东曜药业
TOT BIOPHARM

2021 Corporate Results Presentation

25 March 2022

TOT BIOPHARM International Company Limited

Stock Code: 1875

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1 Performance Overview

1.1 Performance Highlights and Strategic Adjustment

Performance Highlights and Major Milestones – As of March 2022

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Product Launch and Clinical Research

3 Products Launched

- Pusintin® (Bevacizumab Injection)
- Tazian® (Temozolomide Capsule)
- 美适亚® (Megestrol Acetate Oral Suspension)

2 Key Clinical Projects

- ADC drug – TAA013:
  - ✓ Phase III clinical enrollment
- Antibody drug – TAB014:
  - ✓ Phase III clinical trial application was authorized by FDA

Commercialization Milestones

3 Commercial Promotion Cooperations

- Accelerate market expansion of the products with full speed through CSO cooperation: Pusintin® ;Tazian® ; 美适亚®

2 Commercialization License-out

- Pusintin®: Commercialization license for overseas market
- TAB014: Commercialization license in China

CDMO/CMO Business Development

21 Projects (as at Dec 31, 2021)

- 16 Newly added projects
- 12 Completed projects

2 Strategic Cooperations

- Cooperated with BrightGene Bio-Medical (博瑞医药) in the field of ADC-CDMO
- Signed CDMO strategic cooperate agreement with Jemincare

Commercial Capacity

2 GMP Compliance Inspections

- mAb drug commercial production facilities passed GMP compliance inspection
- Chemical drug capsules passed GMP compliance inspection

2 ADC Production Facilities Construction

- Construction of the second ADC commercial production line
- Layout of ADC pilot production facilities

Positive Strategic Transformation Measures

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Rationally allocated resources to maximize competitive advantages. Striving to develop CDMO/CMO business and consolidate ADC commercial platform

1	**Established a Professional CDMO/CMO Management Team**	• Accelerated the establishment of a professional and efficient CDMO/CMO team, expanded customer resources and created diversified income • The well established independent management system, strict information security system and efficient project execution won high recognition by customers
2	**Completed Business Reform in Sales and Marketing**	• Accelerated market expansion of self-developed products through strategic corporations (Pusintin®, Tazian®, 美适亚®) • Established JV company with China Resources Pharmaceutical & Commercial to set up an independent marketing system and effectively controlled marketing expenses
3	**Completed the Separation of Pharmaceutical Team**	• Focusing on key areas, further strengthened advantages in the ADC field and optimized non-core business organization
4	**Consolidated ADC Commercial Production Platform**	• Constructed a second commercial preparation line to well establish a leading ADC commercial production platform in China, thus meeting the needs of projects from R&D to commercialization
5	**Enhanced CDMO/CMO Business Capacity**	• Enhanced process development capabilities and strengthened the delicacy management of the quality system to promote strategic transformation • Started the construction of the global R&D center to improve the diversity and flexibility capacity for CDMO/CMO business

Diversified Strategic Partnerships

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Product Licensing

Kexing Biopharm 科兴制药 | Pusintin® Overseas market commercialization authorization

ZHAOKE 兆科® | TAB014 in mainland China, Hong Kong and Macau

Marketing and Promotion

华润医药商业 CR PHARMA COMM | Set up a marketing joint venture

Jemincare 济民可信 | Pusintin® Tazian®

Frontier 前沿生物 | 美适亚®

Strategic Cooperation

BrightGene 博瑞医药 | ADC-CDMO

HARBOUR BIOMED | Cooperative Development

CDMO/CMO (Customer representatives)

MIRACOGEN

開拓藥業 KINTOR

新理念生物医药 NewBio Therapeutics

Jemincare 济民可信

诗健生物 Escugen

Constantly Enriching Innovative Drug Candidates

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- **Focused on completing the Phase III clinical trial of TAA013 and optimized non-core product pipelines**

Type	Drug Candidate	Indication(s)	Preclinical	Clinical Phase I	Clinical Phase II	Clinical Phase III	NDA	Launched
Launched	TAB008 (anti-VEGF)	nsNSCLC、mCRC、 GBM、OC、CC						
	TOZ309 (temozolomide)	Malignant brain tumor						
Antibody drug conjugate	TAA013 (anti-HER2)	HER2+ breast cancer						
	TAE020 (new target)	Acute myeloid leukemia						
Monoclonal antibody/ Recombinant protein	TAB014 (anti-VEGF)	Wet age-related macular degeneration (wAMD)				ZHAOKE 兆科		
			IND authorized by FDA to directly enter Clinical Phase III					
	TAC020 (new target)	Various solid tumors	Cooperative					
	TAY018 (anti-CD47)	Non-Hodgkin's lymphoma, myelodysplastic syndrome, acute myelogenous leukemia, solid tumors						
Oncolytic virus	TVP211 (genetically modified vaccinia virus)	Solid tumors						
Liposome chemical drug	TID214 (liposomal docetaxel)	Solid tumors						
	TIO217 (liposomal oxaliplatin)	Gastrointestinal tumors						
Chemical drug	TOM312 (megestrol acetate)	Cancer and HIV-associated cachexia				Approved in Taiwan, submitted ANDA in China		
	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						
	TEP118 (modified version of hyaluronidase)	Biliary cancer, gallbladder tumors, metastatic cancer, non-small cell lung cancer (NSCLC), gastric cancer						

