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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)

ANNUAL RESULTS ANNOUNCEMENT FOR THE YEAR ENDED 31 DECEMBER 2022

HIGHLIGHTS OF 2022 ANNUAL RESULTS AND MILESTONES

- **Operating revenue of the Group reached RMB442,178 thousand in 2022, increasing by 479% year-on-year**, mainly attributable to the substantial increase in the sales volume of self-developed products, the continuous development of CDMO business and the increase in milestone payment income from licenses granted in connection with the Group's projects. In particular, revenue from sales of products reached RMB304,361 thousand; revenue from CDMO/CMO business reached RMB72,538 thousand, representing an increase of 35% year-on-year; and revenue from licenses granted reached RMB54,151 thousand.
- **Strategic transformation produced significant results, with other financial indicators also seeing remarkable improvements.** In 2022, net loss of the Group narrowed by 81% year-on-year to RMB50,046 thousand, and its net cash flows from operating activities turned positive for the first time to RMB59,929 thousand.
- **Differentiated competitiveness was further enhanced.** In 2022, the Group built a commercial production base with international competitiveness for innovative drugs, and obtained the EU Qualified Person (QP) certification for both ADC antibodies and ADC commercial production workshops.

The board (the “**Board**”) of directors (the “**Directors**”) of TOT BIOPHARM International Company Limited (the “**Company**”) hereby announces the audited consolidated financial results of the Company and its subsidiaries (together, the “**Group**”, “**TOT BIOPHARM**”, “**we**” or “**us**”) for the year ended 31 December 2022 together with comparative figures for the year ended 31 December 2021 as set out in the section headed “Consolidated Financial Statements” of this announcement.

CEO STATEMENT

Dear Shareholders,

Greetings, everyone! On behalf of the Board, I am pleased to present the annual results and business progress of the Company for the year ended 31 December 2022.

The year of 2022 marked TOT BIOPHARM’s full implementation of its strategic transformation. Despite the ongoing pandemic outbreak, macroeconomic downturn and setbacks in the upstream and downstream development of the pharmaceutical industry, all employees of TOT BIOPHARM have overcome difficulties and made concerted efforts to continuously improve business standards, achieving gratifying results across all its businesses and reaching many important milestones. In 2022, the Group’s revenue was RMB442,178 thousand, representing a significant increase of 479% compared with RMB76,325 thousand in 2021, which was mainly contributed by three components, namely, revenue from product sales of RMB304,361 thousand, revenue from CDMO/CMO business of RMB72,538 thousand, and revenue from licenses granted of RMB54,151 thousand. Net loss reduced by 81% year-on-year to RMB50,046 thousand. Net cash flows from operating activities turned positive for the first year to RMB59,929 thousand.

In 2022, we steadfastly pushed forward with our strategic transformation and upgrade, continued to optimize our capital structure and consolidated our strengths in the ADC field. We successfully completed the commercial licensing of two products, generating substantial revenue from licenses granted.

Over the past year, amidst the difficult times in the capital market, the pharmaceutical industry continued to undergo industrial restructuring. With clear strategic objectives and differentiated competitive advantages, TOT BIOPHARM received long-term support from its substantial shareholders and successfully completed the first round of equity financing after IPO, raising net proceeds of approximately HKD470 million and driving the Company towards the next milestone. In addition, we continued to optimize our capital structure and enhance our profitability. We successfully completed the commercial licensing of Pusintin® in overseas markets and the licensing of TAB014 in the domestic market. We focused our resources on building a domestically scarce “one-base, end-to-end” industrialization platform for antibody-drug conjugates (“**ADC**”) to enhance our technical capabilities, and expanded and upgraded our production capacity to enhance the overall strength of our CDMO business.

In 2022, thanks to our remarkable commercial marketing strategies, we achieved good results for the first year of commercial sales, with annual sales revenue reaching RMB442,178 thousand, contributing stable cash flow to the Company.

Up to now, TOT BIOPHARM has launched a total of three products. In 2022, driven by the remarkable results of our differentiated marketing strategies, Bevacizumab injection – Pusintin[®], our core product, achieved outstanding sales performance in its first year of launch, providing a high-quality and affordable drug to cancer patients in China. In respect of the mainland China market, through close collaboration with the marketing team of Jiangxi Jixin Pharmaceutical Co., Ltd. (江西濟鑫醫藥有限公司), we have tapped into the unmet market space through differentiated channel coverage and opened up the market quickly. In respect of overseas markets, we have also successfully completed the registration applications for launch in a number of countries to meet the demand in overseas markets as soon as possible. We have successfully completed the contract renewal for centralized procurement in different provinces and cities across China in relation to our self-developed chemical drug Temozolomide capsule – Tazian[®], laying a good foundation for our sales in 2023. We have conducted comprehensive market promotion for Megestrol acetate oral suspension – Megaxia[®] in the fields of tumor and AIDS, so as to bring a high-quality drug to more patients in China.

In 2022, we continued to strengthen our differentiated competitiveness in CDMO business, and fully leveraged our “one-base, end-to-end” industrial advantages to provide our customers with customized and exclusive solutions.

CDMO business is the long-term development strategy of TOT BIOPHARM in the next stage, and we are focusing on biological drugs with promising market potential, especially the blue ocean market of ADC field with high technological barriers. Through more than a decade of development and accumulation, the Company possesses a full range of capabilities from drug research and development, process development, clinical trials, registration filing to commercial production, having a leading ranking among biological drug CDMO industry players in China and providing high-quality services to our customers. In 2022, despite the adverse impacts from the pandemic and the external environment, the Group actively explored the market, and our business team, with its rich project experience and targeted solutions, achieved a project delivery rate of 100% successfully and gained high recognition from our customers. In 2022, revenue from the Group’s CDMO/CMO business amounted to RMB72,538 thousand, representing a year-on-year increase of 35%. Among the 45 projects in 2022, there were 18 ADC projects and 23 antibody projects. Our scale of business development continued to expand.

In 2022, we built a commercial production base with international competitiveness for innovative drugs, and obtained the EU Qualified Person (QP) certification for both ADC antibodies and ADC commercial production workshops.

With the rapid growth of China's biological drug market, the demand for CDMO services continues to rise as a result of the boom in the research and development and technological innovation of biological drugs. Based on its early solid foundation and its development over more than a decade, TOT BIOPHARM has laid a solid foundation in the production capacity and experience of CMC (Chemistry, Manufacturing and Controls, i.e. pharmaceutical researches on drug process development, production and quality control, etc.). Meanwhile, our forward-looking construction of diverse and flexible commercial production workshops can meet the individual needs of projects and customers at different stages, enabling us to provide services that cover the entire industry chain in one production base, greatly improving the efficiency of project execution and effectively mitigating various risks in the transfer process.

To date, the Company has workshops for monoclonal antibody (“mAb”) drug substances with a production capacity of 20,000L, which are equipped with production lines for different scales of mAb drug substances production in commercialization projects, pilot tests and small trials, with a designed production capacity of over 300,000L/year. At the same time, there are four commercial production lines for macromolecular drug products, all of which are using equipment from international and domestic leading brands and able to flexibly switch between aqueous injections and freeze-dried drug products and perform continuous filling, ensuring efficient and high-quality production operation. With these, the drug products filling capacity can reach 18,000 vials/hour, the production capacity for freeze-dried products can reach 50,000 vials/batch, and the annual production capacity can reach 150 batches/year. In 2022, we further improved the commercial production capacity for ADCs with world-leading integrated production workshops for ADC drug products and antibody drug substances, which greatly improved our production efficiency and business capacity in various projects, including early research and development projects, IND projects and clinical projects. In addition, the Company's workshops for ADC commercial production and mAb drug substances passed the European Union (“EU”) Qualified Person (“QP”) audit with zero defects, and our quality management system was internationally recognized.

