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 2020

HIGHLIGHTS OF 2020 ANNUAL RESULTS AND MILESTONES

The Group's core products including mAb drug TAB008 and ADC drug TAA013 have achieved key milestones. The Group actively promoted the development of and collaboration relating to innovative drugs and have established an R&D and commercialization platform integrating mAb and ADC drugs. The Group will rapidly expand its CDMO/CMO business to create new momentum for the future development of the Group.

Key milestones of pipeline products:

- TAB008 (anti-VEGF mAb): Phase III clinical results were published, showing that TAB008 has similar efficacy, safety, immunogenicity and pharmacokinetics profiles with the brand-name formulation of bevacizumab. The new drug application under the new version of the Administrative Measures for Drug Registration was submitted, and was accepted by NMPA in September 2020 *(Note: Pre-approval registration inspection was completed in January 2021)*. It is expected to be approved for marketing in 2021.

- TAA013 (anti-HER2 ADC): It is the first T-DM1 ADC product entering Phase III clinical trial in China. The first participant was enrolled in July 2020. Clinical recruitment is progressing smoothly.

- TAB014 (anti-VEGF mAb): Phase III clinical trial application (IND) was submitted to FDA. Upon receiving FDA's authorization, we would be exempted from the Phase II clinical trial and would directly carry out Phase III clinical trial *(Note: FDA authorized the Phase III clinical trial application (IND) in January 2021)*.

- TOZ309 (temozolomide capsule): Pre-approval registration inspection was completed. It is expected to be approved for marketing in the first half of 2021.

Key milestones of commercial production plans:

- In 2020, the construction of the ADC drug substance commercial production facility was completed, and the production of multiple batches of ADC drugs for clinical purposes was accomplished.

- In 2020, the GMP compliance inspection of the production workshop for chemical drugs was completed, laying a foundation for the commercial production of chemical drugs.

Financial highlights:

- Revenue amounted to RMB22,491,000, representing a 50% year-on-year decrease, mainly attributable to the impact of the national volume-based procurement policy on the sales derived from the distribution of brand-name drug S-1 and the alignment of our CDMO business with our customers' planned schedules.

- Research and development expenses amounted to RMB235,196,000, representing a 23% year-on-year increase, mainly attributable to the commencement of Phase III clinical trial for the TAA013 project of the Company in 2020 after the completion of Phase I clinical trial that resulted in an increase in demand for active pharmaceutical ingredients (APIs), excipients and consumables by related contract research (CROs) and those for the preparation of clinical drugs.

- Selling expenses amounted to RMB25,953,000, representing an 18% year-on-year decrease, mainly attributable to the overall economic slowdown as a result of the outbreak of COVID-19 in 2020 which led to the suspension or postponement of various marketing events.

- General and administrative expenses amounted to RMB46,855,000, representing a 51% year-on-year decrease, mainly attributable to the inclusion of listing expenses in the expenses for the same period in 2019.

- In summary, net loss for the year of 2020 amounted to RMB288,498,000, representing a 4% year-on-year decrease.

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 2020 together with comparative figures for the year ended 31 December 2019 as set out in the section headed "Consolidated Financial Information" section of this announcement.

STATEMENT OF CHIEF EXECUTIVE OFFICER

Dear Shareholders,

The year of 2020 was a crucial year for TOT BIOPHARM in which we consolidated our achievements through a decade of development and continued to strive for new progress. I am very honored to have the trust of the Board to serve as CEO and continue to lead the team in jointly promoting the achievement of the Group's strategic objectives. TOT BIOPHARM boasts prominent first-mover advantages of its strategic planning, and is gradually poised for the coordinated development of R&D and commercial production of innovative drugs.

INDUSTRY AND BUSINESS REVIEW

The year of 2020 was full of challenges. Amidst fierce market competition, TOT BIOPHARM has achieved multiple targets during the year, and manifested more prominent competitive advantages. We actively promoted the launch process of drug candidates, and accelerated the upgrade of strategic development by further strengthening our advantages in the antibody drug conjugates (ADCs) field. TAA013, an anti-HER2 ADC drug for the treatment of HER2+ advanced breast cancer, has successfully entered Phase III clinical trial, with a leading position in China in terms of our R&D progress. At the same time, TOT BIOPHARM has established an R&D and commercialization platform integrating monoclonal antibody (mAb) and ADC drugs. In short, medium and long-term development, we will continue to enhance its production capacity planning and rapidly expand its contract development and manufacturing (CDMO)/contract manufacturing (CMO) business, so as to meet international and domestic clinical and commercial needs, and create new momentum for the future development of the Group.

In recent years, as China attaches great importance to innovation and R&D in the pharmaceutical industry, governmental agencies such as the National Medical Products Administration (NMPA), the State Council and the National Health Commission have introduced the drug priority review and approval system, marketing authorization holder (MAH) system, breakthrough therapeutic drug review and other policies, which involve R&D, review, production and post-marketing payment of innovative drugs. These policies shorten the review cycle and accelerate the process of launching innovative drugs, which greatly encourage the development of innovative pharmaceutical enterprises. At the same time, with the continuous promotion and normalization of national volume-based procurement and negotiation on medical insurance for innovative drugs, while keeping medical insurance fees under control, the inclusion of innovative drugs in the National Reimbursement Drug List (NRDL) is accelerated to greatly improve the accessibility of innovative drugs, which is conducive to the rapid increase in the demand for drugs and will continue to benefit innovative drug enterprises.

Since its establishment, TOT BIOPHARM has been unswervingly optimistic about the promising prospect of the innovative pharmaceutical market in China. TOT BIOPHARM has improved its R&D capabilities and focused on long-term development by deploying multiple product pipelines, such as mAbs, ADCs, oncolytic virus and small molecular drugs, and its R&D capabilities and commercial production capabilities for innovative drugs went hand in hand. By virtue of our three self-developed R&D technology platforms, the Group has leading R&D capabilities for innovative drugs such as biological drugs. While satisfying the commercial production of independent R&D projects, the Group also pre-deploys our commercial production platform for biological drugs with international standards, especially the ADC drugs, and speeds up the planning of CDMO/CMO business with the principle of opening up, collaboration and win-win.

Projects under research and their commercialization are accelerated, and our core product is about to enter the harvest phase

In 2020, fighting a fierce battle against COVID-19, all the staff of TOT BIOPHARM overcame difficulties together. A number of key anti-tumor drugs have successfully entered pivotal clinical stages, ranking us among the top echelon in China with encouraging R&D achievements.

- TAB008 (anti-VEGF mAb) (non-squamous non-small-cell lung cancer (nsNSCLC)): As the Group's most advanced biological drug candidate and core product, it has met the primary endpoints of its Phase III clinical trial in April 2020, and the marketing application was submitted, and was accepted in September 2020. As the first bevacizumab biosimilar in China with new drug marketing application (NDA) accepted by NMPA in accordance with the new version of the Administrative Measures for Drug Registration, TAB008 is expected to be approved for marketing in 2021.

