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 2021

HIGHLIGHTS OF 2021 ANNUAL RESULTS AND MILESTONES

- In 2021, our revenue amounted to RMB76,325,000, representing a 239.36% year-on-year increase, mainly attributable to the breakthrough growth of CDMO/CMO business, the revenue from which amounted to RMB53,690,000.
- The National Medical Products Administration granted marketing approvals for three products, including core product bevacizumab injection (Pusintin®), temozolomide capsules (Tazian®), and megestrol acetate oral suspension (Megaxia®).
- We have successfully entered into a number of product promotion collaborations. Through close cooperation with our partners, we are able to quickly introduce our products to the market for the benefit of patients.
- TAA013 (anti-HER2 ADC): Phase III clinical trial is currently underway in over 70 clinical research centers in China, ranking in the top tier in the field of ADC drugs in terms of clinical progress, with patients' enrollment expected to be completed in the first half of 2022.

- TAB014 (anti-VEGF mAb): Phase III clinical trial application (IND) was submitted to and authorized by the United States Food and Drug Administration, thereby exempting us from Phase II clinical trial and permitting Phase III clinical trial to commence directly.

- We carried out construction of the second commercial production line for ADC formulations and deployed ADC pilot production facilities in order to strengthen the competitive edge of our ADC commercial production platform.

- We established a joint venture sales company, Huayao Pharmaceutical (Suzhou) Company Limited, with China Resources Pharmaceutical and Commercial Group in order to realize the transformation of our sales and marketing strategies.

The board (the "**Board**") of directors (the "**Directors**") of TOT BIOPHARM International Company Limited (the "**Company**") hereby announces the audited consolidated financial results of the Company and its subsidiaries (together, the "**Group**", "**TOT BIOPHARM**", "**we**" or "**us**") for the year ended 31 December 2021 together with comparative figures for the year ended 31 December 2020 as set out in the section headed "Consolidated Financial Statements" section of this announcement.

STATEMENT OF CHIEF EXECUTIVE OFFICER

Dear Shareholders,

The year of 2021 marked TOT BIOPHARM's entry into its second decade, and it was also a year in which all employees of TOT BIOPHARM made great efforts to achieve fruitful results. On behalf of the Board, I would like to express my sincere gratitude to our shareholders and investors for their support towards the Group's development over the years, and hereby announce the annual results of the Group for the year of 2021.

INDUSTRY AND BUSINESS REVIEW

With the COVID-19 pandemic sweeping the world and the issuance of guidance for the 14th Five-Year Plan for the pharmaceutical industry by the Ministry of Industry and Information Technology, the construction of a "Healthy China" is in full swing, and a new round of technological evolution and industrial integration in the Chinese pharmaceutical market is imperative. With its base in China and its global outlook, TOT BIOPHARM actively seized the opportunities arising from the rapid development of the pharmaceutical industry, optimized the allocation of market resources, and moved towards the goal of differentiated and innovative development. In 2021, we accelerated the commercialization of our key products, promoted the research and development of our core ADC product pipelines, and vigorously expanded into the CDMO market to further highlight our core competitiveness. We successfully reached our established milestones and we were committed to our strategic transformation objectives in order to lay the foundation for the next phase of rapid development of the Company.

In 2021, the Group's revenue was RMB76,325,000, representing an increase of 239.36% compared with RMB22,491,000 in 2020, of which revenue from CDMO/CMO business was RMB53,690,000. In adherence to the Company's strategic development defensive line, we continued to focus on R&D in key areas, optimize our resource allocation, and control our expenses for non-core and early-stage R&D projects. In 2021, our research and development expenses amounted to RMB214,699,000, representing a decrease of 8.72% compared with RMB235,196,000 of 2020. The research and development expenses were mainly attributable to the Phase III clinical study of the ADC drug TAA013 and the decrease in research and development expenses was due to the successful completion of the Phase III clinical study of the bevacizumab injection TAB008 (Pusintin®)which led to its commercialization during the year.

In 2021, we promoted the commercialization of our products and enhanced the accessibility of our drugs.

The Company's first self-developed biological drug, bevacizumab injection (TAB008; Pusintin®), was approved for marketing. We successively entered into an exclusive marketing partnership with Jiangxi Jixin Pharmaceutical Co., Ltd. (江西濟鑫醫藥有限公司) for the Chinese market, and a commercialization license agreement with Kexing Biopharm Co., Ltd. (科興生物製藥股份有限公司) (688136.SH) for overseas emerging markets. This is the first product of the Company to be commercialized overseas.

The Company has also received marketing approval for the chemical drug temozolomide capsules (TOZ309, Tazian®), and has completed the application for inclusion in provincial online procurement platforms and also entered into a marketing partnership with Jiangxi Jixin Pharmaceutical Co., Ltd. for the Chinese market to fully prepare for centralized procurement contract renewal in 2022.

Megestrol acetate oral suspension (TOM218; Megaxia®) has also been approved for marketing and on 1 March 2022, Frontier Biotechnologies Inc. (前沿生物藥業(南京)股份有限公司) (688221.SH) was granted the marketing promotion license in the field of AIDS to promote the accessibility of the drug in the Chinese market.

In 2021, we continued to promote the development of core products and remained in the top tier of ADC drug field.

The development of ADC drugs has received significant attention from the market. TAA013, an anti-HER2 targeted antibody drug conjugate self-developed by TOT BIOPHARM, is currently under phase III clinical study in over 70 clinical centers in China, being the T-DM1 ADC drug with the fastest clinical progress in China and ranking in the top tier in terms of R&D progress among the ADC drugs.

In 2021, we accelerated the expansion of one-stop innovative drugs CDMO business to provide effective solutions for innovative drugs development.

With an eye on future developments and in the face of international and domestic CDMO market opportunities, TOT BIOPHARM fully leveraged its commercial production platforms and technology platforms and integrated its industry resources to achieve encouraging results in its CDMO business, with new orders exceeding RMB100 million in 2021 and a significant surge in the number of customers and orders. The Company has established a professional CDMO management team and an independent and complete management system to empower its business partners and accelerate the development and production of innovative drugs. At the same time, the Company has entered into a strategic cooperation with BrightGene Bio-Medical Technology Co., Ltd. (博瑞生物醫藥(蘇州)股份有限公司) (688166.SH) to further strengthen our one-stop CDMO service platform through the formation of this solid alliance.

In 2021, we consolidated our commercial production advantages and improved the flexibility of our production capacity and production line.

TOT BIOPHARM has devoted great efforts to developing and improving its production capacity to meet the demand of different scales of production for small trials, pilot tests and commercialization. At present, we have completed the construction of a commercial ADC production plant, which encompasses a workshop for mAb substances and formulations as well as production facilities for ADC drug substance and freeze-dried formulations. It is expected that by the first half of 2022, the production capacity of our commercial production base for biological drugs will reach around 20,000 liters, which will realize the high-quality commercial production of innovative drugs. At the same time, our rational planning of production facilities has created ADC and mAb production lines that can meet the needs of diverse and flexible pilot tests and commercialization, further enhancing our competitive advantages of commercial production capacity and empowering our business partners to accelerate the development of biological drugs for commercial mass production.