OUTLOOK

The year of 2023 will be a year when TOT BIOPHARM takes a step-by-step approach to showcasing a brand new image to the outside world. Our Global Research and Development Center and new commercial production lines will also be put into use. We will seize new opportunities arising from technological innovation and industrial revolution to drive the commercial sales of launched products to a new level. The year of 2023 will also mark a critical year for TOT BIOPHARM to move towards the next milestone. We will continue to implement our CDMO strategic goals thoroughly, accelerate internationalization, enhance our brand influence persistently, strengthen our platform capacity, expand our market reach, and help our partners accelerate their drug development process with our core competitive advantages to safeguard the health of humanity. Meanwhile, we will continue to practice long-termism and sustainable development, advocate a results-oriented approach, and implement a more effective incentive mechanism to stimulate the potential of our talents. With a sound financial structure and enhanced business profitability by continuously optimizing our resource allocation, we will create substantial returns for our shareholders!

Dr. Liu, Jun

Chief Executive Officer and Executive Director

23 March 2023

CONSOLIDATED FINANCIAL STATEMENTS

CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS

	Note	Year ended 31 December	
		2022 RMB'000	2021 RMB'000
Revenue	3	442,178	76,325
Cost of revenue		(71,563)	(48,851)
Research and development expenses		(151,168)	(214,699)
Selling expenses		(203,954)	(22,849)
General and administrative expenses		(62,587)	(56,336)
Net impairment losses on financial and contract assets		(597)	–
Other income		552	167
Other gains – net		8,063	6,543
Operating loss		(39,076)	(259,700)
Finance income		2,265	969
Finance costs		(6,602)	(2,468)
Finance costs – net		(4,337)	(1,499)
Share of net loss of the joint venture accounted for using the equity method		(6,633)	(17)
Loss before income tax		(50,046)	(261,216)
Income tax expense	4	–	–
Loss for the year		(50,046)	(261,216)
Loss is attributable to:			
Equity holders of the Company		(49,916)	(261,216)
Non-controlling interests		(130)	–
		(50,046)	(261,216)
Other comprehensive income/(loss):			
<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		–	326
<i>Items that may be reclassified to profit or loss</i>			
Exchange difference on translation		6,314	(1,282)
Other comprehensive income/(loss) for the year, net of tax		6,314	(956)
Total comprehensive loss for the year		(43,732)	(262,172)

	<i>Note</i>	Year ended 31 December	
		2022	2021
		<i>RMB'000</i>	<i>RMB'000</i>
Total comprehensive loss for the year is attributable to:			
Equity holders of the Company		(43,602)	(262,172)
Non-controlling interests		(130)	–
		<u>(43,732)</u>	<u>(262,172)</u>
Loss per share for the year and attributable to the equity holders of the Company			
– Basic and diluted losses per share (<i>RMB</i>)	5	<u>(0.08)</u>	<u>(0.46)</u>

CONSOLIDATED BALANCE SHEET

		As at 31 December	
		2022	2021
	Note	RMB'000	RMB'000
ASSETS			
Non-current assets			
Property, plant and equipment		465,328	307,668
Prepayments for property, plant and equipment		82,477	55,759
Right-of-use assets		15,007	15,733
Investment properties		3,184	3,583
Intangible assets		4,648	5,123
Investments accounted for using the equity method		–	1,483
Other non-current assets		14,590	14,951
		<u>585,234</u>	<u>404,300</u>
Current assets			
Inventories		94,821	29,558
Other current assets		38,254	79,862
Trade and other receivables	7	53,387	15,032
Prepayments		20,012	16,754
Contract assets		9,278	11,952
Financial assets at fair value through profit or loss		40,278	–
Restricted cash		2,998	–
Cash and cash equivalents		417,769	152,805
		<u>676,797</u>	<u>305,963</u>
Total assets		<u>1,262,031</u>	<u>710,263</u>
EQUITY			
Share capital	8	2,297,499	1,892,906
Other reserves		61,911	37,797
Accumulated losses		(1,645,528)	(1,595,612)
Non-controlling interests		1,557	–
Total equity		<u>715,439</u>	<u>335,091</u>

		As at 31 December	
		2022	2021
	<i>Note</i>	RMB'000	RMB'000
LIABILITIES			
Non-current liabilities			
Borrowings		212,133	59,775
Lease liabilities		345	1,136
Other non-current liabilities		58,767	53,453
		<u>271,245</u>	<u>114,364</u>
Current liabilities			
Borrowings		75,500	146,191
Trade and other payables	9	174,017	86,238
Contract liabilities		19,562	22,199
Lease liabilities		1,551	1,463
Other current liabilities		4,717	4,717
		<u>275,347</u>	<u>260,808</u>
Total liabilities		<u>546,592</u>	<u>375,172</u>
Total equity and liabilities		<u>1,262,031</u>	<u>710,263</u>
Net current assets		<u>401,450</u>	<u>45,155</u>
Total assets less current liabilities		<u>986,684</u>	<u>449,455</u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

1. GENERAL INFORMATION

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

The Company is an investment holding company. The Company and its subsidiaries (together, the “**Group**”) are primarily engaged in research and development (“**R&D**”), manufacturing, and marketing of anti-tumor drugs, contract development and manufacturing organization (“**CDMO**”)/contract manufacture organization (“**CMO**”) business and license-out of self-developed biological drugs in the People’s Republic of China (the “**PRC**”).

The Company’s shares have been listed on the Main Board of The Stock Exchange of Hong Kong Limited (the “**Stock Exchange**”) since 8 November 2019.

These financial statements are presented in thousands of Renminbi (“**RMB’000**”), unless otherwise stated.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

This note provides a list of the significant accounting policies adopted in the preparation of these consolidated financial statements. These policies have been consistently applied to all the years presented, unless otherwise stated. The financial statements are for the Group consisting of the Company and its subsidiaries.

2.1 Basis of preparation

2.1.1 *Compliance with HKFRS and HKCO*

The consolidated financial statements of the Group have been prepared in accordance with the Hong Kong Financial Reporting Standards (“**HKFRSs**”) and requirements of the Hong Kong Companies Ordinance Cap. 622.

2.1.2 *Historical cost convention*

The consolidated financial statements have been prepared on the historical cost basis, as modified by the revaluation of financial assets at fair value through profit or loss, which are carried at fair value.

The preparation of consolidated financial statements in conformity with HKFRSs requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the Group’s accounting policies.

2.1.3 *New and amended standards adopted by the Group*

The Group has applied the following amendments or annual improvements for the first time for their annual reporting period commencing 1 January 2022:

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

The Group did not change its accounting policies or make retrospective adjustments as a result of adopting the abovementioned amended standards or annual improvements.

2.1.4 *New standards and interpretations not yet adopted*

The following new accounting standards, amendments to accounting standards and interpretations have been published that are not mandatory for 31 December 2022 reporting periods and have not been early adopted by the Group. These standards, amendments or interpretations are not expected to have a material impact on the entity in the current or future reporting periods and on foreseeable future transactions.

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

2.2 Changes in accounting policies

2.2.1 Nature of change

In previous years, the Group presented the cash outflow of interest paid on the face of its Consolidated Statement of Cash Flows in operating activity. In 2022, the directors considered the developments of the Group's core business and concluded that to present the interest paid under financing activity would provide reliable and more relevant information. Consequently, the presentation of the Consolidated Statement of Cash Flows for the year ended 31 December 2022 has been revised and the comparative figures have been reclassified in order to conform to the current year's presentation.

