东曜药业

東曜藥業股份有限公司

TOT BIOPHARM International Company Limited

Stock Code: 1875

2019 Annual Results Corporate Presentation

March 2020

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Vision

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TOT BIOPHARM

Improve the quality of life of cancer patients worldwide with innovative technology

Our Value

Make the appropriate anti-cancer drugs accessible to appropriate cancer patients at appropriate treatment stage.

Provide quality anti-cancer drugs at reasonable prices.

Aim to improve cancer patients' physical, psychological and spiritual health.

Mission

Build a leading brand name of oncology treatments trusted by patients and their families as well as medical professionals

Business Review – Development and Key Milestones of TOT

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Business

2009
- Company incorporated

2011
- Began to build sales and marketing team to market S-1, an oncology drug in China

2012
- Completed the construction of No.1 Campus

2016
- The first pilot program for MAH collaborations in Jiangsu Province, recognizing our quality by national authority.
- Obtained clinical trial approval for TAB008, TAD011 and TOZ309

2017
- Commenced Phase III clinical trials for TAB008, our Core Product
- Obtained clinical trial approval for TAB014 and authorization for commercialization of TAB014 in China

2018
- Clinical trial approval for TAA013
- Completed the construction of No. 2 Campus

2019
- Patient enrollment for Phase III clinical trial of TAB008 was completed
- TAA013 was the first T-DM1 ADC product to release Phase I clinical data in the Chinese market
- Marketing applications for TOM218 and TOZ309 have been submitted and have been accepted for filing

Financing

2011
- Completed initial equity financing

2015
- Completed equity financing from Vivo Capital, Centerlab, Prime Success, Formosa Lab, etc.

2018
- Completed issuance of Class B Preferred Shares

2019
- Listed on the Main Board of Stock Exchange

Awards and Recognitions

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Garners the "Outstanding Science and Technology R&D Award" and "Technology Enterprise Listing Award" issued by Suzhou Industrial Park

2019	2018 Annual Economic Contribution Award (Product Innovation)	**2018**	Gazelle Company of the Sunan National Innovation Park
2019	2018 Annual Economic Contribution Award (Making Use of Foreign Capital)	**2018**	Gazelle Company of Suzhou
2019	Jiangsu Zifeng Award for Technological Innovation Enterprises	**2018**	Science and Technology Research and Development Outstanding Contribution Award, Suzhou Industrial Park
2019	Exemplary Case of Corporate Social Responsibility	**2017**	Jiangsu Foreign Research and Development Center
2018	Jiangsu Key Research and Development Program	**2017**	Top 10 Socially Responsible Enterprises, Suzhou Industrial Park
2018	Jiangsu Engineering Technology Research Center	**2017**	2017 Outstanding Economic Contribution Award
2018	Jiangsu Province Natural Science Foundation grantee	**2017** **2014**	National High-Tech Enterprise
2018	Suzhou Incubated Unicorn Company	**2013**	Tumor Gene Therapy Drug Engineering Technology Research Center

CONTENTS

1. Business Review and Outlook

Business Highlights and Key Milestones in 2019

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Authority's permission

- ✓ **TOM218:** ANDA has been submitted and has been accepted for filing
- ✓ **TOZ309:** ANDA has been submitted and has been accepted for filing and we have also filed the patent application
- ✓ **TOM312:** completed the development of key process technology and realized batch scale commercial product capacity.

R&D and clinical trial progress

- ✓ **TAB008:** enrolment of Phase III clinical patients has been completed, enter the stage of marketing application
- ✓ **TAB014**: included in "Major New Drugs Innovation" of the Major Science and Technology Project of the State
- ✓ **TAA013**: being the first T-DM1 category ADC product in China to publish Phase I clinical data
- ✓ **TAD011:** successfully entered Phase I clinical trial

Commercialization and production

- ✓ Profusion-Batch Hybrid Technology (PB-Hybrid Technology) is a technology developed by the Company's platform, with commercial-scale verification already completed through TAB008, TAB014 and TAA013
- ✓ Commenced the construction of an ADC commercial production workshop
- ✓ Completed a liposome injection workshop

Business collaboration

- ✓ Signed new CDMO contracts
- ✓ Jointly developed fully humanised monoclonal antibodies with Harbour Biomed
- ✓ Jointly developed early-stage ADC drug candidates with NewBio Therapeutics
- ✓ Explored combination therapies involving TAB008 and toripalimab, a recombinant humanised anti-PD-1 monoclonal antibody, in the treatment of late-stage liver cancer with Shanghai Junshi
- ✓ Explored combination therapies involving TAB008 and Alphamab's KN046 (a PD-L1 / CTLA-4 bispecific antibody) with Alphamab

Complete Industrial Value Chain & High-quality and Extensive Product Chain

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Innovative Technology Platform

