changes in working capital	(765,085)	(367,528)
Changes in working capital	(284,588)	(12,877)
Net interest paid	(881)	(404)
Income tax paid	(809)	(73)
	<hr/>	<hr/>
Net cash used in operating activities	(1,051,363)	(380,882)
Net cash generated from/(used) in investing activities	92,005	(439,728)
Net cash generated from financing activities	857,418	1,780,298
	<hr/>	<hr/>
Net increase in cash and cash equivalents	(101,940)	959,688
Cash and cash equivalent at the beginning of the year	1,064,689	195,532
Exchange losses on cash and cash equivalents	(36,418)	(90,531)
	<hr/>	<hr/>
Cash and cash equivalent at the end of the year	926,331	1,064,689
	<hr/> <hr/>	<hr/> <hr/>

Net Cash Used in Operating Activities

During the Reporting Period, we derived our cash inflows from operating activities primary from the receipt of upfront payments in connection with the out-licensing of Proxalutamide and government grants. Our net cash used in operating activities mainly consisted of R&D expenses and administrative expenses.

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.

During the year ended 31 December 2020, our net cash used in operating activities was RMB380.9 million, primarily consisting of RMB380.4 million of cash used in operations, interest paid on borrowings of RMB7.6 million and interest received on bank balances of RMB7.2 million.

Net Cash Generated from Investing Activities

During the Reporting Period, our cash flows relating to investing activities primarily reflected purchases of technical know-how and purchases of property, plant and equipment, in-license of intangible assets and purchase of financial products.

During the year ended 31 December 2021 our net cash generated from investing activities was RMB92.0 million, which primarily consisted of (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) intangible assets of RMB29.5 million resulting from milestone payments of PD-L1/TGF- β , partially offset by (i) proceeds received upon maturity of certain time deposits with maturities of over three months and financial assets at fair value through profit or loss of RMB714.8 million; and (ii) payments for restricted cash of RMB1.7 million resulting from payments of deposits for our financial products.

During the year ended 31 December 2020, our net cash used in investing activities was RMB439.7 million, which primarily consisted of (i) purchase of property, plant and equipment of RMB69.0 million for our Suzhou plant; (ii) purchase of intangible assets of RMB27.1 million for the exclusive license we obtained from Gensun to conduct research, development, clinical trials, registration, manufacture and commercialisation of the Licensed Product(s); (iii) purchases of time deposits with maturities of over three months of RMB480.9 million with the unused proceeds from the Global Offering; and (iv) purchases of financial assets at fair value through profit or loss of RMB252.8 million for investments in wealth management products, dual currency wealth management products and foreign exchange forward contracts; partially offset by (i) proceeds from time deposits with maturities of over three months of RMB134.1 million and (ii) proceeds from disposal of financial assets at fair value through profit or loss of RMB254.4 million for redemption of investments in wealth management products, dual currency wealth management products and foreign exchange forward contracts.

Net Cash Generated from Financing Activities

During the Reporting Period, our cash flows relating to financing activities primarily reflected proceeds from the Top-up Placing and bank borrowings.

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 of RMB952.0 million and (ii) proceeds from borrowings of RMB20 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.

During the year ended 31 December 2020, our net cash generated from financing activities was RMB1,780.3 million, which primarily consisted of (i) proceeds from borrowings of RMB239.0 million and (ii) proceeds from the Global Offering of RMB1,652.7 million, partially offset by (i) payment of lease liabilities of RMB3.1 million mainly relating to rental payment for our offices; (ii) repayments of borrowings of RMB79.2 million; and (iii) payment for Listing expenses of RMB29.1 million.

Financial Position

Our net current assets increased from RMB1,251.3 million as of 31 December 2020 to RMB1,306.2 million as of 31 December 2021. Current assets increased from RMB1,420.6 million as of 31 December 2020 to RMB1,525.9 million as of 31 December 2021, primarily due to the net proceeds we received from the Top-up Placing.

Significant Change in Accounting Policy

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

Indebtedness

As of 31 December 2021, the balance of our bank borrowings consisted of long-term bank borrowings of RMB96.5 million 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 of 31 December 2020, the balance of our bank borrowings consisted of short-term bank borrowings of RMB79.9 million which were unsecured and unguaranteed and long-term bank borrowings of RMB138.6 million which were secured by certain land use right, buildings and construction in progress. In the balance of our bank borrowings, RMB83.6 million is repayable within one year or on demand.

