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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 2022

#### HIGHLIGHTS OF 2022 INTERIM RESULTS AND MILESTONES

- **Operating revenue reached RMB182 million, increasing by 687% year-on-year,** mainly attributable to satisfactory sales performance of Pusintin<sup>®</sup>, fast-growing CDMO business and revenue from grant of product licenses. In particular, revenue from sales of products reached RMB104 million, accounting for 57% of the Group's total operating revenue; revenue from CDMO services reached RMB22.66 million, representing an increase of 94% year-on-year; and revenue from licenses granted reached RMB49.43 million, which was attributable to commercial cooperation relating to Pusintin<sup>®</sup> and TAB014 (anti-VEGF mAb). Net loss was reduced by 86% year-on-year to RMB15.72 million.
- **Achieved milestones in two key clinical projects.** The Group completed the patient enrollment for Phase III clinical trial of TAA013 and the enrollment of the first patient for Phase III clinical trial of TAB014. The Group will continue to be responsible for the supply of products at the clinical stage and commercial production upon product launch in the future.
- **Accelerated expansion of ADC production capacity.** The Group accelerated the expansion of its ADC pilot drug substances production workshop and ADC commercialization drug products workshop, which are scheduled for production in the second half of 2022 and the first half of 2023, respectively.

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 2022 together with comparative figures for the six months ended 30 June 2021 as set out in the section headed “Consolidated Financial Information” section of this announcement.

## CONSOLIDATED FINANCIAL INFORMATION

### INTERIM CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS

		<b>Unaudited</b>	
		<b>Six months ended 30 June</b>	
	<i>Note</i>	<b>2022</b>	2021
		<b>RMB'000</b>	<b>RMB'000</b>
Revenue	2	<b>182,019</b>	23,132
Cost of revenue		<b>(23,478)</b>	(9,143)
Research and development expenses		<b>(70,268)</b>	(88,749)
Selling expenses		<b>(70,091)</b>	(11,202)
General and administrative expenses		<b>(25,698)</b>	(26,823)
Net impairment losses on financial assets		<b>(923)</b>	–
Other income		<b>297</b>	–
Other gains/(losses) – net		<b>1,194</b>	(2,660)
<b>Operating loss</b>		<b>(6,948)</b>	(115,445)
Finance income		<b>415</b>	714
Finance costs		<b>(3,418)</b>	(274)
Finance (costs)/income – net		<b>(3,003)</b>	440
Share of net loss of the joint venture accounted for using the equity method		<b>(5,773)</b>	–
<b>Loss before income tax</b>	3	<b>(15,724)</b>	(115,005)
Income tax expense	4	<b>–</b>	–
<b>Loss for the period and attributable to the equity holders of the Company</b>		<b>(15,724)</b>	(115,005)

	<b>Unaudited</b>	
	<b>Six months ended 30 June</b>	
<i>Note</i>	<b>2022</b>	<b>2021</b>
	<b>RMB'000</b>	<b>RMB'000</b>
<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
<i>Items that may be reclassified to profit or loss</i>		
Exchange differences on translation	<u>3,236</u>	<u>(722)</u>
<b>Other comprehensive income for the period, net of tax</b>	<u>3,236</u>	<u>25</u>
<b>Total comprehensive loss for the period and attributable to the equity holders of the Company</b>	<u>(12,488)</u>	<u>(114,980)</u>
<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)	5 <u>(0.03)</u>	<u>(0.20)</u>

## INTERIM CONDENSED CONSOLIDATED BALANCE SHEET

	<i>Note</i>	<b>Unaudited 30 June 2022 RMB'000</b>	Audited 31 December 2021 RMB'000
<b>ASSETS</b>			
<b>Non-current assets</b>			
Property, plant and equipment	6	354,170	307,668
Prepayments for property, plant and equipment		44,233	55,759
Right-of-use assets	6	15,497	15,733
Investment properties		3,383	3,583
Intangible assets	6	4,859	5,123
Investments accounted for using the equity method		860	1,483
Other non-current assets		14,643	14,951
		<b>437,645</b>	404,300
<b>Current assets</b>			
Inventories		56,822	29,558
Trade and other receivables	7	65,572	15,032
Prepayments		27,937	16,754
Contract assets		18,923	11,952
Cash and cash equivalents		154,876	152,805
Other current assets		50,502	79,862
		<b>374,632</b>	305,963
<b>Total assets</b>		<b>812,277</b>	710,263
<b>EQUITY</b>			
Share capital		1,892,906	1,892,906
Other reserves		46,598	37,797
Accumulated losses		(1,611,336)	(1,595,612)
<b>Capital and reserves attributable to the equity holders of the Company</b>		<b>328,168</b>	335,091

