This announcement contains forward-looking statements that involve risks and uncertainties. All statements other than statements of historical fact are forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors, some of which are beyond the Company's control, that may cause the actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. The Company undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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 2023

HIGHLIGHTS OF 2023 ANNUAL RESULTS AND MILESTONES:

- In 2023, operating revenue of the Group was RMB780,629 thousand, representing a year-on-year increase of 77%. In particular, revenue from sales of products was RMB630,207 thousand, representing a year-on-year increase of 107%, mainly attributable to the significant increase in the sales of our core product, Pusintin® (Bevacizumab injection). Revenue from CDMO/CMO business amounted to RMB140,898 thousand, representing a year-on-year increase of 94%. In 2023, there was no one-time revenue from licenses granted, as compared to RMB54,151 thousand in 2022. Excluding the impact of such item, revenue would have increased by 101% year-on-year in 2023. The Group's cash-generating capability was continuously enhanced, and the net cash flow from operating activities continued to be positive and amounted to RMB56,431 thousand. The profitability of the Group continued to improve, with adjusted earnings before interest, taxes, depreciation and amortization (EBITDA) of RMB40,041 thousand, representing a year-on-year increase of 274%.

- In 2023, net loss of the Group was RMB37,757 thousand, representing a decrease of RMB12,289 thousand, or 25%, from the net loss of RMB50,046 thousand in 2022.

- The growth rate of CDMO business was above the industry average, demonstrating a strong development momentum. Our differentiated competitiveness in ADC CDMO has been recognized in the market. Among the 65 projects in progress, both the revenue from and the number of ADC projects increased to 65% as a percentage of all projects. During the year, 39 newly added projects were secured, representing a year-on-year increase of 44%, and the total number of projects reached 95. We successfully secured 4 pre-BLA projects and the total number of pre-BLA projects reached 6, ensuring commercial production for the future.

- We enhanced our one-stop industrialization platform, providing one-stop services from DNA sequencing to commercial production, which bolstered the front-end funnel effect, accelerated drug development and reduced development costs. In addition, we entered into strategic cooperation with ChemExpress (皓元醫藥) to rapidly integrate small molecule intermediates into the conjugation process for development and production, fully accelerating the industrialization process of customers' drugs.

- TOT BIOPHARM entered into cooperation with GlycanLink (糖嶺生物) to jointly develop an ADC site-specific conjugation technology platform – DisacLink™, and accelerate the development and commercialization of customers' innovative drug conjugates.

- A state-of-the-art large-scale commercial production line for ADC drug products was completed and put into use, with an annual production capacity of 5.3 million vials of freeze-dried drug products. There were 4 complete commercial production lines (ADC*2, Antibody*2), significantly improving the flexibility and production capacity of the production lines.

- With the completion of the Global Research and Development Service Center in October 2023, we further focused on CDMO business, offering a stronger foundation for the expansion of CDMO business.

The board (the "**Board**") of directors (the "**Directors**") of TOT BIOPHARM International Company Limited (the "**Company**" or "**TOT BIOPHARM**") hereby announces the audited consolidated financial results of the Company and its subsidiaries (together, the "**Group**", "**we**" or "**us**") for the year ended 31 December 2023 together with comparative figures for the year ended 31 December 2022 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 2023.

The year 2023 witnessed the accelerated growth of our operational results, as well as our proactive efforts against hardships. Embarking on a new journey in 2024, we are poised to forge ahead in high spirits to make new breakthroughs.

Looking back on 2023, our endeavors were rewarded amidst challenges and opportunities. Due to risks and challenges arising from global economic slowdown, the biopharmaceutical industry underwent a systemic integration and experienced formidable uncertainties. However, as a strategic emerging industry intertwined with national economy, public welfare and national security, the biopharmaceutical industry remained in a phase of major strategic opportunities. In 2023, the Company continued to strengthen its CDMO business capabilities, further enhanced its presence in the XDC sector (such as ADC and AXC), and established a scarce one-stop ADC platform, aiming to meet the needs of the whole process of ADC drugs from development to commercial production, and ensure stable supply. Meanwhile, in line with its commitment to following high-standard quality management system in the industry, the Group has successfully passed 7 regulatory inspections conducted by the National Medical Products Administration of China (NMPA) and other global regulatory authorities, as well as inspections conducted by customers and third-party audit bodies (including the EU QP Audit). In particular, the Company has collaborated with its customers in a number of inspections by partnering overseas multinational pharmaceutical companies and audits by institutions, as well as in completing customer authorizations, which were highly recognized by its customers. With an unremitting commitment to quality, the Company continued to gain the interest and trust of more customers and partners. Since its comprehensive transformation in 2020, the Company has rapidly ascended to prominence as a renowned biological drug CDMO company in China within a mere three years. Especially in the ADC sector, the Company has emerged as a leading ADC CDMO company in China. On this basis, the Company further promoted the sales of launched products, and fostered a sustained, rapid growth in commercial sales through differentiated sales strategies. While steadily adhering to high-quality development, the Company achieved growth against the trend.

During the reporting period:

- The Group's revenue amounted to RMB780,629 thousand, representing a year-on-year increase of 77%.

- In particular, revenue from sales of products was RMB630,207 thousand, representing a year-on-year increase of 107%, which was mainly attributable to the significant increase in the sales of Pusintin® (Bevacizumab injection), our core product. Revenue from CDMO/CMO business amounted to RMB140,898 thousand, representing a year-on-year increase of 94%. In 2023, there was no one-time revenue from licenses granted, as compared to RMB54,151 thousand in 2022. Excluding the impact of such item, revenue would have increased by 101% year-on-year in 2023.

- The Group's cash-generating capability was continuously enhanced, and the net cash flow from operating activities continued to be positive and amounted to RMB56,431 thousand. Our profitability continued to improve, with adjusted earnings before interest, taxes, depreciation and amortization (EBITDA) of RMB40,041 thousand, representing a year-on-year increase of 274%.

- The net loss of the Group was RMB37,757 thousand, representing a decrease of RMB12,289 thousand, or 25%, from the net loss of RMB50,046 thousand in 2022.

In 2023, we continued to enhance the construction of technology platforms, prioritize differentiated competitiveness in ADC, and accelerate the revenue growth of CDMO business.

Currently, the Company has established a high-standard commercial production platform that integrates antibody and ADC drug substances and drug products. With significant emphasis on CDMO technology research and development, the Company continued to invest in cell line development technology platform, process optimization and innovation platform, production capacity supporting facilities for large-scale production and other areas, providing customers with one-stop CDMO services covering the whole process from DNA to IND, and to BLA and commercial production. In order to constantly expand the differentiated competitiveness in ADC, the Company entered into cooperation with GlycanLink (糖嶺生物) to jointly develop a site-specific conjugation technology platform – DisacLink™, and accelerate the development and commercialization of customers' innovative drug conjugates. As its differentiated advantages in ADC CDMO have been recognized by the market, the Company has entered into several long-term strategic cooperation with Lepu Biopharma (樂普生物), Escugen (詩健生物), BioRay (博鋭生物), SmartNuclide (智核生物) and ChemExpress (皓元醫藥). Leveraging its outstanding CMC development capacity and success in commercialization projects, the Company has obtained a number of pre-BLA projects, securing the revenue from potential commercialization orders.

