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东曜药业

TOT BIOPHARM International Company Limited

東曜藥業股份有限公司

(Incorporated in Hong Kong with limited liability)

(Stock Code: 1875)

INTERIM RESULTS ANNOUNCEMENT FOR THE SIX MONTHS ENDED 30 JUNE 2021

During the first half of the year, the Group speeded up its strategic adjustment and implementation and fully leveraged its innovative drug technological platform advantages to strengthen its R&D of ADC drugs and industry planning and firmly capitalize on market opportunities, thereby achieving substantial growth in its CDMO/CMO business and bringing diversified cash flows to the Company.

Progress of Launched Products and Clinical Stage Products:

- Temozolomide capsules (Tazian[®]) was approved for launch in China by the National Medical Products Administration of the PRC (NMPA) in May 2021
- Megestrol acetate oral suspension (Megaxia[®]), a product for which the Group is an import agent, was approved for launch in May 2021
- TAB008 (anti-VEGF mAb): currently at the evaluation stage of Center for Drug Evaluation (CDE), it is expected to be approved for launch within 2021
- TAA013 (anti-HER2 ADC): since the commencement of Phase III clinical trials in July 2020, its clinical progress is in a leading position, with over 70 clinical research centers initiated across the country to date

Key Milestones of Commercial Production Planning:

- In January 2021, our mAb drug commercial production facilities completed GMP compliance inspection, the designed capacity of which is 16,000L
- In May 2021, our chemical drug capsules passed GMP compliance inspection
- With the expansion of the construction of production lines for ADC drug formulations, our ADC drug commercialization platform will be further enhanced

Financial Summary:

- Revenue was RMB23,132,000, representing a year-on-year growth of 78% thanks to the Group's proactive expansion of its CDMO/CMO business in line with market changes, with the relevant revenue recording a substantial year-on-year growth of 330%
- R&D expenses were RMB88,749,000, representing a year-on-year decrease of 11%, mainly attributable to the completion of Phase III clinical trials for the TAB008 project at the second half of 2020 which resulted in a year-on-year decrease in costs of clinical trials; meanwhile, the completion of R&D for the TOZ309 project resulted in a significant reduction of the relevant expenses for R&D consumables
- Selling expenses were RMB11,202,000, representing a year-on-year decrease of 18%, mainly attributable to the Company's adjustments to its sales strategies which resulted in a reduction of the relevant expenses
- General and administrative expenses were RMB26,823,000, representing a year-on-year increase of 11%, mainly attributable to the increase in operating and management expenses related to employee, administration and taxation, etc.
- In summary, net loss for the first half of 2021 reached RMB115,005,000, representing a year-on-year decrease of 11%

The board (the "**Board**") of directors (the "**Directors**") of TOT BIOPHARM International Company Limited (the "**Company**" or "**TOT BIOPHARM**") hereby announces the unaudited consolidated financial results of the Company and its subsidiaries (together, the "**Group**", "**we**" or "**us**") for the six months ended 30 June 2021 together with comparative figures for the six months ended 30 June 2020 as set out in the section headed "Consolidated Financial Information" section of this announcement.

The financial information set out in the section headed "Consolidated Financial Information" section of this announcement represents an extract from the condensed consolidated interim financial statements of the Group, which are unaudited but have been reviewed by the Group's external auditor, PricewaterhouseCoopers ("**PwC**"), in accordance with Hong Kong Standard on Review Engagements 2410 and reviewed by the Audit and Connected Transactions Review Committee of the Company. PwC's unmodified review report is included in the 2021 interim report to be dispatched to the shareholders of the Company.

