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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 2024

HIGHLIGHTS OF 2024 ANNUAL RESULTS AND MILESTONES:

- The Company's performance exceeded expectations, with revenue for the year exceeding RMB1 billion, reaching RMB1,098,329 thousand, representing a year-on-year increase of 41%. Revenue from sales of products was RMB877,410 thousand, representing a year-on-year increase of 39%, which was mainly attributable to the steady increase in sales volume of Pusintin® (Bevacizumab injection), our core product. Revenue from CDMO/CMO business amounted to RMB207,133 thousand, representing a year-on-year increase of 47%. With continuously enhanced cash-generating capabilities, the net cash from operating activities has been positive for three consecutive years, reaching RMB116,403 thousand in 2024.
- The Group achieved remarkable results in its CDMO strategic transformation. Its sales of self-developed products also increased steadily. In 2024, the Group's financial performance has turned from a loss to a profit for the first time, with a net profit reaching RMB34,757 thousand for the year.

- The CDMO business has demonstrated strong growth potential, with a notable funnel effect. Leveraging cutting-edge technology platforms, the Company has enhanced front-end promotion, resulting in a significant increase in early-stage projects. During the year, the Company secured 58 new projects, 48 of which were ADC projects, reaching a total of 153 projects. During the year, the Company successfully secured two pre-BLA projects, bringing the total number to eight, fully demonstrating the Company's outstanding capability in late-stage CDMO commercialization projects and further strengthening its potential for future revenue expectations. The Group's service backlog on hand amounted to RMB191 million, representing a year-on-year increase of 39%.
- Widely recognized by the industry world-wide, the Company's high-standard quality management system has passed many production site inspections by relevant drug regulatory authorities and GMP compliance inspections in many countries, as well as several GMP inspections by customers and third-party consulting agencies. In 2024 alone, the Company received 38 GMP audits in total, including 7 official GMP audits (3 by foreign authorities and 4 by domestic authorities) and 2 EU QP audits (one of which was passed with zero defects). The Company also obtained GMP certificates from countries such as Colombia, Egypt, and Indonesia. Additionally, the Company obtained the Accreditation of Foreign Manufacturers by the PMDA in Japan, signifying that TOT BIOPHARM's production lines and quality system comply with Japanese pharmaceutical quality and safety standards. Furthermore, the Company assisted its customers in completing inspections by their overseas partnering multinational pharmaceutical companies and other institutions on multiple occasions, and successfully collaborated with its customers in completing the licensing with high recognition.

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 2024 together with comparative figures for the year ended 31 December 2023 as set out in the section headed “Consolidated Financial Statements” of this announcement.

CEO STATEMENT

Dear Shareholders,

Greetings, everyone! On behalf of the Board, it is my privilege to present the annual results for the financial year ended 31 December 2024, as well as an overview of the Company’s various business developments.

Looking back at 2024, the biopharmaceutical industry was marked by unpredictability and a host of challenges. TOT BIOPHARM has stood firm at the forefront, forging ahead with determination and achieving remarkable success. Thanks to the concerted efforts of all employees, the Company has successfully surpassed a critical milestone, with revenue for the year exceeding RMB1 billion and achieving its first full-year profitability.

In recent years, the field of antibody-drug conjugates (ADCs) has experienced rapid global development, with a sustained surge in the research and development of ADC drugs worldwide. Multinational pharmaceutical companies have significantly expanded their investments in this field, resulting in the approval and launch of several blockbuster ADC drugs and a rapidly expanding market size. Particularly in the field of tumor treatment, ADCs have become a focus of global biopharmaceutical innovation due to their precision targeting and potent killing effect. Concurrently, the domestic biopharmaceutical industry has kept pace with global trends, actively promoting the research, development, and industrialization of cutting-edge fields such as ADCs. During the year, the National Medical Products Administration of China (“**NMPA**”) introduced the “Pilot Work Plan for Segmented Production of Biological Products” and the “Announcement on Strengthening the Supervision and Management of Drug Contract Manufacturing (Draft for Comments),” which have created unprecedented development opportunities for players in the biological drug CDMO industry. These policies have vigorously promoted the contract manufacturing of innovative drugs and urgently needed clinical drugs, actively supported the growth of high-caliber CDMO enterprises, and significantly enhanced the industry ecosystem. TOT BIOPHARM demonstrated exceptional foresight in anticipating policy shifts and responded proactively. By leveraging our deep-rooted expertise and technological leadership in biological drugs, we have further consolidated our position as a market frontrunner.

In terms of business expansion, we have consistently deepened our CDMO strategy. On one hand, we have actively intensified our business expansion efforts and strengthened cooperation with both domestic and international pharmaceutical companies. The Company has consistently supported customers in passing inspections by partnering overseas multinational pharmaceutical companies and institutions, successfully facilitating approvals and earning high acclaim. This has solidified the foundation for overseas expansion and steadily facilitated the growth of our global presence. On the other hand, we have intensified our commitment to operational excellence by continuously refining production processes, optimizing capacity utilization, and driving efficiency improvements, ensuring comprehensive fulfillment of customer requirements. Currently, the Company has been equipped with four commercial production lines from international leading brands, ensuring high-standard production for the projects of our customers and enhancing production scheduling flexibility. Through refined internal management and continuous improvement, we have deeply tapped into production capacity potential and flexibly arranged production schedules to accelerate project progress of our customers.

Technological innovation has consistently been the core engine driving TOT BIOPHARM's robust growth. During the year, the Company continued to increase its investment in research and development, with a precise focus on key areas such as antibodies and ADCs, aiming to build and enhance differentiated competitiveness and continuously refine its technology platform architecture. BDKcell™, the newly launched cell line development platform, delivers innovative bioprocessing solutions to our partners. Designed to cultivate high-yield, high-quality, and stable cell lines for biomolecule process development and GMP production, the platform achieves expression levels of up to 12g/L. It has already supported the development of multiple antibodies, significantly improving overall process efficiency and marking a new milestone in the Company's CMC capabilities. DisacLink™, the site-specific conjugation technology platform optimized by us in cooperation with GlycanLink (糖嶺生物), has garnered significant attention from both domestic and international customers, significantly accelerating the development and commercialization of innovative drug conjugates. Furthermore, the Company has actively engaged in multiple strategic cooperation, injecting strong momentum into customers' projects. Through close cooperation with strategic partners such as Beijing Sipuruige Bio (北京斯普瑞格生物), and ChemPion (北京樺冠生物), we have jointly established a biopharmaceutical research and development service platform to synergistically advance ADC drug development and CDMO services, providing clients with diverse and flexible solutions. Leveraging our outstanding advantages in technological innovation, the Company has earned the trust and recognition of a broader customer base, with a notable increase in new CDMO projects. Both the revenue from and the number of ADC projects steadily increased as a percentage of all projects in process, and several pre-BLA projects were progressing in an orderly manner, injecting robust momentum for the sustained and stable growth of the Company.