	<i>Note</i>	<b>Unaudited 30 June 2022 RMB'000</b>	Audited 31 December 2021 RMB'000
<b>LIABILITIES</b>			
<b>Non-current liabilities</b>			
Borrowings		59,775	59,775
Lease liabilities		737	1,136
Other non-current liabilities		51,125	53,453
		<u>111,637</u>	<u>114,364</u>
<b>Current liabilities</b>			
Borrowings		185,000	146,191
Trade and other payables	8	145,362	86,238
Contract liabilities		35,733	22,199
Lease liabilities		1,624	1,463
Other current liabilities		4,753	4,717
		<u>372,472</u>	<u>260,808</u>
<b>Total liabilities</b>		<u>484,109</u>	<u>375,172</u>
<b>Total equity and liabilities</b>		<u>812,277</u>	<u>710,263</u>
<b>Net current assets</b>		<u>2,160</u>	<u>45,155</u>
<b>Total assets less current liabilities</b>		<u>439,805</u>	<u>449,455</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 2022 has been prepared in accordance with Accounting Standard HKAS 34 Interim Financial Reporting.

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

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

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

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

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

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

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

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

- (i) Contract assets have increased as the Group has provided more services ahead of the agreed payment schedules.
- (ii) Contract liabilities arise from CDMO and CMO which are recognized when the advances are received before the services are rendered to customers and will be recorded as revenue within one year.

(d) **Revenue recognized in relation to contract liabilities**

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

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

(e) **Unfulfilled long-term contracts**

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

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

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

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

Contract duration of CDMO/CMO services are generally for periods of one year or less. As permitted under HKFRS15, the transaction price allocated to these unsatisfied contracts is not disclosed.

(f) **Geographical information**

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

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



### 3 LOSS BEFORE INCOME TAX

	Six months ended 30 June	
	2022	2021
	RMB'000	RMB'000
Loss before taxation has been arrived at after charging:		
– Employee benefit expenses	60,831	65,213
– Clinical trials (exclude employee benefit expenses)	8,431	13,104
– R&D materials and consumables	4,515	13,706
– Depreciation and amortisation charge ( <i>Note 6</i> )	18,681	16,456

### 4 INCOME TAX EXPENSE

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

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

### 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	
	2022	2021
Loss attributable to equity holders of the Company (RMB'000)	(15,724)	(115,005)
Weighted average number of ordinary shares in issue (thousand)	575,197	571,492
Basic loss per share (RMB)	<u>(0.03)</u>	<u>(0.20)</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 2022, the Company had one category of potential ordinary shares: the stock options granted to employees (For the six months ended 30 June 2021: same). As the Group incurred losses for the six months ended 30 June 2022 and 2021, the potential ordinary shares were not included in the calculation of diluted loss per share as their inclusion would be anti-dilutive. Accordingly, diluted loss per share for the six months ended 30 June 2022 and 2021 is the same as basic loss per share of the respective periods.

