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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 2023

#### **HIGHLIGHTS OF 2023 INTERIM RESULTS AND BUSINESS:**

- Operating revenue of the Group was RMB328,063 thousand, representing a year-on-year increase of 80%. If the impact of one-time revenue from licenses granted for the first half of 2022 was excluded, the year-on-year increase of revenue would have reached 147%. In particular, revenue from sales of products was RMB277,881 thousand, representing a year-on-year increase of 167%, mainly attributable to the continuous growth in sales volume of our core product, Pusintin® (Bevacizumab injection). Revenue from CDMO/CMO business reached RMB46,546 thousand, representing a year-on-year increase of 105%. Newly added projects are expected to contribute more revenue to the Group in the second half of the year. The Group's cash-generating capability was continuously enhanced, and the net cash flow from operating activities continued to be positive and amounted to RMB62,413 thousand, increasing by 116% year-on-year.
- Focusing on the differentiated competition of ADC CDMO, the Group's business development strategy achieved remarkable results. There were 45 projects in process, of which 28 were ADC projects, accounting for 62%. In the first half of the year, there were 20 newly added projects, of which 15 were ADC projects, including 3 newly added pre-BLA ADC projects. We quickly locked down potential commercialization orders in order to accelerate cash flow conversion. The Group also successfully entered into several long-term project cooperation with respect to ADC CDMO.

- TOT BIOPHARM’s second and China’s largest commercial production line for ADC drug products was completed and put into use. The second and third commercial production lines for ADC drug substances were also completed.
- TOT BIOPHARM launched a cooperation with GlycanLink (糖嶺生物) to jointly develop an ADC site-specific conjugation technology platform – DisacLink™, creating the world’s most valuable site-specific conjugation technology in terms of application value and accelerating the development of innovative ADC drugs.

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 2023 together with comparative figures for the six months ended 30 June 2022 as set out in the section headed “Consolidated Financial Information” 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>2023</b>	<b>2022</b>
		<b>RMB’000</b>	<b>RMB’000</b>
Revenue	2	<b>328,063</b>	182,019
Cost of revenue		<b>(78,060)</b>	(23,478)
Research and development expenses		<b>(49,969)</b>	(70,268)
Selling expenses		<b>(197,376)</b>	(70,091)
General and administrative expenses		<b>(31,104)</b>	(25,698)
Net impairment reversal/(losses) on financial assets		<b>480</b>	(923)
Other income and gains – net		<b>13,390</b>	1,491
<b>Operating loss</b>		<b>(14,576)</b>	(6,948)
Finance income		<b>1,278</b>	415
Finance costs		<b>(2,261)</b>	(3,418)
Finance costs – net		<b>(983)</b>	(3,003)
Share of profits/(losses) of the joint venture accounted for using the equity method		<b>397</b>	(5,773)
<b>Loss before income tax</b>	3	<b>(15,162)</b>	(15,724)
Income tax expense	4	<b>(1)</b>	–
<b>Loss for the period and attributable to the equity holders of the Company</b>		<b>(15,163)</b>	(15,724)

		<b>Unaudited</b>	
		<b>Six months ended 30 June</b>	
	<i>Note</i>	<b>2023</b>	2022
		<i>RMB'000</i>	<i>RMB'000</i>
<b>Other comprehensive income:</b>			
<i>Items that may be reclassified to profit or loss</i>			
Exchange differences on translation		<u>3,417</u>	<u>3,236</u>
<b>Other comprehensive income for the period, net of tax</b>		<u>3,417</u>	<u>3,236</u>
<b>Total comprehensive loss for the period and attributable to the equity holders of the Company</b>		<u>(11,746)</u>	<u>(12,488)</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>(0.02)</u>	<u>(0.03)</u>

## INTERIM CONDENSED CONSOLIDATED BALANCE SHEET

		Unaudited 30 June 2023 RMB'000	Audited 31 December 2022 RMB'000
<b>ASSETS</b>			
<b>Non-current assets</b>			
Property, plant and equipment	6	599,873	465,328
Prepayments for property, plant and equipment		49,319	82,477
Right-of-use assets	6	14,781	15,007
Investment properties		2,984	3,184
Intangible assets	6	3,991	4,648
Investments accounted for using the equity method		397	–
Other non-current assets		15,431	14,590
		686,776	585,234
<b>Current assets</b>			
Inventories		109,565	94,821
Other current assets		17,545	38,254
Trade and other receivables	7	73,466	53,387
Prepayments		30,751	20,012
Contract assets		13,441	9,278
Financial assets at fair value through profit or loss		–	40,278
Restricted cash		–	2,998
Cash and cash equivalents		432,975	417,769
		677,743	676,797
<b>Total assets</b>		<b>1,364,519</b>	<b>1,262,031</b>
<b>EQUITY</b>			
Share capital	8	2,297,499	2,297,499
Other reserves		71,242	61,911
Accumulated losses		(1,660,691)	(1,645,528)
Non-controlling interests		–	1,557
<b>Capital and reserves attributable to the equity holders of the Company</b>		<b>708,050</b>	<b>715,439</b>

	<i>Note</i>	<b>Unaudited 30 June 2023 RMB'000</b>	Audited 31 December 2022 RMB'000
<b>LIABILITIES</b>			
<b>Non-current liabilities</b>			
Borrowings	9	<b>287,382</b>	212,133
Lease liabilities		<b>117</b>	345
Other non-current liabilities		<b>56,409</b>	58,767
		<b>343,908</b>	271,245
<b>Current liabilities</b>			
Borrowings	9	<b>41,100</b>	75,500
Trade and other payables	10	<b>257,861</b>	174,017
Contract liabilities		<b>7,186</b>	19,562
Lease liabilities		<b>1,697</b>	1,551
Other current liabilities		<b>4,717</b>	4,717
		<b>312,561</b>	275,347
<b>Total liabilities</b>		<b>656,469</b>	546,592
<b>Total equity and liabilities</b>		<b>1,364,519</b>	1,262,031
<b>Net current assets</b>		<b>365,182</b>	401,450
<b>Total assets less current liabilities</b>		<b>1,051,958</b>	986,684

# NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

## 1 SUMMARY OF MATERIAL 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 2023 has been prepared in accordance with 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 announcement is to be read in conjunction with the annual report for the year ended 31 December 2022 and any public announcements made by the Company during the interim reporting period.

The financial information relating to the year ended 31 December 2022 that is included in the condensed consolidated interim financial information for the six months ended 30 June 2023 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 2022 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. 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 and development, manufacturing, selling of anti-tumor drugs, CDMO/CMO business and license-out of self-developed biological drugs. 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>2023</b>	<b>2022</b>
	<b>RMB'000</b>	<b>RMB'000</b>
Timing of revenue recognition		
At a point in time:		
– Sales of goods	277,881	104,170
– CMO	20,492	8,918
– Commission revenue	3,391	4,732
– Revenue from license granted	–	49,434
– Others	109	130
Over time:		
– CDMO	26,054	13,739
– Others	136	896
	<b>328,063</b>	<b>182,019</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>2023</b>	<b>2022</b>
	<b>RMB'000</b>	<b>RMB'000</b>
Contract assets:		
– CDMO/CMO	12,182	7,067
– Sales commission	1,259	2,211
	<b>13,441</b>	<b>9,278</b>
Contract liabilities:		
– CDMO/CMO (i)	(6,087)	(18,420)
– Sales of goods	(1,099)	(1,142)
	<b>(7,186)</b>	<b>(19,562)</b>

(i) Contract liabilities arise from CDMO and CMO which are recognized when the advances are received before the services are rendered to customers.

