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东曜药业

TOT BIOPHARM International Company Limited

東曜藥業股份有限公司

(Incorporated in Hong Kong with limited liability)

(Stock code: 1875)

ANNUAL RESULTS ANNOUNCEMENT FOR THE YEAR ENDED 31 DECEMBER 2019

HIGHLIGHTS OF 2019 ANNUAL RESULTS AND MILESTONES

Financial highlights:

- Revenue amounted to RMB45,308,000, representing a 16% year-on-year increase, mainly attributable to diversified revenue sources such as CMO and CDMO service fees as well as commissions for marketing services provided
- Research and development expenses amounted to RMB191,078,000, representing a 1% year-on-year increase
- Net loss amounted to RMB299,300,000, representing a 12% year-on-year increase mainly due to listing expenses

Key milestones of pipeline products:

- TAB008 (anti-VEGF mAb; core product): Enrollment of patients for Phase III clinical trial was completed, with NDA under preparation
- TAB014 (anti-VEGF mAb): Recognized as a special major project for technologies of “innovative manufacturing of major new drugs” of China
- TAA013 (anti-HER2 ADC): We are the first pharmaceutical company in China to publish Phase I clinical data for an ADC product under the generic name (INN) of T-DM1
- TOZ309 (temozolomide): ANDA was submitted and accepted for filing

Key milestones of production processes:

- Our self-developed Perfusion-Batch Hybrid Technology (PB-Hybrid Technology) was tested through the multi-batch production of TAB008, TAB014 and TAA013, laying the foundation for commercial production
- Construction of an ADC commercial production workshop in progress
- Construction of a liposome injection workshop was completed

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 2019 together with comparative figures for the year ended 31 December 2018 as set out in the section headed “Consolidated Financial Information” section of this announcement.

CHAIRMAN’S STATEMENT

Dear Shareholders,

The year of 2019 is a milestone year in the development of TOT BIOPHARM International Company Limited. With the Company’s successful listing on the Main Board of The Stock Exchange of Hong Kong Limited (the “**Stock Exchange**”) on 8 November 2019, the Group has entered a new stage of internationalization and rapid development. The listing also represents the high recognition by the capital market of our innovative development. We believe that with the support of our shareholders and the capital market, the competitive edge of TOT BIOPHARM will become even more prominent.

The Company is pleased to present its first annual results for the year ended 31 December 2019. Looking back at 2019, the Company’s successful initial public offering (the “**IPO**”) brought in new capital which gave new impetus to our business development. The gross proceeds from the IPO amounted to approximately HK\$589,500,000 (approximately US\$75,000,000), which will be mainly used for R&D, launch and commercialization of our drug candidates. In 2019, with our open technology and collaboration platform, our revenue from diversified sources such as contract manufacturing organization (“**CMO**”) and contract development and manufacturing organization (“**CDMO**”) service fees as well as commissions for marketing services provided amounted to approximately RMB45,308,000, representing an increase of approximately 16% as compared with approximately RMB39,219,000 in 2018, demonstrating a robust cash flow capability of the Company. Our research and development (“**R&D**”) expenses amounted to approximately RMB191,078,000, representing an increase of approximately 1% as compared with approximately RMB188,651,000 in 2018.

INDUSTRY REVIEW

The oncology drug market in China has grown rapidly in recent years. According to a report by Frost & Sullivan, the sales volume of oncology drug market in China has increased from US\$15,000,000,000 in 2014 to US\$24,200,000,000 in 2018, representing a CAGR of 12.8%. The figure is expected to grow at a CAGR of 15.0% from 2018 further to US\$48,700,000,000 in 2023. During the same period, the size of China's oncology drug market has grown at a faster rate than other segments of the pharmaceutical market, and its percentage share in China's pharmaceutical market has also been growing. Given the rapid growth in market demand and the urgent needs for drugs by patients, the Chinese government has stepped up its efforts to introduce favorable policies to drive the development of the pharmaceutical industry, such as promoting pharmaceutical innovation, accelerating the approval of launches of new drug for cancer treatment and continuously expanding the scope of the National Drug Catalogue for Basic Medical Insurance. Driven by the market and policies, the Group has been highly committed to the development of anti-tumor drugs and has equipped itself with full industry chain capabilities to provide optimal solutions at different stages of the product life cycle, creating value for customers, shareholders, patients and medical professionals.