- TAA013 (anti-HER2 ADC) (HER2+ advanced breast cancer): It has successfully entered Phase III clinical trial. It is formed by the bonding of trastuzumab and emtansine (microtubule inhibitor) through a stable thioester bond (Trastuzumab-MCC-DM1). It aims to become an alternative to Roche's marketed drug Kadcyla (trastuzumab emtansine). Currently, TAA013 is the first T-DM1 ADC product entering Phase III clinical trial in China, with the first patient enrolled in July 2020.

- TOZ309 (temozolomide): A generic drug of chemical drug temozolomide, its marketing application has been submitted and the pre-approval registration inspection has been completed by relevant national drug administration authorities. It is expected to be approved for marketing in 2021.

- The Phase III clinical trial application (IND) of TAB014 recombinant humanized anti-vascular endothelial growth factor (VEGF) monoclonal antibody vitreous injection was submitted to the U.S. Food and Drug Administration (FDA) (FDA has granted authorization for the Phase III clinical trial application (IND) in January 2021).

- A GMP-compliant ADC commercial production workshop was constructed and the adjustment and testing of the drug substance production facility and equipment have been completed.

Building a domestic leading, international first-class ADC full industry chain platform, and becoming a leader in the domestic ADC field

In 2020, ADC drug development has attracted much attention and set off an upsurge, which is mainly due to its unique drug action mechanism that combines the toxicity of the high-activity small-molecule cells and the targetedness of monoclonal antibodies. Compared with traditional chemical drugs and biological drugs, ADC drugs have obvious advantages in improving the safety and efficacy of tumor treatment, and meanwhile it imposes extremely high requirements on commercial production capacity. This research field is also considered to be one of the important directions for the development of monoclonal antibody drugs (especially in the field of tumor targeted therapy) in the next decade. According to market forecasts, the global ADC market will reach US$12.9 billion in 2024, representing a CAGR of approximately 35% from 2018 to 2024, with a great potential for market development.

However, due to high technical difficulty of the R&D of ADC drugs, very few drugs can enter the clinical stage. Only 10 ADC drugs were launched globally, two of which were imported drugs sold in China, and about 95% of the R&D projects are in an early clinical stage. In 2013, TOT BIOPHARM has already started to conduct the research for ADC drugs. Fortunately, after years of cumulative efforts, our first self-developed ADC drug TAA013 has entered Phase III clinical trial in 2020 and enrollment of patients has commenced, currently with leading R&D progress in China.

Meanwhile, we have been actively building a commercial production platform for ADC drugs and have during the year completed the construction of the ADC commercial drug substance facility, which is expected to become one of the few ADC commercial production workshops in China that meet GMP production requirements, laying a foundation for the commercial production of ADC drugs.

Creating a commercial production platform with high competitiveness and actively expanding CDMO/CMO business

With industry-leading commercial production planning, the Group established a large-scale production workshop for biological drugs and mAb drugs with international standards back in 2018, with a designed production capacity of 16,000L. Our self-developed innovative cell amplification technology (PB-Hybrid Technology) enables a direct scale-up from a 25L WAVE reactor to a 2,000L bioreactor, and we have successfully produced multiple batches of drugs for clinical trials, such as TAB008 and TAA013. In 2020, the construction of the ADC drug substance facility was completed, and an ADC formulation workshop was planned simultaneously, laying a solid foundation for commercial development.

In the meantime, given the increasing demands of CDMO/CMO markets at home and abroad coupled with the shortage of industrial resources, TOT BIOPHARM enjoys prominent advantages by virtue of its highly competitive commercial production platform and technology platform. As a biotechnology company focusing on innovative drugs, we possess a well-developed technology platform and a well-rounded management team with expertise in R&D, clinical trials, registration and approval to commercial production. We have extensive experience in the process development of core technology and in production, especially in terms of ADC drugs with high technological barriers. In this regard, we have completed several new-generation ADC drug projects in collaboration with multiple strategic partners, and earned the recognition and trust in the industry, giving us full confidence in the development of CDMO/CMO business.

In 2020, with the strong support of the Board, we actively developed our CDMO/CMO business, and simultaneously launched R&D and capacity expansion plans for biological drugs by increasing resource investment and talent deployment. By establishing long-term partnerships with various partners, we can provide more customers with satisfactory and efficient solutions and services through the sound management systems of TOT BIOPHARM.

OUTLOOK

The year of 2021 is full of expectations. Our R&D efforts are about to bear fruit, and many major milestones are expected to be achieved. Our core products, biological drug TAB008 and chemical drug TOZ309, are expected to be approved for marketing, thereby benefiting a large number of cancer patients. We will continue to focus on our R&D efforts of ADC drugs with higher degrees of innovation and sophistication, strengthen the domestic and overseas licensing of our drug candidates, and accelerate our international strategy deployment. In addition, we will actively work with global leading partners to jointly promote the marketing of innovative drugs. In 2021, the CDMO/CMO business is poised for take-off. We will achieve our project cooperation with more comprehensive, granular and high-standard requirements, and continue to expand our production capacity and business volume, to create new sources of revenue growth for the Company.

Looking forward, with the rapid development and fierce competition in China's biological drug industry, we will constantly improve and upgrade our standards of international management, increase our investment in the R&D efforts of innovative drugs, rapidly expand our deployment of commercial production capacity, and strengthen our construction of an international R&D team, so as to provide endless power for our development in the next decade, offer a favourable development platform for the growth of our employees, and create greater value for our shareholders.

Dr. Liu, Jun
Chief Executive Officer and Executive Director

23 March 2021

CONSOLIDATED FINANCIAL INFORMATION

CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS

For the year ended 31 December 2020

		Year ended 31 December	
	Note	**2020**	2019
		RMB'000	*RMB'000*
Revenue	*3*	**22,491**	45,308
Cost of revenue		**(6,961)**	(11,316)
Research and development expenses		**(235,196)**	(191,078)
Selling expenses		**(25,953)**	(31,544)
General and administrative expenses		**(46,855)**	(95,091)
Other gains – net		**3,802**	14,117
Operating loss		**(288,672)**	(269,604)
Finance income		**1,880**	1,680
Finance costs		**(1,706)**	(2,291)
Finance income/(costs) – net		**174**	(611)
Fair value change in financial instruments issued to investors		**–**	(29,085)
Loss before income tax		**(288,498)**	(299,300)
Income tax expense	*4*	**–**	–
Loss for the year and attributable to the equity holders of the Company		**(288,498)**	(299,300)
Other comprehensive income/(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		**85**	1,181
Items that may be reclassified to profit or loss			
Exchange difference on translation		**(3,339)**	(15,111)
Other comprehensive loss for the year, net of tax		**(3,254)**	(13,930)
Total comprehensive loss for the year and attributable to the equity holders of the Company		**(291,752)**	(313,230)
Loss per share for the year and attributable to the equity holders of the Company			
– Basic and diluted losses per share (RMB)	*5*	**(0.51)**	(0.89)