(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>2023</b>	<b>2022</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	17,227	7,430
– Sales of goods	1,138	–
	<b>18,365</b>	<b>7,430</b>

(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, certain development-milestone payments and commercial-milestone payments of RMB84,500,000 (including tax) in aggregate. The contract also includes sales-based royalties. The Group has received the upfront payment and development milestone payments of RMB55,500,000 (including tax) in total as at 30 June 2023. For the six months ended 30 June 2023, there was no development milestone and commercial milestone achieved by the Group (For the six months ended 30 June 2022: certain development milestone of RMB32,400,000 (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 and certain development milestone payments of RMB30,000,000 (including tax) in aggregate. The contract also includes sales-based royalties. For the six months ended 30 June 2023, there was no development milestone and commercial milestone achieved by the Group (For the six months ended 30 June 2022: certain development milestone of RMB20,000,000 (including tax) was achieved). The Group is further entitled to receive up to an aggregate of RMB5,000,000 (including tax) upon the achievement of additional specified milestones related to the development and regulatory approval of the biological antibody drugs.

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

(f) **Geographical information**

Geographical information of revenue and non-current assets other than financial assets for the six months ended 30 June 2023 and 2022 is as follows:

	Six months ended 30 June			
	2023		2022	
	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	328,063	671,034	182,019	422,720
Others	–	314	–	387
	<u>328,063</u>	<u>671,348</u>	<u>182,019</u>	<u>423,107</u>

### 3 LOSS BEFORE INCOME TAX

	Six months ended 30 June	
	2023	2022
	RMB'000	RMB'000
Loss before taxation has been arrived at after charging:		
– Promotion and advertisement expenses	190,576	65,708
– Employee benefit expenses	80,899	60,831
– Clinical trials (exclude employee benefit expenses)	5,674	8,431
– R&D materials and consumables	2,828	4,515
– Depreciation and amortisation charge (Note 6)	18,672	18,681

### 4 INCOME TAX EXPENSE

	Six months ended 30 June	
	2023	2022
Current income tax expenses		
– Adjustment for current income tax of prior year	1	–
Deferred income tax expense	–	–
	<u>1</u>	<u>–</u>

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

### 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	
	2023	2022
Loss attributable to equity holders of the Company (RMB'000)	(15,163)	(15,724)
Weighted average number of ordinary shares in issue (thousand)	<u>725,197</u>	<u>575,197</u>
Basic loss per share (RMB)	<u>(0.02)</u>	<u>(0.03)</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 2023, the Company had one category of potential ordinary shares: the stock options granted to employees (For the six months ended 30 June 2022: same). As the Group incurred losses for the six months ended 30 June 2023 and 2022, 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 2023 and 2022 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 2023</b>			
<b>Opening net book amount as at 1 January 2023</b>	<b>465,328</b>	<b>4,648</b>	<b>15,007</b>
Additions	151,173	188	1,636
Depreciation and amortisation charge	(16,583)	(845)	(1,244)
Disposals	(57)	–	(618)
Net exchange differences	12	–	–
	<hr/>	<hr/>	<hr/>
<b>Closing net book amount as at 30 June 2023</b>	<b>599,873</b>	<b>3,991</b>	<b>14,781</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 2022</b>			
<b>Opening net book amount as at 1 January 2022</b>	307,668	5,123	15,733
Additions	63,619	537	634
Depreciation and amortisation charge	(17,012)	(801)	(868)
Disposals	(96)	–	–
Net exchange differences	(9)	–	(2)
	<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/>

## 7 TRADE AND OTHER RECEIVABLES

	<b>30 June 2023 <i>RMB'000</i></b>	31 December 2022 <i>RMB'000</i>
Trade receivables (a)	<b>70,643</b>	49,721
Less: provision for impairment of trade receivables	<b>(117)</b>	(597)
	<hr/>	<hr/>
Trade receivables – net	<b>70,526</b>	49,124
	<hr/>	<hr/>
Other receivables (b)	<b>2,940</b>	4,263
	<hr/>	<hr/>
Trade and other receivables	<b>73,466</b>	53,387
	<hr/>	<hr/>

(a) **Trade receivables**

	<b>30 June 2023 RMB'000</b>	31 December 2022 RMB'000
Trade receivables	<b>70,643</b>	49,721

Customers are generally granted with credit terms ranging from 45 to 90 days.

As of 30 June 2023 and 31 December 2022, the ageing analysis of the trade receivables based on invoice date is as follows:

	<b>30 June 2023 RMB'000</b>	31 December 2022 RMB'000
Within 30 days	<b>43,235</b>	28,716
31 days to 90 days	<b>25,305</b>	17,490
91 days to 180 days	<b>839</b>	2,210
181 days to 270 days	<b>816</b>	1,298
271 days to 360 days	<b>448</b>	7
	<b>70,643</b>	49,721

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.

(b) **Other receivables**

	<b>30 June 2023 RMB'000</b>	31 December 2022 RMB'000
Deposits	<b>2,500</b>	3,181
Others	<b>440</b>	1,082
Other receivables	<b>2,940</b>	4,263

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

	<b>30 June 2023 RMB'000</b>	31 December 2022 RMB'000
RMB	73,524	53,622
USD	59	362
	<u>73,583</u>	<u>53,984</u>

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

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

## 8 SHARE CAPITAL

	<b>Number of ordinary shares</b>	<b>Share capital RMB'000</b>
As at 1 January 2022 (Audited)	615,229,497	1,892,906
Issue of shares to shareholders ( <i>Note (a)</i> )	150,000,000	404,593
Issue of shares for 2022 Restricted Shares Award Scheme ( <i>Note (b)</i> )	7,558,390	–
	<u>772,787,887</u>	<u>2,297,499</u>
As at 31 December 2022 (Audited)	<u>772,787,887</u>	<u>2,297,499</u>
As at 1 January 2023 (Audited) and 30 June 2023 (Unaudited)	<u>772,787,887</u>	<u>2,297,499</u>

*Note (a):* On 29 July 2022, the Company allotted and issued 150,000,000 subscription shares at the price of HKD3.15 per share to two shareholders: (i) Center Laboratories, Inc. has been allotted and issued 33,750,000 subscription shares; and (ii) Vivo (Suzhou) Health Industry Investment Fund (Limited Partnership) has been allotted and issued 116,250,000 subscription shares. The two shareholders injected capital of approximately HKD472,500,000 (equivalent to approximately RMB405,788,000) in total. The gross proceeds, net of transaction costs, are capitalized as share capital accordingly.

*Note (b):* On 1 November 2022, the Company allotted and issued 7,558,390 ordinary shares to certain trustees at a subscription price of zero under the Company's 2022 Restricted Share Award Scheme. These award shares are within the Company's control until the shares are vested to the participants and hence are considered as treasury shares in substance.

As at 30 June 2023 and 31 December 2022, a total of 47,590,948 ordinary shares are within the Company's control until the shares are vested to the participants and hence are considered as treasury shares in substance.

