



2021  
INTERIM  
REPORT

東曜藥業股份有限公司  
TOT BIOPHARM International Company Limited  
(Incorporated in Hong Kong with limited liability)

Stock Code: 1875



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# CORPORATE INFORMATION

## EXECUTIVE DIRECTORS

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

## NON-EXECUTIVE DIRECTORS

Mr. Fu, Shan (*Chairman of the Board*)  
Dr. Kung, Frank Fang-Chien  
Mr. Kang, Pei  
Mr. Qiu, Yu Min

## INDEPENDENT NON-EXECUTIVE DIRECTORS

Ms. Hu, Lan  
Dr. Sun, Lijun Richard  
Mr. Chang, Hong-Jen

## AUDIT AND CONNECTED TRANSACTIONS REVIEW COMMITTEE

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

## REMUNERATION COMMITTEE

Mr. Chang, Hong-Jen (*Chairman*)  
Mr. Kang, Pei  
Dr. Sun, Lijun Richard

## NOMINATION COMMITTEE

Mr. Fu, Shan (*Chairman*)  
Ms. Hu, Lan  
Dr. Sun, Lijun Richard

## STRATEGY COMMITTEE

Mr. Fu, Shan (*Chairman*)  
Ms. Yeh-Huang, Chun-Ying  
Dr. Liu, Jun  
Mr. Chang, Hong-Jen  
Dr. Sun, Lijun Richard

## JOINT COMPANY SECRETARIES

Mr. Yao, Jau-Chang  
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

## SHARE REGISTRAR

Tricor Investor Services Limited

## REGISTERED OFFICE

Level 54, Hopewell Centre,  
183 Queen's Road East,  
Hong Kong

## HEADQUARTERS AND PRINCIPAL PLACE OF BUSINESS IN THE PRC

120 Changyang Street,  
Suzhou Industrial Park,  
Suzhou, PRC

## COMPANY WEBSITE

[www.totbiopharm.com.cn](http://www.totbiopharm.com.cn)

## PLACE OF LISTING AND STOCK CODE

The Stock Exchange of Hong Kong Limited  
1875

## PRINCIPAL BANKS

Shanghai Pudong Development Bank  
Bank of China

## AUDITOR

PricewaterhouseCoopers  
*Certified Public Accountants and Registered Public Interest Entity Auditor*

## LEGAL ADVISER

Sullivan & Cromwell (Hong Kong) LLP

## INVESTORS AND MEDIA RELATIONS CONSULTANT

Strategic Financial Relations (China) Limited

# MANAGEMENT DISCUSSION AND ANALYSIS

## I. INDUSTRY AND COMPANY PROFILE

Along with the rising incidences of tumor around the world, the market scale of oncology drugs has been growing continuously. According to a report by Frost & Sullivan, the number of cancer cases reached 19.30 million globally in 2020 and the global market scale of oncology drugs was US\$150.3 billion. It is expected that the number of cancer cases will reach 21.60 million globally, and the global market scale of oncology drugs will reach US\$304.8 billion in 2025, representing a compound annual growth rate of 15.2%.

Driven by national policies and innovative R&D initiatives, the oncology market in China showed a booming development trend in recent years, with continuous rollouts of quality and affordable anti-cancer drugs by local pharmaceutical companies for cancer patients in China. According to relevant data, China's market scale of oncology drugs reached US\$28.6 billion in 2020, and is expected to reach US\$60.3 billion in 2025, representing a compound annual growth rate of 16.1%, which is substantially higher than that of the United States and elsewhere in the world for the same period.

TOT BIOPHARM always adheres to the corporate vision of improving the life quality of cancer patients around the world with innovative technologies and spares no effort in establishing itself as a leading brand name of oncology treatments trusted by patients and their families as well as medical professionals. In 2021, the Group continued to implement its strategic planning and endeavored to become a leader of the ADC market in China with its own characteristics and competitiveness. During the first half of the year, the Group speeded up its strategic adjustment and implementation to strengthen its R&D of ADC drugs and industry planning and firmly capitalize on market opportunities, thus making new breakthroughs in the field of innovative drug CDMO/CMO. For the six months ended 30 June 2021, revenue amounted to RMB23,132,000, representing a year-on-year growth of 77.5%, of which revenue from CDMO/CMO business increased substantially to RMB11,668,000,

representing a year-on-year growth of 329.8%, thus bringing diversified cash flows to the Company and earning high recognition from partners.

TOT BIOPHARM possesses "one-base, end-to-end" R&D and technological advantages. We are able to deliver one-stop service ranging from R&D to commercial production at one production base. In particular, we enjoy comprehensive capabilities in respect of the CDMO market of ADC drugs, including customized R&D, process development, application for IND registration, as well as pilot and commercial production in compliance with international standards, thus further strengthening our core competitiveness.

In respect of the R&D of innovative oncology drugs, the Company focuses its resources on the development of more innovative ADC drugs with high technological barriers. We are equipped with core conjugation processes and scale-up technologies as well as a complete ADC analysis technology platform with the ability to conduct independent analysis in respect of ADC critical metric attributes, thus ensuring product quality and stability. Along with the ever-growing scale and business volume of the Company, leveraging the comprehensive and mature industry value chain of the Company, we have opened up our cooperation platform and actively promoted the transfer of sales rights of self-developed products in order to cope with the development trend of the biological drug industry. All these initiatives aim at benefiting a large number of cancer patients by facilitating the cooperation with major international and domestic pharmaceutical corporations in promoting the commercial sales of products.



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## II. THREE INTEGRATED TECHNOLOGY PLATFORMS

Given our experience in R&D and technological development accumulated over the years, TOT BIOPHARM has developed three integrated technology platforms, providing a solid foundation for the development and cooperation in respect of innovative drugs.

### (1) Therapeutic mAb and ADC Technology

**Platform:** The platform is capable of performing a wide range of functions, ranging from screening cell clones and building cell banks to CMC (chemistry, manufacturing and controls) development, pilot research, scale-up production, purification, filling and packaging. To maximize the synergy of the development of antibody drugs, in addition to mAbs, the Group also goes further in the development of ADC products by linking the antibody to the cytotoxic agent. In 2021, based on the completion of the construction of the ADC drug substance production facility, we constructed GMP-compliant ADC commercial production workshops, becoming one of the few companies in China that has integrated commercial production capabilities for both mAbs and ADCs.

### (2) Gene Engineering Based Therapeutic Technology Platform:

This platform integrates anti-tumor immunotherapy, gene therapy and viral therapy and functions as a R&D and production platform for the tumor-targeted recombinant oncolytic viral vector system. The Group has a dedicated R&D team in Zhangjiang Hi-Tech Park, Shanghai focusing on early discovery and enhancing the Group's capability to collaborate with other innovative oncology drug companies. Leveraged on our integrated R&D capabilities, patents and state-of-the-art laboratories for molecular biology, cytology and virology as well as our first-class facilities, more R&D and production of oncolytic virus products will be conducted.

### (3) Innovative Drug Delivery Technology

**Platform:** A high potency drug injection process development and industrialization manufacturing integrated platform, equipped with aseptic freeze-drying and aseptic bottling manufacturing capabilities, complying with the Good Manufacturing Practice (GMP) manufacturing requirement for OEB-5 potency grade freeze-dried powder/liquid injection.

## III. KEY MILESTONES AND BUSINESS PROGRESS

### • Product Pipelines

Since the inception of TOT BIOPHARM in 2009, our vision has been to improve the life quality of cancer patients around the world with innovative technologies. Committed to the oncology field, particularly the development of innovative oncology drugs, we have established ourselves as a high-tech corporation integrating product R&D, manufacturing and commercial production. Currently, we have a comprehensive portfolio of drug candidates targeting various types of cancers, which encompasses various product pipelines, such as monoclonal antibodies (mAbs), antibody drug conjugates (ADCs), oncolytic viruses and small molecular drugs.

TOT BIOPHARM continued to speed up the R&D of its pipeline products in the first half of 2021, with TOZ309 (temozolomide capsules), the first self-developed chemical drug, approved for launch in May. At present, we have 12 drug candidates in the pipeline, including mAb drugs such as TAB008 (anti-VEGF mAb), TAB014 (anti-VEGF mAb) and TAY018 (anti-CD47 mAb), and ADCs such as TAA013 (anti-HER2 ADC), which are indicated for various cancers with high incidence, such as non-small-cell lung cancer, breast cancer, gastric cancer, brain glioma and cervical cancer.