CONSOLIDATED BALANCE SHEET
As at 31 December 2020

	Note	As at 31 December 2020 RMB'000	2019 RMB'000
ASSETS			
Non-current assets			
Property, plant and equipment		**290,367**	300,230
Prepayments for property, plant and equipment		**416**	9,244
Right-of-use assets		**20,639**	28,435
Intangible assets		**3,229**	2,391
Financial assets at fair value through other comprehensive income		**8,076**	7,991
Other non-current assets		**69,229**	54,708
		391,956	402,999
Current assets			
Inventories		**8,114**	15,250
Trade and other receivables	*7*	**5,851**	14,406
Prepayments		**8,827**	10,938
Contract assets		**902**	2,450
Financial assets at fair value through profit or loss		**–**	32,139
Cash and cash equivalents		**225,533**	539,180
		249,227	614,363
Total assets		**641,183**	1,017,362
EQUITY			
Share capital	*8*	**1,874,438**	1,874,438
Other reserves		**49,503**	36,925
Accumulated losses		**(1,341,584)**	(1,053,086)
Total equity attributable to the equity holders of the Company		**582,357**	858,277

	Note	As at 31 December 2020 RMB'000	2019 RMB'000
LIABILITIES			
Non-current liabilities			
Lease liabilities		**6,083**	12,299
Current liabilities			
Borrowings		**–**	60,000
Accruals and other payables	*9*	**42,316**	81,418
Contract liabilities		**9,104**	2,593
Lease liabilities		**1,323**	2,775
		52,743	146,786
Total liabilities		**58,826**	159,085
Total equity and liabilities		**641,183**	1,017,362
Net current assets		**196,484**	467,577
Total assets less current liabilities		**588,440**	870,576

NOTES TO THE CONSOLIDATED FINANCIAL INFORMATION

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 2020:

Amendments to HKAS 1 and HKAS 8	Definition of Material
Amendments to HKFRS 3	Definition of a Business
Amendments to HKFRS 9, HKAS 39 and HKFRS 7	Interest Rate Benchmark Reform
Conceptual Framework for Financial Reporting 2018	Revised Conceptual Framework for Financial Reporting

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 39, HKFRS 4, HKFRS 7, HKFRS 9 and HKFRS 16	Interest Rate Benchmark Reform – Phase 2 (amendments)	1 January 2021
HKFRS 3, HKAS 16 and HKAS 37	Narrow-scope amendments (amendments)	1 January 2022
Amendments to HKAS 1	Classification of liabilities as current or non-current	1 January 2023
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
HKFRS 9, HKFRS 16, HKFRS 1 and HKFRS 41	Annual improvements HKFRS Standards 2018-2020	1 January 2022
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
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	
	2020	2019
	RMB'000	*RMB'000*
Timing of revenue recognition		
At a point in time:		
– Commission revenue	**14,703**	29,822
– CMO	**–**	6,466
– Sales of goods	**521**	911
– Others	**45**	9
Over time:		
– CDMO	**6,423**	8,100
– Revenue from CRO	**799**	–
	22,491	45,308

(c) Geographical information

Geographical information of revenue and non-current assets other than financial assets for the years ended 31 December 2020 and 2019 is as follows:

	Year ended 31 December			
	2020		2019	
	RMB'000	***RMB'000***	*RMB'000*	*RMB'000*
	Revenue	**Non-current assets**	Revenue	Non-current assets
China	**22,491**	**314,275**	45,308	339,349
Others	**–**	**478**	–	1,127
	22,491	**314,753**	45,308	340,476

(d) Information about major customers

The major customers which contributed more than 10% of the total revenue of the Group for the year ended 31 December 2020 and 2019 are listed as below:

	Year ended 31 December	
	2020	2019
	RMB'000	*RMB'000*
Customer A	**14,703**	29,822
Customer B	**3,643**	6,466
Total	**18,346**	36,288

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% (2019: 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% (2019: 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 2023. Accordingly, TOT Suzhou was entitled to a preferential income tax rate of 15% on its estimated assessable profits commencing from 2020 to 2023.

According to the relevant laws and regulations promulgated by the State Administration of Taxation of the PRC that was effective from 2018, and applicable until 2020, enterprises engaging in research and development activities are entitled to claim 175% of their research and development expenses incurred as tax deductible expenses when determining their assessable profits for that year.

(c) Taiwan corporate income tax

No provision for Taiwan corporate income tax has been provided for at a rate of 20% (2019: 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	
	2020	2019
	RMB'000	*RMB'000*
Loss attributable to equity holders of the Company (RMB'000)	**(288,498)**	(299,300)
Weighted average number of ordinary shares in issue (thousand) *(Note)*	**570,334**	335,654
Basic loss per share (RMB)	**(0.51)**	(0.89)

Note: The weighted average number of ordinary shares for the purpose of basic and diluted loss per share for the years ended 31 December 2020 has been adjusted for the compensatory grant and capitalization issue (2019: the weighted average number of ordinary shares for the purpose of basic and diluted loss per share has been adjusted for the capitalization issue).

(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 2020, the Company had one category of potential ordinary shares: the stock options granted to employees (2019: same). As the Group incurred losses for the years ended 31 December 2020 and 2019, the potential ordinary shares were not included in the calculation of diluted loss per share as their inclusion would be anti-dilutive. Accordingly, diluted loss per share for the years ended 31 December 2020 and 2019 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 (2019: Nil).

7 TRADE AND OTHER RECEIVABLES

	As at 31 December	
	2020	2019
	RMB'000	*RMB'000*
Trade receivables from contracts with customers	**1,536**	6,741
Other receivables	**4,315**	7,665
Trade and other receivables	**5,851**	14,406

Trade receivables

	As at 31 December	
	2020	2019
	RMB'000	*RMB'000*
Trade receivables from contracts with customers	**1,536**	6,741

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

As of 31 December 2020 and 2019, the ageing analysis of the trade receivables based on invoice date is as follows:

	As at 31 December	
	2020	2019
	RMB'000	*RMB'000*
Within 30 days	**1,218**	4,727
31 days to 90 days	**318**	2,014
	1,536	6,741

8 SHARE CAPITAL

Issued and fully paid:

	Number of ordinary shares	Share capital *RMB'000*
As at 1 January 2019	84,000,000	537,859
Issue of shares upon exercise of share options *(Note (a))*	2,267,500	19,801
Conversion of Convertible Preferred Shares to ordinary shares *(Note (b))*	51,174,876	817,276
Capitalization issue *(Note (c))*	342,557,624	–
Issue of shares upon initial public offering, net of underwriting commissions and other issuance costs *(Note (d))*	90,000,000	499,502
As at 31 December 2019	570,000,000	1,874,438
As at 1 January 2020	570,000,000	1,874,438
Compensatory Grant *(Note(e))*	30,466,697	–
As at 31 December 2020	600,466,697	1,874,438

Note (a) In July to August 2019, five participants exercised part of their respective share options at an exercise price of USD1.00 per ordinary share, following which a total of 2,267,500 ordinary shares were issued on 6 September 2019. Upon the exercise of the share options, share-based compensation reserve of RMB4,151,000 is transferred to share capital. The exercise price of the outstanding share options had been adjusted subsequently from USD1.00 per share to USD0.29 per share.