## 9 BORROWINGS

	<b>30 June 2023 RMB'000</b>	31 December 2022 RMB'000
<b>Current</b>		
– Unsecured bank borrowings ( <i>Note (a)</i> )	<u>41,100</u>	<u>75,500</u>
<b>Non-current</b>		
– Unsecured bank borrowings ( <i>Note (b)</i> )	<u>287,382</u>	<u>212,133</u>
	<b><u>328,482</u></b>	<b><u>287,633</u></b>

*Note (a):* As at 30 June 2023, bank loans of RMB41,100,000 are unsecured, will be repayable within one year and bear annual interest rate ranging from 2.95% to 4.00% with undrawn facilities up to RMB230,000,000 (As at 31 December 2022: RMB75,500,000, from 3.80% to 4.00%, RMB100,000,000).

*Note (b):* As at 30 June 2023, bank loans of RMB287,382,000 are unsecured, will be repayable over one year and bear annual interest rate ranging from 3.50% to 4.20% with undrawn facilities up to RMB81,018,000 for specific use on construction of plant, production line and equipment (As at 31 December 2022: RMB212,133,000, 3.80% to 4.25%, RMB137,367,000).

As at 30 June 2023 and 31 December 2022, the Group's bank borrowings were repayable as follows:

	<b>30 June 2023 RMB'000</b>	31 December 2022 RMB'000
Within 1 year	41,100	75,500
Between 1 and 2 years	94,220	7,294
Between 2 and 5 years	126,691	183,937
Over 5 years	<u>66,471</u>	<u>20,902</u>
	<b><u>328,482</u></b>	<b><u>287,633</u></b>

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

	<b>30 June 2023</b>	31 December 2022
Bank borrowings	<u>3.94%</u>	<u>3.89%</u>

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

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

As at 30 June 2023, the Group has unutilised bank facilities of RMB311,018,000 (As at 31 December 2022: RMB237,367,000).

## 10 TRADE AND OTHER PAYABLES

	<b>30 June 2023 RMB'000</b>	31 December 2022 RMB'000
Accrued promotion expenses	150,590	77,780
Trade payables	42,274	25,983
Payables for purchase of property, plant and equipment	20,151	12,072
Staff salaries and welfare payables	16,924	21,944
Refund liabilities	5,109	5,987
Tax payable	1,627	2,537
Deposits payables	1,352	15,502
Others	19,834	12,212
	<b>257,861</b>	<b>174,017</b>

As at 30 June 2023 and 31 December 2022, the ageing analysis of trade payables based on invoice date are as follows:

	<b>30 June 2023 RMB'000</b>	31 December 2022 RMB'000
Within 3 months	37,002	24,982
3 months to 6 months	3,241	724
6 months to 12 months	2,031	133
1 year to 2 years	–	76
2 years to 3 years	–	68
	<b>42,274</b>	<b>25,983</b>

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

	<b>30 June 2023 RMB'000</b>	31 December 2022 RMB'000
– RMB	256,360	171,865
– NTD	380	1,011
– HKD	295	586
– USD	826	555
	<b>257,861</b>	<b>174,017</b>

## 11 DIVIDEND

No dividend has been paid or declared by the Company during the six months ended 30 June 2023 (Year ended 31 December 2022: Nil).

## 12 COMMITMENTS

### (a) Capital commitments

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

	<b>30 June 2023 RMB'000</b>	31 December 2022 RMB'000
Property, plant and equipment	<b><u>135,248</u></b>	<u>120,668</u>

### (b) Investment commitments

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

	<b>30 June 2023 RMB'000</b>	31 December 2022 RMB'000
Huayao Pharmaceutical (Suzhou) Company Limited	<b><u>20,250</u></b>	<u>26,250</u>

# MANAGEMENT DISCUSSION AND ANALYSIS OF CERTAIN ASPECTS OF OUR BUSINESS

## I. INDUSTRY AND PERFORMANCE OVERVIEW

With the rapid development of China's biomedical industry, competition in the industry has become increasingly fierce and the adjustment of the industrial structure has accelerated, placing higher requirements on research and development, process, quality, production and other aspects. In the first half of 2023, TOT BIOPHARM achieved rapid growth by continuously implementing its strategic transformation goals to make efforts in business and technology.

In terms of business, TOT BIOPHARM enjoyed continuous and rapid growth in commercial sales with launched products. At the same time, leveraging its first-mover advantage and outstanding competitiveness, the Company's antibody-drug conjugates ("ADC") CDMO business has emerged and become one of the market leaders in China, attracting close attention and high recognition from industry partners and achieving a number of ADC CDMO project cooperation.

For the first half of 2023, the Group's revenue amounted to RMB328,063 thousand, representing a year-on-year increase of 80%. For the first half of 2022, there was no one-time revenue from licenses granted, as compared to RMB49,434 thousand for the first half of 2022. Excluding the impact of such item, revenue would have increased by 147% for the first half of 2023. The sales revenue was RMB277,881 thousand, representing a year-on-year increase of 167%, which was mainly attributable to the significant increase in the sales of Pusintin<sup>®</sup> (Bevacizumab biosimilar), our core product. Revenue from CDMO/CMO business amounted to RMB46,546 thousand, representing a year-on-year increase of 105%. The Group's cash-generating capability was continuously enhanced, and the net cash flow from operating activities continued to be positive and amounted to RMB62,413 thousand, increasing by 116% year-on-year.

In line with its strategy, the Company focused on the development of biological drug CDMO business with a particular attention on the ADC CDMO sector. The business scale has expanded rapidly. As of 30 June 2023, there were 45 CDMO projects in process, representing a year-on-year increase of 96%, well above the industry's average growth rate and demonstrating a strong development momentum. Among these projects, there were 28 ADC projects and 14 antibody projects. The Company has entered into comprehensive cooperation in the fields of ADC drugs, radionuclide-drug conjugates (RDC) and other broader bioconjugates drugs with project partners such as Escugen (詩健生物), Lepu Biopharma (樂普生物), SmartNuclide (智核生物) and BioRay (博銳生物). In addition, we have successfully secured 3 pre-BLA ADC projects, fully demonstrating the Company's outstanding capabilities in the field of ADC CDMO.

In terms of net profit, benefiting from the significant increase in sales revenue and effective cost control, especially in research and development expenses, the net loss for the first half of 2023 decreased to RMB15,163 thousand from RMB15,724 thousand for the same period in 2022. Meanwhile, thanks to the Company's strategic adjustment, research and development expenses were significantly narrowed to RMB49,969 thousand, and the net cash inflows from operating activities were RMB62,413 thousand.

In terms of technology, the Company continued to build a leading ADC CDMO technology platform. In 2023, the Company launched a cooperation with GlycanLink (糖嶺生物) to jointly develop an ADC site-specific conjugation technology platform – DisacLink™, creating the world's most valuable site-specific conjugation technology in terms of application value and accelerating the development of innovative ADC drugs.

## **II. LAUNCHED PRODUCTS AND R&D PIPELINE**

### **1. Overall Marketing Strategy of Products**

In 2023, under the new strategic direction of development, TOT BIOPHARM actively promoted the sales of launched products and the development of two drug candidates. By optimizing the product structure, the Group's research and development expenses of new drugs continued to decrease, effectively improving the cash flow of the Company. For the research and development of TAE020 and TAC020, our early-stage drug candidates, we will promote the cooperation on clinical research and development and commercial licensing of related products under an open and collaborative model, so as to further accelerate the commercialization process of product pipelines and generate potential milestone revenue. At the same time, the commercial production of licensed products can continue to be carried out by TOT BIOPHARM, which will generate revenue for the CDMO services of the Company in the future.