CONSOLIDATED FINANCIAL INFORMATION

INTERIM CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS

		Unaudited	
		Six months ended 30 June	
	<i>Note</i>	2021	2020
		RMB'000	RMB'000
Revenue	2	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)
Operating loss		(115,445)	(128,363)
Finance income		714	698
Finance costs		(274)	(1,518)
Finance income/(costs) – net		440	(820)
Loss before income tax	3	(115,005)	(129,183)
Income tax expense	4	–	–
Loss for the period and attributable to the equity holders of the Company		(115,005)	(129,183)
Other comprehensive income:			
<i>Items that will not be reclassified to profit or loss</i>			
Changes in the fair value of equity instruments at fair value through other comprehensive income		747	1,363
<i>Items that may be reclassified to profit or loss</i>			
Exchange differences on translation		(722)	2,858
Other comprehensive income for the period, net of tax		25	4,221
Total comprehensive loss for the period and attributable to the equity holders of the Company		(114,980)	(124,962)
Loss per share for the six months ended 30 June and attributable to the equity holders of the Company			
– Basic and diluted loss per share (RMB)	5	(0.20)	(0.23)

INTERIM CONDENSED CONSOLIDATED BALANCE SHEET

		Unaudited 30 June 2021 <i>RMB'000</i>	Audited 31 December 2020 <i>RMB'000</i>
	<i>Note</i>		
ASSETS			
Non-current assets			
Property, plant and equipment	6	297,267	290,367
Prepayments for property, plant and equipment		23,648	416
Right-of-use assets	6	15,453	20,639
Intangible assets	6	3,102	3,229
Financial assets at fair value through other comprehensive income		8,823	8,076
Other non-current assets		<u>78,058</u>	<u>69,229</u>
		<u>426,351</u>	<u>391,956</u>
Current assets			
Inventories		19,727	8,114
Trade and other receivables	7	7,611	5,851
Prepayments		20,994	8,827
Contract assets		2,294	902
Cash and cash equivalents		<u>156,243</u>	<u>225,533</u>
		<u>206,869</u>	<u>249,227</u>
Total assets		<u>633,220</u>	<u>641,183</u>
EQUITY			
Share capital		1,892,906	1,874,438
Other reserves		44,681	49,503
Accumulated losses		<u>(1,456,589)</u>	<u>(1,341,584)</u>
Capital and reserves attributable to the equity holders of the Company		<u>480,998</u>	<u>582,357</u>

		Unaudited	Audited
		30 June	31 December
		2021	2020
	<i>Note</i>	RMB'000	RMB'000
LIABILITIES			
Non-current liabilities			
Borrowings		21,440	–
Lease liabilities		1,079	6,083
		<u>22,519</u>	<u>6,083</u>
Current liabilities			
Borrowings		50,735	–
Trade and other payables	8	53,567	42,316
Contract liabilities		24,411	9,104
Lease liabilities		990	1,323
		<u>129,703</u>	<u>52,743</u>
Total liabilities		<u>152,222</u>	<u>58,826</u>
Total equity and liabilities		<u>633,220</u>	<u>641,183</u>
Net current assets		<u>77,166</u>	<u>196,484</u>
Total assets less current liabilities		<u>503,517</u>	<u>588,440</u>

NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

1 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.

1.1 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).

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. Taxes on income in the interim periods are accrued using the tax rate that would be applicable to expected total annual earnings.

2 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).

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

	Six months ended 30 June	
	2021	2020
	RMB'000	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	–
	<u>23,132</u>	<u>13,030</u>

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

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

- (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.

(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	2020
	RMB'000	RMB'000
Revenue recognized that was included in the balance of contract liabilities at the beginning of the period		
– Service revenue – CDMO/CMO	3,834	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	Non-current assets	Revenue	Non-current assets
	RMB'000	RMB'000	RMB'000	RMB'000
Mainland China	23,132	339,162	13,030	396,352
Others	–	523	–	799
	23,132	339,685	13,030	397,151

3 LOSS BEFORE INCOME TAX

	Six months ended 30 June	
	2021	2020
	RMB'000	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 (<i>Note 6</i>)	16,456	15,940

4 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.

5 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)	<u>(0.20)</u>	<u>(0.23)</u>

(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.