The growth rate of CDMO business was above the industry average, demonstrating a strong development momentum. During the year, 39 newly added projects were secured, representing a year-on-year increase of 44%, and the total number of projects reached 95. Among these newly added projects, there were 30 ADC-related projects, highlighting the Company's differentiated advantages in the ADC field. There were 65 projects in process, and both the revenue from and the number of ADC projects increased to 65% as a percentage of all projects. There were a total of 6 pre-BLA projects, including 4 newly added projects, which fully demonstrated our outstanding capabilities in late-stage CDMO commercialization projects and laid a solid foundation for the continued business growth of the Company.

In 2023, we continued to refine our core capabilities in CDMO commercialization, reaching a new height in commercial production.

In 2023, we further enhanced our production lines, significantly improving the flexibility and production capacity of the production lines. Currently, the Company has 4 complete commercial production lines of international leading brands, including 5 workshops for drug substances and 4 workshops for drug products, with the annual production capacity of 300,000L of drug substances and 20 million vials of drug products for antibodies, and the annual production capacity of 960kg of drug substances and over 5.3 million vials of drug products for ADC. Notably, the Company's second commercial production line for ADC drug products has been put into operation since June 2023. During the reporting period, the production line has arranged the production for over 10 projects, including 3 pre-BLA projects, and completed the filling and production for multiple batches. The Company had a leading ranking among biological drug CDMO industry players in China, and became a large-scale one-stop ADC CDMO provider with commercial production capacity in China. In a dedicated effort to bolster its CDMO technical service capabilities, the Company initiated the construction of the Global Research and Development Service Center in 2021, and announced its official inauguration on 19 October 2023. The Center, with a total construction area of 25,000 square meters, serves as the global headquarters of the Company, housing both research and development facilities and administrative offices. It can further strengthen our CDMO business capabilities in technology research, process development and quality research, laying a more solid foundation for the expansion of our CDMO business. Relying on its top-notch talents, technology, concepts and management, the Center will help our customers accelerate their research and development of biological drugs.

In 2023, due to the acceleration of product commercialization, the Company recorded a sales revenue of RMB630 million, contributing to its stable cash flow and laying a solid foundation for its in-depth CDMO strategic transformation.

Up to now, Pusintin® (Bevacizumab injection), a core sales product of the Company, has exhibited remarkable sales performance driven by our differentiated sales strategies, which improved the drug accessibility and affordability for cancer patients in China. Meanwhile, the Company continued to accelerate overseas commercialization. Currently, we have successfully initiated the registration application in 23 overseas countries, and the registration application documents have been accepted by 13 countries. We expect to obtain the first approval from an overseas country in 2024, which is expected to provide new treatment options to a wider range of patients worldwide. In addition, TAB014, a product licensed to Zhaoke Ophthalmology (兆科眼科) by the Company in 2022, completed ahead of schedule the enrolment of patients for the Phase III clinical trial in September 2023, and the Company will continue to be responsible for the clinical product supply and commercialized production of TAB014, which is expected to inject fresh growth impetus into our CDMO revenue.

In 2023, we continued to improve team building to empower the long-term development of the Company.

In line with the rapid development of our CDMO business, we continued to promote talent development at a strategic level to empower the long-term development of the Company. Through introducing exceptional talents at home and abroad and building an echelon of high-end talents, we continued to improve the management structure and gradually optimized the organizational structure of the Company. During the reporting period, the number of CDMO team members rose to 464, representing an increase of 34% as compared with the end of 2022, and accounting for 84% of the total number of staff of the Group. In particular, the core technical team had an average of over 12 years of experience in the biomedical field, and the senior management team had an average of over 15 years of work experience in world-renowned multinational companies. The Company introduced and retained professional talents through planned trainings and promotion, and the retention rate of core CDMO team members reached 95%.

PROSPECTS

Looking back on 2023, we have achieved fruitful results. Looking ahead, we will seek progress while maintaining stability, and dedicate our efforts in solidifying our leading position in CDMO, especially in ADC CDMO. We will continuously strengthen the construction of our quality system, accelerate the global expansion of our business. Leveraging the service capabilities of our innovative technology platform, we will extend the value chain, with a view to injecting new momentum for the long-term growth of the Company and forging a new development paradigm. On behalf of the Board of the Company and all employees of the Group, I would like to express my heartfelt gratitude to all shareholders, all walks of life and our partners for your long-term attention to and support for the Group!

Dr. Liu, Jun
Chief Executive Officer and Executive Director

15 March 2024

CONSOLIDATED FINANCIAL STATEMENTS

CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS

	Note	Year ended 31 December	
		2023	2022
		RMB'000	*RMB'000*
Revenue	*3*	**780,629**	442,178
Cost of revenue		**(206,643)**	(71,563)
Research and development expenses		**(103,890)**	(151,168)
Selling expenses		**(441,019)**	(203,954)
General and administrative expenses		**(68,310)**	(62,587)
Net impairment losses on financial and contract assets		**(11,481)**	(597)
Other income and losses – net		**17,654**	8,615
Operating loss		**(33,060)**	(39,076)
Finance income		**2,974**	2,265
Finance costs		**(5,175)**	(6,602)
Finance costs – net		**(2,201)**	(4,337)
Share of net loss of the joint venture accounted for using the equity method		**(2,495)**	(6,633)
Loss before income tax		**(37,756)**	(50,046)
Income tax expense	*4*	**(1)**	–
Loss for the year		**(37,757)**	(50,046)
Loss is attributable to:			
Equity holders of the Company		**(37,757)**	(49,916)
Non-controlling interests		**–**	(130)
		(37,757)	(50,046)
Other comprehensive income:			
Exchange difference on translation		**1,737**	6,314
Other comprehensive income for the year, net of tax		**1,737**	6,314
Total comprehensive loss for the year		**(36,020)**	(43,732)

	Note	Year ended 31 December	
		2023	2022
		RMB'000	*RMB'000*
Total comprehensive loss for the year is attributable to:			
Equity holders of the Company		**(36,020)**	(43,602)
Non-controlling interests		**–**	(130)
		(36,020)	(43,732)
Loss per share for the year and attributable to the equity holders of the Company			
– Basic and diluted losses per share *(RMB)*	*5*	**(0.05)**	(0.08)