BUSINESS REVIEW

Focusing on oncology and providing integrated solutions

TOT BIOPHARM focuses on the oncology field and is one of the few anti-tumor pharmaceutical enterprises in the industry that integrate the full industry chain capabilities of drug discovery, process development, pre-clinical and clinical development, commercial scale production and marketing. We adopt an open platform business model to enable diversified collaboration with partners at different stages of the industry value chain. With our IPO and listing in Hong Kong, we have gained access to more financing channels which are conducive to the acceleration of various operations of the Group.

Equipped with our integrated technologies, open business platform and full industry value chain capabilities, we are able to operate our business in a more commercial manner. We have a robust and sustainable product pipeline for launch over the next five years to drive sustainable business growth. Of the current 12 drug candidates (11 of which are self-developed drugs), 7 are biologic drug candidates and 5 are chemical drug candidates. Our product pipeline covers 9 of the top 10 cancers with the highest incidence in China, with drugs indicated for common cancers such as non-squamous NSCLC (a common type of lung cancer), breast cancer, malignant brain glioma, nasopharyngeal cancer, esophageal cancer, pancreatic cancer and gastric cancer.

Technological innovation capability highly recognized by China

As one of the biotechnology companies listed in Hong Kong, TOT BIOPHARM is at the forefront of technological innovation and has achieved remarkable results. It is encouraging that our TAB014 has also been recognized by China, with its clinical research and commercialization project recognized as a special major project for technologies of “innovative manufacturing of major new drugs” of China and granted funding from the central government, demonstrating the strength of TOT BIOPHARM in technological innovation. In respect of TAB008, our most advanced biologic drug candidate and our core product, the enrollment of patients for Phase III clinical trial has been completed and the new drug application (“NDA”) is under preparation. We are also the first pharmaceutical company in China to publish Phase I clinical data for an ADC product under the generic name (INN) of T-DM1, namely TAA013, which is our self-developed ADC drug. After consulting with the National Center for Drug Evaluation (CDE), we plan to commence Phase III clinical trial in 2020.

Fruitful achievements in R&D and various operations

In 2019, we made significant progresses in both product R&D and business collaboration, which were progressing as planned.

In terms of clinical trial progress, TAB008 (anti-VEGF mAb) (non-squamous non-small cell lung cancer (nsNSCLC)) is expected to be launched at the end of 2020 or early 2021, and TAD011 has entered Phase I clinical . In terms of commercialization and production, the construction of a commercial-scale production workshop for biological drugs and a liposome injection workshop has been completed, while an ADC commercial production workshop is under construction. We are the first pharmaceutical company in China to maturely exploit the Perfusion-Batch Hybrid Technology (the “**PB-Hybrid Technology**”), with our production processes and capacity upgraded during the year. In terms of strategic collaboration, we have collaborated with a number of well-established pharmaceutical companies in fields such as the development of innovative drugs or combination therapies to promote the implementation of the Company’s long-term development strategy.

OUTLOOK

As the new year began, the outbreak of novel coronavirus pneumonia around the world is a wake-up call to China and all mankind. As a biopharmaceutical company, TOT BIOPHARM played an active role in fulfilling its social responsibilities. We promptly set up an epidemic prevention and control team, donated RMB1,000,000 to the Hubei Charity Federation, and provided frontline medical personnel and cancer patients with nutritional supplements to show our sincere support. At the same time, we actively formulated strict prevention and control measures in accordance with the government's requirements. On the premise of ensuring "health and safety", we received the official approval for resumption of work from the government on 9 February 2020 and formally resumed operation on 10 February 2020. Currently, all operations of the Company are carried out in an orderly manner.

We look ahead brimming with confidence! The oncology drug market in China is rapidly evolving and the Group is well positioned against the backdrop of the continuous national support for the pharmaceutical industry. Facing the global market with a strong foothold in China, TOT BIOPHARM will drive the implementation of the Company's long-term development strategies with openness and innovation. With our solid R&D, clinical and commercialization capabilities, we will push forward the launch of our products as early as possible, provide patients with high-quality, safe and affordable drugs, and create decent returns for our shareholders and investors.

Fu, Shan

Chairman and Non-executive Director

17 March 2020

GENERAL MANAGER’S REPORT

Dear Shareholders,

The year of 2019 was of heartening significance for TOT BIOPHARM. We were listed on the Main Board of the Stock Exchange during the year, successfully entered the international capital market. Remarkable progress has been made in the R&D of various drug candidates with promising market potential. With our proprietary production processes and full industry chain coverage, we are well-prepared for the commercialization of our core product. Embracing the robust development of China’s pharmaceutical industry, we endeavour to strengthen our presence in China and become an international leader. We have established a clear blueprint for our business development and paved our way to further prosper in the future!