Financial Risks

We are exposed to various types of financial and market risks, including foreign exchange risk, cash flow and fair value interest rate risk, credit risk and liquidity risk. The Group currently does not have a foreign currency hedging policy. However, management of the Group continuously monitors foreign exchange exposure and will consider hedging significant foreign currency exposure should the need arise.

Foreign Exchange Risk

The Group's exposure to foreign exchange risk as at 31 December 2021 mainly came from cash at bank and time deposits denominated in USD and HKD which were primarily consisted of the proceeds we received in the Global Offering and the Top-up Placing.

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, 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 of 31 December 2021 and 2020, all of our borrowings carried at fixed rates, which exposed the Group to fair value interest rate risk.

Our management does not anticipate significant impact to 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

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

We expect 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 listed banks. Our 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.

We have 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 our management. As at 31 December 2021 and 2020, other receivables mainly comprise deposits to lessors in respect of the Group's leased properties.

We expect 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

We finance our working capital requirements through the issue of new shares, borrowings and government grants. Our management monitors rolling forecasts of our liquidity reserve on the basis of expected cash flows.

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 RMB1,306.2 million as of 31 December 2021. 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 2021, with comparative figures for the previous year as follows:

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

	<i>Note</i>	Year ended 31 December	
		2021	2020
		<i>RMB'000</i>	<i>RMB'000</i>
Revenue from out-licensing contracts	4	34,231	–
Cost of sales		–	–
Gross profit		34,231	–
Other income		29,311	25,134
Marketing costs	5	(14,698)	(8,628)
Administrative expenses	5	(103,255)	(77,063)
Research and development costs	5	(767,936)	(328,764)
Other losses – net	6	(17,254)	(115,530)
Operating loss			
Finance costs – net		(2,494)	(3,377)
Loss before income tax		(842,095)	(508,228)
Income tax expense	7	–	(73)
Loss and total comprehensive loss for the year attributable to the equity holders of the Company		(842,095)	(508,301)
Basic and diluted loss per share for loss attributable to the equity holders of the Company (in RMB)	9	(2.36)	(1.64)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	<i>Note</i>	As at 31 December	
		2021	2020
		RMB'000	RMB'000
Assets			
Non-current assets			
Property, plant and equipment		223,686	174,612
Intangible assets		235,621	209,760
Right-of-use assets		38,614	12,068
Other non-current assets		44,173	34,419
		<u>542,094</u>	<u>430,859</u>
Current assets			
Inventories	<i>10</i>	351,362	–
Other receivables, deposits and prepayments	<i>11</i>	117,655	31,621
Time deposits		125,071	323,407
Restricted cash		1,658	–
Cash and cash equivalents		930,149	1,065,588
		<u>1,525,895</u>	<u>1,420,616</u>
Total assets		<u><u>2,067,989</u></u>	<u><u>1,851,475</u></u>
Liabilities			
Non-current liabilities			
Borrowings		147,500	134,900
Lease liabilities		2,764	490
Deferred income tax liabilities		38,818	38,818
Deferred income		4,009	–
		<u>193,091</u>	<u>174,208</u>

		As at 31 December	
	<i>Note</i>	2021	2020
		RMB'000	RMB'000
Current liabilities			
Trade and other payables	12	209,863	81,409
Borrowings		7,400	83,600
Lease liabilities		2,069	2,713
Deferred income		–	361
Amounts due to related parties		408	1,250
		<u>219,740</u>	<u>169,333</u>
Total liabilities		<u>412,831</u>	<u>343,541</u>
Equity			
Equity attributable to the equity holders of the Company			
Share capital		273	261
Shares held for the Employee Incentive Scheme		(17)	(17)
Reserves		1,654,902	1,507,690
		<u>1,655,158</u>	<u>1,507,934</u>
Total equity		<u>1,655,158</u>	<u>1,507,934</u>
Total equity and liabilities		<u>2,067,989</u>	<u>1,851,475</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 BASIS OF PREPARATION

The consolidated financial statements of the Group has been prepared in accordance with International Financial Reporting Standards (“**IFRSs**”). The consolidated financial statements has 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) New standards and interpretations adopted by the Group

The Group has adopted the following amendment to standards and interpretations which are mandatory for the year ended 31 December 2021:

Standards	Key requirements	Effective for accounting periods beginning on or after
Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16	Interest Rate Benchmark Reform Phase 2	1 January 2021

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

A number of new standards and amendments to existing standards and interpretations that are relevant to the Group have been issued but are not yet effective for the financial year beginning on 1 January 2021 and have not been early adopted by the Group. These new standards and amendments are set out below:

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 2023
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
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

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 REPORTING

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker. The chief operating decision-maker, who is responsible for allocating resources and assessing performance of the operating segments, has been identified as the executive directors that make strategic decisions.

