东曜药业
TOT BIOPHARM

東曜藥業股份有限公司
TOT BIOPHARM International Company Limited
(於香港註冊成立的有限公司)

股份代號: 1875

2021 Interim Results Corporate Presentation

Aug 13, 2021

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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

1 Business Highlights of 1H 2021

2 Competitive Advantages and Strategic Planning

3 Financial Review

4 Q&A

1 Business Highlights of 1H 2021

Our History

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- **2 products successfully launched**
- **International standard commercial production facilities**
- **CDMO business contributed greatly to 1H results**

- Pipeline Layout
- R&D and project approval

2010

Company Established

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

2011

No.1 Plant Established

- A small molecule oral and injection workshop
- A 500L pilot plant

- Obtained clinical trial approval for three drugs

2016

MAH Pilot Program

MAH 药品上市许可持有人制度试点

- The first pilot program for MAH collaborations in Jiangsu Province and ranked the third in China

- Commence Phase III clinical trial for TAB008
- Clinical Trial Approval for TAB014 and TAA013

2017-2018

No.2 Plant Established

- Biopharmaceutical production workshop
- Capacity of the monoclonal antibody production workshop on the second floor is 16,000L

- TAB008: completed patient enrollment for phase III clinical trial
- TAA013: completed phase I clinical trial
- TAB014: gained the National Science & Technology Major Project 'Creation of Major New Drugs'

2019

Listed on HKEX

HKEX 香港交易所

- Listed on the Main Board of the HKEX in November

- TAA013: completed First -Patient-in for phase III clinical trial
- TAB008 and TOZ309 completed the pre-approval registration inspection

2020

ADC production Workshop Completed

- Completed ADC drug substance facility
- Completed the production of multiple batched of clinical samples

- **TOZ309 and TOM218 launched**
- **TAB014: phase III clinical trial application was authorized by FDA**

2021

- Completed the GMP compliance inspection of antibody drug and chemistry drug facilities.
- The commercial production and quality management system meets the GMP standard
- Enlarged the commercial production scale of ADC drugs

Major Achievements of 1H 2021

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01

Two Products Launched

- In May, temozolomide Capsule（Tazian®）launched
- In May，megestrol Acetate Oral Suspension (美适亚®) launched

02

R&D and Clinical Milestones

- TAB008：Enter the CDE review stage, is expected to be approved for launch in 2021
- TAA013：Phase III clinical trial enrollment as scheduled，with over 70 clinical research centers initiated as of to date
- TAB014：Phase III clinical trial has been approved by the FDA and is in preparation for phase III clinical trial

03

Commercial Production Layout

- In January 2021, our mAb drug commercial production facilities completed GMP compliance inspection （the designed capacity is 16,000L, of which 8,000L in place)
- In May 2021, our chemical drug capsules passed GMP compliance inspection
- Construct the second commercial production line of ADC drugs to further enhance capability of the ADC commercialization platform

04

CDMO/CMO Business

- CDMO/CMO business increased significantly, accounted for 50% of total revenue
- Cooperating with BrightGene Bio-Medical Technology Co., Ltd. to strengthen the one-stop service platform for ADC-CDMO business
- Expended CDMO platform to cooperate with various long-term strategic partners

Constantly Enrich the Innovative Drug Candidates

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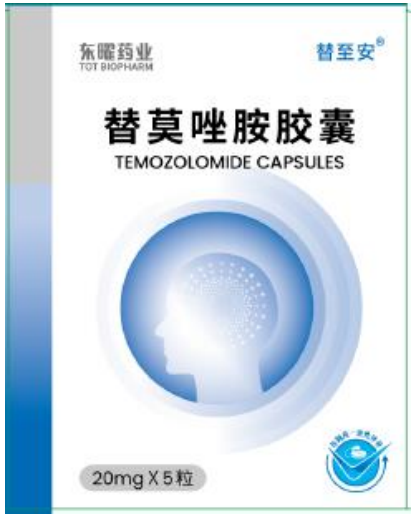
Type	Drug Candidate	Indication(s)	Pre-Clinical	Clinical Phase I	Clinical Phase II	Clinical Phase III	NDA(1)
Antibody drug conjugate	TAA013(anti-HER2)	HER2+ breast cancer					
	TAE020(new target)	Acute myeloid leukemia					
Monoclonal antibody/ Recombinant protein	TAB008(2)(anti-VEGF)	Non-squamous non-small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

Notes:(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 in China for the treatment of non-small cell lung cancer (NSCLC), metastatic colorectal cancer (mCRC) and glioblastoma multiforme (GBM), and for the treatment of hepatocellular carcinoma (HCC) together with atezolizumab. Additional indications of bevacizumab approved in the United States and the European Union include renal cell carcinoma, cervical cancer, ovarian cancer, fallopian tube cancer, peritoneal cancer, breast cancer, etc. (3) TAB014 is an ophthalmic formulation of bevacizumab, with the right of commercialization in mainland China, Hong Kong and Macau licensed out. (4) ANDA is applicable to the application of generic drugs and Category 5.2 imported drugs

Market Strategy of Tazian® (TOZ 309)

Glioma is the most common primary central nervous system tumor, accounting for 50% of all primary nervous system tumors, of which glioblastoma (GBM) and astrocytoma account for about 75%

(The China's market reached RMB 1,800 million in 2020, including 1 brand-name and 2 generic drugs; became the centralized purchase drug in 2021)



