东曜药业

東曜藥業股份有限公司

TOT BIOPHARM International Company Limited

Stock Code: 1875

2020 Interim Results Corporate Presentation

Aug 14, 2020

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Presenters

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General Manager

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

Mr. Yao, Jau-Chang
Vice General Manager
Management Office

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

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TOT BIOPHARM

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

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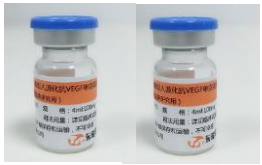

HKEX 香港交易所

2010

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

2012

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

2016

- 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

MAH 药品上市许可持有人制度试点

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, capacity 1600L

2019

- 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

2020 H1

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

Major Shareholders

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

2011 — Completed initial equity financing

晟德 CENTER VENTURES

- Founded in 1959
- A pharmaceutical company dedicates to industrial investment and cultivation in the field of biotechnology
- **20+** biotechnology investments
- Cultivated **8+** listed companies

CHENGWEI 成为资本 capital

- Founded in 1999
- The first Evergreen Fund in China
- **100+** investments in China

2015 — Completed equity financing

VIVO CAPITAL

- Founded in 1996
- A healthcare investment firm focused on investing biotechnology companies
- Investments: **200+** in the US, **40+** in Asia, **10+** in Europe

2018 — Completed Class B Financing

尚城投资 ADVAN · TECH

- Founded in 2016
- Focus on innovation in S&T and the healthcare industry
- **30+** investments in technological innovation and healthcare,
- Cultivated **8+** listed companies

2019 — Listed on the Main Board of HKEX

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

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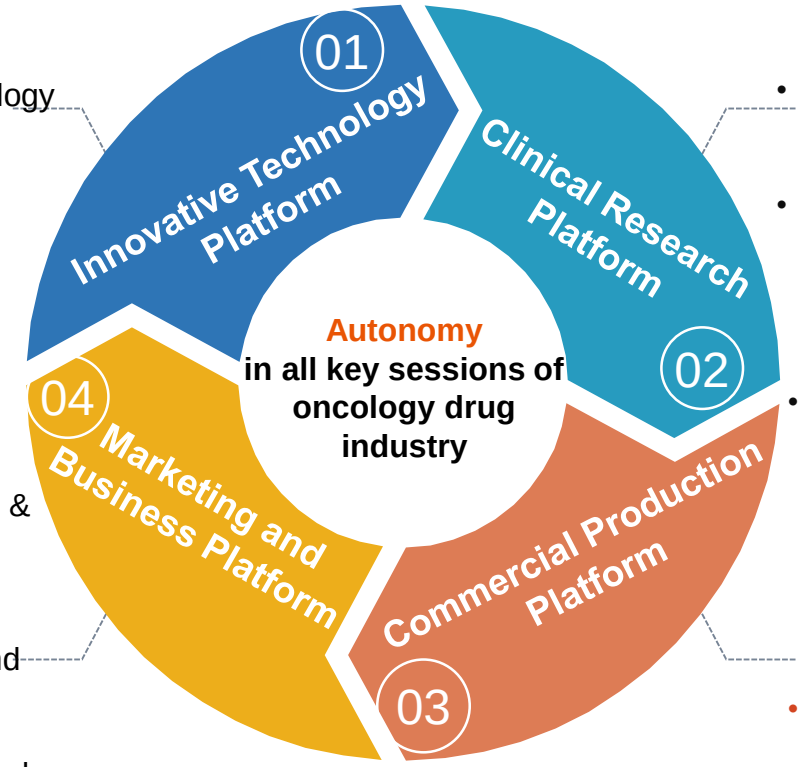
Autonomy "Two Value Chain – Four Platforms"

- **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



- **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**.

- 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

- **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

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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

Strategic Plan and Goals

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

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TAB008

- Phase III clinical trial reached primary endpoint

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

Senior management with expertise in oncology and extensive experience

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

Ms. Yeh-Huang, Chun-Ying

Executive Director, General Manager

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

Dr. Liu, Jun

Executive Director, CSO, COO, 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.

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

Dr. Liu, Ming

Chief Medical Officer, Vice General Manager

- 30+ years of experience in oncology clinical treatment.
- 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.

