东曜药业
TOT BIOPHARM
Stock Code: 1875

東曜藥業股份有限公司
TOT BIOPHARM International Company Limited

# 2022 Corporate Results Presentation

March 24, 2023

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# 1 Performance Overview

## Business Highlights of 2022

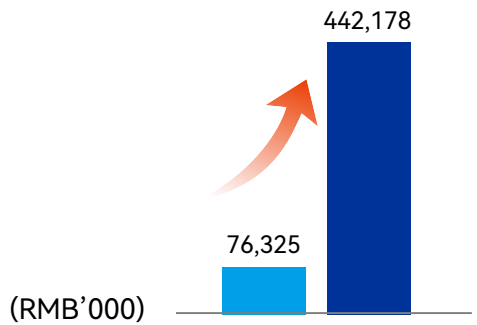
# Performance Review in 2022

- Revenue reached RMB442 million, representing an increase of 479% YoY
- Net loss significantly reduced to RMB50.05 million
- The cash flow from operating activities turned positive for the first time to RMB59.93 million

**Substantial increase in revenue**

Revenue **442**million

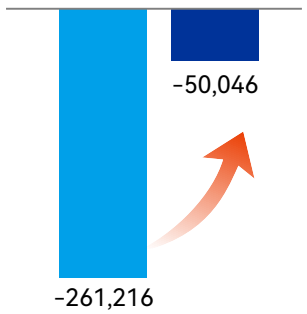
***+479%***




**Continuous improvement of profitability**

Net loss **50.05**million

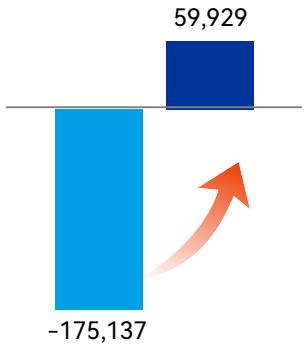
*narrowed by **81%***




**Initially realized hematopoiesis from operating**

Net cash generated from operating activities **59.93**million

***Turned Positive** the 1st time*




2021 2022

# Performance Review in 2022

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- **The remarkable results of the core product with effective commercialization strategy, contributing stable cash flow to the Company**
- **The continuous improvement in CDMO business driving by differentiated competitiveness**

- **Revenue from sales of products: RMB304,361 thousand**
  - **Pusintin®**: first-year sales performance in line with our expectations
  - **Tazian®**: successfully selected as the supplier in the renewal of centralized procurement by the Thirteen Allied Provinces(1), the other six provinces and Beijing
  - **Megaxia®**: cooperation with Frontier Biotechnologies for the marketing in the field of AIDS
- **Revenue from CDMO/CMO business: RMB72,538 thousand 35% increased by YoY**
  - A total of 45 projects in the year, the business scale of the project numbers increased by 114% YoY
  - Accelerated expansion of ADC CDMO projects, with 18 ADC projects increased by 500% YoY
- **Revenue from licenses granted: RMB54,151 thousand**
  - Cooperation with Kexing Biopharm for the licensing of Pusintin® in overseas markets
  - Signed an agreement with Zhaoke Ophthalmology in respect of the license for commercialization of TAB014 in China

*(1) Thirteen Allied Provinces: Thirteen provinces (autonomous regions, municipalities, and XPCC), including Henan, Shanxi, Inner Mongolia, Hubei, Hunan, Guangxi, Hainan, Chongqing, Guizhou, Qinghai, Ningxia, Xinjiang and Xinjiang Production and Construction Corps, form the inter-provincial Alliance*

# Performance Review in 2022

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## Quality system received international recognition

- One-time passed the EU QP audit with zero defects, and the workshops for ADC commercialization and mAb drugs were recognized by the EU
- Cooperated with CDMO customers in verification and third parties in quality system evaluation for 9 times, including the quality system evaluation by former FDA officials

## Steady progress of commercial production capacity and other construction in progress

- The construction of the company's second ADC commercial production workshop, which has the largest scale of production capacity in China, was successfully completed in 2022, and is expected to be put into use in Q2 2023
- The commercial production capacities of antibodies have multiple production lines with different scales, with a total scale exceeding 20,000L
- The main building of the Global R&D Center was completed as scheduled in November, the total building area is 25,000m$^2$, and it is expected to be put into use in mid-2023

## Comprehensively improve the CDMO business management system

- Improved the organizational structure of the CDMO business, in order to improve the operational efficiency for each business segment
- Established financial accounting system by business segment, in order to comprehensively and rationally reflect the Company's various business developments

