



东曜药业

東曜藥業股份有限公司

TOT BIOPHARM International Company Limited

Stock Code: 1875

NDR Presentation

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- 01 Business Outlook and Review**
- 02 Product Pipeline and Strategy**
- 03 Financial Review**
- 04 Q&A**



01 Business Outlook and Review



Vision

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

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 Outlook – Development and Key Milestones of TOT



- Completed the construction of No.1 Campus
- Established a small molecule oral and injection workshop and a 500L pilot plant

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

- Listed on the Main Board of the HKEX
- Patient enrollment for Phase III clinical trial of TAB008 was completed
- Released Phase I clinical data of TAA013
- ANDAs for TOM218 and TOZ309 submitted and accepted for filing

- Suzhou headquarters established, covering an area of 50,000m²

- The first pilot program for MAH collaborations in Jiangsu Province and the third in China, quality system recognized by national authority.
- Obtained clinical trial approval for three drugs

- Clinical trial approval for TAA013
- Completed the construction of No. 2 Campus, capacity 16,000L

- TAB008 Phase III trial met primary endpoint
- Completed the first patient enrollment of TAA013
- Completed the construction of ADC production workshop



Major Shareholders

Integrate industry resources from a unique perspective with shareholders' support for the long term strategic development



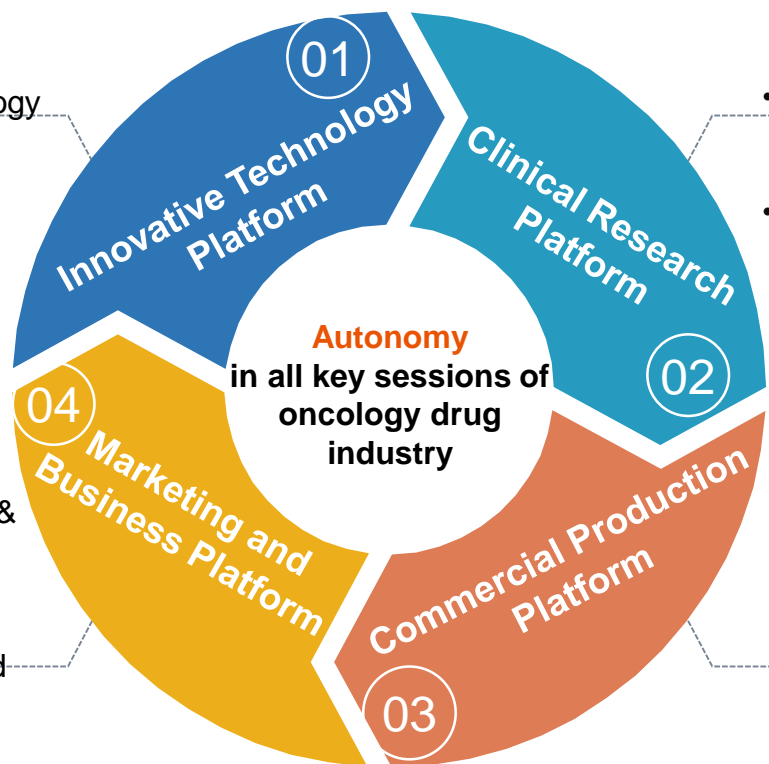
Complete Industry Value Chain & High-quality and Extensive Product Chain

Autonomy “Two Value Chain – Four Platforms”

- **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

- Our professional marketing & sales team focusing on oncology drugs segment
- Sales coverage in **20+** provinces, municipalities and autonomous regions
- Access to **450+** hospitals
- Combining self-operation and strategic cooperation to deepen market expand and promotion



- **12** drug candidates in clinical and R&D stage, including monoclonal antibody, ADC, and small molecule drugs.
- Drug candidates cover the top **10** cancer types in China to cater for patients.
- Self-developed biological drugs approved by IND **at one time.**

- **Monoclonal antibody production facility**

- Total capacity can reach 16,000L, already 2X2000L in operation
- Innovative **PB-Hybrid Technology** has successfully completed commercial production of multiple varieties and batches

- **ADC production workshop**

- ADCs R&D/pilot and commercial plant
- **Small-molecule oral formulations plant and injectable plant**
- GMP-compliant

Strategic Development and Upgrade– Centralize Full Play to Our Resources and Strengths