- **3 advanced technology platforms equipped with full industry value chain capabilities**
  - Therapeutic Monoclonal Antibody and ADC Technology Platform
  - Gene Engineering Based Therapeutics Technology Platform
  - Innovative Drug Delivery Technology Platform

Clinical Research Platform

- **12** drug candidates in pipeline, **11** are in-house developed
- **6** drug candidates in clinical stage
- Clinical drug candidates cover **9** out of Top **10** cancer types in China

Autonomy in all key sessions of oncology drug industry

Marketing and Business Platform

- Our Professional and core marketing team focusing on the sales of oncology drugs segment
- Sales coverage in **20+** provinces, municipalities and autonomous regions
- Access to **450+** hospitals
- expand our sales team and further continue commercial cooperation with CSOs

Commercial Production Platform with high standard

- **Monoclonal antibody production facility**
  - Meets GMP standard
  - Total capacity can reach16,000L, already 2X2000L in operation
  - Innovative PB-Hybrid Technology has successfully completed multiple batches of production at commercial scale
- **ADC production workshop**
  - Already have ADCs research/pilot plant
  - The construction of ADC commercial production workshop is ongoing
- **Small-molecule oral formulations plant and injectable plant**
  - Meets GMP standard

Business and Marketing Platform

Professional Oncology Academic Sales and Marketing System

TOT BIOPHARM has established and developed a patient-oriented professional oncology academic marketing and sales system. This can facilitate cooperation with oncology experts in China, in order to enhance product knowledge and clinical penetration, and ensure professionalism in marketing and sales of oncology drugs in China.

Enhanced Branding Value

To conduct suitable clinical academic promotions and launch patient education activities with medical value, enhancing the branding value of TOT.

Market Coverage

Our core marketing and sales team will continue to enhance development and expand the team. To meet marketing and sales demand after product launch, we will enhance market coverage through our own operations and in cooperation with CSO.

Strategic Layout –
Open Cooperative Platform Integrates Different Strengths

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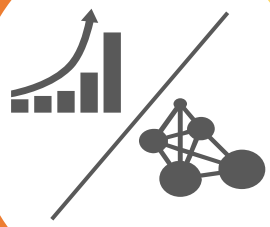
A one-stop full industrial value chain platform comprising R&D, production, clinical trials and commercialization

Link China with the world, aggregate innovative technologies, accelerate R&D progress and build our brand reputation internationally

Our Strengths

Strong ability to cover all stages of industry value chain

- Ability to discover new drugs and evaluation team strengthens the innovativeness of product portfolio
- Three technological platforms, including mAb and ADC technology platform, Gene engineering based therapeutics technology platform, and Innovative drug delivery technology platform.
- Large international standard production base.
- Our clinical teams are experienced in Phase III clinical trials of various drugs
- Our marketing and sales team has over eight years of academic promotion experience with oncology drugs.



Comprehensive Strategic Cooperation

Introduction/ licensing, co-development, technological services and support

- Use our own open platform to actively seek opportunities for international strategic cooperation in co-development of innovative drugs, expansion of indications of drug candidates and tap opportunities in markets.

  Capitalizing on our unique advantages in R&D and production, to enhance new cooperation with CMO, CDMO, and provide sufficient cashflow.

Industry-leading, Experienced and Professional Management Team Supported by a Strong Talent Base

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Experienced management team with diverse backgrounds and skillsets and a proven track record across the industry value chain

Platform

Ms. Yeh-Huang, Chun-Ying
Executive Director , General Manager

Over 30 years of experience in the pharmaceutical industry
Expertise in integrating the industry value chain, building leadership and formulating branding strategies

Clinical

Dr. Liu, Ming
Chief Medical Officer,
Vice General Manager

Engaged in oncology clinical treatment for over 30 years
12 years of experience in drug and tumor markers.
Previously employed by BeiGene USA, Taiwan National Health Research Institute, and National Institute of Cancer Research.

Chemical Drugs

Mr. Chen, Xiaobao
Senior Director of Chemical Drugs

Over 14 years of experience in the development of pharmaceutical products in collaboration with multinational companies
Worked as manager of research and development department of PUMC Pharmaceutical Co., Ltd.

Business Development

Mr. Wu, Chih-Yuan
Senior Director of
Strategic Business and Development

Nearly 20 years of experience in strategic business development in the pharmaceutical industry
Previous positions include Director of market advisory department at Taiho Pharmaceutical of Beijing Co., Ltd.

R&D, QC

Dr. Liu, Jun
Executive Director, Chief Scientific Officer ,
Vice General Manager

20 years of experience in the biotech industry
Previous positions include senior scientist at Bayer US LLC, executive director of biologics research and development department in Shanghai ChemPartner Co., Ltd, etc.