Quality orientation has always been a core principle for TOT BIOPHARM, and the pursuit of continuous improvement remains an ongoing journey. A robust quality system is not only the core pillar of our operations but also the key to maintaining our leading position in the industry. We have consistently invested in building hardware facilities and fostering quality awareness among our team. Building and maintaining an effective pharmaceutical quality management system that complies with the standards of the NMPA in China, those of FDA in the US and those of GMP in the EU is a core strategic goal of the Company. Recently, TOT BIOPHARM has successfully obtained the Accreditation of Foreign Manufacturers by the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan, which fully demonstrates that our production lines and quality system fully comply with Japanese pharmaceutical quality and safety standards. It has laid a solid foundation for TOT BIOPHARM to enter the Japanese market and deliver high-quality CDMO services. At the same time, the Company has successfully met the stringent audit requirements of numerous customers and regulatory authorities, including projects involving filings in the United States, Europe, and China. Moving forward, TOT BIOPHARM will continue to leverage our skilled R&D and production team, as well as our high-standard production quality management system, to deepen our global strategic layout, enhance our competitiveness in the international market, and fully meet the diverse needs of our global customers.

Looking ahead to 2025, we are confident, focused, and guided by clear objectives. The Company will remain steadfast in its strategic focus on biological drug CDMO services, closely monitor policy developments and seize emerging industry opportunities. In terms of business expansion, we will continue to deepen our presence in overseas markets, strengthen cooperation with leading global pharmaceutical companies, and enhance our international operational capabilities and market share. Committed to excellence, we will optimize service quality and production efficiency to deliver higher-quality and more efficient one-stop biopharmaceutical CDMO services to our customers. In terms of technological innovation, we will continue to ramp up investment, actively explore cutting-edge technologies, and strengthen collaborative partnerships with research institutions. By fostering deeper integration of industry, academia, and research, we aim to continuously enhance our technological innovation capabilities and solidify our core competitiveness. In terms of team building, we will continue to attract and nurture top-tier talent, fostering a more professional, efficient, and innovative workforce.

Meanwhile, the Company will actively fulfill its social responsibilities by closely addressing patient needs and relentlessly striving to deliver more high-quality drugs. Through these efforts, TOT BIOPHARM aims to leverage its expertise and strength to contribute to the advancement of the biopharmaceutical industry.

Thank you all!

Dr. Liu, Jun
Chief Executive Officer and Executive Director

11 March 2025

CONSOLIDATED FINANCIAL STATEMENTS

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

	<i>Note</i>	Year ended 31 December	
		2024 <i>RMB'000</i>	2023 <i>RMB'000</i>
Revenue	3	1,098,329	780,629
Cost of revenue		(315,897)	(206,643)
Research and development expenses		(79,313)	(103,890)
Selling expenses		(606,711)	(441,019)
General and administrative expenses		(81,375)	(68,310)
Net impairment gains/(losses) on financial and contract assets		8,005	(11,481)
Other income – net	4	18,216	17,654
Operating profit/(loss)		41,254	(33,060)
Finance income		3,383	2,974
Finance costs		(9,880)	(5,175)
Finance costs – net		(6,497)	(2,201)
Share of net loss of the joint venture accounted for using the equity method		–	(2,495)
Profit/(loss) before income tax		34,757	(37,756)
Income tax expense	5	–	(1)
Profit/(loss) for the year		34,757	(37,757)
Profit/(loss) is attributable to:			
Equity holders of the Company		34,757	(37,757)
Non-controlling interests		–	–
		34,757	(37,757)
Other comprehensive income:			
Exchange difference on translation		2,199	1,737
Other comprehensive income for the year		2,199	1,737
Total comprehensive income/(loss) for the year		36,956	(36,020)

	<i>Note</i>	Year ended 31 December	
		2024	2023
		<i>RMB'000</i>	<i>RMB'000</i>
Total comprehensive income/(loss) for the year is attributable to:			
Equity holders of the Company		36,956	(36,020)
Non-controlling interests		<u>—</u>	<u>—</u>
		<u>36,956</u>	<u>(36,020)</u>
Earnings/(Loss) per share for the year and attributable to the equity holders of the Company			
– Basic and diluted earnings/(loss) per share (<i>RMB</i>)	<i>6</i>	<u>0.05</u>	<u>(0.05)</u>

CONSOLIDATED BALANCE SHEET

		As at 31 December	
	Note	2024	2023
		RMB'000	RMB'000
ASSETS			
Non-current assets			
Property, plant and equipment		722,586	695,804
Prepayments for property, plant and equipment		1,564	1,803
Intangible assets		7,042	8,839
Investment properties		2,385	2,785
Right-of-use assets		13,968	14,258
Other non-current assets		17,950	9,437
		<u>765,495</u>	<u>732,926</u>
Current assets			
Inventories		108,661	126,009
Other current assets		21,275	49,410
Trade and other receivables	8	157,278	88,152
Prepayments		22,269	18,715
Contract assets		36,200	54,916
Restricted cash		16,338	4,373
Cash and cash equivalents		381,256	351,600
		<u>743,277</u>	<u>693,175</u>
Total assets		<u>1,508,772</u>	<u>1,426,101</u>
EQUITY			
Share capital	10	2,297,499	2,297,499
Other reserves		80,684	72,472
Accumulated losses		(1,648,528)	(1,683,285)
Total equity		<u>729,655</u>	<u>686,686</u>

		As at 31 December	
	<i>Note</i>	2024	2023
		RMB'000	RMB'000
LIABILITIES			
Non-current liabilities			
Borrowings		324,425	302,685
Lease liabilities		177	194
Other non-current liabilities		39,152	54,050
		<u>363,754</u>	<u>356,929</u>
Current liabilities			
Borrowings		69,588	41,600
Trade and other payables	9	310,370	322,934
Contract liabilities		29,410	12,063
Lease liabilities		1,278	1,172
Other current liabilities		4,717	4,717
		<u>415,363</u>	<u>382,486</u>
Total liabilities		<u>779,117</u>	<u>739,415</u>
Total equity and liabilities		<u>1,508,772</u>	<u>1,426,101</u>
Net current assets		<u>327,914</u>	<u>310,689</u>
Total assets less current liabilities		<u>1,093,409</u>	<u>1,043,615</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 Room 1918, 19/F, Lee Garden One, 33 Hysan Avenue, Causeway Bay, 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 for accounting periods beginning on or after
Amendments to HKAS 1	Classification of Liabilities as Current or Non-current	1 January 2024
Amendments to HKAS 1	Non-current Liabilities with Covenants	1 January 2024
Amendments to HKFRS 16	Lease Liability in Sale and Leaseback	1 January 2024
Hong Kong Interpretation 5 (Revised)	Presentation of Financial Statements – Classification by the Borrower of a Term Loan that Contains a Repayment on Demand Clause	1 January 2024
Amendments to HKAS 7 and HKFRS 7	Supplier Finance Arrangements	1 January 2024

The amendments and interpretation listed above did not have any material impact on the amounts recognised in prior periods and are not expected to significantly affect the current or future periods.