Optimized pipelines

1 Performance Overview

1.2 Product Strategies and Commercialization

TAA013 Clinical Progress and Marketing Strategy

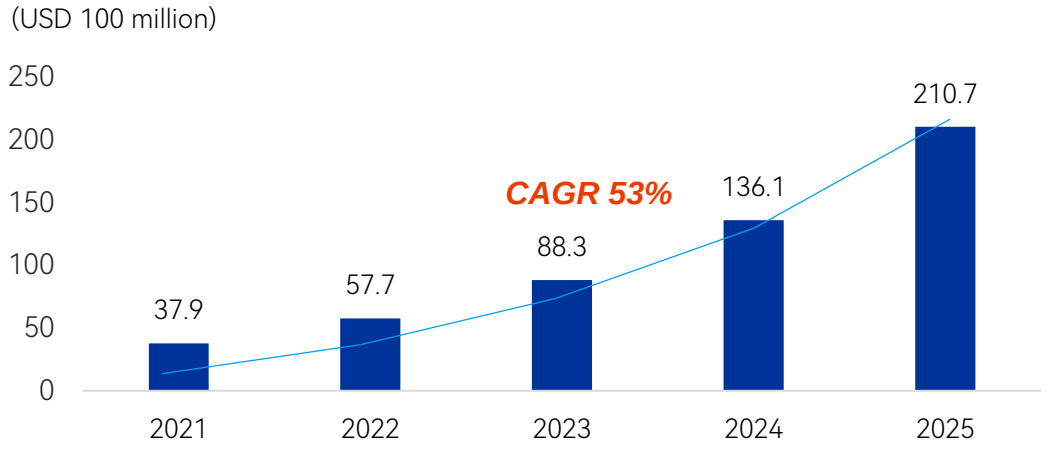
Market Positioning	As an Affordable Alternative Product to Kadcyla
Clinical Progress	The fastest HER2-ADC drug in phase III clinical trial in China Expected to be completed patient enrollment in 1H of 2022
Market Advantage	With Kadcyla as the benchmarking product, which maintained best sales performance in the world, TAA013 will enjoy a matured market and good clinical performance
Market Strategy	Expand market share and improve price structure through commercial corporation and collaboration with strong companies, so as to enhance the accessibility of the drug to patients

China's HER2 Target ADC Drug in the Clinical Stage

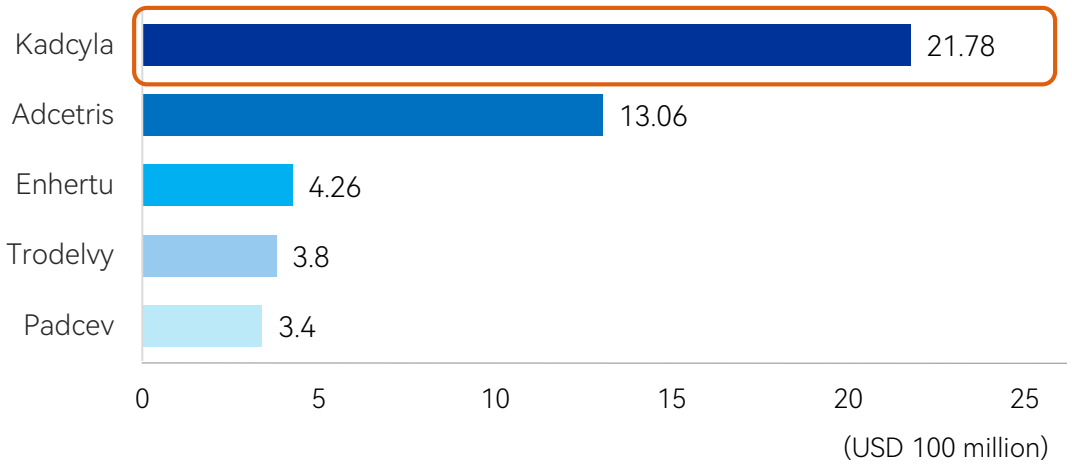
Enterprise	Product	Toxic load	Clinical Stage
TOT Biopharm	**TAA013**	**DM1**	**III**
Company A	ARX788	Amberstatin269	II/III
Company B	DP303c	MMAE	II
Company C	MRG002	MMAE	II
Company D	SHR-A1811	Undisclosed	I/II

(Note: only listed part of the companies' project in phase II clinical stage)

Global ADC Drug Market Forecast



World's Top 5 ADC Drug Sales Volume in 2021



Source: Beacon Targeted Therapies, Chinadrugtrials.org.cn, Grandview

Commercialization Strategy（Ⅰ）: Pusintin®

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Pusintin®
Bevacizumab Injection

Huge potential in the Chinese market

The scale of China's market will reach 6.5 billion RMB by 2023 and exceed 10 billion RMB by 2030

Six indications

nsNSCLC, mCRC, glioblastoma multiforme (GBM), ovarian cancer，cervical cancer *(hepatocellular carcinoma (HCC) application was received by NMPA)*

Exclusive Marketing Cooperation in mainland China

Nationwide Coverage

Jemincare 济民可信

Pricing plan and differentiated layout: Focus resources on 2nd/3rd-tier cities and "Dual-channel" provinces; strengthen penetration into 3rd/4th-tier cities and county level cities

Marketing target: Will cover 70% provinces in the first half of this year (20+)

Reaching the end-market: Optimize distribution and build supply chain resilience to improve circulation efficiency and reduce sales costs

Brand enhancement: Enhance brand awareness through patient care activities

Exclusive Commercial Authorization in Overseas Countries

科兴制药 Kexing Biopharm

Transaction amount: Receive initial payment and R&D milestone payment, as well as project sales milestone of 380 million RMB

Authorized regions: Grant exclusive commercial license to overseas markets (except Europe, America and Japan)

Initial regions: 20+ countries, totaling more than 100 regions

Commercialization Strategy (Ⅱ): Tazian®

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Tazian®
(Temozolomide Capsule)

Jemincare 济民可信

- Glioblastoma multiforme or anaplastic astrocytoma that recurs or progresses after conventional treatment
- Newly diagnosed glioblastoma multiforme, initially combined with radiotherapy, and then as maintenance therapy

Provincial Purchase Network Application

Complete provincial purchase network application and made full preparations for the fourth collective procurement

National Sales of 1.8 Billion RMB in 2020

Domestic sales in 2020: 1 original research + 2 domestic competitor products

Seized 30% Market Share

Cooperate with Jemincare, focusing on 2A/3A grade hospitals

(Brain glioma is the most common primary CNS tumor, accounting for 50% of all primary CNS tumors, among which glioblastoma (GBM) and astrocytoma account for about 75%)

Commercialization Strategy (Ⅲ)：美适亚®,TAB014

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美适亚®

(Market Approval for Megestrol Acetate Oral Suspension)

Precise positioning of patient groups, segmentation of market promotion channels

Frontier 前沿生物

Specialized in fighting AIDS

- Anorexia associated with acquired immunodeficiency syndrome (“AIDS”)
- Significant weight loss of AIDS and cancer patients caused by cachexia

TAB014

(Bevacizumab Ophthalmic Drug)

It is the first bevacizumab antibody under clinical development for the treatment of wet senile macular lesions in China. The global market volume is expected to reach US$3.5 billion by 2030.