Manufacturing

Mr. Liu, Donglian
Vice General Manager

20 years of experience in the pharmaceutical industry
Specializes in the development and manufacturing of monoclonal anti-body drugs
Leading the company to self-development of PB-Hybrid Technology, the first in use in China to large scale production

General Management

Mr. Yao, Jau-Chang
Vice General Manager

25 years of experience in financial and accounting and nearly 10 years of experience in the biotech industry
Previous positions include director at PricewaterhouseCoopers Taiwan, focusing on the biotechnology and technology industries

Commercial-ization

Mr. Lin, Chun-Ming
Senior Director of Sales and Marketing

Over 20 years of experience in the healthcare industry
16 years specializing in the sales and marketing of tumor-related products

2. Product Pipeline and R&D Achievements

R&D Technology Platform Focused on Oncology Drugs

Therapeutic Monoclonal Antibody and ADC Technology Platform

- Covering screening of cell clone, cell banks building, CMC developments, pilot production and scale-up production, purification and filling and packaging
- Developed 4 mAbs or ADC drug candidates to clinical trials
- Integrate capability of R&D of antibodies and production, a production base for the commercialization of biological drugs in GMP standard with a designed capacity of 16,000L, can realize high-quality commercial production

Gene Engineering Based Therapeutics Technology Platform

- Integrates anti-tumor immunotherapy, gene therapy and viral therapy
- R&D and manufacturing platform for the tumor-targeted recombinant oncolytic virus vector system

Innovative Drug Delivery Technology Platform

- Builds integrated platform for the process development and industrialization of highly active drug injections
- Builds commercialization facilities for nanoliposome drugs that are applicable to different technologies
- Adopts co-platform production design of sterile lyophilization and sterile fill to meet GMP production requirements on OEB4/5 active grade lyophilized powder injection/liquid injection

Our Robust Product Pipeline

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- Our comprehensive product pipeline consists of **12** drug candidates, including **7** biological and **5** chemical drug candidates, constituting a risk balanced portfolio
- **6** drug candidates are in or beyond clinical stage, **4** of which are biological drug candidates in clinical stage and **2** of which are chemical drug candidates filed for ANDA or undergoing BE study

Category	Drug Candidate	Indication(s)	Registration Category	Pre-Clinical / Clinical Trial (I / II / III)	NDA[1]	Commercial Rights	Market Size 2024E(RMB)
Monoclonal antibody/ recombinant protein	TAB008[2] (anti-VEGF mAb)	nsNSCLC[3]	Category 2 biosimilar			Worldwide	14.2 billion
	TAD011 (anti-EGFR mAb)	Nasopharyngeal cancer, esophageal cancer, pancreatic cancer	Category 2 new drug		2023 (expected)	Worldwide	2.5 billion
	TAB014 [4] (anti-VEGF mAb)	Wet age-related macular degeneration (wAMD)	Category 1 new drug		2022 (expected)	Worldwide[5]	8.0 billion
	TAY018 (anti-CD47 mAb)	Non-Hodgkin's lymphoma, myelodysplastic syndrome, acute myelogenous leukemia, solid tumors	Category 1 new drug		-	Worldwide	-
	TEP118[6] (modified version of hyaluronidase)	Biliary cancer, gallbladder tumors, metastatic pancreatic cancer, NSCLC, gastric cancer	Category 1 new drug		-	Worldwide	-
ADC drug	TAA013 (anti-HER2 ADC)	HER2-positive breast cancer	Category 1 new drug		2022 (expected)	Worldwide	1.5 billion
Oncolytic virus drug	TVP211 (genetically modified vaccinia virus)	Solid tumors	Category 2 new drug		-	Worldwide	-
Liposome chemical drug	TID214 (liposomal docetaxel)	Solid tumors	Category 2 new drug		-	Worldwide	-
	TIO217 (liposomal oxaliplatin)	Gastrointestinal tumors	Category 2 new drug		-	Worldwide	-

Category	Drug Candidate	Indication(s)	Registration Category	CMC / BE Study / ANDA[7]	Market size 2024E(RMB)
Small molecular chemical drugs	TOZ309 (temozolomide)	Small molecule generics	Category 4 generic drug		2.5 billion
	TOM312 (megestrol acetate)	Cancer- and HIV-associated cachexia	Category 5.2 imported drug	2021 (expected)	843 million
	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	Category 4 generic drug	-	-

Note：The blue parts indicate key milestones after listing on 8 Nov 2019

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

(2) Core Product

(3) TAB008 is a bevacizumab biosimilar. Bevacizumab has been approved for the treatment of nsNSCLC and mCRC in China. Additional indications of bevacizumab approved in the United States or the EU include glioblastoma, renal cell carcinoma, cervical cancer, ovarian cancer and breast cancer