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 21 (Amendments)	Lack of Exchangeability	1 January 2025
HKFRS 9 and HKFRS 7 (Amendments)	Classification and Measurement of Financial Instruments	1 January 2026
HKFRS 18	Presentation and Disclosure in Financial Statements	1 January 2027
HKFRS 19	Subsidiaries without Public Accountability: Disclosures	1 January 2027
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	
	2024 RMB'000	2023 RMB'000
Timing of revenue recognition		
At a point in time:		
– Sales of goods	877,410	630,207
– CDMO/CMO	112,102	35,608
– Commission revenue	11,812	7,930
– Others	1,769	532
Over time:		
– CDMO	95,031	105,290
– Others	205	1,062
	<u>1,098,329</u>	<u>780,629</u>

(c) Geographical information

Geographical information of revenue and non-current assets other than financial assets for the years ended 31 December 2024 and 2023 is as follows:

	Year ended 31 December			
	2024		2023	
	Revenue RMB'000	Non-current assets RMB'000	Revenue RMB'000	Non-current assets RMB'000
Mainland China	1,084,416	765,495	780,629	724,934
Others	13,913	–	–	–
	<u>1,098,329</u>	<u>765,495</u>	<u>780,629</u>	<u>724,934</u>

4 OTHER INCOME – NET

	Year ended 31 December	
	2024	2023
	RMB'000	RMB'000
Other income:		
– Government grants (<i>Note</i>)	22,568	17,786
– Rental income of investment properties	333	330
	<u>22,901</u>	<u>18,116</u>
Other losses – net:		
– Net foreign exchange (losses)/gains – net	(3,973)	2,261
– Losses on disposals of property, plant and equipment	(934)	(3,420)
– Net fair value gains on financial assets at FVPL	–	937
– Others	222	(240)
	<u>(4,685)</u>	<u>(462)</u>
Total other income – net	<u>18,216</u>	<u>17,654</u>

Note: There are no unfulfilled conditions or other contingencies attaching to these grants.

5 INCOME TAX EXPENSE

	Year ended 31 December	
	2024	2023
	RMB'000	RMB'000
Current income tax expenses		
– Tax filing difference for prior Year	–	1
Deferred income tax expense	–	–
	<u>–</u>	<u>1</u>

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% (2023: 16.5%) as the Company has no estimated assessable tax profit for the year ended 31 December 2024 (2023: Nil).

(b) Mainland China

No provision for mainland China income tax has been provided for at the rate of 25% or 15% (2023: 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 tax profit for the year ended 31 December 2024.

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 2024 (2023: 15%).

(c) **Taiwan corporate income tax**

No provision for Taiwan corporate income tax has been provided for at the rate of 20% (2023: 20%) as the Group's Taiwan subsidiary has no estimated assessable tax profit for the year ended 31 December 2024.

6 EARNINGS PER SHARE

(a) **Basic earnings per share**

Basic earnings per share is calculated by dividing the profit/(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	
	2024	2023
Profit/(loss) attributable to equity holders of the Company (RMB'000)	34,757	(37,757)
Weighted average number of ordinary shares in issue (<i>thousand</i>)	725,197	725,197
Basic earnings/(loss) per share (RMB)	0.05	(0.05)

(b) **Diluted earnings/(loss) per share**

Diluted earnings/(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 2024, the Company had two categories of potential ordinary shares: the stock options granted to employees and restricted share award scheme (2023: same). For the year ended 31 December 2024, the diluted earnings per share and the basic earnings per share are RMB0.05 (2023: the diluted loss per share and the basic loss per share are RMB0.05).

7 DIVIDEND

No dividend has been paid or declared by the Company during the year (2023: Nil).

8 TRADE AND OTHER RECEIVABLES

	As at 31 December	
	2024	2023
	RMB'000	RMB'000
Trade receivables	157,728	85,964
Other receivables	3,183	6,977
Less: provision for impairment of trade receivables	(1,169)	(175)
Less: provision for impairment of other receivables	(2,464)	(4,614)
Trade and other receivables	157,278	88,152

(a) **Trade receivables**

	As at 31 December	
	2024	2023
	RMB'000	RMB'000
Trade receivables	157,728	85,964

Customers are generally granted with credit terms ranging from 15 to 90 days.

As of 31 December 2024 and 2023, the ageing analysis of the trade receivables based on invoice date is as follows:

	As at 31 December	
	2024	2023
	RMB'000	RMB'000
Within 30 days	62,877	54,628
31 days to 90 days	41,975	31,213
91 days to 180 days	15,740	116
181 days to 270 days	11,943	–
271 days to 360 days	25,193	–
1 year to 2 years	–	7
	157,728	85,964

As at 31 December 2024, the carrying amounts of the Group's trade receivables are denominated in RMB and approximate to their fair values (2023: same).

9 TRADE AND OTHER PAYABLES

	As at 31 December	
	2024	2023
	RMB'000	RMB'000
Accrued promotion expenses	179,223	193,297
Trade payables	43,307	35,710
Staff salaries and welfare payables	33,572	28,668
Payables for purchase of property, plant and equipment	16,222	42,859
Deposits payables	3,110	800
Tax payable	1,800	1,659
Refund liabilities (<i>Note (i)</i>)	119	170
Others	33,017	19,771
	310,370	322,934

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 2024 and 31 December 2023, the ageing analysis of trade payables based on invoice date are as follows:

	As at 31 December	
	2024 <i>RMB'000</i>	2023 <i>RMB'000</i>
Within 3 months	33,836	33,990
3 months to 6 months	4,371	1,287
6 months to 12 months	4,776	255
1 year to 2 years	255	178
2 years to 3 years	69	–
	<u>43,307</u>	<u>35,710</u>

10 SHARE CAPITAL

	Number of ordinary shares issued	Share capital <i>RMB'000</i>
As at 1 January 2023 and 31 December 2023	<u>772,787,887</u>	<u>2,297,499</u>
As at 1 January 2024 and 31 December 2024	<u>772,787,887</u>	<u>2,297,499</u>

(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 2024, 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 (2023: same).

	2024 <i>Shares</i>	2023 <i>Shares</i>	2024 <i>RMB'000</i>	2023 <i>RMB'000</i>
Shares held for employee share scheme	<u>47,590,948</u>	<u>47,590,948</u>	<u>–</u>	<u>–</u>

MANAGEMENT DISCUSSION AND ANALYSIS OF CERTAIN FINANCIAL ITEMS

FINANCIAL REVIEW

Overview

In 2024, the Group recorded an operating revenue of RMB1,098,329 thousand, representing an increase of RMB317,700 thousand, or 41%, from RMB780,629 thousand in 2023. In 2024, the net profit of the Group was RMB34,757 thousand, as compared to a net loss of RMB37,757 thousand in 2023, turning into profit from loss. In 2024, the Group's research and development expenses were RMB79,313 thousand, as compared to RMB103,890 thousand in 2023. In 2024, the Group's general and administrative expenses were RMB81,375 thousand, as compared to RMB68,310 thousand in 2023. In 2024, the Group's selling expenses were RMB606,711 thousand, as compared to RMB441,019 thousand in 2023.

Operating Revenue and Costs

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

In 2024, the Group's revenue from product sales was RMB877,410 thousand, representing an increase of RMB247,203 thousand from RMB630,207 thousand in 2023, which was mainly due to the steady increase in the sales volume of our core product, Pusintin[®], while the corresponding costs also increased accordingly.

In 2024, the Group's revenue from CDMO/CMO business was RMB207,133 thousand, representing an increase of RMB66,235 thousand from RMB140,898 thousand in 2023, primarily attributable to the continuous 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 the enhancement of the Group's CDMO technology platform and the continuous optimization of products.