National Network Bidding Listing

- Covering >80% of all provinces by 2021
- Covering 100% provinces by 2022/Q1

Cooperate with CSO Companies to Deeply Penetrate in Marketing Channels

- **Centralized purchasing channel**: Focus on Grade A/B-primary hospitals to maximize market share
- **Non-centralized purchasing channel**: Cooperate with CSO

Product Specification	**20 mg/grain; 100 mg/grain**
Indications	- Newly diagnosed glioblastoma multiforme was treated first with radiotherapy and then as maintenance therapy - Recurrence or progression of glioblastoma multiforme or anaplastic astrocytoma after conventional treatment

Local Province Bidding Listing

- By 2022/Q2, prepare for the renewal of 4th purchasing contracts
- Optimization purchasing pricing

美适亚® (TOM218)：New Dosage Form in the Chinese Market

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6 of the top 10 cancers with the highest rates of incidence in China are often accompanied by cachexia, among which the incidence of associated with stomach, gastroesophageal and pancreatic tumors exceeds 65%.

Common Name：Megestrol Acetate Oral Suspension

Indications

- The treatment of anorexia nervosa associated with acquired immunodeficiency syndrome
- Significant weight loss of AIDS and cancer patients caused by cachexia

Specifications

- 150ml/bottle，contains 125mg megestrol acetate per milliliter

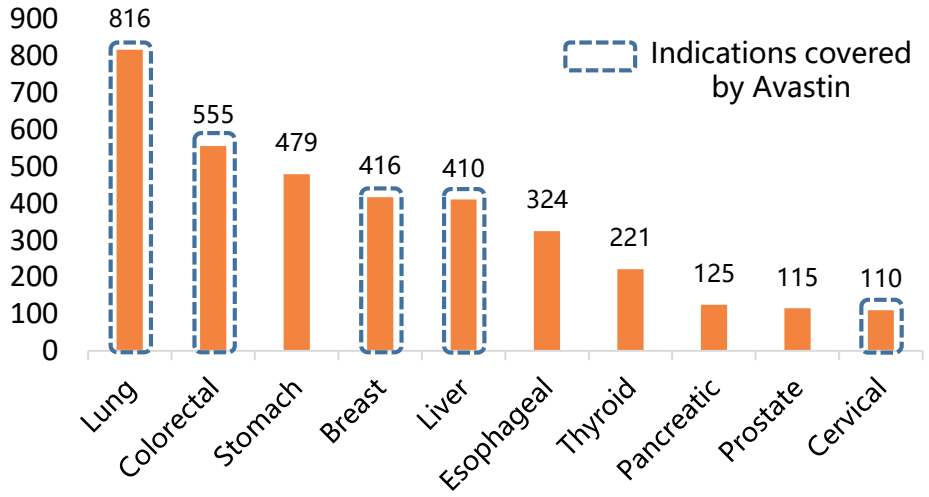
Exclusive Dosage Form & Specific Dose

- Approved for marketing in the US in 2014，TOT Biopharm owns the exclusive agency in China
- The world's **only** commercially nano oral suspension

TAB008 is Expected to be Approved for Marketing by the end of 2021

Ten Most Common Cancers in China of 2020-Number of New Cases

Unit: cases ’000



Resource： The world Health Organization's International Agency for Research on Cancer (IARC) released the latest global cancer burden data of 2020

Regulations Progress for Product Approval

- Intends to use “Pusintin®” as the trade name
- In January 2021, the company has passed the registration verification and GMP verification
- At the evaluation stage of CDE
- Expect to be approved for launch in Q3/Q4

Open Sales Right to Gain the Market Share

- Open sales right to cooperate with local giant pharmaceutical companies
- Owns 16,000L of large-scale monoclonal antibody production capacities to well support the market demand with stable supplement
- Leveraging the competitiveness of PB-hybrid Technology to reduce the production costs significantly

TAA013 Leading Clinical Progress

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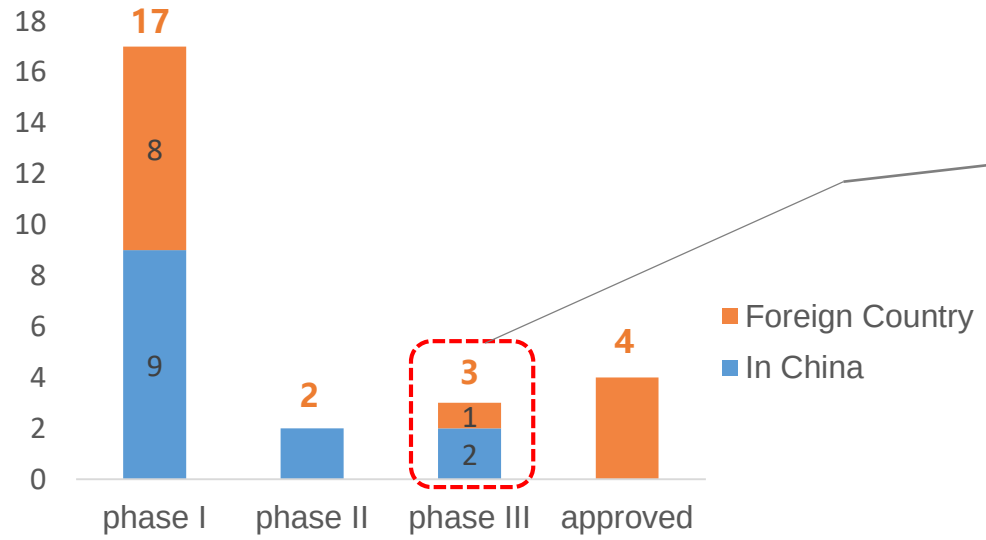
Only 3 HER2 ADC products in phase III clinical stage globally, 2 of them from China