Mr. Yao, Jau-Chang

Vice General Manager

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

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.

Mr. Wu, Chih-Yuan

Senior Director of Strategic Business and Development

- 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.

Mr. Lin, Chun-Ming

Senior Director of Sales and Marketing

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

02 Product Pipeline and Strategy

- Our strengths
- Product pipeline
- Development strategy

Our Strengths: Three Technology Platforms Focused on Oncology Drugs

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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

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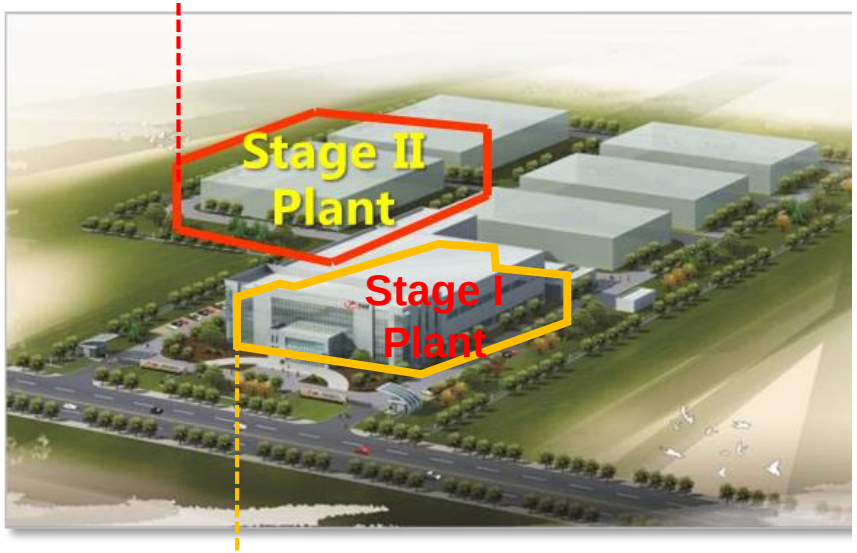
Build monoclonal antibody + ADC in accordance with international standards, and continue to strengthen the industrial layout

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.

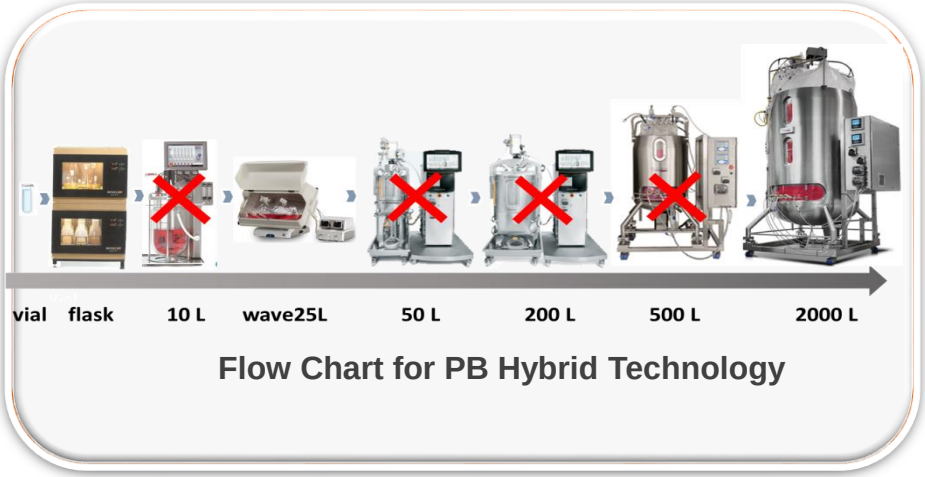


Total area **50,000 m²**

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



Flow Chart for 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 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

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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	Clinical trial 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	Liposome chemical drug			
TIO(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)ANDA is applicable to the application of generic drugs or Category 5.2 imported drugs