The Chinese marketing right was authorized to Zhaoke Ophthalmology; TOT BIOPHARM is responsible for the commercial production of TAB014

ZHAOKE 兆科®

- Wet (neovascular) age-related macular degeneration (“wAMD”), retinal vein occlusion (RVO), choroidal neovascularization (CNV), and other eye diseases

Note: China includes Hong Kong and Macao

Flexible and Diverse Production Capacity

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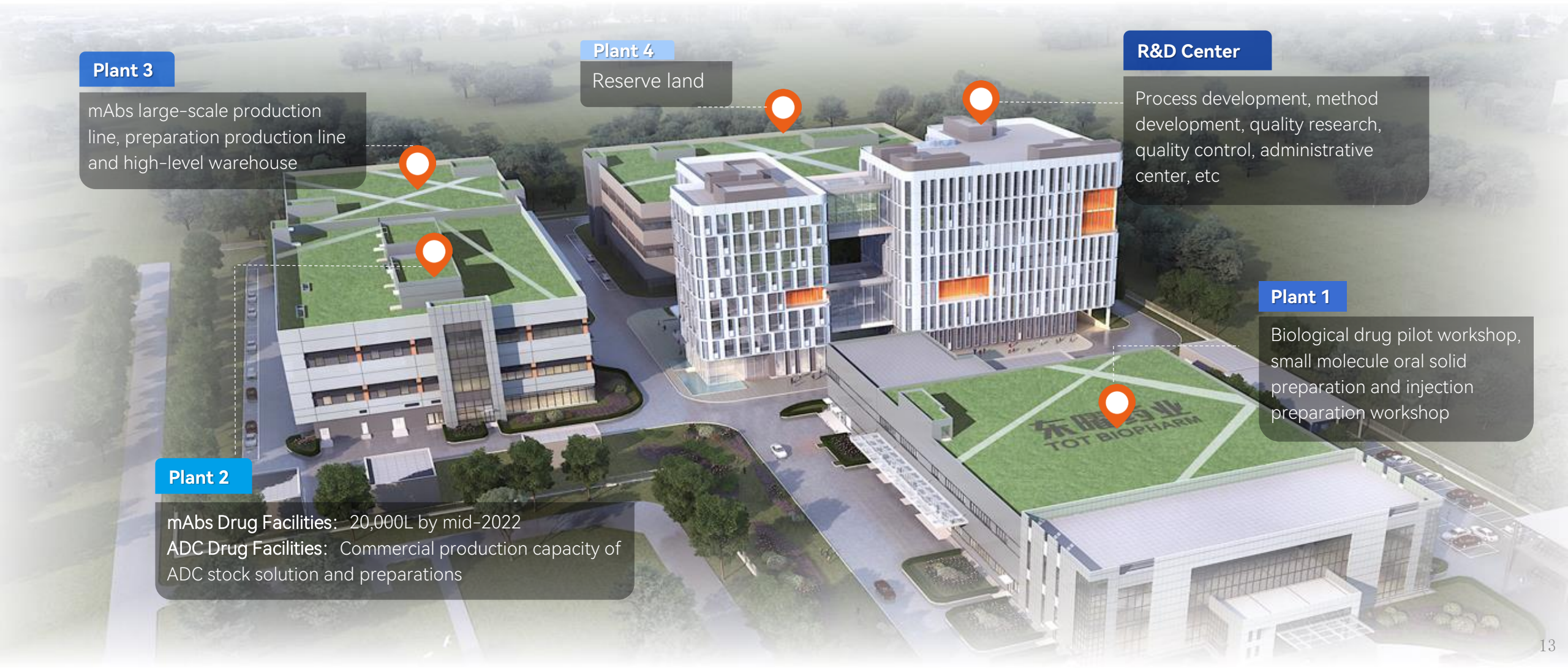
- *"One-Base, End to End"* commercial production platform integrating monoclonal antibody and ADC production lines
- Meeting the capacity requirements of different scales of pilot and commercial production



Industry-leading ADC One-Stop Industrialization Platform

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- ADC commercial production base with GMP compliance production of ADC DS, preparation and ADC naked antibody
- To be the most valuable and leading CDMO industrial resources with high standard quality management system, GMP compliance commercial production capability

"Diversity of Services"&"Compliance"

Plant planning creates production flexibility to meet diverse and flexible capacity requirements

GMP compliant pilot production facility

Commercial GMP manufacturing facility for ADC

OEB-5 active grade freeze-dried powder needle/water needle preparation

GMP Standards

Production quality assurance system with international standards

- Quality Control complies with GMP standards: DS/DP release and stability study
- Quality Assurance System complies with NMPA, FDA, EMA standards
- Execution track record of successful project experience

Rich practical experience for CDMO cooperation

- **Stable Coupling Technology:** more than 10 different types of ADC drug development
- **Mature Production Technology:** 9 production projects of ADC drugs, including phase I and phase III clinical