2.2.2 Impact on the financial statements

As a result of the changes in the entity's accounting policies, prior year financial statements had to be restated. The following tables show the adjustments recognised:

Consolidated Statement of Cash Flows (extract)	Year ended 31 December 2021		
	As originally presented <i>RMB'000</i>	Impact <i>RMB'000</i>	Restated <i>RMB'000</i>
Cash flows from operating activities			
Net cash used in operations	(176,106)	–	(176,106)
Interest received	969	–	969
Interest paid	(2,000)	2,000	–
Net cash used in operating activities	(177,137)	2,000	(175,137)
Cash flows from financing activities			
Proceeds from issue of shares upon exercise of share options	1,990	–	1,990
Proceeds from receipt of the grant consideration for award shares	7,620	–	7,620
Proceeds from bank borrowings	205,966	–	205,966
Interest paid	–	(2,000)	(2,000)
Payment of lease liabilities	(1,494)	–	(1,494)
Net cash generated from financing activities	214,082	(2,000)	212,082

3. 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:

	Year ended 31 December	
	2022 RMB'000	2021 RMB'000
Timing of revenue recognition		
At a point in time:		
– Sales of goods	304,361	6,129
– Revenue from license granted	54,151	5,943
– CDMO/CMO	20,630	9,003
– Commission revenue	9,098	8,673
– Others	708	96
Over time:		
– CDMO	51,908	44,687
– Others	1,322	1,794
	<u>442,178</u>	<u>76,325</u>

(c) Geographical information

Geographical information of revenue and non-current assets other than financial assets for the years ended 31 December 2022 and 2021 is as follows:

	Year ended 31 December			
	2022		2021	
	Revenue RMB'000	Non-current assets RMB'000	Revenue RMB'000	Non-current assets RMB'000
Mainland China	442,178	570,366	76,325	389,062
Others	–	328	–	458
	<u>442,178</u>	<u>570,694</u>	<u>76,325</u>	<u>389,520</u>

4. INCOME TAX EXPENSE

The Group's principal applicable taxes and tax rates are as follows:

(a) **Hong Kong**

No provision for Hong Kong profits tax has been provided for at the rate of 16.5% (2021: 16.5%) as the Company has no estimated assessable profit.

(b) **Mainland China**

No provision for mainland China income tax has been provided for at the rate of 25% or 15% (2021: 25% or 15%) pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the "CIT Law"), as the Group's PRC entities have no estimated assessable profit.

TOT BIOPHARM Co., Ltd. ("TOT Suzhou") was qualified as a "High and New Technology Enterprise" under the relevant PRC laws and regulations from 2020 to 2022. Accordingly, TOT Suzhou was entitled to a preferential income tax rate of 15% commencing from 2020 to 2022.

(c) **Taiwan corporate income tax**

No provision for Taiwan corporate income tax has been provided for at the rate of 20% (2021: 20%) as the Group's Taiwan subsidiary 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 year excluding treasury shares.

	Year ended 31 December	
	2022	2021
Loss attributable to equity holders of the Company (<i>RMB'000</i>)	(49,916)	(261,216)
Weighted average number of ordinary shares in issue (<i>thousand</i>)	<u>639,307</u>	<u>573,360</u>
Basic loss per share (<i>RMB</i>)	<u>(0.08)</u>	<u>(0.46)</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 year ended 31 December 2022, the Company had one category of potential ordinary shares: the stock options granted to employees (2021: same). As the Group incurred losses for the years ended 31 December 2022 and 2021, the potential ordinary shares have not been included in the calculation of diluted loss per share as their inclusion would be anti-dilutive. Accordingly, diluted loss per share for the years ended 31 December 2022 and 2021 is the same as basic loss per share of the respective years.

6. DIVIDEND

No dividend has been paid or declared by the Company or the companies now comprising the Group during the year (2021: Nil).

7. TRADE AND OTHER RECEIVABLES

	As at 31 December	
	2022	2021
	RMB'000	RMB'000
Trade receivables	49,721	11,735
Other receivables	4,263	3,297
Less: provision for impairment of trade receivables	(597)	–
	<u>53,387</u>	<u>15,032</u>

(a) Trade receivables

	As at 31 December	
	2022	2021
	RMB'000	RMB'000
Trade receivables	<u>49,721</u>	<u>11,735</u>

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

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

	As at 31 December	
	2022	2021
	RMB'000	RMB'000
Within 30 days	28,716	1,336
31 days to 90 days	17,490	10,399
91 days to 180 days	2,210	–
181 days to 270 days	1,298	–
271 days to 360 days	7	–
	<u>49,721</u>	<u>11,735</u>

As at 31 December 2022, the carrying amounts of the Group's trade receivables are denominated in RMB and approximate to their fair values (2021: same).

8. SHARE CAPITAL

Issued:

	Number of ordinary shares	Share capital RMB'000
As at 1 January 2021	600,466,697	1,874,438
Issue of shares upon exercise of share options (<i>Note (a)</i>)	1,062,800	3,249
Increase in share capital upon receipt of the grant consideration under 2020 Restricted Shares Award Scheme (<i>Note(b)</i>)	–	15,219
Issue of shares for 2021 Restricted Shares Award Scheme (<i>Note(c)</i>)	13,700,000	–
	<u>615,229,497</u>	<u>1,892,906</u>
As at 31 December 2021		
As at 1 January 2022	615,229,497	1,892,906
Issue of shares to shareholders (<i>Note (d)</i>)	150,000,000	404,593
Issue of shares for 2022 Restricted Shares Award Scheme (<i>Note(e)</i>)	7,558,390	–
	<u>772,787,887</u>	<u>2,297,499</u>
As at 31 December 2022		

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

Note (b) During March to May 2021, award shares representing a total of 4,134,139 ordinary shares were vested to certain participants of the Company's 2020 Restricted Shares Award Scheme at a grant consideration of approximately USD0.29 per ordinary share. Upon the aforesaid vesting of award shares, share-based compensation reserve of RMB7,599,000 was transferred to share capital.

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

Note (d) 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 (e) 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 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 (2021: 40,032,558).

9. TRADE AND OTHER PAYABLES

	As at 31 December	
	2022	2021
	RMB'000	RMB'000
Accrued promotion expenses	77,780	–
Trade payables	25,983	28,214
Staff salaries and welfare payables	21,944	19,898
Deposits payables (<i>Note (i)</i>)	15,502	10,200
Payables for purchase of property, plant and equipment	12,072	6,457
Refund liabilities (<i>Note (ii)</i>)	5,987	5,699
Tax payable	2,537	–
Others	12,212	15,770
	<u>174,017</u>	<u>86,238</u>

Note (i) In December 2020, the Group entered into an exclusive sales promotion agreement with a third party. For the year ended 31 December 2022, the Group received deposits of RMB10,000,000. The return terms of the deposit are linked to the sales condition. The management re-estimated the future sales and evaluated that the deposits will not be returned in one year, so it is reclassified to non-current liabilities this year (2021: RMB10,000,000).

In December 2021, the Group entered into an exclusive sales promotion agreement with a third party. As at 31 December 2022, the Group has received deposits of RMB200,000 (2021: RMB200,000).

In December 2022, the Group entered into an exclusive sales promotion agreement with a third party. For the year ended 31 December 2022, the Group received deposits of RMB15,302,000 (2021: Nil).

Note (ii) Where a customer has a right to return a product, the Group recognises a refund liability for the amount of consideration received for which the entity does not expect to be entitled. The Group also recognises a right to the returned goods measured by reference to the former carrying amount of the goods.

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

	As at 31 December	
	2022	2021
	RMB'000	RMB'000
Within 3 months	24,982	27,037
3 months to 6 months	724	507
6 months to 12 months	133	160
1 year to 2 years	76	510
2 years to 3 years	68	–
	<u>25,983</u>	<u>28,214</u>

10. SUBSEQUENT EVENTS

On 5 January 2023, Vivo Capital Fund VIII, L.P. (“**Vivo Capital Fund VIII**”), the Company and its subsidiary Yaozhan Pharmaceutical Jiangsu Co., Ltd. (“**Yaozhan**”) entered into the Equity Transfer Agreement, pursuant to which the parties agreed to carry out the Equity Transfers, specifically that (i) Vivo Capital Fund VIII agreed to transfer the entirety of its fully paid-up registered capital in Yaozhan amounting to USD500,000 to the Company, which had been completed at 13 January 2023; and (ii) Yaozhan agreed to transfer part of its partially paid-up registered capital in Huayao amounting to RMB6,000,000 (of which RMB3,000,000 has been paid up) to Vivo Capital Fund VIII. Upon the completion of the Equity Transfers, Vivo Capital Fund VIII will no longer be a minority shareholder of Yaozhan and will instead become a minority shareholder of Huayao.

MANAGEMENT DISCUSSION AND ANALYSIS OF CERTAIN FINANCIAL ITEMS

OVERVIEW

In 2022, the revenue generation capability and profitability of the Group have been significantly improved. During the year, the Group recorded an operating revenue of RMB442,178 thousand, representing a year-on-year increase of 479% from RMB76,325 thousand in 2021, which was mainly attributable to the substantial increase in the sales volume of self-developed products, the continuous development of CDMO business and the increase in milestone payment income from licenses granted in connection with the Group's projects. The net loss narrowed significantly by 81% year-on-year to RMB50,046 thousand from RMB261,216 thousand in 2021.