## Product Pipeline of the Company

Type	Drug Candidate	Indication(s)	Preclinical	Clinical Phase I	Clinical Phase II	Clinical Phase III	NDA	Launched
Antibody-drug conjugate	TAE020 (new target)	Acute myeloid leukemia						
Monoclonal antibody	TAB014 (anti-VEGF)	Wet age-related macular degeneration (wAMD)						
	TAC020 (new target)	Various solid tumors						
IND authorized by FDA to directly enter Clinical Phase III								
Drug Name	Indication(s)		Product Specification		Launched			
TAB008: Pusintin® (Bevacizumab Injection)	Advanced, metastatic or recurrent non-squamous non-small cell lung cancer; metastatic colorectal cancer; recurrent glioblastoma multiforme; epithelial ovarian cancer, fallopian tube cancer or primary peritoneal cancer; cervical cancer; hepatocellular carcinoma		100 mg (4 mL)/bottle		Approved for launch by NMPA on 30 November 2021			
TOZ309: Tazian® (Temozolomide Capsule)	Newly diagnosed glioblastoma multiforme, initially combined with radiotherapy, and then as maintenance therapy; glioblastoma multiforme or anaplastic astrocytoma that recurs or progresses after conventional treatment		20 mg x 5 capsules/bottle; 100 mg x 5 capsules/bottle		Approved for launch by NMPA on 31 May 2021			
TOM218: Megaxia® (Megestrol Acetate Oral Suspension)	Anorexia associated with acquired immunodeficiency syndrome (AIDS) as well as significant weight loss of AIDS and cancer patients caused by cachexia		150 mL/bottle		Approved for launch by NMPA on 13 May 2021 <i>(This product is imported from Taiwan; the Company owns the exclusive agency rights of this product in mainland China, Hong Kong and Macau)</i>			

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

Source: The Company

## 2. Marketing Strategy of Launched Products

### – Pusintin® (Bevacizumab injection)

- *Indications: non-small cell lung cancer; metastatic colorectal cancer; recurrent glioblastoma multiforme; epithelial ovarian cancer, fallopian tube cancer or primary peritoneal cancer; cervical cancer; hepatocellular carcinoma*

Pusintin®, the core product of the Company in the field of anti-tumor treatment, is also TOT BIOPHARM's first biological drug approved for launch. As of 30 June 2023, Pusintin® has been approved for the treatment of all six indications that can be treated with the originator drug approved in mainland China. At the same time, with the expansion of clinical research on bevacizumab, new indications that can be treated with bevacizumab and extensive demand for bevacizumab in combination therapies (for use in combination with chemical drugs, double antibodies, ADC and other drugs), the market potential for bevacizumab has continued to grow, making it a major category of biological drugs valued at over RMB10.0 billion. According to the statistics and estimates of Frost & Sullivan, the global market size of bevacizumab is expected to increase to nearly RMB49.0 billion in 2030, with a CAGR of 7.6% from 2021 to 2030, and the market size

of bevacizumab in China is expected to increase to RMB18.4 billion in 2030, with a CAGR of 8.3% from 2021 to 2030. Pusintin<sup>®</sup> was successfully listed on the 2022 National Reimbursement Drug List as a Class B drug, which significantly improved the affordability and drug accessibility for patients, and the market demand continued to grow. Through close cooperation with Jixin Pharmaceutical (濟鑫醫藥), the Company continued to expand the market share of Pusintin<sup>®</sup>.

In 2023, the Company continued to implement differentiated marketing strategies and further consolidated its market position. For the first half of 2023, the sales growth rate of the drug increased by 161% year-on-year through strategies such as focusing on second- and third-tier cities with huge market space and provinces that have adopted dual-channel pharmacies, and continuing to penetrate into third- and fourth-tier cities and county-level cities. In terms of overseas markets, we actively promoted the registration filing for the launch of Pusintin<sup>®</sup> in overseas markets. As of 30 June 2023, we have initiated the registration application in 20 overseas countries, and the registration application documents have been accepted by 8 countries. We aim to obtain the first approval from an overseas country by the end of 2023 in order to penetrate overseas markets.

– ***Tazian<sup>®</sup> (Temozolomide capsule)***

– *Indications: glioblastoma; anaplastic astrocytoma*

Tazian<sup>®</sup> was approved for launch by the National Medical Products Administration (“NMPA”) on 31 May 2021 for the treatment of newly diagnosed glioblastoma or anaplastic astrocytoma. Temozolomide capsules were included in the fourth batch of national centralized procurement catalogue in 2021. Tazian<sup>®</sup> was successfully selected by the Thirteen Allied Provinces in the first half of 2022. As of 30 June 2023, the Company has become the supplier in the renewal of centralized procurement by Jiangsu Province, Hebei Province, Beijing, Guangdong Province, Jiangxi Province, Shandong Province and Shaanxi Province. The Company has entered into a marketing cooperation with Jixin Pharmaceutical (濟鑫醫藥) in China, which has enhanced the penetration of hospital procurement channels.

- **Megaxia® (Megestrol acetate oral suspension)**
  - *Indications: anorexia associated with acquired immunodeficiency syndrome (“AIDS”); significant weight loss of AIDS and cancer patients caused by cachexia*

Megaxia® was approved for launch by the NMPA on 13 May 2021 for the treatment of anorexia associated with AIDS as well as significant weight loss of AIDS and cancer patients caused by cachexia. This product is an oral suspension 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.

Megaxia® is the only oral nanosuspension launched in the world. Compared to traditional oral dosage forms on the market, this dosage form has high absorption, good taste and high patient compliance, which can significantly improve anorexia and weight loss problems suffered by patients. With the introduction of Megaxia®, TOT BIOPHARM continued to improve the brand awareness of the drug through an open and collaborative model, with a view to help cancer patients and AIDS patients improve their quality of life.