CONSOLIDATED BALANCE SHEET

	Note	As at 31 December 2023 RMB'000	2022 RMB'000
ASSETS			
Non-current assets			
Property, plant and equipment		**695,804**	465,328
Prepayments for property, plant and equipment		**1,803**	82,477
Right-of-use assets		**14,258**	15,007
Investment properties		**2,785**	3,184
Intangible assets		**8,839**	4,648
Investments accounted for using the equity method		**–**	–
Other non-current assets		**9,437**	14,590
		732,926	585,234
Current assets			
Inventories		**126,009**	94,821
Other current assets		**49,410**	38,254
Trade and other receivables	*7*	**88,152**	53,387
Prepayments		**18,715**	20,012
Contract assets		**54,916**	9,278
Financial assets at fair value through profit or loss		**–**	40,278
Restricted cash		**4,373**	2,998
Cash and cash equivalents		**351,600**	417,769
		693,175	676,797
Total assets		**1,426,101**	1,262,031
EQUITY			
Share capital	*9*	**2,297,499**	2,297,499
Other reserves		**72,472**	61,911
Accumulated losses		**(1,683,285)**	(1,645,528)
Non-controlling interests		**–**	1,557
Total equity		**686,686**	715,439

	Note	As at 31 December 2023 RMB'000	2022 RMB'000
LIABILITIES			
Non-current liabilities			
Borrowings		**302,685**	212,133
Lease liabilities		**194**	345
Other non-current liabilities		**54,050**	58,767
		356,929	271,245
Current liabilities			
Borrowings		**41,600**	75,500
Trade and other payables	*8*	**322,934**	174,017
Contract liabilities		**12,063**	19,562
Lease liabilities		**1,172**	1,551
Other current liabilities		**4,717**	4,717
		382,486	275,347
Total liabilities		**739,415**	546,592
Total equity and liabilities		**1,426,101**	1,262,031
Net current assets		**310,689**	401,450
Total assets less current liabilities		**1,043,615**	986,684

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 BASIS OF PREPARATION AND CHANGES IN ACCOUNTING POLICY AND DISCLOSURES

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

A number of new or amended standards became applicable for the current reporting period. The Group did not have to change its accounting policies or make retrospective adjustments as a result of adopting these standards.

Standards	Key requirements	Effective Date
HKAS 8 (Amendments)	Definition of Accounting Estimates	1 January 2023
HKAS 12 (Amendments)	Deferred Tax related to Assets and Liabilities arising from a Single Transaction	1 January 2023
HKAS 1 and HKFRS Practice Statement 2 (Amendments)	Disclosure of Accounting Policies	1 January 2023
HKFRS 17	Insurance Contracts	1 January 2023
HKAS 12 (Amendments)	International Tax Reform – Pillar Two Model Rules	1 January 2023

2.1.4 New standards and interpretations not yet adopted

Standards and amendments to standards that have been issued but not yet effective and not been early adopted by the Group during the period are as follows:

Standards	Key requirements	Effective for accounting periods beginning on or after
HKAS 1 (Amendments)	Classification of liabilities as current or non-current	1 January 2024
HKAS 1 (Amendments)	Non-current liabilities with covenants	1 January 2024
HKFRS 16 (Amendments)	Lease Liability in a Sale and Leaseback	1 January 2024
HKAS 7 and HKFRS 7 (Amendments)	Supplier finance arrangements	1 January 2024
HK Int 5 (Revised)	Presentation of Financial Statements-Classification by the Borrower of a Term Loan that Contains a Repayment on Demand Clause	1 January 2024
HKAS 21 (Amendments)	Lack of Exchangeability	1 January 2025
HKFRS 10 and HKAS 28 (Amendments)	Sale or contribution of assets between an investor and its associate or joint venture	To be determined

The Group has already commenced an assessment of the related impact of the above standards and amendments to standards which are relevant to the Group's operation.

There are no other standards that are not yet effective and that are expected to have a material impact on the Group's financial performance and position.

3. 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	
	2023	2022
	RMB'000	*RMB'000*
Timing of revenue recognition		
At a point in time:		
– Sales of goods	**630,207**	304,361
– CMO	**29,552**	20,630
– Commission revenue	**7,930**	9,098
– Revenue from license granted	**–**	54,151
– Others	**532**	708
Over time:		
– CDMO	**111,346**	51,908
– Clinical research and other contract research organisation ("**CRO**")	**1,062**	1,322
	780,629	442,178

(c) Geographical information

Geographical information of revenue and non-current assets other than financial assets for the years ended 31 December 2023 and 2022 is as follows:

	Year ended 31 December			
	2023		2022	
	Revenue	**Non-current assets**	Revenue	Non-current assets
	RMB'000	***RMB'000***	*RMB'000*	*RMB'000*
Mainland China	**780,629**	**724,934**	442,178	570,366
Others	**–**	**–**	–	328
	780,629	**724,934**	442,178	570,694

4 INCOME TAX EXPENSE

	Year ended 31 December	
	2023	2022
	RMB'000	*RMB'000*
Current income tax expenses		
– Tax filing difference for prior year	**1**	–
Deferred income tax expense	**–**	–
	1	–

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% (2022: 16.5%) as the Company has no estimated assessable profit for the year ended 31 December 2023 (2022: Nil).

(b) Mainland China

No provision for mainland China income tax has been provided for at the rate of 25% or 15% (2022: 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 for the year ended 31 December 2023.

TOT BIOPHARM Co., Ltd. ("**TOT Suzhou**") was qualified as a "High and New Technology Enterprise" under the relevant PRC laws and regulations from 2023 to 2025. TOT Suzhou was entitled to enjoy a beneficial income tax rate of 15% for the year ended 31 December 2023 (2022: 15%).

(c) Taiwan corporate income tax

No provision for Taiwan corporate income tax has been provided for at the rate of 20% (2022: 20%) as the Group's Taiwan subsidiary has no estimated assessable profit for the year ended 31 December 2023.

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	
	2023	2022
Loss attributable to equity holders of the Company *(RMB'000)*	**(37,757)**	(49,916)
Weighted average number of ordinary shares in issue *(thousand)*	**725,197**	639,307
Basic loss per share *(RMB)*	**(0.05)**	(0.08)

(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 2023, the Company had one category of potential ordinary shares: the stock options granted to employees (2022: same). As the Group incurred losses for the years ended 31 December 2023 and 2022, 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 2023 and 2022 is the same as basic loss per share of the respective years.

6 DIVIDEND

No dividend has been paid or declared by the Company during the year (2022: Nil).