INDUSTRY REVIEW

The Chinese government has improved the medical and pharmaceutical systems with a rise in quality in recent years for the benefit of the people. Given the accelerated implementation and deepening of multiple medical reform policies in 2019, biomedicine has entered a golden age of development. The expanding coverage of the National Drug Catalogue for Basic Medical Insurance, the accelerated approval of anti-cancer drugs and the quality consistency evaluation system of generic drugs have created a more favorable competitive environment for enterprises. Although opportunities always come along with challenges, China’s pharmaceutical market is still a thriving industry and the market demand is yet to be satisfied. We are confident that we can ride on the development of the industry and stand out from our peers by leveraging our rich product portfolio and unique technological edge.

BUSINESS REVIEW

Leading technologies and commercial production capabilities outperforming our peers

Leading R&D technologies of antibody drug conjugates (ADC)

Antibody drug conjugates (ADC) combines two main advantages, namely the targetedness of antibodies and the high activity of small molecule drugs, and has become one of the two most cutting-edge focused areas in the R&D of new antibody drugs. It is also an important core technology for the strategic development of TOT BIOPHARM. The large-scale commercial production of ADC drugs is extremely challenging worldwide. Benefitting from our forward-looking development plans for oncology drugs, TOT BIOPHARM is one of the few biopharmaceutical companies in China with both ADC drug development and production capabilities. We are optimistic about the prospect of the future development of ADC drugs, and are capable of becoming the leader in such field. Our professional R&D team has been working tirelessly and has conducted extensive R&D over the years, amassing rich experience in the ADC field which allows us to become a forerunner in technology among our peers. Our R&D team will continue to make progress in the R&D of ADC drugs.

TAA013 is an ADC candidate containing trastuzumab emtansine (Trastuzumab-MCC-DM1) which aims to become an affordable alternative drug to Kadcyla for the treatment of breast cancer. The publication of its Phase I clinical data was completed in September 2019. This is also the first ADC product under the generic name (INN) of T-DM1 to have its Phase I clinical data published in the Chinese market. It is encouraging that we plan to commence Phase III clinical trial in 2020 after consulting with the National Center for Drug Evaluation (CDE). We are also fully prepared for its commercial production. We expect to complete Phase III clinical trial by the end of 2022 and launch the drug in 2023. We believe that in the near future TAA013 will become a key new growth driver for the Group.

Self-developed innovative cell expansion technology (PB-Hybrid Technology) with remarkable competitive edge in production

TOT BIOPHARM possesses unique advantages in the commercialization process of biological drugs. We independently developed the PB-Hybrid Technology, and took the lead in using such technology to accomplish large-scale production in China. The PB-Hybrid Technology is a state-of-the-art technology that disrupted the traditional cell expansion process for large-scale monoclonal antibody production. It can be expanded from 25L to 2000L directly without going through the 10L, 50L, 200L and 500L expansion steps, thereby streamlining process flows, optimizing product quality, shortening production cycles and reducing capital expenditures. This brings remarkable advantages to our production.

Apart from fulfilling TOT BIOPHARM's internal demand for production capacity, by leveraging the Company's commercialization experience and technological advantages, this innovative technology can also provide technical services and collaboration opportunities for domestic and foreign biopharmaceutical companies through TOT BIOPHARM's comprehensive one-stop collaboration platform, so as to further enhance TOT BIOPHARM's core position in the biopharmaceutical industry.

Three self-developed R&D technology platforms and highly efficient commercial production facilities

We independently established three advanced integrated technology platforms, through which we can develop more innovative products. We can also combine different platforms for drug development and production. These 3 platforms include: (1) the therapeutic monoclonal antibody and antibody drug conjugates (ADC) technology platform; (2) the gene engineering-based therapeutic technology platform; and (3) the innovative drug administration technology platform. We have invested in the construction of a professional anti-cancer drug R&D and production base (with a site area of approximately 50,000 sq.m.) in accordance with advanced international standards at our headquarters in Suzhou. Divided into a biopharmaceutical R&D and production base as well as workshops for oral form and injection form of small molecular drugs, our production base is capable of achieving commercial production of biological and small molecular drugs. Our designed capacity for monoclonal antibody production reaches 16,000L. In combination with the application of the PB-Hybrid Technology in the commercial production of antibody drugs, our production base has become a prominent competitive edge of TOT BIOPHARM.