The Group's research and development expenses in 2024 were RMB79,313 thousand, representing a decrease of RMB24,577 thousand from RMB103,890 thousand in 2023, 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 2024 were RMB606,711 thousand, representing an increase of RMB165,692 thousand from RMB441,019 thousand in 2023, which was mainly attributable to higher personnel and operational costs associated with market expansion activities, as well as increased marketing and promotion expenses in line with the increase in sales of self-developed products.

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 2024 were RMB81,375 thousand, representing an increase of RMB13,065 thousand from RMB68,310 thousand in 2023, which was mainly attributable to the expansion of the Company's scale and the enhancement of its management system.

Net Impairment on Financial and Contract Assets

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

The Group's impairment gains on financial and contract assets in 2024 was RMB8,005 thousand, as compared to impairment losses on financial and contract assets of RMB11,481 thousand in 2023, which was mainly attributable to the recovery of amounts from previous years, which led to the reversal of impairment losses provided.

Other Income – Net

The Group's net other income and losses in 2024 was RMB18,216 thousand, representing an increase of RMB562 thousand from RMB17,654 thousand in 2023, which was mainly attributable to government grants and the impact of fluctuations in foreign currency.

Finance Income

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

The finance income in 2024 was RMB3,383 thousand, representing an increase of RMB409 thousand from RMB2,974 thousand in 2023.

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 2024 were RMB9,880 thousand, representing an increase of RMB4,705 thousand from RMB5,175 thousand in 2023, mainly due to the increase in loans following the milestone payments made in construction projects.

Income Tax Expense

No income tax expense was incurred in 2024, and the Group's income tax expense in 2023 was RMB1 thousand.

Profit for the Year

In light of the above factors, the net profit in 2024 was RMB34,757 thousand, as compared to a net loss of RMB37,757 thousand in 2023, turning into profit from loss.

Net Assets

The Group's net assets as of 31 December 2024 were RMB729,655 thousand, representing an increase of RMB42,969 thousand from RMB686,686 thousand as of the end of 2023, which was mainly attributable to the profit during the current period.

Cash Movement and Source of Funds

As at 31 December 2024, the Group's cash and cash equivalents were RMB381,256 thousand, representing an increase of RMB29,656 thousand from RMB351,600 thousand as at the end of 2023. Such change was mainly attributable to the following reasons:

In 2024, the Group's net cash inflows for operating activities were RMB116,403 thousand, representing an increase of RMB59,972 thousand from RMB56,431 thousand in 2023, which was mainly attributable to the changes in the above-mentioned operating expenses, and the increase in accounts receivable and contract assets related to the progress of customer projects due to the growth of CDMO business. The Group's net cash outflows for investing activities for the current year were RMB122,505 thousand, representing a decrease of RMB41,600 thousand from RMB164,105 thousand as at the end of 2023, 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 RMB34,183 thousand, representing a decrease of RMB4,042 thousand from RMB38,225 thousand as at the end of 2023, which was mainly attributable to the reasonable allocation of internal funds and bank loans in response to the progress of construction projects, which was a result of the optimization of capital structure.

Indebtedness and Key Liquidity Ratio

As at 31 December 2024, the Group had outstanding bank borrowings that amounted to RMB394,013 thousand (31 December 2023: RMB344,285 thousand) and had unutilised bank facilities of RMB299,050 thousand (31 December 2023: RMB265,715 thousand).

As at 31 December 2024, the Group's total liabilities to total assets ratio was 0.5 (31 December 2023: 0.5).

Material Investment

On 9 November 2021, the Group commenced the construction of its 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 2024, the Group incurred expenditure of RMB8,350 thousand in connection with the construction agreement entered into with Shanghai Baoye Group Corp., Ltd., and expenditure of RMB43,489 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 RMB14,821 thousand was incurred by the Group during the year ended 31 December 2024 in connection with such projects.

Save as disclosed above, the Group did not make any material investment during the year ended 31 December 2024.

Material Acquisitions and Disposals

During the year ended 31 December 2024, the Group did not have any material acquisitions and disposals of subsidiaries, consolidated affiliated entities, associates or joint ventures.

Pledge of Assets

As at 31 December 2024, the Group had no pledge of assets.

Contingent Liabilities

As at 31 December 2024, 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 OVERVIEW

In 2024, the policies governing the biopharmaceutical macromolecule CDMO industry showed a positive trend, creating favorable conditions for the development of enterprises. On 24 January, the NMPA released the “Announcement on Optimizing the Drug Marketing Registration Applications for Overseas-Produced Drugs Launched and Planned to be Produced in China (Draft for Comments)”. This initiative significantly benefits China-based CDMO enterprises with high-quality production capabilities, enabling them to integrate into the global supply chain. The policy continues to guide, optimize, and support the transfer of drug production from foreign countries to China, indicating that China-based CDMO enterprises meeting international standards are well-positioned to meet the supply demands of global pharmaceutical companies. The cooperation between overseas customers and leading China-based CDMO enterprises is expected to accelerate, allowing China-based CDMO companies to undertake a larger share of global commercial drug production projects.

This policy development represents a significant growth opportunity for companies like TOT BIOPHARM, which are dedicated to becoming professional CDMO partners in the field of global drug development. It provides policy-level support and assurance for TOT BIOPHARM to further expand its presence in overseas markets and deepen cooperation with international leading pharmaceutical companies.

II PERFORMANCE SUMMARY

TOT BIOPHARM’s impressive performance in 2024 was supported by two major business segments: CDMO services and sales of self-developed products. In terms of CDMO business, the Company possesses whole process expertise spanning research and development, process engineering, clinical trials, registration filings, and commercial production. It has established comprehensive technology platforms for antibodies, proteins, ADCs, and XDCs. In terms of production, TOT BIOPHARM operates multiple state-of-the-art biological drug commercial production lines that integrate the production of antibodies, ADC drug substances (including non-toxic conjugation), and drug products. With antibody production capacity exceeding the ten-thousand-liter scale and continuous production and supply of commercial products, the Company leads in domestic production capabilities. In terms of quality system, TOT BIOPHARM’s quality management system complies with project application requirements in China, the United States, and Europe. It has successfully passed production site inspections for national drug registration and GMP quality management system audits, backed by extensive experience in product registration and inspection. The Company has delivered over 100 antibody, protein, ADC, and XDC projects, providing process development, clinical application, and production services for customers in China, the United States, and Europe. Furthermore, the Company has implemented large-scale purification and single-use ultrafiltration technologies capable of handling kilogram-scale protein production. These innovations significantly mitigate cross-contamination risks and enhance microbial control, ensuring the efficient, stable, and reliable execution of customers’ projects,

as well as their safe delivery. Such differentiated competitiveness will position TOT BIOPHARM as a standout player in the global market. Besides, in terms of sales of self-developed products, the Company's core product, Pusintin® (Bevacizumab injection), has garnered a strong reputation and continued to penetrate the domestic market, steadily increasing its market share. This success lays a solid foundation for the Company's sustainable development. In terms of business expansion in overseas markets, steady progress is being made. Pusintin® is expected to be approved and commercially launched in the first foreign country by 2025, injecting new momentum for the long-term growth of the Company.