Naked antibody production

ADC stock solution production

Preparation production

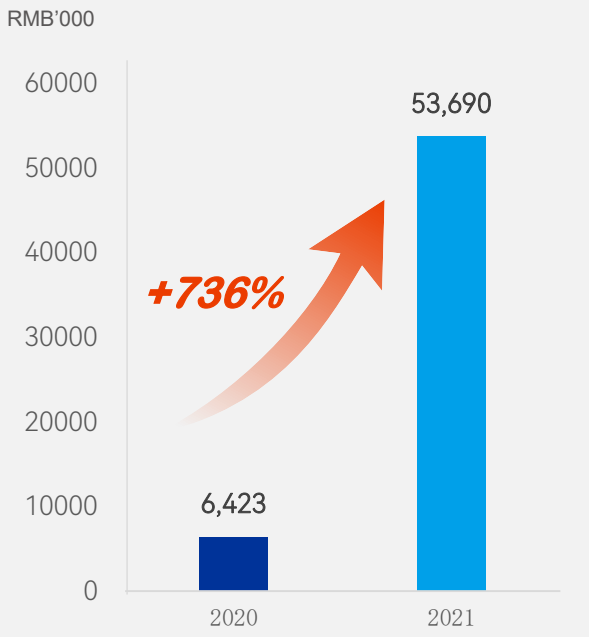
2 New Business Development

CDMO Business

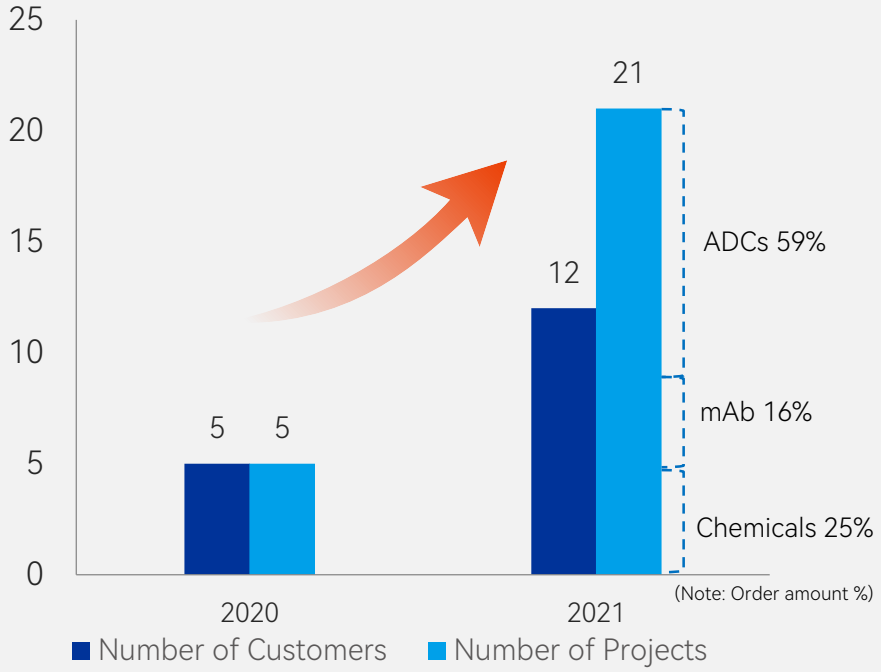
CDMO/CMO Performance in 2021

- CDMO/CMO income was 53.69 million RMB with the amount of new orders exceeding 100 million RMB and the amount of ADC project orders accounting for 59%
- Strategy adjustment produced remarkable results. The number of projects increased by more than 3 times compared with last year, and 12 projects were delivered