During the years ended 31 December 2021 and 2020, the Group has been focusing on research and development of innovative medicine products. Accordingly, the management considers that the Group is operated and managed as a single operating segment and hence no segment information is presented.

4 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 for out-licensing one of its bio-pharmaceutical license to the customer 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.

In August 2021, the Group entered into an agreement with another pharmaceutical company for out-licensing one of its bio-pharmaceutical license to the customer 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.

(c) **Disaggregated revenue information is as follows:**

	Year ended 31 December	
	2021	2020
	RMB'000	RMB'000
Timing of revenue recognition:		
At a point in time		
– Revenue from out-licensing contracts	<u>34,231</u>	<u>–</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 2021 and 2020 is as follows:

	Year ended 31 December	
	2021	2020
	RMB'000	RMB'000
China	30,189	–
Others	4,042	–
	<u>34,231</u>	<u>–</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 2021 and 2020 are listed as below:

	Year ended 31 December	
	2021	2020
	RMB'000	RMB'000
Customer A	30,189	–
Customer B	4,042	–
	<u>34,231</u>	<u>–</u>

5 EXPENSES BY NATURE

	Year ended 31 December	
	2021	2020
	RMB'000	RMB'000
Clinical research expenses	448,870	104,702
Employee benefit expenses	159,748	107,361
Materials and consumables used	147,916	88,223
Outsourced research and development costs	59,419	58,511
Utilities and office expenses	35,856	16,514
Professional fees	9,200	2,010
Depreciation of property, plant and equipment	6,729	3,417
Depreciation of right-of-use assets	3,837	3,117
Less: amounts capitalised in property, plant and equipment	(199)	(199)
	3,638	2,918
Auditors' remuneration	3,356	2,849
Rental expenses	1,365	989
Bank charges	190	187
Amortisation of intangible assets	143	166
Listing expenses	–	20,761
Others	9,459	5,847
	<u>885,889</u>	<u>414,455</u>
Total marketing costs, administrative expenses and research and development costs	<u>885,889</u>	<u>414,455</u>

6 OTHER LOSSES – NET

	Year ended 31 December	
	2021	2020
	RMB'000	RMB'000
Gains on disposal of financial assets at fair value through profit or loss	(777)	(2,132)
Net foreign exchange losses	17,625	118,294
Losses/(gains) on disposal of property, plant and equipment	106	(597)
Gains on disposal of right-of-use assets	–	(40)
Others	300	5
	<u>17,254</u>	<u>115,530</u>

7 INCOME TAX EXPENSE

	Year ended 31 December	
	2021	2020
	RMB'000	RMB'000
Current income tax expense		
– Underprovision in prior year:	–	73
Deferred income tax expense	–	–
	<u>–</u>	<u>73</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% (2020: 16.5%). Since these companies did not have assessable profits during the years ended 31 December 2021 and 2020, 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% (2020: 23.5%). Since Kintor Pharmaceuticals Inc. did not have assessable profits during the years ended 31 December 2021 and 2020, no federal and state income tax has been provided.

Ireland

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

Mainland China

Pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the “**CIT Law**”), the subsidiaries which operate in Mainland China are subject to CIT at a rate of 25% (2020: 25%) on the taxable income. Since the Group’s PRC entities did not have assessable profits during the year ended 31 December 2021 and 2020, no corporate income tax has been provided.

The income tax on the Group’s loss before income tax differs from the theoretical amount that would arise using the enacted tax rate in the PRC applicable to the Group as follows:

	Year ended 31 December	
	2021	2020
	RMB’000	RMB’000
Loss before income tax	(842,095)	(508,228)
Tax calculated at the applicable tax rate of 25%	(210,524)	(127,057)
Difference in overseas tax rates	100,338	39,076
Tax losses not recognised as deferred tax assets	151,712	124,357
Temporary differences not recognised as deferred tax assets	935	(18)
Super deduction in respect of research and development expenditures	(51,609)	(41,789)
Expenses not deductible for income tax purposes	10,396	7,585
Income not subject to taxation	(1,248)	(2,870)
Difference of prior year income tax annual filing	–	789
Income tax expense	–	73

8 DIVIDEND

No dividend has been paid or declared by the Company during the years ended 31 December 2021 and 2020.

