东曜药业
TOT BIOPHARM

2020 Annual Results Corporate Presentation

March 24, 2021

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

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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 Overview and Review

2 Product Pipeline and Clinical Trial

3 Strategic Planning and Forecast

4 Financial Review

5 Q&A

Business Outlook

Synchronous development of innovative drug R&D and commercial production

2010

Company Established

- Pipeline Layout
- R&D and project approval

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

2011

No.1 Campus Founded

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

2016

MAH Pilot Program

- Obtained clinical trial approval for three drugs

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

2017-2018

No.2 Campus Founded

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

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

2019

Listed on HKEX

- 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'

- Listed on the Main Board of the HKEX in November

2020

ADC production Workshop Completed

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

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

Well-established Integral Industry Value Chain

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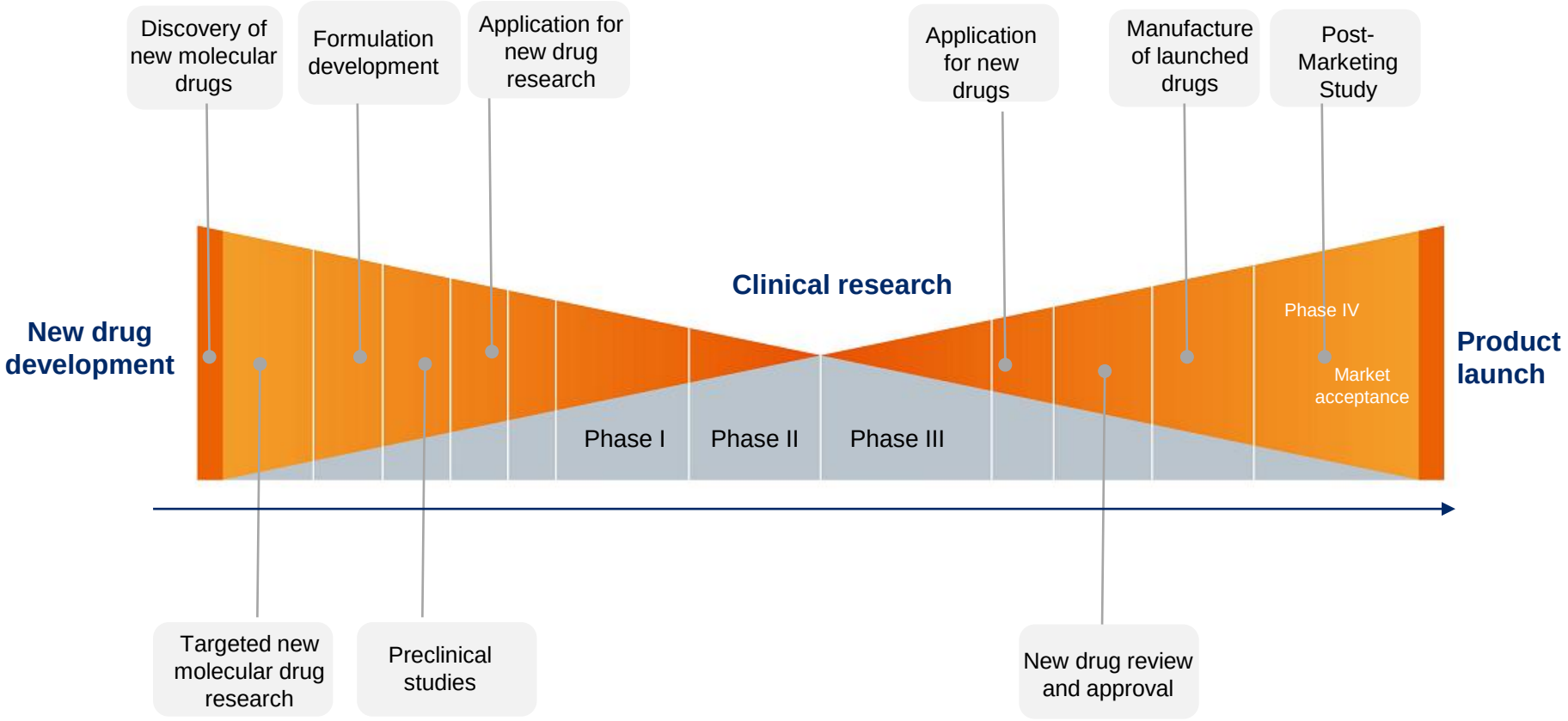
The verified open platform business model, strong new drug development capability, and mature commercialization platform



Our Three Technology Platforms

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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

Highly Competitive Commercial Production Capacity

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The international-standard commercialized production platform of mAb drugs + ADC drugs + chemical drugs

mAb drugs production workshop

The commercialized production workshop, located in the No. 2 plant which was completed in 2018, is equipped with drug substance and formulation production equipment, with a designed capacity of 16,000L

- Located in No. 1 plant, the monoclonal antibody pilot plant is used to produce clinical drugs with a capacity of 500L

ADC drugs production workshop

- The ADC drug substance
- production workshop was completed in September 2020, and has successfully produced multiple batches of TAA013 clinical drugs
- ADC drug commercialized production equipment and conditions