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

## 7 TRADE AND OTHER RECEIVABLES

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

(a) **Trade receivables**

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

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

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

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

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

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

**8 TRADE AND OTHER PAYABLES**

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

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

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

## 9 DIVIDEND

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

## 10 COMMITMENTS

### (a) Capital commitments

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

	<b>30 June 2022 RMB'000</b>	31 December 2021 RMB'000
Property, plant and equipment	<b><u>224,654</u></b>	<u>155,746</u>

### (b) Investment commitments

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

	<b>30 June 2022 RMB'000</b>	31 December 2021 RMB'000
Huayao Pharmaceutical (Suzhou) Company Limited	<b><u>26,250</u></b>	<u>31,400</u>

## 11 SUBSEQUENT EVENTS

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

# MANAGEMENT DISCUSSION AND ANALYSIS OF CERTAIN ASPECTS OF OUR BUSINESS

## I. INDUSTRY AND COMPANY PROFILE

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

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

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

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

## II. BUSINESS HIGHLIGHTS AND PROGRESS

### 1. Updates on Key Product Pipelines

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

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

On 10 March 2022, TOT BIOPHARM entered into a supplemental agreement with Zhaoke (Guangzhou) Ophthalmology Pharmaceutical Limited (兆科(廣州)眼科藥物有限公司) (“**Zhaoke Guangzhou**”), a wholly-owned subsidiary of Zhaoke Ophthalmology Limited (兆科眼科有限公司) (6622.HK), in respect of the license for commercialization of TAB014 (which is used for the treatment of wet (neovascular) age-related macular degeneration, “**wAMD**”), pursuant to which Zhaoke Guangzhou will act as the marketing authorization holder (MAH) of TAB014 in China (including Hong Kong and Macau regions). In June 2022, the enrollment of the first patient for the Phase III clinical trial of TAB014 was completed successfully. TOT BIOPHARM will continue to be responsible for the supply of products during the clinical trial and the commercialized production in the future when it launches.

TAB014 is the first recombinant humanized anti-vascular endothelial growth factor (VEGF) mAb to enter clinical stage in China for the treatment of wAMD. wAMD is a leading cause of vision impairment and blindness in China and worldwide for people over 50 years old. According to China Insights Consultancy (CIC), the market for wAMD drugs in China is expected to increase to RMB3.5 billion by 2030. TOT BIOPHARM will continue to seek well-established partners to bring TAB014 to overseas markets.

## The main product pipelines of the Company:

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

## 2. Marketing Strategy of Launched Products

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

### – Pusintin<sup>®</sup> (Bevacizumab injection)

Pusintin<sup>®</sup> is TOT BIOPHARM’s first antibody drug approved for marketing. We have been actively expanding its market channels and continuously increasing brand marketing efforts since it was approved for launch by the National Medical Products Administration (“NMPA”) on 30 November 2021. Its well-established brand image and efficient operation mechanism were highly recognized by the market, and are in line with market expectations. At the same time, the Company has applied by way of extrapolation for all indications of the originator drug approved in mainland China pursuant to the “Technical Guidelines for Similarity Evaluation and Indication Extrapolation of Biosimilars” (《生物類似藥相似性評價和適應症外推技術指導原則》) issued by the Center for Drug Evaluation of the NMPA and Pusintin<sup>®</sup> has been approved for all six indications, including advanced, metastatic or recurrent non-squamous non-small cell lung cancer (nsNSCLC) and metastatic colorectal cancer (mCRC). Among these six indications, three indications, namely recurrent glioblastoma multiforme; epithelial ovarian cancer, fallopian tube cancer or primary peritoneal cancer; and cervical cancer, were approved on 3 March 2022, while the indication of hepatocellular carcinoma

was approved on 29 March 2022. The approval of new indications has further expanded the market potential of Pusintin<sup>®</sup>, enhanced the accessibility of the drug, and provided high-quality treatment options with same efficacy of the originator drug to more cancer patients. At present, bevacizumab injection has been included in the National Reimbursement Drug List. It is anticipated that bevacizumab will become a next RMB10 billion drug in the Chinese market and its market size is expected to reach RMB6 billion in 2022, indicating promising market prospects.

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

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



– *Tazian® (Temozolomide capsule)*

Tazian® was approved for launch by the NMPA on 31 May 2021 for the treatment of newly diagnosed glioblastoma multiforme, which is used initially together with radiotherapy, and then as maintenance therapy for the treatment of glioblastoma multiforme or anaplastic astrocytoma that recurs or progresses after conventional treatment. Temozolomide capsules were included in the fourth batch of national centralized procurement catalogue in 2021. In the first half of 2022, the Company was selected as the supplier in the renewal of centralized procurement by the Thirteen Allied Provinces, Jiangsu Province and Hebei Province, which helped us to tap into the sales markets. Meanwhile, the Company has entered into marketing cooperation with Jixin Pharmaceutical in China to expand its market share through various and flexible marketing strategies to expand in the non-centralized procurement market channels.