Core Product TAB008: Substantial Market Potential

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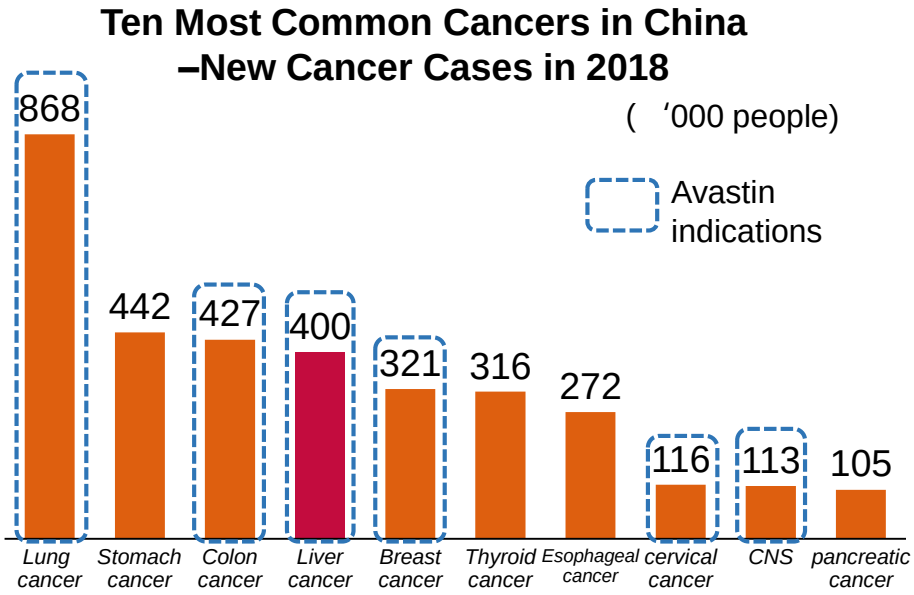

Use Pusintin® as the brand name of TAB008

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

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: 4.285million) . 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

Competitive Edge of TAB008

Source: Frost & Sullivan Report, Report on the Development of Malignant Tumor Studies in China (2018)

Core Product TAA013: Leading Clinical Progress

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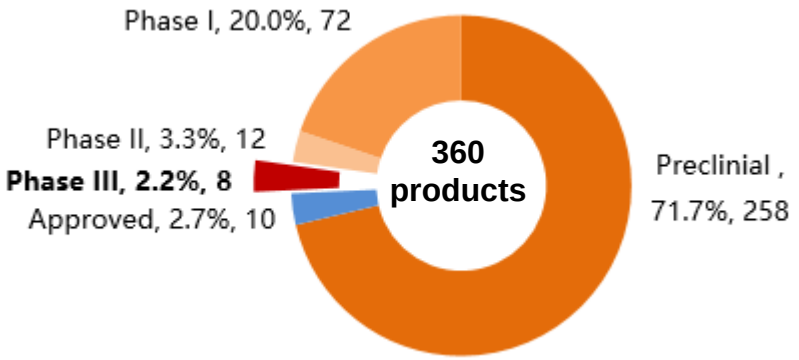
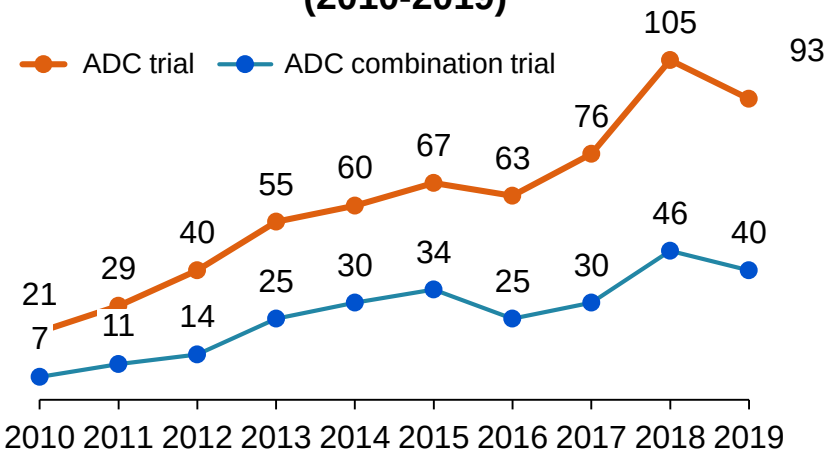
Only 8 ADC products in Phase III clinical trial globally, only 3 in China

Global Clinical Stages of ADC Products



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



World-leading clinical progress of TAA013

- **10 ADC drugs** launched, of which only 2 are approved in China, i.e. Kadcyla 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**

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

Source: Hanson Wade, Beacon Targeted Therapies

Core Product TAA013: Seize Market Opportunities

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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.