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Type	Drug Candidate	Indication(s)	Pre-Clinical	Clinical Phase I	Clinical Phase II	Clinical Phase III	NDA <sup>(1)</sup>
Antibody drug conjugate	TAA013 (anti-HER2)	HER2+ breast cancer	→				🇨🇳
	TAE020 (new target)	Acute myeloid leukemia	→				
Monoclonal antibody/ Recombinant protein	TAB008 <sup>(2)</sup> (anti-VEGF)	Non-squamous non-small cell lung cancer (nsNSCLC)	→				🇨🇳
	TAB014 <sup>(3)</sup> (anti-VEGF)	Wet age-related macular degeneration (wAMD)	→		→		🇨🇳 IND authorized by FDA to directly enter Clinical Phase III
	TAY018 (anti-CD47)	Non-Hodgkin's lymphoma, myelodysplastic syndrome, acute myeloid leukemia, solid tumors	→				
	TAC020 (new target)	Various solid tumors	→				
	TEP118 (modified version of hyaluronidase)	Biliary cancer, gallbladder tumors, metastatic cancer, non-small cell lung cancer (NSCLC), gastric cancer	→				
				→			
Chemical drug	TOZ309 (temozolomide)	Malignant brain tumor	→				Launched 🇨🇳
	TOM312 (megestrol acetate)	Cancer and HIV-associated cachexia	→		Completed BE		Submitted Taiwan ANDA <sup>(4)</sup> 🇨🇳
	TIC318 (carboplatin)	Epithelial-derived ovarian cancer, small-cell lung cancer, head and neck squamous cell carcinoma, testicular tumors, malignant lymphoma, cervical cancer, bladder cancer, NSCLC	→				
Oncolytic virus	TVP211 (genetically modified vaccinia virus)	Solid tumors	→				
Liposome chemical drug	TID214 (liposomal docetaxel)	Solid tumors	→				
	TIO217 (liposomal oxaliplatin)	Gastrointestinal tumors	→				

Notes: (1) NDA is applicable to the application of new drugs and Category 5.1 imported drugs

(2) TAB008 is a bevacizumab biosimilar. Bevacizumab has been approved in China for the treatment of non-small cell lung cancer (NSCLC), metastatic colorectal cancer (mCRC) and glioblastoma multiforme (GBM), and for the treatment of hepatocellular carcinoma (HCC) together with atezolizumab. Additional indications of bevacizumab approved in the United States and the European Union include renal cell carcinoma, cervical cancer, ovarian cancer, fallopian tube cancer, peritoneal cancer, breast cancer, etc.

(3) TAB014 is an ophthalmic formulation of bevacizumab, with the right of commercialization in mainland China, Hong Kong and Macau licensed out

(4) ANDA is applicable to the application of generic drugs and Category 5.2 imported drugs

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• **Management of Drug Registration**

In addition to facilitating the development of the existing product pipelines, the Group has also established an international team for the management of drug registration. With a series of reporting procedures completed, the registration team of TOT BIOPHARM has accumulated extensive and comprehensive practical experience in respect of registration and reporting, ranging from the application for clinical research for INDs to new drug marketing application (NDA), from domestically manufactured drugs to imported products, from chemical drugs to biological drugs (including ADCs etc.) and from filings with the National Medical Products Administration of the PRC (NMPA) to filings with the Food and Drug Administration of the United States (FDA). Consequently, the Group has cultivated and built a registration team capable of analyzing, planning and coordinating resources of all parties and equipped with strong execution and efficient communication capabilities. Given the accumulated experience and resources, a solid foundation for the application and filing procedures of subsequent projects of self-developed products has been laid, which will also provide stronger support to the future development of the CDMO business.

• **Approval for the Launch of Two Products**

- TOZ309 (Tazian<sup>®</sup> – temozolomide capsules), a generic drug of TEMODAR<sup>®</sup>, was approved for launch in China by the NMPA in May 2021. Temozolomide is an alkylating agent of imidazotetrazine with anti-tumor activity that can kill cancer cells by damaging their DNA. With improved efficacy and fewer side effects compared to conventional chemotherapy, temozolomide capsules are used as a first-line medication for both newly diagnosed and recurrent brain glioma as well as recurrent anaplastic



astrocytoma. In China, only 3 kinds of temozolomide capsules have been launched in the domestic market, including the original drug TEMODAR<sup>®</sup>. China's market for temozolomide capsules reached approximately RMB1.8 billion in 2018 and is expected to grow to approximately RMB2.5 billion in 2023, according to Frost & Sullivan. TOZ309 is TOT BIOPHARM's first self-developed chemical drug. We will accelerate the market penetration of the product by cooperating with other pharmaceutical companies in China, and are actively preparing for the renewal of the fourth round of the centralized procurement in China in 2022.

- TOM218 (Megaxia<sup>®</sup> – megestrol acetate oral suspension) is imported from TWI Pharmaceuticals, Inc. by the Group with a specification of 125 mg/mL (150 mL/bottle). The Group owns the exclusive agency rights of the drug in mainland China, Hong Kong and Macau. The main ingredient of Megaxia



is megestrol acetate (a semisynthetic progesterone derivative), which can effectively alleviate the cachexia status of AIDS and cancer patients, including loss of appetite and body weight, as well as occasional nausea and vomiting. Compared to solid dosage form, oral suspension can relieve the patients' discomfort in swallowing more effectively. Megaxia has been approved for marketing in the United States since 2014, and currently is the first high concentration megestrol acetate oral suspension approved for marketing in China. TOM218 oral suspension adopts nanocrystalline technology to improve patients' treatment compliance and absorption into the body. According to the latest 2020 global cancer data released

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by the International Agency for Research on Cancer (IARC) of the World Health Organization, there were 4.57 million new cancer cases and 3 million cancer deaths in China in 2020, and 6 of the top 10 cancers with the highest rates of incidence in China are often accompanied by cachexia, among which the incidence of cachexia associated with gastric cancer, gastroesophageal and pancreatic tumors exceeds 65%. Cachexia is an important factor leading to high mortality and shortened survival of patients with advanced tumors. As a result, TOM218 enjoys enormous market potential in China.

• **Key Products at Clinical Stage and Achievements**

– *Core product TAB008 – Submission and Acceptance of Marketing Application*

TAB008 is a bevacizumab biosimilar self-developed by TOT BIOPHARM for the treatment of malignant tumors including advanced, metastatic and recurrent NSCLC and metastatic colorectal cancer. The new drug application (NDA) of TAB008 was accepted in September 2020. NMPA completed its on-site inspection in January 2021 and the approval for marketing is expected to be received by Q3/Q4 of 2021. Since bevacizumab biosimilar covers a number of cancers commonly seen in China, the market demand is huge. According to relevant data, the global sales of bevacizumab biosimilar reached US\$6.09 billion in 2020, and the market scale in China is expected to reach nearly RMB10 billion in 2030.

– *Core product TAA013 – Phase III Clinical Trial Progress is in a Leading Position*

TAA013 is an ADC candidate containing trastuzumab and an emtansine derivative (Trastuzumab-MCC-DM1) for the treatment of local advanced or metastatic HER2+ breast cancer which could not be cured by trastuzumab and have been proved to be unresectable. In July 2020, the drug was successfully dosed in the first patient

in the Phase III clinical trial. To date, over 70 clinical research centers have been initiated across the country and Phase III clinical projects have made satisfactory progress.

Breast cancer is the most common cancer found in females in China, of which HER2+ breast cancer accounts for 25% of all breast cancers. According to a report by Frost & Sullivan, it is expected that the market scale of ADC products for the treatment of HER2+ breast cancer in China will grow from US\$2.6 million in 2020 to US\$228.9 million in 2024, representing a compound annual growth rate of 207.4%, and will reach US\$414.9 million in 2030.

– *TAB014 (anti-VEGF mAb) (wet age-related macular degeneration (wAMD))*

The sales rights of TAB014 (anti-VEGF mAb) in Greater China was transferred to Zhaoke Ophthalmology Limited (6622.HK). We have taken an active role to consult and communicate with the FDA of the United States and the application for Phase III clinical trials of TAB014 has been approved by the FDA. We applied for approval based on the data from the Phase I clinical trial of TAB014 and relevant clinical literature. This application was a direct application for authorization to conduct Phase III clinical trials (being exempted from Phase II clinical trials). The Phase I clinical trials of TAB014 have been completed in the first half of 2021, and the Phase III clinical trials will initiate instantly in the second half of the year.