Encouraging progress in product R&D

Our vision is to improve 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, and providing more cancer patients with access to high-quality and affordable anti-cancer drugs, thereby promoting their physical, mental and spiritual well-being. Our product pipeline consists of various biological drugs and small molecular products, covering 9 of the top 10 cancers with the highest incidence in China and satisfying patients' demand for comprehensive cancer treatment solutions. During the year, we achieved encouraging milestones with the joint effort of our team:

Applications for approval

We have submitted the abbreviated new drug application (“**ANDA**”) for TOZ309 which has been accepted for filing, and we have also filed the relevant patent application. Besides, we have submitted the ANDA for TOM218 which has been accepted for filing.

Clinical trial progress

Clinical trials for our drug candidate pipeline are progressing as planned. In respect of TAB008 (anti-VEGF mAb) (non-squamous non-small-cell lung cancer (nsNSCLC)), our soon-to-be-commercialized product, the enrollment of patients for Phase III clinical trial has been completed and the NDA is under preparation, with the approval for launch expected to be obtained at the end of 2020 or early 2021. In respect of TAA013 (anti-HER2 ADC), the publication of Phase I clinical data was completed in 2019 and we plan to commence Phase III clinical trial in 2020. In respect of TAD011, Phase I clinical trial has commenced as planned.

Commercialization and production

Our production workshop for biological drugs with a total capacity of 16,000L has been tested through the production of multiple batches of medicine for clinical trials, laying a solid foundation for the production and marketing of our products in the future. The construction of a liposome injection workshop was completed during the year. Meanwhile, the construction of an ADC commercial production workshop is underway, with the construction of its drug substance production facility scheduled to be completed in 2020.

Strategic collaboration

Our advanced technological capabilities, production strengths and stringent quality control have attracted companies at different stages of the industry chain to establish strategic partnerships with us. During the year, we established various collaborative relationships for joint R&D in innovative drugs and other combination therapies, CMO/CDMO and other operations. Such collaborative relationships will enrich and innovate our product pipeline and extend our product life cycles, and will continuously enhance the Company's brand recognition while fully realizing its advantages, thereby allowing the Company to continue to stride towards a broader market.

Operations such as CMO, CDMO and provision of marketing services generating diversified revenue

We possess CMO and CDMO service capabilities as well as marketing capability, which equip us with a diversified revenue model prior to the marketing of our new products. We have a high production capacity and a well-developed comprehensive technology platform for oncology R&D. While fulfilling our internal demand, we are also capable of providing high-standard and high-quality CMO and CDMO services to domestic and foreign pharmaceutical companies. We have established a comprehensive sales network of oncology drugs that covers over 20 provinces, municipalities and autonomous regions through the provision of marketing services, which guarantees the rapid transformation of our products into value. Although TOT BIOPHARM is still a Chapter 18A company, we are one of the few companies among our counterparts that can generate revenue. Leveraging our solid technology platform and independent development capabilities, we have established diversified revenue channels and created value for shareholders, partners and society. For the year ended 31 December 2019, our total revenue amounted to approximately RMB45,308,000, which consisted of diversified revenue such as CMO and CDMO fees as well as marketing commissions. This fully reflects the trust and support of our partners in TOT BIOPHARM, and allows us to accumulate extensive experience for marketing self-developed products in the future.

Ready to embrace a wide range of market opportunities

The morbidity and mortality rates of malignant tumors in China have been on the rise, and there is a keen demand for anti-cancer drugs which has also brought plenty of room for development to China's pharmaceutical market. Antibody drugs are crucial for tumor treatment and see a continuously expanding market. Covering the popular targets for drug development, they currently rank among the top 10 drugs worldwide in terms of sales volume. According to a report by Frost & Sullivan, as of 2018, antibody drugs accounted for more than half of the global biologics market but only approximately 6.1% of the Chinese market, representing a huge unmet potential.