- Phase III clinical trial enrollment as scheduled, the blind state assessment showed positive effects
- **25%** cases are HER2-positive breast cancer among the overall breast cancer patients in China
- The market size of ADC drug for indication of HER2-positive breast cancer is expected to increase from 2024 to $228.9 million with a CAGR of 207.4% and reach $414.9 million by 2030, in China

Global HER2 ADC Clinical Trials and Approvals



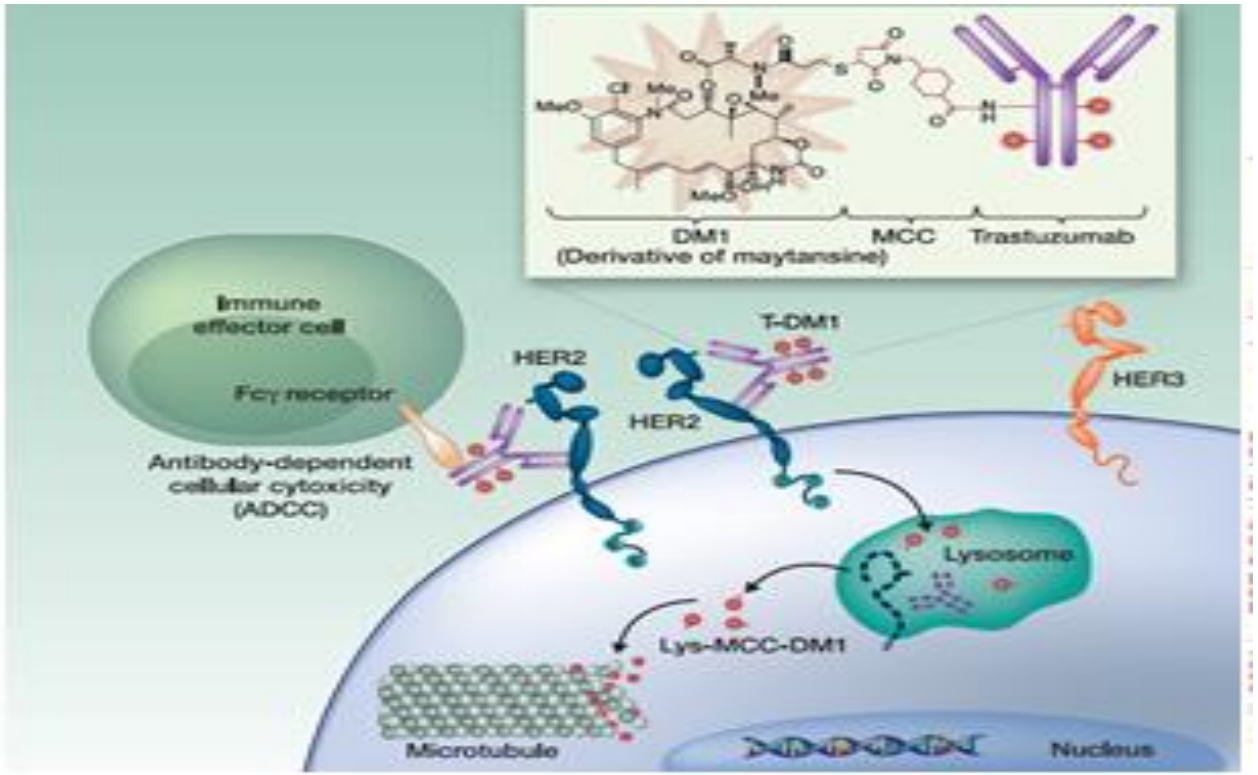
Source：Beacon Targeted Therapies，Chinadrugtrials.org.cn

Clinical Process of Domestic HER2 Target ADC Products

Enterprise	Product	Toxic load	State
TOT Biopharm	**TAA013**	**DM1**	**III**
Company A	ARX788	Amberstatin269	II/III
Company B	DP303c	MMAE	II
Company C	MRG002	MMAE	II
Company D	SHR-A1811	Undisclosed	I/II

TAA013 Phase I Clinical Trial

- **Based on the positive clinical study data of phase I clinical trial, TAA013 entered phase III clinical trial directly in according with NMPA's comments**
- **The safety tolerance and effectiveness both reached the preset end point**
- **In December 2020 , the results of phase I clinical were released at SABCS**



Action Mechanism :

- With the targeting of trastuzumab, it binds to the specific antigen on the tumor cell membrane to induce endocytosis
- Highly active cytotoxic drug DM1 enters cells
- The combination of DM1 and tubulin destroys the microtubule network in the cell and induces apoptosis

Open label, single arm, 3+3 dose climbing design is used for the Phase I clinical

Phase I Clinical Design

Filter	Test design	Purpose
• Received trastuzumab treatment and disease progression • HER2-positive breast cancer • Survival period ≥ 3 months	• **3+3 dose climbing** • 5 dose groups: 0.6mg/kg, 1.2mg/kg, 2.4mg/kg, 3.6mg/kg, 4.8mg/kg.	• Assess safety and tolerability • Evaluate pharmacokinetic characteristics, immunogenicity and effectiveness