As the population aging problem worsens in China, the market scale of drugs for wAMD has been expanding gradually. In 2019, the market scale in China reached US\$240 million, and is expected to substantially increase to US\$3.5 billion in 2030, representing a compound annual growth rate of 27.5%.

#### IV. BUSINESS HIGHLIGHTS

- **Prominent Competitiveness of ADC Drugs**

ADC drug is an innovative drug composed of antibodies, toxics and linkers, enabling it to convey toxics to, and kill or damage, tumor cells precisely. Consequently, it is hailed as a “biomissile”. Given the unique medical efficacy and remarkable clinical effect of ADC drugs, the development of which has received extensive attention from the industry and the capital market, making it the main direction in the research on innovative drugs. Currently, 12 ADC drug products have been approved for marketing around the world. In China, 4 products, which are mainly imported, have been approved for marketing.

TOT BIOPHARM possesses core conjugation process technologies and have successfully developed several stable production processes for ADC drug substances and formulations to ensure stability and a high degree of batch-to-batch consistency of products. We have a complete ADC analysis technology platform and independent analysis capabilities in respect of ADC critical metric attributes to ensure the successful development of ADC processes and the high quality of products. Accordingly, we have achieved technical breakthroughs in the regulation of glycoforms, enabling precise control of the composition of each glycoform. Given the difficulties in technological development, over 70% of ADC drugs development projects around the world are currently at the preclinical stage, and fewer than 10 are able to enter the Phase III clinical stage. Amongst these products, TAA013, the ADC drug independently developed by TOT BIOPHARM, is one of three HER2+ breast cancer drugs in phase III clinical stage across the world. It has attracted much attention in the market and is expected to be a better treatment option for patients in China.

On 19 June 2021, at the inaugural BioChina – Summit Forum of Innovative Biomedical of China held in Suzhou, TOT BIOPHARM was rated as one of the “Top 10 Leading ADC Drugs Corporations in China” according to the database of PharmCube and a comprehensive evaluation based on 4 major factors, including the representativeness of institutional investors, the number of a corporation’s R&D pipelines and the number of indications under development, the degree of a corporation’s concentration on the sector, and the support from investment institutions.

In early July 2021, TOT BIOPHARM convened a national researchers seminar for the Phase III clinical trials of ADC drug TAA013 in Chengdu, at which comprehensive discussions and exchanges on the Phase III clinical trials of TAA013 were conducted amongst about 100 researchers from over 60 research centers across China. Professor Yin Yongmei and Dr. Liu Min, the Chief Medical Officer of TOT BIOPHARM, both the principal investigators of the Phase III clinical trials of TAA013, concluded the seminar and highly acknowledged the achievements made since the inception of the project.

TOT BIOPHARM has established an expert team for the R&D of conjugation process technologies of ADCs and an analysis team for complex ADC molecular structures. Boasting their extensive practical experience, successful exemplary cases and comprehensive experience ranging from R&D, process development, clinical trials, registration and filing for approval to commercial production, both teams have completed the R&D and production of a number of new generation ADC drugs for our strategic partners, and placed their candidate products at the top tier in the R&D of ADCs in China. The harvest period of the ADC industry will come in the following years, meaning that the industry will be fully commercialized, the market capacity will continue to grow and the market potential is huge.

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• **Leaping Growth of CDMO/CMO Business**

– *Establishment of One-stop Innovative Drug CDMO Solution*

Given the intense competition in the biological drugs sector, TOT BIOPHARM capitalized on market opportunities by fully leveraging the open technological platform and commercial production capability of the Company, thereby speeding up the development of CDMO/CMO business under the “one-stop, one-base” model. We particularly focused on the CDMO/CMO business of the ADC sector, and acted as a first-mover in the market by securing a series of cooperation opportunities. TOT BIOPHARM cherishes its long-term and diversified cooperation relationships with its partners and has made every effort to provide our clients with one-stop CDMO solutions, ranging from R&D, process development, clinical trials, registration, filing to commercial production.

Leveraging its extensive project experience and mature research on processes, TOT BIOPHARM possesses advantages in core conjugation process technologies and scale-up technologies, and has also established independent analytical capability on ADC critical metric attributes so as to guarantee the high quality R&D of products. At the same time, we are also equipped with the “perfusion-batch hybrid technology” to satisfy the commercial production of mAb drugs by scaling up the productivity from 25L to 2,000L directly, which is able to simplify the production process by shortening the production cycle, thereby enhancing the economic efficiency of commercial CDMO/CMO projects greatly. Thanks to the long-term mutual trust established with our partners, we secured multiple new CDMO/CMO projects during the first half of 2021, representing a substantial increase in terms of number of partners and business scale.

Geographically speaking, TOT BIOPHARM completed all stages ranging from R&D to the production of end products within the same production base at our Suzhou headquarters, greatly reducing the risks and difficulties in terms of management, transportation and technology brought about by the segmented subcontracting of suppliers. Given its competitiveness in terms of R&D and production, TOT BIOPHARM has carried out a variety of strategic cooperation with domestic and overseas pharmaceutical corporations. We adhered to the service concept of “facilitating innovation and mutual growth with a focus on quality” to accelerate the development and production of chemical drugs and biological drugs, especially ADC drugs, and to empower our partners for the sake of benefiting a large number of patients.



– *Strategic Cooperation for ADC Drug CDMO Business*

On 19 July 2021, TOT BIOPHARM entered into a strategic cooperation relationship with BrightGene Bio-Medical Technology Co., Ltd. (688166.SH) to strengthen the one-stop service platform for ADC drug CDMO business, thereby supporting the R&D and commercialization of innovative drugs.

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Both parties will collaborate together to provide services in respect of preliminary development of production processes, scale-up of the production of intermediates and GMP-compliant production of ADC products. Boasting our competitiveness, TOT BIOPHARM will focus on the production of mAb drugs as well as the CMC process development, conjugation and formulation bottling of ADC drugs, and will provide GMP-compliant production services for pre-clinical research, clinical research and commercialization. Such localized cooperation will improve the efficiency of production, preventing the risk of cross-regional regulations and enabling us to collaborate with other renowned industry players through complementing each other's technologies and resources. This will further enhance the CDMO service platform of ADC drugs and will enable us to provide various innovative drug corporations with one-stop solutions.

- **Comprehensive International Quality Management System**

The Group continued to improve its quality management system by establishing a critical quality management system according to the requirement under the rules and guidelines of the NMPA, the FDA and the European Medicines Agency (EMA) for the processes from R&D to commercialization, including the quality management system, the production management system, the material management system, the packaging and labelling management system, the plant facility and equipment management system and the quality control management system, so as to provide support for our product quality and ensure that it is in line with international production standards. All these initiatives aimed at benefiting a large number of cancer patients.

During the first half of 2021, our chemical drug capsules passed the GMP compliance inspection by the Medical Products Administration of Jiangsu Province in a single attempt, suggesting that our quality control system has been highly recognized by the NMPA. Meanwhile, the registrational on-site inspection and GMP compliance inspection of our biological product mAb injections were also completed in January 2021.

In 2021, along with the enhancement and standardization of the quality management system of the Company, we made full use of digital management tools to realize electronic and systematic management so as to guarantee the completeness, reliability and trackability of our data, files and records, thus greatly enhancing the management efficiency of the Company. In addition, we set quality goals for the Company and mobilized various departments to organize all sorts of training sessions as planned. All these measures served to strengthen and upgrade the professional skills of our staff members and to enhance the concept of quality control through a training model integrating theory and practice. During the first half of 2021, we started an internal audit on our quality control system by conducting in-depth analysis and audit against GMP regulations of the FDA or the EMA. We strengthened the compliance sense of our employees and facilitated the sustained upgrade of the quality control function of the Company through continuous improvement of our management flow and operation procedures, thereby ensuring that our product quality is in line with the international standard.

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- **Commercialization Planning**

In line with the upgrade of the business scale of the Company and for the purpose of meeting the market demand, we continued to expand our commercial production capabilities in respect of antibody drugs and ADC products, not only to satisfy the demand of our self-developed products, but also for making sufficient preparation for the development of our CDMO/CMO business, based on the existing production capacity of 16,000L mAb drugs. In September 2020, the construction of drug substance production facilities were completed for the commercial production of ADCs and based on this achievement, we began to expand the ADC formulation production line. In 2021, we will continue to make every full effort to implement the plan for ADC pilot and commercial production facilities, including:

*GMP-compliant pilot production facilities: OEB-5 potency-level freeze-dried powder/liquid injection formulation*



- Production capacity of ADC drug substance: 1~300g/batch
- Production capacity of ADC formulation line: 500~5,000 vials/batch

*GMP-compliant ADC commercial production facilities*



- Production capacity of ADC drug substance: 1,000~3,000g/batch
- Production capacity of increased ADC formulation line: 10,000~15,000 vials/batch

As a result, ADC commercial production facilities with remarkable competitive advantages was established, enabling us to produce GMP-compliant mAb and ADC drug substances and formulations at the same production base. The research on the release and stability of drug substances/end products not only meets the requirements of quality control at GMP standards but also fulfills the requirements of quality assurance systems internationally.