### **III. ANTIBODY-DRUG CONJUGATES (ADC) ARE ENJOYING A GOLDEN PERIOD OF RAPID DEVELOPMENT**

#### **1. Market Size of Biological Drugs**

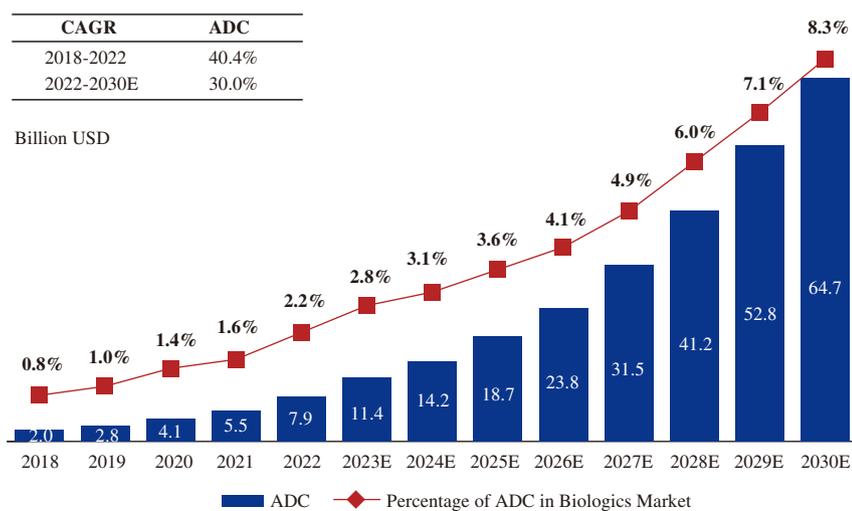
Driven by the rapid development of biotechnology and the increased investment in research and development, China’s biomedical industry is entering a period of rapid development, and the market size is steadily expanding. According to the statistics and estimates of Frost & Sullivan, the market size of biological drugs in China will increase from RMB410.0 billion in 2021 to RMB710.2 billion in 2025, representing a CAGR of 14.7%. In the future, with the improvement of residents’ affordability, the growth of patient groups, and the expansion of medical insurance coverage, it is expected that the market size of biological drugs in China will be further expanded to RMB1 trillion by 2030. ADC drug, with high specificity inherent to antibody and the high anti-tumor activity inherent to cytotoxin, is of more controllable safety, and is currently one of the hot research topics in the field of tumor treatment. In 2023, the number of overseas licensing projects for China’s ADC drugs will increase, opening up new grounds in China’s ADC drug market.

## 2. Market Opportunities for ADC

### – *Rapid growth of the ADC drug market*

The global popularity of research and development and investment in ADC drugs has grown steadily in recent years. A number of high-value product licensing deals and corporate mergers and acquisitions around the world have been in the field of ADC drugs, attracting great attention from the market. ADC has become one of the hottest segments in the innovative drug industry, which is expected to grow significantly over the next decade. According to the statistics and estimates of Frost & Sullivan, the global market size of ADC drugs is expected to increase from USD7.9 billion in 2022 to USD64.7 billion in 2030, representing a CAGR of 30%. As one of the major countries for research and development of ADC drugs, China has huge potential for growth in the ADC drug market.

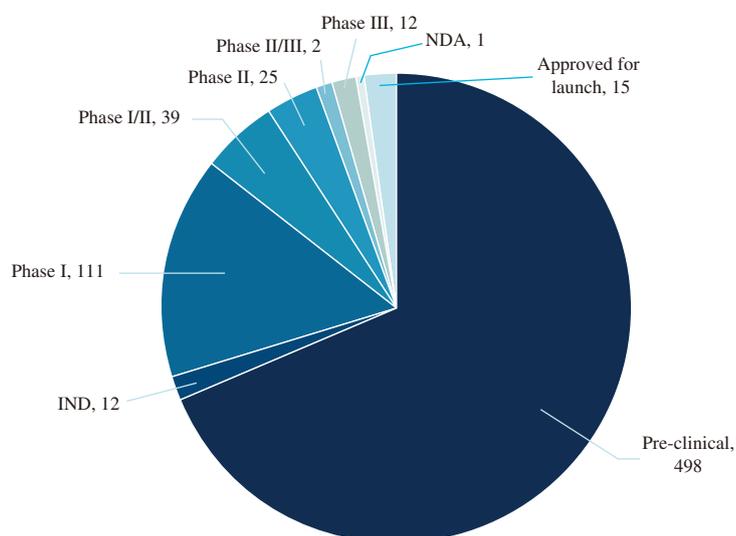
**Global Market Size of ADC Between 2018 and 2030E**



Source: Frost & Sullivan

As the market size of ADC drugs began to surge, the clinical applications for ADC drugs also expanded rapidly. According to the information released by PHARMCUBE (醫藥魔方) in May 2023, there are over 700 active traditional ADC drugs in the world, of which only 15 products have been approved for launch. There are still more than 200 products in various stages of clinical research, the majority of which are still in the pre-clinical stage, which offers great growth potential for the ADC CDMO business market.

### Global R&D Phase of ADC Drugs



Source: PHARMCUBE (醫藥魔方)

#### – *ADC CDMO facilitated the acceleration of ADC drug development*

Due to the complexity and high toxicity of ADC drugs, there are extremely high requirements for process development, stability, batch-to-batch consistency and CMC compliance. As a result, ADC drugs have relatively high barriers to entry compared to small molecule and antibody drugs in terms of commercial production technology, facility investment and maintenance, and other aspects. In particular, with the increasing complexity of late-stage clinical and commercialization, the requirements for project development experience and compliance become higher. Cooperation with professional CDMOs can significantly reduce drug development costs, shorten development cycles and reduce operational risks. According to the relevant statistics, the outsourcing rate can be as high as approximately 70%, which is much higher than the 34% outsourcing rate for other biologics.

Statistics show that the global market size of ADC CDMO reached USD1.5 billion in 2022, representing a CAGR of 34.5% from 2018 to 2022, which outpaced the 21.8% CAGR of the overall biopharmaceutical outsourcing services market over the same period. It is expected that the market size of ADC CDMO will grow significantly to USD11.0 billion by 2030, representing a CAGR of 28.4% from 2022 to 2030. At the same time, validated research and development and industrialization platforms that integrate antibodies, ADC drug substances and ADC drug products are very scarce in China. All these factors offered good opportunities and prospects for the development of the Company's ADC CDMO business.

#### **IV. DEVELOPMENT AND COMPETITIVE ADVANTAGES OF CDMO BUSINESS OF TOT BIOPHARM**

##### **1. Highlights of CDMO Performance in the First Half of the Year**

In 2023, TOT BIOPHARM received strong support from shareholders and strategic partners after successfully implementing the effective strategic transformation of focusing on biological drugs and concentrating efforts on ADC CDMO. The Company expanded its portfolio of early-stage pipeline projects and enhanced its customer stickiness by focusing on the biological drug CDMO business. In the first half of the year, the Company achieved outstanding performance in its CDMO business, with revenue from CDMO/CMO of RMB46,546 thousand, representing a year-on-year increase of 105%. As of 30 June 2023, there were 45 projects in process, representing a year-on-year increase of 96%. With efforts made on the field of ADC, the business scale increased rapidly, of which 28 were ADC projects, accounting for 62% of total projects.

Leveraging its outstanding ADC commercial production capacity and project experience, the Company quickly undertook late-stage clinical projects and accelerated cash flow conversion. In the first half of the year, 20 newly added projects were secured, of which 15 were ADC projects, including 3 newly added pre-BLA ADC projects. 17 pre-IND projects were newly added, including 2 early-stage R&D/testing projects. Such newly added projects are expected to contribute more revenue to the Group in the second half of the year.

##### **2. Facilitating the Broader Development of Bioconjugates Drugs through a Number of Long-term Project Cooperation on ADC CDMO**

In the first half of 2023, TOT BIOPHARM entered into a number of in-depth project cooperation with its partners:

- TOT BIOPHARM entered into a close cooperation with Escugen (詩健生物), pursuant to which we will fully assist Escugen in the research and development and production of ADC drugs from late-stage clinical to commercialization, and utilizing our rich practical experience in the whole value chain of drug development to ensure the success of Escugen.