7 TRADE AND OTHER RECEIVABLES

	As at 31 December	
	2023	2022
	RMB'000	*RMB'000*
Trade receivables	**85,964**	49,721
Other receivables	**6,977**	4,263
Less: provision for impairment of trade receivables	**(175)**	(597)
Less: provision for impairment of other receivables	**(4,614)**	–
Trade and other receivables	**88,152**	53,387

(a) Trade receivables

	As at 31 December	
	2023	2022
	RMB'000	*RMB'000*
Trade receivables	**85,964**	49,721

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

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

	As at 31 December	
	2023	2022
	RMB'000	*RMB'000*
Within 30 days	**54,628**	28,716
31 days to 90 days	**31,213**	17,490
91 days to 180 days	**116**	2,210
181 days to 270 days	**–**	1,298
271 days to 360 days	**–**	7
1 year to 2 years	**7**	–
	85,964	49,721

As at 31 December 2023, the carrying amounts of the Group's trade receivables are denominated in RMB and approximate to their fair values (2022: same).

8 TRADE AND OTHER PAYABLES

	As at 31 December	
	2023	2022
	RMB'000	*RMB'000*
Accrued promotion expenses	**193,297**	77,780
Payables for purchase of property, plant and equipment	**42,859**	12,072
Trade payables	**35,710**	25,983
Staff salaries and welfare payables	**28,668**	21,944
Tax payable	**1,659**	2,537
Deposits payables	**800**	15,502
Refund liabilities *(Note (i))*	**170**	5,987
Others	**19,771**	12,212
	322,934	174,017

Note (i): 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 2023 and 2022, the ageing analysis of trade payables based on invoice date are as follows:

	As at 31 December	
	2023	2022
	RMB'000	*RMB'000*
Within 3 months	**33,990**	24,982
3 months to 6 months	**1,287**	724
6 months to 12 months	**255**	133
1 year to 2 years	**178**	76
2 years to 3 years	**–**	68
	35,710	25,983

9 SHARE CAPITAL

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

Note (a): On 29 July 2022, the Company allotted and issued 150,000,000 subscription shares at the price of HKD 3.15 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 HKD 472,500,000 (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.

(i) Share capital

Ordinary shares are classified as equity. Incremental costs directly attributable to the issue of equity instruments are shown in equity as a deduction, net of tax, from the proceeds.

(ii) Shares held for employee share scheme

As at 31 December 2023, 47,590,948 ordinary shares included in all ordinary shares issued are within the Company's control until the shares are vested to the participants and hence are considered as treasury shares in substance (2022: same).

	2023	2022	**2023**	2022
	Shares	*Shares*	***RMB'000***	*RMB'000*
Shares held for employee share scheme	**47,590,948**	47,590,948	**–**	–

MANAGEMENT DISCUSSION AND ANALYSIS OF CERTAIN FINANCIAL ITEMS

OVERVIEW

In 2023, the Group recorded an operating revenue of RMB780,629 thousand, representing an increase of RMB338,451 thousand, or 77%, from RMB442,178 thousand in 2022. In 2023, the net loss of the Group was RMB37,757 thousand, representing a decrease of RMB12,289 thousand, or 25%, from the net loss of RMB50,046 thousand in 2022. In 2023, the Group's research and development expenses were RMB103,890 thousand, as compared to RMB151,168 thousand in 2022. In 2023, the Group's general and administrative expenses were RMB68,310 thousand, as compared to RMB62,587 thousand in 2022. In 2023, the Group's selling expenses were RMB441,019 thousand, as compared to RMB203,954 thousand in 2022.

OPERATING REVENUE AND COSTS

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

In 2023, the Group's revenue from sales of products was RMB630,207 thousand, representing an increase of RMB325,846 thousand from RMB304,361 thousand in 2022, which was mainly due to the significant 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 2023 was RMB140,898 thousand, representing an increase of RMB68,360 thousand from RMB72,538 thousand in 2022, primarily attributable to the large-scale expansion of CDMO/CMO business segment, while the costs for raw materials, labor and production, etc. also increased accordingly.

RESEARCH AND DEVELOPMENT EXPENSES

During the reporting period, the Group's research and development expenses primarily consist of expenses related to clinical trial research for pipeline product candidates, and expenses related to the enhancement of the Group's CDMO technology platform.

The Group's research and development expenses in 2023 were RMB103,890 thousand, representing a decrease of RMB47,278 thousand from RMB151,168 thousand in 2022, which was mainly attributable to the streamlining of product pipelines and the further allocation of research and development resources to ADC CDMO process development and technological innovation.

SELLING EXPENSES

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

The Group's selling expenses in 2023 were RMB441,019 thousand, representing an increase of RMB237,065 thousand from RMB203,954 thousand 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, legal advisory fees, and expenses for professional services related to audit and tax, etc.

The Group's general and administrative expenses in 2023 were RMB68,310 thousand, representing an increase of RMB5,723 thousand from RMB62,587 thousand 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.

NET IMPAIRMENT LOSSES ON FINANCIAL AND CONTRACT ASSETS

The Group's net impairment losses on financial and contract assets mainly include bad debt provision and reversal for trade and other receivables, other current and non-current assets, etc.

The Group's net impairment losses on financial and contract assets in 2023 were RMB11,481 thousand, representing an increase of RMB10,884 thousand from RMB597 thousand in 2022, which was mainly attributable to the impairment provision for other receivables and other assets in prior years in response to the strategic transformation.

OTHER INCOME AND LOSSES – NET

The Group's net other income and losses in 2023 was RMB17,654 thousand, representing an increase of RMB9,039 thousand from RMB8,615 thousand in 2022, which was mainly attributable to the increase in government grants and net foreign exchange gains.

FINANCE INCOME

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

The finance income in 2023 was RMB2,974 thousand, representing an increase of RMB709 thousand from RMB2,265 thousand 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 in 2023 were RMB5,175 thousand, representing a decrease of RMB1,427 thousand from RMB6,602 thousand in 2022, mainly due to the repayment of part of the working capital loans.

INCOME TAX EXPENSE

The Group's income tax expense in 2023 was RMB1 thousand, which was recognized for adjustments made to the current income tax in the last year (2022: nil).

LOSS FOR THE YEAR

In view of the abovementioned factors, the Group recorded a net loss of RMB37,757 thousand in 2023, representing a decrease of RMB12,289 thousand from RMB50,046 thousand in 2022.

NET ASSETS

The Group's net assets as of 31 December 2023 were RMB686,686 thousand, representing a decrease of RMB28,753 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 31 December 2023, the Group's cash and cash equivalents were RMB351,600 thousand, representing a decrease of RMB66,169 thousand from RMB417,769 thousand as at the end of 2022. Such change was mainly attributable to the following reasons:

In 2023, the Group's net cash inflows for operating activities were RMB56,431 thousand, representing a decrease of RMB3,498 thousand from RMB59,929 thousand in 2022, which was attributable to the changes in the above-mentioned operating expenses in the current year, coupled with the impact of revenue from licenses granted in 2022. The Group's net cash outflows for investing activities for the current year were RMB164,105 thousand, representing a decrease of RMB118,659 thousand from RMB282,764 thousand as at the end of 2022, which was mainly attributable to the nearing completion of projects such as the construction of the Global Research and Development Service Center. The Group's net cash inflows for financing activities were RMB38,225 thousand, representing a decrease of RMB443,015 thousand from RMB481,240 thousand as at the end of 2022, which was mainly attributable to the receipt of funds from financing in 2022 and the optimization of the capital structure on the basis of the continued positive net cash inflows for operating activities in 2023.