Leverage self-developed innovative technology platform and commercial production capacity and enhance our core competitiveness



Strengthen the advantages of ADC platform

R&D and production results verification
One-stop cooperation platform



- **One-stop ADC drug cooperation model**
- Leading R&D and production platform for mAb and ADC drugs
- Rich practical experience with the results of multiple project cooperation
- Actively expand cooperation at home and abroad to accelerate the creation of economic benefits



Product optimization and upgrade

High-tech barriers
High economic value



- Expedite the launch of existing drug candidates and promote strategic cooperation
- Employ the three independent core technology platforms, **focus on the development of high-threshold drugs, enhance product innovation** and diversify the product pipeline
- Guideline: **technological innovation + integration with global pharmaceutical community**



Open strategic cooperation

Licensing-in/out, co-development, technological services and support



- Tap the advantages of our own **open platform**, enhance CDMO/CMO business cooperation, and diversify the cash flow
- Proactively seek strategic partners, promote collaborative development and the overseas authorization of products



■ Become the leading ADC player in China

- Leading domestic, world-class ADC industry chain platform
- Strengthen and enrich the pipeline of innovative products
- Actively promote ADC project cooperation and development
- International strategic cooperation



■ Competitive CDMO/CMO business

- Open the advanced technology platform, employ the biotechnology agglomeration effects in Suzhou, seize market opportunities, and create new growth of revenue
- Adopt PB-Hybrid Technology to improve the large-scale commercial production capacity of biological drugs (mAb + ADC)
- Complete life cycle of drug management solutions and services

Business Highlights and Key Milestones from January 2020 to July 2020



TAB008

- Successfully submitted NDA and been accepted



ADC drug substance facility

- Completed the construction of the ADC drug substance facility



TAA013

- Successfully commenced Phase III clinical trial
- Completed first patient enrollment in July 2020



Business collaboration

- Reached global collaboration project in innovative drug with early stage innovative drug development company



TAB014

- Completed FDA Pre-IND consultation
- Completed clinical consultation with the Paul Ehrlich Institute (PEI) on European clinical regulations and submitted key clinical consultations results to the CDE



TOM312

- Completed the commercial-scale process validation
- Two invention patents have submitted and accepted



02 Product Pipeline and Strategy

- Our strengths
- Product pipeline
- Development strategy

Our Strengths: Three Technology Platforms Focused on Oncology Drugs



Therapeutic Monoclonal Antibody and ADC Technology Platform

- Covering screening of cell clone, cell banks construction, CMC developments, pilot production and scale-up production, purification and filling and packaging
- The first-of-its-kind innovative PB-Hybrid technology has delivered multiple batches of production of multiple products
- Integrating R&D and capability of antibodies and ADC production to realize high-quality commercial production



Gene Engineering Based Therapeutics Technology Platform

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



Innovative Drug Delivery Technology Platform

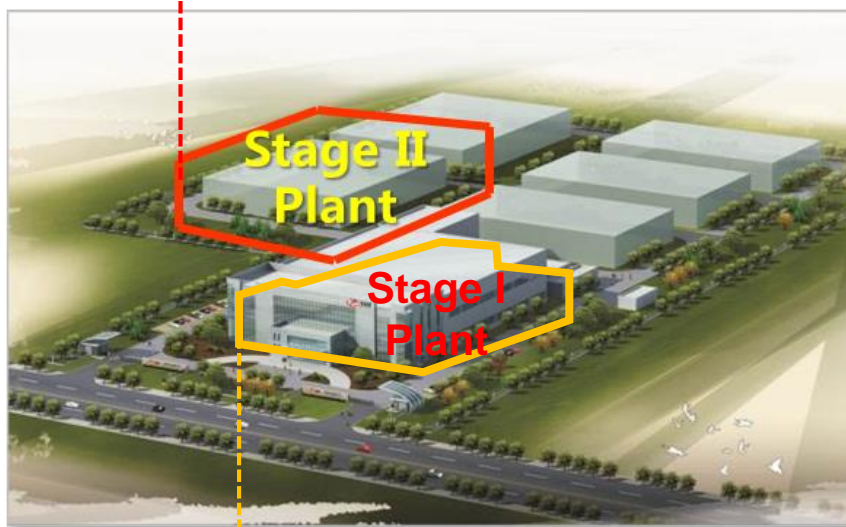
- Builds integrated platform for the development and large-scale production of high-potency drug injections
- Commercialization facilities for nanoliposome drugs applicable to different technologies are in place
- Adopts co-platform production design of sterile lyophilization and sterile filling to meet GMP production requirements on OEB4/5 active grade lyophilized powder injection/liquid injection