In 2022, the Group's research and development expenses were RMB151,168 thousand, as compared to RMB214,699 thousand in 2021. In 2022, the selling expenses were RMB203,954 thousand, as compared to RMB22,849 thousand in 2021. In 2022, the general and administrative expenses were RMB62,587 thousand, as compared to RMB56,336 thousand in 2021.

OPERATING REVENUE AND COSTS

The Group's diversified revenue is mainly derived from sales revenue, revenue for providing CDMO/CMO services, revenue from licenses granted, etc.

The Group's sales revenue in 2022 was RMB304,361 thousand, which was mainly attributable to the steady increase in the sales volume of our core product, Pusintin[®], while the corresponding costs also increased accordingly.

The Group's revenue from CDMO/CMO business in 2022 was RMB72,538 thousand, representing an increase of RMB18,848 thousand from RMB53,690 thousand in 2021, 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.

The Group's revenue from licenses granted in 2022 was RMB54,151 thousand, representing an increase of RMB48,208 thousand from RMB5,943 thousand in 2021, primarily attributable to the increase in milestone payments received from 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 in 2022 were RMB151,168 thousand, representing a decrease of RMB63,531 thousand from RMB214,699 thousand in 2021, which was mainly attributable to the reduction of clinical expenses and raw material procurement as a result of the completion of patient enrolment for the TAA013 project of the Company, 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 in 2022 were RMB203,954 thousand, representing an increase of RMB181,105 thousand from RMB22,849 thousand in 2021, 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, legal advisory fees, and expenses for professional services related to audit and tax, etc.

The Group's general and administrative expenses in 2022 were RMB62,587 thousand, representing an increase of RMB6,251 thousand from RMB56,336 thousand in 2021, primarily attributable to the increase in costs incurred for structural reform and increased personnel, etc.

OTHER GAINS, NET – GOVERNMENT GRANTS

The Group's government grants consist of incentives for research and development activities, interest subsidies and other subsidies.

The Group's government grants in 2022 were RMB8,260 thousand, representing a decrease from RMB10,956 thousand in 2021, primarily attributable to the approval of grants to certain projects receiving clinical trial approvals in 2021.

OTHER GAINS, NET – NET FOREIGN EXCHANGE GAINS

The Group recorded net foreign exchange gains of RMB1,302 thousand in 2022, representing an increase of RMB58 thousand from net foreign exchange gains of RMB1,244 thousand in 2021, primarily attributable to fluctuations of exchange rates.

FINANCE INCOME

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

The finance income in 2022 was RMB2,265 thousand, representing an increase of RMB1,296 thousand from RMB969 thousand in 2021, mainly attributable to the availability of funds from the equity financing conducted by the Company in 2022 (the “**2022 Equity Financing**”) and the optimization of fund allocation.

FINANCE COSTS

The Group's finance costs are primarily interest expenses on bank borrowings.

The Group's finance costs in 2022 were RMB6,602 thousand, representing an increase of RMB4,134 thousand from RMB2,468 thousand in 2021, primarily attributable to the increase in interest expenses as a result of the banking facilities being utilized by the Group since mid-2021 and the moderately increased credit limits in 2022.

INCOME TAX EXPENSE

The Group did not incur any income tax expense in 2022 and 2021 as the Group did not generate any taxable income during these two years.

LOSS FOR THE YEAR

In view of the abovementioned factors, the Group recorded a net loss of RMB50,046 thousand in 2022, representing a decrease of RMB211,170 thousand from RMB261,216 thousand in 2021.

NET ASSETS

The Group's net assets as at 31 December 2022 were RMB715,439 thousand, representing an increase of RMB380,348 thousand from RMB335,091 thousand as at 31 December 2021, primarily attributable to the availability of funds from the 2022 Equity Financing.

CASH MOVEMENT AND SOURCE OF FUNDS

As at 31 December 2022, the Group's cash and cash equivalents were RMB417,769 thousand, representing an increase of RMB264,964 thousand from RMB152,805 thousand as at 31 December 2021. Such change was mainly attributable to the availability of funds from the 2022 Equity Financing, and the cash outflows and inflows related to operating loss, capital expenditures, and bank borrowings taken out and repaid, etc.

In 2022, the Group's net cash inflows for operating activities were RMB59,929 thousand, as compared to net cash outflows of RMB175,137 thousand in 2021, which was 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 were RMB282,764 thousand, representing an increase of RMB174,371 thousand from RMB108,393 thousand in 2021, 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 RMB481,240 thousand, representing an increase of RMB269,158 thousand from RMB212,082 thousand in 2021, which was mainly attributable to the availability of funds from the 2022 Equity Financing, and the optimization of capital structure by moderately increasing medium- and long-term bank loans in response to the funding requirements for project construction.

MAJOR INVESTMENT

On 9 November 2021, the Group commenced the construction of its Global Research and Development Center. The proposed total investment for the project is approximately RMB180 million. On 31 December 2021, TOT BIOPHARM Co., Ltd. (a wholly-owned subsidiary of the Company) entered into a construction agreement with Shanghai Baoye Group Corp., Ltd. (上海寶冶集團有限公司), under which the total contract sum payable to Shanghai Baoye Group Corp., Ltd. is RMB83,500 thousand. Further details are set out in the announcement of the Company dated 31 December 2021. Up to 31 December 2022, the Group incurred expenditure of RMB44,704 thousand in connection with the construction agreement entered into with Shanghai Baoye Group Corp., Ltd., and expenditure of RMB49,778 thousand in total in connection with the construction of the Global Research and Development Center.

In 2021, the Group commenced the project of upgrading its ADC commercial production workshops and the project of renovating and upgrading its pilot production workshops for the purpose of increasing its production capacity as well as enhancing its production efficiency. A total of RMB189,342 thousand was incurred by the Group during the year ended 31 December 2022 in connection with such projects.

Save as disclosed above, the Group did not make any major investment during the year ended 31 December 2022.

MAJOR ACQUISITIONS AND DISPOSALS

During the year ended 31 December 2022, the Group did not have any major acquisitions and disposals of subsidiaries, consolidated affiliated entities or associates.

PLEDGE OF ASSETS

As at 31 December 2022, the Group had no pledge of assets.

CONTINGENT LIABILITIES

As at 31 December 2022, the Group had no significant contingent liabilities.

MANAGEMENT DISCUSSION AND ANALYSIS OF CERTAIN ASPECTS OF OUR BUSINESS

I. INDUSTRY AND COMPANY PROFILE

As a strategic industry related to national welfare, economic development and national security, the biomedical industry is leading technological innovation and has entered an unprecedented period of rapid development. With the accelerated development of biotechnology and continued heavy investment in research and development, the market size of the industry has steadily expanded with better clinical efficacy. According to the latest data from Frost & Sullivan in 2022, the market size of China's biomedical industry will rise from RMB410.0 billion to RMB710.2 billion from 2021 to 2025, representing a CAGR of 14.7%. Among them, antibody drugs are entering a period of vigorous development, resulting in the rapid expansion of the market size. From 2017 to 2021, the market size increased rapidly from RMB11.8 billion to RMB58.5 billion, representing a CAGR of 49.2%.

In 2022, TOT BIOPHARM firmly seized market opportunities and rapidly promoted the commercial sales of its launched products through differentiated marketing strategies. The sales volume of our core product, Pusintin[®] (Bevacizumab injection), showed a continuous growth momentum. In respect of overseas markets, we have reached a cooperation agreement with Kexing Biopharm Co., Ltd. (科興生物製藥股份有限公司) (688136.SH) for the commercial licensing of Pusintin[®] in overseas markets, so as to accelerate the launch of the product in the vast markets of emerging countries and contribute to our efforts to provide high-quality and affordable drugs to patients around the world.