(4) TAB014 is an ophthalmic formulation of bevacizumab

(5) We licensed out the right of commercialization in China, Hong Kong and Macau

(6) Recombinant protein

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

TAB008 – Bevacizumab Market Sees Substantial Market Potential

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Phase I Clinical Trial for TAB008

- Data reflects PK and safety levels highly similar to originator. Related results have been published in internationally renowned academic forums and journals

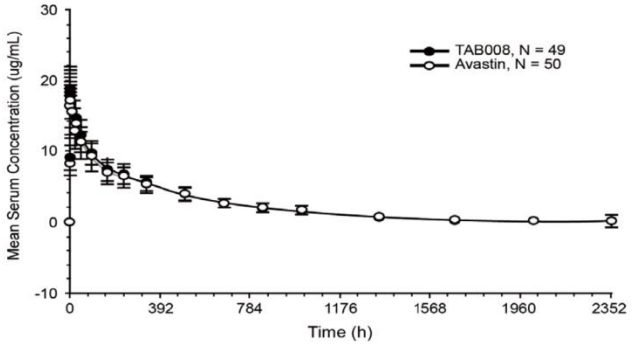
ASCO® AMERICAN SOCIETY OF CLINICAL ONCOLOGY

frontiers in Pharmacology

CLINICAL TRIAL published: 15 August 2019 doi: 10.3389/fphar.2019.00906

A Phase I, Randomized, Single-Dose Study Evaluating the Biosimilarity of TAB008 to Bevacizumab in Healthy Volunteers

*Jin Wang†, Lu Qi†, Long Liu, Zejuan Wang, Gang Chen, Yu Wang, Xiaona Liu, Ying Liu, Huijuan Liu, Yuanxu Tong, Chen Liu, Chunpu Lei and Xinghe Wang**



Phase III Clinical Trial for TAB008

- Completed patient enrolment for Phase III clinical trial in November 2019 and currently preparing for marketing application
- Expected to be launched by end of 2020 or early 2021
- Expected to become Tier 1 product in related market to meet strong demand from patients

Broad market potential, many opportunities for combination therapy and indications

- Bevacizumab has a wide range of indications
- The global bevacizumab market reached US $7.38 in 2019
- The bevacizumab market in China reached RMB 3.2 billion in 2018
- Market demand is expected to grow rapidly, which is still unmet

Advantage in Scalable Production

- Enjoy Cost Effectiveness
- Maintain Product Quality
- Stable Production and Supply

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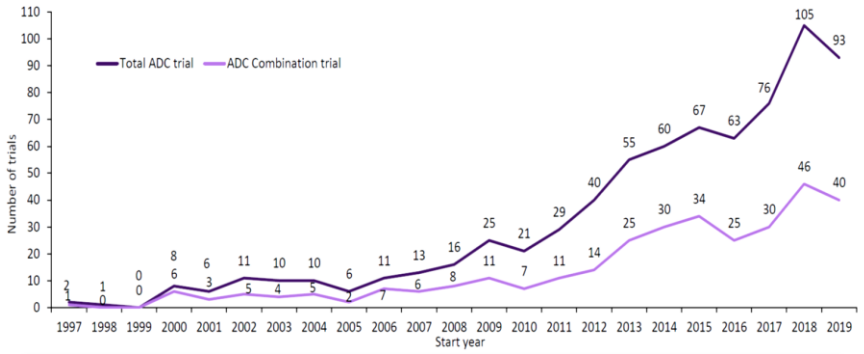
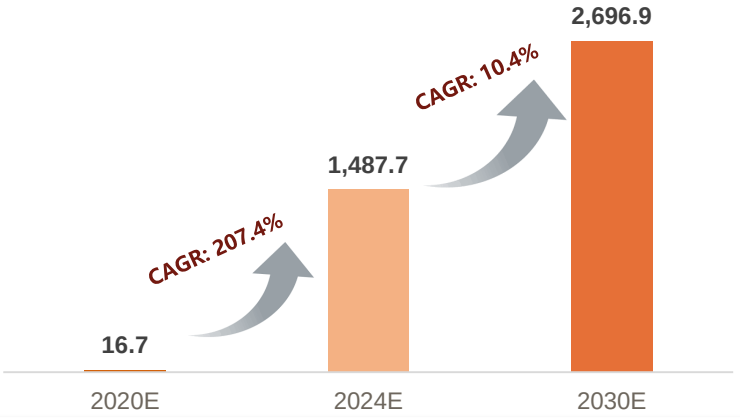
ADC – Key R&D area for antibody drug

No. of Clinical trial of ADC product increased significantly since 2016



- ADC market is expected to reach US $7.5 billion before 2025, with a CAGR of 19.4% from 2017 to 2019

Expected rapid growth of ADC products targeting treatment of HER2+ breast cancer in China