- **Strengthened Industry Cooperation and Communication**

Being a leader in the ADC field, TOT BIOPHARM has established trusting partnership based on long-term mutual trust with a number of partners in the ADC field. In 2021, we proactively organized and participated in seminars in respect of biological drugs and ADCs so as to have close communication with investment institutions in the pharmaceutical industry,

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thereby enabling more partners and investors to have a better understanding of the potential value and strategic planning of TOT BIOPHARM and earning their high recognition. In the ADC section of the 6th Enmore Bio Conference held in Suzhou in March 2021, TOT BIOPHARM invited several ADC experts to share their views on the topic “Antibody Drugs – The Whole Process of the Development of ADCs”. Through the sharing made by the guests regarding the production solution of ADC drugs from the laboratory stage to the clinical stage, it drives the industry’s active discussion on the production of ADCs.



*Dr. Liu Jun, our CEO and Executive Director, gave a speech at the ADC Session of the 6th Enmore Bio Conference held in Suzhou in March 2021*

## V. RESPONSE TO COVID-19 AND CORPORATE SOCIAL RESPONSIBILITIES

As the prevention and control of COVID-19 normalizes, the Group has established a comprehensive routine control and management system by implementing sustainable reaction plans so as to reduce the impact of the pandemic on R&D, clinical trials and supply chains. The Group has also launched various project-based contingency plans and measures in advance to ensure stable business operations.

The Group reserved a special budget for fighting against COVID-19 to maintain the continuous supply of precautionary materials for our employees and to pay part of the expenses for nucleic acid testing

and quarantine. In order to strengthen the protection of the health of our employees and to respond proactively to the government’s urge, we have arranged our employees to receive vaccination by batches since April 2021 to guarantee the continuous operation of the Group during the pandemic period.

Meanwhile, we took an active role to formulate and prepare the management procedures for ESG (Environmental, Social and Governance reporting) in accordance with the Listing Rules to strengthen our internal communication and cooperation mechanism and to promote ESG management in our routine functions for the sake of improving the quality of ESG management, strengthening the sense of risk management and supporting the long-term sustainable development of the Company.

## VI. PROSPECTS AND STRATEGIES

It is expected that TAB008, the first biological drug of the Group, will be approved for launch in 2021 and we will cooperate with other large pharmaceutical companies to promote marketing. At the same time, we will speed up the clinical progress of TAA013 and enrich the product pipelines of ADCs. Along with the booming development of the biological drug CDMO business in China, we will step up our effort to strengthen the brand image of our CDMO business in respect of ADCs with inherent advantages, take an active role in identifying overseas and domestic strategic partners, and make full use of the financing platform in Hong Kong capital markets, so as to further improve and enhance our market position.

Looking ahead, we believe that TOT BIOPHARM will continue to showcase its competitive advantages. We will also keep improving our standards of international management and speed up our plan for international collaboration so as to offer a favourable development platform for the growth of our employees, to provide our partners with the best strategic solutions and to create value for our shareholders.

# FINANCIAL REVIEW

## OVERVIEW

For the first half of 2021, the Group recorded a revenue of RMB23,132,000 and a net loss of RMB115,005,000, as compared to a revenue of RMB13,030,000 and a net loss of RMB129,183,000 for the same period in 2020. The Group's research and development expenses for the first half of 2021 were RMB88,749,000, as compared to RMB99,325,000 for the same period in 2020. The Group's general and administrative expenses for the first half of 2021 were RMB26,823,000, as compared to RMB24,118,000 for the same period in 2020. The Group's selling expenses for the first half of 2021 were RMB11,202,000, as compared to RMB13,726,000 for the same period in 2020.

## OPERATING REVENUE AND COSTS

The Group's diversified revenue mainly includes revenue for providing CDMO and CMO services, revenue from royalties, and commission revenue from marketing services received from strategic business partners, etc.

The Group's revenue from CDMO and CMO for the first half of 2021 was RMB11,668,000, representing an increase of RMB8,953,000 from RMB2,715,000 for the same period in 2020, 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 royalties for the first half of 2021 was RMB5,943,000, which was the milestone payment received in connection with the completion of Phase I clinical trials for the TAB014 project.

The Group's commission revenue for the first half of 2021 was RMB4,268,000, representing a decrease of RMB5,843,000 from RMB10,111,000 for the same period in 2020, primarily attributable to the decline in sales of the distributed product S-1 caused by the national volume-based procurement policy.

## RESEARCH AND DEVELOPMENT EXPENSES

The Group's research and development expenses primarily consist of salaries and benefits for research and development staff, expenses for clinical trials, research and development materials and consumables, 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 2021 were RMB88,749,000, representing a decrease of RMB10,576,000 from RMB99,325,000 for the same period in 2020, which was mainly attributable to the absence of related significant expenses for clinical trials in 2021 subsequent to the Company's completion of Phase III clinical trials for the TAB008 project during the second half of 2020.

## SELLING EXPENSES

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

The Group's selling expenses for the first half of 2021 were RMB11,202,000, representing a decrease of RMB2,524,000 from RMB13,726,000 for the same period in 2020, which mainly reflected the Group's adjustments to its sales strategies by forming industry alliances.

## 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 2021 were RMB26,823,000, representing an increase of RMB2,705,000 from RMB24,118,000 for the same period in 2020, mainly attributable to the increase in operating and management expenses related to employee, administration and taxation, etc.

► Financial Review

### FINANCE INCOME

The Group's finance income is primarily interest income on bank deposits. The finance income for the first half of 2021 was RMB714,000, representing an increase of RMB16,000 from RMB698,000 for the same period in 2020, which basically remained flat. The interest income on the placement of principal-guaranteed structured deposits with licensed commercial banks during the prior period was recorded as other income instead of finance income.

### FINANCE COSTS

The Group's finance costs are primarily interest expenses on bank borrowings for operational purposes and for increasing production capacity, etc.

The Group's interest expenses on bank borrowings for the first half of 2021 were RMB274,000, representing a decrease of RMB1,244,000 from RMB1,518,000 for the same period in 2020, mainly attributable to the banking facilities being utilized only since mid-2021, and the lower level of average borrowings recorded for the current period as compared to the same period in 2020.

### INCOME TAX EXPENSE

For the first half of 2021 and the same period in 2020, the Group did not incur any income tax expense because the Group had not generated any taxable income during these periods.

### LOSS FOR THE PERIOD

In view of the abovementioned factors, the Group recorded a net loss of RMB115,005,000 for the first half of 2021, representing a decrease of RMB14,178,000 from RMB129,183,000 for the same period in 2020.

### NET ASSETS

The Group's net assets as at 30 June 2021 were RMB480,998,000, representing a decrease of RMB101,359,000 from RMB582,357,000 as at the end of 2020, which was primarily attributable to the net loss during the current period.

### CASH MOVEMENT AND SOURCE OF FUNDS

As at 30 June 2021, the Group's cash and cash equivalents were RMB156,243,000, representing a decrease of RMB69,290,000 from RMB225,533,000 as at the end of 2020. Such change was mainly attributable to the cash outflows and inflows related to operating loss, capital expenditures, and the taking out of bank borrowings, etc.

During the first half of 2021, the Group's net cash outflows for operating activities were RMB93,624,000, representing a decrease of RMB13,324,000 from RMB106,948,000 for the same period in 2020, due to the reduction in net loss and the changes in working capital during the current period. The Group's net cash outflows for investing activities for the current period were RMB55,510,000, representing a decrease of RMB180,281,000 from RMB235,791,000 for the same period in 2020, which was mainly attributable to the placement of more principal-guaranteed structured deposits with licensed commercial banks during the prior period. The Group's net cash inflows for financing activities were RMB80,937,000, as compared to the net cash outflows for financing activities of RMB79,399,000 for the same period in 2020, which was mainly attributable to the taking out of new bank borrowings during the current period as opposed to repayment during the prior period.