In 2022, we continued to deepen our strategic transformation. Relying on our comprehensive capabilities in technology, quality and production in the biomedical field, we conducted in-depth cooperation with industry partners and provided them with “one-stop CDMO solutions” through customized and exclusive services. Since our strategic transformation, we have focused on resources and continued to strengthen our differentiated technology platform for ADC drugs to solidify our market position in the field of ADCs and create a “one-base, end-to-end” industrialization platform for ADC drugs with strong market competitiveness, thereby enabling the rapid development of the biomedical industry.

On 29 July 2022, 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**”), major shareholders of TOT BIOPHARM, subscribed for shares at a premium. Proceeds raised amount to HKD470 million, which provide funding support for the rapid development of the Company in the next stage.

In 2022, TOT BIOPHARM continued to enhance its international quality management standard, and continuously improved its business capabilities through internal self-inspection and evaluation as well as QP audits on CDMO projects. In October 2022, TOT BIOPHARM passed the EU QP audit in one go with zero defects, making it one of the few commercialization bases in China that have obtained the EU QP certification for both antibodies and ADC drugs. It is also another milestone achieved by TOT BIOPHARM in quality management system after passing the GMP on-site verification of China, laying a strong foundation for TOT BIOPHARM to provide customers with one-stop biological drug CDMO services that meet the drug regulatory requirements of the European Medicines Agency (“EMA”), the National Medical Products Administration of China (“NMPA”) and the United States Food and Drug Administration (“FDA”).

II. BUSINESS HIGHLIGHTS AND PROGRESS

1. Marketing Strategy of Launched Products

– *TAB008: Pusintin® (Bevacizumab injection)*

On 30 November 2021, our core product Pusintin® received marketing approval from the NMPA and became TOT BIOPHARM’s first biological drug approved for marketing. 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. As of March 2022, Pusintin® has been approved for the treatment of all six indications that can be treated with approved originator drug in mainland China, including advanced, metastatic or recurrent non-squamous non-small cell lung cancer (nsNSCLC), metastatic colorectal cancer (mCRC), recurrent glioblastoma multiforme, epithelial ovarian cancer, fallopian tube cancer or primary peritoneal cancer, cervical cancer and hepatocellular carcinoma. The approval of new indications has further expanded the market potential and enhanced the accessibility of Pusintin®. At present, bevacizumab injection has been included in the National Reimbursement Drug List, providing an affordable option with efficacy equivalent to the originator drugs for more cancer patients.

According to the statistics of Frost & Sullivan, the global market size of bevacizumab reached USD6.9 billion in 2021, and the market size in China was RMB9.0 billion. Accordingly, bevacizumab is expected to become another product with a market size of over RMB10.0 billion in China in 2022. With the continuous rise in cancer incidence rates, the demand for medication from patients will continue to increase.

In 2022, despite the pressures from the recurring COVID-19 pandemic and market uncertainty, the sales of Pusintin[®] continued to increase steadily, and our annual sales target was successfully achieved by completing the production plan as scheduled and ensuring a stable market supply. In terms of marketing strategy, through close cooperation with Jiangxi Jixin Pharmaceutical Co., Ltd. (江西濟鑫醫藥有限公司) (“**Jixin Pharmaceutical**”), our business team has developed market channels covering 31 provinces, autonomous regions and municipalities (excluding Hong Kong, Macau and Taiwan) across the country, with a focus on the second and third-tier cities with huge market space and provinces that adopt dual-channel pharmacy, and continued to penetrate into third and fourth-tier cities and county-level cities. Through our own commercial production base with the scale of 20,000L, we can meet the demand for continuous and stable market supply with a product qualification rate of 100%. At the same time, we worked with Jixin Pharmaceutical to carry out a variety of patient support activities and provide professional consultations to benefit the vast cancer patients, thus increasing brand influence. In respect of overseas markets, to date, we have initiated the registration filing in 14 countries to launch Pusintin[®] in overseas markets as soon as possible, and the registration documents for launch in 8 of these countries have been accepted.

– ***TOZ309: Tazian[®] (Temozolomide capsule)***

Tazian[®] was approved for launch by the NMPA on 31 May 2021 for the treatment of newly diagnosed glioblastoma multiforme. It 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 respect of the market, TOT BIOPHARM actively promoted the provincial centralized procurement activities in 2022. In the first half of the year, the Company was selected as the preferred supplier in the renewal of centralized procurement by the Thirteen Allied Provinces, Jiangsu Province and Hebei Province. In the second half of the year, the Company was also elected as the preferred supplier in Beijing, Guangdong Province, Jiangxi Province, Shandong Province and Shaanxi Province, which made us well prepared for market sales in 2023. In addition, the Company has entered into marketing cooperation with Jixin Pharmaceutical in China to develop the market channels of non-centralized procurement and expand market share through flexible and diverse market strategies.

– ***TOM218: 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 is a nano-grade oral suspension that has been launched in the United States 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 Frontier Biotechnologies was granted the marketing promotion license of Megaxia[®] in the field of AIDS. This cooperation represents a powerful combination of both parties’ strengths in products and channels, which will enhance the accessibility of the drug and actively contribute to the treatment of AIDS cachexia.

2. Updates on Key Product Pipelines

In 2022, TOT BIOPHARM actively carried out strategic transformation and upgrade, and continued to optimize its non-key early-stage product pipelines. We obtained considerable commercial returns through project licensing, and promoted project progress through cooperative development and other strategies. We rationally controlled our research and development costs and converged our resources, and effectively improved our operating cash flow.

Main product pipelines:

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						

Drug Name	Indication(s)	Product Specification	Launched
TAB008: Puzintin® (Bevacizumab Injection)	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)	100mg(4mL)/bottle	Approved for launch by NMPA on 30 November 2021
TOZ309: Tazian® (Temozolomide Capsule)	Treatment of newly diagnosed glioblastoma multiforme, which is initially combined with radiotherapy, and then as maintenance therapy for glioblastoma multiforme or anaplastic astrocytoma that recurs or progresses after conventional treatment	20mg x 5 capsules/bottle; 100mg x 5 capsules/bottle	Approved for launch by NMPA on 31 May 2021
TOM218: Megaxia® (Megestrol Acetate Oral Suspension)	Treatment of anorexia associated with acquired immunodeficiency syndrome (AIDS) as well as significant weight loss of AIDS and cancer patients caused by cachexia	125mg/mL (150mL/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.

In the first half of 2022, we completed the patient enrolment for the Phase III clinical trial of our ADC drug TAA013. In March 2023, based on a comprehensive and prudent analysis and evaluation of the future commercial value and market sales of TAA013, and taking into account the Company’s strategic planning, we decided to terminate the Phase III clinical trial study and development of TAA013 in China. Further details are set out in the announcement of the Company dated 17 March 2023.

On 10 March 2022, we 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 commercial licensing 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 enrolment of the first subject for the Phase III clinical trial of TAB014 was completed successfully. We will continue to be responsible for the supply of products during the clinical trial and the commercialized production in the future when it launches.

In respect of research and development of new drugs, we are actively leveraging 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.

III. A PROVEN QUALITY MANAGEMENT SYSTEM THAT MEETS INTERNATIONAL STANDARDS

TOT BIOPHARM has established a quality management system for commercial production that meets international standards. In accordance with the regulatory requirements of NMPA, FDA and EMA, the system includes dual quality control both pre-production and during production, covering the whole process from research and development to commercialization. The Company's production workshops for mAb drugs and oral drug products of chemical drugs have passed GMP compliance inspection, and the commercial production bases for antibodies and ADCs have passed the EU QP audit. The Company has a GMP laboratory with independent quality control of more than 1,500m². In accordance with the lifecycle management requirements of ICH Q8, Q9, Q10 drug quality system, we have specified management responsibilities in the laboratory to ensure data integrity, traceable records and successful project experience. In 2022, the Company cooperated with CDMO customers in project verification and third-party quality system evaluation for a total of 9 times, including quality system evaluation by former FDA officials.