TAA013 Phase III Clinical Study

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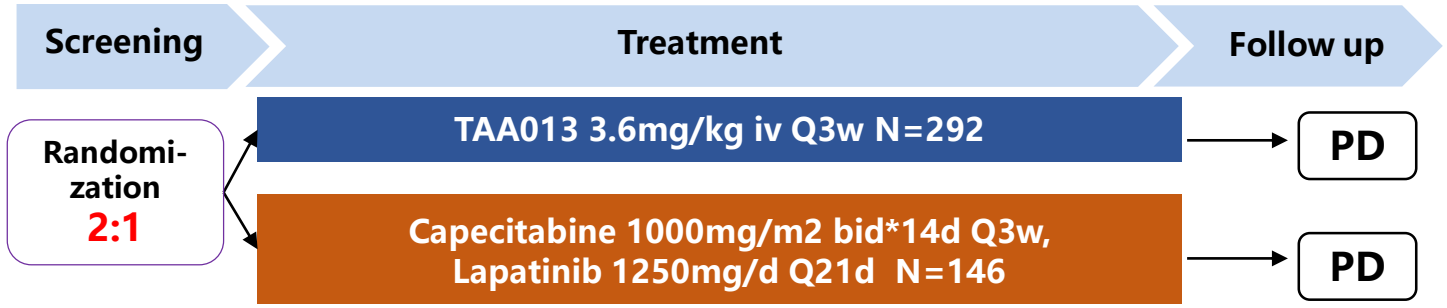
Study Design：randomized, open label, controlled study of TAA013 （in 2nd line Her2+ breast cancer patients）



- **Indication：** Her2+breast cancer patients who have failed trastuzumab based first line therapy
- **Sample size：** 438
- **Stratification：** brain metastases, internal organ metastases.

Primary end point: PFS independently assessed by a third party

- **Secondary end points:** OS, ORR(blind state assessment)， DoR, security (non-blind state evaluation), Pharmacokinetics, Immunogenicity
- PFS assumed HR=0.7 and bilateral test level was 0.05

Photo: In July 2021, Researchers Meeting for Project TAA013 was successfully held in Chengdu

Accelerating the Layout of the ADC Industry Chain

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Accelerate the improvement of ADC platform with high standard quality management system and advanced R&D & production facilities to promote the development of ADC drugs




- **GMP compliant pilot production facility:**
  - *Capacity of DS： 1g~300g/Batch*
  - *Capacity of Preparation： 500~5000 Vials/Batch*
- **OEB-5 active grade freeze-dried powder needle/water needle preparation**
- **Commercial GMP manufacture facility for ADC**
  - *Capacity of DS： 1000g~3000g /Batch*
  - *Capacity of Preparation： 25,000-50,000 Vials/Batch*

GMP Standards

- **Quality Control complies with the GMP standards:** DS/DP release and stability study
- **Quality Assurance System complies with the GMP quality assurance regulatory standard of NMPA, FDA, EMA**



CDMO/CMO Business Achieved Significant Growth

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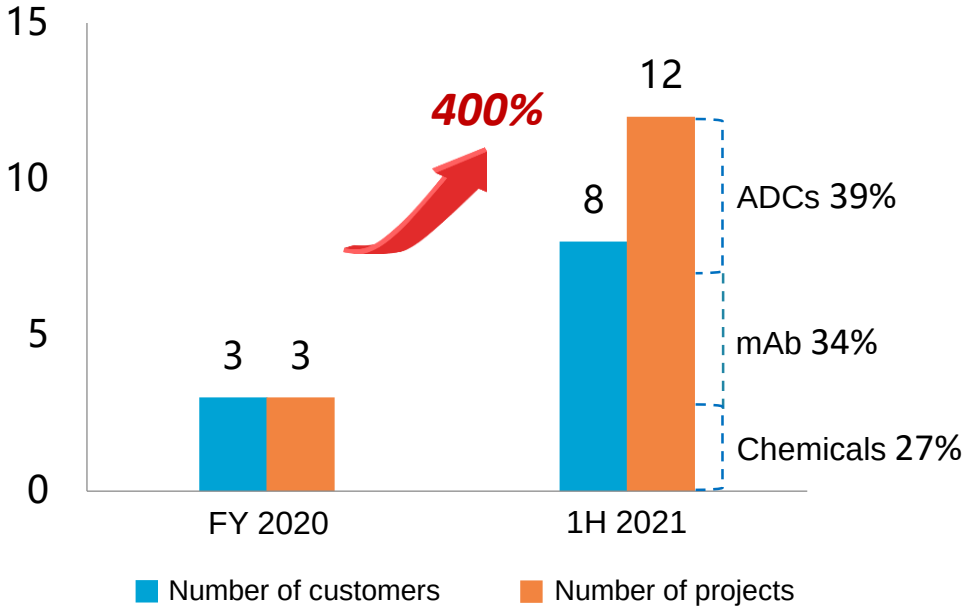
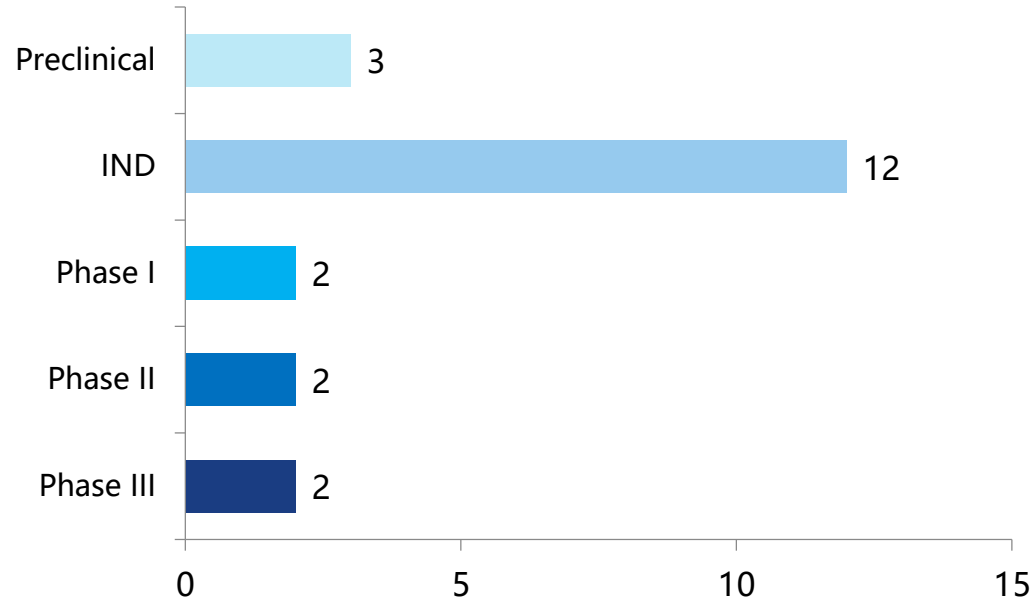
- Remarkable achievements in CDMO business with strategy adjustment，ADC projects account for **nearly 40%** of the total contracts
- Compare with FY2020, the number of newly signed orders **for 4** times, newly signed contracts amounted approximately RMB100 million, 9 projects will be accomplished within 2021

