

东曜药业
TOT BIOPHARM

東曜藥業股份有限公司
TOT BIOPHARM International Company Limited

2022
Interim Report



(Incorporated in Hong Kong with limited liability)

Stock Code: 1875

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CORPORATE INFORMATION

EXECUTIVE DIRECTORS

Dr. Liu, Jun (*Chief Executive Officer*)
Ms. Yeh-Huang, Chun-Ying (*Vice Chairman of the Board*)

NON-EXECUTIVE DIRECTORS

Mr. Fu, Shan (*Chairman of the Board*)
Mr. Qiu, Yu Min

INDEPENDENT NON-EXECUTIVE DIRECTORS

Ms. Hu, Lan
Mr. Chang, Hong-Jen
Dr. Wang, De Qian

AUDIT AND CONNECTED TRANSACTIONS REVIEW COMMITTEE

Ms. Hu, Lan (*Chairlady*)
Mr. Qiu, Yu Min
Mr. Chang, Hong-Jen

REMUNERATION COMMITTEE

Mr. Qiu, Yu Min (*Chairman*)
Mr. Chang, Hong-Jen
Dr. Wang, De Qian

NOMINATION COMMITTEE

Mr. Fu, Shan (*Chairman*)
Ms. Hu, Lan
Dr. Wang, De Qian

STRATEGY AND ESG COMMITTEE

Mr. Fu, Shan (*Chairman*)
Dr. Liu, Jun
Ms. Yeh-Huang, Chun-Ying
Mr. Qiu, Yu Min
Dr. Wang, De Qian

JOINT COMPANY SECRETARIES

Mr. Chen, Yifan
Mr. Lui, Wing Yat Christopher (*Associate member of the Hong Kong Chartered Governance Institute and the Chartered Governance Institute in the United Kingdom*)

AUTHORIZED REPRESENTATIVES

Dr. Liu, Jun
Mr. Lui, Wing Yat Christopher

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COMPANY WEBSITE

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PLACE OF LISTING AND STOCK CODE

The Stock Exchange of Hong Kong Limited
1875

PRINCIPAL BANKS

Shanghai Pudong Development Bank
Bank of China
Agricultural Bank of China
China Merchants Bank
Bank of Jiangsu

AUDITOR

PricewaterhouseCoopers
Certified Public Accountants and Registered Public Interest Entity Auditor

LEGAL ADVISER

Sullivan & Cromwell (Hong Kong) LLP

INVESTORS AND MEDIA RELATIONS CONSULTANT

Hong Kong ZHIXIN Financial News Agency Limited



MANAGEMENT DISCUSSION AND ANALYSIS

I. INDUSTRY AND COMPANY PROFILE

Along with the rising number of new cancer cases in China, people's demand for oncology drugs and related industry services has increased. According to the statistics and forecast of Frost & Sullivan, the size of China's oncology drug market is expected to reach RMB416.2 billion by 2025, representing a CAGR of approximately 16.1% between 2020 and 2025.

Riding on the wave of biomedical research and development, ADC has ushered in its golden age. According to Grandview, the potential of ADC drug market has yet to be fully unleashed and the size of global ADC drug market exceeded US\$5 billion in 2021, which is estimated to grow at a CAGR as high as 53.0% between 2021 and 2025 (compared to a CAGR of 32.9% between 2015 and 2020). In addition, with the advancement of ADC drug technology that sees antibodies achieving precision therapy, stronger toxin efficacy and further optimized linker site-specific conjugation technology, it is anticipated that the market penetration rate of ADC products will rise further and is expected to rapidly increase to US\$21.1 billion by 2025, with the market size in China expected to reach US\$3.52 billion by 2024.

During the first half of 2022, we kept on expanding the market channels of Pusintin® and Tazian®, two of the launched products self-developed by TOT BIOPHARM, and achieved outstanding results. We continued to drive strategic upgrades to strengthen our competitive advantages in the ADC field, with an aim to build a leading international one-stop ADC industry platform, and to focus on our innovative drug CDMO business. For the six months ended 30 June 2022, our revenue amounted to RMB182 million, representing a year-on-year increase of 687%. Among this, revenue from sales of products increased to RMB104 million, which was mainly attributable to the contribution from the launch of Pusintin®; revenue from CDMO business increased to RMB22.66 million, representing a year-on-year increase of 94%; and revenue from licenses granted amounted to RMB49.43 million.

On 31 May 2022, TOT BIOPHARM entered into share subscription agreements with Vivo (Suzhou) Health Industry Investment Fund (Limited Partnership) (維梧(蘇州)健康產業投資基金(有限合夥)) ("Vivo Suzhou Fund") and Center Laboratories, Inc. (晟德大藥廠股份有限公司) (4123.TW) ("Centerlab"). On 29 July 2022, all conditions precedent under the subscription agreements were satisfied and the subscriptions were completed in full. The total amount of funds raised by TOT BIOPHARM from such share subscriptions amounted to HKD472.5 million (approximately RMB405.8 million). This transaction marked another major milestone in the development of TOT BIOPHARM, which will help the Company to strengthen its strategic synergy with industry partners, foster its advantages on resources, and enhance the commercialization capability and comprehensive competitiveness of its product lines.

II. BUSINESS HIGHLIGHTS AND PROGRESS

1. Updates on Key Product Pipelines

During the first half of 2022, TOT BIOPHARM continued to push forward its strategic upgrade, and actively carried out the Phase III clinical trial of its self-developed ADC drug TAA013 (an ADC composed of a recombinant humanized anti-HER2 mAb covalently linked to the microtubule inhibitor DM1 through linker SMCC). Patient enrollment for the Phase III clinical trial of TAA013 has been completed, and is currently undergoing follow-up interviews with the subjects. As for the market cooperation in respect of TAA013, the Company's business team has been actively seeking domestic and overseas cooperation opportunities, and will submit EMA consultation paper.

Management discussion and analysis

In respect of research and development of new drugs, the Company is actively leveraging on the technical advantages of the ADC platform to promote the pre-clinical development of TAE020, an ADC candidate with new target. The development of TAC020, a new target antibody drug jointly developed with HBM Holdings Limited (和铂醫藥控股有限公司) (2142.HK), is progressing smoothly.

On 10 March 2022, TOT BIOPHARM entered into a supplemental agreement with Zhaoke (Guangzhou) Ophthalmology Pharmaceutical Limited (兆科(廣州)眼科藥物有限公司) ("Zhaoke Guangzhou"), a wholly-owned subsidiary of Zhaoke Ophthalmology Limited (兆科眼科有限公司) (6622.HK), in respect of the license for commercialization of TAB014 (which is used for the treatment of wet (neovascular) age-related macular degeneration, "wAMD"), pursuant to which Zhaoke Guangzhou will act as the

marketing authorization holder (MAH) of TAB014 in China (including Hong Kong and Macau regions). In June 2022, the enrollment of the first patient for the Phase III clinical trial of TAB014 was completed successfully. TOT BIOPHARM will continue to be responsible for the supply of products during the clinical trial and the commercialized production in the future when it launches.

TAB014 is the first recombinant humanized anti-vascular endothelial growth factor (VEGF) mAb to enter clinical stage in China for the treatment of wAMD. wAMD is a leading cause of vision impairment and blindness in China and worldwide for people over 50 years old. According to China Insights Consultancy (CIC), the market for wAMD drugs in China is expected to increase to US\$3.5 billion by 2030. TOT BIOPHARM will continue to seek well-established partners to bring TAB014 to overseas markets.

The main product pipelines of the Company:

Type	Drug Candidate	Indication(s)	Preclinical	Clinical Phase I	Clinical Phase II	Clinical Phase III	NDA	Launched
Launched	TAB008 (anti-VEGF)	Advanced, metastatic or recurrent non-squamous non-small cell lung cancer (nsNSCLC); metastatic colorectal cancer (mCRC); recurrent glioblastoma multiforme (GBM); epithelial ovarian cancer (OC); fallopian tube cancer or primary peritoneal cancer; cervical cancer (CC); hepatocellular carcinoma (HCC)						
	TOZ309 (temozolomide)	Malignant brain tumor						
Antibody drug conjugate	TAA013 (anti-HER2)	HER2+ breast cancer						
	TAE020 (new target)	Acute myeloid leukemia						
Monoclonal antibody/Recombinant protein	TAB014 (anti-VEGF)	Wet age-related macular degeneration (wAMD)						
	TAC020 (new target)	Various solid tumors						

Cautionary statement required by Rule 18A.05 of the Listing Rules: The Company cannot guarantee that it will be able to successfully develop and ultimately market TAA013 and other drug candidates. Shareholders and potential investors of the Company are advised to exercise due care when dealing in the securities of the Company.

Management discussion and analysis

2. Marketing Strategy of Launched Products

At present, TOT BIOPHARM has three products approved for launch: TAB008 (Pusintin® – Bevacizumab injection), TOZ309 (Tazian® – Temozolomide capsule) and TOM218 (Megaxia® – Megestrol acetate oral suspension). The Company accelerated the expansion of the market channels of products through market promotion and commercialization licensing cooperation. In the first half of 2022, sales revenue amounted to RMB104 million, which was mainly contributed by the core product Pusintin®.



Pusintin®

- **Pusintin® (Bevacizumab injection)**
Pusintin® is TOT BIOPHARM's first antibody drug approved for marketing. We have been actively expanding its market channels and continuously increasing brand marketing efforts since it was approved for launch by the NMPA on 30 November 2021. Its well-established brand image and efficient operation mechanism were highly recognized by the market, and are in line with market expectations. At the

same time, the Company has applied by way of extrapolation for all indications of the originator drug approved in mainland China pursuant to the "Technical Guidelines for Similarity Evaluation and Indication Extrapolation of Biosimilars" (《生物类似药相似性评价和适应症外推技术指导原则》) issued by the Center for Drug Evaluation of the NMPA and Pusintin® has been approved for all six indications, including advanced, metastatic or recurrent non-squamous non-small cell lung cancer (nsNSCLC) and metastatic colorectal cancer (mCRC). Among these six indications, three indications, namely recurrent glioblastoma multiforme; epithelial ovarian cancer, fallopian tube cancer or primary peritoneal cancer; and cervical cancer, were approved on 3 March 2022, while the indication of hepatocellular carcinoma was approved on 29 March 2022. The approval of new indications has further expanded the market potential of Pusintin®, enhanced the accessibility of the drug, and provided high-quality treatment options with same efficacy of the originator drug to more cancer patients. At present, bevacizumab injection has been included in the National Reimbursement Drug List. It is anticipated that bevacizumab will become a next RMB10 billion drug in the Chinese market and its market size is expected to reach approximately RMB6 billion in 2022, indicating promising market prospects.

Management discussion and analysis

In respect of the domestic market, TOT BIOPHARM has entered into an exclusive promotion service agreement with Jiangxi Jixin Pharmaceutical Co., Ltd. (江西濟鑫醫藥有限公司) (“Jixin Pharmaceutical”), a wholly-owned subsidiary of Jiangxi Jimin Kexin Pharmaceutical Industry Investment Co., Ltd. (江西濟民可信醫藥產業投資有限公司) (“Jimin Kexin Pharmaceutical”), for the marketing of Pusintin® in mainland China. Leveraging on Jimin Kexin Pharmaceutical’s strong marketing network and extensive promotion experience, Pusintin®’s market channels have expanded rapidly. In the first half of 2022, with the close cooperation of both parties, the sales network of Pusintin® covered all provinces and autonomous regions across China other than the Tibet Autonomous Region. Through comprehensive market analysis and differentiated marketing strategies, the Company has developed and tapped into potential markets and key prefecture-level cities with concentrated patient groups, and has achieved remarkable results in second and third-tier cities and provincial markets that adopt dual-channel pharmacy. We have also gradually penetrated into third and fourth-tier cities and county-level cities, thereby greatly enhancing the drug accessibility for cancer patients. In addition, TOT BIOPHARM has provided high-quality and efficient market supply through its large-scale commercial production platform and professional logistic channels, which can meet the increasing market demand of Pusintin® and benefit cancer patients.

In respect of overseas markets, on 11 January 2022, TOT BIOPHARM entered into license cooperation with Kexing Biopharm Co., Ltd. (科興生物製藥股份有限公司) (688136.SH) (“Kexing Biopharm”) for the commercial licensing of Pusintin® in overseas markets. Through this cooperation, TOT BIOPHARM will join hands with Kexing Biopharm to introduce Pusintin® to international markets, expand its market presence in emerging countries, and provide cancer patients in emerging countries with high-quality and affordable drugs. As of the first half of 2022, through the good cooperation between the parties, the parties have reached preliminary cooperation intentions with more than ten countries and have completed the collection and collation of registration application materials in several countries. We will initiate the project data submission process in the second half of the year.



Tazian®

- *Tazian® (Temozolomide capsule)*
Tazian® was approved for launch by the NMPA on 31 May 2021 for the treatment of newly diagnosed glioblastoma multiforme, which is used initially together with radiotherapy, and then as maintenance therapy for the treatment of glioblastoma multiforme or anaplastic astrocytoma that recurs or progresses after conventional treatment. Temozolomide capsules were included in the fourth batch of national centralized procurement catalogue in 2021.