– Passing the EU QP Audit in One Go with Zero Defects

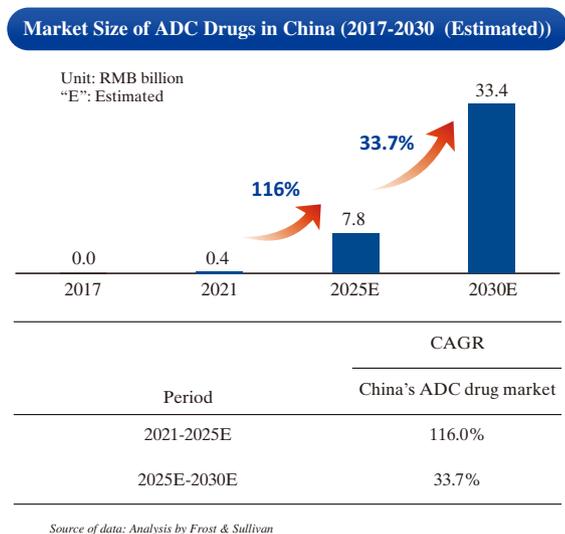
In October 2022, TOT BIOPHARM received a compliance inspection report certified and issued by a QP from the EU, pursuant to which the commercial production base for antibodies and ADCs located at TOT BIOPHARM's headquarters in Suzhou Industrial Park passed the QP audit with zero defects, demonstrating that the commercial production base and quality management system of the Company meet EU GMP standards. This made it one of the few commercialization bases in China that have obtained the EU QP certification for both antibodies and ADC drugs.

TOT BIOPHARM will strengthen its capabilities in technology research and development and commercial production, and continue to enhance its advantages in quality management system. It aims to provide domestic and foreign customers with one-stop CDMO services for drug research and development and production with higher efficiency and better quality, empowering its business partners and promoting the high-quality development of the industry.

IV. INTERNATIONALLY COMPETITIVE ADC INDUSTRY CHAIN PLATFORM

1. Rapid growth of the ADC drug market

In recent years, with the explosive growth of research and development of ADC drugs, it is expected that more and more ADC products will be commercialized in the future. According to the statistics and estimates of Frost & Sullivan, the market size of ADC drugs in China has entered a phase of rapid growth, with CAGR of 116.0% and 33.7% from 2021 to 2025 and 2025 to 2030, respectively. The market size of ADC drugs in China is expected to reach RMB7.8 billion in 2025.



2. Industry-leading “one-base, end-to-end” ADC industrialization platform

Based on a scarce and proven integrated R&D and industrialization platform for antibodies and ADCs, and relying on its advantages in advanced core conjugation technology and ADC analysis technology as well as its high-standard quality management system and GMP-compliant commercialization capabilities, the Company has become the best strategic partner in the field of ADC drug development.



– ***Production within One Production Base by Centralizing Resources***

TOT BIOPHARM is actively constructing its ADC commercial production capacity and has a complete integrated GMP-compliant ADC commercial production workshop that can produce ADC naked antibodies, ADC drug substances and ADC drug products, enabling the completion of key processes in one production base. With better control over time, cost and risks, the workshop has become a highly competitive industrialized resource. The construction of the Company’s second ADC commercial production workshop, which has the largest scale of production capacity in China, was successfully completed in 2022.

– ***High-quality Development with Comprehensive Capabilities***

TOT BIOPHARM enjoys technological advantages in core conjugation process and amplification with its self-developed products, especially in the development of conjugation processes for both cytotoxic and non-cytotoxic drugs, and in the amplification process from milligram- to kilogram-level. It has also established a complete ADC analysis technology platform, which possesses the ability to autonomously analyse key quality attributes of ADCs and also a comprehensive quality control capability that meets the regulatory requirements of NMPA, FDA and EMA. On this basis, we have established a comprehensive quality management system for the development of mAb processes and the conjugation processes of ADC drugs. Relying on the comprehensive capabilities of CMC platform, we can carry out customized CDMO technical services.

– ***Experienced Team Covering the Whole Process***

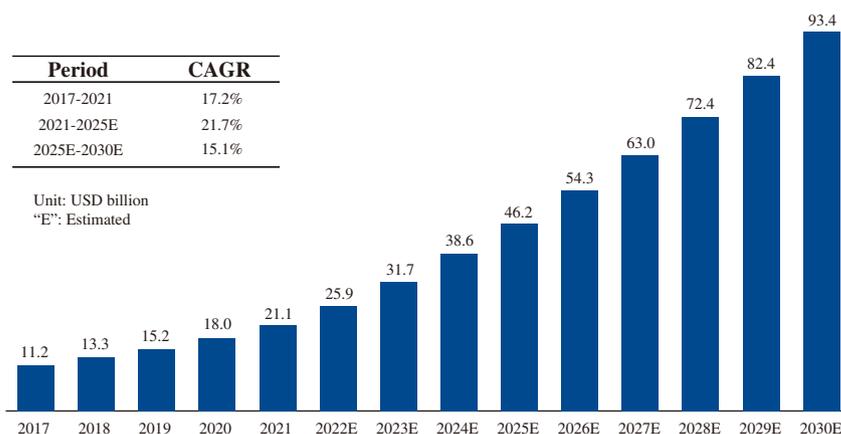
The core team of TOT BIOPHARM is mature and stable, with extensive industry experience in process development, quality, regulatory filing and commercial production, especially in the field of ADCs. With experts in research and development of ADC conjugation process technology and an ADC complex molecular structure analysis team, we have established an industry-leading “one-base, end-to-end” ADC industrialization platform with comprehensive capabilities from early development, process development to large-scale commercial production. More than 20 clinical production projects with drug process development involving different ADC technologies and at different stages (including pre-market process validation) have been completed.

V. DEVELOPMENT AND COMPETITIVE ADVANTAGES OF CDMO BUSINESS

1. Development of CDMO Business

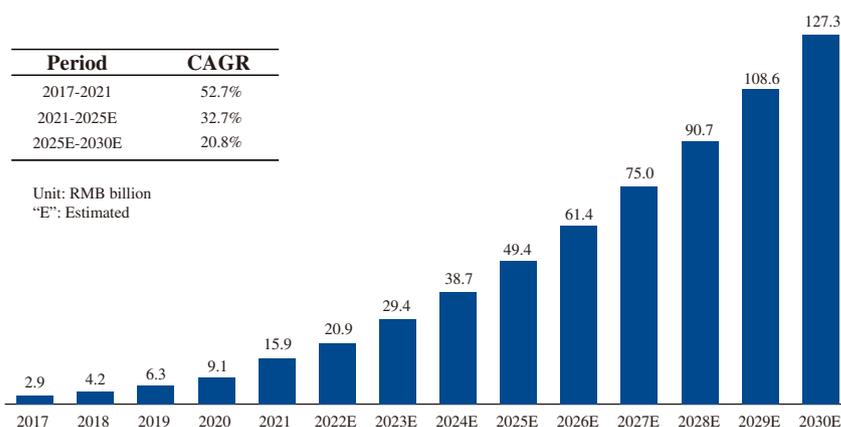
In recent years, biological drug CDMO has gradually become an important field in the development of the pharmaceutical industry. Market demand gradually expanded and government policy support continued to increase. According to data from Frost & Sullivan, the global market size of biological drug CDMO is expected to reach USD35.3 billion in 2025 and USD67.9 billion in 2030, and the market size of biological drug CDMO in China is expected to reach RMB37.3 billion in 2025 and RMB85.3 billion in 2030.

Global Market Size of Biological Drug CDMO (2017-2030 (Estimated))



Source of data: Report by Frost & Sullivan

Market Size of Biological Drug CDMO in China (2017-2030 (Estimated))



Source of data: Report by Frost & Sullivan

In 2022, TOT BIOPHARM has advanced with perseverance under the severe market environment, aiming to become the world's leading best biopharmaceutical partner trusted by customers. Leveraging its extensive practical experience and mature technology platform and quality system, the Company provides one-stop CDMO solutions for drug development and production, which accelerate the development and production of biological drugs, especially ADC drugs. In 2022, the revenue from the Company's CDMO/CMO business amounted to RMB72,538 thousand, representing a year-on-year increase of 35%; of which revenue amounting to RMB49,881 thousand was attributed to the second half of 2022, accounting for 69% of the annual revenue of CDMO/CMO business and demonstrating a higher growth rate as compared to that of the first half of 2022. A total of 45 CDMO projects were carried out throughout the year, including 18 ADC drug projects, 23 antibody drug projects, 2 chemical drug projects and 2 research and testing projects, covering the early research and development projects, IND projects, Phase I clinical projects and Phase III clinical projects. 25 projects were completed and delivered, winning high recognition from customers.