Note (b) All preferred shares were converted into 51,174,876 ordinary shares upon the initial public offering on 8 November 2019. The principal amount of these preferred shares and the cumulative changes in fair value are capitalized as share capital accordingly.

Note (c) On 8 November 2019, pursuant to the resolution passed by the shareholders on 30 September 2019, 342,557,624 shares were allotted and issued without payment and as fully paid shares to existing shareholders after the conversion of the Convertible Preferred Shares and prior to the completion of the initial public offering.

Note (d) On 8 November 2019, the Company issued 90,000,000 ordinary shares at HK$6.55 per share, and raised gross proceeds of approximately HK$589,500,000. The Company's shares were listed on the Main Board of The Stock Exchange of Hong Kong Limited on 8 November 2019. The gross proceeds, net of underwriting commissions and other issuance costs, are capitalized as share capital accordingly.

Note (e) On 28 December 2020, the Company allotted and issued 30,466,697 ordinary shares to certain trustees under the Company's Restricted Share Award Scheme.

9 ACCRUALS AND OTHER PAYABLES

	As at 31 December	
	2020	2019
	RMB'000	*RMB'000*
Staff salaries and welfare payables	**11,405**	10,108
Payables for purchase of property, plant and equipment	**5,752**	15,879
Payables for research and development	**18,006**	20,200
Payables for promotion and advertisement	**182**	1,017
Listing expenses	**–**	20,629
Payables due to related parties	**–**	520
Others	**6,971**	13,065
	42,316	81,418

MANAGEMENT DISCUSSION AND ANALYSIS OF CERTAIN FINANCIAL ITEMS

OVERVIEW

In 2020, the Group recorded a revenue of RMB22,491,000, as compared to RMB45,308,000 in 2019; and a net loss of RMB288,498,000 in 2020, as compared to a net loss of RMB299,300,000 in 2019. The Group's research and development expenses in 2020 were RMB235,196,000, as compared to RMB191,078,000 in 2019. The Group's general and administrative expenses in 2020 were RMB46,855,000, as compared to RMB95,091,000 in 2019. The selling expenses in 2020 were RMB25,953,000, as compared to RMB31,544,000 in 2019.

OPERATING REVENUE AND COST OF REVENUE

The Group's diversified revenue was mainly derived from our strategic business partners, including commissions for marketing services in connection with the commercialization of S-1 and revenue for providing CDMO and CMO services to other biotechnology companies, etc.

The Group's commission revenue in 2020 was RMB14,703,000, representing a decrease of RMB15,119,000 from RMB29,822,000 in 2019, primarily attributable to the impact of the national volume-based procurement policy on the sales derived from the distribution of brand-name drug S-1.

The Group's revenue from CDMO and CMO services in 2020 was RMB6,423,000, representing a decrease of RMB8,143,000 from RMB14,566,000 in 2019, primarily attributable to the alignment with our customers' planned R&D schedules. The provision of materials, labor and expenses, etc. necessary for CDMO and CMO services also decreased along with the variation in business activities.

RESEARCH AND DEVELOPMENT EXPENSES

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

The Group's research and development expenses in 2020 were RMB235,196,000, representing an increase of RMB44,118,000 from RMB191,078,000 in 2019, mainly attributable to the commencement of Phase III clinical trial for the TAA013 project of the Company in 2020 after the completion of Phase I clinical trial that resulted in an increase in demand for active pharmaceutical ingredients (APIs), excipients and consumables by related contract research (CROs) and those for the preparation of clinical drugs.

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 2020 were RMB25,953,000, representing a decrease of RMB5,591,000 from RMB31,544,000 in 2019, mainly attributable to the overall economic slowdown as a result of the outbreak of COVID-19 in 2020 which led to the suspension or postponement of various marketing events.

GENERAL AND ADMINISTRATIVE EXPENSES

The Group's general and administrative expenses primarily consist of salaries and benefits for management and administrative staff, listing expenses, legal advisory fees, and expenses for professional services related to audit and tax.

The Group's general and administrative expenses in 2020 were RMB46,855,000, representing a decrease of RMB48,236,000 from RMB95,091,000 in 2019, primarily attributable to the inclusion of listing expenses in the expenses for the same period in 2019.

FINANCE INCOME

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

The Group's finance income in 2020 was RMB1,880,000, representing an increase of RMB200,000 from RMB1,680,000 in 2019.

FINANCE COSTS

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

The Group's interest expenses on bank borrowings in 2020 were RMB1,185,000, representing a decrease of RMB334,000 from RMB1,519,000 in 2019, primarily attributable to the funds raised from the IPO in 2019 and the repayment of bank borrowings in the first half of 2020, which resulted in a relatively low level of average bank borrowings in 2020.

FAIR VALUE CHANGE IN FINANCIAL INSTRUMENTS ISSUED TO INVESTORS

The Group's financial instruments issued to investors were the convertible preferred shares issued in 2018, which were automatically converted into ordinary shares of the Company upon the IPO on 8 November 2019.

The fair value change in the financial instruments issued to investors was determined mainly with reference to the total equity value of the Group as determined by an independent valuer. In 2020, the Group had no financial instrument issued to investors, while the fair value loss in financial instruments issued by the Group to investors amounted to RMB29,085,000 in 2019.

INCOME TAX EXPENSES

During 2020 and 2019, the Group did not incur any income tax expense because 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 RMB288,498,000 in 2020, representing a decrease of RMB10,802,000 from RMB299,300,000 in 2019.

NET ASSETS

The Group's net assets as at 31 December 2020 were RMB582,357,000, representing a decrease of RMB275,920,000 from net assets of RMB858,277,000 as at 31 December 2019, primarily attributable to the net loss for the year of 2020.

LIQUIDITY, FINANCIAL RESOURCES AND CASH MOVEMENT

As at 31 December 2020, the Group's cash and cash equivalents were RMB225,533,000, representing a decrease of RMB313,647,000 from RMB539,180,000 as at 31 December 2019, mainly attributable to the cash outflows related to operating loss, capital expenditures and the repayment of bank borrowings.

In 2020, the Group's net cash outflows for operating activities were RMB263,116,000, representing an increase of RMB11,787,000 from net cash outflows of RMB251,329,000 in 2019, primarily attributable to employee benefit expenses and the progress of research and development projects. The Group's net cash inflows from investing activities were RMB12,526,000, as compared to net cash outflows of RMB51,102,000 in 2019, primarily attributable to the redemption of principal-guaranteed structured deposits with licensed commercial banks and a decrease in capital expenditures. The Group's net cash outflows for financing activities were RMB61,707,000, as compared to net cash inflows of RMB583,022,000 in 2019, primarily attributable to the proceeds from the IPO in 2019 and the repayment of bank borrowings in 2020.