Management discussion and analysis

In the first half of 2022, the Company was selected as the supplier in the renewal of centralized procurement by the Thirteen Allied Provinces, Jiangsu Province and Hebei Province, which helped us to tap into the sales markets. Meanwhile, the Company has entered into marketing cooperation with Jixin Pharmaceutical in China to expand its market share through various and flexible marketing strategies to expand in the non-centralized procurement market channels.



Megaxia®

- **Megaxia® (Megestrol acetate oral suspension)**
Megaxia®, a product for which the Company is an import agent, was approved for launch by the NMPA on 13 May 2021 for the treatment of anorexia associated with acquired immunodeficiency syndrome (“AIDS”) as well as significant weight loss of AIDS and cancer patients caused by cachexia. This product was imported from TWi Pharmaceuticals, Inc. (安成國際藥業股份有限公司) with a specification of 125 mg/mL (150 mL/bottle). The Company owns the exclusive agency rights of this product in mainland China, Hong Kong and Macau.

In March 2022, TOT BIOPHARM reached an agreement with Frontier Biotechnologies Inc. (前沿生物藥業(南京)股份有限公司) (688221.SH) (“Frontier Biotechnologies”) in respect of marketing in mainland China, pursuant to which TOT BIOPHARM granted Frontier Biotechnologies the marketing promotion license of Megaxia® in the field of AIDS. This cooperation represents a powerful combination of both parties’ advantages in products and channels. Frontier Biotechnologies is a leading domestic company in the field of innovative antiviral drugs and has established the most extensive and in-depth marketing system covering medical institutions in the field of domestic AIDS prevention and treatment in mainland China. This marketing cooperation will enhance the accessibility of the drug, actively contribute to the treatment of AIDS cachexia and improve patients’ quality of life.

3. Internationally Competitive ADC Industry Chain Platform

Known as the “magic bullet”, ADC has already undergone many times of technical iterations and generated good clinical data, and the industry has attached great attention to it. ADC has emerged as a new force for the treatment of oncology. According to the market forecast of the Nature research journal, the global ADC drug market will reach USD16.4 billion by 2026. As of June 2022, 14 ADC drugs have been approved for launch worldwide, and 4 products have been approved for launch in mainland China, with most of them being imported. Among them, TAA013, a self-developed ADC drug by TOT BIOPHARM, is in the Phase III clinical study stage and has attracted close attention from the market.

Management discussion and analysis

– *Industry-leading ADC one-stop industrialization platform*

In 2020, as our ADC product TAA013 entered into Phase III clinical trial, TOT BIOPHARM set up a commercial production platform for ADC at its headquarters in Suzhou Industrial Park, thereby building a complete industrial platform that covers drug research and development, pilot test process, clinical production through commercial production. The Company has already built a complete GMP-compliant ADC commercialization production workshop that can produce ADC naked antibodies, drug substances and drug products, which is scarce in mainland China. The workshop is equipped with OBE-5 grade isolators, enjoys advanced coupling core technology and ADC analysis technology advantages, and has high standard quality management system and GMP-compliant commercialization capability. In addition, TOT BIOPHARM is actively constructing its ADC commercial capacity, with a designed annual production capacity of ADC pilot and commercial production workshop of 60,000g, where all key production processes of ADC can be completed within the same production base, thus fulfilling the need for different production scales for small trials, pilot tests and commercialization. Apart from having flexible and diverse production capacity, the production platform also makes supply chain management and risk management and control easier, resulting in better control over time, cost and risks.



ADC Production Facility

– *A quality management system that meets domestic and international compliance requirements*

TOT BIOPHARM has established a complete ADC analysis technology platform through self-developed products. It enjoys technological advantages of core coupling process and amplification, has the ability to independently evaluate and analyze the key quality attributes of ADC, and has established a comprehensive quality assurance system in compliance with NMPA, FDA and EMA regulations, thus ensuring high-quality production and control of products. At the same time, in order to further strengthen our competitive advantages in the ADC field, we have established a single quality system for the development of the mAb process and the coupling process of ADC drugs. It is equipped with a stable platform that spans from coupling process development to mass production, covering drug development of more than 10 different ADC technologies including process optimization and product quality control, and employs mature production technology incorporating the production experience of 9 ADC projects, including Phase I and Phase III clinical projects.



Quality Control GMP Laboratory

Management discussion and analysis

– *Full-process technical team with extensive experience*

TOT BIOPHARM has a complete team covering the whole process from process research and development, clinical production, registration and approval application to commercial production, as well as ADC coupling process technology research and development experts and an ADC complex molecular structure analysis team. So far, more than ten clinical production projects with drug process development involving different ADC technologies and at different stages (including pre-market process validation) have been completed, and extensive practical experience has been accumulated.

III. COMMERCIAL PRODUCTION AND CONSTRUCTION OF GLOBAL RESEARCH AND DEVELOPMENT CENTER

1. Commercial Production Bases and Construction Projects

TOT BIOPHARM has established an internationally competitive biopharmaceutical commercial production base equipped with advanced production facilities and a quality management system that meets domestic and international standards. The production scale of mAb drug substances has reached 20,000L, and multi-

batch commercial production of bevacizumab injection (Pusintin®) products has been successfully carried out, with a product qualification rate of 100%. With its key ADC commercialized production platform, the Company has become a leading enterprise in the industry and has been highly recognized by industrial partners. TOT BIOPHARM has a GMP-compliant complete ADC commercial production platform which is scarce in China that integrates ADC naked antibodies, drug substances and drug products, which can realize the whole product completion process in one production base. At present, we have successfully completed the commercial-scale production of multiple projects at different stages from Phase I to Phase III clinical stages. Our well-established technical team, advanced processes, comprehensive production facilities and well-established assurance system serve as a guarantee for the high quality of products.

In the first half of 2022, TOT BIOPHARM continued to expand its commercial production capacity, improve the comprehensive capabilities of its ADC commercial production platform, and successfully completed the renovation of its ADC pilot production workshop. At the same time, it actively promoted the construction of the second ADC drug products commercial production line and ADC drug substances pilot production line.



Cell Culture Room



Purification Room

Management discussion and analysis

In 2022, the Company's production capacity by category as well as the particulars of construction in progress and production lines are as follows:

mAb drug substances production (mAb DS)	
Workshops for mAb drug substances	<ul style="list-style-type: none"> • Gained GMP certification by NMPA • Production capacity reached 20,000L for different scales of mAb drug substances production, such as commercialization projects, pilot tests and small trials • International leading brand of disposable bioreactors with flexible and continuous production capability
mAb drug products production (mAb DP)	
Workshops for mAb commercialization drug products	<ul style="list-style-type: none"> • Gained GMP certification by NMPA, which can meet the commercial production of self-developed products and the production of CDMO products • International leading brand of automatic filling injection production line
Workshops for mAb pilot drug products <i>(Planned for production in the first half of 2023)</i>	<ul style="list-style-type: none"> • International leading brand of isolator filling linkage production line, which can meet the needs of different specifications of products • Equipped with a 6-DOF clean and sterile robot arm which enjoys enormous advantages of supplementary filling in case of insufficient filling, supplementary provision of rubber stoppers and aluminum caps, minimized tailing loss, high yield and convenient replacement of specifications • Independent design of automatic filling line, automatic feeding and discharging as well as capping, which can realize freeze-drying, injection switching and continuous production, and maximize the utilization of production capacity
ADC drug substances production (ADC DS)	
Workshops for ADC commercialization drug substances	<ul style="list-style-type: none"> • Up to 500L ADC drug substances production scale • Completed clinical production and process validation of multiple batches of ADC drugs, which are compliant with GMP standards and meet flexible and diverse commercial production needs
Workshops for ADC pilot drug substances <i>(Planned for production in the second half of 2022)</i>	<ul style="list-style-type: none"> • Equipped with ADC drug substances production facilities of 100L, 200L, 500L and other scales • GMP standard compliant and with commercialization capability
ADC drug products production (ADC DP)	
Workshops for ADC commercialization drug products <i>(Planned for production in the first half of 2023)</i>	<ul style="list-style-type: none"> • The international leading brand of high-activity isolator filling linkage production line • Specially designed for the production of scarce high-activity products to ensure aseptic production while meeting the needs of personnel safety protection • Independent design of automatic filling line, automatic feeding and discharging as well as capping, which can realize freeze-drying, injection switching and continuous production, and maximize production capacity
Workshops for ADC pilot drug products	<ul style="list-style-type: none"> • High-activity isolator filling linkage production line, which has successfully completed clinical production and process validation of multiple batches in multiple ADC projects
Small molecule drug production	
Workshops for oral solid drug products	<ul style="list-style-type: none"> • Equipped with commercial production capacity for tablet and capsule drug products • Completed clinical production and process validation of multiple batches in CDMO projects • Gained GMP certification from NMPA regarding the commercial production of self-developed products • Equipped with an independent OEB-5 production line for highly active cytotoxic products

Management discussion and analysis

2. Construction of Global Research and Development Center

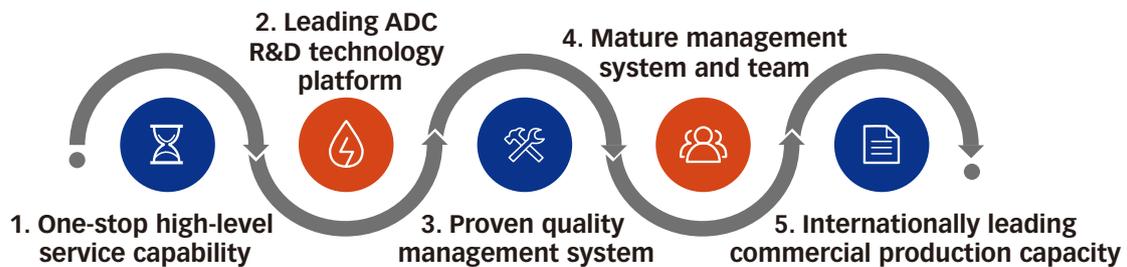
In order to further strengthen its technological advantages in the R&D of innovative drugs, TOT BIOPHARM actively promoted the construction of its Global Research and Development Center. The main building is expected to be completed in 2023, with a gross floor area of 25,000 m² and will house divisions such as early R&D, process development, quality research and head office. The core R&D experimental zone will be able to hold 280 to 300 R&D staff members and simultaneously handle the research, process development and other tasks in relation to multiple mAb drugs, ADC drugs, oncolytic virus drugs and special small molecule oncology drugs, and will be seamlessly connected with the production zone. In addition, placing R&D and production under one roof will facilitate the synergic efficiency for the whole drug development process, thereby enhancing the R&D efficiency and cost advantages.

between 2021 and 2025, and China’s overall CDMO/CMO market revenue is expected to be RMB123.5 billion in 2025. Specifically, the biological drug CDMO/CMO business will grow at a CAGR of 36.7% between 2021 and 2025. TOT BIOPHARM actively seized the opportunities of the rapid development of China’s pharmaceutical industry, accelerated its transformation and upgrade, and actively expanded its CDMO business, demonstrating strong and sustainable development potential. As of the first half of 2022, revenue from the Company’s CDMO business amounted to RMB22.66 million, representing a year-on-year increase of 94%. In terms of the number and types of projects, there were 23 collaborative projects in the first half of the year, including 8 ADC projects, 10 antibody projects and 5 chemical drug and other projects. In terms of project phases, they covered projects of different stages including pre-clinical, IND, Phase I clinical, Phase II clinical and Phase III clinical, of which the majority was 19 projects in the IND stage, including 16 projects for both NMPA and FDA, 2 projects for FDA, and 1 project for EMA. With the continuous expansion of the CDMO market potential, TOT BIOPHARM will provide more customers with high-level one-stop CDMO services and build a world-class CDMO service brand by drawing upon its accumulated experience in various stages from product R&D to commercial production.

IV. DEVELOPMENT AND COMPETITIVE ADVANTAGES OF CDMO BUSINESS

With the booming development of CDMO/CMO business, market demand is rapidly increasing in China. According to Frost & Sullivan, China’s CDMO/CMO market revenue will grow at a CAGR of 30.0%

Competitive Advantages of TOT BIOPHARM’s CDMO/CMO Business:



Management discussion and analysis

1. Competitive Advantages of CDMO/CMO Business

(1) *One-stop high-level service capability*

TOT BIOPHARM is committed to becoming a professional partner for customers in the global innovative drug field. Through its open technology platform and industry-leading commercial production capabilities, the Company provides “one-stop, one-base” CDMO services to its partners and customers. TOT BIOPHARM enjoys a great industrial location advantage. It can realize all the stages from R&D to finished product manufacturing in its Suzhou Industrial Park headquarters, which greatly decreases the risks and costs of transfer in terms of project management and transportation. At the same time, relying on its rich project experience, the Company can customize precise solutions according to the different needs of customers. Through its sound technology transfer process, high-standard GMP production platform, well-established GMP quality system, experienced regulatory support as well as mature and stable technical team, the Company is capable of completing projects with high quality and high efficiency.