In 2021, we focused on enhancing our integrated strengths in technology R&D and led our development with innovation.

Leveraging our location in the biomedical industry hub of Suzhou Industrial Park, TOT BIOPHARM launched the construction of its global R&D center on 9 November 2021 under the guidance of the Group's regional positioning and strategic planning. The global R&D center will have a total gross floor area of 25,000 square meters and will be equipped with functions such as early-stage R&D, process development, quality control and head office. The completion of the global R&D center will further enhance our strengths in innovative drug process development, deepen TOT BIOPHARM's leading position in the field of ADC drugs, and further strengthen the functions of the Group's global headquarters and its corporate brand image.

In 2021, we continued to practice good corporate governance and organizational development to safeguard the Company's sustainable operation.

With all the changes in the external environment, society and the industry, all personnel of TOT BIOPHARM have continued to cultivate their skills and capabilities. They are fully aware of the importance of innovation and development as well as social responsibility. In 2021, the Board established the "Strategy and ESG Committee" to better promote the healthy development of the Company and the industry. In accordance with the Company's strategic plan, we have further strengthened our organization and team-building in alignment with the Company's key businesses, and have optimized the organization of non-core businesses such as chemical drugs and marketing, thereby driving the Company into the next decade of healthy, rapid and sustainable development.

In 2021, with the increasing participation of Chinese pharmaceutical companies in the fight against the global pandemic, we provided CDMO services for COVID-19 neutralizing antibodies project of Jiangxi Jemincare Group Co., Ltd. (江西濟民可信集團有限公司), and completed the delivery of the project 1.5 months ahead of schedule. We also assisted Kintor Pharmaceutical Limited (開拓藥業有限公司) (9939.HK) by providing technical services and support for the clinical trials in respect of proxalutamide conducted simultaneously in countries such as Brazil and the United States against COVID-19 indications.

OUTLOOK

To usher in a new era in the Year of Tiger, we shall seize every opportunity to shine in the future! In 2022, all personnel of TOT BIOPHARM will advance with perseverance and strive to continue our mission, always uphold the Company's vision of "improving the well-being and quality of life of cancer patients around the world with innovative technologies", and work closely with our industrial partners to contribute to the innovative development of China's pharmaceutical industry!

Dr. Liu, Jun
Chief Executive Officer and Executive Director

24 March 2022

CONSOLIDATED FINANCIAL STATEMENTS

CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS

For the year ended 31 December 2021

	Note	Year ended 31 December	
		2021	2020
		RMB'000	*RMB'000*
Revenue	*3*	**76,325**	22,491
Cost of revenue		**(48,851)**	(6,961)
Research and development expenses		**(214,699)**	(235,196)
Selling expenses		**(22,849)**	(25,953)
General and administrative expenses		**(56,336)**	(46,855)
Other income		**167**	–
Other gains – net		**6,543**	3,802
Operating loss		**(259,700)**	(288,672)
Finance income		**969**	1,880
Finance costs		**(2,468)**	(1,706)
Finance (costs)/income – net		**(1,499)**	174
Share of net loss of the joint venture accounted for using the equity method		**(17)**	–
Loss before income tax		**(261,216)**	(288,498)
Income tax expense	*4*	**–**	–
Loss for the year and attributable to the equity holders of the Company		**(261,216)**	(288,498)
Other comprehensive loss:			
Items that will not be reclassified to profit or loss			
Changes in the fair value of equity instruments at fair value through other comprehensive income		**326**	85
Items that may be reclassified to profit or loss			
Exchange difference on translation		**(1,282)**	(3,339)
Other comprehensive loss for the year, net of tax		**(956)**	(3,254)
Total comprehensive loss for the year and attributable to the equity holders of the Company		**(262,172)**	(291,752)
Loss per share for the year and attributable to the equity holders of the Company			
– Basic and diluted losses per share *(RMB)*	*5*	**(0.46)**	(0.51)

CONSOLIDATED BALANCE SHEET
As at 31 December 2021

	Note	As at 31 December 2021 RMB'000	2020 RMB'000
ASSETS			
Non-current assets			
Property, plant and equipment		**307,668**	290,367
Prepayments for property, plant and equipment		**55,759**	416
Right-of-use assets		**15,733**	20,639
Investment properties		**3,583**	–
Intangible assets		**5,123**	3,229
Investments accounted for using the equity method		**1,483**	–
Financial assets at fair value through other comprehensive income		**–**	8,076
Other non-current assets		**14,951**	69,229
		404,300	391,956
Current assets			
Inventories		**29,558**	8,114
Trade and other receivables	*7*	**15,032**	5,851
Prepayments		**16,754**	8,827
Contract assets		**11,952**	902
Cash and cash equivalents		**152,805**	225,533
Other current assets		**79,862**	–
		305,963	249,227
Total assets		**710,263**	641,183
EQUITY			
Share capital	*8*	**1,892,906**	1,874,438
Other reserves		**37,797**	49,503
Accumulated losses		**(1,595,612)**	(1,341,584)
Total equity attributable to the equity holders of the Company		**335,091**	582,357

	Note	As at 31 December 2021 RMB'000	2020 RMB'000
LIABILITIES			
Non-current liabilities			
Borrowings		**59,775**	–
Lease liabilities		**1,136**	6,083
Other non-current liabilities		**53,453**	–
		114,364	6,083
Current liabilities			
Borrowings		**146,191**	–
Trade and other payables	*9*	**86,238**	42,316
Contract liabilities		**22,199**	9,104
Lease liabilities		**1,463**	1,323
Other current liabilities		**4,717**	–
		260,808	52,743
Total liabilities		**375,172**	58,826
Total equity and liabilities		**710,263**	641,183
Net current assets		**45,155**	196,484
Total assets less current liabilities		**449,455**	588,440

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 Level 54, Hopewell Centre, 183 Queen's Road East, 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 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

The consolidated financial statements of the Group have been prepared in accordance with the Hong Kong Financial Reporting Standards ("**HKFRSs**") issued by HKICPA and requirements of the Companies Ordinance (Chapter 622 of the Laws of Hong Kong).

The consolidated financial statements have been prepared under the historical cost convention, as modified by the revaluation of financial assets and financial liabilities at fair value through profit or loss and financial assets at fair value through other comprehensive income, 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.

(a) Adoption of amendments to standards and interpretations

The Group has adopted the following amendment to standards and interpretations which are mandatory for the year ended 31 December 2021:

		Effective for annual periods beginning on or after
Amendments to HKFRS 9, HKAS 39, HKFRS 7, HKFRS4 and HKFRS 16	Interest Rate Benchmark Reform – Phase 2 (amendments)	1 January 2021

The adoption of these amendments to standards and interpretations did not have any impact on the consolidated financial statements or result in any significant changes in the Group's significant accounting policies.