Chemical drugs production workshop

The No. 1 campus completed in 2012 has:

- Virology workshop with BSL-2 Certification
- Anti-cancer drug oral and formulation workshop
- Commercialization facilities for nanoliposome drugs

Advantageous Production Capacity of mAb and ADC Drugs

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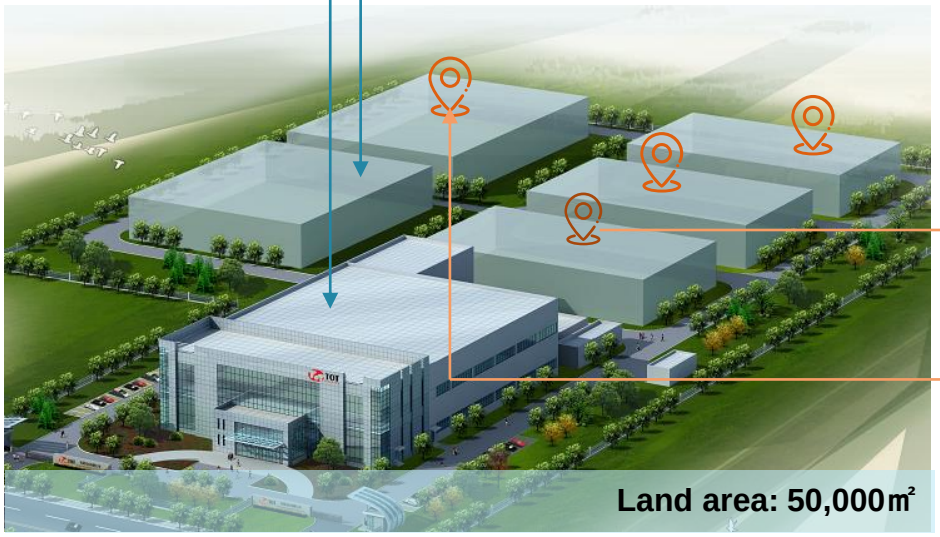
Accelerate expanding commercialized production capacity to create diversified and stable cash flow

- It has a 500L pilot plant for biopharmaceuticals
- Virology workshop with BSL 2 Certification

Commercialized production workshop of **ADC drug substance+ formulation**

Large-scale production base of mAb drugs



Expansion project of R&D and commercialized production platform

Start the construction project of Global R&D headquarters

Expand the manufacturing capacity of mAb and ADC, and increase multiple different production lines

Strategic Plan 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

Main Achievements from 2020 to March 2021

- **The development of innovative drugs entered into a new stage; the clinical progress of core products TAB008 and TAA013 were exceed expectation**
- **Layout of commercial production leads the industry; CDMO/ CMO business continues to expand**

A

Milestones of product in clinical phases

- **TAB008**: submitted the drug launch application, completed the on-site verification, and released the results of phase III clinical research
- **T0Z309:** completed the on-site verification
- **TAA013**: started phase III clinical trial and has been recruiting successfully
- **TAB014**: Phase III clinical trial is approved by FDA

B

Layout of Commercial production

- **Production workshop for ADC commercial drug substance** was put into operation
- Manufactured multiple batches of ADC drugs for clinical use
- **The production base of mAb drugs and chemical drugs** have passed the on-site verification of GMP compliance

C

CDMO/CMO business

- Reached long term cooperation agreements with several innovative drug and biological companies
- A number of CDMO/CMO projects for mAb drugs, ADC drugs and small molecule drugs were in progress, including the cooperation with **Kintor** in the global clinical supplies manufacture for COVID-19

D

Innovative drug development

- Developed innovative targeted biological drugs in cooperation with **Harbour BioMed**
- Independently developed innovative targeted ADC drugs

2 Product Pipeline and Clinical Trial

Continuous Improvement of Product Pipeline Innovation

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Types	Drug Candidates	Indication(s)	Pre-Clinical	Phase I	Phase II	Phase III	NDA(1)
ADC	TAA013(anti-HER2)	HER2+ breast cancer					
	TAE020(new target)	Acute myeloid leukemia					
Monoclonal Antibody product/Recombinant protein	TAB008(2)(anti-VEGF)	nsNSCLC					
	TAB014(3)(anti-VEGF)	Wet age-related macular degeneration (wAMD)					
	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 drugs	TOZ309 (temozolomide)	Malignant brain tumor					
	TOM312(megestrol acetate)	Cancer and HIV-associated cachexia					
	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 product	TVP211(genetically modified vaccinia virus)	Solid tumors					
Liposome chemical drug	TID214(liposomal docetaxel)	Solid tumors					
	TIO217(liposomal oxaliplatin)	Gastrointestinal tumors					

IND authorized by FDA, directly enter phase III

ANDA(4)

BE

Taiwan ANDA

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, mCRC and glioblastoma（GBM）in China. Additional indications of bevacizumab approved in the United States or the EU include renal cell carcinoma, cervical cancer, ovarian cancer, breast cancer, Fallopian tube cancer, peritoneal 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