We are ready to seize the huge market opportunities. In 2020, we will continue to push forward the NDA of TAB008 in order to ensure that the product will be approved for launch as scheduled and become one of the pioneers. TOZ309 and TOM218 are close to commercialization. TAA013, an ADC product, is moving towards Phase III clinical trial. The R&D and clinical research of other products will progress as planned. Looking forward, we will accelerate our R&D activities, focus on advancing the clinical research of drugs such as TAB008, TAA013 and TAB014, further open up our operations and platforms, and introduce different collaborative partners, thereby enriching our product pipeline and achieving diversified revenue.

We will always adhere to our business philosophy of “Balance of Humanity and Technology” with anti-tumor drugs playing a pivotal role and “technological innovation + internationalization” as guiding principles. We will integrate the existing “industry value chain and product chain”, consolidate the “innovative technology platform, commercial production platform, clinical research platform as well as marketing and business platform”, and build a “two-chain four-platform” system. We are committed to developing new anti-tumor drug products with high technological barriers and economic value, providing an appropriate and affordable product portfolio, and creating satisfactory value for our shareholders and society.

Yeh-Huang, Chun-Ying

General Manager and Executive Director

17 March 2020

CONSOLIDATED FINANCIAL INFORMATION

CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS

For the year ended 31 December 2019

		Year ended 31 December	
	Note	2019	2018
		RMB'000	RMB'000
Revenue	3	45,308	39,219
Cost of revenue		(11,316)	(5,980)
Research and development expenses		(191,078)	(188,651)
Selling expenses		(31,544)	(38,935)
General and administrative expenses		(95,091)	(54,638)
Other gains – net		14,117	11,808
Operating loss		(269,604)	(237,177)
Finance income		1,680	727
Finance costs		(2,291)	(2,404)
Finance costs – net		(611)	(1,677)
Fair value change in financial instruments issued to investors		(29,085)	(29,409)
Loss before income tax		(299,300)	(268,263)
Income tax expense	4	–	–
Loss for the year and attributable to the equity holders of the Company		(299,300)	(268,263)
Other comprehensive income/(loss):			
<i>Items that will not be reclassified to profit or loss</i>			
Changes in the fair value of equity instruments at fair value through other comprehensive income		1,181	355
<i>Items that may be reclassified to profit or loss</i>			
Exchange difference on translation		(15,111)	(19,563)
Other comprehensive loss for the year, net of tax		(13,930)	(19,208)
Total comprehensive loss for the year and attributable to the equity holders of the Company		(313,230)	(287,471)
Loss per share for the year and attributable to the equity holders of the Company			
– Basic and diluted losses per share (RMB)	5	(0.89)	(0.91)

CONSOLIDATED BALANCE SHEET

As at 31 December 2019

		As at 31 December	
		2019	2018
	<i>Note</i>	<i>RMB'000</i>	<i>RMB'000</i>
ASSETS			
Non-current assets			
Property, plant and equipment		300,230	294,420
Prepayments for property, plant and equipment		9,244	7,042
Right-of-use assets		28,435	29,324
Intangible assets		2,391	1,901
Financial assets at fair value through other comprehensive income		7,991	6,810
Other non-current assets		54,708	38,054
		402,999	377,551
Current assets			
Inventories		15,250	3,105
Trade and other receivables	7	14,406	9,694
Prepayments		10,938	10,745
Contract assets		2,450	2,060
Financial assets at fair value through profit or loss		32,139	17,332
Cash and cash equivalents		539,180	256,751
		614,363	299,687
Total assets		1,017,362	677,238
EQUITY			
Share capital	8	1,874,438	537,859
Other reserves		36,925	31,449
Accumulated losses		(1,053,086)	(753,786)
Capital and reserves attributable to the equity holders of the Company		858,277	(184,478)
Total equity/(deficit)		858,277	(184,478)

		As at 31 December	
		2019	2018
	<i>Note</i>	<i>RMB'000</i>	<i>RMB'000</i>
LIABILITIES			
Non-current liabilities			
Financial instruments issued to investors		–	773,767
Lease liabilities		<u>12,299</u>	<u>12,810</u>
		<u>12,299</u>	<u>786,577</u>
Current liabilities			
Borrowings		60,000	500
Accruals and other payables	9	81,418	69,300
Contract liabilities		2,593	3,022
Lease liabilities		<u>2,775</u>	<u>2,317</u>
		<u>146,786</u>	<u>75,139</u>
Total liabilities		<u>159,085</u>	<u>861,716</u>
Total equity and liabilities		<u>1,017,362</u>	<u>677,238</u>
Net current assets		<u>467,577</u>	<u>224,548</u>
Total assets less current liabilities		<u>870,576</u>	<u>602,099</u>

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 are listed on the Main Board of The Stock Exchange of Hong Kong Limited (the “**Stock Exchange**”).