(b) New standards and amendments to standards 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 year are as follows:

Standards	Key requirements	Effective for accounting periods beginning on or after
HKFRS 16 (Amendments)	Covid-19-related Rent Concessions	1 April 2021
Annual Improvements to HKFRS Standards 2018–2020		1 January 2022
Amendments to HKAS 16	Property, Plant and Equipment: Proceeds before intended use	1 January 2022
Amendments to HKFRS 3	Reference to the Conceptual Framework	1 January 2022
Amendments to HKAS 37	Onerous Contracts – Cost of Fulfilling a Contract	1 January 2022
AG 5 (Revised)	Merger Accounting for Common Control Combinations	1 January 2022
Amendments to HKAS 1	Classification of liabilities as current or non-current	1 January 2023
HKFRS 17	Insurance Contracts	1 January 2023
Amendments to HKAS 1 and HKFRS Practice Statement 2	Disclosure of Accounting Policies	1 January 2023
Amendments to HKAS 8	Definition of Accounting Estimates	1 January 2023
Amendments to HKAS 12	Deferred Tax related to Assets and Liabilities arising from a Single Transaction	1 January 2023
HK Int 5 (2020)	Presentation of Financial Statements – Classification by the Borrower of a Term Loan that Contains a Repayment on Demand Clause	Applied when an entity applies Amendments to HKAS 1
HKFRS 10 and HKAS 28	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture (amendments)	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 engaged in the research, development and licensing of self-developed biological drug. The outcome of the Group's research and development activities will be given preference to be used by the Group for its own commercialization. There is one team managing and operating all revenue streams. Accordingly, management considers there is only one segment and hence no segment information is presented.

(b) The amount of each category of revenue is as follows:

	Year ended 31 December	
	2021	2020
	RMB'000	*RMB'000*
Timing of revenue recognition		
At a point in time:		
– CDMO/CMO	**9,003**	–
– Commission revenue	**8,673**	14,703
– Revenue from license granted	**5,943**	–
– Sales of goods	**6,129**	521
– Others	**96**	45
Over time:		
– CDMO/CMO	**44,687**	6,423
– Others	**1,794**	799
	76,325	22,491

(c) Geographical information

Geographical information of revenue and non-current assets other than financial assets for the years ended 31 December 2021 and 2020 is as follows:

	Year ended 31 December			
	2021		2020	
	Revenue	**Non-current assets**	Revenue	Non-current assets
	RMB'000	***RMB'000***	*RMB'000*	*RMB'000*
Mainland China	**70,442**	**389,062**	22,491	314,275
Others	**5,883**	**458**	–	478
	76,325	**389,520**	22,491	314,753

(d) Information about major customers

The major customers which contributed more than 10% of the total revenue of the Group for the years ended 31 December 2021 and 2020 are listed as below:

	Year ended 31 December	
	2021	2020
	RMB'000	*RMB'000*
Customer A	**21,006**	–
Customer B	**18,478**	–
Customer C	**8,673**	14,703
Customer D	**7,737**	799
Total	**55,894**	15,502

4 INCOME TAX EXPENSE

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

(a) Hong Kong

No provision for Hong Kong profits tax has been provided for at the rate of 16.5% (2020: 16.5%) as the Company has no estimated assessable profit.

(b) Mainland China

No provision for Mainland China income tax has been provided for at a rate of 25% or 15% (2020: 25% or 15%) pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the "**CIT Law**"), as the Group's PRC entities have no estimated assessable profit.

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

(c) Taiwan corporate income tax

No provision for Taiwan corporate income tax has been provided for at a rate of 20% (2020: 20%) as the Group's Taiwan subsidiary has no estimated assessable profit.

5 LOSS PER SHARE

(a) Basic loss per share

Basic loss per share is calculated by dividing the loss of the Group attributable to owners of the Company by weighted average number of ordinary shares issued during the year.

	Year ended 31 December	
	2021	2020
	RMB'000	*RMB'000*
Loss attributable to equity holders of the Company *(RMB'000)*	**(261,216)**	(288,498)
Weighted average number of ordinary shares in issue (thousand)	**573,360**	570,334
Basic loss per share (RMB)	**(0.46)**	(0.51)

(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 2021, the Company had one category of potential ordinary shares: the stock options granted to employees (2020: same). As the Group incurred losses for the years ended 31 December 2021 and 2020, 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 2021 and 2020 is the same as basic loss per share of the respective years.

6 DIVIDEND

No dividend has been paid or declared by the Company or the companies now comprising the Group during the year (2020: Nil).

7 TRADE AND OTHER RECEIVABLES

	As at 31 December	
	2021	2020
	RMB'000	*RMB'000*
Trade receivables	**11,735**	1,536
Other receivables	**3,297**	4,315
Trade and other receivables	**15,032**	5,851

Trade receivables

	As at 31 December	
	2021	2020
	RMB'000	*RMB'000*
Trade receivables	**11,735**	1,536

Customers are generally granted with credit terms ranging from 15 to 60 days.

As of 31 December 2021 and 2020, the ageing analysis of the trade receivables based on invoice date is as follows:

	As at 31 December	
	2021	2020
	RMB'000	*RMB'000*
Within 30 days	**1,336**	1,218
31 days to 90 days	**10,399**	318
	11,735	1,536

8 SHARE CAPITAL

Issued:

	Number of ordinary shares	Share capital *RMB'000*
As at 1 January 2020 and 31 December 2020 *(Note(a))*	570,000,000	1,874,438
Issue of shares for 2020 Restricted Share Award Scheme *(Note(a))*	30,466,697	–
As at 31 December 2020	600,466,697	1,874,438
As at 1 January 2021	600,466,697	1,874,438
Issue of shares upon exercise of share options *(Note (b))*	1,062,800	3,249
Increase in share capital upon receipt of the grant consideration under 2020 Restricted Share Award Scheme *(Note(c))*	–	15,219
Issue of shares for 2021 Restricted Share Award Scheme *(Note(d))*	13,700,000	–
As at 31 December 2021 *(Note(d))*	615,229,497	1,892,906

Note (a) On 28 December 2020, the Company allotted and issued 30,466,697 ordinary shares ("**award shares**") to certain trustees at a subscription price of zero under the Company's Restricted Share Award Scheme ("**2020 Restricted Share Award Scheme**"). These award shares are within the Company's control until the shares are vested to the participants and hence are considered as treasury shares in substance.

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

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

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

As at 31 December 2021, a total of 40,032,558 ordinary shares are within the Company's control until the shares are vested to the participants and hence are considered as treasury shares in substance.

9 TRADE AND OTHER PAYABLES

	As at 31 December	
	2021	2020
	RMB'000	*RMB'000*
Trade payables	**28,214**	18,006
Staff salaries and welfare payables	**19,898**	11,405
Deposits payables *(Note (i))*	**10,000**	–
Payables for purchase of property, plant and equipment	**6,457**	5,752
Refund liabilities *(Note (ii))*	**5,699**	–
Others	**15,970**	7,153
	86,238	42,316

Note (i) In December 2020, the Group entered into an exclusive sales promotion agreement with a third party. For the year ended 31 December 2021, the Group received deposits of RMB10,000,000.

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

As at 31 December 2021 and 2020, the ageing analysis of trade payables based on invoice date are as follows:

	As at 31 December	
	2021	2020
	RMB'000	*RMB'000*
Within 3 months	**27,037**	17,537
3 months to 6 months	**507**	220
6 months to 12 months	**160**	183
1 year to 2 years	**510**	66
	28,214	18,006

10 SUBSEQUENT EVENTS

No major subsequent events have occurred since the end of the year and up to the date of this announcement.