Our Strengths: Commercial Production Capability of Monoclonal Antibody & ADC

Build monoclonal antibody + ADC in accordance with international standards, and continue to strengthen the industrial layout

NO. 2 Campus: Completed in 2018

- NO. 2 Campus is the R&D and production base of monoclonal antibody and ADC products. The monoclonal antibody production capacity is **16,000L**. The ADC drug substance production facility will be completed and put into use in Sept. 2020.



Total area 50,000 m²



NO. 1 Campus: Completed in 2012

- 500L biological drug pilot plant and a BSL-2 certified virus plant, a small molecule oral and injection plant, and nanoliposome drug commercial production facilities

Our Strengths: Innovative Commercial Production Capability, PB-Hybrid Technology

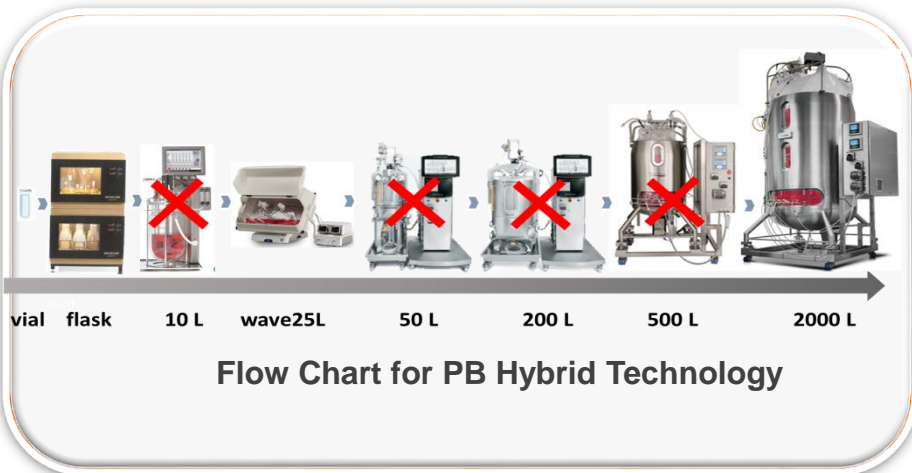


Strong production competitive edge

- Simplify process, reduce production risks, and cut capital expenditures
- Shorten the production cycle and enhance production capacity
- Reduce production costs and improve cost advantages
- Successfully applied to multiple batches of 2,000L-production of TAB008, TAB014, TAA013, laying a solid foundation for product commercialization

First application of PB-Hybrid Technology in China

- Break through the traditional process of cell expansion for large-scale mAb production. Conduct seed expansion from 25L to 2,000L directly without going through the 10L, 50L, 200L and 500L expansion steps



Product Pipeline-Expedite the Launch Process of Key Products

Gather core resources to accelerate our five key products' progress

Drug Candidates	Indication(s)	Pre-Clinical	Clinical Trial I	Clinical Trial II	Clinical Trial III	NDA ⁽¹⁾	
TAB008 ⁽²⁾ (anti-VEGF mAb)	nsNSCLC	Monoclonal antibody (mAb)					
TAA013(anti-HER2 ADC)	HER2-positive breast cancer	ADC					
TAB014 ⁽³⁾ (anti-VEGF mAb)	Wet age-related macular degeneration (wAMD)	mAb					
TAY018(anti-CD47 mAb)	Non-Hodgkin's lymphoma, myelodysplastic syndrome, acute myelogenous leukemia, solid tumors	mAb					
Small molecular chemical drugs							
TOZ309 (temozolomide)	Small molecule generics	Submission of ANDA ⁽⁴⁾					
TOM312 (megestrol acetate)	Cancer- and HIV-associated cachexia	BE study					
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	CMC					
Optimized and platformized product							
TAD011(Anti-EGFR mAb)	Nasopharyngeal cancer, esophageal cancer, pancreatic cancer	Phase I					Monoclonal Antibody product
TEP118 (modified version of hyaluronidase)	Biliary cancer, gallbladder tumors, metastatic pancreatic cancer, NSCLC, gastric cancer	Pre-clinical					Recombinant protein
TVP211 (genetically modified vaccinia virus)	Solid tumors	Pre-clinical					Oncolytic virus product
TID214 (liposomal docetaxel)	Solid tumors	Pre-clinical					
TIO217(liposomal oxaliplatin)	Gastrointestinal tumors	Pre-clinical					Liposome chemical drug