(2) *Leading ADC R&D technology platform*

Based on the domestic R&D and industrialization platform which is scarce in China that integrates mAb and ADC, TOT BIOPHARM enjoys the advantages of advanced coupling core technology and ADC analysis technology, and has high-standard quality management system and GMP standard compliant commercialization capabilities, which empowers ADC drug development.

TOT BIOPHARM has a complete team covering the whole process from process research and development, clinical production, registration and approval application to commercial production. So far, the team has completed more than ten drugs which employ different ADC technologies, including pre-clinical to Phase I, II and III clinical R&D and production projects, and pre-commercial production projects with pre-market process validation, thereby accumulating rich practical experience. The team is capable of providing high-quality and cost-effective system solutions for the R&D and production of ADC drugs, and providing partners with reliable CDMO services in the ADC field.

(3) *Proven quality management system*

“Zero Tolerance for Quality Defects” has always been the quality standard of TOT BIOPHARM, and high quality assurance is crucial to drug development. We have continuously improved and upgraded our quality management system. According to the requirements of NMPA, FDA and EMA regulations and guidelines, as well as lifecycle management requirements of ICH Q8, Q9, Q10 drug quality system, we have established a key quality management system spanning from research and development to commercialization, and have traceable records and successful project experiences. The entire team can provide customers with comprehensive regulatory support and quality management services during the entire lifecycle of product development, registration application (clinical trial & marketing) and post-marketing, and has extensive experience in project registration application and regulatory communication. To date, the team has completed more than 10 domestic and overseas registration application projects, including domestic and overseas IND applications and ANDA/NDA applications.

Management discussion and analysis

The Company's chemical drug capsule drug products production workshops and mAb drug substances and drug products production workshops have been completed and have passed the national drug registration production site inspection and GMP compliance inspection, indicating that TOT BIOPHARM's quality management system has been approved by the national drug regulatory authority.

At the same time, on the basis of the improvement and standardized management of the Company's quality management system, we make full use of data management tools to greatly improve electronic system management and ensure the completeness, truthfulness and traceability of data. We also continuously enhance our quality management capabilities to ensure that our product quality meets international standards.

(4) CDMO management system and team

The Company has set up a professional CDMO management system to carry out independent project management and performance management to ensure the safety, compliance and orderly progress of each project, and has established a good communication mechanism with customers. Our professional and considerate services have won customers' recognition. In addition, as a company listed in Hong Kong, TOT BIOPHARM attaches great importance to IP protection and strictly abides by relevant regulations. Our CDMO services rely on technological optimization to promote process development, which enables customers to benefit from the experience of process development.

The CDMO core technology team of TOT BIOPHARM has extensive industry experience in biopharmaceutical process development, commercial production, quality and compliance, and regulatory filing. The senior management of the Company has extensive management experience in well-known multinational pharmaceutical companies. At the same time, the Company continues to introduce high-caliber talents, with approximately 22.3% of the CDMO team being holders of master or doctoral degrees, which ensure the smooth and efficient progress of customers' projects.

(5) World-class commercial production capacity

The Company has developed its business in Suzhou for more than a decade, and has already built a large-scale biopharmaceutical production base that complies with GMP standards and employs production equipment that meets high international standards. The production base is designed for flexible production and has sufficient capacity to meet the demand of different scales of production for small trials, pilot tests and commercialization. In response to the development and changes of the industry, TOT BIOPHARM has made the most of its competitive advantages and actively expanded its CDMO business, aiming to lay a solid foundation for the Company's long-term development and create diversified income. The continuous expansion of commercial production capacity has laid a solid foundation for the commercial production of our self-developed products and CDMO business development.



mAb and ADC Drug Production Base that Meets International Standards

Management discussion and analysis

2. Strategic Cooperation of CDMO/CMO Business

TOT BIOPHARM has firmly grasped market opportunities, with its business covering diversified needs for various products including chemical drugs, mAb drugs and ADC drugs. The Company joins hands with industry partners to accelerate the research and development of innovative drugs so as to satisfy patients' drug accessibility needs. So far, the Company has undertaken different project orders from pharmaceutical companies and R&D biotechnology companies, and has received positive feedback and secured repeat orders from customers. In addition, leveraging on our geographical advantage, we have accelerated the expansion of new customer resources and demonstrated our competitive advantages, and have ushered in a new era whereby our business continued to grow and was highly recognized by investors and partners. In January 2022, TOT BIOPHARM signed a CDMO strategic cooperation agreement with Jiangxi Jemincare Group Co., Ltd. (江西濟民可信集團有限公司) to provide one-stop services that covers drug R&D through commercial production.



Strategic CDMO Cooperation with Jiangxi Jemincare Group Co., Ltd.

V. COMMUNICATION WITHIN THE INDUSTRY

Through fostering closer connections with industry partners with the help of digital information and communication, TOT BIOPHARM has continuously enhanced its reputation and brand image. During the first half of the year, we launched a brand new creative interactive campaign to strengthen the Company's external digital brand-communication by donating books through our WeChat official account. The campaign enabled all participants to learn more about TOT BIOPHARM through reading and sharing. In addition, as a leading enterprise in the ADC field, TOT BIOPHARM actively interacted and communicated with its industrial partners to promote the Company's strategy, latest business developments and corporate culture through online channels.

On 30 March 2022, TOT BIOPHARM set up a digital virtual booth at the "2022 New Biopharmaceutical Advanced Technology Summit" (2022新型生物藥先進技術峰會) and has shared our strategies for and the challenges in ADC drug development by way of cloud-based exhibition. On 19 May 2022, Dr. Liu, Jun, CEO of TOT BIOPHARM, was invited to participate in the Enmore Cloud Summit (易貿雲峰會) as guest of honor to share with other guests the market prospects and development model of the ADC pharmaceutical industry.

VI. USE OF FUNDS AND FINANCING

On 31 May 2022, TOT BIOPHARM entered into share subscription agreements with Vivo Suzhou Fund and Centerlab. Pursuant to the subscription agreements, Vivo Suzhou Fund and Centerlab would subscribe for 116,250,000 and 33,750,000 shares of TOT BIOPHARM respectively, at the subscription price of HKD3.15 per share. The aggregate of 150,000,000 shares represented approximately 24.38% of the issued share capital of the Company as at the date of the announcement of the subscriptions. Such subscription price represented a premium of approximately 4.79% over the average closing price of the five trading days prior to the date of the subscription agreements. On 29 July 2022, all conditions precedent under each of the subscription agreements were satisfied and the subscriptions were completed in full. After completion of the subscriptions, Vivo Capital LLC and Centerlab have a shareholding of approximately 28.68% and 28.66%, respectively. The funds raised are intended to be primarily used for: the further expansion of the CDMO business and strengthening project-based collaboration with domestic and foreign pharmaceutical companies; the on-going construction of the Global Research and Development Center and upgrade of our ADC commercial production capacity so as to improve cost-effectiveness; completion of Phase III clinical trial of TAA013 as well as ongoing pre-clinical and clinical trials of TAE020, TAC020 and other drug candidates; and the commercial production, marketing and sales activities of Pusintin®, Tazian® and Megaxia®. Such funds will improve the Company's liquidity without incurring additional interest burden, enlarge the Company's capital base, optimize the Company's capital structure and provide support for the Company's long-term development, while at the same time demonstrating the confidence and continuous support for the Group's development from our two largest shareholders.

VII. RESPONSE TO COVID-19 OUTBREAKS AND SUSTAINABLE DEVELOPMENT

In the first half of the year, while responding to a series of pandemic prevention and control tasks carried out by the government, TOT BIOPHARM formulated a number of management policies and contingency plans. While strictly implementing the pandemic prevention measures, the Company overcame a string of difficulties including tight schedules, heavy workload and logistical disruptions, actively maintained its production lines and stabilized its production capacity to ensure meeting market demand for the Company's products and services. As such, we were highly recognized by our customers and industrial partners. Up to now, all operational projects of the Company have been progressing in an orderly manner, and the impact of the COVID-19 outbreaks on the Company has been minimized.

In order to further improve the standard of corporate governance, on the basis of the Strategy and ESG (Environmental, Social and Governance) Committee, TOT BIOPHARM has conducted a thorough study and review on the internal and external environments relating to the Company, and formulated reasonable and normalized working mechanisms and goals in line with the actual development of the Company, so as to incorporate ESG concepts into all aspects of the Company's operations, thereby effectively improving the standard of corporate governance and enhancing the sustainable development capabilities of the Company.

VIII. PROSPECTS

Looking into the second half of 2022, with the impact of COVID-19 easing off, there is a positive future development trend in the economic environment. TOT BIOPHARM will deploy various resources to boost the development of its key businesses.

The Company will actively promote the Phase III clinical data analysis and marketing approval process of TAA013, and expedite the marketing planning for Pusintin® and Tazian® with an aim to continuously increase the market share of its products and generate stable cash flow for the Company. We will also deepen our communication with CDMO partners and keep on exploring new customer groups so as to rapidly grow the scale of our CDMO business and strengthen the Company's cash generating capabilities. In addition, the Company will accelerate the upgrade of its ADC commercial production capacity, promote the construction of its Global Research and Development Center, and cooperate with leading industrial partners to take advantage of each other's resources and enjoy synergies. Based on its long-term strategic needs, TOT BIOPHARM will continue to optimize its capital structure, and support the strategic transformation of the Company and the leapfrog development of its CDMO business through diversified financing and strategic cooperation.

Looking ahead, we will capitalize on our strengths, focus on our main businesses, accelerate our internationalization, improve our management standards, strengthen our cooperation with industry partners and show more care to our employees. We believe that our core competitiveness will continue to be strengthened and our ability to create greater value for our shareholders will be further enhanced.



FINANCIAL REVIEW

OVERVIEW

For the first half of 2022, the Group recorded an operating revenue of RMB182,019 thousand, representing an increase of RMB158,887 thousand, or 687%, from RMB23,132 thousand for the same period in 2021. For the first half of 2022, the net loss of the Group was RMB15,724 thousand, representing a decrease of RMB99,281 thousand, or 86%, from the net loss of RMB115,005 thousand for the same period in 2021. The Group's research and development expenses for the first half of 2022 were RMB70,268 thousand, as compared to RMB88,749 thousand for the same period in 2021. The Group's general and administrative expenses for the first half of 2022 were RMB25,698 thousand, as compared to RMB26,823 thousand for the same period in 2021. The Group's selling expenses for the first half of 2022 were RMB70,091 thousand, as compared to RMB11,202 thousand for the same period in 2021.

OPERATING REVENUE AND COSTS

The Group's diversified revenue mainly includes sales revenue, revenue for providing CDMO and CMO services, revenue from licenses granted, etc.

The Group's sales revenue for the first half of 2022 was RMB104,170 thousand, which was mainly due to the steady increase in the sales volume of our core product, Pusintin[®], while the corresponding costs also increased accordingly.

The Group's revenue from CDMO and CMO for the first half of 2022 was RMB22,657 thousand, representing an increase of RMB10,989 thousand, or 94%, from RMB11,668 thousand for the same period in 2021, primarily attributable to the new orders brought about by the strategic expansion of the CDMO and CMO business segments during the current period, while the corresponding materials, labor and manufacturing expenses, etc. also increased accordingly.

The Group's revenue from licenses granted for the first half of 2022 was RMB49,434 thousand, which represented the milestone payments received in connection with the Group's projects.

RESEARCH AND DEVELOPMENT EXPENSES

The Group's research and development expenses primarily consist of expenses for clinical trials, research and development materials and consumables, salaries and benefits for research and development staff, depreciation and amortization, and third-party contracting costs for clinical and non-clinical research, etc.

The Group's research and development expenses for the first half of 2022 were RMB70,268 thousand, representing a decrease of RMB18,481 thousand from RMB88,749 thousand for the same period in 2021, which was mainly attributable to the reduction of raw material procurement as a result of the completion of patient enrollment for the TAA013 project, and the optimization of product pipelines that resulted in a convergence of research and development resources.

SELLING EXPENSES

The Group's selling expenses primarily consist of expenses for marketing and promotion activities, salaries and benefits for marketing staff, conference fees, and travelling expenses, etc.

The Group's selling expenses for the first half of 2022 were RMB70,091 thousand, representing an increase of RMB58,889 thousand from RMB11,202 thousand for the same period in 2021, which was mainly due to the increase in sales of self-developed products and the increase in marketing and promotion expenses resulting therefrom.

GENERAL AND ADMINISTRATIVE EXPENSES

The Group's general and administrative expenses primarily consist of salaries and benefits for management and administrative staff and expenses for professional services related to legal advisory as well as audit and tax, etc.

The Group's general and administrative expenses for the first half of 2022 were RMB25,698 thousand, representing a decrease of RMB1,125 thousand from RMB26,823 thousand for the same period in 2021.