MANAGEMENT DISCUSSION AND ANALYSIS OF CERTAIN ASPECTS OF OUR BUSINESS

INDUSTRY OVERVIEW

The oncology drug market in China has grown rapidly in recent years. According to a Frost & Sullivan report, the sales volume of oncology drugs increased from US$16.9 billion in 2015 to US$28.1 billion in 2019, representing a CAGR of 13.5%; and it is expected to reach US$56.5 billion in 2024 and US$101.8 billion in 2030, respectively, representing an average CAGR of approximately 15.0%. The enormous oncology market in China has created opportunities for the development of innovative pharmaceutical technology companies with the support of the national policy of encouraging innovative drugs, and more domestic innovative oncology drugs will be marketed to meet the huge market demand in the future.

TOT BIOPHARM OVERVIEW

Focusing on the innovative oncology drugs and therapies, TOT BIOPHARM has a fully integrated platform of drug discovery, product development, pre-clinical and clinical development, as well as commercial production. Currently, we have a comprehensive portfolio of drug candidates targeting various types of cancers, which includes various product pipelines, such as monoclonal antibodies (mAbs), antibody drug conjugates (ADCs), oncolytic virus and small molecular drugs. We are committed to the commercial production strategic deployment with well-rounded production capacity and processes, and have a 16,000L mAb drugs production workshop and a commercial production workshop for ADC drug substance. We always adhere to our corporate vision of improving the quality of life of cancer patients worldwide with innovative technologies. We are committed to building a leading brand name of oncology treatments trusted by patients and their families as well as medical professionals.

In the past year, we focused on our core resources, accelerated the progress of five key products, and enhanced our innovative product pipeline with two innovative biological candidates.

At present, we have 13 drug candidates, including biological drugs such as TAB008 (anti-VEGF mAb), TAB014 (anti-VEGF mAb) and TAY018 (anti-CD47 mAb), and ADCs such as TAA013 (anti-HER2 ADC), which are indicated for various cancers with high incidence, such as non-small-cell lung cancer, breast cancer, gastric cancer, esophageal cancer and cervical cancer.

Product Pipeline

Type	Drug Candidate	Indication(s)	Pre-Clinical	Phase I	Phase II	Phase III	NDA[1]
Antibody drug conjugate	TAA013 (anti-HER2)	HER2-positive breast cancer					
	TAE020 (new target)	Acute myeloid leukemia, AML					
Monoclonal antibody/ Recombinant protein	TAB008[2] (anti-VEGF)	nsNSCLC					
	TAB014[3] (anti-VEGF)	Wet age-related macular degeneration (wAMD)					
							IND authorized by FDA to directly enter Phase III
	TAY018 (anti-CD47)	Non-Hodgkin's lymphoma, myelodysplastic syndrome, acute myelogenous leukemia, solid tumors					
	TAC020 (new target)	Various solid tumors					
	TEP118 (modified version of hyaluronidase)	Biliary cancer, gallbladder tumors, metastatic cancer, NSCLC, gastric cancer					
Chemical drug	TOZ309 (temozolomide)	Malignant brain tumor					Submitted ANDA[4]
	TOM312 (megestrol acetate)	Cancer and HIV-associated cachexia				BE	Submitted Taiwan ANDA
	TIC318 (carboplatin)	Epithelial-derived ovarian cancer, small-cell lung cancer, head and neck squamous cell carcinoma, testicular tumors, malignant lymphoma, cervical cancer, bladder cancer, NSCLC					
Oncolytic virus	TVP211 (genetically modified vaccinia virus)	Solid tumors					
Liposome chemical drug	TID214 (liposomal docetaxel)	Solid tumors					
	TIO217 (liposomal oxaliplatin)	Gastrointestinal tumors					

Note:

(1) NDA is applicable to the application of new drugs and Category 5.1 imported drugs

(2) TAB008 is a bevacizumab biosimilar and is TOT BIOPHARM's most advanced biological drug candidate. Bevacizumab has been approved for the treatment of NSCLC, mCRC and malignant brain tumor in China. Additional indications of bevacizumab approved in the United States or the EU include renal cell carcinoma, cervical cancer, ovarian cancer, breast cancer, liver cancer, etc.

(3) TAB014 is an ophthalmic formulation of bevacizumab, with the right of commercialization in Mainland China, Hong Kong and Macau licensed out

(4) ANDA is applicable to the application of generic drugs or Category 5.2 imported drugs

Commercialization Planning

TOT BIOPHARM adheres to the business philosophy of the integration of innovative R&D and commercial production, and constantly improves its production capacity and scale construction.

In 2012, the construction of Stage I Plant was completed, which was equipped with a 500L pilot workshop for biological drugs and a BSL-2 certified viral facility, workshops for oral form and injection form of small molecular anti-cancer drugs, and commercial production facilities for nanoliposome drugs. In 2018, the construction of Stage II Plant was completed, which had a 16,000L capacity for monoclonal antibody production. In September 2020, the construction of drug substance production facility was completed for the commercial production of ADCs, and the clinical drug production of multiple batches of ADC drugs was completed. In 2020, the production workshop for chemical drugs has completed the GMP compliance inspection, which laid a foundation for the commercial production of chemical drugs.

In the next three years, the Group will continue to expand the scale of commercial production with bioreactors of different specifications and to achieve tens of thousands of liters of production capacity. On the basis of meeting the marketing demands for our own products, we seize the market opportunities of commercial production to intensify the investment in the construction of commercial production. Leveraging our well-developed process development capability, we accelerate the expansion of CDMO/CMO business. Through our independent operation, we connect all links of the upstream and downstream of the industry to provide customers with comprehensive, safe and high-quality services.

BUSINESS REVIEW

Paving the way for the next decade of strategic development of TOT BIOPHARM, the Group constantly improves the governance framework, and continues to drive the achievement of strategic objectives of the Group. The Group is committed to develop TOT BIOPHARM into an ADC leader in China, and synchronously promote the rapid expansion of CDMO/CMO business and accelerate the international strategic collaboration to further strengthen the was competitive advantages of the Group.

Soon-to-be-commercialized Drugs

- TAB008 (anti-VEGF mAb) (non-squamous non-small-cell lung cancer (nsNSCLC)): The new drug application was submitted under the new version of the Administrative Measures for Drug Registration, and was accepted in September 2020. It is expected to be marketed in 2021.

- TOZ309 (temozolomide capsules (200mg,100mg)): The pre-approval registration inspection in respect of the temozolomide generic drug, which is a chemical drug, was completed. It is expected to be approved for marketing in the first half of 2021.

- TOM312 (megestrol acetate): We have completed the commercial-scale formulation process validation through continuous technological optimization, and have successfully submitted the abbreviated new drug application (ANDA) in Taiwan.