- TOT BIOPHARM established a long-term ADC project cooperation with Lepu Biopharma (樂普生物), pursuant to which we will provide comprehensive services from research and development to clinical and commercialization for its ADC drugs.
- TOT BIOPHARM entered into a strategic cooperation agreement with SmartNuclide (智核生物), pursuant to which the two parties will promote the development of radionuclide-drug conjugates (RDC), an innovative radiopharmaceutical based on conjugation technology. This cooperation demonstrated the strong growth potential of TOT BIOPHARM in the emerging field of drug conjugates.
- TOT BIOPHARM entered into a comprehensive strategic cooperation in the field of CDMO with BioRay (博銳生物), pursuant to which we will provide BioRay with one-stop CDMO services for various ADC research and development projects, as well as whole process services for drug research and development, and will support BioRay on ADC drugs from research and development to IND, and clinical approval and commercial production in the future.

### **3. The Company’s Differentiated Competitiveness in CDMO**

#### **– 3.1 “One-base, end-to-end” ADC industrialization platform**

TOT BIOPHARM, with the establishment of a “one-base, end-to-end” commercial production line that integrates antibodies, ADC drug substances and ADC drug products, has become one of the internationally leading, domestically scarce CDMO service companies that can offer one-stop services from development to commercialization of ADC. It can meet the needs of the whole process of biological drugs from development to commercial production, avoiding the compliance uncertainties associated with domestic segmented production. The Company has the largest ADC commercial production workshop in China, equipped with the most advanced production line for ADC drug products in the industry. The Company has its own production capacity of 20,000L of antibodies and antibody intermediates, 3 ADC conjugation workshops and 2 production lines for ADC drug products, which can meet the current production capacity requirements of most ADC drugs in China. TOT BIOPHARM’s headquarters and integrated commercial production workshops are located in Suzhou Industrial Park. With the support of the Suzhou government and regulatory authorities, geographical advantages, established supply chain, stable customer base and excellent talent pool, the Company can meet the needs of the whole process of ADC drugs from early development to commercial production, and ensure stable supply.

– ***3.2 Technology platform with continuous iteration***

TOT BIOPHARM continued to build the most competitive ADC CDMO technology platform. In 2023, the Company and GlycanLink (糖嶺生物) launched a cooperation to jointly develop an ADC site-specific conjugation technology platform – DisacLink™. The parties agreed to cooperate on the optimization, process development and commercial amplification of DisacLink™ technology, and to offer this technology as one of the CDMO services of TOT BIOPHARM to provide customers with high-quality development and manufacturing solutions for ADC drugs. In addition, the parties will collaborate on the marketing and commercialization of this technology to expand its global influence and competitiveness. The DisacLink™ technology, one of the site-specific conjugation technologies for third-generation ADC drugs, is characterized by high homogeneity, concise process, short reaction time, mild reaction conditions, and low overall process cost. It has shown good efficacy and safety in pre-clinical studies of the products. DisacLink™ technology is currently China's most valuable site-specific conjugation technology in terms of application value and one of the world's most advanced site-specific conjugation technologies with independent patents, which will enable the accelerated development of the ADC industry, further unleash the Company's innovation ability, and effectively promote the Company's development.

– ***3.3 A validated quality management system that meets international standards***

TOT BIOPHARM has established a quality management system that conforms to commercial production, covering the whole process from research and development to commercialization. At present, it has supported the commercial production of two launched products, and the quality system is continuously regulated by regulations and meets relevant standards. In 2022, the Company passed the EU QP certification with zero defects on the first attempt, enabling it to meet the requirements of project applications in China, the United States, Europe and other countries or regions. TOT BIOPHARM is committed to continuously improving and upgrading the international quality management system in order to provide customers with comprehensive and high-quality services and to become the industry-leading and most trusted partner in biomedicine.

– ***3.4 Flexible and diverse production capacity***

TOT BIOPHARM has built a “one-base, end-to-end” commercial production line that integrates antibodies, ADC drug substances and ADC drug products. The Company has the largest commercial production workshop for ADC drug products in China, equipped with the most advanced production equipment for ADC drug products in the industry. The Company has built two production workshops for antibody and antibody intermediate drug substances, equipped with 200L, 500L and 2,000L disposable bioreactors of international leading brands, as well as production facilities for various scales of drug substances, with a total production capacity of more than 20,000L. In terms of the production of ADC drug substances and ADC drug products, the Company has 3 ADC conjugation and drug substances production workshops, and 2 production lines for ADC drug products, which are equipped with high-standard equipment in the industry, and can meet the production capacity requirements of ADC and antibody drugs of various sizes in small trials, pilot tests and commercialization, and realize continuous production of different projects.

– ***3.5 Continuously expanded CDMO team***

TOT BIOPHARM continued to introduce key talents and expanded team echelon construction in line with business development. The Company has a mature and stable core CDMO team, consisting of talents with extensive industry experience in fields such as biopharmaceutical process development, commercial production, quality, and regulatory filing. The senior management of the Company has many years of extensive management experience in well-known multinational pharmaceutical companies. The CDMO team has continuously expanded in line with the rapid increase of the Company’s CDMO business volume. In the first half of the year, the number of staff of CDMO team increased by 13%, accounting for 80% of the total number of staff of the Group. Among them, the total number of staff of technology research and development, production and quality accounted for 83% of the total number of staff of CDMO team.

– ***3.6 Corporate reputation***

Leveraging its advantageous background in research and development of new drugs, TOT BIOPHARM is equipped with the experience in the whole project process from drug research and development to commercial production and launch, and has successfully expanded the CDMO business, gaining trust and recognition from industry partners. We can complete project delivery efficiently with high quality based on in-depth understanding of customer needs and practical solutions. In the first half of 2023, TOT BIOPHARM undertook 3 pre-BLA ADC projects, which fully demonstrated its strong research and development and production capacity for late-stage clinical and commercialization projects, and laid a solid foundation for the medium- and long-term business development of the Company.

## V. INDUSTRY-LEADING AND DIVERSE PRODUCTION CAPACITY

### 1. Commercial Production Bases

With the commercialization of the Company's core products and its strategic transformation, TOT BIOPHARM continued to expand its production capacity to meet customer demand and increase market share. In the first half of 2023, the expansion of commercial production capacity and its results were as follows:

- TOT BIOPHARM's second production line for antibody drug substances was completed and put into production and operation. The production line is equipped with two cell thawing functional rooms as well as 200L, 500L and 2,000L bioreactors, which can meet the needs from clinical to commercial production.
- TOT BIOPHARM's second and third production lines for ADC drug substances that meet international GMP standards were completed. The production lines are equipped with OEB-5 isolators, flexible production equipment that can be adapted to a variety of ADC conjugation processes, and equipped with 100L, 200L and 500L reaction kettles. The conjugation scale can reach 5 kg/batch.
- TOT BIOPHARM's second and China's largest commercial production line for ADC drug products was completed and put into use. The filling equipment is Syntegon filling equipment from Germany, equipped with 40m<sup>2</sup> (2\*20m<sup>2</sup>) Kyowa freeze-drying machines from Japan, which adopt disposable filling system, isolator filling linkage line, automatic feeding and discharging freeze-drying system, can produce freeze-dried products that meets 2R-50R specification, with the fastest running speed of 200 vials/min. The production line adopts rapid transfer port (RTP), equipped with online weighing function and light protection function. The pilot production line adopts 100% full weighing control mode, and the commercial production line adopts statistical sampling weighing module with dual-weighing complementary function. The production line is independently designed for filling, automatic feeding and discharging, and capping, which can realize freeze-drying, injection switching and continuous production.