Financial review

FINANCE INCOME

The Group’s finance income is primarily interest income on bank deposits. The finance income for the first half of 2022 was RMB415 thousand, representing a decrease of RMB299 thousand from RMB714 thousand for the same period in 2021, which was mainly due to the increase in operating activities.

FINANCE COSTS

The Group’s finance costs are primarily interest expenses on bank borrowings for satisfying operational needs and capital expenditures for capacity enhancement, etc.

The Group’s interest expenses on bank borrowings for the first half of 2022 were RMB3,418 thousand, representing an increase of RMB3,144 thousand from RMB274 thousand for the same period in 2021, mainly attributable to the increase in interest expenses as a result of the Group’s banking facilities being utilized since mid-2021.

INCOME TAX EXPENSE

For the first half of 2022 and the same period in 2021, the Group did not incur any income tax expense because the Group had not generated any taxable income during the two periods.

LOSS FOR THE PERIOD

In view of the abovementioned factors, the Group recorded a net loss of RMB15,724 thousand for the first half of 2022, representing a significant decrease of RMB99,281 thousand from RMB115,005 thousand for the same period in 2021.

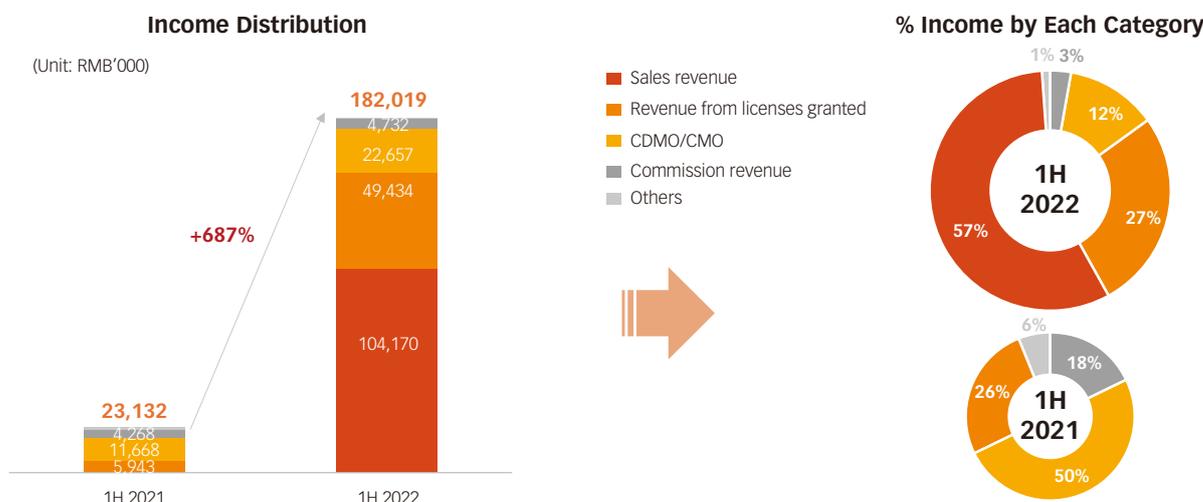
NET ASSETS

The Group’s net assets as at 30 June 2022 were RMB328,168 thousand, representing a decrease of RMB6,923 thousand from RMB335,091 thousand as at the end of 2021, which was mainly attributable to the net loss during the current period.

CASH MOVEMENT AND SOURCE OF FUNDS

As at 30 June 2022, the Group’s cash and cash equivalents were RMB154,876 thousand, representing an increase of RMB2,071 thousand from RMB152,805 thousand as at the end of 2021. Such change was mainly attributable to the cash outflows and inflows related to operating loss, capital expenditures, and taking out bank borrowings, etc.

During the first half of 2022, the Group’s net cash inflows for operating activities were RMB24,241 thousand, while the net cash outflows for the same period in 2021 were RMB93,624 thousand, which was mainly due to the significant increase in sales revenue during the current period. The Group’s net cash outflows for investing activities for the current period were RMB63,411 thousand, representing an increase of RMB7,901 thousand from RMB55,510 thousand for the same period in 2021, which was mainly attributable to capital investment for enhancing production capacity and the increase in investment in joint ventures. The Group’s net cash inflows for financing activities were RMB37,994 thousand, representing a decrease of RMB42,943 thousand from RMB80,937 thousand for the same period in 2021, which was mainly attributable to the repayment of bank borrowings during the current period.



Financial review

INDEBTEDNESS AND KEY LIQUIDITY RATIO

As at 30 June 2022, the Group had outstanding bank borrowings that amounted to RMB244,775 thousand (31 December 2021: RMB205,966 thousand) and had unutilised bank facilities of RMB140,225 thousand (31 December 2021: RMB120,225 thousand). For further details, please refer to note 12 to the interim condensed consolidated financial information.

As at 30 June 2022, the Group's total liabilities to total assets ratio was 0.6 (31 December 2021: 0.5). The increase was mainly attributable to the increase in prepayments brought by the growth of product sales and CDMO business of the Group.

MAJOR INVESTMENT

On 9 November 2021, the Group commenced the construction of its global R&D center. The proposed total investment for the project is approximately RMB180 million. On 31 December 2021, TOT Suzhou (a wholly-owned subsidiary of the Company) entered into a construction agreement with Shanghai Baoye Group Corp., Ltd. (上海寶冶集團有限公司), under which the total contract sum payable to Shanghai Baoye Group Corp., Ltd. is RMB83,500,000.14. Further details are set out in the announcement of the Company dated 31 December 2021. During the six months ended 30 June 2022, the Group incurred expenditure of RMB19,722,700.03 in connection with the construction agreement entered into with Shanghai Baoye Group Corp., Ltd. and RMB23,387,979.47 in total in connection with the construction of the global R&D center.

In 2021, the Group also commenced the project of upgrading its ADC formulations production workshop for the purpose of increasing its production capacity as well as enhancing its production efficiency. A total of RMB72,571,013.98 was incurred by the Group during the six months ended 30 June 2022 in connection with the project of upgrading its ADC formulations production workshop.

Save as disclosed above, the Group did not make any major investment during the six months ended 30 June 2022.

MAJOR ACQUISITIONS AND DISPOSALS

During the first half of 2022, the Group did not have any major acquisitions and disposals of subsidiaries, consolidated affiliated entity or associates.

PLEDGE OF ASSETS

As at 30 June 2022, the Group had no pledge of assets.

CONTINGENT LIABILITIES

As at 30 June 2022, the Group had no significant contingent liabilities.

FOREIGN EXCHANGE RISK

Certain bank balances and cash, trade receivables and other receivables, contract assets and other payables are denominated in foreign currencies of respective group entities which are exposed to foreign exchange risk. Foreign exchange risk also arises from future commercial transactions and recognized assets and liabilities denominated in a currency other than the functional currency of the relevant group entity. The Group has entities operating in USD, NTD and RMB, and the Group will constantly review the economic situation and its foreign exchange risk profile, and will consider appropriate hedging measures in the future when necessary.

Financial review

EMPLOYEES AND REMUNERATION

As at 30 June 2022, the Group had a total of 355 employees. The following table sets forth the total number of employees by function as of 30 June 2022:

Function	Number of employees	% of total
Research and development	209	58.87%
Sales and marketing	93	26.20%
General and administration	40	11.27%
Manufacturing	13	3.66%
Total	355	100%

In the first half of 2022, the Group incurred employee benefit expenses of RMB60,831 thousand, as compared to RMB65,213 thousand in the first half of 2021. The employee benefit expenses of the Group include salaries, wages, bonuses, contributions to employee provident fund and social security funds, payments for other benefits and share-based compensation expenses, etc. In accordance with applicable PRC laws, the Group has made contributions to social security insurance funds, including basic pension insurance, medical insurance, work-related injury insurance, unemployment insurance and maternity insurance, and housing provident funds for its employees. In accordance with applicable Taiwan laws, the Group has made contributions to social security insurance funds.

INTERIM CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS

	Note	Unaudited Six months ended 30 June	
		2022 RMB'000	2021 RMB'000
Revenue	5	182,019	23,132
Cost of revenue		(23,478)	(9,143)
Research and development expenses		(70,268)	(88,749)
Selling expenses		(70,091)	(11,202)
General and administrative expenses		(25,698)	(26,823)
Net impairment losses on financial assets		(923)	–
Other income		297	–
Other gains/(losses) – net		1,194	(2,660)
Operating loss		(6,948)	(115,445)
Finance income		415	714
Finance costs		(3,418)	(274)
Finance (costs)/income – net		(3,003)	440
Share of net loss of the joint venture accounted for using the equity method		(5,773)	–
Loss before income tax	6	(15,724)	(115,005)
Income tax expense	7	–	–
Loss for the period and attributable to the equity holders of the Company		(15,724)	(115,005)
Other comprehensive income:			
<i>Items that will not be reclassified to profit or loss</i>			
Changes in the fair value of equity instruments at fair value through other comprehensive income		–	747
<i>Items that may be reclassified to profit or loss</i>			
Exchange differences on translation		3,236	(722)
Other comprehensive income for the period, net of tax		3,236	25
Total comprehensive loss for the period and attributable to the equity holders of the Company		(12,488)	(114,980)
Loss per share for the six months ended 30 June and attributable to the equity holders of the Company			
– Basic and diluted loss per share (RMB)	8	(0.03)	(0.20)

The above condensed consolidated statement of profit or loss should be read in conjunction with the accompanying notes.



INTERIM CONDENSED CONSOLIDATED BALANCE SHEET

	Note	Unaudited 30 June 2022 RMB'000	Audited 31 December 2021 RMB'000
ASSETS			
Non-current assets			
Property, plant and equipment	9	354,170	307,668
Prepayments for property, plant and equipment		44,233	55,759
Right-of-use assets	9	15,497	15,733
Investment properties		3,383	3,583
Intangible assets	9	4,859	5,123
Investments accounted for using the equity method		860	1,483
Other non-current assets		14,643	14,951
		437,645	404,300
Current assets			
Inventories		56,822	29,558
Trade and other receivables	10	65,572	15,032
Prepayments		27,937	16,754
Contract assets		18,923	11,952
Cash and cash equivalents		154,876	152,805
Other current assets		50,502	79,862
		374,632	305,963
Total assets		812,277	710,263
EQUITY			
Share capital	11	1,892,906	1,892,906
Other reserves		46,598	37,797
Accumulated losses		(1,611,336)	(1,595,612)
Capital and reserves attributable to the equity holders of the Company		328,168	335,091

Interim condensed consolidated balance sheet

	Note	Unaudited 30 June 2022 RMB'000	Audited 31 December 2021 RMB'000
LIABILITIES			
Non-current liabilities			
Borrowings	12	59,775	59,775
Lease liabilities		737	1,136
Other non-current liabilities		51,125	53,453
		111,637	114,364
Current liabilities			
Borrowings	12	185,000	146,191
Trade and other payables	13	145,362	86,238
Contract liabilities		35,733	22,199
Lease liabilities		1,624	1,463
Other current liabilities		4,753	4,717
		372,472	260,808
Total liabilities		484,109	375,172
Total equity and liabilities		812,277	710,263
Net current assets		2,160	45,155
Total assets less current liabilities		439,805	449,455

The above condensed consolidated balance sheet should be read in conjunction with the accompanying notes.



INTERIM CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

	Unaudited			
	Attributable to equity holders of the Company			
	Share capital	Other reserves	Accumulated losses	Total equity
	RMB'000	RMB'000	RMB'000	RMB'000
Balance at 1 January 2022	1,892,906	37,797	(1,595,612)	335,091
Loss for the period	–	–	(15,724)	(15,724)
Other comprehensive income	–	3,236	–	3,236
Total comprehensive loss	–	3,236	(15,724)	(12,488)
Transactions with owners				
Share-based compensation expense	–	5,565	–	5,565
Total transactions with owners	–	5,565	–	5,565
Balance at 30 June 2022	1,892,906	46,598	(1,611,336)	328,168
Balance at 1 January 2021	1,874,438	49,503	(1,341,584)	582,357
Loss for the period	–	–	(115,005)	(115,005)
Other comprehensive income	–	25	–	25
Total comprehensive loss	–	25	(115,005)	(114,980)
Transactions with owners				
Share-based compensation expense	–	4,011	–	4,011
Issue of shares upon exercise of share options	3,249	(1,259)	–	1,990
Increase in share capital upon receipt of the grant consideration for award shares	15,219	(7,599)	–	7,620
Total transactions with owners	18,468	(4,847)	–	13,621
Balance at 30 June 2021	1,892,906	44,681	(1,456,589)	480,998

The above condensed consolidated statement of changes in equity should be read in conjunction with the accompanying notes.