Clinical Trial Progress and Achievement

- TAB008 (anti-VEGF mAb) (non-squamous non-small-cell lung cancer (nsNSCLC)): Its Phase III clinical results have reached the endpoints. The study results were published in an E-Poster at European Society for Medical Oncology Asia Congress (ESMO ASIA) in November 2020.

- TAA013 (anti-HER2 ADC) (HER2-positive breast cancer): Phase III clinical trial was initiated in June 2020 with the first patient enrolled in July, and it is currently at the stage of clinical recruitment. The Phase I clinical results in December 2020 were published in an E-Poster at the San Antonio Breast Cancer Symposium (SABCS).

- TAB014 (anti-VEGF mAb) (wet age-related macular degeneration (wAMD)): We have completed the pivotal Phase III clinical trial and the consultation with the Center for Drug Evaluation (CDE) of the National Medical Products Administration, and directly carried out the Phase III clinical trial exempting from the domestic Phase II clinical trial. At the same time, we submitted the investigational new drug (IND) application in respect of the Phase III clinical trial application of TAB014 to the US FDA, based on the data from the Phase I clinical trial of TAB014 conducted in China and relevant clinical literature data. This IND application is a direct application for authorization to conduct Phase III clinical trial (being exempted from Phase II clinical trial).

- TOM312 (megestrol acetate) (cancer and HIV-associated cachexia): We have submitted the abbreviated new drug application (ANDA) in Taiwan. The clinical protocol of the bioequivalency study (BE study) was approved by the Ethics Committee of Research Center. Meanwhile, the BE study in human will be carried out in Mainland China. We plan to complete relevant studies in 2021.

- TIC318 (carboplatin) (epithelial-derived ovarian cancer, small cell lung cancer, head and neck squamous cell carcinoma, testicular tumors, malignant lymphoma, cervical cancer, bladder cancer and NSCLC): We have completed commercial-scale formulation process validation in the high-activity drug injection workshop.

Key Products in Clinical Trial

- *Core product TAB008 – the New Drug Application submitted and accepted*

  TAB008 is the TOT BIOPHARM's independently developed bevacizumab biosimilar for the treatment of nsNSCLC. The new drug application (NDA) submitted under the new version of the Administrative Measures for Drug Registration and was accepted in September 2020. The pre-approval registration inspection was completed at the beginning of 2021 and the drug is planned to be marketed in 2021, which will be the first marketed biological drug of the Group.

  The study compares TAB008 and bevacizumab combined with paclitaxel and carboplatin chemotherapy for the first-line treatment of advanced or recurrent nsNSCLC. The primary endpoint compares the efficacy of TAB008 and Avastin by evaluating the objective response rate (ORR) of two groups of patients within the first 18 weeks of treatment (i.e. six three-week cycles). A total of 549 patients were enrolled in the clinical, including 277 patients and 272 patients (of which one patient without medication was not included in the full analysis set after randomization) in the TAB008 group and brand-name drug research group, respectively, and there is no significant difference of baseline characteristics between the two groups. The clinical results show that TAB008 has similar efficacy, safety, immunogenicity and pharmacokinetics profiles for the first-line treatment of advanced or recurrent nsNSCLC after locally treatment with the brand-name formulation of bevacizumab.

- *TAA013 – successfully entered Phase III clinical trial with dosing in the first patient completed*

  TAA013 is currently the first ADC product of T-DM1 entering Phase III clinical trial in China's market. It is an ADC candidate containing trastuzumab and emtansine (Trastuzumab-MCC-DM1), aiming to become an affordable alternative drug to Kadcyla for the treatment of HER2-positive breast cancer. In July 2020, we successfully dosed in the first patient in the Phase III clinical trial which is the stage of recruitment, and we plan to launch the drug in the market in 2023. According to a Frost & Sullivan report, the market size of ADC products for HER2-positive breast cancer in China is expected to increase from US$2.6 million in 2020 to US$228.9 million in 2024, representing a CAGR of 207.4%, and it is expected to reach US$414.9 million in 2030.

  In December 2020, the Phase I clinical results of TAA013 were published in an E-Poster at the San Antonio Breast Cancer Symposium (SABCS). This study is an open-label, single-arm, "3+3" dose escalation study with five dosage groups, including 0.6mg/kg, 1.2 mg/kg, 2.4 mg/kg, 3.6 mg/kg and 4.8 mg/kg, for the treatment of HER2-positive breast cancer patients who have previously gone through disease progression after trastuzumab treatment, to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamic profiles of TAA013. The study results show that TAA013 is safe and well tolerated, and the preliminary efficacy has been seen in HER2-positive breast cancer patients who received multiline anti-HER2 targeted drug therapy.

- *TOZ309 – pre-approval registration inspection completed*

  TOZ309, a generic drug for temozolomide capsule, is used as a chemical drug for the treatment of malignant brain gliomas and is used as a first-line medication for the treatment of newly diagnosed and recurrent brain gliomas. The pre-approval registration inspection was completed in December 2020. The GMP compliance inspection of the chemical drugs production workshops located in Suzhou, Jiangsu Province was completed, laying the foundation for the commercial production of small molecules in the future. It is expected that the TOZ309 will be approved for marketing in 2021.

- *TOM312 – BE research approved by Ethics Committee*

  TOM312 is a generic drug candidate for Megace (megestrol acetate oral suspension) for the treatment of cancer and HIV-associated cachexia. We have completed the development of key processes and technologies as well as process validation, and achieved large-scale batch commercial production capacity. The BE clinical protocol of TOM312 was approved by the Ethics Committee of Research Center, and we plan to complete all clinical research work in 2021.

Business Highlights

TOT BIOPHARM, a biopharmaceutical high-tech enterprise specializing in the R&D and production of new anti-tumor drugs, is headquartered in Suzhou Industrial Park, Suzhou City, Jiangsu Province, China, and is equipped with R&D centers and manufacturing facilities. We have an early R&D center in Zhangjiang Hi-Tech Park, Shanghai and a regulation and clinical medicine center in Beijing. The three self-developed technology platforms of the Group have the commercial production capacity for mAbs and ADCs and a sound international quality management system and registration team, which lay a foundation for accelerating the progress of R&D, international market plan and CDMO business.

- *Our three integrated technology platforms*

  (1) **Therapeutic mAb and ADC technology platform**: The platform is capable of performing a wide range of functions, from screening cell clones and building cell banks to chemistry, manufacturing and controls (CMC) development, pilot production, scale-up production, purification, filling and packaging. To maximize the synergy of the development of antibody drugs, in addition to mAbs, the Group also further develops ADCs by linking the antibody to the cytotoxic agent. In September 2020, after the construction of ADC drug substance production facility was completed and put into operation, we became one of the few companies in China that has integrated commercial production capabilities for mAbs and ADCs. Accordingly, TOT BIOPHARM will open up its platform, strengthen collaboration, accelerate product R&D, and develop competitive CDMO/CMO business.