On-site Verification of Key Product-TAB008 was completed Before Launch

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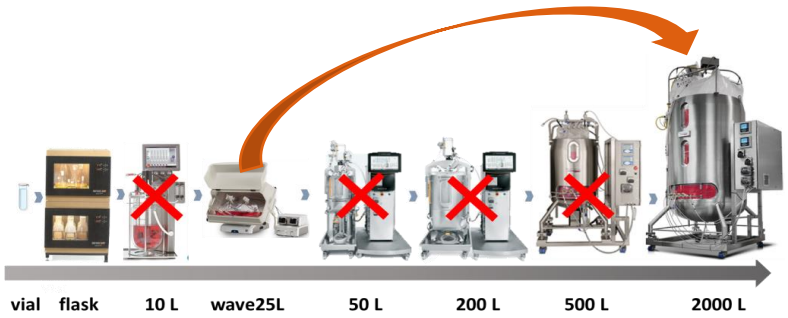
贝伐珠单抗注射液

BEVACIZUMAB INJECTION

PB-Hybrid Technology Flow Chart



Open Sales Right to Gain the Market Share

- Intended to use Pusintin® as the trade name
- passed the registration verification and GMP verification
- The first biopharmaceuticals to be approved

Stable Production Supply and Cost-effectiveness

- Apply PB-Hybrid Technology for commercialized production to expand capacity from 25L to 2,000L
- Simplify the process and reduce production risks
- Shorten the production cycle and greatly enhance production capacity
- Reduce production costs to improve cost advantages

TAB008 Clinical Progress-Phase III Clinical Trial Results Release 1/2

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Phase III clinical study on chemotherapy treatment of advanced or recurrent non-squamous cell and non-small cell lung cancer by TAB008 combined paclitaxel and carboplatin versus Avastin® combined paclitaxel and carboplatin

Test design

Target patients

- **Stage IIIB + C/IV or recurrent metastatic non-squamous non-small cell lung cancer**
- **EGFR wild type**
- **Measurable target lesions (RECIST v.1.1)**
- **Adequate organ function**
- **Survival for over 3 months**
- **Asymptomatic CNS metastasis**

Random

TAB008 15mg/kg IV + Carboplatin / Paclitaxel Q3W*6 (n=273)	TAB008 7.5mg/kg IV Q3W
Bevacizumab 15mg/kg IV + Carboplatin / Paclitaxel Q3W*6 (n=273)	Bevacizumab 7.5mg/kg IV Q3W

End of study

Screening period

TAB008/bevacizumab: 6 cycles
Carboplatin/paclitaxel: ≤6 cycles

Maintain treatment stage

VIRTUAL 2020 ESMO ASIA
20-22 NOVEMBER 2020

ESMO ASIA 2020 VIRTUAL

TAB008 Clinical Progress-Phase III Clinical Trial Results Release 2/2

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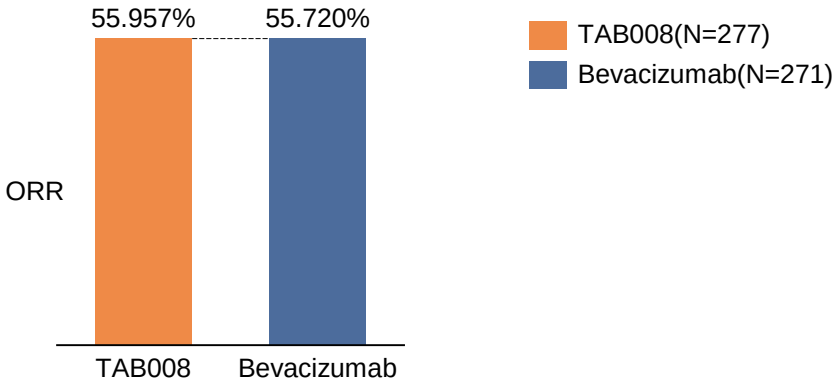
Effectiveness, TAB008 and the original ORR are **55.957% and 55.720%**, respectively, with similar efficacy

Safety, the incidence of adverse events and serious adverse events in the treatment of the original study group is basically similar, the difference between the groups is not statistically significant, and it is clinically controllable

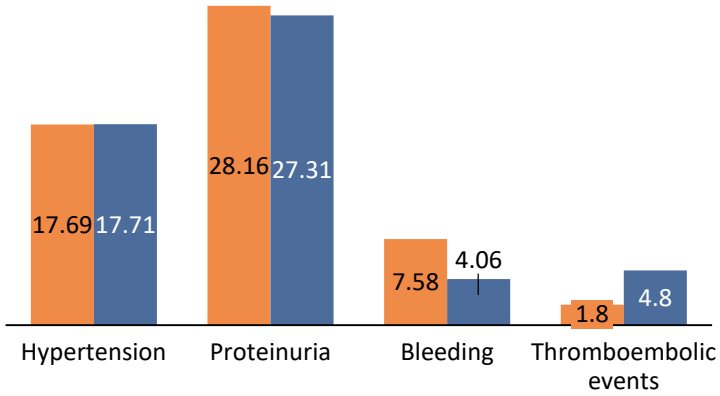
Bioequivalence, bioequivalence with the steady-state trough concentration of the original drug after administration