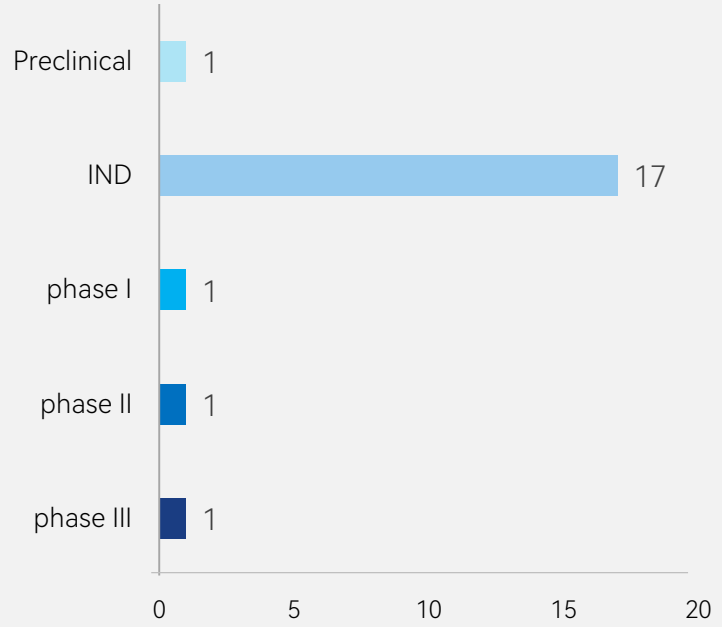
Income Comparison



Business Scale Comparison



Phased Project Comparison



100% Project Success Rate / 100% Customer Satisfaction Rate

Completed Porject Ahead of Schedule, Winning Highly Recognized from Customers

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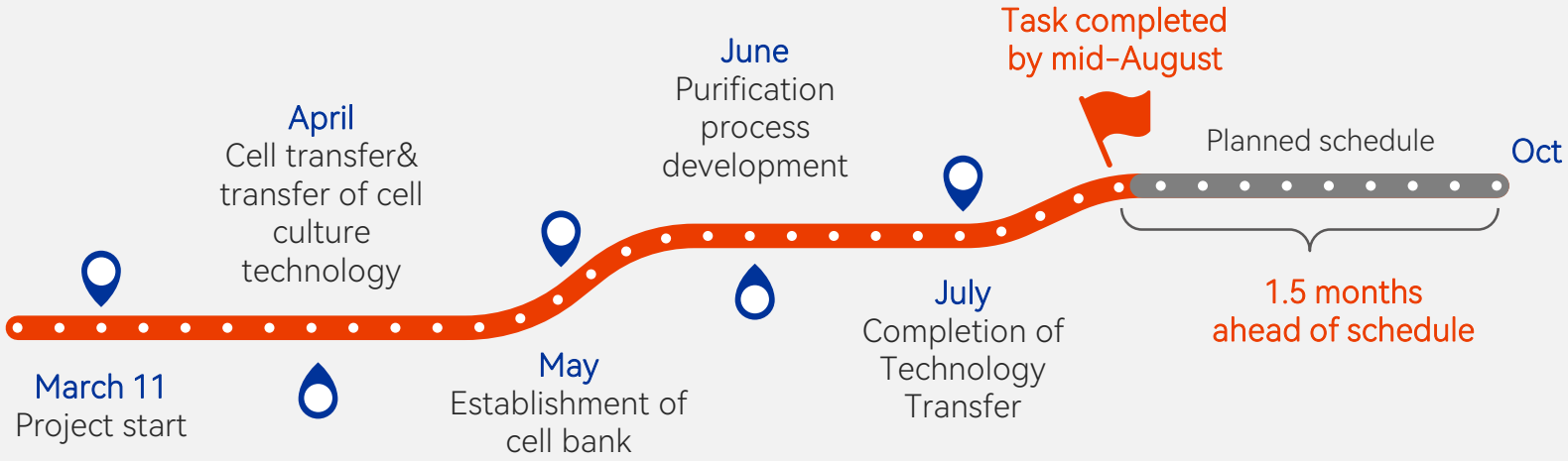
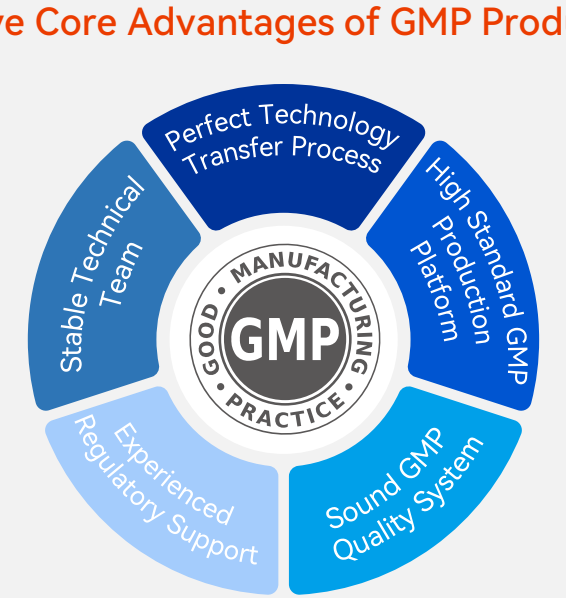
- Jemincare Antibody Project: 1.5 months ahead of schedule





Sophisticated Amplification Process	Completed the amplification process with directly enlarged commercial scale from 200L to 2,000L at One Stretch
Precised Solutions	Provided cost reduction and efficiency increase solutions for customers, Specifically, domestic materials replacement, which significantly reduced costs; recycling rate increased by 9% thanks to process optimization
Efficient Execution	Completed the project ahead of schedule, which covering 18 batches of laboratory research, 9 transfer methods, and 4 development methods and validations

Established Long-term Win-Win Cooperative Relationship Based on Mutual Trust & Mutual Benefit

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On January 5th, 2022, signed a CDMO strategic cooperation agreement with Jemincare to provide **one-stop services from R&D to commercialization**

In 1H2021, established close partnership on marketing service for Tazian® in the Chinese Mainland.

In 2H2021, entered into an exclusive marketing service agreement with each other in respect of Pusintin® in the Chinese Mainland.

In 2021, the company completed CDMO service of antibody project, about1.5 months ahead of schedule.

Comprehensive Industrial Value Chain and “One-Stop” CDMO Services

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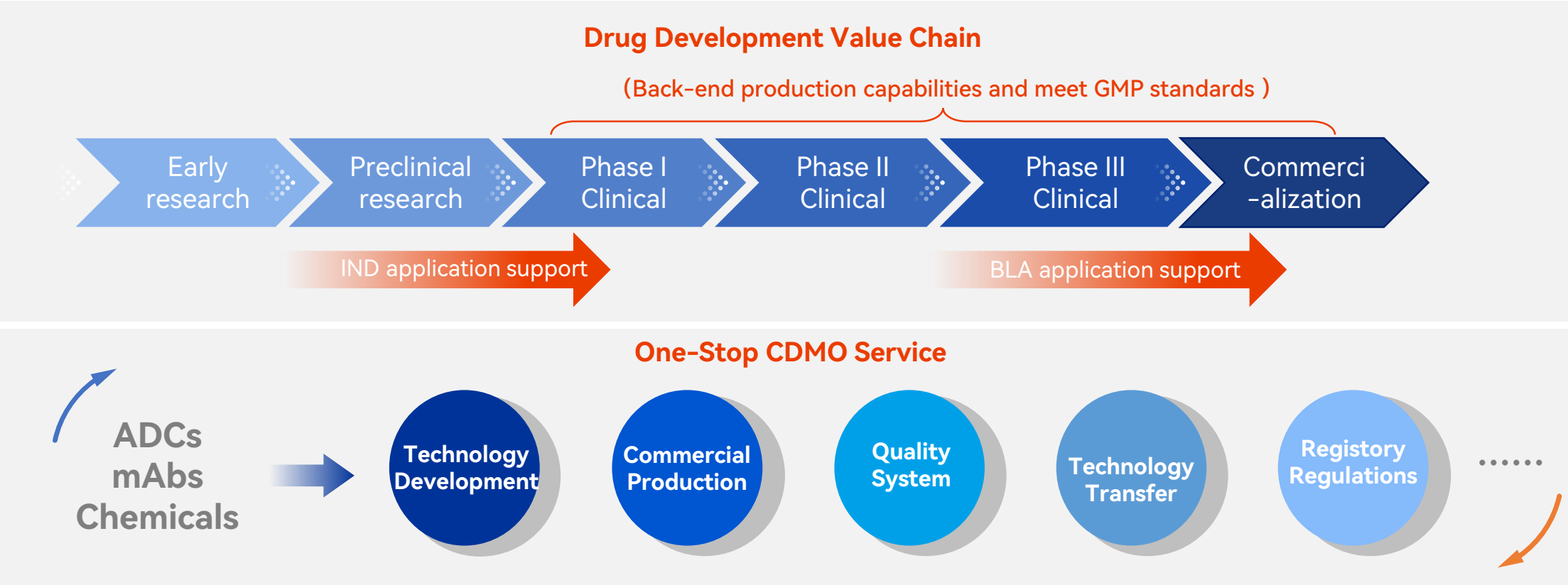
- Comprehensive industrial value chain that further binds customers with the Company and brings long-term value, creating sustainable business growth
- With the changes in the industry, early-stage drug discovery companies are increasingly dependent on the back-end resources of the clinical and commercialization production. Transforming from new drug development to entering the field of CDMO business with an in-depth understanding of the drug life cycle and is able to provide all-roundl value-added services from non-clinical stage to clinical stage as well as commercial production for customers.