### INDEBTEDNESS AND KEY LIQUIDITY RATIO

As at 30 June 2021, the Group had outstanding bank borrowings amounted to RMB72,175,000 (31 December 2020: Nil) and had unutilised bank facilities of RMB293,560,000 (31 December 2020: RMB150,000,000). For further details, please refer to note 12 to the interim condensed consolidated financial information.

As at 30 June 2021, the Group's total liabilities to total assets ratio was 0.2 (31 December 2020: 0.1). The increase was mainly attributable to increase in bank borrowings in the first half of 2021.

► Financial Review

### MAJOR INVESTMENT

During the first half of 2021, the Group did not make any major investment.

### MAJOR ACQUISITIONS AND DISPOSALS

During the first half of 2021, the Group did not have any major acquisitions and disposals of subsidiaries, consolidated affiliated entity or associates.

### PLEDGE OF ASSETS

As at 30 June 2021, the Group had no pledge of assets.

### CONTINGENT LIABILITIES

As at 30 June 2021, 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.

### EMPLOYEES AND REMUNERATION

As at 30 June 2021, the Group had a total of 354 employees. The following table sets forth the total number of employees by function as of 30 June 2021:

Function	Number of employees	% of total
Research and development	116	32.8%
Sales and marketing	54	15.2%
General and administration	41	11.6%
Manufacturing	143	40.4%
<b>Total</b>	<b>354</b>	<b>100%</b>

In the first half of 2021, the Group incurred employee benefit expenses of RMB65,213,000, as compared to RMB54,927,000 in the first half of 2020. The employee benefit expenses of the Group includes 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.

# REPORT ON REVIEW OF INTERIM FINANCIAL INFORMATION

## To the Board of Directors of TOT BIOPHARM International Company Limited

*(incorporated in Hong Kong with limited liability)*

### INTRODUCTION

We have reviewed the interim financial information set out on pages 17 to 38, which comprises the interim condensed consolidated balance sheet of TOT BIOPHARM International Company Limited (the “Company”) and its subsidiaries (together, the “Group”) as at 30 June 2021 and the interim condensed consolidated statement of comprehensive loss, the interim condensed consolidated statement of changes in equity and the interim condensed consolidated statement of cash flows for the six-month period then ended, and a summary of significant accounting policies and other explanatory notes. The Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited require the preparation of a report on interim financial information to be in compliance with the relevant provisions thereof and Hong Kong Accounting Standard 34 “Interim Financial Reporting” issued by the Hong Kong Institute of Certified Public Accountants. The directors of the Company are responsible for the preparation and presentation of this interim financial information in accordance with Hong Kong Accounting Standard 34 “Interim Financial Reporting”. Our responsibility is to express a conclusion on this interim financial information based on our review and to report our conclusion solely to you, as a body, in accordance with our agreed terms of engagement and for no other purpose. We do not assume responsibility towards or accept liability to any other person for the contents of this report.

### SCOPE OF REVIEW

We conducted our review in accordance with Hong Kong Standard on Review Engagements 2410, “Review of Interim Financial Information Performed by the Independent Auditor of the Entity” issued by the Hong Kong Institute of Certified Public Accountants. A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Hong Kong Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

### CONCLUSION

Based on our review, nothing has come to our attention that causes us to believe that the interim financial information of the Group is not prepared, in all material respects, in accordance with Hong Kong Accounting Standard 34 “Interim Financial Reporting”.

**PricewaterhouseCoopers**

*Certified Public Accountants*

Hong Kong, 12 August 2021

# INTERIM CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS

	Note	Unaudited Six months ended 30 June	
		2021 RMB'000	2020 RMB'000
Revenue	5	23,132	13,030
Cost of revenue		(9,143)	(3,141)
Research and development expenses		(88,749)	(99,325)
Selling expenses		(11,202)	(13,726)
General and administrative expenses		(26,823)	(24,118)
Other losses – net		(2,660)	(1,083)
<b>Operating loss</b>		<b>(115,445)</b>	(128,363)
Finance income		714	698
Finance costs		(274)	(1,518)
Finance income/(costs) – net		440	(820)
<b>Loss before income tax</b>	6	<b>(115,005)</b>	(129,183)
Income tax expense	7	–	–
<b>Loss for the period and attributable to the equity holders of the Company</b>		<b>(115,005)</b>	(129,183)
<b>Other comprehensive income:</b>			
<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	1,363
<i>Items that may be reclassified to profit or loss</i>			
Exchange differences on translation		(722)	2,858
<b>Other comprehensive income for the period, net of tax</b>		<b>25</b>	4,221
<b>Total comprehensive loss for the period and attributable to the equity holders of the Company</b>		<b>(114,980)</b>	(124,962)
<b>Loss per share for the six months ended 30 June and attributable to the equity holders of the Company</b>			
– Basic and diluted loss per share (RMB)	8	(0.20)	(0.23)

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 2021 RMB'000	Audited 31 December 2020 RMB'000
<b>ASSETS</b>			
<b>Non-current assets</b>			
Property, plant and equipment	9	297,267	290,367
Prepayments for property, plant and equipment		23,648	416
Right-of-use assets	9	15,453	20,639
Intangible assets	9	3,102	3,229
Financial assets at fair value through other comprehensive income		8,823	8,076
Other non-current assets		78,058	69,229
		<b>426,351</b>	391,956
<b>Current assets</b>			
Inventories		19,727	8,114
Trade and other receivables	10	7,611	5,851
Prepayments		20,994	8,827
Contract assets		2,294	902
Cash and cash equivalents		156,243	225,533
		<b>206,869</b>	249,227
<b>Total assets</b>		<b>633,220</b>	641,183
<b>EQUITY</b>			
Share capital	11	1,892,906	1,874,438
Other reserves		44,681	49,503
Accumulated losses		(1,456,589)	(1,341,584)
<b>Capital and reserves attributable to the equity holders of the Company</b>		<b>480,998</b>	582,357

## ▶ Interim condensed consolidated balance sheet

	Note	Unaudited 30 June 2021 RMB'000	Audited 31 December 2020 RMB'000
<b>LIABILITIES</b>			
<b>Non-current liabilities</b>			
Borrowings	12	21,440	–
Lease liabilities		1,079	6,083
		<b>22,519</b>	6,083
<b>Current liabilities</b>			
Borrowings	12	50,735	–
Trade and other payables	13	53,567	42,316
Contract liabilities		24,411	9,104
Lease liabilities		990	1,323
		<b>129,703</b>	52,743
<b>Total liabilities</b>		<b>152,222</b>	58,826
<b>Total equity and liabilities</b>		<b>633,220</b>	641,183
<b>Net current assets</b>		<b>77,166</b>	196,484
<b>Total assets less current liabilities</b>		<b>503,517</b>	588,440

**Dr. Liu, Jun**  
Director

**Ms. Yeh-Huang, Chun-Ying**  
Director

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
<b>Balance at 1 January 2021</b>	<b>1,874,438</b>	<b>49,503</b>	<b>(1,341,584)</b>	<b>582,357</b>
Loss for the period	–	–	(115,005)	(115,005)
Other comprehensive income	–	25	–	25
<b>Total comprehensive loss</b>	<b>–</b>	<b>25</b>	<b>(115,005)</b>	<b>(114,980)</b>
<b>Transactions with owners</b>				
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
<b>Total transactions with owners</b>	<b>18,468</b>	<b>(4,847)</b>	<b>–</b>	<b>13,621</b>
<b>Balance at 30 June 2021</b>	<b>1,892,906</b>	<b>44,681</b>	<b>(1,456,589)</b>	<b>480,998</b>
<b>Balance at 1 January 2020</b>	1,874,438	36,925	(1,053,086)	858,277
Loss for the period	–	–	(129,183)	(129,183)
Other comprehensive income	–	4,221	–	4,221
<b>Total comprehensive loss</b>	<b>–</b>	<b>4,221</b>	<b>(129,183)</b>	<b>(124,962)</b>
<b>Transactions with owners</b>				
Share-based compensation expense	–	10,774	–	10,774
<b>Total transactions with owners</b>	<b>–</b>	<b>10,774</b>	<b>–</b>	<b>10,774</b>
<b>Balance at 30 June 2020</b>	1,874,438	51,920	(1,182,269)	744,089