2. Strategic Cooperation of CDMO Business

TOT BIOPHARM carries out diversified strategic cooperation with domestic and foreign pharmaceutical companies, thereby continuously strengthening its differentiated competitiveness in the CDMO business. With a focus on project cooperation in biological drugs, especially ADC drugs, TOT BIOPHARM accelerated its product R&D cycle. With the continuous expansion of the biological drugs CDMO market, market competition has intensified and demonstrated the trends of diversification and differentiation in segmented fields. TOT BIOPHARM provides customized and flexible strategic solutions based on customer demands to establish a long-term win-win cooperation model with customers.

Based on our long-term cooperation projects, we have consolidated and expanded our cooperation with existing customers and actively explored new customer groups, covering both biotech companies specialized in innovative drugs and established pharmaceutical companies. Notwithstanding the unusual period of pandemic outbreak, the Company ensured the timely delivery of all CDMO/CMO projects through the rapid launch of plans to stock up epidemic prevention supplies and ensure a stable supply of raw materials, as well as the implementation of flexible production deployment solutions, winning trust and recognition from customers.

In the next phase, in addition to domestic market presence, the Company will actively pursue cooperation in overseas markets, fully demonstrate and take advantage of the technology platform and production capacity of TOT BIOPHARM, and constantly expand its market share to improve its brand influence.

– *Enabling the cooperation of innovative ADC projects*

TOT BIOPHARM has extensive experience in ADC CDMO development and can undertake projects requiring one-stop services in the development of conjugation processes, analysis and production of different ADC drugs to support clinical filings in China, the United States and Europe. In July 2021, the Company received an innovative ADC project request which posed particular challenges in terms of process development and production, and also a tight timeline for IND filing. TOT BIOPHARM project team provided targeted solutions to the many difficulties faced. In the end, the innovative ADC project only took 10 months in total from kick-off to completion of pilot level GMP production as well as submission of IND filing to FDA, and was an example of early project delivery with high quality. The high-efficiency execution, solid CMC development technology and stable scale-up process ability of TOT BIOPHARM were fully demonstrated in the project, winning a high level of trust and recognition from customers.

3. Competitive Advantages of CDMO

(1) Competitive ADC industrialization platform

TOT BIOPHARM has established a “one-base, end-to-end” ADC industrialization platform by taking advantage of its core R&D technology, which enables the integrated commercial production of drug substances and drug products for antibodies and ADC drugs within one production base at its headquarters in Suzhou Industrial Park, thereby substantially reducing production costs and mitigating the risks brought about by segmented production.

(2) Quality management system

TOT BIOPHARM has established key quality management systems throughout the entire process from R&D to commercialization by continually improving and strengthening the quality management system for commercial production. Meanwhile, TOT BIOPHARM has passed the EU QP audit in one go with zero defects, and its commercial production base and quality control system are compliant with the EU GMP standards, thus receiving international certification.

(3) Flexible and diverse production capacity

TOT BIOPHARM’s large-scale biological drug production base is located at its headquarters in Suzhou Industrial Park, which has an integrated commercial production capacity for antibodies and ADC drugs, thus fulfilling the need of different production scales for small trials, pilot tests and commercialization. The base is equipped with several complete upstream and downstream production lines, uses equipment of high industry standards, and has an antibody production capacity of over 20,000L.

(4) *Mature and stable core team*

TOT BIOPHARM has a mature and stable core CDMO team with extensive industry experience in fields including biopharmaceutical process development, commercial production, quality, and regulatory filing. The senior management team of the Company has extensive management experience in well-known multinational pharmaceutical companies. At the same time, the Company continues to recruit high-caliber talents. At present, among all 431 employees of the Group, the CDMO business segment accounts for 77% of them, among whom 11 employees have a doctor's degree and 75 employees have a master's degree.

(5) *Corporate reputation*

TOT BIOPHARM has been highly trusted and recognized in the industry thanks to its solid CDMO service quality and sound service reputation. The Company has established a quality management system suitable for commercial production throughout the whole process from R&D to commercialization stage. The Company also strictly implements customer IP protection, enhances customer stickiness and establishes long-term cooperative relationship, thereby laying a good foundation for future commercial projects.

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

1. Commercial Production Bases

At present, TOT BIOPHARM has supported commercial production of products and successfully completed commercial-scale production for multiple projects spanning different stages from Phase I to Phase III clinical stages. Its mature technical team, advanced processes, comprehensive production facilities and well-established assurance system ensure the high quality of products. TOT BIOPHARM continues to expand its commercial production capacity and owns an GMP-compliant pilot test and commercial production workshops for ADC drug substances. Equipped with OEB-5 isolators and combined with 100L, 200L and 500L reaction kettles, the designed annual production capacity of ADC drug substances reaches 60,000g, and the maximum conjugation scale can reach 5kg/batch. The two production lines for ADC drug products with production capability for injections and freeze-dried sterile drug products have been constructed. The Company uses internationally imported filling lines (300 vials/min) with automatic feeding and discharging system and multiple 5m² and 20m² freeze-dryers, which can rapidly switch between and continuously produce freeze-dried sterile injections and liquid injections. The production capacity of freeze-dried drug products is about 40,000-50,000 vials/batch, which matches the production needs of key clinical to commercialization stages. The construction of TOT BIOPHARM's second and China's largest ADC commercial production workshop has been successfully completed, and it is expected to be put into operation in the second quarter of 2023.

– ***Production of drug substances***

We are equipped with 5 independent antibody drug substances production lines, which can provide drug substances production in different scales of 200L, 500L and 2,000L, and with a total production capacity exceeding 20,000L. Through one-off production technology and highly flexible production strategy, we have completed the production of dozens of drug substances, including the production of multiple batches of launched products, and achieved annual production capacity of more than 150 batches, approximately a scale of 300,000L.

– ***Production of drug products***

We have 4 automatic filling production lines (3 isolator filling lines, 1 o-RABS filling line and several freeze-dryers with automatic feeding and discharging system function), which have the ability to produce freeze-dried injection drug products and small-volume liquid injection. Equipped with international leading brand of production equipment, advanced disposable liquid dispensing filling system, and isolator linkage line with advanced sterile robot arm, the production capacity of drug products filling and freeze-dried products exceed 18,000 vials/hour and 50,000 vials/batch, and the production lines of injections and freeze-drying exceed 250 batches and 150 batches/year, respectively.

The Company’s production workshop layout by category:

Drug substances production (designed annual production capacity >150 batches; designed annual production capacity >300,000L)	
mAb drug substances production (mAb DS)	
Workshops for mAb drug substances	<ul style="list-style-type: none"> • Production capacity reached 20,000L for different scales of mAb drug substances production, such as commercialization projects, pilot tests and small trials • International leading brand of disposable bioreactors with flexible and continuous production capability for different projects • Gained GMP certification from NMPA

ADC drug substances production (ADC DS)	
Workshops for ADC commercialization drug substances	<ul style="list-style-type: none"> • Up to 500L ADC drug substances production scale • Completed clinical production and process validation production of multiple batches of ADC drugs, which are compliant with GMP standards and meet commercialization needs
Workshops for ADC pilot drug substances	<ul style="list-style-type: none"> • Equipped with 100L, 200L and 500L ADC drug substances production scales • Compliant with GMP standards and equipped with commercialization capabilities
Drug products production (production capacity for drug products filling >18,000 vials/hour; production capacity for freeze-dried products >50,000 vials/batch; liquid injection production line >250 batches; freeze-drying production line >150 batches/year)	
mAb drug products production (mAb DP)	
Workshops for mAb commercialization drug products	<ul style="list-style-type: none"> • International leading brand of automatic filling injection production line • Gained GMP certification by NMPA, which can meet the needs of commercial production of self-developed products and the production of CDMO products
Workshops for mAb pilot drug products	<ul style="list-style-type: none"> • International leading brand of isolator filling linkage production line, which can meet the needs of different specifications of products • Equipped with a 6-DOF clean and sterile robot arm, which enjoys enormous advantages of supplementary filling in case of insufficient filling, supplementary provision of rubber stoppers and aluminum caps, minimized tailing loss, high yield and convenient replacement of specifications • Independent design of automatic filling 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