Comparison of Objective Remission Rate (within 6 cycles)

Ratio=1 (90%CI:0.89,1.14)



AESI Incidence Rate Comparison (%)



Leading Clinical Progress in Key Product-TAA013

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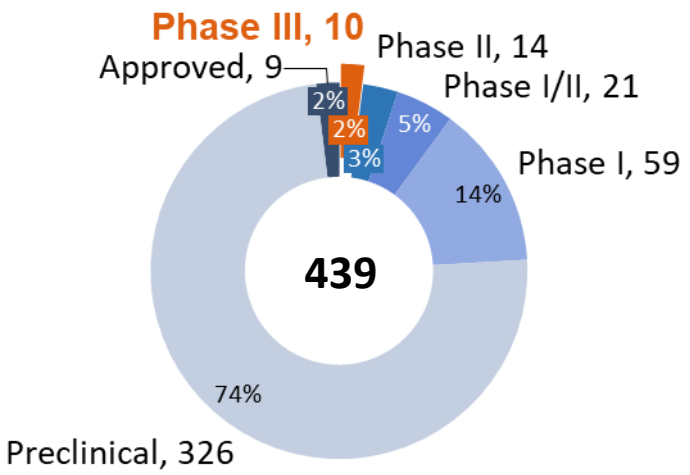
10 companies in the world and 3 domestic companies entered the phase III clinical stage, and TAA013 phase III clinical progress is leading in China

- The enrollment of the first patient in Phase III clinical trials has been completed in **July 2020** and it is in the recruitment stage currently
- **438 patients are pre-recruited for phase III clinical trials**, leading the recruitment schedule
- **Phase I clinical results** were released in **November 2020**, no serious drug-related adverse reactions occurred, and the adverse reactions were clinically controlled

Clinical Stage Distribution of Global ADC Product

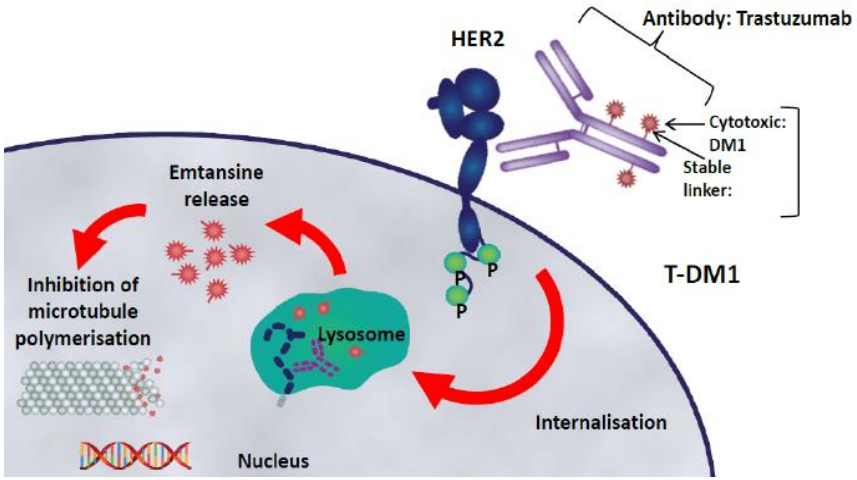


Clinical Schedule of Domestic HER2 Target ADC Products

Enterprise	Target	Toxic Load	State	Start Time of the State
TOT BIOPHARM	**HER2**	**DM1**	**III**	**2020/7(FPI)**
X Company	HER2	Amberstatin269	III	2020/8(FPI)
Y Company	HER2	MMAE	III	2020/9(FPI)
A Company	HER2	DM1	Ia	2018/9
B Company	HER2	DM1	I	2019/6
C Company	HER2	DM1	I	2019/6
D Company	HER2	DM1	I	2019/8

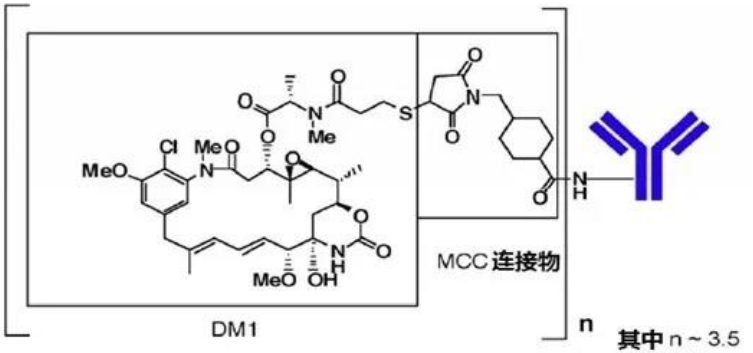
Source：Beacon Targeted Therapies，Chinadrugtrials.org.cn

TAA013 Clinical Progress-Phase I Clinical Trial Results Release 1/2



Mechanism of Action

- 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



Maitansine's derivatives

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

Phase I Alinical 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 Clinical Progress-Phase I Clinical Trial Results Release 2/2