MANAGEMENT DISCUSSION AND ANALYSIS OF CERTAIN FINANCIAL ITEMS

OVERVIEW

In 2021, the Group recorded an operating revenue of RMB76,325,000 and a net loss of RMB261,216,000, as compared to an operating revenue of RMB22,491,000 and a net loss of RMB288,498,000 in 2020. The Group's research and development expenses in 2021 were RMB214,699,000, as compared to RMB235,196,000 in 2020. The Group's general and administrative expenses in 2021 were RMB56,336,000, as compared to RMB46,855,000 in 2020. The Group's selling expenses in 2021 were RMB22,849,000, as compared to RMB25,953,000 in 2020.

OPERATING REVENUE AND COST OF REVENUE

The Group's diversified revenue mainly includes revenue for providing CDMO and CMO services, revenue from royalties and commissions for marketing services from our strategic business partners, etc.

The Group's revenue from CDMO and CMO services in 2021 was RMB53,690,000, representing an increase of RMB47,267,000 from RMB6,423,000 in 2020, primarily attributable to increase in orders brought by our strategic expansion of CDMO and CMO business in the current year. As a result, costs for raw materials, labor and production, etc. also increased.

The Group's revenue from royalties in 2021 was RMB5,943,000 (2020: Nil), primarily attributable to the milestone payment received from a project.

The Group's commission revenue in 2021 was RMB8,673,000, representing a decrease of RMB6,030,000 from RMB14,703,000 in 2020, primarily attributable to the decrease in sales of distributed product S-1 caused by the national volume-based procurement policy.

RESEARCH AND DEVELOPMENT EXPENSES

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

The Group's research and development expenses in 2021 were RMB214,699,000, representing a decrease of RMB20,497,000 from RMB235,196,000 in 2020, mainly attributable to the absence of related expenses for clinical trials in 2021 subsequent to the Company's completion of the Phase III clinical trial of TAB008 project in the second half of 2020.

SELLING EXPENSES

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

The Group's selling expenses in 2021 were RMB22,849,000, representing a decrease of RMB3,104,000 from RMB25,953,000 in 2020, mainly due to the adjustment of sales strategies which resulted in a decrease in related expenses.

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 2021 were RMB56,336,000, representing an increase of RMB9,481,000 from RMB46,855,000 in 2020, primarily attributable to increase in costs incurred for structural reform, enhancement of compliance management, and human resources and administrative affairs, etc.

FINANCE INCOME

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

The finance income in 2021 was RMB969,000, representing a decrease of RMB911,000 from RMB1,880,000 in 2020, mainly attributable to increase in operation activities. In addition, the interest income on the principal-guaranteed structured deposits previously placed with licensed commercial banks was recorded as other income instead of finance income.

FINANCE COSTS

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

The Group's finance costs in 2021 were RMB2,468,000, representing an increase of RMB762,000 from RMB1,706,000 in 2020, primarily attributable to increase in interest expense as a result of the banking facilities being utilized by the Group since mid-2021.

INCOME TAX EXPENSE

The Group did not incur any income tax expense in 2021 and 2020 as the Group did not generate any taxable income during these two years.

LOSS FOR THE YEAR

In view of the abovementioned factors, the Group recorded a net loss of RMB261,216,000 in 2021, representing a decrease of RMB27,282,000 from RMB288,498,000 in 2020.

NET ASSETS

The Group's net assets as at 31 December 2021 were RMB335,091,000, representing a decrease of RMB247,266,000 from net assets of RMB582,357,000 as at 31 December 2020, primarily attributable to the net loss recorded for the current year.

CASH MOVEMENT AND SOURCE OF FUNDS

As at 31 December 2021, the Group's cash and cash equivalents were RMB152,805,000, representing a decrease of RMB72,728,000 from RMB225,533,000 as at 31 December 2020, mainly attributable to cash inflows and outflows for operating loss, capital expenditures and the taking out of bank borrowings, etc.

In 2021, the Group's net cash outflows for operating activities were RMB177,137,000, representing a decrease of RMB85,979,000 from net cash outflows of RMB263,116,000 in 2020, primarily attributable to decrease in net loss in the current year and the change in working capital. The Group's net cash outflows from investing activities were RMB108,393,000, as compared to net cash inflows of RMB12,526,000 in 2020, primarily attributable to the placement of more principal-guaranteed structured deposits with licensed commercial banks during the prior period. The Group's net cash inflows for financing activities were RMB214,082,000, as compared to net cash outflows of RMB61,707,000 in 2020, primarily attributable to the taking out of new bank borrowings by the Group in 2021 as opposed to repayment of borrowings by the Group in the previous year.

MANAGEMENT DISCUSSION AND ANALYSIS OF CERTAIN ASPECTS OF OUR BUSINESS

INDUSTRY AND COMPANY PROFILE

Alongside the new stage of rapid development of the domestic pharmaceutical market, technological revolution and industrial integration have accelerated, thus providing a vast number of cancer patients in China with more diversified and affordable treatment alternatives and greatly improving the health of the Chinese people. According to a report by Frost & Sullivan, the size of the Chinese oncology drugs market reached US$28.6 billion in 2020, and is expected to reach US$60.3 billion in 2025, representing a compound annual growth rate of 16.1%, which is substantially higher than that of other regions around the world for the same period, including the United States.

In 2021, in line with the development of the international and domestic pharmaceutical markets, TOT BIOPHARM actively adjusted its strategic planning and fully capitalized on its competitive edges with the aim of becoming a leader of the ADC market in China. The Company strengthened its R&D and industrial planning for ADC drugs and achieved new breakthroughs in the field of CDMO for innovative drugs. With the marketing approvals for three products granted by the National Medical Products Administration ("**NMPA**"), namely bevacizumab injection (TAB008; Pusintin®), temozolomide capsules (TOZ309; Tazian®) and megestrol acetate oral suspension (TOM218; Megaxia®), the Company successfully launched these products and entered into strategic marketing partnerships with renowned pharmaceutical companies in China. The Company also formed a strategic cooperation with Kexing Biopharm Co., Ltd. (科興生物製藥股份有限公司) (688136.SH) ("**Kexing Biopharm**") for the commercial licensing of Pusintin® in overseas markets, thereby strengthening TOT BIOPHARM's presence in domestic and international markets.

Following the reform and development trend of state policies for the pharmaceutical industry, national volume-based procurement and medical insurance negotiation for innovative drugs became normalized, resulting in the continued expansion of the National Reimbursement Drug List. The Group joined hands with China Resources Pharmaceutical and Commercial Group International Trade Company Limited (華潤醫藥商業集團國際貿易有限公司) ("**China Resources Pharmaceutical and Commercial Group**") to actively promote the revolution of our business and operating model for oncology drugs, to explore the innovative development of the oncology drugs market, and to incorporate our existing sales team into the joint venture, namely Huayao Pharmaceutical (Suzhou) Company Limited (華曜醫藥(蘇州)有限公司) ("**Huayao Pharmaceutical**"), thereby reasonably controlling our marketing expenses and upgrading the operational efficiency of the Company as a whole.