INTERIM CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS

	Unaudited Six months ended 30 June	
	2022 RMB'000	2021 RMB'000
Cash generated from/(used in) operating activities		
Net cash generated from/(used in) operations	28,437	(94,292)
Interest received	415	714
Interest paid	(4,611)	(46)
Net cash generated from/(used in) operating activities	24,241	(93,624)
Cash flow used in investing activities		
Purchase and prepayment of property, plant and equipment	(57,872)	(55,140)
Purchase of intangible assets	(405)	(384)
Proceeds from disposal of property, plant and equipment	16	14
Cash injection into a joint venture	(5,150)	–
Net cash used in investing activities	(63,411)	(55,510)
Cash flows generated from financing activities		
Proceeds from bank borrowings	100,000	72,175
Repayments of bank borrowings	(61,191)	–
Proceeds from issue of shares upon exercise of share options	–	1,990
Proceeds from receipt of the grant consideration for award shares	–	7,620
Payment of lease liabilities	(815)	(848)
Net cash generated from financing activities	37,994	80,937
Net decrease in cash and cash equivalents	(1,176)	(68,197)
Cash and cash equivalents at beginning of the period	152,805	225,533
Exchange gains/(losses) on cash and cash equivalents	3,247	(1,093)
Cash and cash equivalents at end of the period	154,876	156,243

The above condensed consolidated statement of cash flows should be read in conjunction with the accompanying notes.



NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

1 GENERAL INFORMATION

TOT BIOPHARM International Company Limited (the “Company”) was incorporated in Hong Kong on 4 December 2009 as a company with limited liability under the Hong Kong Law. The address of its registered office is 5/F, Manulife Place, 348 Kwun Tong Road, Kowloon, Hong Kong.

The Company is an investment holding company. The Company and its subsidiaries (together, the “Group”) are principally engaged in research and development (“R&D”), manufacturing, and marketing of anti-tumor drugs in the People’s Republic of China (the “PRC”).

The Company’s shares are listed on the Main Board of The Stock Exchange of Hong Kong Limited (the “Stock Exchange”).

These financial statements are presented in thousands of Renminbi (“RMB’000”), unless otherwise stated. This condensed consolidated interim financial information was approved for issue by the Board of Directors on 12 August 2022.

2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

2.1 Basis of preparation

This condensed consolidated interim financial report for the half-year reporting period ended 30 June 2022 has been prepared in accordance with Accounting Standard HKAS 34 Interim Financial Reporting.

The interim report does not include all the notes of the type normally included in an annual financial report. Accordingly, this report is to be read in conjunction with the annual report for the year ended 31 December 2021 and any public announcements made by the Company during the interim reporting period.

The financial information relating to the year ended 31 December 2021 that is included in the condensed consolidated interim financial information for the six months ended 30 June 2022 as comparative information does not constitute the Company’s statutory annual consolidated financial statements for that year but is derived from those financial statements. Further information relating to these statutory financial statements required to be disclosed in accordance with section 436 of the Hong Kong Companies Ordinance (Cap. 622) is as follows:

The Company has delivered the financial statements for the year ended 31 December 2021 to the Registrar of Companies as required by section 662(3) of, and Part 3 of Schedule 6 to, the Hong Kong Companies Ordinance (Cap. 622).

The accounting policies adopted are consistent with those of the previous financial year and corresponding interim reporting period, except for the adoption of new and amended standards as set out below. Taxes on income in the interim periods are accrued using the tax rate that would be applicable to expected total annual earnings.

Notes to the interim condensed consolidated financial information

2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont'd)**2.1 Basis of preparation** (cont'd)*(a) New and amended standards adopted by the Group*

A number of new or amended standards became applicable for the current reporting period. The Group did not have to change its accounting policies or make retrospective adjustments as a result of adopting these standards.

Standards	Key requirements	Effective for accounting periods beginning on or after
Amendments to HKAS 16	Property, Plant and Equipment: Proceeds before intended use	1 January 2022
Amendments to HKFRS 3	Reference to the Conceptual Framework	1 January 2022
Amendments to HKAS 37	Onerous Contracts – Cost of Fulfilling a Contract	1 January 2022
AG 5 (Revised)	Merger Accounting for Common Control Combinations	1 January 2022
HKFRS 9, HKFRS 16, HKFRS 1 and HKFRS 41	Annual improvements HKFRS Standards 2018-2020	1 January 2022

(b) Impact of standards issued but not yet applied by the Group

Standards and amendments to standards that have been issued but not yet effective and not been early adopted by the Group during the period are as follows:

Standards	Key requirements	Effective for accounting periods beginning on or after
Amendments to HKAS 12	Deferred Tax related to Assets and Liabilities arising from a Single Transaction	1 January 2023
Amendments to HKAS 1	Classification of liabilities as current or non-current	1 January 2023
HKFRS 17	Insurance Contracts	1 January 2023
Amendments to HKAS 1 and HKFRS Practice Statement 2	Disclosure of Accounting Policies	1 January 2023
Amendments to HKAS 8	Definition of Accounting Estimates	1 January 2023
HK Int 5 (2020)	Presentation of Financial Statements – Classification by the Borrower of a Term Loan that Contains a Repayment on Demand Clause	1 January 2023
HKFRS 10 and HKAS 28	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture (amendments)	To be determined

The Group has already commenced an assessment of the related impact of the above standards and amendments to standards which are relevant to the Group's operation.

There are no other standards that are not yet effective and that are expected to have a material impact on the Group's financial performance and position.

Notes to the interim condensed consolidated financial information

3 FINANCIAL RISK MANAGEMENT**3.1 Financial risk factors**

The Group's activities expose it to a variety of financial risks: market risk (including foreign exchange risk, price risk and cash flow and fair value interest rate risk), credit risk and liquidity risk. The Group's overall risk management programme focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on the Group's financial position and financial performance.

The interim condensed consolidated financial information do not include all financial risk management information and disclosures required in the annual financial statements, and should be read in conjunction with the Group's annual financial statements as at 31 December 2021.

There have been no changes in the risk management mechanism since the year ended 31 December 2021 or in any risk management policies since the year end.

3.2 Liquidity risk

The Group aims to maintain sufficient cash and cash equivalents. Due to the dynamic nature of the underlying businesses, the policy of the Group is to regularly monitor the Group's liquidity risk and to maintain adequate cash and cash equivalents to meet the Group's liquidity requirements.

The table below analyses the Group's non-derivative financial liabilities that will be settled into relevant maturity grouping based on the remaining period at each balance sheet date to the contractual maturity date. The amounts disclosed in the table are the contractual undiscounted cash flows.

As at 30 June 2022

	Less than 1 year RMB'000	Between 1 and 2 years RMB'000	Between 2 and 5 years RMB'000	Over 5 years RMB'000	Total RMB'000
Trade and other payables (Note 13)	124,255	-	-	-	124,255
Borrowings (including interest payables)	190,269	12,409	53,287	-	255,965
Lease liabilities (including interest payables)	1,832	822	-	-	2,654
	316,356	13,231	53,287	-	382,874

Notes to the interim condensed consolidated financial information

3 FINANCIAL RISK MANAGEMENT (cont'd)**3.2 Liquidity risk** (cont'd)

As at 31 December 2021

	Less than 1 year RMB'000	Between 1 and 2 years RMB'000	Between 2 and 5 years RMB'000	Over 5 years RMB'000	Total RMB'000
Trade and other payables (Note 13)	60,403	–	–	–	60,403
Borrowings (including interest payables)	152,102	2,540	62,873	–	217,515
Lease liabilities (including interest payables)	1,530	1,000	198	–	2,728
	214,035	3,540	63,071	–	280,646

3.3 Fair value estimation

The carrying amounts of the Group's financial instruments not measured at fair value (including cash and cash equivalents, trade and other receivables (excluding prepayments), contract assets, borrowings and accruals and other payables) approximate their fair values.

The Group applies HKFRS 13 for financial instruments that are measured in the consolidated balance sheet at fair value, which requires disclosure of fair value measurements by levels of the following fair value measurement hierarchy:

- Level 1: The fair value of financial instruments traded in active markets (such as publicly traded derivatives, and trading and available-for-sale securities) is based on quoted market prices at the end of the reporting period. The quoted market price used for financial assets held by the Group is the current bid price.
- Level 2: The fair value of financial instruments that are not traded in an active market (For example, over-the-counter derivatives) is determined using valuation techniques which maximize the use of observable market data and rely as little as possible on entity-specific estimates. If all significant inputs required to fair value an instrument are observable, the instrument is included in level 2.
- Level 3: If one or more of the significant inputs is not based on observable market data, the instrument is included in level 3.

Notes to the interim condensed consolidated financial information

3 FINANCIAL RISK MANAGEMENT *(cont'd)***3.3 Fair value estimation** *(cont'd)*

There were no Group's assets that were measured at fair value at 30 June 2022 (31 December 2021: Nil):

Specific valuation techniques used to value financial instruments include:

- Quoted market prices or dealer quotes for similar instruments; and
- Other techniques, such as discounted cash flow analysis, are used to determine fair value for the remaining financial instruments.

There were no changes in valuation techniques during the six months ended 30 June 2022 (For the six months ended 30 June 2021: same).

There were no transfers between levels 1, 2 and 3 for recurring fair value measurements during the period for the six months ended 30 June 2022 (For the six months ended 30 June 2021: same).

4 CRITICAL ACCOUNTING ESTIMATES AND JUDGEMENTS

The preparation of interim condensed consolidated financial information requires management to make judgements, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets and liabilities, income and expense. Actual results may differ from these estimates.

In preparing this condensed consolidated interim financial information, the significant judgements made by management in applying the Group's accounting policies and the key sources of estimation uncertainty were the same as those that applied to the consolidated financial statements for the 2021 annual report.

5 SEGMENT AND REVENUE INFORMATION**(a) Description of segments and principal activities**

The Group is mainly engaged in the research, development and licensing of self-developed biological 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.

Notes to the interim condensed consolidated financial information

5 SEGMENT AND REVENUE INFORMATION (cont'd)

(b) The amount of each category of revenue is as follows:

	Six months ended 30 June	
	2022 RMB'000	2021 RMB'000
Timing of revenue recognition		
At a point in time:		
– Sales of goods	104,170	13
– Revenue from license granted	49,434	5,943
– CDMO/CMO	8,918	4,404
– Commission revenue	4,732	4,268
– Others	130	–
Over time:		
– CDMO	13,739	7,264
– Others	896	1,240
	182,019	23,132

(c) The following table presents the analysis of contract assets and contract liabilities related to the above-mentioned arrangements.

	30 June 2022 RMB'000	31 December 2021 RMB'000
Contract assets:		
– CDMO/CMO (i)	17,418	11,210
– Sales commission	1,505	742
Contract liabilities:		
– CDMO/CMO (ii)	(34,515)	(22,199)
– Sales of goods	(1,218)	–
	(16,810)	(10,247)

(i) Contract assets have increased as the Group has provided more services ahead of the agreed payment schedules.

(ii) Contract liabilities arise from CDMO and CMO which are recognized when the advances are received before the services are rendered to customers and will be recorded as revenue within one year.

Notes to the interim condensed consolidated financial information

5 SEGMENT AND REVENUE INFORMATION (cont'd)**(d) Revenue recognized in relation to contract liabilities**

The following table shows how much of the revenue recognized in the current reporting period relates to carried-forward contract liabilities.

	Six months ended 30 June	
	2022 RMB'000	2021 RMB'000
Revenue recognized that was included in the balance of contract liabilities at the beginning of the period		
– Service revenue – CDMO/CMO	7,430	3,834

(e) Unfulfilled long-term contracts

In January 2017, the Group entered into an agreement with a pharmaceutical company for licensing one of its bio-pharmaceutical know-how to the customer for development and commercialization for a period of 10 years.

The license contract includes an upfront fee of RMB8,400,000 (including tax), development milestone payments and commercial milestone payments of RMB76,100,000 (including tax) in aggregate. The contract also includes sales-based royalties. The Group has received the upfront payment and development milestone payments of RMB23,100,000 (including tax) in total as at 31 December 2021. For the six months ended 30 June 2022, certain development milestone and commercial milestones of RMB32,400,000 (including tax) in total were achieved by the Group (For the six months ended 30 June 2021: certain development milestone of RMB6,300,000 (including tax) was achieved). The Group is entitled to receive up to an aggregate of RMB29,000,000 (including tax) upon the achievement of additional development and commercial milestones.

In January 2022, the Group entered into an agreement with a pharmaceutical company for licensing one of its biological antibody drugs to the customer for development and commercialization in certain overseas regions (the "Cooperation Area") for 10 years after the date of obtaining the marketing authorization by the first regulatory authority in the Cooperation Area.

The license contract includes an upfront fee of RMB10,000,000 (including tax), and development milestone payments of RMB20,000,000 (including tax) in aggregate. The contract also includes sales-based royalties. For the six months ended 30 June 2022, the technology has been transferred and the Group has received the upfront payment and the first development milestone of RMB20,000,000 (including tax) in total. The Group is entitled to receive up to an aggregate of RMB10,000,000 (including tax) upon the achievement of additional specified milestones related to the development and regulatory approval of the biological antibody drugs.

Contract duration of CDMO/CMO services are generally for periods of one year or less. As permitted under HKFRS 15, the transaction price allocated to these unsatisfied contracts is not disclosed.