ADC drug products production (ADC DP)	
Workshops for ADC commercialization drug products	<ul style="list-style-type: none"> • International leading brand of high-activity isolator filling linkage production line • Specially designed for the production of scarce high-activity products to ensure aseptic production while meeting the needs of personnel safety protection • Independent design of automatic filling line, automatic feeding and discharging as well as capping, which can realize freeze-drying, liquid injection switching and continuous production, and maximize production capacity
Workshops for ADC pilot drug products	<ul style="list-style-type: none"> • High-activity isolator filling linkage production line, which has successfully completed clinical production and process validation production of multiple batches of ADC drugs and in CDMO projects
Small molecule chemical drug production	
Workshops for oral solid drug products	<ul style="list-style-type: none"> • Equipped with commercial production capacity for tablet and capsule drug products • Completed clinical production and process validation production of multiple batches in CDMO projects • Gained GMP certification from NMPA regarding the commercial production of self-developed products • Equipped with an independent OEB-5 production line for highly active cytotoxic products

2. Construction of Global Research and Development Center

TOT BIOPHARM's Global Research and Development Center is located in Suzhou Industrial Park, with a gross floor area of 25,000m². In November 2022, the topping out of the main body of TOT BIOPHARM's Global Research and Development Center successfully took place and the Global Research and Development Center will be put into use in the second half of 2023.

The construction of the Global Research and Development Center is an important milestone in the establishment of TOT BIOPHARM's global headquarters, marking another solid step in the industrialization layout of R&D and the globalization of the Company. After the completion of the center, the Company will further gather outstanding talents, strengthen its technological innovation and process development ability, and enhance the refined management of its quality system. At the same time, the seamless connection between the R&D area and the production area will enable efficient coordination throughout the entire drug development process, providing a stronger safeguard for the Company's expansion of its one-stop CDMO business. In the future, by fully leveraging its advantages in biological drug technology development and industrialization, TOT BIOPHARM will strengthen its technology platform and one-stop CDMO technology service capability to provide reliable and high-quality services to global customers, and empower the industry to develop in a high-quality manner.

VII. COMMUNICATION WITHIN THE INDUSTRY

In 2022, TOT BIOPHARM enhanced its brand image through providing valuable information on industry technologies and its business development to the outside world with a new image. In terms of its development focus, namely its CDMO business, TOT BIOPHARM empowered the biopharmaceutical industry through diversified industry cooperation and communication. Throughout the year of 2022, the Company organized or participated in more than 10 exhibitions and events, and invited its outstanding technical experts to discuss and exchange ideas in hot topics from different aspects such as R&D, production, regulations and quality.

On 30 March 2022, TOT BIOPHARM set up a digital virtual booth at the 2022 Advanced Technology Summit of New Biological Drugs (2022新型生物藥先進技術峰會) and 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 a guest of honor to share with other guests the market prospects and development patterns of the ADC pharmaceutical industry.

In August 2022, at the exhibition of the 6th China Bio-Pharm Partnering Forum (第六屆中國生物醫藥創新合作大會), TOT BIOPHARM collaborated with BrightGene Bio-Medical Technology Co., Ltd. (博瑞生物醫藥(蘇州)股份有限公司) (688166.SH) to promote ADC CDMO business through a joint exhibition for the first time. Through this cooperation, TOT BIOPHARM was able to deeply leverage resources, gain industry attention and prominently highlight the strengths of its “one-base, end-to-end” and high-quality CDMO platform, and was highly acclaimed by the industry players.

VIII. RESPONSE TO COVID-19 OUTBREAKS AND SUSTAINABLE DEVELOPMENT

In 2022, given the severe situation arising from the recurrence of the pandemic in China, TOT BIOPHARM formulated a series of pandemic prevention and control policies and contingency plans. While strictly implementing pandemic prevention measures, the Company overcame a string of difficulties including tight schedule, heavy workload and logistics disruptions, actively maintained its production lines and stabilized its production capacity, so as to solve urgent problems for customers and ensure the normal operation of its different businesses. Through our efforts, we achieved 100% delivery of production projects and have gained trust and high recognition from the market and customers. In addition, in terms of sustainable development, the Company further enhanced its ESG governance standards. Through various activities such as new employee trainings, team activities and collection of case studies, the Company has raised the level of ESG awareness of all employees, integrated ESG concepts into daily work and management, and effectively stimulated different departments such as production, safety and quality to improve their management awareness and work efficiency with new ideas, thus effectively improving the level of sustainable governance of the Company.

IX. PROSPECTS

Looking ahead, the trend of the booming development in China’s biopharmaceutical industry will continue, and TOT BIOPHARM will adhere to the concept of “facilitating innovation and mutual growth with a focus on quality” and make full use of its unique strengths to promote the rapid development of the industry together with industry partners. In 2023, we will continue to promote our strategic transformation, strengthen our brand image, focus on providing high-quality products and services to empower high-quality development of the industry, and develop one-stop biological drug CDMO services. We will build a leading “one-base, end-to-end” ADC industrialization platform to rapidly enhance the business scale and market competitiveness of our CDMO business. In addition, we will create sustainable and stable cash flows through a diversified business model to create greater value for our shareholders and contribute to society.

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 consolidated financial statements of the Group for the year ended 31 December 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.

SCOPE OF WORK OF PRICEWATERHOUSECOOPERS

The figures in respect of the Group’s consolidated statement of comprehensive loss and consolidated balance sheet and the related notes thereto for the year ended 31 December 2022 as set out in this announcement have been agreed by the Group’s auditor, PricewaterhouseCoopers, to the amounts set out in the Group’s audited consolidated financial statements for the year. The work performed by PricewaterhouseCoopers in this respect did not constitute an assurance engagement in accordance with Hong Kong Standards on Auditing, Hong Kong Standards on Review Engagements or Hong Kong Standards on Assurance Engagements issued by the Hong Kong Institute of Certified Public Accountants and consequently no assurance has been expressed by PricewaterhouseCoopers on this announcement.

DIVIDEND

The Board does not recommend the distribution of a final dividend for the year ended 31 December 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 Company is committed to maintaining high standard of corporate governance to safeguard the interests of the shareholders of the Company and to enhance corporate value and responsibility.

The Board is of the view that during the year ended 31 December 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 year ended 31 December 2022 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 Centerlab and 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 year ended 31 December 2022, 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.

During the year ended 31 December 2022, such Net Proceeds amounting to approximately RMB97,140 thousand were used, and the unused amount of the Net Proceeds was approximately RMB307,453 thousand as at 31 December 2022. The amount of the Net Proceeds which remain unused were being 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 year ended 31 December 2022 and an expected timeline for the use of the unused portion will be disclosed in the 2022 annual report of the Company.

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

Save as otherwise disclosed in this announcement, neither the Company nor any of its subsidiaries purchased, sold or redeemed any listed securities of the Company during the year ended 31 December 2022.

PUBLICATION OF THE ANNUAL RESULTS ANNOUNCEMENT, ANNUAL REPORT AND NOTICE OF ANNUAL GENERAL MEETING

This announcement is published on the websites of the Company (www.totbiopharm.com.cn) and the Stock Exchange (www.hkexnews.hk). The 2022 annual report of the Company and the notice convening the 2023 annual general meeting of the Company will be dispatched to the shareholders of the Company and made available on the same websites in due course.

STATUTORY FINANCIAL STATEMENTS

The consolidated financial information set out in the section headed “Consolidated Financial Statements” of this announcement does not constitute the Company’s statutory financial statements for the year ended 31 December 2022 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 Companies Ordinance (Chapter 622 of the Laws of Hong Kong) (the “**Companies Ordinance**”) is as follows:

The Company will deliver 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 Companies Ordinance in due course.

The Company’s auditor has reported on the financial statements of the Group for the year ended 31 December 2022. The auditor’s report is unqualified, does not include a reference to any matter to which the auditor drew attention by way of emphasis without qualifying its reports, and does not contain a statement under section 406(2) or 407(2) or (3) of the Companies Ordinance.

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

Hong Kong, 23 March 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.