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

	Property, plant and equipment <i>RMB'000</i>	Intangible assets <i>RMB'000</i>	Right-of-use assets <i>RMB'000</i>
Six months ended 30 June 2021			
Opening net book amount as at 1 January 2021	290,367	3,229	20,639
Additions	27,345	384	2,246
Depreciation and amortisation charge (<i>Note 3</i>)	(14,929)	(511)	(1,016)
Disposals	(5,514)	–	(6,417)
Net exchange differences	(2)	–	1
	<hr/>	<hr/>	<hr/>
Closing net book amount as at 30 June 2021	297,267	3,102	15,453
	<hr/>	<hr/>	<hr/>
	Property, plant and equipment <i>RMB'000</i>	Intangible assets <i>RMB'000</i>	Right-of-use assets <i>RMB'000</i>
Six months ended 30 June 2020			
Opening net book amount as at 1 January 2020	300,230	2,391	28,435
Additions	24,985	835	–
Depreciation and amortisation charge (<i>Note 3</i>)	(14,262)	(387)	(1,291)
Disposals	(133)	–	(5,913)
Net exchange differences	–	–	16
	<hr/>	<hr/>	<hr/>
Closing net book amount as at 30 June 2020	310,820	2,839	21,247
	<hr/>	<hr/>	<hr/>

7 TRADE AND OTHER RECEIVABLES

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

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:

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

8 TRADE AND OTHER PAYABLES

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

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

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

9 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).

10 CAPITAL COMMITMENTS

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

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

MANAGEMENT DISCUSSION AND ANALYSIS OF CERTAIN ASPECTS OF OUR BUSINESS

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.

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.

Type	Drug Candidate	Indication(s)	Pre-Clinical	Clinical Phase I	Clinical Phase II	Clinical Phase III	NDA ⁽¹⁾
Antibody drug conjugate	TAA013 (anti-HER2)	HER2+ breast cancer					
	TAE020 (new target)	Acute myeloid leukemia					
Monoclonal antibody/ Recombinant protein	TAB008 ⁽²⁾ (anti-VEGF)	Non-squamous non-small cell lung cancer (nsNSCLC)					
	TAB014 ⁽³⁾ (anti-VEGF)	Wet age-related macular degeneration (wAMD)					
	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					
	TOM312 (megestrol acetate)	Cancer and HIV-associated cachexia					
	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

- **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[®] – temozolomide capsules), a generic drug of TEMODAR[®], 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[®]. 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[®] – 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 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.

- **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. 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.

- **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 ACD 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, 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.

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.

MANAGEMENT DISCUSSION AND ANALYSIS OF CERTAIN FINANCIAL ITEMS

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.

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.

OTHER INFORMATION

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 Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (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 Corporate Governance Code (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 for Securities Transactions by Directors of Listed Issuers (the “**Model Code**”) as set out 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 announcement.

USE OF NET PROCEEDS FROM THE GLOBAL OFFERING

The net proceeds raised during the Company’s global offering and listing on the Main Board of the Stock Exchange (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 will be disclosed in the 2021 interim report of the Company.

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.

PUBLICATION OF THE INTERIM RESULTS ANNOUNCEMENT AND INTERIM REPORT

This announcement is published on the websites of the Company (www.totbiopharm.com.cn) and the Stock Exchange (www.hkexnews.hk). The 2021 interim report of the Company will be dispatched to the shareholders of the Company and made available on the same websites in due course.

By order of the Board
TOT BIOPHARM International Company Limited
Dr. Liu, Jun
Chief Executive Officer and Executive Director

Hong Kong, 12 August 2021

As at the date of this announcement, the executive directors of the Company are Ms. Yeh-Huang, Chun-Ying and Dr. Liu, Jun; the non-executive directors of the Company are Mr. Fu, Shan, Dr. Kung, Frank Fang-Chien, Mr. Kang, Pei and Mr. Qiu, Yu Min; and the independent non-executive directors of the Company are Ms. Hu, Lan, Dr. Sun, Lijun Richard and Mr. Chang, Hong-Jen.