### 2. Layout of the Company's Production Workshops by Category

The layout of TOT BIOPHARM's GMP-compliant ADC CDMO commercial production workshops, which integrate antibodies, ADC drug substances and ADC drug products with leading production capacity in China, is as follows:

<b>Antibody production workshops</b>	
<p>– <b>Antibody drug substances manufacturing (McAb DS)</b></p> <p>2 independent workshops with annual production capacity of 150 batches, and a designed annual production capacity of 300,000L</p> <p>200L to 2,000L disposable bioreactors of different scales have been installed to support the production of antibody drug substances, with a total production capacity exceeding 20,000L</p>	
<p>Workshop for antibody drug substances</p>	<ul style="list-style-type: none"> <li>• Production capacity exceeding 20,000L for different scales of antibody drug substances production, namely commercialization projects, pilot tests and small trials</li> <li>• Disposable bioreactors of international leading brands with flexible and continuous production capability for different projects</li> <li>• Gained GMP certification by NMPA</li> </ul>
<p>– <b>Antibody drug products manufacturing (McAb DP)</b></p> <p>2 filling lines (including 1 freezing line and 1 injection line)</p> <p>Annual production capacity of 250 batches, and 18,000 vials/h</p>	
<p>Workshops for antibody drug products</p> <p>(able to meet the needs of injection and freeze-dried products at the same time)</p>	<ul style="list-style-type: none"> <li>• International leading brands of Bosch’s fully automatic filling injection production line and Steriline’s isolator filling linkage production line, which can meet the needs of antibody liquid-injection and freeze-dried 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 linkage line, automatic feeding and discharging as well as capping, which can realize freeze-drying (15m<sup>2</sup>), liquid injection switching and continuous production, and maximize the utilization of production capacity</li> </ul>

	<ul style="list-style-type: none"> <li>Gained GMP certification by NMPA, which can meet the needs of commercial production of self-developed products and the production of CDMO products</li> </ul>
<p><b>ADC production workshops</b></p>	
<p><b>– ADC drug substances manufacturing</b></p> <p>3 independent workshops with annual production capacity of 150 batches and a designed annual production capacity of 600 kg</p> <p>Equipped with OEB-5 isolators for weighing active small molecules, and also equipped with 100L, 200L and 500L disposable coupling reactors, with a conjugation scale of up to 5 kg/batch</p>	
Workshop for ADC drug substances	<ul style="list-style-type: none"> <li>International leading brand of Merck’s reaction kettles of different scales (5L-500L) and chromatography systems</li> <li>Up to conjugation scale of 5 kg/batch</li> <li>Completed clinical production and process validation production of multiple batches of ADC drugs, which are compliant with GMP standards and meet commercialization needs</li> </ul>
<p><b>– ADC drug products manufacturing</b></p> <p>Top conjugation drug products manufacturing line in China, equipped with isolators and freeze-drying machines of international leading brands, with an annual production capacity of 5.3 million vials</p> <p>Two ADC drug products manufacturing lines that can produce 2R-50R specifications of freeze-dried products, with a maximum running speed of 200 vials/min</p> <p>Equipped with one 5m<sup>2</sup> and two 20m<sup>2</sup> freeze-drying machines, all equipped with fully automatic feeding and discharging systems</p>	
Workshop for ADC drug products	<ul style="list-style-type: none"> <li>International leading brands of Syntegon’s high-activity isolator filling linkage production lines and Japan-based Kyowa’s freeze-drying machines</li> </ul>

	<ul style="list-style-type: none"> <li>• Specially designed for the production of scarce high-activity products and equipped with OEB-5 isolators to ensure aseptic production while meeting the needs of personnel safety protection</li> <li>• Independent design of automatic filling linkage line, automatic feeding and discharging as well as capping, which can realize freeze-drying, liquid injection switching and continuous production, and maximize the utilization of production capacity</li> <li>• Equipped with a non-toxic conjugation workshop, which can support non-toxic conjugation projects</li> </ul>
<b>Small molecule chemical drug manufacturing</b>	
Workshop 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 production of multiple batches in CDMO projects</li> <li>• Gained GMP certification by 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>

## VI. COMMUNICATION WITHIN THE INDUSTRY AND BRAND PROMOTION

In the first half of the year, we focused on stepping up our efforts to promote our brand in biological drug CDMO, shaping a new brand image through diversified industrial cooperation and exchanges, strengthened product exchanges and the consolidation of industry resources, and accurately targeted customer groups. Based on the best delivery results and excellent delivery records, the Company has been highly recognized by customers. By continuously improving service quality, technical capabilities and customer empowerment, the Company has continued to bring value to regular customers in order to build trusting relationships and enhance customer stickiness. TOT BIOPHARM strives to become a leading CDMO company in the field of ADC, XDC, AXC and other broader bioconjugates drugs to enable the rapid development of the industry, and is committed to becoming a professional CDMO partner in the field of global drug development.

- In April 2023, TOT BIOPHARM participated in the 8th China Bio-Pharm Partnering Forum (第八屆中國生物醫藥創新合作大會), and joined discussions with many industry partners on the new trends of biomedicine, in particular the development trend of ADC.
- In May 2023, TOT BIOPHARM, together with PHARMCUBE (醫藥魔方) and many major players in ADC industry, held a salon on the topic of “Innovation Space for Domestic ADC (國產ADC創新空間)” to jointly discuss “How domestic ADC can grow in a challenging environment (國產ADC如何逆流而上)”, promoting the development of biomedical industry to a new level.
- In May 2023, TOT BIOPHARM, as a special guest, discussed the production technology and strategy of antibody drugs with industry partners at the 4th BIONNOVA Leaders Forum (第四屆BIONNOVA生物醫藥創新者論壇).

### Special Booth of TOT BIOPHARM



At the same time, the CDMO strategic transformation of TOT BIOPHARM has received high attention from the capital market. A number of leading brokerage analysts and institutional investors visited the Company for on-site research, communicated face-to-face with the management, and conducted in-depth exchanges with the Company on its ADC CDMO business development and strategic planning, which gained high recognition from the capital market. The Company’s management is confident in the future strategic development of the Company, and will continue to strengthen communication with all sectors in the industry to showcase the Company’s latest developments and business highlights.

## **VII. CORPORATE VISION, MISSION AND VALUES**

In response to the Company's strategic transformation, we have reshaped corporate culture to promote the long-term sustainable development of the Company. With a focus on result-oriented and process management, we actively reduce costs and increase efficiency, and carry out technology management. Meanwhile, we pay attention to team communication and cooperation, and have a strong sense of responsibility to improve customer satisfaction and achieve long-term cooperation. We strive to become the industry-leading and most trusted partner in biomedicine.

- Our vision: empowering pharmaceutical innovation to improve the quality of life and safeguard human health
- Our mission: to be an industry-leading and the best customer-trusted partner in biopharmaceuticals
- Our values: people caring, quality oriented, professional & efficient, cooperative & win-win, innovative & passionate
- Our slogan: strive for better you

## **VIII. FUTURE PROSPECTS**

With the continued support of technological innovation and medical reform policies, the prospects for the development of the biomedical industry are promising. TOT BIOPHARM will continue to focus on ADC CDMO and expand the number of customers and projects, while actively expanding the domestic and overseas markets for launched drugs and promoting the research and development of early-stage products. The Company will enhance customer stickiness with excellent service quality and regulatory support services. The Company will build a cutting-edge innovative technology platform, accumulate extensive project experience, and actively explore more innovative emerging fields such as XDC, AXC and other broader bioconjugates drugs, so as to provide continuous growth impetus to the Company's development, establish long-term trustworthy cooperative relationships with customers, and promote the high-quality development of the biological drug industry.