– *Megaxia® (Megestrol acetate oral suspension)*

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

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

### 3. Internationally Competitive ADC Industry Chain Platform

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

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

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

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

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

- *Full-process technical team with extensive experience*

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

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

#### 1. Commercial Production Bases and Construction Projects

TOT BIOPHARM has established an internationally competitive biopharmaceutical commercial production base equipped with advanced production facilities and a quality management system that meets domestic and international standards. The production scale of mAb drug substances has reached 20,000L, and multi-batch commercial production of bevacizumab injection (Pusintin®) products has been successfully carried out, with a product qualification rate of 100%. With its key ADC commercialized production platform, the Company has become a leading enterprise in the industry and has been highly recognized by industrial partners. TOT BIOPHARM has a GMP-compliant complete ADC commercial production platform which is scarce in China that integrates ADC naked antibodies, drug substances and drug products, which can realize the whole product completion process in one production base. At present, we have successfully completed the commercial-scale production of multiple projects at different stages from Phase I to Phase III clinical stages. Our well-established technical team, advanced processes, comprehensive production facilities and well-established assurance system serve as a guarantee for the high quality of products.

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

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

#### **mAb drug substances production (mAb DS)**

Workshops for mAb drug substances	<ul style="list-style-type: none"><li>• Gained GMP certification by NMPA</li><li>• Production capacity reached 20,000L for different scales of mAb drug substances production, such as commercialization projects, pilot tests and small trials</li><li>• International leading brand of disposable bioreactors with flexible and continuous production capability</li></ul>
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## **mAb drug products production (mAb DP)**

- |  |  |
|--|--|
| Workshops for mAb commercialization drug products  | <ul style="list-style-type: none"><li>• Gained GMP certification by NMPA, which can meet the commercial production of self-developed products and the production of CDMO products</li><li>• International leading brand of automatic filling injection production line</li></ul>   |
| Workshops for mAb pilot drug products<br><i>(Planned for production in the first half of 2023)</i> | <ul style="list-style-type: none"><li>• International leading brand of isolator filling linkage production line, which can meet the needs of different specifications of products</li><li>• Equipped with a 6-DOF clean and sterile robot arm which enjoys enormous advantages of supplementary filling in case of insufficient filling, supplementary provision of rubber stoppers and aluminum caps, minimized tailing loss, high yield and convenient replacement of specifications</li><li>• Independent design of automatic filling line, automatic feeding and discharging as well as capping, which can realize freeze-drying, injection switching and continuous production, and maximize the utilization of production capacity</li></ul> |

## **ADC drug substances production (ADC DS)**

- |   |   |
|---|---|
| Workshops for ADC commercialization drug substances   | <ul style="list-style-type: none"><li>• Up to 500L ADC drug substances production scale</li><li>• Completed clinical production and process validation of multiple batches of ADC drugs, which are compliant with GMP standards and meet flexible and diverse commercial production needs</li></ul> |
| Workshops for ADC pilot drug substances<br><i>(Planned for production in the second half of 2022)</i> | <ul style="list-style-type: none"><li>• Equipped with ADC drug substances production facilities of 100L, 200L, 500L and other scales</li><li>• GMP standard compliant and with commercialization capability</li></ul>   |

## **ADC drug products production (ADC DP)**

- |  |   |
|--|---|
| Workshops for ADC commercialization drug products<br><i>(Planned for production in the first half of 2023)</i> | <ul style="list-style-type: none"><li>• The international leading brand of high-activity isolator filling linkage production line</li><li>• Specially designed for the production of scarce high-activity products to ensure aseptic production while meeting the needs of personnel safety protection</li><li>• Independent design of automatic filling line, automatic feeding and discharging as well as capping, which can realize freeze-drying, injection switching and continuous production, and maximize production capacity</li></ul> |
| Workshops for ADC pilot drug products  | <ul style="list-style-type: none"><li>• High-activity isolator filling linkage production line, which has successfully completed clinical production and process validation of multiple batches in multiple ADC projects</li></ul>  |