Quality Management System Approved by the Regulatory Authority

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- Through the application for market launch and commercial production of self-developed drugs Pusintin® and TAA013, the Company has established a comprehensive quality system to ensure drug quality.

ICH Q8-Q10 Pharmaceutical Quality System Lifecycle Management

Pharmaceutical development → Technology Transfer → Commercial Manufacturing → Product Discontinuation

Investigational Products

GMP

Management Responsibilities

PQS elements

Process Performance & Continued Process Quality verification
DV & Corrective Action / Preventive Action (CAPA) System
Change Management System
Annual Product Quality Management Review

Accelerators

Knowledge Management

Quality Risk Management

Data Integrity

Record controlled management
DMS Electronic control, QA document coding and anti-counterfeiting

Record specification filling
Timely, authentic, clarity, integrated, traceable

Electronic data management
Electronic data audit, data backup and restoration

Computerized system management
User/password policy、authority management, andit trail

Focusing on CDMO Team

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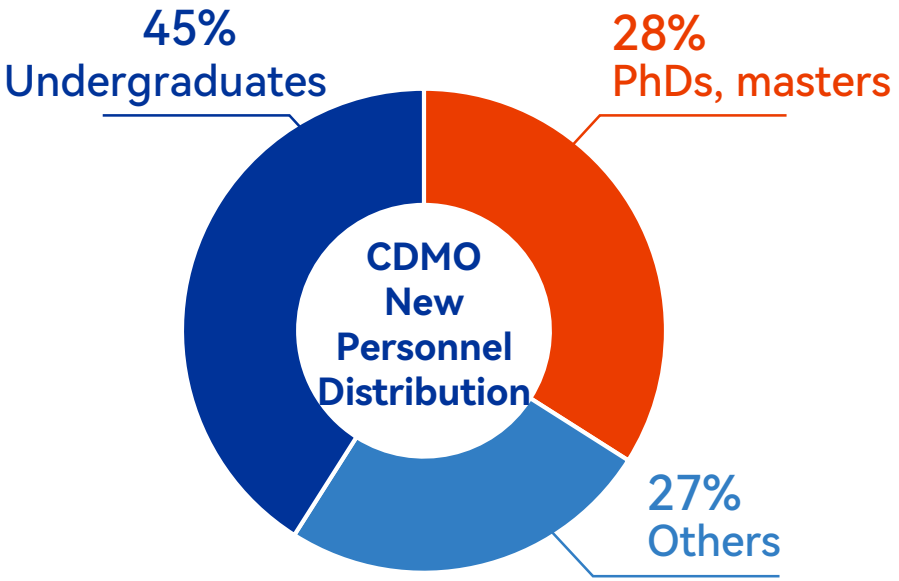
In 2021, we accelerated introduction of new CDMO key professionals, which accounted for over 90% of the total newly introduced talent of the Company, from which 73% are PhDs, Masters, and undergraduates

1. In line with business development, we introduced key professionals at home and abroad , improve the comprehensive strength of CDMO/CMO business.
2. Integrated functional departments and quality assurance system; strengthened division of work among different departments, and set up project management department, technical support department, and other department etc.
3. Strengthened R&D and production capacities of ADC, and set up departments specialized in ADC project development and production workshops, etc.
4. Motivated the team to innovate and achieve breakthroughs via an innovative incentive performance system focusing on value creation.



Why Choose US

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1. Large-scale biological pharmaceutical commercial production base complying with GMP standard; Sufficient production capacity adopting industry advanced facilities

2. ADC one-stop industrialization platform with core R&D technology advantages; enable to complete key production links of naked antibody, DS, and preparation of ADC drug in one production base, thus reduce transfer costs and reduce regulatory risks significantly

3. Clinical and commercial quality management system approved by industry regulators, throughout the whole process from research and development to commercialization

4. Owning a sophisticated and stable core technology team with rich experience in biopharmaceutical process development, commercial production, quality and compliance, regulatory application

5. Trusted and recognized by industry partners with a good reputation and track record

3 Expectation

Outlook for 2022

Outlook for 2022

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1. R&D and Marketing of Self-developed Products

- Accelerate the marketing process of ADC drug TAA013 and achieve commercial authorization cooperation
- Actively promote the market share of listed products, benefiting the vast number of patients

2. CDMO/CMO Business Strategy Development

- Further improve business scale and market position
- Build efficient and professional CDMO/CMO core assets

3. Production Capacity Layout

- Complete the construction of ADC pilot workshop and large-scale preparation workshop
- Promote the expansion of McAb stock solution workshop
- Complete the main body construction of the global R&D center

4. Organizational Structure Adjustment and Incentive Mechanism

- Adjust internal structure and functions according to company strategy
- Strengthen talent introduction and team building
- Continuously improve operational efficiency and optimize cost control

Epidemic Prevention and Supply Chain Management

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- Improve company resilience by strengthening supply chain and production management capabilities
- When the epidemic breaks out, prevention and control policies are to be launched to ensure the orderly operation of production and operation without adverse effects such as production suspension or output reduction

Employee Health and Safety Management

- Launch a special epidemic prevention and control team and rapidly deploy epidemic prevention policies
- Epidemic prevention materials shall be allocated and implemented in time
- Formulate the management system during the epidemic to ensure the health of personnel and effective coordination of work
- Strengthen employee care and troubleshoot issues for employees

Production Operation Control Measures

- Formulate a plan for the storage of epidemic prevention materials and the stable supply of raw and auxiliary materials
- Flexible capacity allocation plan to ensure the orderly implementation of the project plan
- Diversified supplier cooperation, replace imported materials with domestic fillers to reduce production risks