- Global sales of Kadcyla, a ADC drug biosimilar, was US$1 billion in 2018 and US$1.47 billion in 2019
- In 2018, 27,900 HER2+ breast cancer cases were confirmed in China. The number is expected to increase to 31,600 by 2023
- As several new products will be launched in early 2020, ADC products targeting treatment of HER2+ breast cancer will enter a period of rapid growth in China

Hanson Wade, Jan 2020

Source: Frost & Sullivan Report, Rouche 2019 Annual Report

TAA013 – New Growth Driver, Quick Entry Into the Market

TAA013

- ADC candidate containing trastuzumab and emtansine (Trastuzumab-MCC-DM1) aims to become an affordable alternative of Kadcyla

Key focus for product development, quick entry into the market

2019

- Completed the development and trial production for ADC product
- The first T-DMI ADC production to release phrase I clinical data in the Chinese market
- Completed several strategic cooperations in ADC product development and production

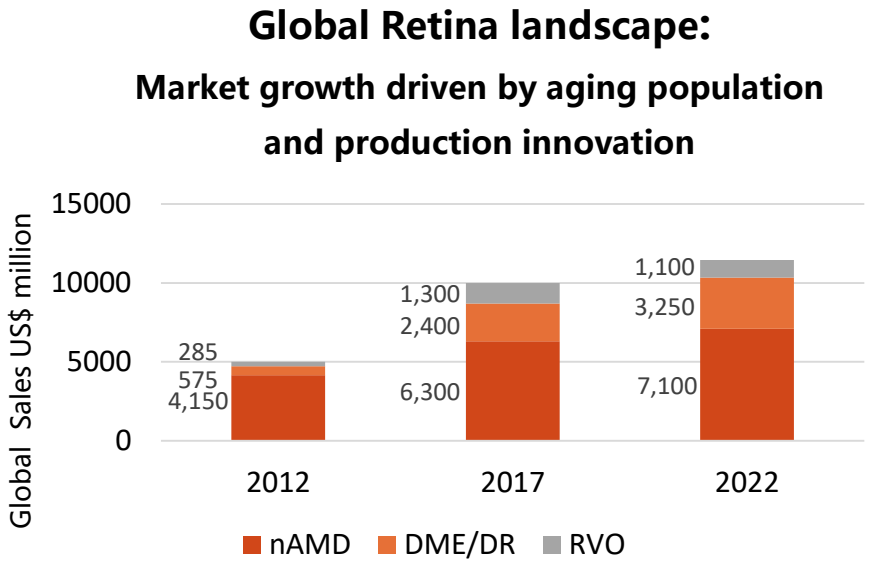
2020

1 Commence Phase III clinical trial, ahead of schedule

2 Construct ADC Commercial Production Workshop

- The ADC commercial production workshop under construction is to be one of the few ADC commercial production workshops in China
- To lay a foundation for the development and quick entry into the market in the ADC market

TAB014 - Listed in National Major Projects and Enters Internationalization Stage

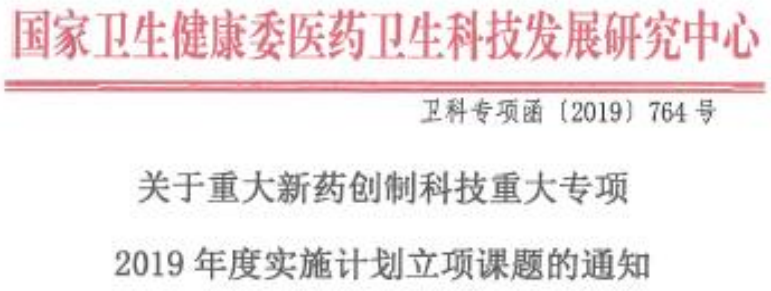


Market Potential

- Anti-VEGF is used to treat ophthalmological problems. The product has bright market prospects with value expected to reach USD11.4 billion by 2022

The Progress of TAB014

- Undergoing Phase I clinical research
- Completed regulatory consultations for FDA in the US and PEI in Europe between 2019 and 2020. Expected to complete IND application in the US in 2020, followed by key clinical progress
- Expected to complete Phase III clinical research by 2022 and be launched in 2023


国家卫生健康委医药卫生科技发展研究中心

卫科专项函〔2019〕764号

关于重大新药创制科技重大专项

2019年度实施计划立项课题的通知

- The country places great importance on TAB014 included in the “Major New Drugs Innovation” of the Major Science and Technology Project of the State