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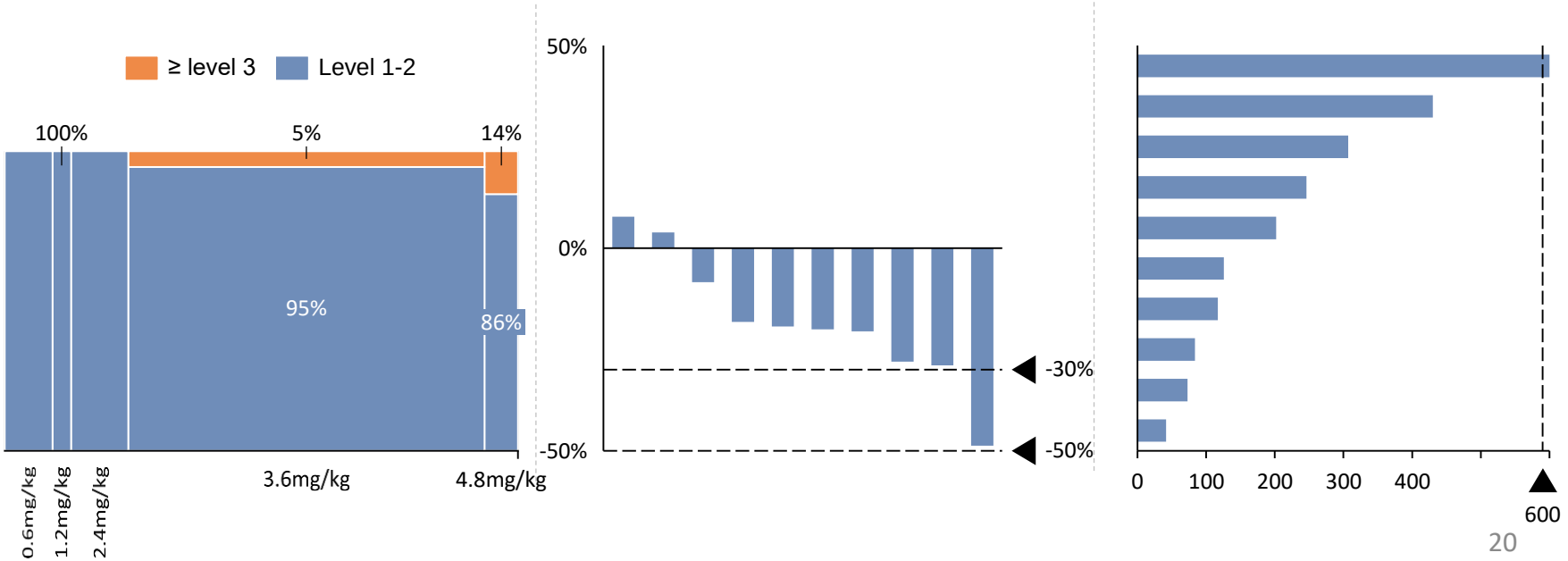
- **Safety tolerance: no DLT was observed** in each dose group, most of the adverse events were rated as grade 1-2, clinically controllable
- **Effectiveness:** The subjects received 4-line treatment on average and the objective remission rate of 10 subjects was 10% after receiving the recommended dose of 3.6mg/kg; the target lesions of 2 subjects shrank by nearly 30%, and the disease control rate reached 70%. The median progression-free survival was more than 5 months, and one subject had been treated for more than 600 days

Adverse events chart (all doses) | **Waterfall plot of target lesion (3.6mg/kg)** | **Treatment time (days,3.6mg/kg)**

Phase I results has published at the SABCS in December 2020



3 Strategic Planning and Forecast

Centralize Full Play to Our Resources and Strengths

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

Strengthen 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

Competitive advantage of ADC drugs R&D and production

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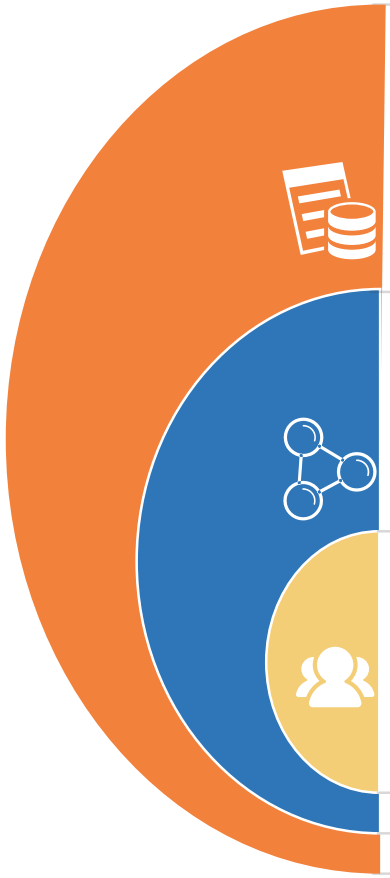
One of the few capabilities of ADC drug R&D and commercial production in China