KEY MILESTONES AND BUSINESS PROGRESS

- **Updated Product Pipelines**

In 2021, TOT BIOPHARM focused on advancing the R&D progress of its main product pipelines at the late clinical stage, with three products approved for launch. The Group also prioritized the Phase III clinical trial of TAA013. Two self-developed products were approved for launch by the NMPA, including the bevacizumab injection (TAB008; Pusintin®) on 30 November and the chemical drug temozolomide capsules (TOZ309; Tazian®) in May. In addition, an imported in-licensed drug named megestrol acetate oral suspension (TOM218; Megaxia®) was also approved for launch in May. Meanwhile, along with the strategic adjustment of the Company, drug candidates at the early clinical stage as well as non-core product pipelines, including chemical drugs and liposome drugs, were optimized to converge the Group's advantages and resources so as to enhance its core competitiveness.

Optimization of pipelines

Type	Drug Candidate	Indication(s)	Preclinical	Clinical Phase I	Clinical Phase II	Clinical Phase III	NDA	Launched
Launched	TAB008 (anti-VEGF)	Non-squamous non-small cell lung cancer (nsNSCLC), metastatic colorectal cancer (mCRC), glioblastoma multiforme (GBM), hepatocellular carcinoma (HCC), ovarian cancer (OC), cervical cancer (CC)						
	TOZ309 (temozolomide)	Malignant brain tumor						
Antibody drug conjugate	TAA013 (anti-HER2)	HER2+ breast cancer						
	TAE020 (new target)	Acute myeloid leukemia						
Monoclonal antibody/ Recombinant protein	TAB014 (anti-VEGF)	Wet age-related macular degeneration (wAMD)						
	TAC020 (new target)	Various solid tumors						
	TAY018 (anti-CD47)	Non-Hodgkin's lymphoma, myelodysplastic syndrome, acute myelogenous leukemia, solid tumors						
Oncolytic virus	TVP211 (genetically modified vaccinia virus)	Solid tumors						
Liposome chemical drug	TID214 (liposomal docetaxel)	Solid tumors						
	TIO217 (liposomal oxaliplatin)	Gastrointestinal tumors						
Chemical drug	TOM312 (megestrol acetate)	Cancer and HIV-associated cachexia						
	TIC318 (carboplatin)	Epithelial-derived ovarian cancer, small-cell lung cancer, head and neck squamous cell carcinoma, etc.						
	TEP118 (modified version of hyaluronidase)	Biliary cancer, gallbladder tumors, metastatic cancer, non-small cell lung cancer (NSCLC), gastric cancer						

ZHAOKE 兆科

IND authorized by FDA to directly enter Phase III clinical trial

Cooperative development

Launched in Taiwan with ANDA submitted in mainland China

- **Drug Development Partnerships**

In respect of cooperation for the R&D of innovative oncology drugs, TOT BIOPHARM launched its collaborative platform to facilitate global strategic cooperation in the joint R&D of innovative target antibody drugs with HBM Holdings Limited (和鉑醫藥控股有限公司) (2142.HK). Leveraging on TOT BIOPHARM's key R&D technologies and high-quality production capabilities, both parties worked together to initiate an antibody R&D project on innovative tumor targets and started the joint R&D and commercialization of innovative humanized antibody drugs.

- **Three Products Approved for Launch**

  Having an international team for drug registration management and with a series of completed reporting procedures, TOT BIOPHARM accumulated extensive and comprehensive practical experience in 2021, ranging from applications for clinical research (INDs) to new drug marketing applications (NDAs), from domestically manufactured drugs to imported products, from chemical drugs to biological drugs (including ADCs etc.) and from filings with the NMPA to filings with the United States Food and Drug Administration (the "**FDA**"). Meanwhile, the Group maintained smooth communication with relevant drug administration authorities in China, the United States and Europe, enabling it to closely monitor changes in domestic and international regulations and policies on registration and filing and efficiently arrange targeted research and analysis. Through close cooperation with Kexing Biopharm for the filing of Pusintin®, the Group has learnt more about the filing regulations and policies for drugs in overseas markets and accumulated more practical experience, thus preparing it to secure a foothold in the international market in the future and providing stronger support to the development of its CDMO/CMO business.

  – **TAB008 (Pusintin® – bevacizumab injection)** was approved for launch by the NMPA on 30 November 2021 for the treatment of advanced, metastatic or recurrent non-squamous non-small cell lung cancer and metastatic colorectal cancer. Pusintin® is an anti-vascular endothelial growth factor monoclonal antibody (anti-VEGF mAb) and a biosimilar of Avastin®, and is also the first antibody drug of TOT BIOPHARM approved for launch. Since bevacizumab biosimilars cover a number of cancers with high incidences in China, its market demand is enormous. According to relevant data, the global sales of bevacizumab biosimilars reached US$6.09 billion in 2020, and is expected to reach approximately RMB10 billion in the Chinese market in 2030.

    Upon the launch of this product, and in accordance with the relevant requirements of the "Technical Guidelines for Clinical Changes of Marketed Chemical Drugs and Biological Products" (《已上市化學藥品和生物製品臨床變更技術指導原則》) and the "Technical Guidelines for Similarity Evaluation and Indication Extrapolation of Biosimilars" (《生物類似藥相似性評價和適應症外推技術指導原則》), in addition to the two approved applications of Pusintin® for the treatment of metastatic colorectal cancer and advanced, metastatic or recurrent non-small cell lung cancer, three other indications, namely (i) recurrent glioblastoma multiforme, (ii) epithelial ovarian cancer, fallopian tube cancer or primary peritoneal cancer, and (iii) cervical cancer, were approved by NMPA in early March 2022, while the application for hepatocellular carcinoma has been accepted for processing.

– **TOZ309 (Tazian® – temozolomide capsules)**, a generic TEMODAR® drug was approved for launch by the NMPA in May 2021. Temozolomide is an alkylating agent of imidazotetrazine with anti-tumor activity that can kill cancer cells by damaging their DNA. With improved efficacy and fewer side effects than conventional chemotherapy, temozolomide capsules are used as a first-line medication for both newly diagnosed and recurrent brain glioma as well as recurrent anaplastic astrocytoma.

– **TOM218 (Megaxia® – megestrol acetate oral suspension)** was approved for launch by the NMPA in May 2021 and was imported and in-licensed from TWi Pharmaceuticals, Inc. (安成國際藥業股份有限公司) by the Group with a specification of 125 mg/mL (150 mL/bottle). The Group owns the exclusive agency rights of the drug in mainland China, Hong Kong and Macau. The drug's main ingredient is megestrol acetate (a semisynthetic progesterone derivative), which can effectively alleviate cachexia symptoms in AIDS and cancer patients, including loss of appetite and decreasing body weight, as well as occasional nausea and vomiting. The oral suspension can relieve the patients' discomfort in swallowing more effectively than the solid dosage form. This product has been approved for launch in the United States since 2014 and is currently the first concentrated megestrol acetate oral suspension approved for launch in China. TOM218 oral suspension adopts nanocrystalline technology to improve patient treatment compliance, thus facilitating more effective absorption by their bodies.