Looking to the future, as a China-based company with a global vision, TOT BIOPHARM will actively expand business in overseas markets, gain in-depth understanding of international market needs, and establish good relationships with customers in overseas markets such as Europe, Japan and South Korea. With the recognition gained from overseas partners through its international corporate image, the Company aims to become the best partner for global biomedical customers by providing high-quality and efficient services.

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

### **OVERVIEW**

For the first half of 2023, the Group recorded an operating revenue of RMB328,063 thousand, representing an increase of RMB146,044 thousand, or 80%, from RMB182,019 thousand for the same period in 2022. For the first half of 2023, the net loss of the Group was RMB15,163 thousand, representing a decrease of RMB561 thousand, or 4%, from the net loss of RMB15,724 thousand for the same period in 2022. The Group's research and development expenses for the first half of 2023 were RMB49,969 thousand, as compared to RMB70,268 thousand for the same period in 2022. The Group's general and administrative expenses for the first half of 2023 were RMB31,104 thousand, as compared to RMB25,698 thousand for the same period in 2022. The Group's selling expenses for the first half of 2023 were RMB197,376 thousand, as compared to RMB70,091 thousand for the same period in 2022.

### **OPERATING REVENUE AND COSTS**

The Group's diversified revenue mainly includes sales revenue, revenue for providing CDMO/CMO services, etc.

The Group's sales revenue for the first half of 2023 was RMB277,881 thousand, representing an increase of RMB173,711 thousand, or 167%, from RMB104,170 thousand for the same period in 2022, which was mainly due to the significant 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/CMO for the first half of 2023 was RMB46,546 thousand, representing an increase of RMB23,889 thousand, or 105%, from RMB22,657 thousand for the same period in 2022, primarily attributable to the continuous increase of CDMO/CMO business segment in the current year, while the costs for raw materials, labor and production, etc. also increased accordingly.

### **RESEARCH AND DEVELOPMENT EXPENSES**

The Group's research and development expenses primarily consist of expenses related to clinical trial research for pipeline product candidates, expenses related to the exploration and development and pre-clinical research of the early-stage pipeline, and expenses related to the enhancement of the Group's CDMO technology platform.

The Group's research and development expenses for the first half of 2023 were RMB49,969 thousand, representing a decrease of RMB20,299 thousand from RMB70,268 thousand for the same period in 2022, which was mainly attributable to the optimization of product pipelines and 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 2023 were RMB197,376 thousand, representing an increase of RMB127,285 thousand from RMB70,091 thousand for the same period in 2022, which was mainly attributable 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 2023 were RMB31,104 thousand, representing an increase of RMB5,406 thousand from RMB25,698 thousand for the same period in 2022, which was mainly attributable to the increase in taxation resulting from the increase in sales of self-developed products, and the increase in provision for share-based compensation expenses.

## **FINANCE INCOME**

The Group's finance income is primarily interest income on bank deposits.

The finance income for the first half of 2023 was RMB1,278 thousand, representing an increase of RMB863 thousand from RMB415 thousand for the same period in 2022, which was mainly attributable to the optimization of fund allocation.

## **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 finance costs for the first half of 2023 were RMB2,261 thousand, representing a decrease of RMB1,157 thousand from RMB3,418 thousand for the same period in 2022, mainly due to the repayment of part of the working capital loans.

## **INCOME TAX EXPENSE**

The Group's income tax expense for the first half of 2023 was RMB1 thousand, and no income tax expense was incurred for the same period in 2022.

## **LOSS FOR THE PERIOD**

As a result of the above as a whole, the net loss for the first half of 2023 decreased to RMB15,163 thousand from RMB15,724 thousand for the same period in 2022.

## **NET ASSETS**

The Group's net assets as of 30 June 2023 were RMB708,050 thousand, representing a decrease of RMB7,389 thousand from RMB715,439 thousand as of the end of 2022, which was mainly attributable to the net loss during the current period.

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

As at 30 June 2023, the Group's cash and cash equivalents were RMB432,975 thousand, representing an increase of RMB15,206 thousand from RMB417,769 thousand as at the end of 2022. Such change was mainly attributable to the following reasons:

During the first half of 2023, the Group's net cash inflows for operating activities were RMB62,413 thousand, representing an increase of RMB33,561 thousand from RMB28,852 thousand for the same period in 2022, which was mainly attributable to the significant increase in sales revenue and changes in the above-mentioned operating expenses in the current year. The Group's net cash outflows for investing activities for the period were RMB84,748 thousand, representing an increase of RMB21,337 thousand from RMB63,411 thousand for the same period in 2022, which was mainly attributable to the increase in capital investment for enhancing production capacity and promoting the construction of its Global Research and Development Center. The Group's net cash inflows for financing activities were RMB34,085 thousand, representing an increase of RMB702 thousand from RMB33,383 thousand for the same period in 2022, which was mainly attributable to the optimization of capital structure.

## **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 2023, 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 2023.

## **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 2023, 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 2023 and up to the date of this announcement.

## **USE OF NET PROCEEDS FROM THE SUBSCRIPTIONS**

On 31 May 2022, the Company entered into subscription agreements with Center Laboratories, Inc. (晟德大藥廠股份有限公司) (4123.TW) (“**Centerlab**”) and 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**”) respectively, pursuant to which Centerlab and Vivo Suzhou Fund 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 held 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) Centerlab was allotted and issued 33,750,000 shares; and (ii) Vivo Suzhou Fund was allotted and issued 116,250,000 shares.

The gross proceeds from the Subscriptions were approximately HKD472,500,000 (equivalent to approximately RMB405,788 thousand), and the net proceeds from the Subscriptions after the deduction of the relevant fees and expenses were approximately HKD471,116,000 (equivalent to approximately RMB404,593 thousand) (the “**Net Proceeds**”).

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 (the “**Circular**”).

During the six months ended 30 June 2023, part of the Net Proceeds were utilized in accordance with the proposed applications as set out in the paragraph headed “Letter from the Board – Connected Transactions Involving the Subscriptions – Use of Proceeds” in the Circular.

The unused amount of the Net Proceeds was approximately RMB307,453 thousand as at 31 December 2022. During the six months ended 30 June 2023, such Net Proceeds amounting to approximately RMB84,783 thousand were used, and the unused amount of the Net Proceeds was approximately RMB222,670 thousand as at 30 June 2023. The unused Net Proceeds were kept by the Group as deposits with licensed commercial banks. Such unused Net Proceeds are intended to be applied in accordance with the proposed applications as set out in the Circular.

A breakdown of the use of the aforesaid Net Proceeds during the six months ended 30 June 2023 and an expected timeline for the use of the unused portion will be disclosed in the 2023 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 2023.

#### **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 2023 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, 11 August 2023

*As at the date of this announcement, the executive director of the Company is Dr. Liu, Jun; the non-executive directors of the Company are Mr. Fu, Shan, Ms. Yeh-Huang, Chun-Ying 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.*