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	
	2021	2020
	RMB'000	RMB'000
<b>Cash used in operating activities</b>		
Net cash used in operations	(94,292)	(106,312)
Interest received	714	698
Interest paid	(46)	(1,334)
<b>Net cash used in operating activities</b>	<b>(93,624)</b>	<b>(106,948)</b>
<b>Cash flow used in investing activities</b>		
Purchase and prepayment of property, plant and equipment	(55,140)	(27,177)
Purchase of intangible assets	(384)	(835)
Proceeds from disposal of property, plant and equipment	14	5
Investment in financial assets at fair value through profit or loss	–	(343,000)
Proceeds from disposal of financial assets at fair value through profit or loss	–	135,216
<b>Net cash used in investing activities</b>	<b>(55,510)</b>	<b>(235,791)</b>
<b>Cash flows generated from/(used in) financing activities</b>		
Proceeds from bank borrowings	72,175	–
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 for listing expenses	–	(18,219)
Repayment of bank borrowings	–	(60,000)
Payment of lease liabilities	(848)	(1,180)
<b>Net cash generated from/(used in) financing activities</b>	<b>80,937</b>	<b>(79,399)</b>
<b>Net decrease in cash and cash equivalents</b>	<b>(68,197)</b>	<b>(422,138)</b>
Cash and cash equivalents at beginning of the period	225,533	539,180
Exchange losses on cash and cash equivalents	(1,093)	(3,533)
<b>Cash and cash equivalents at end of the period</b>	<b>156,243</b>	<b>113,509</b>

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 Level 54, Hopewell Centre, 183 Queen’s Road East, 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 2021.

## 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 2021 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 2020 and any public announcements made by the Company during the interim reporting period.

The financial information relating to the year ended 31 December 2020 that is included in the condensed consolidated interim financial information for the six months ended 30 June 2021 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 2020 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 Company’s auditor has reported on those financial statements. The auditor’s report was unqualified; did not include a reference to any matters to which the auditor drew attention by way of emphasis without qualifying its report; and did not contain a statement under sections 406(2), 407(2) or (3) of the Hong Kong Companies Ordinance (Cap. 622).

▶ Notes to the interim condensed consolidated financial information

## 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont'd)

### 2.1 Basis of preparation (cont'd)

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.

(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.

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

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
HKFRS 3, HKAS 16 and HKAS 37	Narrow-scope amendments (amendments)	1 January 2022
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
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
HKFRS 9, HKFRS 16, HKFRS 1 and HKFRS 41	Annual improvements HKFRS Standards 2018-2020	1 January 2022
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
HKFRS 10 and HKAS 28	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture (amendments)	To be determined

► Notes to the interim condensed consolidated financial information

## 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (cont'd)

### 2.1 Basis of preparation (cont'd)

#### (b) Impact of standards issued but not yet applied by the entity (cont'd)

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.

## 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 2020.

There have been no changes in the risk management mechanism since the year ended 31 December 2020 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 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
Borrowings (including interest payables)	53,268	–	22,539	–	75,807
Trade and other payables (Note 13)	40,293	–	–	–	40,293
Lease liabilities (including interest payables)	1,019	977	189	–	2,185
	94,580	977	22,728	–	118,285

▶ Notes to the interim condensed consolidated financial information

### 3 FINANCIAL RISK MANAGEMENT (cont'd)

#### 3.2 Liquidity risk (cont'd)

As at 31 December 2020

	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)	30,911	–	–	–	30,911
Lease liabilities (including interest payables)	1,357	1,131	3,361	3,012	8,861
	32,268	1,131	3,361	3,012	39,772

#### 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)

The following table presents the Group's assets that were measured at fair value at 30 June 2021:

	Level 1 RMB'000	Level 2 RMB'000	Level 3 RMB'000	Total RMB'000
<b>Assets:</b>				
Financial assets at fair value through other comprehensive income	8,823	–	–	8,823

The following table presents the Group's assets that were measured at fair value at 31 December 2020:

	Level 1 RMB'000	Level 2 RMB'000	Level 3 RMB'000	Total RMB'000
<b>Assets:</b>				
Financial assets at fair value through other comprehensive income	8,076	–	–	8,076

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 2021 (For the six months ended 30 June 2020: 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 2021 (For the six months ended 30 June 2020: same).

▶ Notes to the interim condensed consolidated financial information

#### 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 2020 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.

##### (b) License agreement with a customer

In January 2017, the Group entered into an agreement with a pharmaceutical company for licensing one of its bio-pharmaceutical know-how (the "product") to the customer for development and commercialization for a period of 10 years. The agreement includes non-refundable upfront payment, license-granted payment, milestone payments and sales-based royalty upon commercialization of the know-how. For the six months ended 30 June 2021, the customer made a payment of RMB5,943,000 upon the enrollment of the first subject in a Phase 2 clinical trial for the product (For the six months ended 30 June 2020, no milestone was achieved and therefore, no revenue was recognized).

► Notes to the interim condensed consolidated financial information

**5 SEGMENT AND REVENUE INFORMATION** (cont'd)

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

	Six months ended 30 June	
	2021 RMB'000	2020 RMB'000
Timing of revenue recognition		
At a point in time:		
– Commission revenue	4,268	10,111
– Sales of goods	13	204
– CDMO/CMO	4,404	–
Over time:		
– CDMO/CMO	7,264	2,715
– Revenue from CRO	1,240	–
– Revenue from license granted	5,943	–
	<b>23,132</b>	13,030

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

	30 June 2021 RMB'000	31 December 2020 RMB'000
Contract assets:		
– Consideration for services delivered-CDMO/CMO	729	22
– Consideration for commission	1,565	880
Contract liabilities-CDMO/CMO	<b>(24,411)</b>	(9,104)
	<b>(22,117)</b>	(8,202)

(i) 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)

### (e) 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	
	2021 RMB'000	2020 RMB'000
Revenue recognized that was included in the balance of contract liabilities at the beginning of the period		
– Service revenue-CDMO/CMO	<b>3,834</b>	2,128

### (f) Unfulfilled long-term contracts

The license contract includes an upfront fee of RMB8,400,000 (including tax) and development milestone payments of RMB48,100,000 (including tax) in aggregate. The contract also includes license-granted fee and sales-based royalty. The Company has recorded the upfront payment and first development milestone payment as revenue during the year ended 31 December 2017. For the six months ended 30 June 2021, the second development milestone was achieved and therefore, RMB5,943,000 was recognized as revenue (For the six months ended 30 June 2020: nil). The Company is entitled to receive up to an aggregate of RMB33,400,000 (including tax) upon the achievement of additional specified milestones related to the development and regulatory approval of the product.

Except for the above-mentioned contract, all other CDMO/CMO revenue contracts are for periods of one year or less and are billed based on milestone or at a point. As permitted under HKFRS 15, the transaction price allocated to these unsatisfied contracts is not disclosed.

### (g) Geographical information

Geographical information of revenue and non-current assets other than financial assets for the six months ended 30 June 2021 and 2020 is as follows:

	Six months ended 30 June			
	2021		2020	
	Revenue RMB'000	Non-current assets RMB'000	Revenue RMB'000	Non-current assets RMB'000
Mainland China	<b>23,132</b>	<b>339,162</b>	13,030	396,352
Others	–	<b>523</b>	–	799
	<b>23,132</b>	<b>339,685</b>	13,030	397,151

## ▶ Notes to the interim condensed consolidated financial information

**6 LOSS BEFORE INCOME TAX**

	Six months ended 30 June	
	2021 RMB'000	2020 RMB'000
Loss before taxation has been arrived at after charging:		
– Employee benefit expenses	65,213	54,927
– Clinical trials (exclude employee benefit expenses)	13,104	23,880
– R&D materials and consumables	13,706	17,355
– Depreciation and amortisation charge (Note 9)	16,456	15,940

**7 INCOME TAX EXPENSE**

Income tax expenses is recognised 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	
	2021	2020
Loss attributable to equity holders of the Company (RMB'000)	(115,005)	(129,183)
Weighted average number of ordinary shares in issue (thousand)	571,492	570,000
Basic loss per share (RMB)	(0.20)	(0.23)

**(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 2021, the Company had one category of potential ordinary shares: the stock options granted to employees (For the six months ended 30 June 2020: same). As the Group incurred losses for the six months ended 30 June 2021 and 2020, 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 2021 and 2020 is the same as basic loss per share of the respective periods.