• **Key Products at Clinical Stage and Achievements**

– *Core Product TAA013 – Steady Progress in Phase III Clinical Trial*

TAA013 is an ADC drug candidate containing trastuzumab and an emtansine derivative (Trastuzumab – MCC-DM1) for the treatment of local advanced or metastatic HER2+ breast cancer which cannot be cured by trastuzumab and is unresectable. In July 2020, the drug was successfully administered to the first patient in the Phase III clinical trial. As of the end of 2021, the Phase III clinical trial of TAA013 had progressed as expected and more than 70 clinical research centers across the country had initiated clinical trials. It is expected that the patient enrollment of the Phase III clinical trial of the drug will be completed in the first half of 2022. Our clinical progress is in a leading position in China.

– *TAB014 (anti-VEGF mAb) (wet age-related macular degeneration (wAMD))*

The sales rights of TAB014 (anti-VEGF mAb) in mainland China, Hong Kong and Macau were transferred to Zhaoke Ophthalmology Limited (兆科眼科有限公司) (6622.HK). In early March 2022, TOT BIOPHARM entered into a supplementary agreement with Zhaoke Ophthalmology Limited, pursuant to which the Group will continue to leverage its competitiveness in the commercial production of antibody drugs to manufacture high-quality drugs for the benefit of a vast number of patients suffering from ophthalmologic diseases in China.

Following correspondence with the NMPA's Center for Drug Evaluation (CDE), the Group has been granted permission to begin the Phase III clinical trial directly, bypassing Phase II, based on the data from the Phase I clinical trial and relevant clinical literature. Meanwhile, the Group took an active role in consulting and communication with the FDA and filed an application with the FDA for the Phase III clinical trial (conducted in China only). The FDA approved the commencement of the Phase III clinical trial and clinical data derived therefrom could form part of the key clinical data supporting the application for launch in the United States.

MARKETING AND STRATEGIC COOPERATION

In order to actively respond to the changes in the commercialization market of the pharmaceutical industry, TOT BIOPHARM has opened up its cooperation platform for alliance formation and complementary market collaboration in order to establish long-term, mutually-beneficial strategic relationships with its industry partners.

- **Strategic Marketing Cooperation with Jimin Kexin Pharmaceutical**

  Jiangxi Jixin Pharmaceutical Co., Ltd. (江西濟鑫醫藥有限公司) ("**Jixin Pharmaceutical**"), a wholly-owned subsidiary of Jiangxi Jimin Kexin Pharmaceutical Industry Investment Co., Ltd. (江西濟民可信醫藥產業投資有限公司) ("**Jimin Kexin Pharmaceutical**"), is known for its extensive experience and outstanding results in the Chinese oncology drug market. Its marketing network covers third and fourth-tier cities and county-level cities, which greatly improves patients' accessibility to drugs. TOT BIOPHARM entered into exclusive promotion agreements with Jixin Pharmaceutical for the marketing of TOZ309 Tazian® and TAB008 Pusintin® in mainland China to promote the products in the market at a quick pace and to continuously strengthen product awareness through patient patronage and academic promotion activities. In 2021, in respect of TOZ309 Tazian®, procedures for its inclusion in provincial online procurement platforms were carried out in line with marketing strategy, and marketing and promotion activities aiming at non-centralized procurement channels were also commenced. Accordingly, the drug was included in the provincial centralized procurement platforms of more than 90% of China's provinces, thus accelerating its market penetration and making full preparation for the renewal of the fourth round of national centralized procurement.

- **Cooperation with Kexing Biopharm in Overseas Markets**

  In order to secure a foothold in overseas markets, TOT BIOPHARM announced on 11 January 2022 that it had entered into a cooperation agreement with Kexing Biopharm in respect of the commercial licensing of Pusintin® in overseas markets. Through this cooperation, TOT BIOPHARM will work with Kexing Biopharm to promote Pusintin® in markets in overseas countries. This is a critical move to facilitate Pusintin®'s penetration into the international market and also an important initiative to heed the call from the state by following the "One Belt One Road" strategy so as to provide cancer patients in emerging countries with high-quality and affordable drugs. We are looking forward to our new page in the international market that will be turned by Pusintin® in 2022.

- **Joint Venture with China Resources Pharmaceutical and Commercial Group**

  After consolidating its internal and external resources, TOT BIOPHARM established Yaozhan Pharmaceutical Jiangsu Co., Ltd. (曜展醫藥江蘇有限公司) in May 2021 as a subsidiary independently engaged in sales activities. The Group also established a joint venture, Huayao Pharmaceutical, with China Resources Pharmaceutical and Commercial Group in November 2021 to facilitate the transformation of its marketing strategies. The Group exclusively in-licensed Megaxia®, a megestrol acetate oral suspension, which is the first concentrated oral suspension formulation product approved for launch in mainland China to date and has been introduced to the market through Huayao Pharmaceutical's dedicated marketing platform. Given the extensive drug marketing and logistics channels of China Resources Pharmaceutical and Commercial Group and the Group's professional marketing team for anti-tumor drugs, the Group believes that there is enormous potential for further development in the market.

STRATEGIC DEVELOPMENT AND COMPETITIVE EDGES

- **Competitive Edges in the Development of ADC Drugs**

  ADCs are becoming more prevalent in the oncology field. According to the market forecast from "Nature" research journals, global ADC sales will reach US$16.4 billion in 2026. There are currently 12 ADC products approved for launch around the world, with four approved for launch in China, most of which are imported. The ADC drug TAA013 independently developed by TOT BIOPHARM is one of the three oncology drugs for HER2+ breast cancer at the Phase III clinical stage, and is receiving great attention from the market.

  TOT BIOPHARM boasts competitive edges in respect of the core conjugation process and the scale-up of technology, and has successfully developed several stable production processes for ADC drug substance and formulations to ensure the stability and high batch-to-batch consistency of products. The Group has a complete analytical technology platform for ADCs and independent analysis capabilities in respect of critical metric attributes of ADCs to ensure the successful development of ADC processes and the production of high-quality products.

Meanwhile, TOT BIOPHARM has established an expert team for the R&D of ADC conjugation process technologies and an analysis team for complex ADC molecular structures. Boasting extensive practical experience and successful exemplary cases, and with the commencement of a series of ADC CDMO/CMO cooperation projects, TOT BIOPHARM has earned recognition and acknowledgement from other industry players. The Group has accumulated comprehensive experience spanning R&D, process development, clinical trials, registration and filing for approval as well as commercial production.

- **Development and Competitive Edges of CDMO/CMO Business**

  The CDMO/CMO market in China is booming and demand is continually increasing. According to data from Frost & Sullivan, the revenue of the CDMO/CMO market in China will record an average compound annual growth rate of 30.0% for the period between 2021 and 2025, and the total revenue of the CDMO/CMO market in China is expected to increase to RMB123.5 billion by 2025, of which the average compound annual growth rate of CDMO/CMO services for biological drugs for the period between 2021 and 2025 will be 36.7%. TOT BIOPHARM endeavors to accelerate the development of its partners' new drugs with its comprehensive industry platform and mass production capacity.