INDEBTEDNESS AND KEY LIQUIDITY RATIO

As at 31 December 2023, the Group had outstanding bank borrowings that amounted to RMB344,285 thousand (31 December 2022: RMB287,633 thousand) and had unutilised bank facilities of RMB265,715 thousand (31 December 2022: RMB237,367 thousand).

As at 31 December 2023, the Group's total liabilities to total assets ratio was 0.5 (31 December 2022: 0.4). The increase was mainly attributable to the increase of bank borrowings drawn for promoting the construction of the Global Research and Development Service Center.

MATERIAL INVESTMENT

On 9 November 2021, the Group commenced the construction of the Global Research and Development Service 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. During the year ended 31 December 2023, the Group incurred expenditure of RMB70,949 thousand in connection with the construction agreement entered into with Shanghai Baoye Group Corp., Ltd., and expenditure of RMB140,932 thousand in total in connection with the construction of the Global Research and Development Service 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 RMB246,743 thousand was incurred by the Group during the year ended 31 December 2023 in connection with such projects.

Save as disclosed above, the Group did not make any material investment during the year ended 31 December 2023.

MATERIAL ACQUISITIONS AND DISPOSALS

During the year ended 31 December 2023, the Group did not have any material acquisitions and disposals of subsidiaries, consolidated affiliated entities or associates.

PLEDGE OF ASSETS

As at 31 December 2023, the Group had no pledge of assets.

CONTINGENT LIABILITIES

As at 31 December 2023, the Group had no significant contingent liabilities.

FOREIGN EXCHANGE RISK

Certain bank balances and cash, trade receivables and other receivables, contract assets and other payables are denominated in foreign currencies of respective group entities which are exposed to foreign exchange risk. Foreign exchange risk also arises from future commercial transactions and recognized assets and liabilities denominated in a currency other than the functional currency of the relevant group entity. The Group has entities operating in USD, NTD and RMB, and the Group will constantly review the economic situation and its foreign exchange risk profile, and will consider appropriate hedging measures in the future when necessary.

MANAGEMENT DISCUSSION AND ANALYSIS OF CERTAIN ASPECTS OF OUR BUSINESS

I. INDUSTRY AND PERFORMANCE OVERVIEW

In 2023, the Company continued to implement its strategic transformation goals and make efforts in business and technology. While steadily adhering to high-quality development, the Company achieved growth against the trend. In terms of operations and management, the Company continued to capitalize on its diversified business structure to cope with industry and market challenges. Since the strategic transformation towards CDMO in 2020, the Company has remained steadfast in its mission of "to be an industry-leading and the best customer-trusted partner in biopharmaceuticals" and its vision of "empowering pharmaceutical innovation to improve the quality of life and safeguard human health", with focus on biological drug CDMO business, especially the differentiated layout of ADC CDMO.

In 2023, the Group's revenue amounted to RMB780,629 thousand, representing a year-on-year increase of 77%. In particular, revenue from sales of products was RMB630,207 thousand, representing a year-on-year increase of 107%, which was mainly attributable to the significant increase in the sales of Pusintin® (Bevacizumab injection), our core product. Revenue from CDMO/CMO business amounted to RMB140,898 thousand, representing a year-on-year increase of 94%. In 2023, there was no one-time revenue from licenses granted, as compared to RMB54,151 thousand in 2022. Excluding the impact of such item, revenue would have increased by 101% year-on-year in 2023. The Group's cash-generating capability was continuously enhanced, and the net cash from operating activities continued to be positive and amounted to RMB56,431 thousand. Our profitability continued to improve, with adjusted earnings before interest, taxes, depreciation and amortization (EBITDA) of RMB40,041 thousand. The net loss of the Group was RMB37,757 thousand, representing a decrease of RMB12,289 thousand, or 25%, from the net loss of RMB50,046 thousand in 2022.

The growth rate of CDMO business was above the industry average, demonstrating a strong development momentum. During the year, 39 newly added projects were secured, representing a year-on-year increase of 44%, and the total number of projects reached 95. Among these newly added projects, there were 30 ADC projects and 6 antibody projects. As the differentiated advantages in ADC CDMO have been recognized by the market, there were 65 projects in process, and both the revenue from and the number of ADC projects increased to 65% as a percentage of all projects. The Company has entered into comprehensive cooperation in the fields of ADC drugs, radionuclide-drug conjugates (RDC) and other broader bioconjugates drugs with strategic partners such as Lepu Biopharma (樂普生物), Escugen (詩健生物), BioRay (博鋭生物), SmartNuclide (智核生物) and ChemExpress (皓元醫藥). In addition, we have successfully secured 4 pre-BLA project orders, and the total number of pre-BLA projects reached 6, which fully demonstrated the Company's outstanding capabilities in late-stage CDMO commercialization projects and laid a solid foundation for the continued business growth of the Company.

In terms of technology, the Company continued to build a leading ADC CDMO technology platform. The Company entered into cooperation with GlycanLink (糖嶺生物) to jointly develop an ADC site-specific conjugation technology platform – DisacLink™, and accelerate the development of the ADC industry.

II. DEVELOPMENT AND COMPETITIVE ADVANTAGES OF CDMO BUSINESS OF TOT BIOPHARM

1. Highlights of CDMO Performance

In 2023, TOT BIOPHARM continued to expand its portfolio of early-stage pipeline projects and enhance its customer stickiness by focusing on the biological drug CDMO business. With an unremitting commitment to quality, the Company continued to gain the interest and trust of more customers and partners. During the year, the Company achieved outstanding performance in its CDMO business. As of 31 December 2023, the revenue from CDMO/CMO was RMB140,898 thousand, representing a year-on-year increase of 94%. As the differentiated advantages in ADC CDMO have been recognized by the market, there were 65 projects in process, and both the revenue from and the number of ADC projects increased to 65% as a percentage of all projects.

Leveraging its outstanding commercial production capacity and project experience, the Company quickly undertook late-stage clinical projects and accelerated cash flow conversion. During the year, 39 newly added projects were secured, of which 30 were ADC projects. 33 pre-IND projects were newly added, which expanded the portfolio of pipeline projects and enhanced the front-end promotion. There were a total of 6 pre-BLA projects, and 4 pre-BLA projects were newly added, including 3 ADC projects, which are poised to secure sustainable profits in the future.

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

In 2023, TOT BIOPHARM entered into a number of in-depth strategic cooperation with its partners:

- TOT BIOPHARM established 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 subsequent commercialization for its ADC drugs.

- TOT BIOPHARM entered into 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 safeguard the success of Escugen.