 Key product  Optimized and platformized product

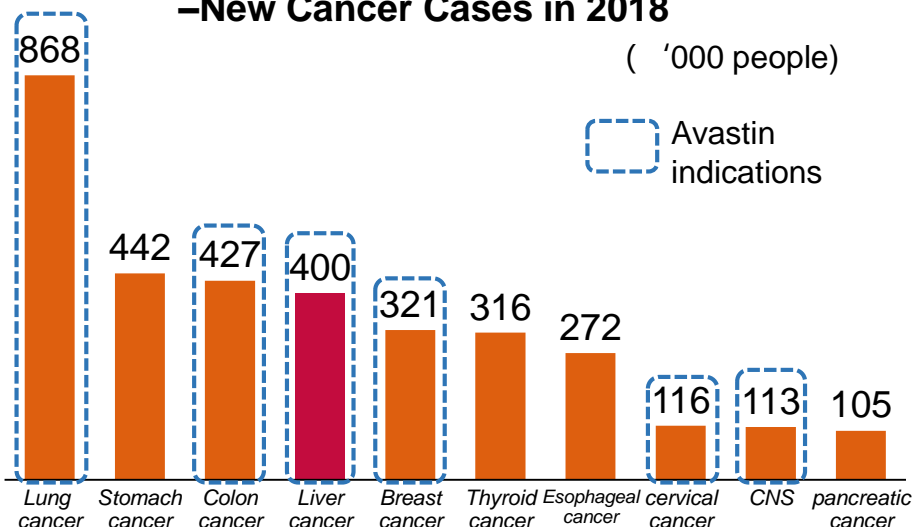
Note: (1) NDA is applicable to the application of new drugs and Category 5.1 imported drugs (2) TAB008 is a bevacizumab biosimilar. Bevacizumab has been approved for the treatment of nsNSCLC and mCRC in China. Additional indications of bevacizumab approved in the United States or the EU include glioblastoma, renal cell carcinoma, cervical cancer, ovarian cancer, breast cancer and Hepatocellular Carcinoma (3) TAB014 is an ophthalmic formulation of bevacizumab and we licensed out the right of commercialization in China, Hong Kong and Macau (4)ANDAs are applicable to the application of generic drugs or Category 5.2 imported drugs

Core Product TAB008: Substantial Market Potential

Ten Most Common Cancers in China –New Cancer Cases in 2018

('000 people)

Avastin indications



Use Pusintin® as the brand name of TAB008

- Phase III clinical trial reached primary endpoint
- Preparing to submit NDA application
- Scheduled to be launched in 2021

Competitive Edge of TAB008



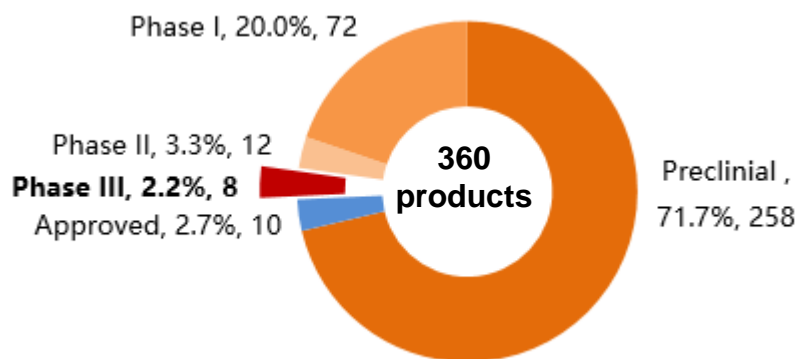
Wide range of indications & combination therapy