Notes to the interim condensed consolidated financial information

5 SEGMENT AND REVENUE INFORMATION (cont'd)**(f) Geographical information**

Geographical information of revenue and non-current assets other than financial assets for the six months ended 30 June 2022 and 2021 is as follows:

	Six months ended 30 June			
	2022		2021	
	Revenue RMB'000	Non-current assets RMB'000	Revenue RMB'000	Non-current assets RMB'000
Mainland China	182,019	422,720	23,132	339,162
Others	–	387	–	523
	182,019	423,107	23,132	339,685

6 LOSS BEFORE INCOME TAX

	Six months ended 30 June	
	2022 RMB'000	2021 RMB'000
Loss before taxation has been arrived at after charging:		
– Employee benefit expenses	60,831	65,213
– Clinical trials (exclude employee benefit expenses)	8,431	13,104
– R&D materials and consumables	4,515	13,706
– Depreciation and amortisation charge (Note 9)	18,681	16,456

7 INCOME TAX EXPENSE

Income tax expense is recognized based on the management's estimate of the annual income tax rate expected for the full financial year.

No provision for income tax has been provided for as the Group has no estimated assessable profit.

8 LOSS PER SHARE**(a) Basic loss per share**

Basic loss per share is calculated by dividing the loss of the Group attributable to owners of the Company by weighted average number of ordinary shares issued during the period.

	Six months ended 30 June	
	2022	2021
Loss attributable to equity holders of the Company (RMB'000)	(15,724)	(115,005)
Weighted average number of ordinary shares in issue (thousand)	575,197	571,492
Basic loss per share (RMB)	(0.03)	(0.20)

Notes to the interim condensed consolidated financial information

8 LOSS PER SHARE (cont'd)**(b) Diluted loss per share**

Diluted loss per share is calculated by adjusting the weighted average number of ordinary shares outstanding to assume conversion of all dilutive potential ordinary shares. For the six months ended 30 June 2022, the Company had one category of potential ordinary shares: the stock options granted to employees (For the six months ended 30 June 2021: same). As the Group incurred losses for the six months ended 30 June 2022 and 2021, the potential ordinary shares were not included in the calculation of diluted loss per share as their inclusion would be anti-dilutive. Accordingly, diluted loss per share for the six months ended 30 June 2022 and 2021 is the same as basic loss per share of the respective periods.

9 PROPERTY, PLANT AND EQUIPMENT, INTANGIBLE ASSETS AND RIGHT OF USE ASSETS

	Property, plant and equipment RMB'000	Intangible assets RMB'000	Right-of-use assets RMB'000
Six months ended 30 June 2022			
Opening net book amount as at 1 January 2022	307,668	5,123	15,733
Additions	63,619	537	634
Depreciation and amortisation charge	(17,012)	(801)	(868)
Disposals	(96)	–	–
Net exchange differences	(9)	–	(2)
Closing net book amount as at 30 June 2022	354,170	4,859	15,497
Six months ended 30 June 2021			
Opening net book amount as at 1 January 2021	290,367	3,229	20,639
Additions	27,345	384	2,246
Depreciation and amortisation charge	(14,929)	(511)	(1,016)
Disposals	(5,514)	–	(6,417)
Net exchange differences	(2)	–	1
Closing net book amount as at 30 June 2021	297,267	3,102	15,453

Notes to the interim condensed consolidated financial information

10 TRADE AND OTHER RECEIVABLES

	30 June 2022 RMB'000	31 December 2021 RMB'000
Trade receivables (a)	62,595	11,735
Less: provision for impairment of trade receivables	(923)	–
Trade receivables – net	61,672	11,735
Other receivables (b)	3,900	3,297
Trade and other receivables	65,572	15,032

(a) Trade receivables

	30 June 2022 RMB'000	31 December 2021 RMB'000
Trade receivables	62,595	11,735

Customers are generally granted with credit terms ranging from 60 to 90 days.

As of 30 June 2022 and 31 December 2021, the ageing analysis of the trade receivables based on invoice date is as follows:

	30 June 2022 RMB'000	31 December 2021 RMB'000
Within 30 days	53,239	1,336
31 days to 90 days	5,445	10,399
91 days to 180 days	3,911	–
	62,595	11,735

The carrying amounts of the Group's trade receivables are denominated in RMB and approximate their fair values.

The maximum exposure to credit risk at the reporting date is the carrying value of trade receivables mentioned above.

Notes to the interim condensed consolidated financial information

10 TRADE AND OTHER RECEIVABLES (cont'd)

(b) Other receivables

	30 June 2022 RMB'000	31 December 2021 RMB'000
Advances to a supplier (Note (i))	2,536	2,577
Advances to employees (Note (ii))	388	624
Other receivables	976	96
Other receivables	3,900	3,297

Note (i) According to the purchase contract, the amount of the advance will be used to offset the purchase amount. In the scenario where the relevant purchase contract is early terminated and the advance has not been fully utilised, the supplier will repay the remaining amount within 60 days on an interest-free basis. The amount is unsecured.

Note (ii) The advances to employees are unsecured, interest bearing at 6% (2021: 6%) per annum, and repayable within one year.

The carrying amounts of the Group's trade and other receivables are denominated in the following currencies:

	30 June 2022 RMB'000	31 December 2021 RMB'000
RMB	65,997	14,556
USD	498	473
HKD	–	3
	66,495	15,032

The maximum exposure to credit risk at the reporting date is the carrying value of each class of receivables mentioned above.

The carrying amounts of the Group's other receivables approximate their fair values.

Notes to the interim condensed consolidated financial information

11 SHARE CAPITAL

	Number of ordinary shares	Share capital RMB'000
As at 1 January 2021 (Audited)	600,466,697	1,874,438
Issue of shares upon exercise of share options (Note (a))	1,062,800	3,249
Increase in share capital upon receipt of the grant consideration under 2020 Restricted Shares Award Scheme (Note (b))	–	15,219
Issue of shares for 2021 Restricted Shares Award Scheme (Note (c))	13,700,000	–
As at 31 December 2021 (Audited)	615,229,497	1,892,906
As at 1 January 2022 (Audited) and 30 June 2022 (Unaudited)	615,229,497	1,892,906

Note (a) A total of 1,062,800 ordinary shares were issued from March to May 2021 pursuant to the Company's Pre-IPO Share Option Scheme at an exercise price of approximately USD0.29 per ordinary share. Upon the aforesaid exercise of share options, share-based compensation reserve of RMB1,259,000 was transferred to share capital.

Note (b) During March to May 2021, award shares representing a total of 4,134,139 ordinary shares were vested to certain participants of the Company's Restricted Share Award Scheme at a grant consideration of approximately USD0.29 per ordinary share. Upon the aforesaid vesting of award shares, share-based compensation reserve of RMB7,599,000 was transferred to share capital.

Note (c) On 23 December 2021, the Company allotted and issued 13,700,000 ordinary shares to certain trustees at a subscription price of zero under the Company's 2021 Restricted Share Award Scheme. These award shares are within the Company's control until the shares are vested to the participants and hence are considered as treasury shares in substance.

As at 30 June 2022 and 31 December 2021, a total of 40,032,558 ordinary shares are within the Company's control until the shares are vested to the participants and hence are considered as treasury shares in substance.

Notes to the interim condensed consolidated financial information

12 BORROWINGS

	30 June 2022 RMB'000	31 December 2021 RMB'000
Current		
– Unsecured bank borrowings (Note (a))	185,000	146,191
Non-current		
– Unsecured bank borrowings (Note (b))	59,775	59,775
	244,775	205,966

Note (a): Bank loans of RMB185,000,000 (As at 31 December 2021: RMB136,101,000 and EUR1,300,000, equivalent to RMB10,090,000) are unsecured, will be repayable in 2022 and bear annual interest rate ranging from 1.68% to 3.85% (As at 31 December 2021: 1.68% to 3.95%) with undrawn facilities up to RMB50,000,000 (As 31 December 2021: Nil).

Note (b): Bank loans of RMB59,775,000 (As at 31 December 2021: same) are unsecured, will be repayable in 2024, 2025 and 2026 and bear annual interest rate of 4.25% with undrawn facilities up to RMB90,225,000 (As at 31 December 2021: RMB120,225,000) for specific use on construction of plant, production line and equipment.

As at 30 June 2022 and 31 December 2021, the Group's bank borrowings were repayable as follows:

	30 June 2022 RMB'000	31 December 2021 RMB'000
Within 1 year	185,000	146,191
Between 2 and 5 years	59,775	59,775
	244,775	205,966

The weighted average effective interest rates at each balance sheet date were as follows:

	30 June 2022	31 December 2021
Bank borrowings	3.79%	3.78%

The carrying amounts of the Group's borrowings are denominated in RMB and EUR.

The fair values of borrowings equal to their carrying amounts as the discounting impact is not significant.

As at 30 June 2022, the Group has unutilised bank facilities of RMB140,225,000 (As at 31 December 2021: RMB120,225,000).

Notes to the interim condensed consolidated financial information

13 TRADE AND OTHER PAYABLES

	30 June 2022 RMB'000	31 December 2021 RMB'000
Trade payables	76,012	28,214
Deposits payables	30,450	10,000
Staff salaries and welfare payables	13,966	19,898
Payables for purchase of property, plant and equipment	8,772	6,457
Refund liabilities	6,878	5,699
Others	9,284	15,970
	145,362	86,238

As at 30 June 2022 and 31 December 2021, the ageing analysis of trade payables based on invoice date are as follows:

	30 June 2022 RMB'000	31 December 2021 RMB'000
Within 3 months	63,759	27,037
3 months to 6 months	11,971	507
6 months to 12 months	155	160
1 year to 2 years	127	510
	76,012	28,214

The Group's trade and other payables are denominated in the following currencies:

	30 June 2022 RMB'000	31 December 2021 RMB'000
– RMB	144,455	81,098
– NTD	518	638
– HKD	298	3,862
– USD	91	74
– EUR	–	566
	145,362	86,238

Notes to the interim condensed consolidated financial information

14 DIVIDEND

No dividend has been paid or declared by the Company during the six months ended 30 June 2022 (Year ended 31 December 2021: Nil).

15 COMMITMENTS**(a) Capital commitments**

Capital expenditures contracted for at each balance sheet date, but not yet incurred are as follows:

	30 June 2022 RMB'000	31 December 2021 RMB'000
Property, plant and equipment	224,654	155,746

(b) Investment commitments

The investment of the Group to the joint venture but not yet injected is as follows:

	30 June 2022 RMB'000	31 December 2021 RMB'000
Huayao Pharmaceutical (Suzhou) Company Limited ("Huayao Suzhou")	26,250	31,400

16 RELATED PARTY TRANSACTIONS

Parties are considered to be related if one party has the ability, directly or indirectly, to control the other party or exercise significant influence over the other party in making financial and operation decisions. Parties are also considered to be related if they are subject to common control.

The following is a summary of the significant transactions carried out between the Group and its related parties in the ordinary course of business during the six months ended 30 June 2022 and 2021, and balances arising from related party transactions as at 30 June 2022 and 31 December 2021.

(a) Name and relationship with related parties

Name of related party	Nature of relationship
Center Laboratories Inc. ("Centerlab")	Entity having significant influence over the Company
Lumosa Therapeutics Co., Ltd.	Associate of Center Laboratories, Inc.
Huayao Suzhou	Joint venture of the Company

Notes to the interim condensed consolidated financial information

16 RELATED PARTY TRANSACTIONS (cont'd)**(b) Transactions with related parties***(i) Rental expenses charged by related parties*

	Six months ended 30 June	
	2022 RMB'000	2021 RMB'000
Lumosa Therapeutics Co., Ltd.	41	22

The related party transactions above were carried out on terms mutually agreed between the parties. In the opinion of the directors of the Company, these transactions are in the ordinary courses of business of the Group and in accordance with the terms of underlying agreements.

(c) Balances with related parties*(i) Payables on rental expenses*

	30 June 2022 RMB'000	31 December 2021 RMB'000
Lumosa Therapeutics Co., Ltd.	40	81

(ii) Other receivables from related parties

	30 June 2022 RMB'000	31 December 2021 RMB'000
Huayao Suzhou	435	–

The balances due to related parties were unsecured, non-interest bearing and had no fixed repayment term as at 30 June 2022.

Notes to the interim condensed consolidated financial information

16 RELATED PARTY TRANSACTIONS (cont'd)**(d) Leasing arrangements**

In February 2016, the Group signed a five-year office rental contract with Centerlab, which has an option for automatic extension upon expiry of the contract. This rental contract with Centerlab was terminated in September 2021. In October 2021, the Group entered into a 15-month office rental contract with Lumosa Therapeutics Co., Ltd. in substitution. The lease terms and prices were determined in accordance with mutual agreement, and rental payments are made on a monthly basis.