  – *Provision of "One Stop, One Base" CDMO/CMO Services*

    TOT BIOPHARM capitalized on market opportunities by fully leveraging the Company's open technology platforms and commercial production capabilities, thereby speeding up the development of CDMO/CMO business under the "one stop, one base" model. Its base at the Suzhou headquarters is capable of completing all production stages, ranging from R&D to the production of end products, under one roof, which greatly mitigates the risks and difficulties in terms of management, transportation and technology otherwise brought about by the segmented subcontracting of suppliers. Consequently, TOT BIOPHARM is able to provide clients with "one stop" CDMO/CMO solutions spanning R&D, process development, clinical trials, registration and filing for approval as well as commercial production, thereby satisfying the diversified demand for products such as chemical drugs, mAb drugs and ADC drugs.

  – *Establishment of Professional Management System and Team for CDMO/CMO Business*

    In addition to the R&D of new drugs, CDMO/CMO business has gradually become another important area for TOT BIOPHARM's development. In 2021, the Group commenced independent project management and performance management with the establishment of an independent CDMO/CMO management system and the implementation of stringent standards and requirements for business ethics management, for the sake of ensuring the safety, compliance and orderly execution of each project. The key to laying a solid foundation for these initiatives was effective internal and external coordination and communication. Owing to the good collaboration of the CDMO/CMO business team, TOT BIOPHARM established a timely and effective communication mechanism with its clients, thus earning the confidence and praise of partners within the industry.

– *Quality Management System with International Standards*

A sound quality management system is surely a guard rail for the development of CDMO/CMO business. TOT BIOPHARM is an innovative drug R&D company equipped with a high-standard quality management system satisfying the requirements of GMP-compliant commercial production. Accordingly, this system has become a leading resource of the CDMO/CMO business and complies with the standards stipulated in the GMP quality assurance regulations of China, the United States and the European Union, and with a traceable track record of proven experience and successful projects. In 2021, the Group continued to optimize and upgrade the quality management system and established an essential quality management system covering stages from R&D to commercialization in accordance with the requirements set out in the regulations and guidelines of the NMPA, the FDA and the European Medicines Agency (EMA). Given the Company's sound and fully regulated quality management system, the Group fully capitalized on digital management tools to realize electronic and systematic management and to upgrade its quality management capability, thereby ensuring that its product quality is in line with international standards.

– *Performance Highlights of CDMO/CMO Business in ADC Field*

Unlike the vast majority of CDMO/CMO companies in China which launched their businesses with small molecular drugs, TOT BIOPHARM is an innovative oncology drug R&D company targeting CDMO/CMO business in the ADC field with more promising market prospects and stronger competitive edges. Consequently, TOT BIOPHARM achieved a new breakthrough in terms of operating results, and has received great acclaim from its clients.

• **CDMO/CMO Business Strategic Cooperation**

– *Strategic CDMO Cooperation with BrightGene Bio-Medical*

On 19 July 2021, TOT BIOPHARM entered into a strategic cooperation with BrightGene Bio-Medical Technology Co., Ltd. (博瑞生物醫藥(蘇州)股份有限公司) (688166.SH) to strengthen the "one stop" service platform for ADC drug CDMO business, thus facilitating the R&D and commercialization of innovative drugs. The agreement enabled the Group to collaborate with other renowned industry players through the mutual sharing of each other's technologies and resources, and to further upgrade and expand its service platform for ADC drug CDMO, thus providing companies engaged in the production of innovative drugs with "one stop" solutions by mitigating risks associated with R&D and improving the efficiency for commercialization.

– *CDMO Strategic Cooperation with Jimin Kexin Pharmaceutical*

Given the sound cooperation between the Group and a wholly-owned subsidiary of Jimin Kexin Pharmaceutical, both parties entered into a CDMO strategic cooperation agreement in January 2022, under which TOT BIOPHARM will provide production services for drugs for use in clinical trials and CDMO services for the production of newly launched drugs.

- **Commencement of Construction of Global R&D Center**

In order to strengthen its technological advantages in the R&D of innovative drugs, TOT BIOPHARM commenced the construction of a global R&D center in Suzhou on 9 November 2021, which will accelerate the R&D process of anti-tumor drugs through its first-class talents, technologies, ideas and management. With a gross floor area of 25,000 m^2, the main building is expected to be completed in 2023 and will house functions such as early R&D, process development, quality research and head office. The core R&D experimental zone will be able to hold 280 to 300 R&D technicians and simultaneously handle a number of experiments for the research and process development of mAb drugs, ADC drugs, oncolytic virus drugs and special small molecular oncology drugs, making it possible to realize a seamless connection with the production zone. In addition, placing R&D and production under one roof will facilitate the synergic efficiency for the whole drug development process, thereby enhancing the R&D efficiency and cost advantages.

COMMERCIAL PRODUCTION CAPACITY AND MARKET COOPERATION

- **Commercial Production Base**

TOT BIOPHARM has built an internationally-competitive, GMP-compliant, large-scale biological drug commercial production base in Suzhou Industrial Park. With an increasing number of innovative drugs having gradually entered the late clinical stage and being commercialized in China, small-to-medium sized innovative drug companies with a focus on early-stage drug R&D urgently need to address issues such as compliance and stable volume-based productivity. TOT BIOPHARM has planned for long-term development by building new plants. A commercial production base for mAb drugs with a capacity of 16,000 liters was built and put into operation in 2018, which is one of the most sizable industrialized bases of biological drugs in China. To date, the construction of commercial production facilities comprising workshops for mAb drug substance and formulations as well as ADC drug substance and ADC freeze-dried formulations has been completed, contributing to the commercial production of self-developed drugs and the commercialization of innovative drug companies in China.

Meanwhile, the Group has established a high-quality, electronic and traceable quality management system for drug registration management in compliance with international standards as well as an internationalized registration team, which have become a guard rail for TOT BIOPHARM's product quality. In January 2021, the on-site inspection for the registration of the biological product mAb injections and the GMP compliance inspection were completed and passed. The Group received the production approval for chemical drug capsules and biological antibody drugs in May 2021 and December 2021 respectively, and its quality assurance system was highly acclaimed by the NMPA. At the same time, the Group has also started the construction of the second commercial production line for ADC formulations in a bid to substantially expand the production scale of ADC drugs to further strengthen the ADC commercialization platform. The production capacity of biological drug commercial production bases is expected to reach 20,000 liters in the first half of 2022, thereby realizing the high-quality commercial production of innovative drugs.

- **Planning for Commercial Production of ADC Drugs**

  In order to pursue a differentiated path for development, TOT BIOPHARM has upgraded its R&D and innovation capabilities and is determined to target the ADC field which has a higher threshold for technologies and a higher barrier to commercial production. Given its years of research in technologies and processes and the planning for the TAA013 commercial production lines, TOT BIOPHARM has provided differentiated and "one stop" industrial services and technological support to an increasing number of domestic pharmaceutical companies entering the ADC field.

  In September 2020, building upon the completion of drug substance production workshops for the commercial production of ADCs, TOT BIOPHARM began planning for workshops for the volume-based commercial production of ADC freeze-dried liquid injections. In May 2021, TOT BIOPHARM exerted great effort to implement its plan for ADC pilot and commercial production facilities and established the second ADC commercial production line for freeze-dried liquid injection formulations.