  (2) **Gene engineering-based therapeutic technology platform**: This platform integrates anti-tumor immunotherapy, gene therapy and viral therapy and functions as an R&D and manufacturing platform for the tumor-targeted recombinant oncolytic virus vector system. The Group has a dedicated R&D team in Zhangjiang Hi-Tech Park, Shanghai focusing on early discovery and enhancing the Group's capability to collaborate with other innovative oncology drug companies. The Group has developed TVP211, an oncology drug based on vaccinia virus, and continues to use this drug for platform verification. With integrated R&D capabilities, patents and state-of-the-art laboratories for molecular biology, cytology, and virology as well as our first-class facilities, more R&D and production of oncolytic virus products will be conducted.

(3) **Innovative drug delivery technology platform**: An advanced targeted liposome drug delivery system is developed on this platform. Liposomes are increasingly used as a delivery system due to their biocompatibility, biodegradability, low toxicity, and aptitude to trap both hydrophilic and lipophilic drugs and simplify site-specific drug delivery to tumor tissues. Commercial-scale production of liposomes as a drug delivery system is difficult due to the sophistication of the technologies involved, and so far, only around 10 liposome drug products have been launched globally. We have developed commercial-scale, GMP-compliant manufacturing capability for liposome drugs. The production lines utilize aseptic isolators to produce OE-B-5 chemical injections while ensuring quality consistency. In addition, this system is concentrated and located on the target tissue, the target organ, or target cells with sustained release of the active molecules. The Group has accumulated extensive practical experience, in the future, we will also focus on the research and technology development of liposome drug delivery systems for small molecule chemical and nucleic acid drugs with special preparations and complex formulations.

- *Our competence in ADC drug R&D leads the Chinese market*

  Compared to conventional chemotherapy and mAbs, ADCs have superior efficacy. With the help of an antibody, an ADC can specifically target tumor cells and deliver the cytotoxic drug conjugated to such antibody into tumor cells, possessing both the high-efficiency cancer cell killing power of chemical drugs and the targeting ability of biological drugs.

  TAA013, as a self-developed ADC drug of TOT BIOPHARM, has completed the enrollment of the first participant in Phase III clinical trial in July 2020. As the most advanced ADC product under the generic name (INN) of T-DM1 currently in China's market, TAA013 demonstrates a sharp competitive edge in the market.

  In terms of technology, we have core conjugation process technologies and have successfully established several stable production processes for ADC drug substance and formulations to ensure stability and a high degree of batch-to-batch consistency of products; we have a complete ADC analysis technology platform and independent analysis capabilities in respect of ADC critical metric attributes to ensure the successful development of ADC processes and the high quality of products; we have achieved technical breakthroughs in the regulation of glycoforms, enabling precise control of the composition of each glycoform to make them similar to the brand-name drug candidate Kadcyla (赫賽萊).

  In terms of commercial production, we possess one of the few domestic GMP-compliant ADC commercial production workshops that integrate mAb and ADC drug substance and drug preparation. We have an ADC pilot workshop that meets the OEB-5 level and a GMP-compliant large-scale commercial drug substance production facility, which were put into operation in September 2020 and have produced multiple batches of medicine for the Phase III clinical trial of TAA013.

In terms of team composition, we have R&D professionals specializing in ADC conjugation process technologies and an analysis team specializing in of complex ADC molecular structures. We have completed the R&D and production of several new-generation ADC drugs of strategic partners with extensive practical experience and successful cases.

- *Commercial production advantages and CDMO/CMO strategic collaboration*

  With a comprehensive commercial production platform of high international standards and a strict project control system, we increased resource investment, actively promoted CDMO/CMO business, and developed diversified strategic collaboration with domestic and foreign pharmaceutical companies to provide customers with high-standard and high-quality CDMO/CMO services.

  The Group's commercial production technologies demonstrate a sharp competitive edge in cost-effectiveness. Its self-developed perfusion-batch combined process flows, PB-Hybrid Technology, can realize commercial production from 25L to 2,000L without going through the 10L, 100L and 200L steps in the cell culture process, thereby streamlining process flows and reducing production risks, while at the same time shortening production cycles, lowering production costs, and greatly improving production capacity and cost advantages. Leveraging our edges in platform and commercial production capabilities, we will continuously enhance external collaboration.

  In terms of monoclonal antibody drugs, antibody drug conjugates and chemical drugs, the Company provides fully-integrated services and possesses teams ranging from R&D, process development, clinical trials, registration application to commercial production. For the year of 2020, the Company has reached commercial collaboration with several innovative pharmaceutical companies to provide CDMO/CMO services for new drug R&D partners, including the CDMO collaboration with Kintor Pharmaceutical Limited (9939.HK) to continuously provide clinical supplies manufacturing and technical support for its core product Proxalutamide (普克魯胺) in China and the United States. At the same time, we provide Kintor with clinical supplies manufacture for the novel coronavirus (COVID-19) overseas (including the United States, Brazil, etc.). With the provision of CDMO/CMO services to new drug R&D partners, we are pursuing diversified collaboration opportunities while increasing the Company's cash flows.

- *Comprehensive international quality management system and drug registration team*

  TOT BIOPHARM has established a comprehensive quality management system that complies with the required standards of the International Conference on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The system covers the entire product life cycle from R&D to process development, clinical drug production, commercial drug production, material and product supplier management, as well as post-marketing tracking. We have obtained ISO14000 Environmental Management System certification and possess practical experience including new drug research, clinical application and marketing application. We have a professional quality control team which has remarkably completed a series of quality-related work in drug R&D, investigational new drug (IND) applications, clinical sample production and commercial production of products.

We have specialized regulatory affairs offices at our Suzhou headquarters and in Beijing, with knowledge of domestic and foreign drug regulations and practical experience in registration applications. We maintain good communication with relevant medical regulatory bodies in China, the United States and Europe, pay close attention to changes in domestic and international regulatory registration and filing policies, and conduct targeted research and analysis work to make full preparation for successful marketing and internationalization of products in the future.

During the reporting period, we have completed the communication with the Center for Drug Evaluation (CDE) of the National Medical Products Administration and with the U.S. Food and Drug Administration (FDA) on the clinical implementation strategy of TAB014. With dual IND submissions in both China and the United States, we have laid the foundation for expanding the international market. In September 2020, the new drug marketing application (NDA) for bevacizumab injection (TAB008) was submitted in accordance with the requirements of the new Drug Administration Law and the Administrative Measures for Drug Registration and has been accepted. According to the new regulations, the approval time will be greatly shortened, and the marketing process will be accelerated.

At the same time, fully appreciating that the proprietary nature of and protection afforded to our drug candidates and prescription processes are an important part of the strategies for product development and commercialization of new drugs, the Group attaches particular importance to patent protection. We have filed patent applications for certain drugs and drug candidates such as TAA013, TOZ309 and TOM312 in China while proactively seeking additional patent protection overseas.