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 applied HKFRS 16 consistently throughout the years ended 31 December 2019 and 2018.

The Group has adopted the following amendment to standards and interpretations which are mandatory for the year ended 31 December 2019:

Annual Improvements Project	Annual Improvements 2015-2017 Cycle
Amendments to HKAS 19	Plan Amendment, Curtailment or Settlement
Amendments to HKAS 28	Long-term Interests in Associates and Joint Ventures
Amendments to HKFRS 9	Prepayment Features with Negative Compensation
HK(IFRIC)-Int 23	Uncertainty over Income Tax Treatments

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:

		Effective for annual periods beginning on or after
Amendments to HKFRS 3	Definition of a Business	1 January 2020
Amendments to HKAS 1 and HKAS 8	Definition of Material	1 January 2020
HKFRS 17	Insurance Contracts	1 January 2021
Conceptual Framework for Financial Reporting 2018	Revised Conceptual Framework for Financial Reporting	1 January 2020
Amendments to HKAS 39, HKFRS 7 and HKFRS 9	Hedge Accounting	1 January 2020
Amendments to HKFRS 10 and HKAS 28	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture	To be determined

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

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

3. SEGMENT AND REVENUE INFORMATION

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.

The amount of each category of revenue is as follows:

		Year ended 31 December	
		2019	2018
		RMB'000	RMB'000
Timing of revenue recognition			
At a point in time:			
– Commission revenue		29,822	26,111
– CMO		6,466	11,274
– Sales of goods		911	527
– Others		9	107
Over time:			
– CDMO		8,100	1,200
		45,308	39,219

Geographical information of revenue and non-current assets other than financial assets for the years ended 31 December 2019 and 2018 is as follows:

	Year ended 31 December			
	2019		2018	
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
	Revenue	Non-current assets	Revenue	Non-current assets
China	45,308	339,349	39,219	331,642
Others	–	1,127	–	1,241
	<u>45,308</u>	<u>340,476</u>	<u>39,219</u>	<u>332,883</u>

The major customers which contributed more than 10% of the total revenue of the Group for the year ended 31 December 2019 and 2018 are listed as below:

	Year ended 31 December	
	2019	2018
	<i>RMB'000</i>	<i>RMB'000</i>
Customer A	29,822	26,111
Customer B	<u>6,466</u>	<u>11,278</u>
Total	<u>36,288</u>	<u>37,389</u>

4. INCOME TAX EXPENSE

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

Hong Kong

No provision for Hong Kong profits tax has been provided for at the rate of 16.5% (2018: 16.5%) as the Company has no estimated assessable profit.

Mainland China

No provision for Mainland China income tax has been provided for at a rate of 25% or 15% (2018: 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 profits.

TOT BIOPHARM Co., Ltd. ("TOT Suzhou") is qualified as a "High and New Technology Enterprise" under the relevant PRC laws and regulations in 2014 and 2017. Accordingly, TOT Suzhou was entitled to a preferential income tax rate of 15% on its estimated assessable profits commencing from 2014 to 2020.

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.

Taiwan corporate income tax

No provision for Taiwan corporate income tax has been provided for at a rate of 20% (2018: 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	
	2019	2018
	RMB'000	RMB'000
Loss attributable to equity holders of the Company (RMB'000)	(299,300)	(268,263)
Weighted average number of ordinary shares in issue (thousand) (Note)	335,654	293,359
Basic loss per share (RMB)	(0.89)	(0.91)

Note: The weighted average number of ordinary shares for the purpose of basic and diluted loss per share for the years ended 31 December 2019 and 2018 has been retrospectively 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 2019, the Company had one category of potential ordinary shares: the stock options granted to employees (2018: the Company had two category of potential ordinary shares: the Convertible Preferred Shares and the stock options granted to employees). As the Group incurred losses for the years ended 31 December 2019 and 2018, 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 2019 and 2018 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 (2018: Nil).