Comparison of DMO/CMO Business Volume



Projects in Different Phrase



MIRACOGEN 開業拓藥 BrightGene 博瑞医药 新理念生物医药 NewBio Therapeutics 诗健生物 Escugen

2 Competitive Advantages and Strategic Planning

Strategic Planning and Positioning

Become a Domestic Leading Player in the Field of ADC

- 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 up the advanced technology platform, employ the biotechnology agglomeration effects in Suzhou, seize market opportunities, and create revenue growth opportunities
- Maximizing the customers' input and output benefits via production flexibility and diversified service capabilities
- Providing complete life cycle drug management solutions and services
- Leveraging the competitive advantages of "one-base" business model for ADC CDMO business

Outstanding Competitive Advantages of ADC--- Rich Practical Experiences

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Ensuring High Quality Development for Each Product

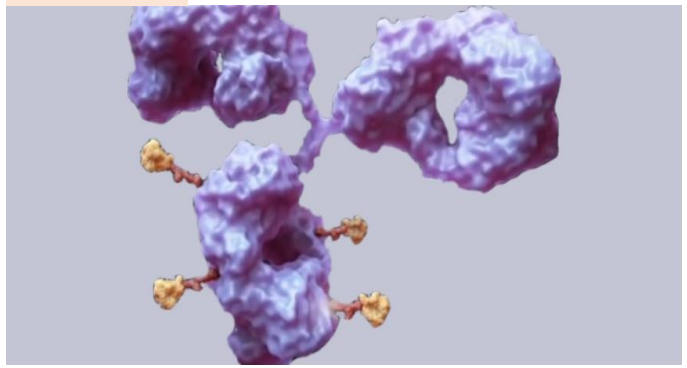
Accumulated different development and production experiences in different types ADC drugs / different clinical stages

- **Stable Coupling Technology:**

  4 different types ADC drugs development

- **Mature Production Technology:**

  5 production projects of ADC drugs, including phase I and phase III clinical



Outstanding Competitive Advantages of ADC--- Comprehensive Technical Capability

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Continuously to Consolidate ADC Technology Platform Advantages

- Integrate the comprehensive technical capabilities refer to antibody, small molecule toxin and biological coupling, etc
- Strengthen the cooperation to accelerate technological innovation and breakthroughs via the way of *" combination of strengths and complementary advantages"*

01 Formed advantages of core coupling and amplification technology

02 Complete ADC analysis technology platform, rigorous and scientific biological analysis methods, and rich practical experience

03 Ability to independently analyze ADC key quality attributes

04 Freeze-drying technical capability

05 Well established cleaning management capabilities for operating facilities

06 Close cooperation and linkage among experts in various fields

Outstanding Competitive Advantages of ADC--- Leading industrial layout

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Technical Advantage

- Has the **core coupling process and amplification technology**, well establishment of a stable production process for several ADC stock solutions and preparations to ensure product stability and a high degree of consistency between batches
- **Complete ADC analysis technology platform**, ability to independently analyze ADC key quality attributes to ensure successful ADC process development and high product quality

Commercial Production Advantage

- Pilot plant for antibody conjugated drugs (ADC) conforming to **OEB-5** grade
- **Large scale commercial stock solution production workshop** in line with GMP standards was put into operation in September 2020
- Rare domestic ADC commercial production facilities that **meets THE GMP standard and integrates ADC stock solution, preparation and monoclonal antibody**