As of 31 December 2024:

- The Company's performance exceeded expectations, with revenue for the year exceeding RMB1 billion, reaching RMB1,098,329 thousand, representing a year-on-year increase of 41%.
- Revenue from sales of products was RMB877,410 thousand, representing a year-on-year increase of 39%, which was mainly attributable to the steady increase in sales volume of Pusintin® (Bevacizumab injection), our core product. Revenue from CDMO/CMO business amounted to RMB207,133 thousand, representing a year-on-year increase of 47%. With continuously enhanced cash-generating capabilities, the net cash from operating activities has been positive for three consecutive years, reaching RMB116,403 thousand in 2024.
- The Group achieved remarkable results in its CDMO strategic transformation. Its sales of self-developed products also increased steadily. The Group's financial performance has turned from a loss to a profit, with a net profit reaching RMB34,757 thousand for the year.
- The CDMO business has demonstrated strong growth potential, with a notable funnel effect:
 - Leveraging cutting-edge technology platforms, the Company has enhanced front-end promotion, resulting in a significant increase in early-stage projects. During the year, the Company secured 58 new projects, 48 of which were ADC projects, reaching a total of 153 projects.
 - During the year, the Company successfully secured two pre-BLA projects, bringing the total number to eight, fully demonstrating the Company's outstanding capability in late-stage CDMO commercialization projects and further strengthening its potential for future revenue expectations.
 - The Group's service backlog on hand amounted to RMB191 million, representing a year-on-year increase of 39%.

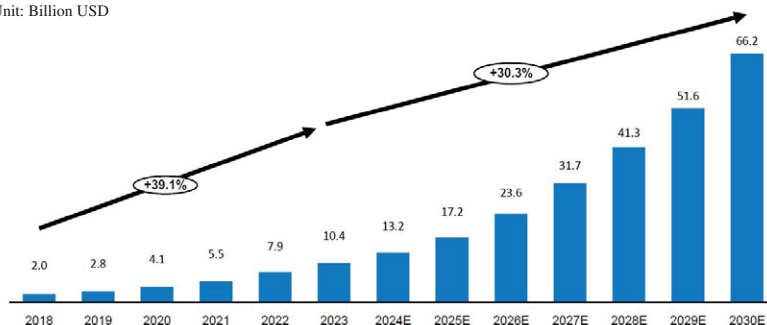
III. ANTIBODY-DRUG CONJUGATES (ADC) ARE ENJOYING A GOLDEN PERIOD OF RAPID DEVELOPMENT

1. Prospects for Drug Conjugates is Promising

The Company achieved remarkable success in the field of bioconjugates drugs in 2024. Global industry enthusiasm continued to surge, marked by the successive approval and launch of new drugs, steady progress in cooperative transactions, and a growing number of ADC molecules in clinical trials demonstrating therapeutic potential. The remarkable performance of ADCs globally underscores the flourishing innovation within this field. Since the launch of the first ADC drug in 2000, a total of 17 ADC products have been approved for launch worldwide, targeting various hematologic cancers and solid tumors, demonstrating significant market potential and attracting numerous innovative pharmaceutical companies. In 2023, the top five ADC drugs by global sales each surpassed USD1 billion, driving explosive growth in the ADC drug market. According to the statistics of Frost & Sullivan, the global market size of ADC drugs increased from USD2.0 billion in 2018 to USD10.4 billion in 2023, representing a CAGR of 39.1%. From 2023 to 2030, the global market size of ADC drugs is expected to maintain the growth momentum with a CAGR of 30.3%, reaching USD66.2 billion by 2030.

Figures: Global ADC Market Size and Prediction, 2018-2030E

Unit: Billion USD



Source: Analysis by Frost & Sullivan

2. ADC CDMO Facilitated the Acceleration of ADC Drug Development

The production and preparation processes for ADC drugs are highly complex, posing unique challenges in manufacturing, quality control, non-clinical research, and clinical research. Such complexity has driven significant outsourcing demand for production and research and development. Currently, the outsourcing rate for ADC production is notably higher than that for other biological drugs. Leveraging economies of scale and expertise, pharmaceutical companies and CDMO companies can cooperate with each other to optimize the production of ADC drugs. The rapid growth of the ADC CDMO market has prompted CDMO companies to actively expand their ADC production capacities, further driving the growth of the ADC drug market. However, validated research and development and industrialization platforms with commercial production experience that integrate antibodies, ADC drug substances and ADC drug products are still very scarce. All these factors have offered good opportunities and prospects for the development of the Company's ADC CDMO business.

Diagram: Global Production Outsourcing Penetration Rate¹ for ADCs and Biological Drugs in 2022

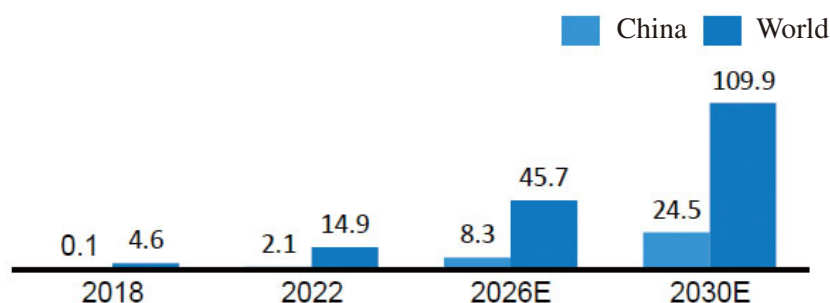


Note 1: Outsourcing penetration rate refers to the actual outsourcing market size divided by the theoretical outsourceable market size for relevant companies.

Source: Analysis by Frost & Sullivan

Diagram: Global and China's Market Size of ADC CDMO Between 2018 and 2030E

100 Million USD



Source: Analysis by Frost & Sullivan

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

1. Highlights of CDMO Performance for the Year

TOT BIOPHARM, leveraging its unparalleled experience in online commercial production and its advanced integrated industrial platform, has accumulated experience in executing over 100 ADC to XDC projects that meet international standards. This underscores the Company's exceptional comprehensive service capabilities.

As of 31 December 2024:

- During the year, revenue from CDMO/CMO was RMB207,133 thousand, representing a year-on-year increase of 47%, of which revenue from ADC projects (including antibody production) accounted for 86%.
- Leveraging cutting-edge technology platforms, the Company has enhanced front-end promotion. During the year, the Company secured 58 new projects, 48 of which were ADC projects.
- The Company has a total of 8 pre-BLA projects, 2 of which were newly added in the year.
- The volume of clinical-stage orders associated with our overseas operations has shown sustained growth. We have assisted our customers in successfully passing inspections by overseas partnering multinational pharmaceutical companies and securing licensing agreements on multiple occasions.
- Due to the high quality of project delivery results, the Company has seen a continuous increase in the number of audits. Among them, multinational pharmaceutical companies have all given positive feedback during their visits, highly recognizing the Company's quality system. Positive customer and regulatory audit results have validated the Company's capabilities in providing services from clinical stage to commercial production stage.

2. The Company's Differentiated Competitiveness in CDMO

– 2.1 *“One-base, end-to-end” industrialization platform with commercial production experience*

TOT BIOPHARM, with the establishment of a “one-stop, one-base, end-to-end” antibody, protein and ADC service platform, has become one of the leading CDMO service companies internationally that can offer one-stop service from development to commercialization of antibody and drug conjugates. Its services covered the whole life cycle of drug development, including antibody process, conjugation process, drug product process

development, analytical method development and validation, as well as pilot production for research and development, and commercial-scale production. The Company has established a quality management system that conforms to commercial production, and has supported the commercial production of several launched products.