9 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 2021 and 2020.

In determining the weighted average number of ordinary shares in issue during year ended 31 December 2021 and 2020, the capitalisation issue of 249,337,890 shares, pursuant to the shareholders' resolution dated 30 April 2020, was retrospectively adjusted. Out of aforementioned 249,337,890 shares arising from the capitalization issue, 23,613,590 shares held for the employee incentive scheme (including 21,252,231 shares arising from the relevant capitalization issue) was not taken account into in determining the weighted average number of ordinary shares in issue during the year ended 31 December 2021 and 2020.

	Year ended 31 December	
	2021	2020
	RMB'000	RMB'000
Loss for the year	(842,095)	(508,301)
Weighted average number of ordinary shares in issue (in thousand)	<u>356,393</u>	<u>309,350</u>
Basic loss per share (in RMB)	<u>(2.36)</u>	<u>(1.64)</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 2021 and 2020.

10 INVENTORIES

	As at 31 December	
	2021	2020
	RMB'000	RMB'000
Raw materials	346,285	–
Work in progress	<u>5,077</u>	<u>–</u>
	<u>351,362</u>	<u>–</u>

11 OTHER RECEIVABLES, DEPOSITS AND PREPAYMENTS

	As at 31 December	
	2021	2020
	RMB'000	RMB'000
Prepayments to suppliers	115,026	25,432
Deposits	1,509	4,127
Advances to employees	428	1,507
Others	692	555
	<u>117,655</u>	<u>31,621</u>

As at 31 December 2021 and 2020, the carrying amounts of other receivables and deposits were denominated in RMB and approximated their fair values.

12 TRADE AND OTHER PAYABLES

	As at 31 December	
	2021	2020
	RMB'000	RMB'000
Payables for materials and consumbles (<i>Note (a)</i>)	128,256	130
Payables for service suppliers (<i>Note (a)</i>)	44,700	28,681
Salary and staff welfare payables	21,905	13,321
Payables for property, plant and equipment	7,223	28,513
Payables for audit services	3,000	2,800
Payables for individual income tax and other taxes	2,097	1,179
Payables for interest expenses	213	261
Payables for intangible asset	–	3,500
Payables for listing expenses	–	2,030
Others	2,469	994
	<u>209,863</u>	<u>81,409</u>

As at 31 December 2021 and 2020, 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 2021 and 2020, the ageing analysis of payables for materials and consumbles and payables for service suppliers based on invoice date are as follows:

	As at 31 December	
	2021	2020
	RMB'000	RMB'000
– Within 1 year	<u>172,956</u>	<u>28,811</u>

FUTURE AND OUTLOOK

Our mission is focusing on the research, development, and commercialization of products for diseases with unmet clinical needs. In response to the global spread of the COVID-19 pandemic, we will make our best effort to promote the commercialisation of Proxalutamide and make it an effective and safe treatment for COVID-19 in clinical use as soon as possible, making our contribution to the combat against COVID-19.

To accomplish that mission, we plan continue to advance the clinical development, regulatory approvals and commercial launch of Proxalutamide first in China and strategically progress the clinical development and commercialisation of Proxalutamide in other countries and regions out of China. Since July 2020, we have been progressing on our clinical trials of Proxalutamide for the treatment of COVID-19. According to the clinical data we have collected, the safety and efficacy profiles of Proxalutamide in the treatment of patients with COVID-19 are outstanding. We strive to launch Proxalutamide to the market for COVID-19 treatment as soon as possible, and help people around the globe to defeat COVID-19.

We also plan to leverage our expertise in AR-related research and continue our clinical development of Ppyrilutamide for androgenetic alopecia and acne vulgaris in both China and the U.S.. Also, we plan to develop ALK-1 as a potential first-in-class drug, as well as PD-L1/TGF- β as a potential best-in-class drug, in combination therapies with a variety of antibodies or bispecific antibodies for the treatment of various solid tumours and leveraging the expertise of our biologics R&D personnel to enhance our biologics R&D capabilities. We also plan to further leverage our PROTAC platform in development of small molecule drugs such as GT20029 and seeking innovative drug strategies of applying PROTAC molecule in local treatment.