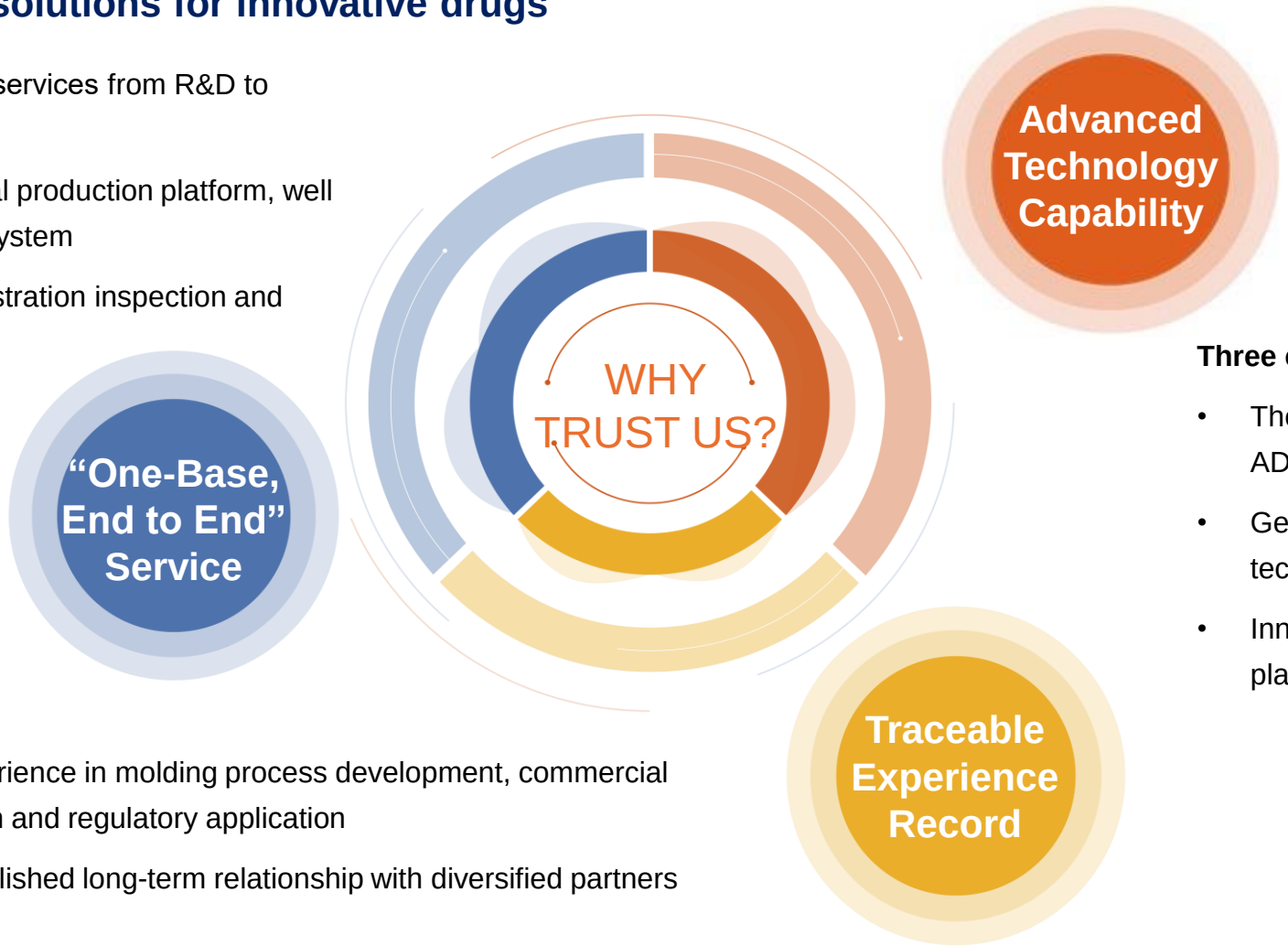
Team Advantage

- We have an expert team from **R&D, process development, clinical trial, drug registration to commercial production**
- ADC coupling technology development expertise and complex ADC molecular structure analysis team
- Completed the development and production of several next-generation ADC drugs for strategic partners with rich practical experience and successful cases

Best Strategic Partner

“One-stop” CDMO solutions for innovative drugs

- Providing “ one-base, end to end” services from R&D to commercialization
- First-class international commercial production platform, well established project management system
- The company has passed the registration inspection and GMP inspection by the NMPA



Three core technology platforms:

- Therapeutic monoclonal antibody and ADC technology platform,
- Genetic engineer-based therapy technology platform
- Innovative drug delivery technology platform

- Rich experience in molding process development, commercial production and regulatory application
- Has established long-term relationship with diversified partners

Advantages of Diversified Cooperation & CDMO/CMO Services

Optimized Production Process → Mature Technology Transfer → Production Scale → Increased Economic Efficiency

Owns Scarce Resources in mAbs + ADCs Production Capacity

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- Accelerate the expansion of commercial production capacity to create diversified and stable cash flow
- Expand production capacity of monoclonal antibody and ADC, and add multiple production lines