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

“One-stop” CDMO/CMO Cooperation Platform

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Customized Development

- Production of clinical sample
- Commercialized production
- Preparation

Quality System

- Assistance in IND application
- Assistance in BLA registration and application

- Cell strain development
- Cell bank preparation
- Production process development including upstream and downstream
- Drug substance and finished product
- Research on production and stability of cGMP stock solution and finished product

GMP Production

- Quality assurance
- Quality control

Registration & Application

Advantages of Diversified Cooperation & CDMO/CMO Services

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

Endless Devotion of Resource and Support

More Efforts in R&D

- Continuously innovate drug R&D and development and Industry-University-Research Coordination
- Provide complete R&D infrastructure and create a good research environment
- Increase and attract more international talents

More Efforts in Management System

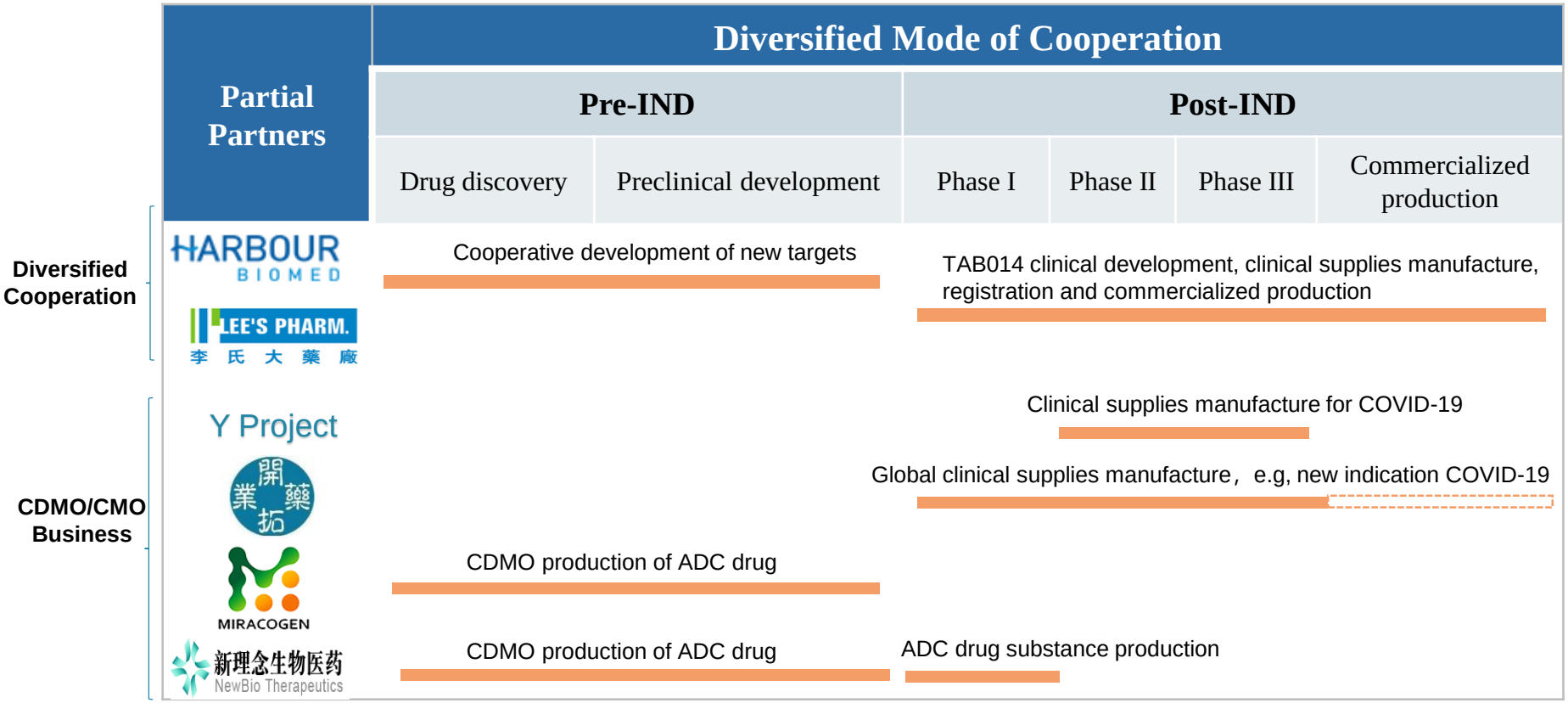
- GMP-standard international production plant
- International quality management system
- Patent application and protection at home and abroad
- Strict business ethics

More Efforts in Capacity

- Expand mAb capacity and increase independent production lines to meet self owned business and CDMO business
- Build a complete “one-stop” and ADC commercialized production platform