- TOT BIOPHARM entered into comprehensive strategic cooperation in the field of CDMO with BioRay (博鋭生物), 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.

- 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) 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 strategic cooperation with ChemExpress (皓元醫藥), pursuant to which the two parties will work closely relying on their respective advantages to deepen the establishment of a one-stop CDMO quality service platform covering the whole process from ADC drug research and development to industrialization.

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 antibody and ADC drug substances and drug products, has become one of the state-of-the-art 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 a large-scale ADC commercial production workshop in China equipped with industry-leading production line for drug products, which were put into operation in June. TOT BIOPHARM's headquarters and integrated commercial production workshops are located in Suzhou Industrial Park. With the support of the Suzhou government and provincial and municipal 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 July 2023, the Company entered into in-depth strategic cooperation with GlycanLink (糖嶺生物) to jointly develop an ADC site-specific conjugation technology platform – DisacLink™. The parties agreed to cooperate on GlycanLink's licensing to TOT BIOPHARM in respect of the use of DisacLink™ technology, the joint development of DisacLink™ technology by both parties, and 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. This cooperation will accelerate the development and commercialization of customers' innovative drug conjugates, further unleash the Company's innovation ability, and effectively promote the Company's development.

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

In line with its commitment to following high-standard quality management system in the industry, the Company 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. Meanwhile, in line with its commitment to following high-standard quality management system in the industry, the Group has successfully passed 7 regulatory inspections conducted by the National Medical Products Administration of China (NMPA) and other global regulatory authorities, as well as inspections conducted by customers and third-party audit bodies (including the EU QP Audit). In particular, the Company has collaborated with its customers in a number of inspections by partnering overseas multinational pharmaceutical companies and audits by institutions, as well as in completing customer authorizations, which were highly recognized by its customers. 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 and put into operation a large-scale commercial production line in China that integrates ADC naked antibodies as well as ADC drug substances and drug products. The Company has completed the construction of the second and third commercial production lines for ADC drug substances, with a production capacity of 5kg/batch for each line. The second commercial production line for antibodies has been completed, significantly increasing the production capacity and flexibility of production lines. Currently, the Company has 4 complete commercial production lines of international leading brands, including 5 workshops for drug substances and 4 workshops for drug products, with the annual production capacity of 300,000L of drug substances and 20 million vials of drug products for antibodies, and the annual production capacity of 960kg of drug substances and over 5.3 million vials of drug products for ADC. Notably, the Company's second commercial production line for ADC drug products has been put into operation since June 2023. During the reporting period, the production for more than 10 projects, including 3 pre-BLA projects, has been carried out in the production line, which has completed several batches of filling and production. The Company has a leading ranking among biological drug CDMO industry players in China, and is also a leading one-stop ADC CDMO provider in China in terms of production capacity.

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

In order to empower its long-term development, 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 an average of over 15 years of extensive management experience in well-known multinational companies. In line with the rapid development of the Company's CDMO business, as of 31 December 2023, the number of CDMO team members were expanded to 464, representing a year-on-year increase of 34%, and accounting for 84% of the total number of staff of the Group. Among them, the core technical team had an average of over 12 years of experience in the biomedical field, which safeguards the success of its projects. The Company attracted and retained professional talents through planned trainings and promotion, and the retention rate of core CDMO team members reached 95%.

– *3.6 Corporate reputation*

Leveraging its advantages 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. TOT BIOPHARM has completed a number of late-stage pre-BLA 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.

III. LAUNCHED PRODUCTS AND R&D PIPELINE

1. Overall Marketing Strategy of Products

In 2023, under the new strategic direction of development, the Group's research and development expenses of new drugs continued to decrease by streamlining pipelines. TOT BIOPHARM actively promoted the sales of launched products, effectively improving the cash flow of the Company.

In March 2022, we entered into an 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), 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) and be responsible for the Phase III clinical trial. According to an announcement published by Zhaoke Ophthalmology in October 2023, the enrolment of patients for the Phase III clinical trial of TAB014 was completed ahead of schedule on 16 September 2023, and TOT BIOPHARM will continue to be responsible for the commercialized production of TAB014 in the future.

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)				ZHAOKE 兆科		
						IND authorized by FDA to directly enter Clinical Phase III		
	TAC020 (new target)	Various solid tumors	Co-development					

Drug Name	Indication(s)	Product Specification	Launched
Pusintin® (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
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.	20mg x 5 capsules/bottle; 100mg x 5 capsules/bottle	Approved for launch by NMPA on 31 May 2021
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	150mL/bottle	Approved for launch by NMPA on 13 May 2021 *(This product is imported from Taiwan; the Company owns the exclusive agency rights of this product in mainland China, Hong Kong and Macau)*

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.

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; and hepatocellular carcinoma

Pusintin®, the core product of the Company in the field of anti-tumor treatment, was approved for launch in 2021. As of 31 December 2023, Pusintin® has been approved for the treatment of all six indications that can be treated with the originator drug Avastin® approved in mainland China. The special mechanism of bevacizumab enables it to cover a number of cancer treatments, and 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® 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 Jiangxi Jixin Pharmaceutical Co., Ltd. (江西濟鑫醫藥有限公司), the Company continued to expand the market share of Pusintin®.

In 2023, the Company continued to implement differentiated marketing strategies and further consolidated its market position. Through our differentiated layout, the sales volume of the drug in 2023 increased by 115% year-on-year. In terms of overseas markets, we actively promoted the registration filing for the launch of the drug in overseas markets. As of 31 December 2023, we have initiated the registration application in 23 overseas countries, and the registration application documents have been accepted by 13 countries. We expect to obtain the first approval from an overseas country in 2024.

– *Tazian® (Temozolomide capsule)*

  – Indications: glioblastoma; anaplastic astrocytoma

    Tazian® 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. In 2022, Tazian® was successfully selected for renewal in the centralized procurement of several allied provinces. As of 31 December 2023, the Company has become the supplier in the renewal of centralized procurement by Jiangsu Province, Hebei Province, Beijing, Guangdong Province and Jiangxi Province during the second year of centralized procurement.

IV. INDUSTRY-LEADING LARGE-SCALE AND FLEXIBLE PRODUCTION CAPACITY

1. Commercial Production Bases

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

- In April 2023, the second production line for antibody drug substances was completed and put into production and operation, which was 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.

- In June 2023, the second and third production lines for ADC drug substances that meet international GMP standards were completed, which were 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 5kg/batch. At the same time, they were equipped with a non-toxic conjugation workshop, which can support non-toxic conjugation projects.

- In June 2023, TOT BIOPHARM's second large-scale commercial production line in China for ADC drug products was completed and put into use. It is equipped with 40m^2 (2*20m^2) freeze-drying machines, 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. The production line is independently designed for filling, automatic feeding and discharging, and capping, which can realize freeze-drying, injection switching and continuous production.