COMMUNICATION WITH SOCIETY

TOT BIOPHARM continued to enhance its brand awareness and corporate image by maintaining good communication with all sectors of society, the industry, the media and the investing public. It also delivered its messages on its corporate strategies, latest business development and corporate culture to society via diversified channels.

As a leader in the ADC field, TOT BIOPHARM has established long-term and trusted relationships with a number of partners within the ADC field. In 2021, it proactively organized and participated in seminars on biological drugs and ADCs, strengthened and expanded its impact in the capital markets through investor open days, online roadshows for investors, corporate surveys and other activities, and publicized the latest information on the Company's business development through timely and transparent disclosures. All these initiatives had the aim of enabling investors to gain a better understanding of the potential value for investment and strategic planning of TOT BIOPHARM.

In respect of its communication within the industry, TOT BIOPHARM took the lead in attending industry forums. In the ADC session of the 6th Enmore Bio Conference held in Suzhou in March 2021, TOT BIOPHARM invited several ADC experts to share their views on the topic "Antibody Drugs – The Whole Process of the Development of ADCs". On 1 April 2021, Tongxieyi held the "2021 Summit for Advanced Process and Industrialized Development of Antibody Drug" in Suzhou, in which Dr. Liu Jun, the Chief Executive Officer of TOT BIOPHARM, attended the "Early Process Development of Antibody Drugs" roundtable forum as a guest to discuss strategies for CMC process development and clinical studies for ADC drugs.

In respect of the ADC field, TOT BIOPHARM, as a committed supporting unit, attended the "3rd World Conference on Forefront Technology of Biomedicines" held in the Convention and Exhibition Center of Suzhou Industrial Park from 10 to 12 July 2021, and participated in the "Key Issues on Commercial Production of Antibody Drugs" roundtable forum and the "One Stop Platform for the Integration of ADC Drugs and CMC" project roadshow, for the purpose of promoting the Company's CDMO/CMO business and enhancing the Company's brand image. From 12 to 13 November 2021, TOT BIOPHARM took part in the "First Young BiG Youth Forum 2021" and co-organized the "From ADC to XDC - Innovative Conjugate Drugs" special forum, in which the Company shared its views on the R&D and production of the ADC field with other top industry players and discussed the development patterns and trends of innovative antibody drug conjugates.

APPLICATION OF FUNDS AND FINANCING

As at 31 December 2021, the Group had carried out its operations in adherence to the Company's new strategic plan after adjustment and 2021 business targets in line with the demand of its CDMO/CMO business with the aims of consolidating its resources to expand the commercial production capabilities of biological drugs (especially the comprehensive capabilities in ADC field) and enhancing its CDMO business teams to develop a CDMO/CMO business operation with competitive edges. In order to support the R&D and sustainable development of the Company and to raise funds for the construction of the global R&D center, the Group has relied on its continuously improving revenue generation capability in conjunction with the adoption of flexible financing measures.

In 2022, the Group will continue the commercial cooperation and licensing of TAA013 in domestic and international markets and mobilize sufficient resources in the capital markets through various funding channels to add new momentum to the development of its CDMO/CMO business. Furthermore, the Group will continue to adjust the financial structure of the Company to implement its strategic goals.

RESPONSE TO COVID-19 AND ENHANCEMENT OF ESG MANAGEMENT

With COVID-19 becoming a part of everyday life, the Company implemented its anti-pandemic control measures with reference to changes in local pandemic policies in 2021. It strictly controlled the movement of personnel, regularly distributed masks and protective items to all personnel and devised procurement plans in advance to ensure a sufficient supply of operating equipment as well as materials such as ingredients and excipients. The Company also responded to the volatile pandemic situation by adjusting its preventive measures and enabling timely internal coordination to guarantee the normal operation of all of the Company's businesses.

In order to further enhance the corporate governance of the Company, the Board established the Strategy and ESG Committee, which will closely align ESG issues with the Company's strategies. Following continuous evaluation of the external environment and taking into account the development of the Company, the Strategy and ESG Committee will determine reasonable work mechanisms and targets so as to realize the Company's goal of sustainable development.

PROSPECTS

Looking ahead to 2022, the Group will accelerate the marketing and sales activities of its launched products, which are expected to give rise to a substantial increase in revenue from product sales. We believe that innovation is the key to the Company's development and will therefore continue to step up and upgrade the technological research of innovative ADC drugs and take an active role in the development and strategic cooperation of ADC projects. In addition, we will accelerate the Phase III clinical trial of our ADC core product TAA013 and its commercialization licensing, continue to strengthen the position of our ADCs in the CDMO market and proactively identify domestic and international strategic partners, thereby providing our clients with long-term value. Through diversified funding channels and optimized cash flows, the Company expects to enjoy new growth in its operating results and see new breakthroughs in 2022.

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 2021, 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 2021 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 2021.

COMPLIANCE WITH THE CODE PROVISIONS OF THE CORPORATE GOVERNANCE CODE

The Company has adopted the principles and code provisions of the Corporate Governance Code (the "**CG Code**") contained in Appendix 14 to the Listing Rules as the basis of the Company's corporate governance practices. The Company is committed to maintaining high standard of corporate governance to safeguard the interests of the shareholders of the Company and to enhance corporate value and responsibility. The Board is of the view that during the year ended 31 December 2021, the Company has complied with all the applicable code provisions as set out in the CG Code.

COMPLIANCE WITH THE MODEL CODE FOR SECURITIES TRANSACTIONS BY DIRECTORS

The Company has adopted the Model Code for Securities Transactions by Directors of Listed Issuers (the "**Model Code**") as set out in Appendix 10 to the Listing Rules. The Company has made specific enquiry of all the Directors and the Directors have confirmed that they have complied with the Model Code during the year ended 31 December 2021 and up to the date of this announcement.

USE OF NET PROCEEDS FROM GLOBAL OFFERING

The net proceeds raised during the Company's global offering and listing on the Main Board of the Stock Exchange (the "**Global Offering**") were approximately RMB448,615,000 after deduction of the underwriting fees and commissions and expenses payable by the Company in connection with the Global Offering (the "**Net Proceeds**").

As at 31 December 2020, the unused amount of the Net Proceeds was approximately RMB182,161,000. During the year ended 31 December 2021, such Net Proceeds were utilized in accordance with the proposed applications as set out in the Company's announcement dated 27 October 2020 titled "Change in Use of Net Proceeds from the Global Offering". As at 31 December 2021, the Company had utilized all Net Proceeds.

A breakdown of the use of the aforesaid Net Proceeds during the year ended 31 December 2021 will be disclosed in the 2021 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 2021.

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 2021 annual report of the Company and the notice convening the 2021 annual general meeting of the Company will be dispatched to the shareholders of the Company and made available on the same websites in due course.

STATUTORY FINANCIAL STATEMENTS

The consolidated financial information set out in the section headed "Consolidated Financial Statements" section of this announcement does not constitute the Company's statutory financial statements for the year ended 31 December 2021 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 2021 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 2021. 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, 24 March 2022

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