# Pipeline Updates and Launch Products

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| Type | Drug Candidate | Indication(s) | Preclinical | Clinical Phase I | Clinical Phase II | Clinical Phase III | NDA | Launched |
|---|---|---|---|---|---|---|---|---|
| Antibody drug conjugate | TAE020 (new target) | Acute myeloid leukemia | | | | | | |
| Monoclonal Antibody | 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 | Co-development | | | | | |

| Drug Name | Indication(s) | Product Specification | Launched |
|---|---|---|---|
| Pusintin® (Bevacizumab Injection) | Advanced, metastatic or recurrent non-squamous non-small cell lung cancer (nsNSCLC); metastatic colorectal cancer (mCRC); recurrent glioblastoma multiforme (GBM); epithelial ovarian cancer (OC), fallopian tube cancer or primary peritoneal cancer; cervical cancer (CC); hepatocellular carcinoma (HCC) | 100mg(4ml)/bottle | Approved for launch by NMPA on 30 November 2021 |
| Tazian® (Temozolomide Capsule) | newly diagnosed glioblastoma multiforme, initially combined with radiotherapy, and then as maintenance therapy;<br>glioblastoma multiforme or anaplastic astrocytoma that recurs or progresses after conventional treatment. | 20mgx5 capsules/bottle;<br>100mgx5 capsules/bottle | Approved for launch by NMPA on 31 May 2021 |
| Megaxia® (Megestrol Acetate Oral Suspension) | anorexia associated with acquired immunodeficiency syndrome ("AIDS") as well as significant weight loss of AIDS and cancer patients caused by cachexia | 125mg/mL(150mL/bottle) | Approved for launch by NMPA on 13 May 2021<br>*(This product is imported from Taiwan; the Company owns the exclusive agency rights of this product in mainland China, Hong Kong and Macau)* |

# 2 Business Development

## Marketing Highlights of Our Products

# Market Prospect of Bevacizumab

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## China's market size is expected to RMB10 billion with a higher growth rate than the global market

- In 2022, the global bevacizumab market is expected to reach US$7.3 billion (approximately RMB49.6 billion), of which China's market is estimated to RMB11.5 billion accounting for 23% of the global market
- The biosimilar drug of bevacizumab is gradually replacing original drug market position. In 2022, the sales of Avastin decreased to US$2.81 billion accounting for 38.5% of the global market, while biosimilar accounted for 61.5%
- The China's market will reach RMB18.4 billion in 2030, has entered rapid growth period with a CAGR of 14.9% from 2021 to 2025, compared to a CAGR of 2.5% of the global

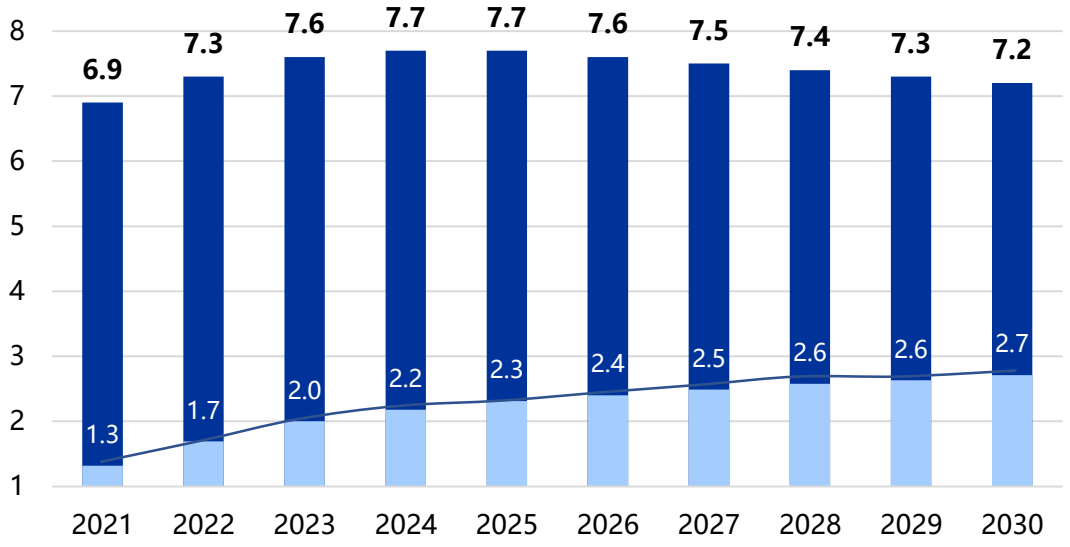
## A wide range of indications and clinical applications

- Covers China and global top 10 indications, including including lung cancer, colorectal cancer and liver cancer
- 7 indications have been approved internationally and 6 have been approved domestically
- can be combined with chemical drugs, double antibody, ADC and other kinds of drugs, which contains potential market space

***Six Indications in China:*** *nsNSCLC, mCRC, glioblastoma multiforme (GBM), ovarian cancer, cervical cancer, hepatocellular carcinoma (HCC)*

**Bevacizumab Market Trend**
(2021~2030E)

Unit: US$ billion
*(the exchange rate of RMB to US$ dollar 1:6.8)*




**Global Market (including China)**

| Period | CAGR |
|---|---|
| 2021-2025E | 2.5% |
| 2025-2030E | -1.1% |

**China's Market**

| Period | CAGR |
|---|---|
| 2021-2025E | 14.9% |
| 2025-2030E | 3.2% |

*Source: Frost Sullivan Report*

# Pusintin® (Bevacizumab Injection)

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- **The sales growth in 2H VS 1H was over 80% in 2022, maintaining a good sales momentum**