(i) Acquisition of right-of-use assets:

	Six months ended 30 June	
	2022 RMB'000	2021 RMB'000
Centerlab	–	133

(ii) Lease liabilities:

– Outstanding balance:

	30 June 2022 RMB'000	31 December 2021 RMB'000
Lumosa Therapeutics Co., Ltd.	40	81

(iii) Rental Payment:

	Six months ended 30 June	
	2022 RMB'000	2021 RMB'000
Lumosa Therapeutics Co., Ltd.	41	–
Centerlab	–	192
	41	192

17 SUBSEQUENT EVENTS

On 31 May 2022, the Company entered into subscription agreements with Center Laboratories Inc. and Vivo (Suzhou) Health Industry Investment Fund (Limited Partnership), and agreed to allot and issue 150,000,000 subscription shares at the price of HKD3.15 per share. The gross proceeds from the subscriptions would be approximately HKD472,500,000, and the net proceeds from the subscriptions after the deduction of the relevant fees and expenses were estimated to be approximately HKD470,920,000. In July 2022, Center Laboratories Inc. and Vivo (Suzhou) Health Industry Investment Fund (Limited Partnership) injected capital of approximately HKD472,500,000 (equivalent to approximately RMB405,788,000) in total for the subscriptions.



OTHER INFORMATION

DIRECTORS' AND CHIEF EXECUTIVES' INTERESTS AND SHORT POSITIONS IN SHARES AND UNDERLYING SHARES AND DEBENTURES OF THE COMPANY OR ANY OF ITS ASSOCIATED CORPORATIONS

As at 30 June 2022, the interests or short positions of the Directors or chief executives of the Company in any of the Shares, underlying Shares and debentures of the Company or its associated corporation (within the meaning of Part XV of the SFO), as notified to the Company and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO, or as recorded in the register required to be kept by the Company pursuant to section 352 of the SFO, or as otherwise notified to the Company and the Stock Exchange pursuant to the Model Code were as follows:

Interests in shares or underlying shares of the Company

Name of Director or chief executive	Nature of interest	Number of Shares interested ⁽¹⁾	Approximate percentage of interest in the Company ⁽²⁾
Ms. Yeh-Huang, Chun-Ying	Beneficial owner	7,115,700 (L)	1.16%
	Interest through equity derivatives ⁽³⁾	1,162,500 (L)	0.19%
	Beneficiary of a trust ⁽⁴⁾	2,897,383 (L)	0.47%
Dr. Liu, Jun	Interest through equity derivatives ⁽³⁾	1,100,000 (L)	0.18%
	Beneficiary of a trust ⁽⁴⁾	2,741,609 (L)	0.45%

Notes:

- (1) The letter "L" denotes the person's long position in the Shares.
- (2) The calculation is based on the total number of 615,229,497 Shares in issue as at 30 June 2022 and rounded off to two decimal places.
- (3) These interests represent the interests in Shares underlying the Pre-IPO Share Options (being unlisted physically-settled equity derivatives) held by Ms. Yeh-Huang, Chun-Ying and Dr. Liu, Jun, respectively.
- (4) These interests represent the Restricted Award Shares held by Teeroy Limited on trust for Ms. Yeh-Huang, Chun-Ying and Dr. Liu, Jun, respectively.

Save as disclosed above, as at 30 June 2022, so far as it was known to the Directors or chief executives of the Company, none of the Directors or chief executives of the Company had or was deemed to have any interests or short positions in the Shares, underlying Shares or debentures of the Company or its associated corporations as notified to the Company and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO, or as recorded in the register required to be kept by the Company pursuant to section 352 of the SFO, or as otherwise notified to the Company and the Stock Exchange pursuant to the Model Code.

Other information

SUBSTANTIAL SHAREHOLDERS' INTERESTS AND SHORT POSITIONS IN THE SHARES AND UNDERLYING SHARES OF THE COMPANY

As at 30 June 2022, so far as it was known to the Directors or chief executives of the Company, the following persons (other than the Directors and chief executives of the Company) had interests or short positions in the Shares or underlying Shares of the Company as disclosed to the Company pursuant to Divisions 2 and 3 of Part XV of the SFO, or as recorded in the register required to be kept by the Company pursuant to section 336 of the SFO:

Interests in shares or underlying shares of the Company

Name of Shareholder	Nature of interest	Number of Shares interested⁽¹⁾	Approximate percentage of interest in the Company⁽²⁾
Center Laboratories Inc.	Beneficial owner	179,561,700 (L)	29.19%
Mr. Pang Kee Chan Hebert ⁽³⁾	Interest in controlled corporation	49,136,800 (L)	7.99%
Advantech Capital Partners II Limited ⁽³⁾	Interest in controlled corporation	49,136,800 (L)	7.99%
Advantech Capital II L.P. ⁽³⁾	Interest in controlled corporation	49,136,800 (L)	7.99%
Advantech Capital II Master Investment Limited ⁽³⁾	Interest in controlled corporation	49,136,800 (L)	7.99%
Advantech Capital Investment V Limited ⁽³⁾	Beneficial owner	49,136,800 (L)	7.99%
Chengwei Evergreen Management, LLC ⁽⁴⁾	Interest in controlled corporation	56,573,500 (L)	9.20%
Chengwei Evergreen Capital, L.P. ⁽⁴⁾	Interest in controlled corporation	56,573,500 (L)	9.20%
Prime Success International Limited ⁽⁴⁾	Beneficial owner	56,573,500 (L)	9.20%
Vivo Capital LLC ⁽⁵⁾	Interest in controlled corporation	103,245,000 (L)	16.78%
Vivo Capital VIII, LLC ⁽⁵⁾	Interest in controlled corporation	103,245,000 (L)	16.78%
Vivo Capital Fund VIII, L.P. ⁽⁵⁾	Beneficial owner	90,718,100 (L)	14.75%
Tricor Trust (Hong Kong) Limited ⁽⁶⁾	Trustee	34,393,566 (L)	5.59%

Other information

SUBSTANTIAL SHAREHOLDERS' INTERESTS AND SHORT POSITIONS IN THE SHARES AND UNDERLYING SHARES OF THE COMPANY (cont'd)

Notes:

- (1) The letter "L" denotes the person's long position in the Shares.
- (2) The calculation is based on the total number of 615,229,497 Shares in issue as at 30 June 2022 and rounded off to two decimal places.
- (3) Advantech Capital Investment V Limited, an exempted company with limited liability incorporated under the laws of Cayman Islands, directly held 49,136,800 Shares. Advantech Capital Investment V Limited is wholly owned by Advantech Capital II Master Investment Limited, an exempted company with limited liability incorporated under the laws of the Cayman Islands, which is in turn wholly owned by Advantech Capital II L.P., a private equity fund incorporated under the laws of the Cayman Islands. The general partner of Advantech Capital II L.P. is Advantech Capital Partners II Limited, an exempted company with limited liability incorporated under the laws of the Cayman Islands. Advantech Capital Partners II Limited is wholly owned by Mr. Pang Kee Chan Hebert. For the purpose of the SFO, Advantech Capital II Master Investment Limited, Advantech Capital II L.P., Advantech Capital Partners II Limited and Mr. Pang Kee Chan Hebert are deemed to have an interest in the Shares held by Advantech Capital Investment V Limited.
- (4) Prime Success International Limited directly held 56,573,500 Shares. Prime Success International Limited is a company with limited liability incorporated under the laws of Hong Kong, which is wholly owned by Chengwei Evergreen Capital, L.P., a venture capital fund incorporated under the laws of the Cayman Islands. The general partner of Chengwei Evergreen Capital, L.P. is Chengwei Evergreen Management, LLC, a limited liability company incorporated under the laws of the Cayman Islands. For the purpose of the SFO, Chengwei Evergreen Capital, L.P. and Chengwei Evergreen Management, LLC are deemed to have an interest in the Shares held by Prime Success International Limited.
- (5) Vivo Capital Fund VIII, L.P. directly held 90,718,100 Shares, and Vivo Capital Surplus Fund VIII, L.P. directly held 12,526,900 Shares. Both Vivo Capital Fund VIII, L.P. and Vivo Capital Surplus Fund VIII, L.P. (referred to collectively as Vivo Capital) are limited partnerships organized under the laws of the State of Delaware of the United States. The general partner of Vivo Capital is Vivo Capital VIII, LLC, which is registered in the State of Delaware of the United States. Vivo Capital LLC, registered in the State of California of the United States, serves as the management company of Vivo Capital and has a form of advisory agreement with Vivo Capital VIII, LLC. For the purpose of the SFO, Vivo Capital VIII, LLC and Vivo Capital LLC are deemed to have an interest in the Shares held by Vivo Capital.
- (6) Tricor Trust (Hong Kong) Limited directly held 34,393,566 Shares as trustee of a trust established by the trust deed dated 29 May 2020 entered into with the Company in connection with the Restricted Share Award Scheme for the benefit of participants who are not connected persons of the Company.

Save as disclosed above, as at 30 June 2022, no person, other than the Directors or chief executives of the Company whose interests are set out in the paragraph headed "Directors' and Chief Executives' Interests and Short Positions in Shares and Underlying Shares and Debentures of the Company or Any of its Associated Corporations" in this report, had any interests or short positions in the Shares or underlying Shares as disclosed to the Company pursuant to Divisions 2 and 3 of Part XV of the SFO, or as recorded in the register required to be kept by the Company pursuant to section 336 of the SFO.

Other information

PRE-IPO SHARE OPTION SCHEME

On 20 February 2013, the Company adopted the Pre-IPO Share Option Scheme with an aim to attract and retain talent necessary for the Group's development, and to incentivize the Group's employees and enhance their cohesion and productivity, thereby creating value for the Company and its Shareholders. The Pre-IPO Share Option Scheme was subsequently amended on 11 December 2017, 20 December 2018, 12 March 2019, 16 April 2019 and 22 July 2019. No further Pre-IPO Share Options may be granted on or after the Listing Date.

Details of the movements of the Pre-IPO Share Options granted under the Pre-IPO Share Option Scheme during the six months ended 30 June 2022 are as follows:

Date of grant	Date of vesting	Exercise period	Exercise price (per Share)	Number of Shares underlying the Pre-IPO Share Options				Outstanding as at 30 June 2022
				Outstanding as at 31 December 2021	Granted (during the six months ended 30 June 2022)	Exercised	Cancelled/ Lapsed	
1. Ms. Yeh-Huang, Chun-Ying (Director)								
20 February 2013	All vested	Till 19 February 2023	Approximately US\$0.286	0	-	-	-	0
14 December 2017	Vested in four equal installments at each of the first four anniversaries of the date of grant	From the date of vesting till 13 December 2027	Approximately US\$0.286	1,162,500	-	-	-	1,162,500
2. Dr. Liu, Jun (Director)								
25 December 2017	Vested in four equal installments on 1 January 2019, 2020, 2021 and 2022	From the date of vesting till 24 December 2027	Approximately US\$0.286	1,000,000	-	-	-	1,000,000
21 January 2019	To be vested in five equal installments at the fulfillment of certain R&D targets and the second, third, fourth and fifth anniversaries thereof	From the date of vesting till 20 January 2029	Approximately US\$0.286	100,000	-	-	-	100,000
3. Senior management and other grantees (being employees of and consultants to the Group)								
Between 20 February 2013 and 18 June 2019	Either vested or to be vested from one to six years from the date of grant or to be vested from zero to five years from the fulfillment of certain R&D targets	Generally, from the date of vesting till the date which is one day preceding the tenth anniversary of the date of grant	Approximately US\$0.286	7,592,800	-	-	905,700	6,687,100
Total				9,855,300	-	-	905,700	8,949,600

The Pre-IPO Share Option Scheme is not subject to the provisions of Chapter 17 of the Listing Rules. For further details of the Pre-IPO Share Option Scheme, please refer to pages V-36 to V-47 of the Prospectus.

Other information

RESTRICTED SHARE AWARD SCHEME

On 29 May 2020, the Company adopted the Restricted Share Award Scheme with an aim (i) to attract and retain talent necessary for the Group's development, and to incentivize the Group's employees and enhance their cohesion and productivity, thereby creating value for the Company and its Shareholders; and (ii) to compensate participants of the Pre-IPO Share Option Scheme for the dilutive effect of the capitalization issue in connection with the Global Offering on their Pre-IPO Share Options. On the same day, the Company entered into two trust deeds with the respective trustees to constitute the trusts in connection with the Restricted Share Award Scheme for the purpose of the grant of Restricted Award Shares to selected participants (who may be employees (including Directors) of or consultants to the Group) from time to time. The Restricted Share Award Scheme was subsequently amended on 29 July 2020 and 23 December 2021. The Restricted Share Award Scheme shall remain valid and effective for a period of ten years from the date of adoption. The aggregate number of Shares which may be allotted and issued to the trustees under the Restricted Share Award Scheme may not exceed 57,000,000 Shares. Pursuant to the terms of the Restricted Share Award Scheme, the maximum number of Shares which may be allotted and issued to the trustees under the Restricted Share Award Scheme during each financial year from 2021 onwards is 14,250,000 Shares. On 23 December 2021, the Board resolved to further amend the terms of the Restricted Share Award Scheme with regards to unvested Shares (i.e. Restricted Award Shares that have failed to vest or have lapsed in respect of a grantee). See the Company's announcement dated 23 December 2021 titled "(1) Grant of Award Shares under Restricted Share Award Scheme (2) Issue of New Shares under General Mandate (3) Amendment to Scheme Rules" for further details of the amendment.