► Notes to the interim condensed consolidated financial information

## 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
<b>Six months ended 30 June 2021</b>			
<b>Opening net book amount as at 1 January 2021</b>	<b>290,367</b>	<b>3,229</b>	<b>20,639</b>
Additions	27,345	384	2,246
Depreciation and amortisation charge (Note 6)	(14,929)	(511)	(1,016)
Disposals	(5,514)	–	(6,417)
Net exchange differences	(2)	–	1
<b>Closing net book amount as at 30 June 2021</b>	<b>297,267</b>	<b>3,102</b>	<b>15,453</b>
<b>Six months ended 30 June 2020</b>			
<b>Opening net book amount as at 1 January 2020</b>	<b>300,230</b>	<b>2,391</b>	<b>28,435</b>
Additions	24,985	835	–
Depreciation and amortisation charge (Note 6)	(14,262)	(387)	(1,291)
Disposals	(133)	–	(5,913)
Net exchange differences	–	–	16
<b>Closing net book amount as at 30 June 2020</b>	<b>310,820</b>	<b>2,839</b>	<b>21,247</b>

## ▶ Notes to the interim condensed consolidated financial information

**10 TRADE AND OTHER RECEIVABLES**

	<b>30 June 2021 RMB'000</b>	31 December 2020 RMB'000
Trade receivables from contracts with customers	<b>4,172</b>	1,536
Other receivables	<b>3,439</b>	4,315
Trade and other receivables	<b>7,611</b>	5,851

	<b>30 June 2021 RMB'000</b>	31 December 2020 RMB'000
Trade receivables from contracts with customers	<b>4,172</b>	1,536

Customers are generally granted with credit terms ranging from 15 to 60 days.

As of 30 June 2021 and 31 December 2020, the ageing analysis of the trade receivables based on invoice date is as follows:

	<b>30 June 2021 RMB'000</b>	31 December 2020 RMB'000
Within 30 days	<b>1,546</b>	1,218
31 days to 90 days	<b>2,626</b>	318
	<b>4,172</b>	1,536

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)

### (a) Other receivables

	30 June 2021 RMB'000	31 December 2020 RMB'000
Advances to a supplier (Note (i))	2,591	2,598
Advances to employees (Note (ii))	358	812
Other receivables	490	905
Other receivables	<b>3,439</b>	4,315

Note (i) The party is a supplier of TOT Taipei. 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% (2020: 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 2021 RMB'000	31 December 2020 RMB'000
RMB	4,659	2,507
USD	361	729
NTD	2,591	2,612
HKD	-	3
	<b>7,611</b>	5,851

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 2020 (Audited)	570,000,000	1,874,438
Compensatory Grant (Note (a))	30,466,697	–
As at 31 December 2020 (Audited)	600,466,697	1,874,438
Issue of shares upon exercise of share options (Note (b))	1,062,800	3,249
Increase in share capital upon receipt of the grant consideration of award shares (Note (c))	–	15,219
As at 30 June 2021 (Unaudited)	601,529,497	1,892,906

Note (a) On 28 December 2020, the Company allotted and issued 30,466,697 ordinary shares (“award shares”) to certain trustees at a subscription price of zero under the Company’s 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.

Note (b) 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 (c) 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.

As at 30 June 2021, a total of 26,332,558 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 2021 RMB'000	31 December 2020 RMB'000
<b>Current</b>		
– Unsecured bank borrowings (Note (a))	50,735	–
Non-current		
– Unsecured bank borrowings (Note (b))	21,440	–
	<b>72,175</b>	–

Note (a): Bank loans of RMB50,735,000 are unsecured, will be repayable in 2022 and bear annual interest rate ranging from 1.68% to 3.95% with undrawn facilities up to RMB135,000,000.

Note (b): Bank loans of RMB21,440,000 are unsecured, will be repayable in 2024 and 2025 and bear annual interest rate of 4.25% with undrawn facilities up to RMB158,560,000 for specific use on construction of plant, production line and equipment.

As at 30 June 2021 and 31 December 2020, the Group's bank borrowings were repayable as follows:

	30 June 2021 RMB'000	31 December 2020 RMB'000
Within 1 year	50,735	–
Between 2 and 5 years	21,440	–
	<b>72,175</b>	–

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

	30 June 2021	31 December 2020
Bank borrowings	3.79%	–

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 2021, the Group has unutilised bank facilities of RMB293,560,000 (As at 31 December 2020: RMB150,000,000).

## ▶ Notes to the interim condensed consolidated financial information

**13 TRADE AND OTHER PAYABLES**

	<b>30 June 2021 RMB'000</b>	31 December 2020 RMB'000
Staff salaries and welfare payables	<b>13,274</b>	11,405
Payables for purchase of property, plant and equipment	<b>1,189</b>	5,752
Trade payables	<b>21,990</b>	18,006
Deposits payables	<b>10,000</b>	–
Others	<b>7,114</b>	7,153
	<b>53,567</b>	42,316

As at 30 June 2021 and 31 December 2020, the ageing analysis of trade payables based on invoice date are as follows:

	<b>30 June 2021 RMB'000</b>	31 December 2020 RMB'000
Within 3 months	<b>20,093</b>	17,537
3 months to 6 months	<b>461</b>	220
6 months to 12 months	<b>1,205</b>	183
1 year to 2 years	<b>231</b>	66
	<b>21,990</b>	18,006

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

	<b>30 June 2021 RMB'000</b>	31 December 2020 RMB'000
– RMB	<b>52,399</b>	40,128
– USD	<b>301</b>	1,494
– NTD	<b>867</b>	694
	<b>53,567</b>	42,316

**14 DIVIDEND**

No dividend has been paid or declared by the Company during the six months ended 30 June 2021 (Year ended 31 December 2020: Nil).

► Notes to the interim condensed consolidated financial information

## 15 CAPITAL COMMITMENTS

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

	<b>30 June 2021 RMB'000</b>	31 December 2020 RMB'000
Property, plant and equipment	<b>71,043</b>	6,914

## 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 2021 and 2020, and balances arising from related party transactions as at 30 June 2021 and 31 December 2020.

### (a) Name and relationship with related parties

<b>Name of related party</b>	<b>Nature of relationship</b>
Center Laboratories Inc. ("Centerlab") Lumosa Therapeutics Co., Ltd.	Entity having significant influence over the Company Associate of Center Laboratories, Inc.

### (b) Transactions with related parties

#### **Continuing transactions**

##### *(i) Rental expenses*

	<b>Six months ended 30 June</b>	
	<b>2021 RMB'000</b>	2020 RMB'000
Lumosa Therapeutics Co., Ltd.	<b>22</b>	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.

## ▶ Notes to the interim condensed consolidated financial information

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

## (c) Balances with related parties – trade

## (i) Payables on rental expenses

	30 June 2021 RMB'000	31 December 2020 RMB'000
Lumosa Therapeutics Co., Ltd.	8	–

The balances due to related parties were unsecured, non-interest bearing and had no fixed repayment term as at 30 June 2021.

## (d) Leasing arrangements

In May 2021, the Group signed an office rental contract with Centerlab, which has an option for automatic extension upon expiry of the contract. 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	
	2021 RMB'000	2020 RMB'000
Centerlab	133	–

## (ii) Lease liabilities:

– Outstanding balance:

	30 June 2021 RMB'000	31 December 2020 RMB'000
Centerlab	120	52

## (iii) Rental Payment:

	Six months ended 30 June	
	2021 RMB'000	2020 RMB'000
Centerlab	192	315

## 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 2021, 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 <sup>(1)</sup>	Approximate percentage of interest in the Company <sup>(2)</sup>
Ms. Yeh-Huang, Chun-Ying	Beneficial owner	7,115,700 (L)	1.18%
	Interest through equity derivatives <sup>(3)</sup>	1,162,500 (L)	0.19%
	Beneficiary of a trust <sup>(4)</sup>	2,897,383(L)	0.48%
Dr. Liu, Jun	Interest through equity derivatives <sup>(3)</sup>	1,100,000 (L)	0.18%
	Beneficiary of a trust <sup>(4)</sup>	2,741,609(L)	0.46%

Notes:

- (1) The letter "L" denotes the person's long position in the Shares.
- (2) The calculation is based on the total number of 601,529,497 Shares in issue as at 30 June 2021 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 2021, 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 2021, 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 <sup>(1)</sup>	Approximate percentage of interest in the Company <sup>(2)</sup>
Center Laboratories Inc.	Beneficial owner	179,561,700 (L)	29.85%
Mr. Pang Kee Chan Hebert <sup>(3)</sup>	Interest in controlled corporation	49,136,800 (L)	8.17%
Advantech Capital Partners II Limited <sup>(3)</sup>	Interest in controlled corporation	49,136,800 (L)	8.17%
Advantech Capital II L.P. <sup>(3)</sup>	Interest in controlled corporation	49,136,800 (L)	8.17%
Advantech Capital II Master Investment Limited <sup>(3)</sup>	Interest in controlled corporation	49,136,800 (L)	8.17%
Advantech Capital Investment V Limited <sup>(3)</sup>	Beneficial owner	49,136,800 (L)	8.17%
Chengwei Evergreen Management, LLC <sup>(4)</sup>	Interest in controlled corporation	56,573,500 (L)	9.40%
Chengwei Evergreen Capital, L.P. <sup>(4)</sup>	Interest in controlled corporation	56,573,500 (L)	9.40%
Prime Success International Limited <sup>(4)</sup>	Beneficial owner	56,573,500 (L)	9.40%
Vivo Capital LLC <sup>(5)</sup>	Interest in controlled corporation	103,245,000 (L)	17.16%
Vivo Capital VIII, LLC <sup>(5)</sup>	Interest in controlled corporation	103,245,000 (L)	17.16%
Vivo Capital Fund VIII, L.P. <sup>(5)</sup>	Beneficial owner	90,718,100 (L)	15.08%

► 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 601,529,497 Shares in issue as at 30 June 2021 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.