- In September 2023, TOT BIOPHARM's second commercial production line for antibody injection was completed. It is equipped with a rare 6-axis clean and sterile robot arm, which has high precision and few specifications, and can stably cope with filling requirements. Filling machine and capping machine all adopt a full-feed and full-exhaust fresh air isolator, which can effectively protect the safety of products and operators. At the same time, it is equipped with a 15m^2 freeze-drying machines and automatic feeding and discharging freeze-drying system, which can produce injection and freeze-dried injection products that meets 2R-50R specification. It can achieve 100% full weighing and designated weighing control modes as well as weighing compensation for filling. 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:

<table>
<tr><td colspan="2">Antibody production workshops</td></tr>
<tr><td colspan="2">– Antibody drug substances manufacturing

2 independent workshops with annual production capacity of 150 batches and 300,000L

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</td></tr>
<tr><td>Workshop for antibody drug substances</td><td>• Production capacity exceeding 20,000L for different scales of antibody drug substances production, namely commercialization projects, pilot tests and small trials

• Disposable bioreactors of international leading brands with flexible and continuous production capability for different projects

• Gained GMP certification by NMPA</td></tr>
<tr><td colspan="2">– Antibody drug products manufacturing

2 filling lines (including 1 freezing line and 1 injection line)

Annual production capacity of 250 batches and annual output of 20 million bottles</td></tr>
<tr><td>Workshops for antibody drug products</td><td>• International leading brands of fully automatic filling injection production line and isolator filling linkage production line, which can meet the needs of antibody liquid-injection and freeze-dried 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 (15m^2), liquid injection switching and continuous production, and maximize the utilization of production capacity</td></tr>
</table>

	• Gained GMP certification by NMPA, which can meet the needs of commercial production of self-developed products and the production of CDMO products
ADC production workshops	
– ADC drug substances manufacturing 3 independent workshops with annual production capacity of 240 batches and annual output of 960kg 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	
Workshop for ADC drug substances	• International leading brand of reaction kettles of different scales (5L-500L) and chromatography systems • Up to conjugation scale of 5 kg/batch • Completed clinical production and process validation production of multiple batches of ADC drugs, which are compliant with GMP standards and meet commercialization needs
– ADC drug products manufacturing High-end 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 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 Equipped with one $5m^2$ (DP05) and two $20m^2$ (DP06) freeze-drying machines, all equipped with fully automatic feeding and discharging systems	

Workshop for ADC drug products	• International leading brands of high-activity isolator filling linkage production lines and freeze-drying machines • 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 • 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 • Equipped with a non-toxic conjugation workshop (DS05), which can support non-toxic conjugation projects
Small molecule chemical drug manufacturing	
Workshop for oral solid drug products	• 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 by NMPA regarding the commercial production of self-developed products • Equipped with an independent OEB-5 production line for highly active cytotoxic products

V. COMMUNICATION WITHIN THE INDUSTRY AND BRAND PROMOTION

In 2023, 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 high-standard 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 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 September 2023, TOT BIOPHARM hosted the pre-forum leaders' closed-door meeting of the "2023 China ADC Autumn Forum" titled "Rejuvenating Journey, Entering TOT BIOPHARM." Dr. Liu, Jun, chief executive officer and executive Director of TOT BIOPHARM, along with the ADC core technology team, engaged in discussions with guests on the path to mutual success between Chinese ADC R&D enterprises and CDMO companies. They also toured TOT BIOPHARM's "one-stop, one-base" antibody & ADC commercial production base, exploring the future development of the ADC industry.

Photo of Leaders' Closed-Door Meeting

- In October 2023, TOT BIOPHARM's Global Research and Development Service Center was officially completed. With a total construction area of 25,000m^2, it serves as the global headquarters of TOT BIOPHARM, fulfilling both R&D and office functions. The core experiment area includes cell culture process development, purification process development, cell banking, analytical method development, and quality control laboratories. The establishment of the Global Research and Development Service Center integrates the Company's scientific research resources and gathers outstanding talents, further strengthening the Company's capabilities in technical research, process development and quality research for CDMO business. It solidifies a comprehensive layout for drug development and production, providing a more robust foundation for the expansion of CDMO business.

Photo of Global Research and Development Service Center

- In November 2023, Dr. Liu, Jun, chief executive officer and executive Director of TOT BIOPHARM, was invited to attend the 2023 annual meeting of the Sino-American Pharmaceutical Professionals Association-China (SAPA-China). He participated in the roundtable discussion session of the main forum, engaging with numerous industry peers to explore the cutting-edge scientific advancements in innovative drug development.

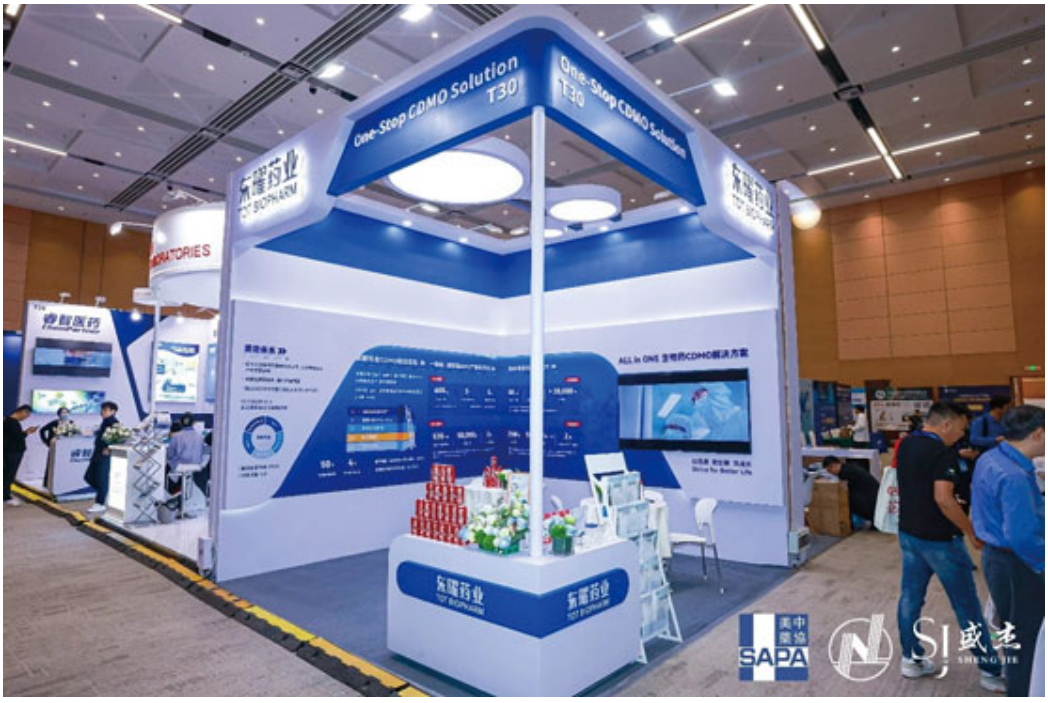

Photo of SAPA Venue

VI. INVESTOR RELATIONS

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 remains committed to establishing effective communication with the capital market, enhancing the transparency, timeliness and completeness of information disclosure, with the aim of increasing investors' understanding and recognition of the Company. Currently, the Company has established a multi-channel communication system to ensure that shareholders and investors can keep abreast of the Company's key business developments from various public platforms. At present, the communication platform includes general meetings, interim and annual reports, announcements, press releases, roadshows, market strategy meetings, investor and analyst presentations, as well as investor open days held by the Company from time to time. Through effective communication with the capital market, the Group has gained high recognition from the market and has won multiple awards.