TOT BIOPHARM's headquarters and integrated commercial production workshops are located in Suzhou Industrial Park. With a favourable geographical location, an established supply chain, a stable customer base, and a robust talent pool, the Company is equipped to support the whole process of biological drugs and ADC drugs from early development to commercial production, while ensuring a stable supply.

– ***2.2 Quality management system complying with GMP standards in China, the United States and Europe***

TOT BIOPHARM steadfastly adheres to the quality policy of “Quality-oriented, continuous improvement and providing customers with high-quality products and services.” The Company has established a quality management system based on ICH Q10 and six major systems of FDA, adhering to the principle of ALOCA+ on data integrity to meet the requirements in relation to project application and commercial production in China/the United States/the EU. Such increasingly robust quality management system, compliant with China's GMP requirements for commercial production, serves as the cornerstone of TOT BIOPHARM's quality assurance. The system has undergone and successfully passed multiple GMP audits. It is the Company's core strategic goal to continuously maintain an effective pharmaceutical quality management system that complies with the standards of the NMPA in China, those of FDA in the United States and those of GMP in the EU. Widely recognized by the industry at home and abroad, the Company's high-standard quality management system and high-satisfaction project delivery have passed many production site inspections by relevant drug regulatory authorities and GMP compliance inspections in many countries, as well as several GMP inspections by customers and third-party consulting agencies. In 2024 alone, the Company received 38 GMP audits in total, including 7 official GMP audits (3 by foreign authorities and 4 by domestic authorities) and 2 EU QP audits (one of which was passed with zero defects). The Company also obtained GMP certificates from countries such as Colombia, Egypt and Indonesia. Additionally, the Company obtained the Accreditation of Foreign Manufacturers by the PMDA in Japan, signifying that TOT BIOPHARM's production lines and quality system comply with Japanese pharmaceutical quality and safety standards, providing strong support for its expansion into the Japanese market and its ability to deliver high-quality CDMO services.

Furthermore, the Company assisted its customers in completing inspections by their overseas partnering multinational pharmaceutical companies and other institutions on multiple occasions, and successfully collaborated with its customers in completing the licensing with high recognition. In addition, the Company attaches great importance to data integrity to protect the rights and interests of customers and partners, and has invested heavily in its quality system, especially in the implementation of information systems, including the Document Management System (DMS), Enterprise Resource Planning (ERP), Environmental Monitoring System (EMS), VAISALA System, Laboratory Information Management System (LIMS), Electronic Lab Notebook (ELN) and others, which have greatly reduced the risk of data integrity and improved the overall compliance status of the Company. At the same time, the Company has placed a high priority on continuous investment in quality system, including talent recruitment and employee training in quality system. The Company has recruited several key personnel with global perspectives, including the chief technology officer, chief operating officer and vice president of quality. All of them possess extensive experience in working for multinational companies. These key personnel have brought global perspectives to the CDMO business of TOT BIOPHARM and have become advocates for the compliance of the quality system. Meanwhile, the Company has always emphasized the importance of employee training, which includes quality leadership training, compliance awareness training, and training on specific operation of quality system such as inspections (deviations, audit findings, etc.), data integrity, and process validation. Employee training in quality system has enhanced employees' awareness of GMP compliance. They have integrated compliance behaviors into daily business operations. As a result, the Company is able to achieve the mission of benefiting patients around the world with higher quality biological drugs.

– ***2.3 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 – GL-DisacLink™, with an aim to accelerate the development and commercialization of customers' innovative drug conjugates. In terms of CDMO service, TOT BIOPHARM can apply the technology of such platform to drug conjugate related services and further promote the process optimization and commercial amplification of the technology with GlycanLink (糖嶺生物). Owing to its simplicity, efficiency, and broad applicability, this technology has successfully captured significant attention from customers, serving as a powerful driver for promoting front-end projects. TOT BIOPHARM's XDC early-stage research service includes not only the pilot production of samples using conventional conjugation technology, but also the pilot production of sample conjugates using GL-DisacLink® technology. By extending the service from ADC process development to front-end and early vertical integration with the CMC stage,

TOT BIOPHARM can provide customers with a more efficient and more certain development process.

In 2024, TOT BIOPHARM took solid strides in technological innovation and partnership expansion, forging in-depth cooperation with Beijing Sipuruige Bio (北京斯普瑞格生物) and ChemPion (北京樺冠生物). These partnerships introduced the “OS One-Step Conjugation” and HydroTrio technologies, respectively. The “OS One-Step Conjugation” site-specific conjugation technology can effectively enhance research and development efficiency in the development of drug conjugates (ADC/Bioconjugates). By constructing ADC model molecules modified with the “OS One-Step Conjugation” technology, TOT BIOPHARM can comprehensively evaluate their performance across pharmacology, process development, in vitro biological activity, and other parameters. Furthermore, the Company can optimize processes in terms of conjugation efficiency and substrate utilization, as well as scale up processes at the pilot level, thereby enhancing robustness and cost-effectiveness for industrial applications. This capability provides customers with a broader range of technical options for the development of drug conjugates, addressing the growing demand for customized solutions.

The introduction of HydroTrio technology enables the development of drug conjugates with high DAR (Drug-to-Antibody Ratio) values and high homogeneity, which is crucial for enhancing clinical efficacy and market competitiveness of drugs, addressing specific needs in drug development.

Moving forward, TOT BIOPHARM will continue to cooperate with leading industry partners to drive continuous progress and technological innovation in the biopharmaceutical field.

– ***2.4 Flexible and diverse production capacity***

Currently, the Company has four complete commercial production lines (two for antibodies, two for ADC) from international leading brands, including five workshops (including non-toxic coupling workshops) for drug substances and four workshops for drug products. Specifically, the Company has an annual production capacity for 300,000L of drug substances and 30 million vials of drug products for antibodies. The Company has an annual production capacity for 960kg of drug substances and over 5.3 million vials of drug products for ADC. Following the capacity expansion milestones achieved in 2023, the Company has further built up a talent pipeline of experienced CDMO professionals to provide strong support for its projects. The Company has completed the production of drug substances and drug products for ADC projects of dozens of customers. Under the premise of ensuring product quality, the Company has further improved the production capacity and optimized the production technology, with all projects delivered on time. This has earned the Company high recognition from its customers and continuously strengthened its customer relationships. Following the completion and operation of its second high-end commercial production line for ADC drug products, the Company has successfully completed dozens of

batches of projects, including several pre-BLA projects. The Company has a leading ranking among biological drug CDMO industry players in China, and is also a one-stop ADC CDMO provider in China with leading production capacity.