Save as disclosed above, as at 30 June 2021, 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 interim 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 2021 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 1 January 2021	Granted (during the six months ended 30 June 2021)	Exercised	Cancelled/Lapsed	Outstanding as at 30 June 2021
<b>1. Ms. Yeh-Huang, Chun-Ying (Director)</b>								
20 February 2013	All vested (and all were exercised prior to 1 January 2020)	Till 19 February 2023	Approximately US\$0.286	0	-	-	-	0
14 December 2017	To be vested in four equal installments at each of the first four anniversaries of the date of grant (of which the first installment was exercised prior to 1 January 2020)	From the date of vesting till 13 December 2027	Approximately US\$0.286	1,162,500	-	-	-	1,162,500
<b>2. Dr. Liu, Jun (Director)</b>								
25 December 2017	To be 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
<b>3. Senior management and other grantees (being employees of and consultants to the Group)</b>								
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	9,811,500	-	1,062,800	434,500	8,314,200
<b>Total</b>				<b>12,074,000</b>	<b>-</b>	<b>1,062,800</b>	<b>434,500</b>	<b>10,576,700</b>

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. 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.

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 under the Restricted Share Award Scheme, representing approximately 5.07% of the total number of Shares in issue as at 31 December 2020, including 5,638,992 Shares to Teeroy Limited (holding Shares on behalf of grantees who are connected persons of the Company) and 24,827,705 Shares to Tricor Trust (Hong Kong) Limited (holding Shares on behalf of other grantees). Such Shares were allotted and issued at a subscription price of zero and therefore no proceeds were raised.

As at 30 June 2021, the remaining number of Shares capable of being allotted and issued to the trustees under the Restricted Share Award Scheme was 26,533,303 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.

## ► 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 2021 are as follows:

Trustee	Grantee	Grant consideration (per Share)	Number of Restricted Award Shares					Outstanding as at 30 June 2021	Earliest vesting date	Expiry date
			Outstanding as at 31 December 2020	Allotted and issued trustees between 1 January and 30 June 2021	Vested between 1 January and 30 June 2021	Lapsed between 1 January and 30 June 2021	Outstanding as at 30 June 2021			
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	
		US\$0.28634	49,847	-	-	-	49,847	The fifth 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	24,453,850	-	4,134,139	1,082,691	19,237,020	Various dates, some of which are linked to the fulfillment of certain R&D targets	Various dates	
<b>Total</b>			<b>30,092,842</b>	<b>-</b>	<b>4,134,139</b>	<b>1,082,691</b>	<b>24,876,012</b>			

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.

► Other Information

### **DIRECTORS' RIGHTS TO ACQUIRE SHARES OR DEBENTURES**

Save as disclosed in this interim report, at no time during the six months ended 30 June 2021 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 2021, 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 2021.

### **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 2021, the Company has complied with all the applicable code provisions as set out in 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 2021 and up to the date of this report.

## ▶ Other Information

**USE OF NET PROCEEDS FROM GLOBAL OFFERING**

The net proceeds raised during the Global Offering were approximately RMB448,615,000 after deduction of the underwriting fees and commissions and expenses payable by the Company in connection with the Global Offering (the “Net Proceeds”).

During the six months ended 30 June 2021, the Net Proceeds were utilized in accordance with the proposed applications as set out in the Company’s announcement dated 27 October 2020 titled “Change in Use of Net Proceeds from the Global Offering”. As at 30 June 2021, the unused Net Proceeds amounted to approximately RMB28,632,000, and were being kept as bank deposits. Such unused Net Proceeds are intended to continue to be applied in accordance with the proposed applications as set out in the aforesaid announcement.

A breakdown of the use of the Net Proceeds during the six months ended 30 June 2021 and an expected timeline for the use of the unused portion are set forth as follows:

Purpose	Unused amount as at 31 December 2020	Used between 1 January 2021 and 30 June 2021	Unused amount as at 30 June 2021	Expected timing for the full utilization of the unused amount
	(RMB'000, approximate)	(RMB'000, approximate)	(RMB'000, approximate)	
(1) For ongoing and planned clinical trials, preparation for registration filings, planned commercial launches (including sales and marketing) of TAB008	19,750	12,104	7,646	On or before 30 September 2021
(2) For ongoing and planned clinical trials, expansion of facilities, registration filings and potential commercial launch (including sales and marketing) of TAA013	53,737	53,737	-	-
(3) For ongoing and planned pre-clinical and clinical trials, expansion of facilities, preparation for registration filings and potential commercial launches (including sales and marketing) as well as transformation and upgrade of platform technologies of the other drug candidates in our pipeline, including but not limited to TOZ309, TOM312 and TAB014	24,094	24,094	-	-
(4) For non-project specific capital expenditure and production capacity upgrade for overall integrated applications	65,416	44,430	20,986	On or before 30 September 2021
(5) For our working capital and other general corporate purposes	19,164	19,164	-	-
<b>Total</b>	<b>182,161</b>	<b>153,529</b>	<b>28,632</b>	

► Other Information

### 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 2021.

### CHANGES IN DIRECTORS' EMOLUMENTS AND DIRECTORS' AND SENIOR MANAGEMENT'S BIOGRAPHICAL DETAILS

With effect from April 2021, 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 2021	Remuneration from April 2021
Dr. Liu, Jun	The Company	Annual Director's fee of HK\$1 and attendance fee of RMB500 for each Board meeting or Board committee meeting	Unchanged
	The Company	Monthly salary of RMB16,000 plus bonuses (if any) as the vice general manager and then the chief executive officer	Monthly salary of RMB70,000 plus bonuses (if any) as the chief executive officer
	TOT BIOPHARM Co., Ltd. (東曜藥業有限公司)	Monthly salary of RMB74,000 plus subsidies and bonuses (if any) as the vice general manager and then the chief executive officer	Monthly salary of RMB64,000 plus subsidies and bonuses (if any) as the chief executive officer

Mr. Fu, Shan was appointed as director of Genetron Holdings Limited (NASDAQ: GTH) on 30 June 2021.

Save as disclosed above, there is no change in the emoluments of the Directors or the biographical details of the Directors and the senior management of the Company since the date of the 2020 Annual Report (being 23 March 2021) which is required to be disclosed pursuant to Rule 13.51B(1) of the Listing Rules.

### 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 2020 Annual Report.

## DEFINITIONS

“ADC”	antibody drug conjugate
“ANDA”	abbreviated new drug application
“Board”	the board of Directors of the Company
“CDE”	the Center for Drug Evaluation of the NMPA
“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 2021, 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
“Group”, “we”, “us” or “TOT BIOPHARM”	the Company and its subsidiaries
“HK\$”	Hong Kong dollar(s), the lawful currency of Hong Kong
“HKFRS”	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
“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

► Definitions

“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
“mCRC”	metastatic colorectal cancer
“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
“NSCLC”	non-small-cell lung cancer
“nsNSCLC”	non-squamous NSCLC
“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, details of which are disclosed on pages 8 to 21 of the Company’s circular dated 3 August 2020
“SFO”	the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time

 Definitions

“Share(s)”	ordinary share(s) of the Company
“Shareholder(s)”	holder(s) of Share(s)
“Stock Exchange” or “Hong Kong Stock Exchange”	The Stock Exchange of Hong Kong Limited
“United States” or “US”	the United States of America
“US\$” or “USD”	United States dollar(s), the lawful currency of the United States
“wAMD”	wet age-related macular degeneration