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 contained in Appendix 14 to the Listing Rules. During the year ended 31 December 2021, 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 as set out in Appendix 10 of the Listing Rules 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 period from the Listing Date to the date of this announcement.

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 period from the Listing Date to the date of this announcement.

USE OF PROCEEDS

Global Offering

With the Shares of the Company 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**”), which will be utilised for the purposes as set out in our Prospectus. As of 31 December 2021, IPO proceeds of HK\$980.8 million has been utilised and we expect to utilise the balance of the IPO proceeds by 31 December 2022.

As at 31 December 2021, details of intended application of net proceeds are set out as follow:

	Approximate % of total net proceeds %	Planned use of actual net proceeds HKD'million	Utilised net proceeds up to 31 December 2021 HKD'million	Proceeds unused HKD'million	Expected timeline for utilizing the remaining balance of net proceeds from the Global Offering ⁽¹⁾
Development and commercialisation of Proxalutamide	42.0	721.3	460.5	260.8	Expected to be fully utilised by 31 December 2022
Development and commercialisation of Ppyrilutamide	28.0	480.8	120.6	360.2	Expected to be fully utilised by 31 December 2022
Our ongoing and planned clinical trials for our other clinical-stage drug candidates	14.0	240.4	124.9	115.5	Expected to be fully utilised by 31 December 2022
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	980.8	736.5	

Note:

- (1) The Company intends to use the remaining unused net proceeds in the coming years in accordance with the purpose set out in the Prospectus. The Company will continue to evaluate the Group’s business objectives and will change or modify the plans against the changing market conditions to suit the business growth of the Group. We will issue an appropriate announcement if there is any material change to the above proposed use of proceeds.

The delay in the expected date by which the remaining proceeds will be fully utilised from 30 June 2022 to 31 December 2022 was mainly because some of the R&D and clinical trial works on Proxalutamide, Ppyrilutamide and our other clinical-stage drug candidates were conducted in-house instead of outsourced, which was more cost effective.

The Company does not intend to change the purpose of the IPO proceeds as set out in the Prospectus and will gradually utilise the residual amount of the IPO proceeds in accordance with their intended purpose.

Top-up Placing

The completion of the Top-up Placing took place on 31 May 2021. The Top-up Placing 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. An aggregate of 21,900,000 placing Shares were successfully placed by the placing agent to no less than six placees who are professional, institutional and individual investors at the placing price of HK\$64.50 for each placing Share pursuant to the terms and conditions of the placing agreement. The Company allotted and issued 18,200,000 subscription Shares to KT International Investment Limited at HK\$64.50 per subscription share on 2 June 2021 in accordance with the terms and conditions of the subscription agreement. Based on the closing price of HK\$70.7 per Share as quoted on the Stock Exchange as at the date of the subscription agreement, the market value of the subscription Shares was HK\$1,286,740,000. The net placing price for the Shares sold by KT International Investment Limited was approximately HK\$63.85 per placing share. The net proceeds from the subscription are approximately HK\$1.16 billion, net of professional fees and out-of-pocket expenses. The Company intends to use all of the net proceeds for development and commercialisation of Proxalutamide and working capital for general corporate purpose.

The following table sets out a breakdown of the use of net proceeds as at 31 December 2021:

	Approximate % of total net proceeds %	Planned use of actual net proceeds HKD'million	Utilised net proceeds up to 31 December 2021 HKD'million	Proceeds unused HKD'million	Expected timeline for utilizing the remaining balance of net proceeds from the Top-up Placing
Phase III multi-regional clinical trials (MRCT) of Proxalutamide in the U.S., China and a few other countries	60	696.0	389.1	306.9	Expected to be fully utilised by 30 June 2023
Procurement of study material and active pharmaceutical ingredient (API) in preparation for the commercialisation of Proxalutamide	33	382.8	312.9	69.9	Expected to be fully utilised by 31 December 2022
Working capital for general corporate purpose	7	81.2	81.2	–	–
Total	100	1,160	783.2	376.8	

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. As it is expected that the phase III MRCT of Proxalutamide in the U.S., China and other countries will be completed in the first half of 2023, the expected timeline by which the remaining proceeds intended for this purpose will be fully utilised is delayed from December 2022 to June 2023.

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

During the financial year ended 31 December 2021, neither the Company nor any of its subsidiaries has purchased, sold or redeemed any of the Company's listed securities.