7. TRADE AND OTHER RECEIVABLES

		As at 31 December	
		2019	2018
	Note	RMB'000	RMB'000
Trade receivables from contracts with customers	(a)	6,741	6,938
Other receivables		7,665	2,756
		<u>14,406</u>	<u>9,694</u>

Note (a) Customers are generally granted with credit terms ranging from 15 to 60 days. As of 31 December 2019 and 2018, the ageing analysis of the trade receivables based on invoice date is as follows:

	As at 31 December	
	2019	2018
	RMB'000	RMB'000
Within 30 days	4,727	4,792
31 days to 90 days	2,014	2,146
	<u>6,741</u>	<u>6,938</u>

8. SHARE CAPITAL

Issued and fully paid:

	Number of ordinary shares	Share capital RMB'000
As at 1 January 2018 and 31 December 2018	84,000,000	537,859
Issue of shares upon exercise of share options (<i>Note (a)</i>)	2,267,500	19,801
Conversion of convertible preferred shares to ordinary shares (<i>Note (b)</i>)	51,174,876	817,276
Capitalization issue (<i>Note (c)</i>)	342,557,624	–
Issue of shares upon initial public offering, net of underwriting commissions and other issuance costs (<i>Note (d)</i>)	90,000,000	499,502
As at 31 December 2019	<u>570,000,000</u>	<u>1,874,438</u>

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.

9. ACCRUALS AND OTHER PAYABLES

	As at 31 December	
	2019	2018
	RMB'000	RMB'000
Staff salaries and welfare payables	10,108	9,605
Payables for purchase of property, plant and equipment	15,879	18,448
Accrued costs for research and development	20,200	27,419
Accrued promotion and advertisement fee	1,017	622
Accrued listing expenses	20,629	5,679
Payables due to related parties	520	3,071
Accrued office expenses and others	13,065	4,456
	<u>81,418</u>	<u>69,300</u>

10. SUBSEQUENT EVENTS

After the outbreak of Coronavirus Disease 2019 (“COVID-19 outbreak”) in early 2020, a series of precautionary and control measures have been and will continue to be implemented across the PRC, including but not limited to temporary suspension of on-site works, restrictions on enterprises from resuming work and stringent control over hygiene measures. The Group has officially resumed work since 10 February 2020. However, some of the research and development projects are still subject to various regulatory or administrative measures to control the outbreak of COVID-19, which resulted in delays in resumption of clinic trials in hospitals and delays in our research and development progress.

The Group will pay close attention to the development of the COVID-19 outbreak and evaluate its impact on the financial position and operating results of the Group. Pending development of such subsequent non-adjusting event, the Group's financial results may be affected, the extent of which could not be estimated as at the date of this announcement.

MANAGEMENT DISCUSSION AND ANALYSIS OF CERTAIN FINANCIAL ITEMS

OVERVIEW

In 2019, the Group recorded a revenue of RMB45,308,000, as compared to RMB39,219,000 in 2018; and a net loss of RMB299,300,000 in 2019, as compared to a net loss of RMB268,263,000 in 2018. The Group's research and development expenses in 2019 were RMB191,078,000, as compared to RMB188,651,000 in 2018. The Group's general and administrative expenses in 2019 were RMB95,091,000, as compared to RMB54,638,000 in 2018. The selling expenses in 2019 were RMB31,544,000, as compared to RMB38,935,000 in 2018.

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 CMO and CDMO services to other biotechnology companies, etc.

The Group's commission revenue in 2019 was RMB29,822,000, representing an increase of RMB3,711,000 from RMB26,111,000 in 2018, primarily attributable to the sales growth of S-1.

The Group's revenue from CMO and CDMO services in 2019 was RMB14,566,000, representing an increase of RMB2,092,000 from RMB12,474,000 in 2018, primarily attributable to the continuous support of our CMO and CDMO partners. The materials, labor and expenses, etc. necessary for the CMO and CDMO services increased along with the business growth.

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 2019 were RMB191,078,000 and the research and development expenses in 2018 were RMB188,651,000, which remained basically stable and aligned with the Company's development plan.

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 2019 were RMB31,544,000, representing a decrease of RMB7,391,000 from RMB38,935,000 in 2018. Such decrease was primarily attributable to changes in the arrangements for conference events and the decrease in salaries and benefits for marketing staff, etc.

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 2019 were RMB95,091,000, representing an increase of RMB40,453,000 from RMB54,638,000 in 2018, primarily attributable to the Group's listing expenses. General and administrative expenses excluding listing expenses remained basically stable.