– ***2.5 Further strengthened capabilities of CDMO team***

In 2024, TOT BIOPHARM made significant strides and achieved remarkable progress in team building, contributing to the steady growth of its business. With a team of research and development and industrialization talents with international expertise and rich experience, the Company is committed to building an open and inclusive talent development platform. 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 core members of the senior management team of the Company, with an average of over 15 years of extensive work and management experience in well-known multinational companies, are familiar with the pharmaceutical laws and regulations of Europe, the United States and China, as well as emerging countries. As of 31 December 2024, 75% of the CDMO team members had a bachelor's degree or higher, reflecting the Company's progress in upgrading the team's educational level to meet the rapid growth of CDMO business. In line with the enhanced capabilities of its core business, the number of ADC CDMO team members increased by 17% year-on-year, with 85% of the members holding master's or doctoral degrees. This ensures the high-quality implementation of projects and highlights the Company's significant achievements in attracting and cultivating high-end research and development talents. The Company places a strong emphasis on talent development and the enhancement of team expertise. Through a combination of internal training, external advanced studies, and project practice, the Company has built a high-quality professional team. In 2024, the CDMO team successfully navigated the complexities of multiple challenging projects, delivering exceptional services to clients and earning their high acclaim.

– ***2.6 Corporate reputation***

Leveraging its advantageous background in research and development of new drugs for over ten years, TOT BIOPHARM is equipped with the practical experience in the whole process from drug research and development, marketing filing to commercial production, and has successfully established its biopharmaceutical CDMO business, gaining trust and recognition from industry partners. In 2024, the Company undertook multiple ADC and XDC projects, once again demonstrating its exceptional comprehensive service capabilities and extensive project experience. The successful delivery of the projects, along with the achievement of several late-stage clinical projects, fully demonstrated customers' recognition of TOT BIOPHARM's robust capabilities in delivering late-stage clinical and commercialization projects. This has laid a solid foundation for the medium- and long-term business development of the Company.

V. LAUNCHED PRODUCTS AND R&D PIPELINES

Overall Marketing Strategy of Products

In 2024, TOT BIOPHARM continued to focus on biopharmaceutical CDMO, and concentrate on its core business. By streamlining its pipelines, the Group's research and development expenses of new drugs continued to decrease. Actively promoting the sales of launched products has effectively improved the cash flow of the Company, marking a milestone turnaround to profitability.

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) (“**Zhaoke Ophthalmology**”), 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 was authorised to 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. In January 2025, Zhaoke Ophthalmology-B (6622.HK) announced the positive top-line results from the Phase III clinical trial of TAB014. The clinical trial successfully met its primary endpoints and key secondary endpoints. According to the agreement, 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)							
	TAC020 (new target)	Various solid tumors	Co-development						
			IND authorized by FDA to directly enter Clinical Phase III						
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);		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				

Note: In response to the Company's strategic adjustment to focus on the development of ADC CDMO business, the Company decided to terminate the sales agency of Megaxia in China and completed the return of the relevant rights and interests in the first half of 2024. The related deposits and other payments have been fully recovered.

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: Metastatic colorectal cancer; advanced, metastatic or recurrent non-squamous non-small cell lung cancer; recurrent glioblastoma multiforme; epithelial ovarian cancer; fallopian tube cancer or primary peritoneal cancer; cervical cancer*

Pusintin[®], the core product of the Company in the field of anti-tumor treatment, was approved for launch in 2021. As of 31 December 2024, Pusintin[®] has been approved for the treatment of 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 reach 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) (“**Jixin Pharmaceutical**”), the Company continued to expand the market share of Pusintin[®].

In 2024, the Company continued to implement its differentiated marketing strategies and further consolidated its market position. During the year, the sales of the drug increased by 42% 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 2024, we have initiated the registration applications in 34 overseas countries, and the applications have been accepted by 20 countries. We expect to obtain the first approval from an overseas country in 2025 to penetrate overseas markets.

– *Tazian[®] (Temozolomide capsule)*

- *Indications: Glioblastoma and anaplastic astrocytoma*

Tazian[®] was approved for launch by the 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 2024, the Company has become the supplier in the renewal of centralized procurement by Jiangsu Province, Hebei Province, Beijing, Guangdong Province and Jiangxi Province since the Company was selected as the supplier in ongoing centralized procurement.

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

Commercial Production Bases

TOT BIOPHARM's production base is built to a high standard, with a robust quality management system and commercialization capabilities that comply with international GMP standards. The Company currently has one of the few commercial production lines in China that can produce antibody and ADC drug substances/drug products. It is also one of the few CDMO service companies in the world with a comprehensive industry chain for antibody-drug conjugates. The production base is equipped with a number of complete upstream and downstream production lines. The total production capacity of antibody bioreactors exceeds 20,000L. The workshop for ADC drug substances is equipped with a number of 100L to 500L coupling reaction kettles, reaching a conjugation scale of 5kg/batch. In addition, the GMP-compliant commercial workshops for ADC drug products have a capacity of 6,000 to 50,000 vials/batch, equipped with state-of-the-art production equipment to meet the scale requirements of different project stages. Furthermore, the ADC workshops and filling lines are designed to meet light-shielding requirements, enabling the Company to handle a wider range of bioconjugates drug project needs.

VII. COMMUNICATION WITHIN THE INDUSTRY AND BRAND PROMOTION

In 2024, we continued to enhance our brand presence in biological drug CDMO by leading and organizing multiple industrial cooperation and exchanges. These efforts helped shape our brand image, strengthened the integration of industry resources, and precisely targeted our customer base. With outstanding delivery records and quality, the Company has been highly recognized by customers. By continuously improving service quality, technical capabilities and customer empowerment, TOT BIOPHARM has earned customers' trust and enhanced customer stickiness. TOT BIOPHARM strives to become a leading CDMO company in the fields 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.

Marketing and branding highlights for 2024 are summarized below:

- In April 2024, TOT BIOPHARM was invited to participate in the first Future XDC New Drugs Conference (首屆未來XDC新藥大會) to pursue the future development of XDC industry together with many industry leaders. As a CDMO service company for biological drugs, especially for Ab/ADC/XDC and other drugs, TOT BIOPHARM has established a concrete service result of providing complete nuclide coupling development services for nuclide drug conjugates, and was honored as "Pioneer Enterprise in New Infrastructure for ADC/Nuclide Drugs (ADC/核藥新基建先鋒企業)" at the conference.

- In June 2024, TOT BIOPHARM and BiG (Biomedical Innovation Group) held TOT BIOPHARM – Private Board Meeting on Double Antibody & ADC (東曜－雙抗 & ADC私董會). The founders of new drug research and development, investment partners, clinical physicians and others were specifically invited to engage in a dialogue about the promising next decade for double antibody/ADC development. The event was well-attended, with lively discussions that sparked many insightful exchanges. The guests were deeply impressed by TOT BIOPHARM’s corporate culture, its one-stop CDMO services capabilities, as well as its internationally standardized manufacturing facilities and equipment.



- In June 2024, the inaugural annual conference of the Chinese Biopharmaceutical Association, USA (CBA-China) was successfully held in Suzhou. As a one-stop biological drug CDMO company specializing in antibodies and ADC/XDC, TOT BIOPHARM was invited to participate and showcased its innovative achievements and service capabilities in the ADC field, contributing to the high-quality development of the biopharmaceutical industry. The CBA-China annual conference is a pivotal event for Chinese scientists in the biopharmaceutical field in the United States, playing a critical role in facilitating the recruitment of overseas talent, securing projects, and leveraging international resources. Additionally, TOT BIOPHARM was awarded the CBA-China Corporate Membership Certificate, signifying high recognition of its professional expertise and opening new opportunities for its strategic positioning as well as cooperation and expansion in the global biopharmaceutical industry.