## **Small molecule drug production**

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|--|---|
| Workshops for oral solid drug products | <ul style="list-style-type: none"><li>• Equipped with commercial production capacity for tablet and capsule drug products</li><li>• Completed clinical production and process validation of multiple batches in CDMO projects</li><li>• Gained GMP certification from NMPA regarding the commercial production of self-developed products</li><li>• Equipped with an independent OEB-5 production line for highly active cytotoxic products</li></ul> |
|--|---|

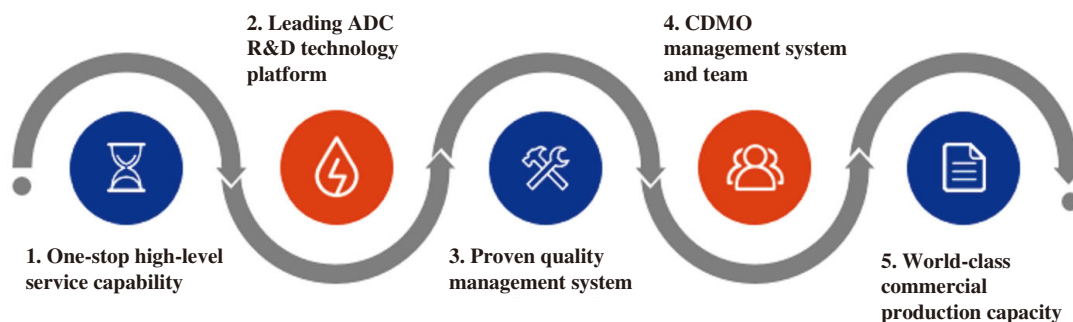
## 2. Construction of Global Research and Development Center

In order to further strengthen its technological advantages in the R&D of innovative drugs, TOT BIOPHARM actively promoted the construction of its Global Research and Development Center. The main building is expected to be completed in 2023, with a gross floor area of 25,000 m<sup>2</sup> and will house divisions such as early R&D, process development, quality research and head office. The core R&D experimental zone will be able to hold 280 to 300 R&D staff members and simultaneously handle the research, process development and other tasks in relation to multiple mAb drugs, ADC drugs, oncolytic virus drugs and special small molecule oncology drugs, and will be seamlessly connected with the production zone. In addition, placing R&D and production under one roof will facilitate the synergic efficiency for the whole drug development process, thereby enhancing the R&D efficiency and cost advantages.

## IV. DEVELOPMENT AND COMPETITIVE ADVANTAGES OF CDMO BUSINESS

With the booming development of CDMO/CMO business, market demand is rapidly increasing in China. According to Frost & Sullivan, China's CDMO/CMO market revenue will grow at a CAGR of 30.0% between 2021 and 2025, and China's overall CDMO/CMO market revenue is expected to be RMB123.5 billion in 2025. Specifically, the biological drug CDMO/CMO business will grow at a CAGR of 36.7% between 2021 and 2025. TOT BIOPHARM actively seized the opportunities of the rapid development of China's pharmaceutical industry, accelerated its transformation and upgrade, and actively expanded its CDMO business, demonstrating strong and sustainable development potential. As of the first half of 2022, revenue from the Company's CDMO business amounted to RMB22.66 million, representing a year-on-year increase of 94%. In terms of the number and types of projects, there were 23 collaborative projects in the first half of the year, including 8 ADC projects, 10 antibody projects and 5 chemical drug and other projects. In terms of project phases, they covered projects of different stages including pre-clinical, IND, Phase I clinical, Phase II clinical and Phase III clinical, of which the majority was 19 projects in the IND stage, including 16 projects for both NMPA and FDA, 2 projects for FDA, and 1 project for EMA. With the continuous expansion of the CDMO market potential, TOT BIOPHARM will provide more customers with high-level one-stop CDMO services and build a world-class CDMO service brand by drawing upon its accumulated experience in various stages from product R&D to commercial production.