VII. COMPANY AWARDS

During the reporting period, the Company's rapidly developing CDMO business and its excellent service quality have earned itself numerous awards and industry recognition, including:

- Honored as one of the "Top 10 Most Promising CDMO Companies" on the 2023 China Biomedical Industry Value List by Huayibang (華醫榜). The selection was based on a comprehensive and in-depth evaluation across six key dimensions: competitive factors, value factors, strategic factors, product factors, team factors and others, affirming the industry influence and growth potential of the Company in the biomedical field.

- Awarded the "2023 Transformation Pioneer" by Gelonghui (格隆匯), a leading global investment research platform in China. The award reflects the recognition of the Company's exceptional financial performance, innovation, resilience and a balanced focus on social and economic benefits.

- Recognized in the "2023 TOP20 China Listed Pharmaceutical Companies in ESG Competitiveness" by Healthcare Executive (E藥經理人), a media with a core team of senior pharmaceutical media professionals and positioned as the "News and Resource Center of the Pharmaceutical Industry," validating the Company's outstanding performance in ESG practices.

- Awarded the "2023 Green Sustainable Development Contribution Award" by syobserve.com (數央網) and gongyidaily.com (數央公益), in collaboration with numerous domestic mass and financial media during the International Green Zero Carbon Festival and ESG Leaders Summit. The award highly acknowledges a company's proactive promotion of green environmental concepts and sustainable development in governance measures, energy saving and emission reduction, supplier management, key raw material control and corporate environmental behaviour evaluation.

VIII. 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. Adhering to the values of people-caring, quality-oriented, professional & efficient, cooperative & win-win, innovative & passionate, we strive to improve customer satisfaction and achieve long-term cooperation, and are committed to becoming the industry-leading and most customer-trusted partner in biopharmaceuticals. We continuously strive for the vision of empowering pharmaceutical innovation to improve the quality of life and safeguard human health.

IX. FUTURE PROSPECTS

During the reporting period, despite various external challenges and uncertainties, coupled with the slowdown in economic growth, TOT BIOPHARM still achieved growth against the headwind. In 2023, the Group further developed in the biological drug CDMO field, earning the trust of clients and partners with high-standard delivery results. Looking forward to 2024, the Company will continue to focus on XDC CDMO, advancing the implementation of more projects from multiple dimensions. In addition, relying on the brand influence of the Company in the field of CDMO, it will continue to expand its differentiated competitiveness, continue to build a cutting-edge innovative technology platform, and actively explore other broader fields of drug conjugates to inject sustained growth momentum into the Company. In terms of overseas business development, the Company will continue to strengthen the construction of international quality systems, promote more cooperation with leading international biopharmaceutical companies to increase its market share. At the same time, the Company will further leverage its advantage in production capacity and expand the economies of scale effect, continuously advancing the industrialization of its platform. Through a diversified revenue model that includes CDMO and the commercial sales of launched products, the Company will continue to create value for shareholders and contribute to the cause of human health.

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 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.

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 2023 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 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 C1 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 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 C3 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 2023 and up to the date of this announcement.

USE OF NET PROCEEDS FROM THE SUBSCRIPTIONS AND CHANGE IN USE OF UNUSED NET PROCEEDS

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) ("**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 year ended 31 December 2023, Net Proceeds amounting to RMB197,097 thousand were used 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. As at 31 December 2023, the unused amount of the Net Proceeds amounted to approximately RMB110,356 thousand, and were being kept by the Group as bank deposits.

As disclosed in the Company's announcement dated 17 March 2023, based on a comprehensive and prudent analysis and evaluation of the future commercial value and market sales of TAA013, the Group's self-developed HER2 targeted antibody-drug conjugate, and taking into account the Company's strategic planning, the Group decided to terminate the Phase III clinical trial study and development of TAA013 in China (the "**TAA013 Trial Termination**"). Upon the TAA013 Trial Termination, based on the disease progression and drug availability in respect of certain subjects who remain in the trial, and taking into account the judgment of researchers and the wishes of those subjects, the Group would decide on the provision of appropriate treatment options for those subjects (the "**Subsequent Matters**"). Having considered, among other things, the TAA013 Trial Termination, the Subsequent Matters and the development of the Group, the Board resolved on 15 March 2024 to re-allocate a portion (being RMB30,000 thousand) of the unused Net Proceeds for the Phase III clinical trial of TAA013 to two other purposes as set out in the table below (the "**Re-allocation**"). The Board confirms that there are no material changes in the nature of the business of the Group and considers that the Re-allocation will not have any material adverse impact on the existing business and operations of the Group and is in the best interests of the Company and its shareholders as a whole. Save as the Re-allocation, the Board confirms that there are no other changes to the use of the unused Net Proceeds.

Purpose	**Net Proceeds allocated based on the Circular** *(RMB'000)*	**Used during the year ended 31 December 2023** *(RMB'000)*	**Unused amount as at 31 December 2023 before the Re-allocation** *(RMB'000)*	**Unused amount as at 31 December 2023 after the Re-allocation** *(RMB'000)*	**Expected timing for the full utilization of the unused amount**
For the Phase III clinical trial of TAA013(anti-HER2 ADC, HER2+ advanced breast cancer) and the Subsequent Matters in connection therewith.	63,643	11,970	41,977	11,977	31 December 2024
For capital expenditure on the construction of Global Research and Development Service Center and upgrade of production workshops to expand production capacity and to enhance production efficiency.	141,608	72,489	35,428	50,428	31 December 2025
For the continuous optimization of launched products.	–	–	–	15,000	31 December 2025

A breakdown of the use of the aforesaid Net Proceeds during the year ended 31 December 2023 and an expected timeline for the use of the unused portion (taking into account the Re-allocation) will be disclosed in the 2023 annual 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 year ended 31 December 2023.

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 2023 annual report of the Company and the notice convening the 2024 annual general meeting of the Company will 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 2023 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 2023 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 2023. 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, 15 March 2024

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 Dr. Liu, Weidong; and the independent non-executive directors of the Company are Ms. Hu, Lan, Mr. Chang, Hong-Jen and Dr. Wang, De Qian.