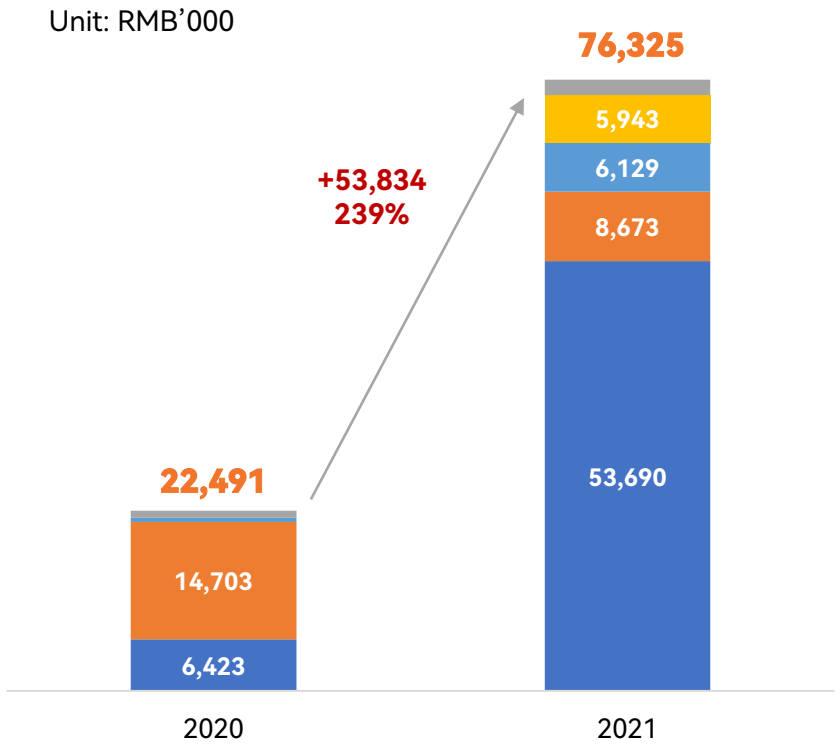
4 Financial Review

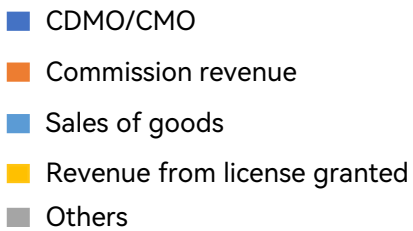
2021 Financial Analysis

Key Financial Data – Revenue

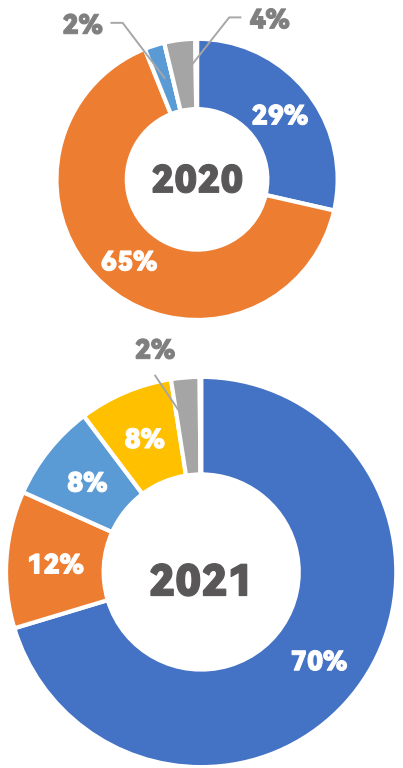
- In 2021, the annual revenue reached 76.325 million RMB, representing a year-on-year growth rate of **239%**
- In 2021, we actively expanded CDMO/CMO business, which generated a revenue of 53.69 million RMB, representing a significant year-on-year growth rate of **736%**
- The sales of agency product S-1 was affected by China's volume-based procurement policy, resulting in a decline in commission income
- The sales revenue of self-developed products reached 6.13 million RMB (excluding the commercial sales of Pusintin®)