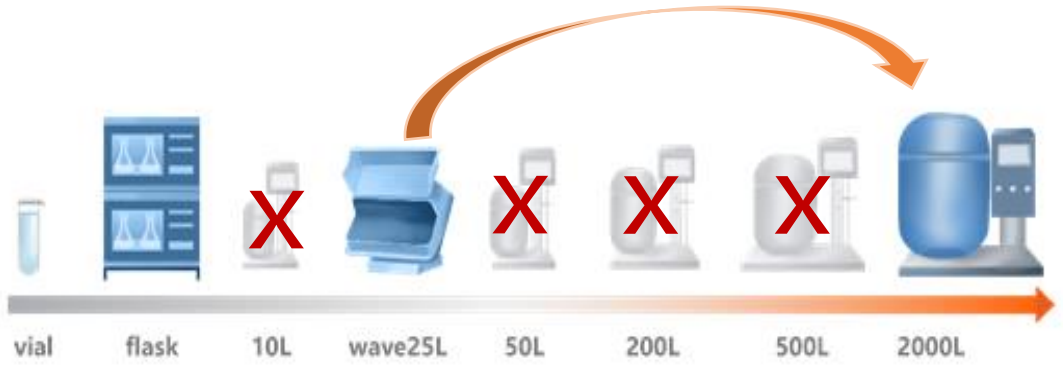
No. 2 Plant

ADC Drug Facilities: Pilot test+commercialization

mAbs Drug Facilities: 16,000L+expended new lines

Covers:50,000㎡

PB-Hybrid Technology Flow Chart



Outlook for 2021

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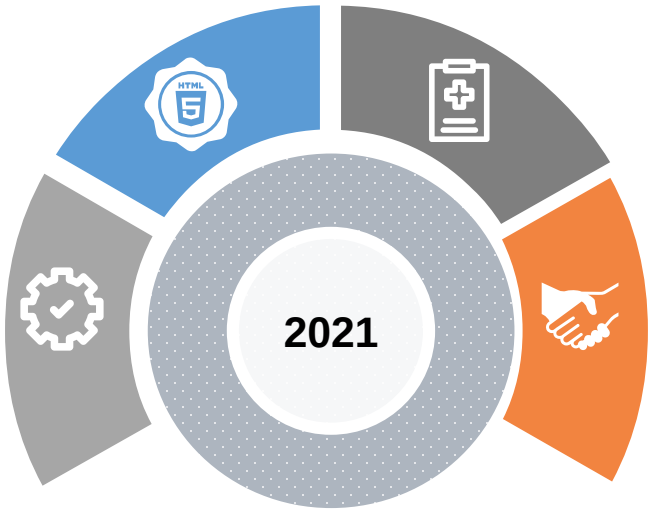
Product Launch and Sales

- TAB008 will approved by the NMPA, and strengthening celebrations in sales
- Promote sales layout of TOZ309 and TOM218



Production Capacity

- Complete the construction of ADC pilot scale and large-scale preparation facilities
- Expanding the production capbilities of the monoclonal antibody stock solution facilities

Clinical Progress

- Accelerate clinical recruitment for TAA013
- Initiate phase III clinical trials of TAB014

CDMO and Collaboration

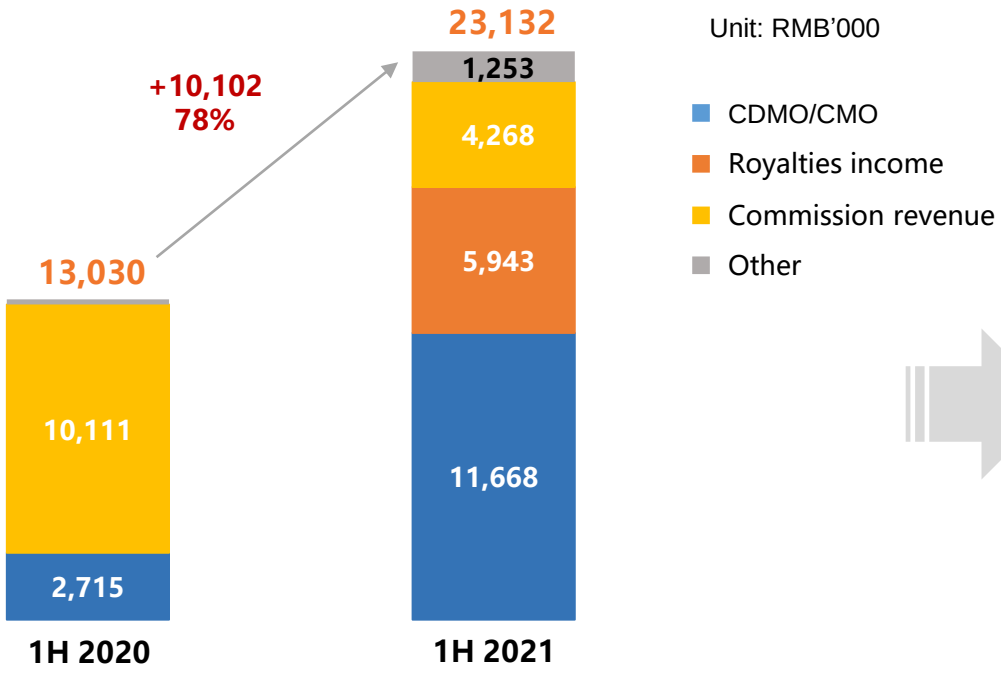
- Transfer of sales rights of self-developed products
- Rapid improvement of CDMO business scale, consolidate innovative DRUG CDMO market position
- Actively promote diversified cooperation of innovative drugs