OTHER GAINS, NET – GOVERNMENT GRANT

The Group's government grants primarily consist of incentives and other subsidies for research and development activities as well as interest subsidies, which mainly include government incentives granted according to the clinical development progress of our drug candidates. The Group's government grants in 2019 were RMB13,390,000, representing a slight increase from RMB12,514,000 in 2018.

OTHER GAINS, NET – NET FOREIGN EXCHANGE GAINS/(LOSSES)

The Group recorded net foreign exchange gains of RMB2,396,000 in 2019, representing an increase of RMB3,587,000 from net foreign exchange losses of RMB1,191,000 in 2018, primarily attributable to the valuation of foreign currency-denominated assets and liabilities as well as the foreign exchange settlement and conversion in relation to financial planning.

FINANCE INCOME

The Group's finance income is primarily interest income on bank deposits. The finance income in 2019 was RMB1,680,000, representing an increase of RMB953,000 from RMB727,000 in 2018, attributable to the higher average balance of our bank deposits 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 2019 were RMB1,519,000, representing a decrease of RMB601,000 from RMB2,120,000 in 2018.

FAIR VALUE CHANGE IN FINANCIAL INSTRUMENTS ISSUED TO INVESTORS

The Group's financial instruments issued to investors were 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 our Group, which was determined by an independent valuer. The Group's fair value loss in 2019 on financial instruments issued to investors was RMB29,085,000, as compared to RMB29,409,000 in 2018, reflecting an increase in the fair value of these financial instruments.

INCOME TAX EXPENSE

During 2019 and 2018, 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 loss of RMB299,300,000 in 2019, representing an increase of RMB31,037,000 from RMB268,263,000 in 2018.

NET ASSETS/(LIABILITIES)

The Group's net assets as of the end of 2019 were RMB858,277,000, representing an increase of RMB1,042,755,000 from net liabilities of RMB184,478,000 as of the end of 2018, primarily attributable to the proceeds from the IPO and the conversion of convertible preferred shares into share capital, which resulted in a significant improvement in the overall financial structure.

CASH MOVEMENT AND SOURCE OF FUNDS

As at 31 December 2019, the Group's cash and cash equivalents were RMB539,180,000, representing an increase of RMB282,429,000 from RMB256,751,000 as at 31 December 2018. Such increase was mainly attributable to the proceeds from the IPO and bank borrowings as partially offset by the outflows for operating activities and investing activities.

In 2019, the Group's net operating cash outflows were RMB251,329,000, representing an increase of RMB74,497,000 from RMB176,832,000 in 2018, primarily attributable to an increase in employee benefit expenses and listing expenses (the portion recognized as expense in profit and loss). The Group's net investing cash outflows were RMB51,102,000, representing an increase of RMB4,035,000 from RMB47,067,000 in 2018, which remained basically stable. The Group's net financing cash inflows were RMB583,022,000, representing an increase of RMB125,421,000 from RMB457,601,000 in 2018, mainly attributable to the proceeds from the IPO and new bank borrowings as partially offset by the repayment of bank borrowings.

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 2019, 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 2019 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 2019.

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 CG Code has been applicable to the Company with effect from 8 November 2019 (the “**Listing Date**”) and was not applicable to the Company during the period from 1 January 2019 to 7 November 2019.

The Board is of the view that throughout the period from the Listing Date to 31 December 2019, the Company has complied with all the applicable code provisions as set out in the CG Code, except for the following:

Code provision A.2.7 of the CG Code stipulates that the chairman of the Board should at least annually hold meetings with independent non-executive Directors without the presence of other directors. As the Company was only listed on the Stock Exchange on 8 November 2019, the Company had not yet complied with such code provision within the less than two months’ period before the end of 2019. Arrangements have been made for compliance with such code provision in 2020 and beyond.

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.

Specific enquiry has been made of all the Directors and the Directors have confirmed that they have complied with the Model Code for the period from the Listing Date to 31 December 2019 and up to the date of this announcement.

USE OF NET PROCEEDS FROM THE 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.

Since the Listing Date and up to 31 December 2019, the Company had not utilized any net proceeds amount raised from the Global Offering. Such net proceeds are intended to be applied in accordance with the proposed applications as set out in the section headed “Future Plans and Use of Proceeds” in the Company’s prospectus dated 29 October 2019 in connection with the Global Offering.

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 period from the Listing Date to 31 December 2019.

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 2019 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 2019 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 2019 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 2019. 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
Yeh-Huang, Chun-Ying
Executive Director

Hong Kong, 17 March 2020

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.