Income Distribution

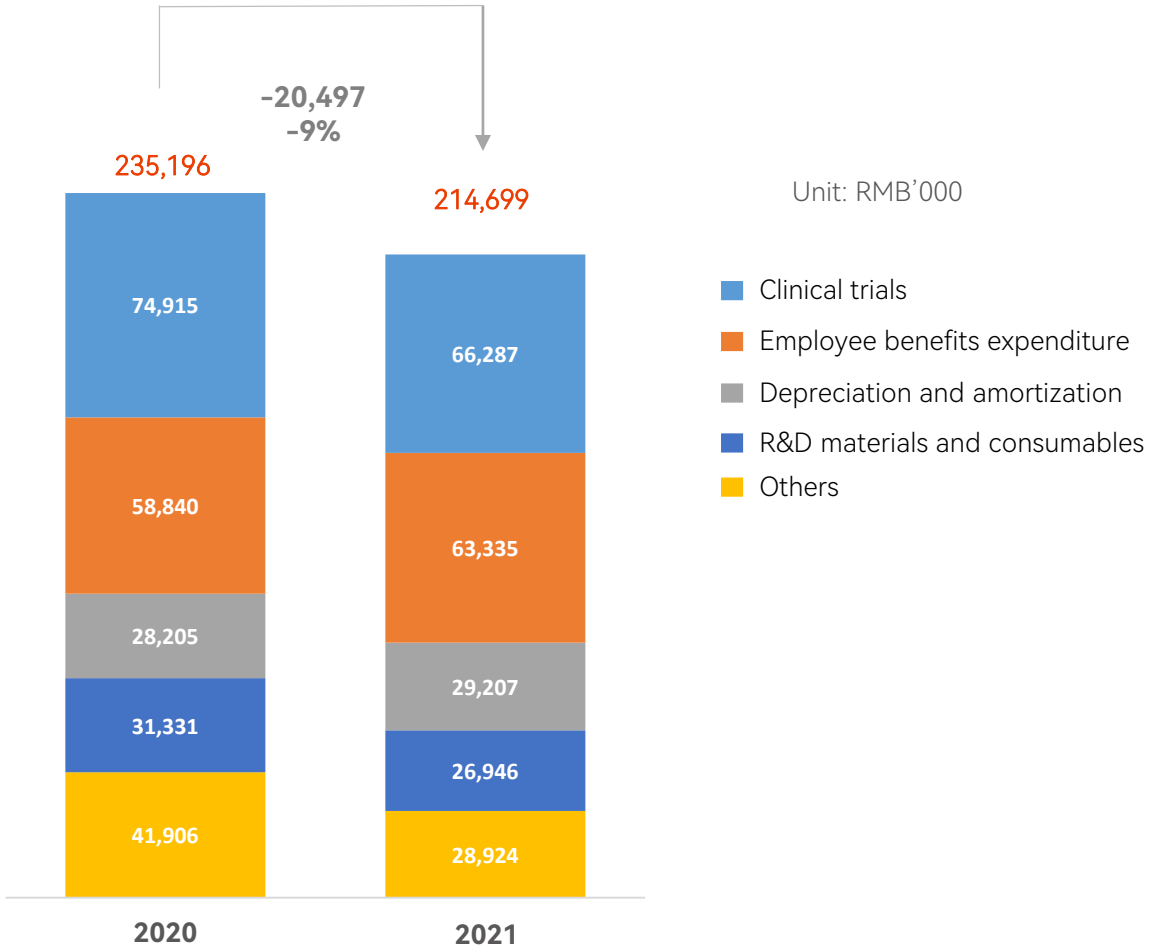




% Income by Each Category



Key Financial Data – R&D Expenses



R&D expenses in 2021 totaled 214.699 million RMB, a year-on-year decrease of 9%, which is mainly attributable to:

- **Clinical trials:** Due to the completion of Pusintin® TAB008 phase III clinical trials at the end of 2020, clinical trial costs decreased year-on-year
- **R&D materials:** Due to the completion of Tazian® TOZ309 project research and development, the quantity of related research and development consumables decreased significantly
- **Others:** Due to pipeline optimization, related research costs were reduced

Key Financial Data – P&L Statement

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Unit: RMB'000

Items	2020	2021	Diff%
Revenue	22,491	76,325	239%
Cost of revenue	(6,961)	(48,851)	602%
R&D expense	(235,196)	(214,699)	-9%
Cost of sales	(25,953)	(22,849)	-12%
Management fees	(46,855)	(56,336)	20%
Other income and expenditure (net)	3,802	6,710	76%
Operating profit (loss)	**(288,672)**	**(259,700)**	**-10%**
Non-operating income and expenditure (net)	174	(1,516)	NA
Net profit (loss)	**(288,498)**	**(261,216)**	**-9%**

- **Revenue:** In addition to the increase in recognized revenue, total revenue from outstanding orders increased by 488% year-on-year
- **Cost of revenue:** The 602% year-on-year increase was attributable to costs related to CDMO projects and CRO projects
- **R&D expense:** The year-on-year decrease of 9% was attributable to the decrease in R&D labor costs and clinical expenses
- **Selling expenses:** The year-on-year decrease of 12% was mainly due to the company's sales strategy adjustment which reduced related expenses
- **Administrative expenses:** The year-on-year increase of 20% was mainly due to restructuring, improvement in compliance management as well as increase in personnel and administrative expenses

In order to support the R&D and sustainable development of the Company and to raise funds for the construction of the global R&D center, the Group has relied on its continuously improving revenue generation capability in conjunction with the adoption of flexible financing measures.

5 Appendix

Company Introduction

Company Development History

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Company Founding First Plant Established

2010-2011

- Suzhou headquarters established, covering an area of 50,000m²
- A small molecule oral and injection workshop
- A 500L pilot workshop

- Pipeline Layout
- R&D and project approval in the early stage

The monoclonal antibody production and R&D milestone

2017-2018

- The monoclonal antibodies production base was built, and the capacity reached 20,000L
- Commence Phase III clinical trial for TAB008
- Clinical Trial Approval for TAB014 and TAA013

MAH 药品上市许可持有人制度试点

- Obtained clinical trial approval for three drugs
- The first pilot program for MAH collaborations in Jiangsu Province and ranked the third in China

2016

MAH Pilot Program Start CDMO business

Strategic layout in ADC

2020

- Completed ADC drug substance workshop
- Completed the production of multiple batches of clinical samples
- TAA013: phase III clinical trial

HKEX 香港交易所

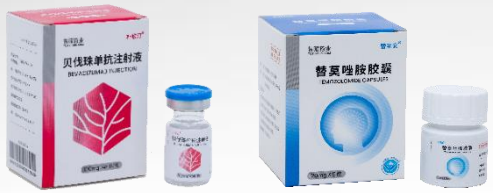
- Listed on the Main Board of the HKEX in November
- ADC drugs TAA013: completed phase I clinical trial
- TAB014: gained the National Science & Technology Major Project 'Creation of Major New Drugs'

2019

Listed on HKEX

2022 (Jan-Mar)

- Exclusive Commercialization License and Cooperation Agreement With Kexing Biopharm in Respect of TAB008 for Overseas Markets
- TAB014: China commercialization licensing with Zhaoke Ophthalmology
- Reached business promotion agreement with Frontier for Megestrol Acetate products



- TAB008、TOZ309 and TOM218 launched, three Commercial promotion Cooperation.
- Completed the GMP compliance inspection of antibody drug and chemistry drug facilities.
- Increased the commercial production scale of ADC drugs
- TAB014: phase III clinical trial application was authorized by the FDA

2021

Product launch Commercialized production

2021 Company Awards

东曜药业
TOT BIOPHARM

- Project for Commercialization of Technological Results in Jiangsu Province
- Potential Iconic Company in Biological Drug Industry of Suzhou Award
- Headquarter Company of Suzhou Industrial Park (Integrated Headquarters)
- Pioneering Manufacturing Company of Suzhou Industrial Park
- Award for Launch of Innovative Products of Biological Drugs
  Outstanding Award for Technology R&D
- Top 10 Leading ADC Drug Companies in China
- Top 30 Innovative Companies of Antibody Drug in China
- Best Listed Company in Greater China Area • Award of Greatest Growth Potential
- The Membership Unit of the “Innovative Alliance of Biological Drug Industry in Shanghai”
- The Standing Councilor Unit of the “Biological Technology Association of Jiangsu Province”

AWARDS

THANK YOU!