3 Financial Review

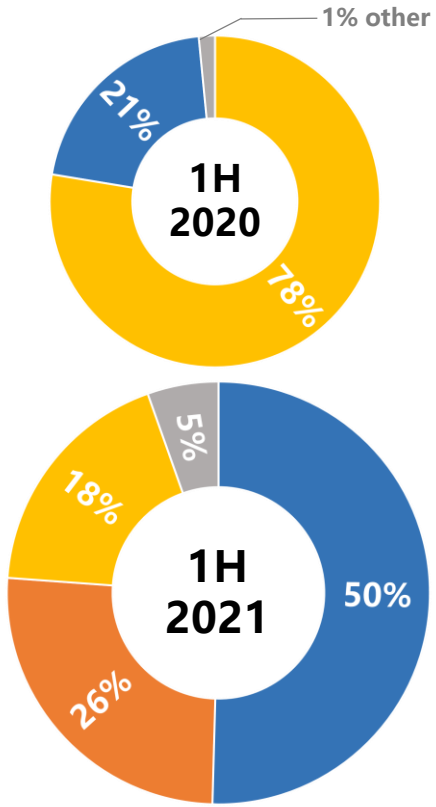
Key Financial Data – Revenue (during the first half of 2021)

- Speeding up the development of CDMO/CMO business, representing a YOY growth of 329.8%
- The milestone payment income was RMB 5.94 million mainly attributable to the phase I clinical trial of monoclonal antibody drug TAB014.
- The sales of the agency product S-1 was affected by the country's volume-based procurement, resulting in a decline in commission income

Income Distribution
1H 2021 VS 1H 2020



% Income by Each Category



Key Financial Data – Statements of Profit or Loss

Unit: RMB'000

Items	H1 2020	H1 2021	Diff%
Operating income	13,030	23,132	78%
Operating cost	(3,141)	(9,143)	191%
Research and development costs	(99,325)	(88,749)	-11%
Cost of sales	(13,726)	(11,202)	-18%
Management fees	(24,118)	(26,823)	11%
Other income and expenditure (net)	(1,083)	(2,660)	146%
Operating profit (loss)	**(128,363)**	**(115,445)**	**-10%**
Non-operating income and expenditure (net)	(820)	440	-154%
Net profit (loss)	**(129,183)**	**(115,005)**	**-11%**

- **Operating cost:** Increased 191% year on year, mainly from the growth of CDMO /CRO projects
- **R&D expense:** Decreased 11% year on year, mainly due to the increase of R&D labor costs and clinical trial costs.
- **Sales expense:** Decreased 18% year on year, mainly due to the company's sales strategy adjustment, related costs reduced accordingly
- **Administrative expenses:** Increase 11% year on year, mainly due to the increase of employee, administrative management and tax expenses.

Key Financial Data – R&D Expenses

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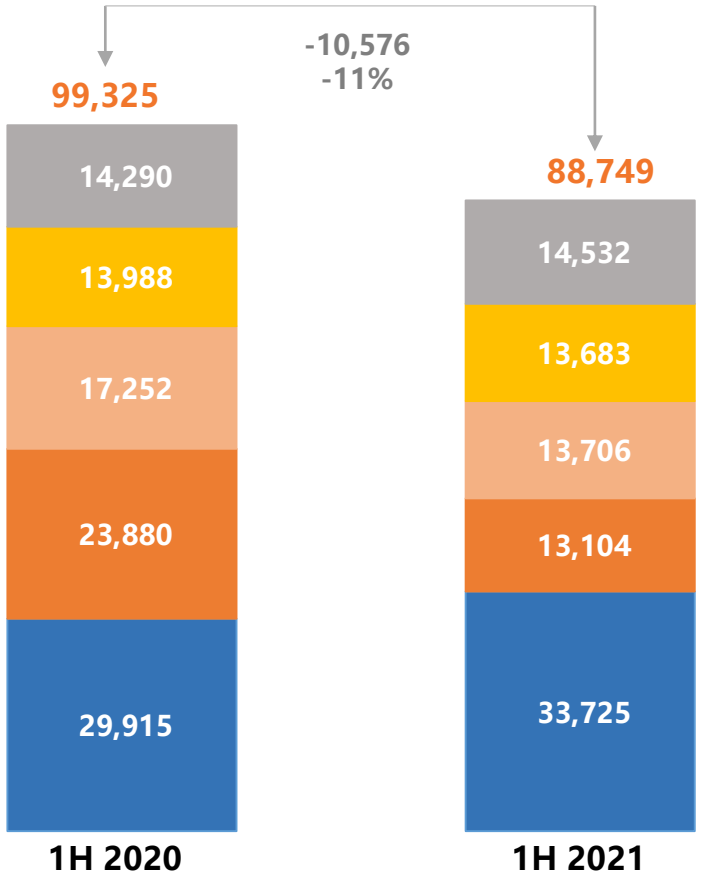
R&D expenses were RMB8,874,900, representing a year-on-year decrease of 11%



Unit: RMB'000

- Employee benefits expenditure
- Clinical trials
- R&D materials and consumables
- Depreciation and amortization
- Other

The changes are mainly from :

- **Clinical trial:** Phase III clinical trial of TAB008 was completed by the end of 2020, the related expense decreased
- **Employee benefits expense** : for the enlarge of the R&D team and increased employee welfare with the continuous development of R&D projects
- **Raw material for R&D** : the completion of R&D for the TOZ309 project resulted in a significant reduction of the relevant expenses for R&D consumables

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