- In September 2024, TOT BIOPHARM exhibited at BioJapan, showcasing its innovative achievements and exceptional services. It engaged in in-depth discussions with global industry leaders, exploring the latest cutting-edge technologies and industry developments, sharing the latest information and industry trends, and fostering practical and commercial cooperation in the global bioindustry field. As a premier event in Japan’s biotech and pharmaceutical fields, BioJapan provided TOT BIOPHARM with a platform to enhance its brand influence in the Japanese and global markets, paving the way for strategic positioning and cooperation opportunities in Japan and the Asia-Pacific region, and further advancing its role in the international biopharmaceutical field.
- In October 2024, as a pioneer in the ADC/drug conjugates field in China, TOT BIOPHARM attended the SAPA-China 2024 Pharmaceutical Industry Conference, where TOT BIOPHARM’s booth attracted numerous industry experts, customers and partners for having exchanges, highlighting its capabilities in the antibodies/ADC/drug conjugates. TOT BIOPHARM showcased cutting-edge technologies and conducted in-depth discussions with global industry participants, promoting innovation and cooperation to shape the future of the industry.



- In November 2024, GlycanLink (糖嶺生物), in collaboration with Kaisi Club (愷思俱樂部) and TOT BIOPHARM, hosted the “ADC & XDC Drug Conjugates Development and Innovation Technology Exchange Conference,” exploring new ideas, technologies, and methods in the research and development of drug conjugates. This exchange conference played a positive role in promoting the GL-DisacLink® technology and further solidified the synergistic benefits of the cooperation between GlycanLink (糖嶺生物) and TOT BIOPHARM in the research and development and production of innovative drugs.

- In November 2024, TOT BIOPHARM had the privilege of attending the 15th World ADC Conference in San Diego, the United States. As a leader in the field of antibody-drug conjugates (ADCs), TOT BIOPHARM collaborated with global industry leaders to explore future innovations and advancements. Recognized as the foremost international event in the development of drug conjugates, the World ADC Conference served as a key platform for TOT BIOPHARM to demonstrate its cutting-edge research and development capabilities and global strategy. This participation not only enhanced TOT BIOPHARM's international brand presence but also strengthened its momentum in global business expansion, underscoring its critical role in advancing innovation and progress in the global ADC field.

VIII. INVESTOR RELATIONS

In 2024, TOT BIOPHARM actively participated in investor relations activities from multiple dimensions, strengthening communication with investors and enhancing its transparency and market influence. As one of the leading biological drug CDMO companies in China, TOT BIOPHARM has attracted significant attention from the capital markets, drawing the interest of numerous securities firms and investment institutions. In the future, TOT BIOPHARM will continue to prioritize effective communication with the capital markets, adhering to the principles of compliance, equality, proactiveness, and integrity. It will actively manage investor relations activities and promptly respond to the demands of the capital markets. 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.



IX. 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.



X. FUTURE PROSPECTS

Based on the remarkable results of the CDMO strategic transformation and the steady increase in sales of self-developed products, TOT BIOPHARM has achieved stable and sustainable cash-generating capabilities.

Looking ahead, our core strategy will be anchored in a global perspective and multi-dimensional deployment to holistically enhance our international competitiveness. By accelerating our expansion into overseas markets, elevating service quality, fortifying our international quality management systems, and deepening strategic cooperation with leading pharmaceutical firms in the world, we aim to further boost our international operational capabilities and global market presence. Concurrently, we will remain steadfast in addressing customer needs, developing a technology platform with distinct competitiveness, particularly by advancing our expertise in the cutting-edge field of antibody-drug conjugates, to cultivate differentiated technological strengths. We are committed to providing customers with comprehensive and diversified technical support spanning from early-stage research and development to commercial production, thereby facilitating the efficient development and industrialization of innovative drugs worldwide. In terms of service quality, with a philosophy of commitment to excellence, we will continue to optimize resource allocation to ensure a seamless alignment between resources and project requirements, thereby comprehensively enhancing our market competitiveness. By attracting and nurturing top-tier professional talent, we will build a core team with international vision and extensive experience, driving the successful execution of high-quality projects through exceptional operational efficiency and project management capabilities, ultimately delivering greater value to our customers.

Furthermore, we will uphold lean management principles to strengthen financial stability, balancing strategic investments with sustainable profit growth while maintaining cash-generating capabilities. Through refined operations and digital management, we will comprehensively improve internal efficiency and profitability, laying a solid foundation for the sustainable development of the Company. Moving forward, we will harness innovation as our driving force, center our efforts on customer satisfaction, and pursue internationalization with determination. We strive to become a trusted partner in the global biopharmaceutical field, contributing more 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 2024, 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 income and consolidated balance sheet and the related notes thereto for the year ended 31 December 2024 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 2024.

EVENTS AFTER THE REPORTING PERIOD

There are no significant events after the end of the reporting period.

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 2024, 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 2024 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**”).

On 15 March 2024, the Board resolved to change the proposed applications of a certain portion of the then unused Net Proceeds (the “**2024 Re-allocation**”). Details of the 2024 Re-allocation were set out in the section headed “Other Information – Use of Net Proceeds from the Subscriptions and Change in Use of Unused Net Proceeds” in the 2023 annual results announcement of the Company dated 15 March 2024.

During the year ended 31 December 2024, 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 (as amended by 2024 Re-allocation).

During the year ended 31 December 2024, such Net Proceeds amounting to approximately RMB72,132 thousand were used, and the unused amount of the Net Proceeds was approximately RMB38,224 thousand as at 31 December 2024. The unused Net Proceeds were kept by the Group as deposits with licensed commercial banks.

In line with the Company’s strategic planning and focus on core business operations, the Board resolved on 11 March 2025, to reallocate a portion (being RMB10,000 thousand) of the unused net proceeds originally designated for ongoing and planned pre-clinical and clinical trials of TAE020 (new target ADC, acute myeloid leukemia) and TAC020 (new target mAb/ recombinant protein, various solid tumors) to other purposes as set out in the table below (the “**2025 Re-allocation**”). The Board confirms that there are no material changes in the nature of the business of the Group and considers that the 2025 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 2025 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 2024 (RMB'000)	Unused amount as at 31 December 2024 before the 2025 Re-allocation (RMB'000)	Unused amount as at 31 December 2024 after the 2025 Re-allocation (RMB'000)	Expected timing for the full utilization of the unused amount (taking into account the 2025 Re-allocation)
To fund ongoing and planned pre-clinical and clinical trials of TAE020 (new target ADC, acute myeloid leukemia) and TAC020 (new target mAb/ recombinant protein, various solid tumors)	32,448	6,736	14,894	4,894	By 31 December 2026
For the continuous development of the Company’s antibody and conjugation technology platform				10,000	By 31 December 2026

A breakdown of the use of the aforesaid Net Proceeds during the year ended 31 December 2024 and an expected timeline for the use of the unused portion (taking into account the 2025 Re-allocation) will be disclosed in the 2024 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 2024.

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 2024 annual report of the Company and the notice convening the 2025 annual general meeting of the Company will be 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 2024 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 2024 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 2024. 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, 11 March 2025

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.