- ✓ Bevacizumab was approved for 8 indications globally, covering 6 of top 10 cancers in China
- ✓ The total number of patients with covered 6 indications above reached 2.245 million, accounting for about 52% of the total number of cancer patients in China in 2018 (total: 4.285 million). The market is expected to reach almost RMB 10 billion by 2030
- ✓ FDA has approved the combination of Avastin and PD-L1 for the first-line treatment of unresectable liver cancer. It has been granted priority review and approval by NMPA. It will be a major breakthrough in the field of liver cancer

Core Product TAA013: Leading Clinical Progress

Only 8 ADC products in Phase III clinical trial globally, only 3 in China

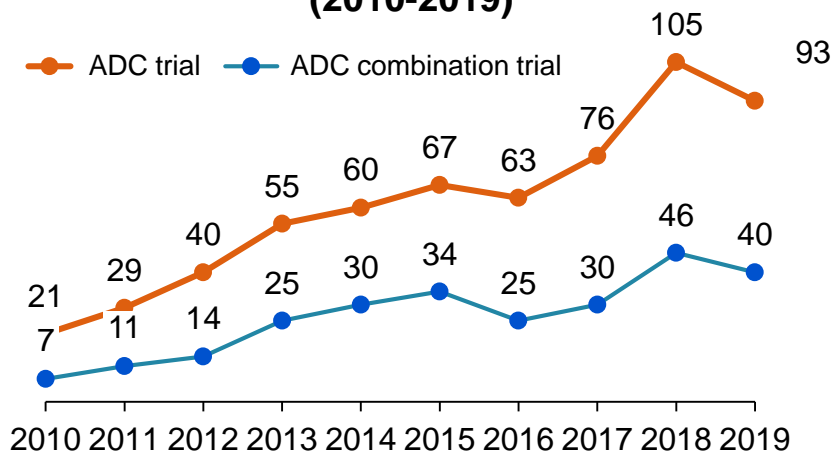
Global Clinical Stages of ADC Products



World-leading clinical progress of TAA013

- **10 ADC drugs** launched, of which only 2 are approved in China, i.e. Kadcyra by Roche (January) and Adcetris by Takeda Pharmaceutical (May). Both are imported and unaffordable drugs
- **About 95% of ADC products under research** are at an early clinical stage
- **TAA013 is one of the 8 drugs entered Phase III clinical trial**

Global R&D Trend of ADC Products (2010-2019)



Growing global popularity of ADC drug research and development

- Global ADC drugs under research intensively grew from 2016
- More cooperation opportunities with innovation in single use and combined use of ADC drug

Core Product TAA013: Seize Market Opportunities

TAA013 containing trastuzumab and emtansine (Trastuzumab-MCC-DM1) aims to become an **affordable alternative of Kadcyla**



The first T-DM1 ADC product to enter Phase III clinical trial in China

Competitive layout of T-DM1 ADC products in China

Company	Target	Toxicity	Stage	Stage commenced
TOT BIOPHARM	HER2	DM1	III	2020/6/3
Company A	HER2	DM1	Ia	2018/9/27
Company B	HER2	DM1	I	2019/6/18
Company C	HER2	DM1	I	2019/6/21
Company D	HER2	DM1	I	2019/8/13



✓ First Patient Dosed in Phase III Clinical Trial

- The first subject dosed successfully in July
- There were five dose groups in Phase I clinical trial. No severe adverse reaction related to the drug has been occurred during the trial. Finally, 3.6 mg/kg was determined as the dose for Phase III clinical trial.
- Phase III clinical trial planned to enroll 438 patients. We will continue to enroll subjects to accelerate the process.

One of the few R&D and commercialization platforms in China for both monoclonal antibodies + ADC products

Technology

- ✓ Own core conjugate technology and expertise; Successfully complete various stable production processes by using ADC drug substance and preparation to ensure product stability and highly lot-to-lot consistency
- ✓ Comprehensive ADC analysis technical platform capable of independently analysing key quality attributes of ADC for the successful development of ADC process and high quality of products

Commercial Production

- ✓ OEB-5 compliant ADC pilot testing facilities
- ✓ GMP compliant large-scale commercial substance production facilities scheduled, to be put into use in Sept. 2020
- ✓ One of the few GMP compliant ADC commercial production facilities in China for ADC substance, preparation, and monoclonal antibodies