**PEI: Paul-Ehrlich-Institut: German Federal Institute for Vaccines and Biomedical Drugs*

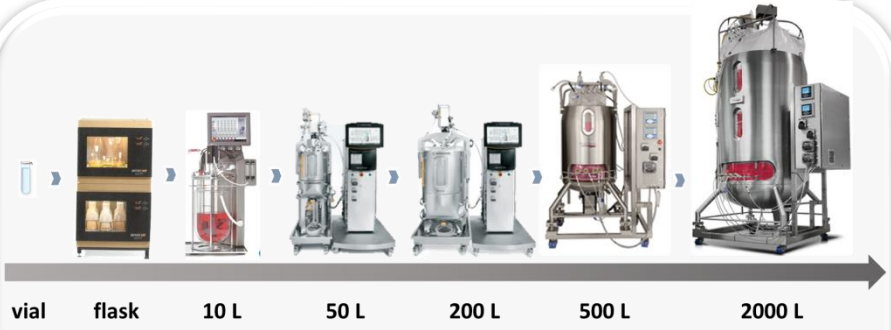
Innovative Commercial Production Capability

16,000L Monoclonal Antibody Production Workshop

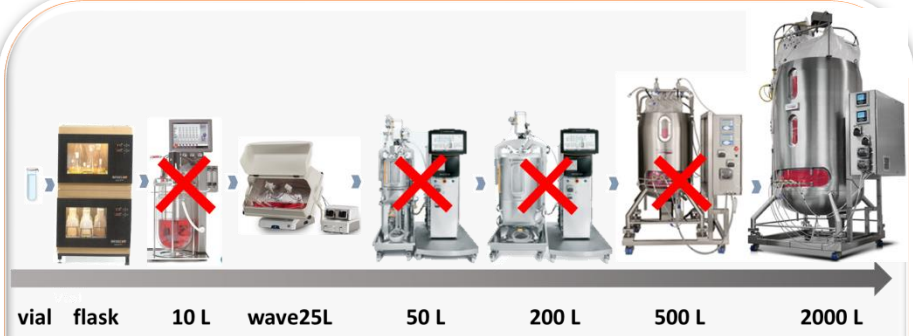
- **GMP-compliant, designed capacity of 16,000L, cost-efficient, with 4,000L production capacity in operation**

PB-Hybrid Technology Strong production competitive advantages

- TOT BIOPHARM's self-developed innovative cell expansion technology
- Can be expanded from 25L to 2,000L directly without going through the 10L, 50L, 200L and 500L expansion steps
- Strong overall production advantages can simplify process, optimise product quality, shorten production cycle and lower costs
- Successfully applied to the production of the monoclonal antibody segment of TAB008, TAB014, TAA013, multiple batches of, laying a solid foundation for product commercialization



Flow Chart for Typical Traditional Process



Flow Chart for PB Hybrid Technology

2020 Key Milestones

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TAB008

- A public report of Phase III clinical data will be issued in 2020
- Expected to be approved at the end of 2020 or the beginning of 2021

TAB014

- Expect to complete US IND submission in 2020
- PEI* (Europe) consultation has been completed in early 2020
- Continuously advance clinical progress

TAA013

- Commence Phase III clinical trial of TAA013
- Patient enrollment is expected to be completed in 2021

TOM218

- Concentrated Nanoparticles Megestrol Acetate Oral Suspension
- ANDA is expected to be approved in 2020

ADC

- ADC commercial production workshop is under construction, expect to complete the construction of an ADC drug substance workshop in 2020

TOZ309

- Temozolomide capsule
- ANDA is expected to be approved in 2020

**PEI: Paul-Ehrlich-Institut: an agency of the German Federal Ministry of Health.Its research and control activities promote*

4. Financial review

Key Financial Data – Statements of Profit or Loss

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Unit： RMB'000

Items	2018	2019	Diff
Operating revenue	¥ 39,219	¥ 45,308	16%
Operating costs	(5,980)	(11,316)	89%
R&D expenses	(188,651)	(191,078)	1%
Selling expenses	(38,935)	(31,544)	-19%
Management expenses	(54,638)	(95,091)	74%
Other expenses（net）	11,808	14,117	20%
Profit from Operations（Loss）	**(237,177)**	**(269,604)**	**14%**
Non-operating income and expenses（net）	(31,086)	(29,696)	-4%
Net Profit（Loss）	**(268,263)**	**(299,300)**	**12%**
Adjusted Net Profit（Loss）*	**¥ (194,973)**	**¥ (206,739)**	**6%**

Note*: Adjusted listing and financing costs, warrant expenses, valuation loss on convertible preferred shares, and exchange loss