Diversified Mode of Cooperation

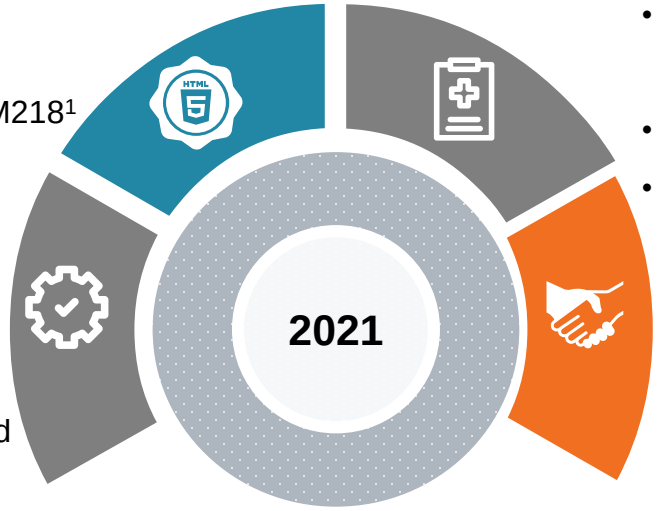
- **Open cooperative platform: the best strategic partner for drug development, clinical trial and commercialization**
- **Flexible and diverse service platform: to meet the needs of projects running through different links from IND to product market**



Forecasts for 2021

Product Launch

- Complete the launch of TAB008、TOZ309 and TOM218[1]



Clinical Progress

- Accelerate the recruitment of the subjects for TAA013 clinical trials
- Start Phase III clinical trial of TAB014
- Finish BE test on TOM312

Production Capacity

- Start ADC pilot-scale test and build large-scale formulation workshop
- Begin to expand the workshop of mAb drug substance

Product Licensing and Cooperation

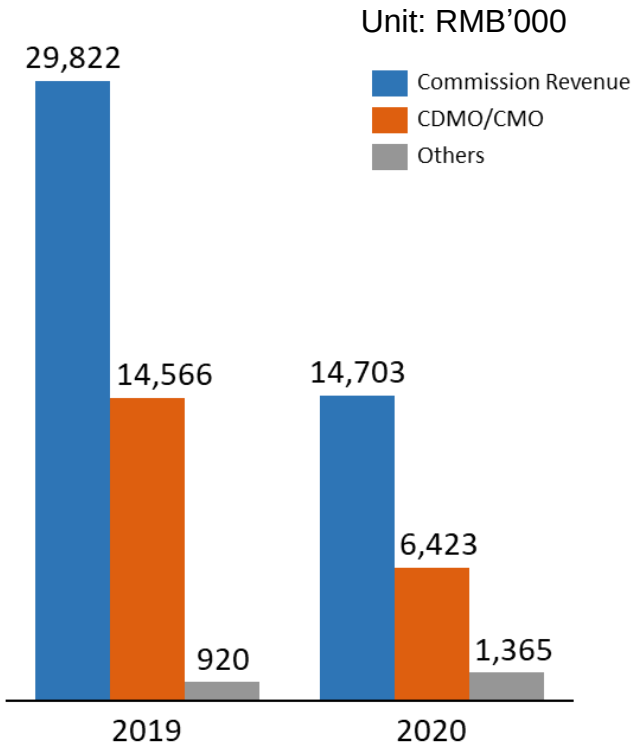
- Transfer of sales rights of self-developed products
- Surpass the revenue milestone of 100 million for CDMO business orders
- Cooperative development of innovative drugs

Note: 1) TOM218 (megestrol acetate)，the imported drug from Taiwan

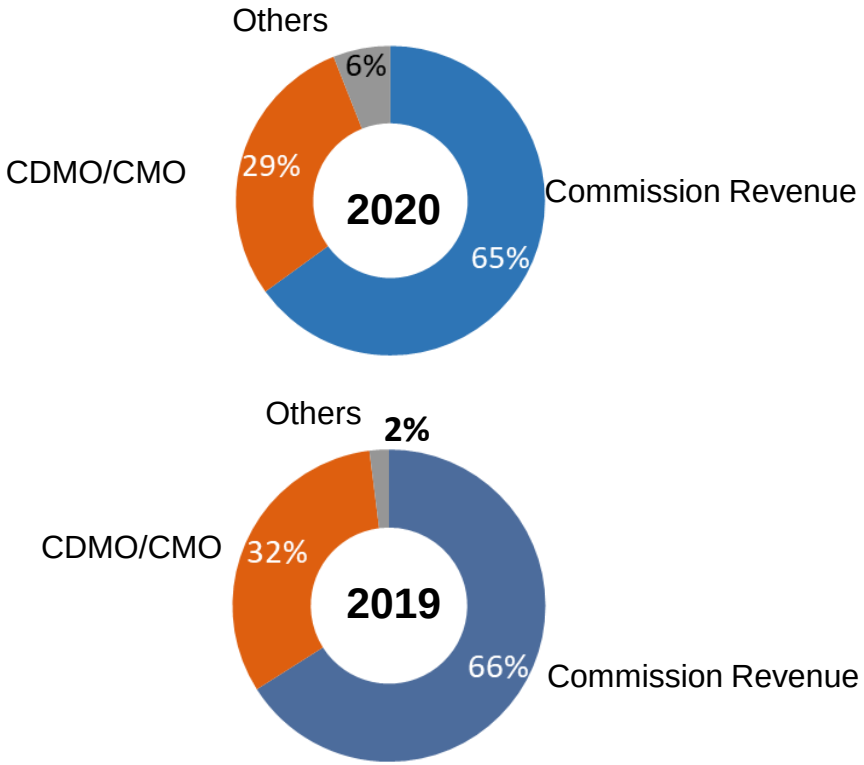
4 Financial Review

Key Financial Data – Revenue

Income Distribution



Percentage Revenue by Categories



- **Diversified revenue mainly include sales agency and CDMO/CMO business cooperation**
- **The sales of the agency product S-1 was affected by the country's volume-based procurement, resulting in a decline in commission income**
- **The change of CDMO/CMO revenue mainly due to match with our customers' project schedules**