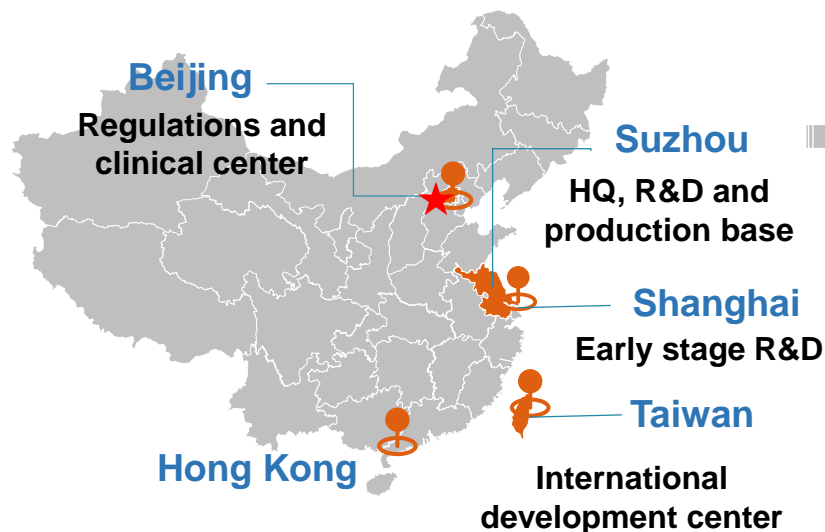
Technical Team

- ✓ A inclusive team enabling R&D, process development, clinical trials, registration and application and commercial production
- ✓ R&D professionals of ADC coupling technology and analysts of complex ADC molecular structure
- ✓ Completed several strategic cooperation in ADC product development and production, gaining extensive practices and successful cases

Implementation of Strategies

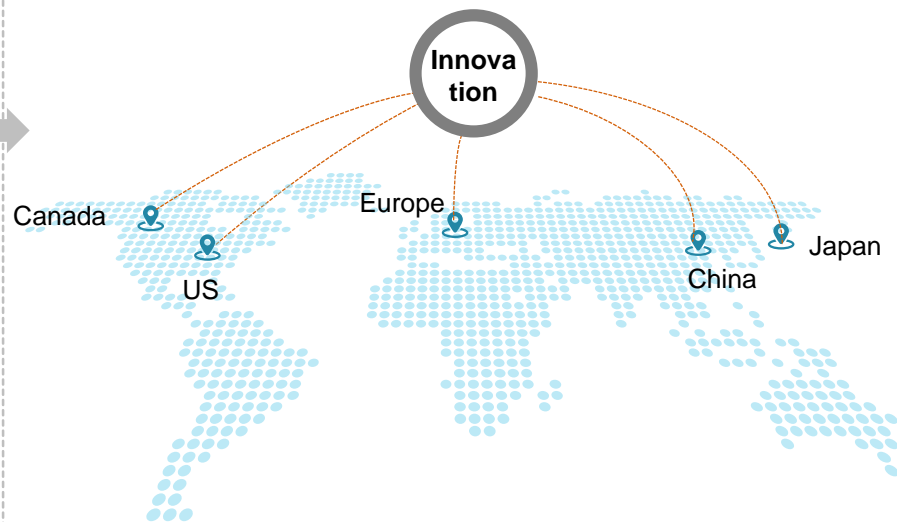


Establishments in China



- TOT BIOPHARM sets its headquarters, R&D and production base in Suzhou and has developed branches and offices across the country
- Strengthens talent acquisition for R&D and professionals