Key Financial Data – Adjusted Net Loss, EBITDA and EPS

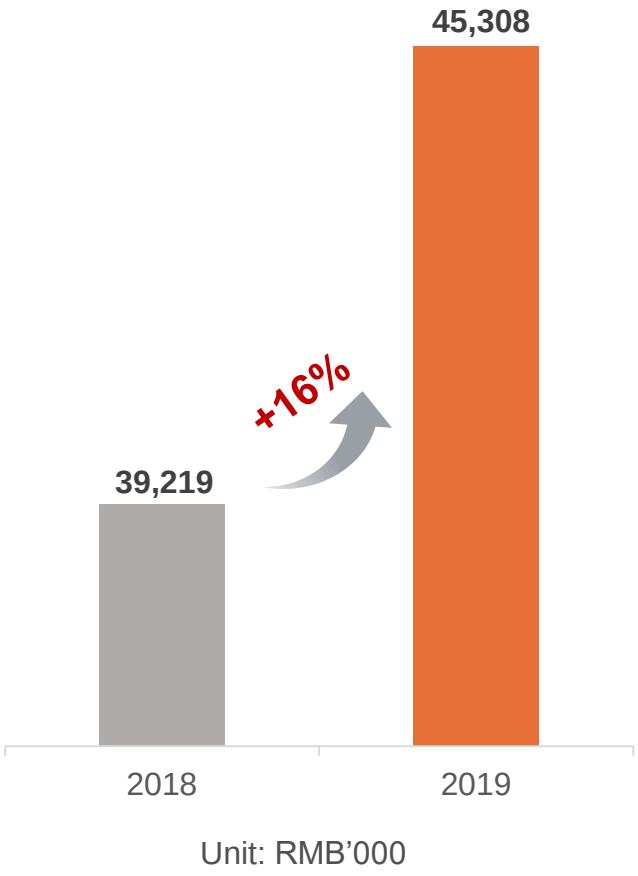
Unit： RMB'000

	For the Year Ended 31 Dec	
	2018	2019
Net Loss	**¥ (268,263)**	**¥ (299,300)**
Adjusted Net Loss	**(194,973)**	**(206,739)**
EBITDA	**¥ (250,203)**	**¥ (269,658)**
Adjusted EBITDA	**(176,913)**	**(177,097)**

Unit： RMB/ Share

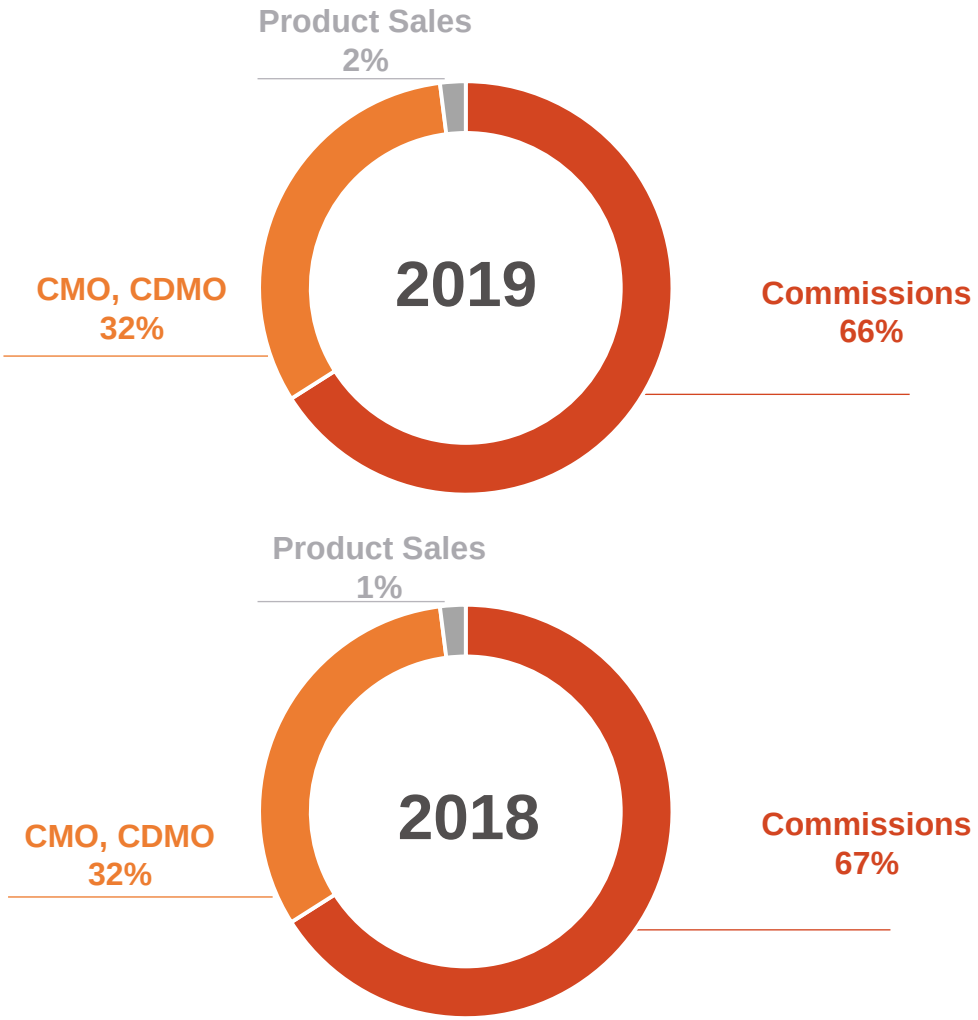
	2018	2019
EPS	**¥ (0.91)**	**¥ (0.89)**
Adjusted EPS	**(0.66)**	**(0.62)**