Source: Public information collation

Core Product TAA013: Marked Competitive Edge

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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 producion 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

- ✓ An 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

Accelerating the launch processes of clinical-stage products

Focusing on core strengths, diversifying the pipeline of ADC products, and improving innovation capabilities

Fully opening up the R&D technology platform to foster collaboration among strong market players, thereby reducing the cost and risks of new drug development and accelerating the launch processes of new drugs

Proactively expanding the CDMO/CMO businesses, strengthening project collaboration, and creating new resources of revenue growth

Intensifying the recruitment and motivation of talents

Talent-Driven Innovation

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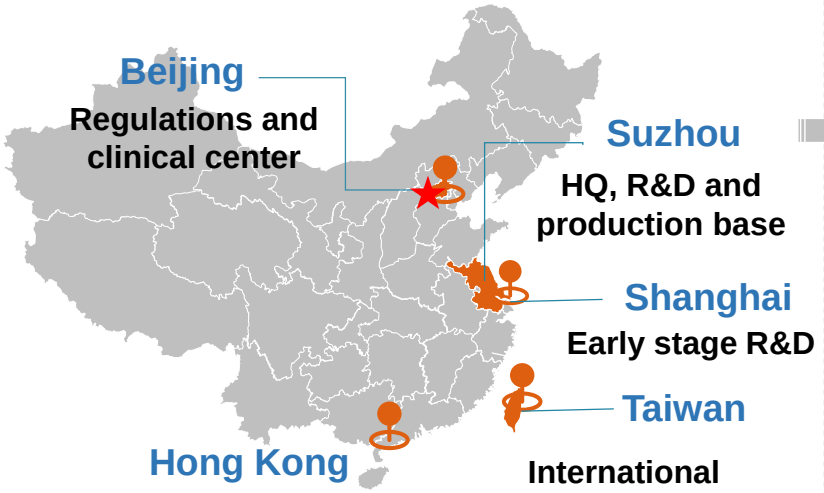
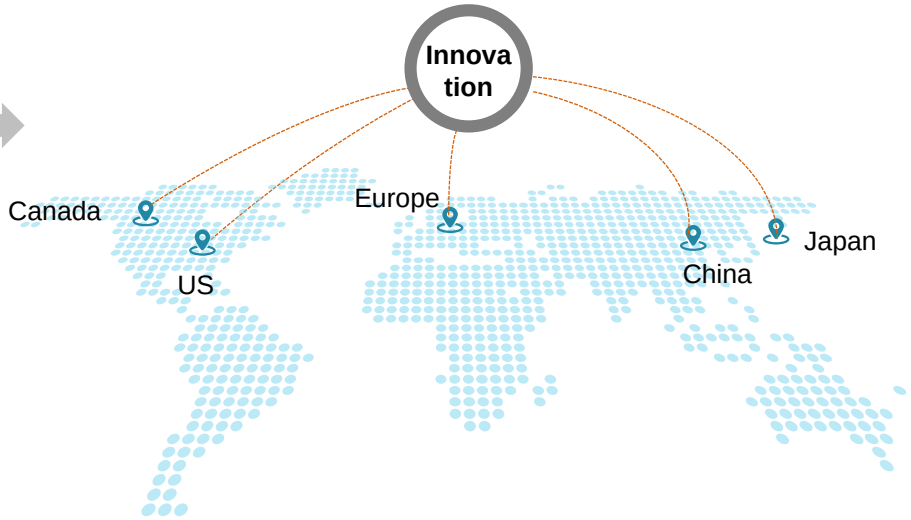
Establishments in China



Global distribution of granted patents



- 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

- 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

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- **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.**

Cooperation	R&D	Clinical	Production	Commercialization
HARBOUR BIOMED	✓	✓	✓	✓
新理念生物医药 NewBio Therapeutics	✓			
KINTOR	✓		✓	
LEE'S PHARM. 李氏大藥廠		✓		✓
TAIHO 大鵬薬品				✓