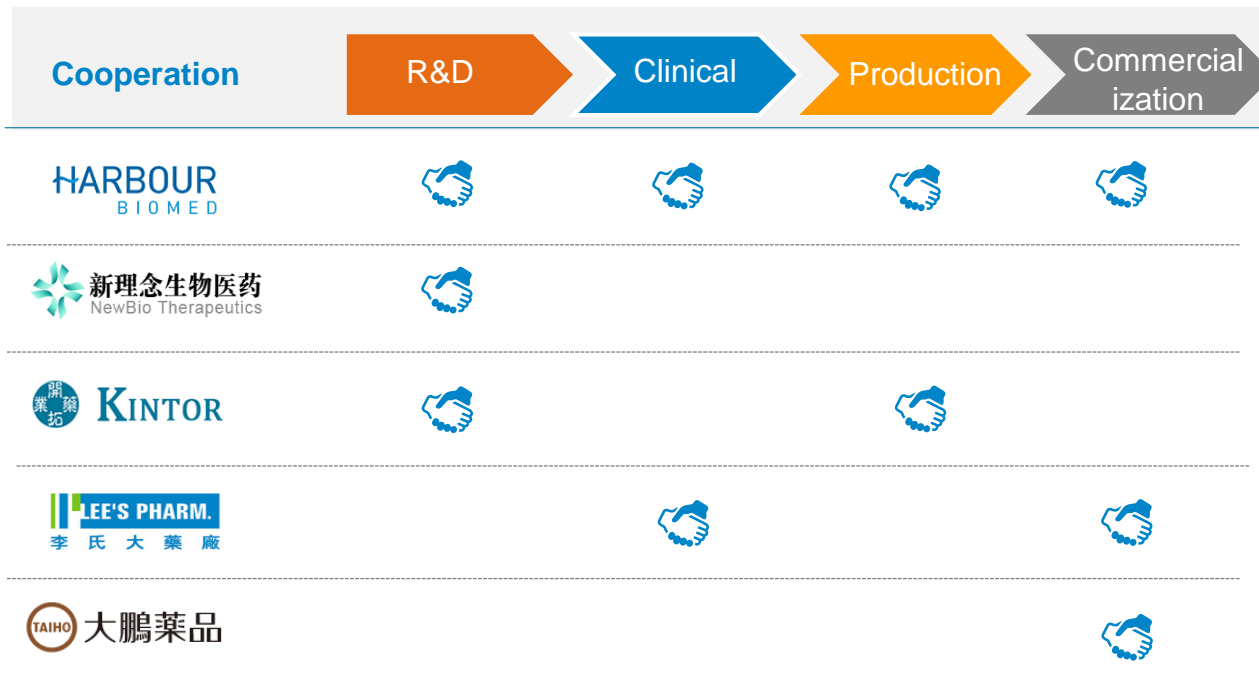
Global distribution of granted patents




- A total of 20 invention patents have been granted and deployed in core countries/regions including the US, Europe, Japan, Canada, etc
- Increase the number of PCT applications filed for ADC and oncolytic virus products

Open Cooperation

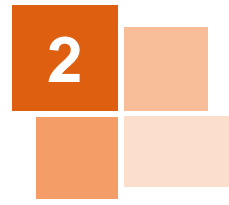
- Draw on our one-stop whole industry value chain platform that includes R&D, clinical trials, production, and commercialization, actively seek strategic cooperation with domestic and foreign strategic partners to enhance joint development and diversify the product pipeline.
- Leverage our unique advantages in R&D and production to strength CDMO/CMO businesses and to create diversified cash flow.



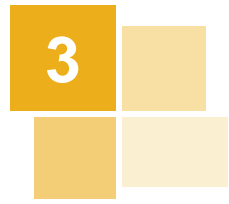
Authority's permission

- 
- Accelerating the submit processes of TAB008, TOZ309, and TOM218


Clinical progress

- 
- Patient enrollment for Phase III clinical trial of TAA013
 - Successfully commence Phase II/III clinical trial of TAB014

Production & commercialization

- 
- Complete the construction of the ADC drug substance production facility and start operation.
 - Enhance to build the ADC commercialization platform

Business cooperation

- 
- Accelerating to expand CDMO/CMO cooperation to create new resources of revenue growth
 - Promote the overseas authorization of core products



03 Financial Review

Key Financial Data – Statements of Profit or Loss

Unit: RMB'000

Items	2019年 H1	2020年 H1	Diff
Operating revenue	¥ 24,606	¥ 13,030	-47.0%
Operating costs	(7,352)	(3,141)	-57.3%
R&D expenses	(75,804)	(99,325)	31.0%
Selling expenses	(16,848)	(13,726)	-18.5%
Management expenses	(35,055)	(24,118)	-31.2%
Other expenses (net)	(524)	(1,083)	106.7%
Profit from Operations (Loss)	(110,977)	(128,363)	15.7%
Non-operating income and expenses (net)	(4,709)	(820)	-82.6%
Net Profit (Loss)	(115,686)	(129,183)	11.7%
Adjusted Net Profit (Loss) *	¥ (83,403)	¥ (117,361)	40.7%