Key Financial Data – Revenue

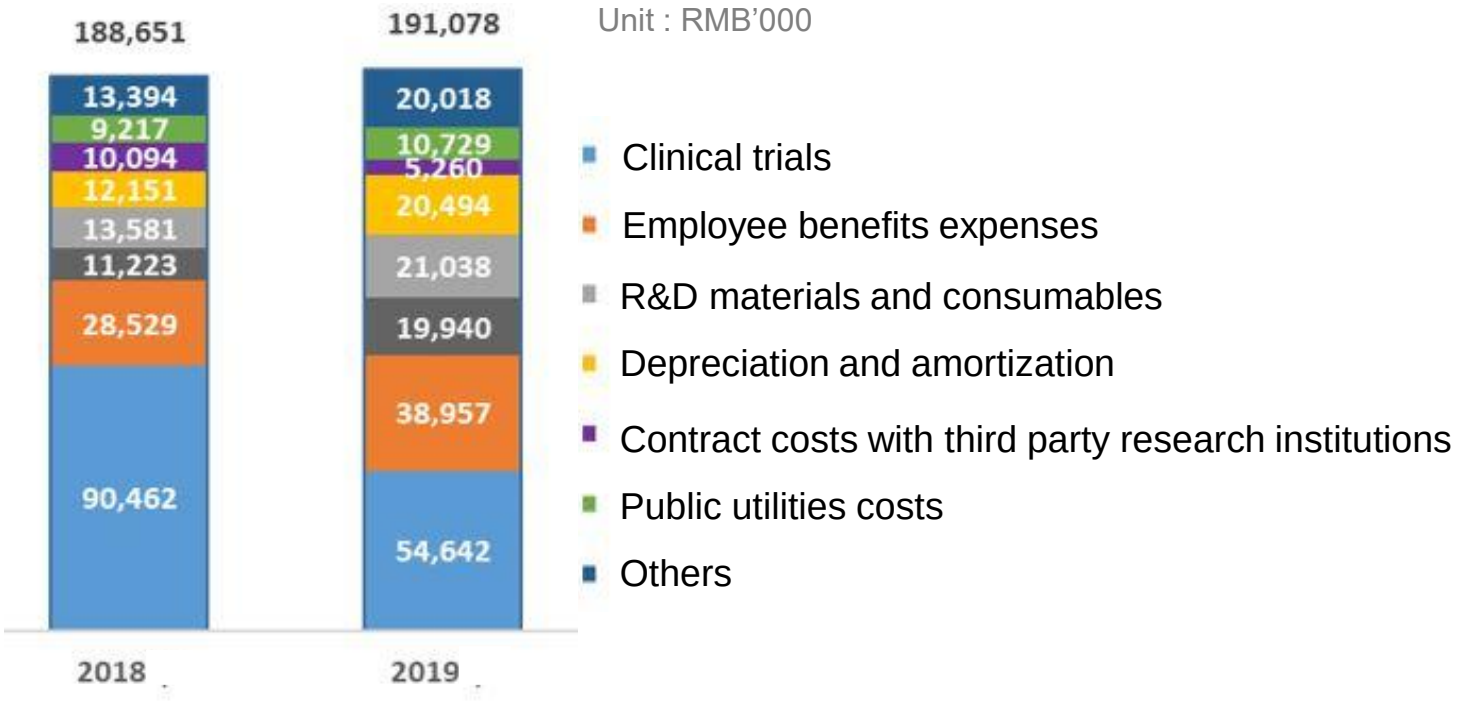


Unit: RMB'000

Revenue Breakdown



Key Financial Data – R&D Expenses



R&D expenses in 2019 were RMB2.4 million higher than 2018, which was mainly attributable to:

- Increase in staff numbers and warranty expenses boosted labour cost of R&D staff
- Drug candidates on clinical trials required more R&D materials and consumables
- Amortisation and depreciation increased after Suzhou production centre was completed
- As TAB008 commences Phase III clinical trials, more reference drugs were procured in 2018

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TOT BIOPHARM

A biopharmaceutical company dedicated to developing and commercializing innovative oncology drugs and therapies.

Your **Best** Partner in
the **Fight Against Cancer**

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4. Q&A