On 29 May 2020, following the adoption of the Restricted Share Award Scheme, the Board also resolved to make a grant of 31,413,796 Restricted Award Shares to 84 grantees (including two Directors) under the Restricted Share Award Scheme; subsequently, on 28 December 2020, 30,466,697 Shares were allotted and issued to the trustees. On 23 December 2021, the Board resolved to make a further grant to 28 grantees (not including any Director) involving a total of 13,700,000 Restricted Award Shares; subsequently, on 30 December 2021, 13,700,000 Shares were allotted and issued to the relevant trustee.

As at 30 June 2022, the remaining number of Shares capable of being allotted and issued to the trustees under the Restricted Share Award Scheme was 12,833,303 Shares, and the number of unvested Shares held by Tricor Trust (Hong Kong) Limited and capable of being reallocated to other non-connected person grantees under the Restricted Share Award Scheme was 6,065,236 Shares.

Other information

RESTRICTED SHARE AWARD SCHEME (cont'd)

Details of the movements of the Restricted Award Shares granted under the Restricted Share Award Scheme during the six months ended 30 June 2022 are as follows:

Trustee	Grantee	Grant consideration (per Share)	Number of Restricted Award Shares						Earliest vesting date	Expiry date
			Outstanding as at 31 December 2021	Granted, and allotted and issued to trustees (during the six months ended 30 June 2022)	Vested	Lapsed	Outstanding as at 30 June 2022			
Teeroy Limited	Ms. Yeh-Huang, Chun-Ying (Director)	US\$0.28634	965,795	-	-	-	965,795	14 December 2019	13 December 2027	
		US\$0.28634	965,794	-	-	-	965,794	14 December 2020	13 December 2027	
		US\$0.28634	965,794	-	-	-	965,794	14 December 2021	13 December 2027	
			2,897,383	-	-	-	2,897,383			
Teeroy Limited	Dr. Liu, Jun (Director)	US\$0.28634	623,093	-	-	-	623,093	1 January 2019	24 December 2027	
		US\$0.28634	623,093	-	-	-	623,093	1 January 2020	24 December 2027	
		US\$0.28634	623,093	-	-	-	623,093	1 January 2021	24 December 2027	
		US\$0.28634	623,093	-	-	-	623,093	1 January 2022	24 December 2027	
		US\$0.28634	49,848	-	-	-	49,848	The date of the fulfillment of certain R&D targets	20 January 2029	
		US\$0.28634	49,848	-	-	-	49,848	The second anniversary of the fulfillment of certain R&D targets	20 January 2029	
		US\$0.28634	49,847	-	-	-	49,847	The third anniversary of the fulfillment of certain R&D targets	20 January 2029	
		US\$0.28634	49,847	-	-	-	49,847	The fourth anniversary of the fulfillment of certain R&D targets	20 January 2029	
			2,741,609	-	-	-	2,741,609			
Tricor Trust (Hong Kong) Limited	Senior management and other grantees (being employees of and consultants to the Group)	US\$0.28634	17,397,321	-	-	2,368,991	15,028,330	Various dates, some of which are linked to the fulfillment of certain R&D targets	Various dates	
		HK\$0.6	13,700,000	-	-	400,000	13,300,000	Various dates, which are linked to the fulfillment of certain business and R&D targets	28 May 2030	
			31,097,321	-	-	2,768,991	28,328,330			
Total			36,736,313	-	-	2,768,991	33,967,322			

Other information

RESTRICTED SHARE AWARD SCHEME *(cont'd)*

The Restricted Share Award Scheme does not constitute a share option scheme or an arrangement analogous to a share option scheme for the purpose of Chapter 17 of the Listing Rules, and is a discretionary scheme of the Company. For further details of the Restricted Share Award Scheme, please refer to pages 8 to 21 of the Company's circular dated 3 August 2020 and its announcement dated 23 December 2021 titled "(1) Grant of Award Shares under Restricted Share Award Scheme (2) Issue of New Shares under General Mandate (3) Amendment to Scheme Rules".

DIRECTORS' RIGHTS TO ACQUIRE SHARES OR DEBENTURES

Save as disclosed in this interim report, at no time during the six months ended 30 June 2022 was the Company or any of its subsidiaries a party to any arrangements to enable the Directors to acquire benefits by means of the acquisition of shares in, or debentures of, the Company or any other body corporate; and none of the Directors, or any of their spouse or children under the age of 18, had any right to subscribe for equity or debt securities of the Company, or had exercised any such right.

REVIEW BY AUDIT AND CONNECTED TRANSACTIONS REVIEW COMMITTEE

The Audit and Connected Transactions Review Committee of the Company has reviewed the financial reporting processes, risk management and internal control systems of the Group and the condensed consolidated interim financial statements of the Group for the six months ended 30 June 2022, and is of the opinion that these statements have complied with the applicable accounting standards, the Listing Rules and legal requirements, and that adequate disclosure has been made.

DIVIDEND

The Board has resolved not to declare an interim dividend for the six months ended 30 June 2022.

COMPLIANCE WITH THE CODE PROVISIONS OF THE CORPORATE GOVERNANCE CODE

The Company has adopted the principles and code provisions of the CG Code contained in Appendix 14 to the Listing Rules as the basis of the Company's corporate governance practices. The Board is of the view that during the six months ended 30 June 2022, the Company has complied with all the applicable code provisions as set out in Part 2 of the CG Code.

COMPLIANCE WITH THE MODEL CODE FOR SECURITIES TRANSACTIONS BY DIRECTORS

The Company has adopted the Model Code contained in Appendix 10 to the Listing Rules. The Company has made specific enquiry of all the Directors and the Directors have confirmed that they have complied with the Model Code during the six months ended 30 June 2022 and up to the date of this report.

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

Neither the Company nor any of its subsidiaries purchased, sold or redeemed any listed securities of the Company during the six months ended 30 June 2022.

CHANGES IN DIRECTORS' AND SENIOR MANAGEMENT'S INFORMATION

Pursuant to the service contracts entered into or renewed between the Company and each of the Directors in March to April 2022, the Directors are no longer entitled to the attendance fee of RMB500 for each Board meeting or Board committee meeting.

Other information

CHANGES IN DIRECTORS' AND SENIOR MANAGEMENT'S INFORMATION (cont'd)

Besides, with effect from April 2022, the emoluments of Dr. Liu, Jun pursuant to his service contracts with members of the Group were adjusted as follows:

Director	Member of the Group	Remuneration before April 2022	Remuneration from April 2022
Dr. Liu, Jun	The Company	Annual Director's fee of HK\$1	Unchanged
	The Company	Monthly salary of RMB70,000 plus bonuses (if any) as the chief executive officer	Monthly salary (inclusive of subsidies) of RMB90,000 plus bonuses (if any) as the chief executive officer
	TOT BIOPHARM Co., Ltd. (東曜藥業有限公司)	Monthly salary of RMB64,000 plus subsidies and bonuses (if any) as the chief executive officer	Monthly salary (inclusive of subsidies) of RMB90,000 plus bonuses (if any) as the chief executive officer

Save as disclosed above, there is no change in the information of the Directors and the senior management of the Company since the date of the 2021 Annual Report (being 24 March 2022) which is required to be disclosed pursuant to Rule 13.51B(1) of the Listing Rules.

SUBSEQUENT EVENTS

On 31 May 2022, the Company entered into subscription agreements with Center Laboratories Inc. and Vivo (Suzhou) Health Industry Investment Fund (Limited Partnership) respectively, pursuant to which Center Laboratories Inc. and Vivo (Suzhou) Health Industry Investment Fund (Limited Partnership) conditionally agreed to subscribe for and the Company conditionally agreed to allot and issue to them a total of 150,000,000 shares (the "Subscription Shares") at the subscription price of HKD3.15 per share (the "Subscriptions"). The subscription agreements and transactions contemplated thereunder were subject to, among other things, the approval by the independent shareholders of the Company at the extraordinary general meeting on 22 July 2022, and the Listing Committee of the Stock Exchange approving the listing of, and the permission to deal in, the Subscription Shares.

On 29 July 2022, all conditions precedent under each of the subscription agreements were satisfied and completion of the Subscriptions took place in full, pursuant to which (i) Center Laboratories Inc. was allotted and issued 33,750,000 shares; and (ii) Vivo (Suzhou) Health Industry Investment Fund (Limited Partnership) was allotted and issued 116,250,000 shares. The gross proceeds from the Subscriptions were approximately HKD472,500,000, and the net proceeds from the Subscriptions after the deduction of the relevant fees and expenses were approximately HKD470,920,000. Details of the Subscriptions were set out in the announcements of the Company dated 31 May 2022, 22 June 2022, 30 June 2022 and 29 July 2022 and the circular of the Company dated 5 July 2022.

DISCLOSURE OF FINANCIAL INFORMATION

Pursuant to paragraph 40(2) of Appendix 16 to the Listing Rules headed "Disclosure of Financial Information", save as disclosed in this interim report, the Company confirms that as at the date of this report, the Group's current information in relation to those matters set out in paragraph 32 of Appendix 16 to the Listing Rules has not changed materially from the information disclosed in the 2021 Annual Report.

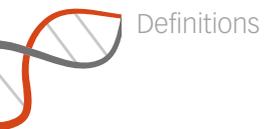


DEFINITIONS

“ADC”	antibody drug conjugate
“Board”	the board of Directors of the Company
“CDMO”	contract development and manufacturing organization, which is a pharmaceutical company that develops and manufactures drugs for other pharmaceutical companies on a contractual basis
“CG Code”	the Corporate Governance Code contained in Appendix 14 to the Listing Rules
“CMO”	contract manufacturing organization, which is a pharmaceutical company that manufactures drugs for other pharmaceutical companies on a contractual basis
“Company”	TOT BIOPHARM International Company Limited (東曜藥業股份有限公司) (formerly known as TOT BIOPHARM International Company Limited (東源國際醫藥股份有限公司)), a company incorporated in Hong Kong with limited liability on 4 December 2009 whose Shares are listed on the Stock Exchange (stock code: 1875)
“date of this report”	12 August 2022, being the latest practicable date for the purpose of ascertaining certain information contained in this interim report prior to its publication
“Director(s)”	the director(s) of the Company
“FDA”	the Food and Drug Administration of the United States
“GMP”	good manufacturing practice
“Group”, “we”, “us” or “TOT BIOPHARM”	the Company and its subsidiaries
“HK\$” or “HKD”	Hong Kong dollar(s), the lawful currency of Hong Kong
“HKAS(s)”	Hong Kong Accounting Standards issued by the Hong Kong Institute of Certified Public Accountants
“HKFRS(s)”	Hong Kong Financial Reporting Standards issued by the Hong Kong Institute of Certified Public Accountants
“Hong Kong”	the Hong Kong Special Administrative Region of the PRC
“IND”	investigational new drug application

Definitions

“IPO” or “Global Offering”	the initial public offering of the Company which was completed on the Listing Date
“Listing Date”	8 November 2019, the date on which the Shares were listed on the Stock Exchange
“Listing Rules”	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended, supplemented or otherwise modified from time to time
“mAb”	monoclonal antibody
“Model Code”	the Model Code for Securities Transactions by Directors of Listed Issuers contained in Appendix 10 to the Listing Rules
“NDA”	new drug application
“NMPA”	the National Medical Products Administration of the PRC
“NTD”	New Taiwan dollar(s), the lawful currency of Taiwan
“PRC” or “China”	the People’s Republic of China, excluding, for the purpose of this interim report, Hong Kong, Macau Special Administrative Region and Taiwan
“Pre-IPO Share Option(s)”	the share option(s) granted under the Pre-IPO Share Option Scheme
“Pre-IPO Share Option Scheme”	the pre-IPO share option scheme adopted by the Company on 20 February 2013 and subsequently amended on 11 December 2017, 20 December 2018, 12 March 2019, 16 April 2019 and 22 July 2019, details of which are disclosed on pages V-36 to V-47 of the Prospectus
“Prospectus”	the prospectus dated 29 October 2019 published by the Company
“R&D”	research and development
“RMB”	Renminbi, the lawful currency of the PRC
“Restricted Award Share(s)”	the Share(s) granted under the Restricted Share Award Scheme and allotted and issued (or to be allotted and issued) to the trustees thereunder
“Restricted Share Award Scheme”	the restricted share award scheme adopted by the Company on 29 May 2020 and subsequently amended on 29 July 2020 and 23 December 2021, details of which are disclosed on pages 8 to 21 of the Company’s circular dated 3 August 2020 and in its announcement dated 23 December 2021



“SFO”	the 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) of the Company
“Shareholder(s)”	holder(s) of Share(s)
“Stock Exchange”	The Stock Exchange of Hong Kong Limited
“United States”	the United States of America
“US\$” or “USD”	United States dollar(s), the lawful currency of the United States