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





## 1. Competitive Advantages of CDMO/CMO Business

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

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

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

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

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



(3) *Proven quality management system*

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

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

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

(4) *CDMO management system and team*

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

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

(5) *World-class commercial production capacity*

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

**2. Strategic Cooperation of CDMO/CMO Business**

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

## **V. COMMUNICATION WITHIN THE INDUSTRY**

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

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

## **VI. USE OF FUNDS AND FINANCING**

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

## **VII. RESPONSE TO COVID-19 OUTBREAKS AND SUSTAINABLE DEVELOPMENT**

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

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

## **VIII. PROSPECTS**

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

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

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

## **MANAGEMENT DISCUSSION AND ANALYSIS OF CERTAIN FINANCIAL ITEMS**

### **OVERVIEW**

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

### **OPERATING REVENUE AND COSTS**

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

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

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

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

### **RESEARCH AND DEVELOPMENT EXPENSES**

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

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

## **SELLING EXPENSES**

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

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

## **GENERAL AND ADMINISTRATIVE EXPENSES**

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

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

## **FINANCE INCOME**

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

## **FINANCE COSTS**

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

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

## **INCOME TAX EXPENSE**

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



## **LOSS FOR THE PERIOD**

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

## **NET ASSETS**

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

## **CASH MOVEMENT AND SOURCE OF FUNDS**

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

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

## **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 2022, 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 2022.

## **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 2022, the Company has complied with all the applicable code provisions as set out in Part 2 of the CG Code.

## **COMPLIANCE WITH THE MODEL CODE FOR SECURITIES TRANSACTIONS BY DIRECTORS**

The Company has adopted the Model Code 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 2022 and up to the date of this announcement.

## **PURCHASE, SALE OR REDEMPTION OF THE COMPANY’S LISTED SECURITIES**

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

## **SUBSEQUENT EVENTS**

On 31 May 2022, the Company entered into subscription agreements with Center Laboratories Inc. and Vivo (Suzhou) Health Industry Investment Fund (Limited Partnership) respectively, pursuant to which Center Laboratories Inc. and Vivo (Suzhou) Health Industry Investment Fund (Limited Partnership) conditionally agreed to subscribe for and the Company conditionally agreed to allot and issue to them a total of 150,000,000 shares (the “**Subscription Shares**”) at the subscription price of HKD3.15 per share (the “**Subscriptions**”).

The subscription agreements and transactions contemplated thereunder were subject to, among other things, the approval by the independent shareholders of the Company at the extraordinary general meeting on 22 July 2022, and the Listing Committee of the Stock Exchange approving the listing of, and the permission to deal in, the Subscription Shares.



On 29 July 2022, all conditions precedent under each of the subscription agreements were satisfied and completion of the Subscriptions took place in full, pursuant to which (i) Center Laboratories Inc. was allotted and issued 33,750,000 shares; and (ii) Vivo (Suzhou) Health Industry Investment Fund (Limited Partnership) was allotted and issued 116,250,000 shares.

The gross proceeds from the Subscriptions were approximately HKD472,500,000, and the net proceeds from the Subscriptions after the deduction of the relevant fees and expenses were approximately HKD470,920,000.

Details of the Subscriptions were set out in the announcements of the Company dated 31 May 2022, 22 June 2022, 30 June 2022 and 29 July 2022 and the circular of the Company dated 5 July 2022.

## **PUBLICATION OF THE INTERIM RESULTS ANNOUNCEMENT AND INTERIM REPORT**

This announcement is published on the websites of the Company ([www.totbiopharm.com.cn](http://www.totbiopharm.com.cn)) and the Stock Exchange ([www.hkexnews.hk](http://www.hkexnews.hk)). The 2022 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 2022

*As at the date of this announcement, the executive Directors of the Company are Dr. Liu, Jun and Ms. Yeh-Huang, Chun-Ying; the non-executive Directors of the Company are Mr. Fu, Shan and Mr. Qiu, Yu Min; and the independent non-executive Directors of the Company are Ms. Hu, Lan, Mr. Chang, Hong-Jen and Dr. Wang, De Qian.*