Our response to COVID-19 and fulfillment of social responsibilities

2020 was particularly unusual because of the outbreak of COVID-19. In the face of the global outbreak of COVID-19, the Group promptly took precautionary and control measures and implemented business continuity plan to reduce the impact of the pandemic on R&D, clinical trials and production. Through the unremitting efforts of the employees and management team during the pandemic, the Group resumed full operation on 10 February 2020. At the same time, in view of the continued spread of the pandemic across the world, after the Board and management team carefully assessed internal and external risk factors and considered the potential objective factors such as the increase in price of raw materials and the prolongation of equipment procurement cycles caused by the pandemic, TOT BIOPHARM has launched various plans and measures in advance to ensure stable business operations.

Meanwhile, with the strong support of the Board, we actively fulfilled our social responsibilities. We donated money and goods to the Hubei Charity Federation and relevant medical institutions, provided epidemic prevention supplies for employees and their families, and formulated flexible and caring measures for employees commuting to ensure their health and safety.

Reallocation of Listing Proceeds

During the reporting period, in order to cater for the strategic development and business model adjustments of TOT BIOPHARM, the Group reallocated unused listing proceeds and converged our resources to build a domestic leading ADC R&D and production platform and develop the CDMO/CMO business with competitive advantages.

The Group will continue to accelerate the progress of the Phase III clinical trial of TAA013, enhance its R&D and production platform technologies for ADC products, and expand its ADC product pipelines. The Group seeks to join hands with well-known domestic pharmaceutical companies by proactively negotiating licensing or collaboration schemes for the marketing rights in respect of several soon-to-be-commercialized product pipelines including TAB008, TOZ309, TAA013 and others. The Group adjusts its focus of R&D resource allocation to concentrate its resources on the R&D projects in respect of product pipelines that possess greater market superiority, and to reduce the resources devoted to non-core product pipelines. The Group fully leverages its existing production processes and production capacity advantages to, on the basis of meeting the supply of soon-to-be-commercialized products, further strategically expand its high-value-added potential business opportunities and invest more resources in commercial development, facilities as well as ingredients and excipients to an appropriate extent.

Prospects and Strategies

In the future, the Group will continue to converge its resources, increase the expansion of commercial production capacities, fully realize the advantages of its commercial production platform and accelerate the expansion of CDMO/CMO business while fulfilling the production demands for its own products. With a global outlook, the Group will actively promote its internationalization strategy, and is committed to opening up the global commercial rights of drug candidates. Through powerful collaboration, the Group aims to increase its market share rapidly and achieve stable cash flow.

In 2021, we will continue to focus on resources and advance the following development strategies:

Accelerate the expansion of production capacity and actively deploy CDMO/CMO business: In 2021, our key product TAB008 will be commercialized soon, and we will establish long-term partnerships with multiple suppliers to promote the rapid growth of the CDMO/CMO business of TOT BIOPHARM. According to market demand, we will introduce new different specifications of bioreactors based on the existing 16,000L production capacity of mAb drugs to ultimately achieve tens of thousands of liters of production capacity, aiming to become a domestic mAb and ADC commercial production platform with high competitiveness and provide customers with high-quality and comprehensive services.

Continue to strengthen the construction of the ADC R&D and commercial platform: We actively promote the enrollment of Phase III clinical patients in respect of TAA013 by internal and external collaboration and communication. We converge resources and promote collaboration to constantly launch and enrich our ADC product pipelines. Leveraging TOT BIOPHARM's outstanding strengths in the ADC field, we simultaneously deploy our ADC commercial platform, which will be equipped with hydro-acupuncture and lyophilized preparations workshops, and are committed to developing TOT BIOPHARM into a company with pilot and commercial drug substance and formulation production workshops of ADC drugs meeting international standards.

Embrace openness and win-win collaboration to promote domestic and international commercial collaboration for drug candidates: At present, TOT BIOPHARM has multiple product pipelines such as biological drugs, ADC drugs and chemical drugs, and is soon entering upon a new phase of commercialization with huge market potential. TOT BIOPHARM has been adhering to the principle of openness, collaboration and win-win, and exploring future commercial development strategies with various domestic and foreign partners. With a one-stop, whole-industry-chain platform which encompasses R&D, clinical trials, regulatory applications, manufacturing and commercialization, TOT BIOPHARM actively seeks strategic collaboration domestically and internationally. We will receive milestone payments through the transfer of domestic and foreign sales rights. Through diversified collaboration models, we share resources, accelerate the progress of product R&D and marketing, and rapidly increase our domestic and foreign market share to enhance our market competitiveness. Leveraging our unique advantages in R&D and production, we strengthen CDMO/CMO business collaboration to provide pharmaceutical companies with production capacity and technological requirements which they are lacking in, and help customers shorten production time and reduce production costs in a cost-effective manner.

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 2020, 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 2020 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 2020.

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 2020, 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 2020 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**").

The Net Proceeds were utilized in accordance with the proposed applications as set out in the section headed "Future Plans and Use of Proceeds" in the prospectus published by the Company on 29 October 2019 during the period from 1 January 2020 to 27 October 2020. On 27 October 2020, the Board resolved to change the use of the Net Proceeds with effect from that date. For further details, please refer to the announcement of the Company dated 27 October 2020 (the "**October Announcement**"). Since 27 October 2020, the Net Proceeds were utilized in accordance with the proposed applications as set out in the October Announcement. During the year ended 31 December 2020, such Net Proceeds amounting to approximately RMB266,454,000 were used, and the unused amount of the Net Proceeds was approximately RMB182,161,000 as at 31 December 2020. The amount of the Net Proceeds which remain unused were being kept by the Group as deposits with licensed commercial banks. Such unused Net Proceeds are intended to be applied in accordance with the proposed applications as set out in October Announcement.

A breakdown of the use of the aforesaid Net Proceeds during the year ended 31 December 2020 and an expected timeline for the use of the unused portion will be disclosed in the 2020 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 2020.

SUBSEQUENT EVENTS

No major subsequent events have occurred since 1 January 2021 and up to the date of this announcement.

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 2020 annual report of the Company and the notice convening the 2020 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 Information" section of this announcement does not constitute the Company's statutory financial statements for the year ended 31 December 2020 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 2020 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 2020. The auditor's report is unqualified, does not include a reference to any matter to which the auditor drew attention by way of emphasis without qualifying its reports, and does not contain a statement under section 406(2) or 407(2) or (3) of the Companies Ordinance.

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

Hong Kong, 23 March 2021

As at the date of this announcement, the executive Directors of the Company are Ms. Yeh-Huang, Chun-Ying and Dr. Liu, Jun; the non-executive Directors of the Company are Mr. Fu, Shan, Dr. Kung, Frank Fang-Chien, Mr. Kang, Pei and Mr. Qiu, Yu Min; and the independent non-executive Directors of the Company are Ms. Hu, Lan, Dr. Sun, Lijun Richard and Mr. Chang, Hong-Jen.