Outlook for 2020

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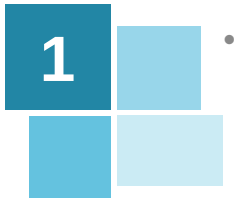
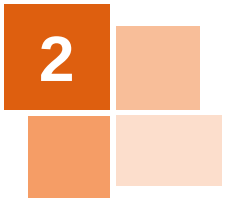


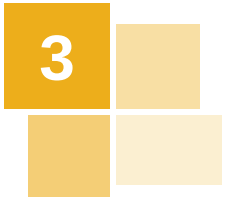
- Accelerating the submit/launch processes of TAB008, TOZ309, and TOM218

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

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Unit： RMB'000

Items	H1 2019	H1 2020	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

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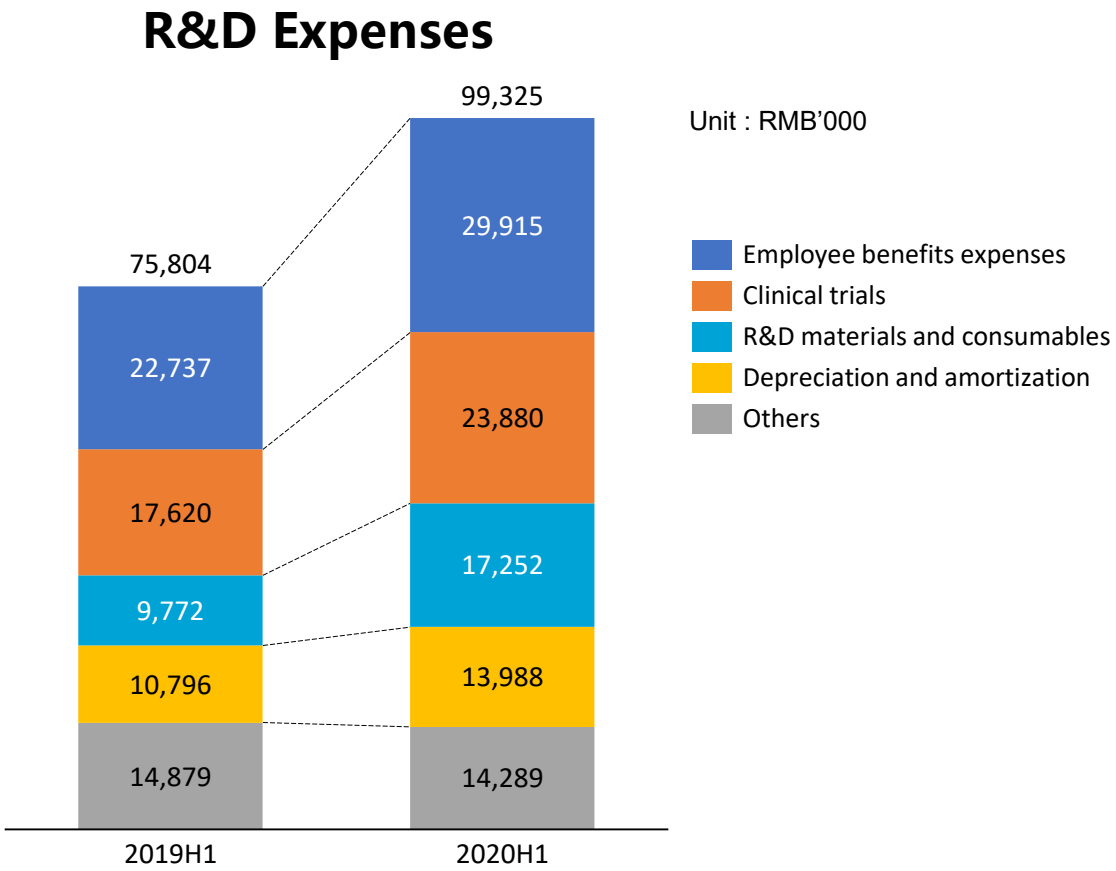
Unit： RMB'000

	For the Six Months Ended 30 Jun		
	H1 2019	H1 2020	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

	H1 2019	H1 2020	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

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