Key Financial Data – Statements of Profit or Loss

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Unit: RMB’ 000

Items	2019	2020	Diff%
Operating revenue	¥ 45,308	¥ 22,491	-50.4%
Operating costs	(11,316)	(6,961)	-38.5%
R&D expenses	(191,078)	(235,196)	23.1%
Selling expenses	(31,544)	(25,953)	-17.7%
Management expenses	(95,091)	(46,855)	-50.7%
Other expenses（net）	14,117	3,802	-73.1%
Profit from Operations （Loss）	**(269,604)**	**(288,672)**	**7.1%**
Non-operating income and expenses（net）*	(29,696)	174	N/A
Net Profit（Loss）	**(299,300)**	**(288,498)**	**-3.6%**
Adjusted Net Profit（Loss）**	**¥ (206,739)**	**¥ (272,666)**	**31.9%**

- **Operating cost:** Decrease in line with a drop in income.
- **Sales expenses:** due to the suspension or postponement of a number of marketing activities due to the impact of the COVID-19.
- **Administrative expenses**: due to the listing expenses included in the same period in 2019.
- **Other income and expenditure (net):** due to the decrease in government subsidies**.**

Note: * Government subsidies and exchange gains and losses
** 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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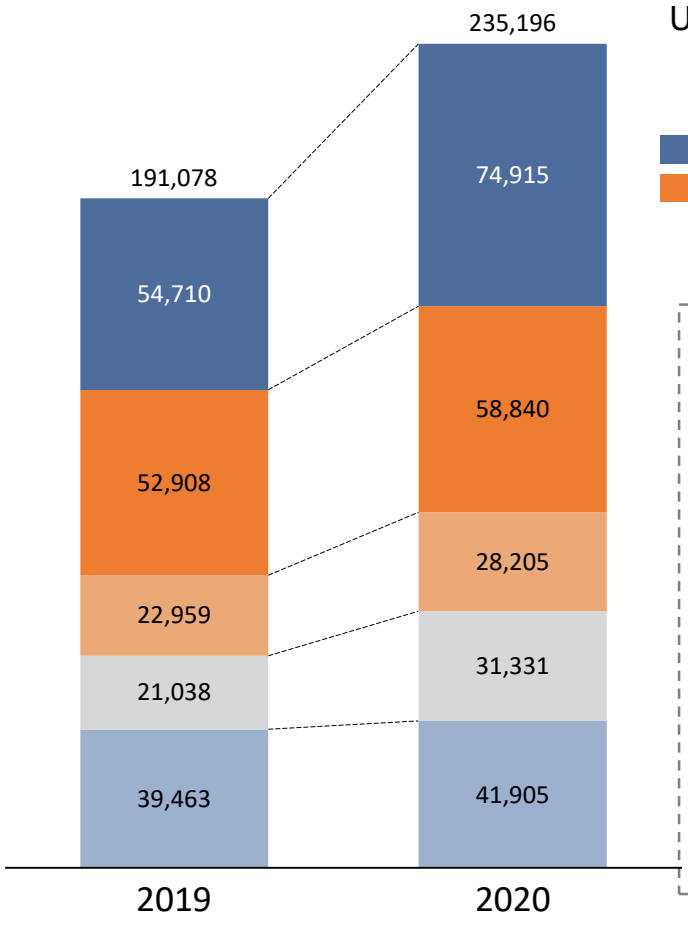
For the Year Ended 31 Dec			Unit: RMB'000
	2019	2020	Diff
Net Loss	¥ (299,300)	¥ (288,498)	-3.6%
Adjusted Net Loss	(206,739)	(272,666)	31.9%
EBITDA	¥ (269,658)	¥ (254,710)	-5.5%
Adjusted EBITDA	(177,097)	(238,878)	34.9%

Unit: RMB/Share

	2019	2020	Diff
EPS	¥ (0.89)	¥ (0.51)	-42.7%
Adjusted EPS	(0.62)	(0.48)	-22.6%

Key Financial Data – R&D Expenses

R&D Expenses Comparison in 2020 VS 2019



R&D expenses amounted to RMB235,196,000, an increase of RMB 44,118,000 compared to 2019, mainly attributable to:

- The commencement of **Phase III clinical trial for the TAA013** project of the Company in 2020 after the completion of Phase I clinical trial that resulted in an increase in demand for active pharmaceutical ingredients (APIs), excipients and consumables by related contract research (CROs) and those for the preparation of clinical drugs
- **Increase in depreciation** due to the addition of commercial production facilities and GMP-related continuous construction

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