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

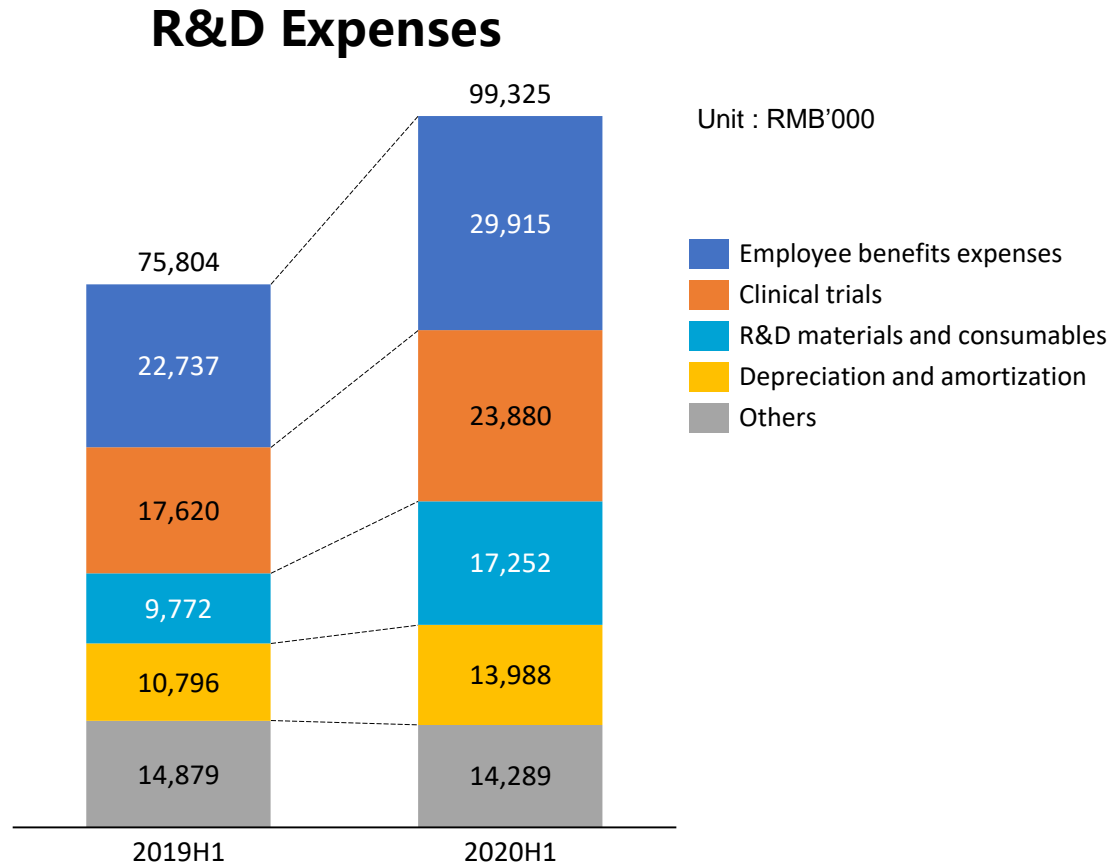
Unit: RMB'000

	For the Year Ended 31 Dec		
	2019年 H1	2020年 H1	Diff
Net Loss	¥ (115,686)	¥ (129,183)	11.7%
Adjusted Net Loss	(83,403)	(117,361)	40.7%
EBITDA	¥ (102,184)	¥ (111,725)	9.3%
Adjusted EBITDA	(69,900)	(99,903)	42.9%

Unit: RMB/ Share

	2019年 H1	2020年 H1	Diff
EPS	¥ (0.39)	¥ (0.23)	-41.0%
Adjusted EPS	(0.28)	(0.21)	-25.0%

Key Financial Data – R&D Expenses



The R&D expenses increased by RMB 23,521,000 in the first half of 2020, due to:

- Increase in the number of R&D and adjustment of annual salary has resulted in an increase in employee welfare expenses
- Increase in the clinical trials and R&D materials arisen from TAA013 completed its phase I clinical trial and entered phase III clinical trial
- Increase in depreciation due to increase in commercial production facilities and continuous construction related to GMP



04 Q&A

东曜药业

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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