SUBSEQUENT EVENTS

Save as disclosed in this announcement, 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, Dr. Yan WANG. 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 2021. 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 the audited annual results for the year ended 31 December 2021) 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 2021 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 2021.

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 2021 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 2022.

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 CYP 17A 1 inhibitor and the active metabolite of abiraterone acetate, an ester and prodrug of abiraterone that is used in the treatment of prostate cancer
“AGA”	androgenetic alopecia
“ALK-1”	activin receptor-like kinase-1, an antagonistic mediator of lateral transforming growth factor-beta/ALK-5 signalling, 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 signalling due to its druggability as well as its centrality and specificity in the pathway
"ANVISA "	the Brazilian Health Regulatory Agency
“AR”	androgen receptor
“AR+”	androgen receptro positive
“Audit Committee”	the audit committee of the Board
“BCC”	basal-cell carcinoma

“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
“CDE”	the Centre for Drug Evaluation of NMPA
“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 consists of Proxalutamide (GT0918), Ppyrilutamide (KX-826) and ALK-1 (GT90001)
“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 signalling 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
“FDA”	Food and Drug Administration of the U.S.
“Global Offering”	has the meaning ascribed to it under the Prospectus
“Grantees”	the employees of the Group who were granted RSUs in accordance with the Employee Incentive Scheme on 26 March 2021.
“Group”	the Company and its subsidiaries (or our Company and any one or more of its subsidiaries, as the context may require)
“HCC”	hepatocellular carcinoma, a common type of liver cancer
“Hong Kong” or “HK”	the Hong Kong Special Administrative Region of the PRC
“HKD” or “HK\$”	Hong Kong dollar, the lawful currency of Hong Kong
“IFRS”	International Financial Reporting Standards as issued by the International Accounting Standards Board
“IIT”	investigator-initiated trial
“IND”	investigational new drug
“Kintor US”	Kintor Pharmaceuticals, Inc., an wholly-owned subsidiary of the Company incorporated under the laws of the State of Delaware
“KN046”	a bispecific antibodies (bsAb) immune checkpoint inhibitor simultaneously targeting two clinically-validated immune checkpoints, PD-L1 and CTLA-4
“leukaemia”	a group of cancers that usually begin in the bone marrow and result in high numbers of abnormal white blood cells
“Listing”	the listing of the Shares on the Main Board of the Stock Exchange
“Listing Date”	the date, Friday, 22 May 2020, from which the Shares are listed and dealings therein were first permitted to take place on the Stock Exchange
“Listing Rules”	the Rules Governing the Listing of Securities on the Stock Exchange, as amended or supplemented from time to time

“Macao”	The Macao Special Administrative Region of the PRC
“mCRPC”	the acronym of 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-signalling 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, PCD1,) 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
“Nomination Committee”	Nomination committee of the Board
“PD”	Pharmacodynamics
“PD-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)
“Proxalutamide” or “GT0918”	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
“RMB” or “Renminbi”	Renminbi yuan, the lawful currency of the PRC
“Remuneration Committee”	Remuneration committee of the Board
“Reorganisation”	the reorganisation of our Group in preparation of the Listing
“Reporting Period”	the year ended 31 December 2021
“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
“SFO”	Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong) as amended, supplemented or otherwise modified from time to time
“Share(s)”	ordinary share(s) in the share capital of the Company, currently of nominal value US\$0.0001 each
“Shareholder(s)”	holder(s) of the Shares
“SMO”	smoothed, a Class Frizzled G protein-coupled receptor that is a component of the hedgehog signalling pathway
“Stock Exchange”	The Stock Exchange of Hong Kong Limited
“Suzhou Kintor”	Suzhou Kintor Pharmaceutical, Inc.* (蘇州開拓藥業股份有限公司), a wholly-owned subsidiary of the Company

“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
“Top-up Placing”	(i) the placing of 18,200,000 existing Shares by KT International Investment Limited and 3,700,000 existing Shares by KG Development Limited to independent professional, institutional and/or individual investors procured by the placing agent pursuant to a placing agreement dated 26 May 2021; and (ii) the subscription by KT International Investment Limited of an aggregate of 18,200,000 new Shares issued by the Company on 2 June 2021 pursuant to a subscription agreement dated 26 May 2021
“U.S.” or “US”	the United States of America
“USD” or “US\$”	U.S. dollars, the lawful currency 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
“WHO”	World Health Organization
“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, 25 March 2022

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

* *For identification purpose only*