## 1. Impressive performance of differentiated marketing

- In the first year of market, the sales network has covered all **31** provinces, autonomous regions and municipalities (excluding Hong Kong, Macao and Taiwan)
- Continue to explore unmet market space, and gradually penetrate from 2nd/3rd-tier cities and "Dual-channel" provinces; strengthen penetration into 3rd/4th-tier cities and county level cities

## 2. Stable market supply

- Equipped with a 20,000L disposable bioreactor. In 2022, **tens of batches** of stock solutions and preparations were produced
- Perfect supply chain system, reduce the intermediate links of circulation, reach the terminal directly, effectively improve efficiency and reduce costs


## 3. Affordable biologic drug

- Usually the annual cost per patient of biosimilar drugs is at least **24% lower** than that of original drugs, compared with the RMB180,000 of the original drug (varies by treatment regimen)
- Drugs included in the NRDL Category B typically have reimbursement percentages ranging between **70%-90%** with variations among provinces

## 4. Powerful alliance to enhance brand influence

- Through the exclusive market promotion cooperation with Jiminxin in the mainland, carried out various patient support activities to improve the brand awareness

**Overseas Market:**

**Exclusive Commercial License**

- **Progress Update:** first batch of registration applications for marketing in **14 countries**, of which **8 countries** have been accepted by the local agencies up to now
- **Initial Regions: 20+ countries**, totaling **more than 100 regions**
- **Authorized Regions:** Grant exclusive commercial license to overseas markets (except Europe, America and Japan)

# Tazian® (Temozolomide Capsule)

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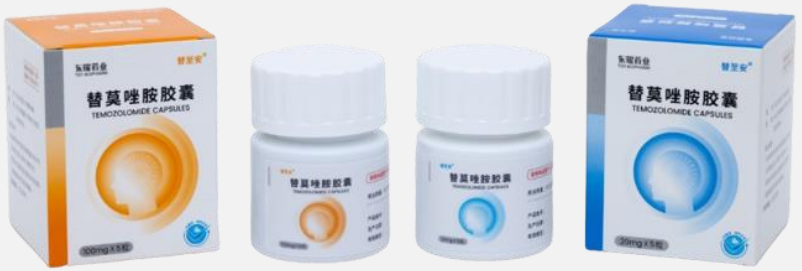
- **Actively expand provincial centralized procurement channels to lay a good foundation for sales in 2023**

## Selected areas in 2022


## Drug collection and renewal

- Tazian® was approved in May 2021 and applied to the fourth batch of national centralized drug procurement documents
- The company started the contract renewal work in 2022, including provincial alliance procurement




20mgx5 capsules/bottle; 100mgx5 capsules/bottle

### Incidence and indications

- 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%
- 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

# 2 Business Development

## CDMO Business Highlights

# CDMO Performance in 2022

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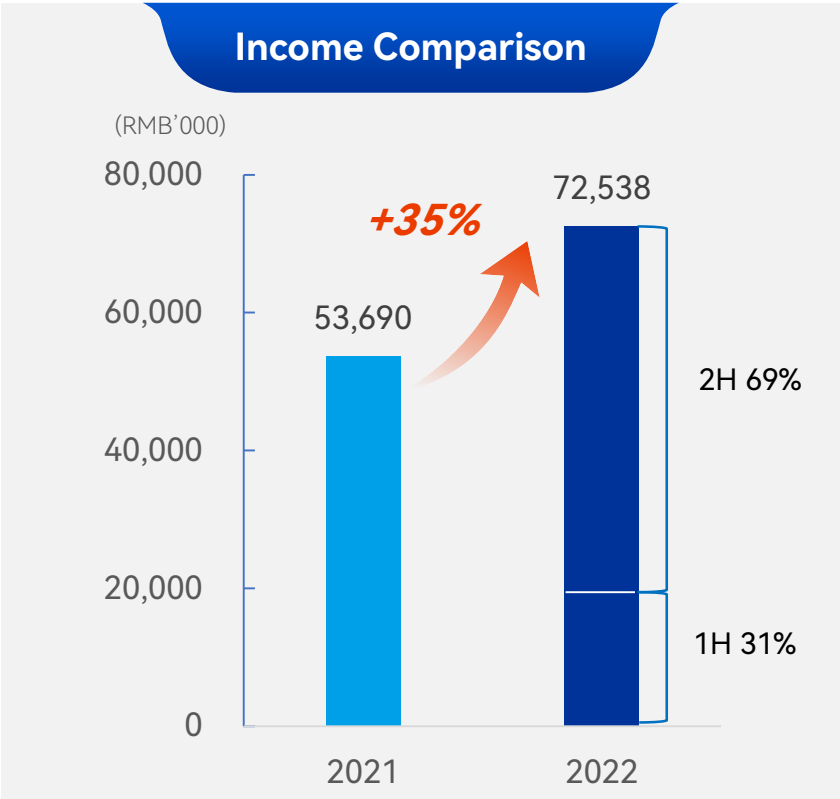
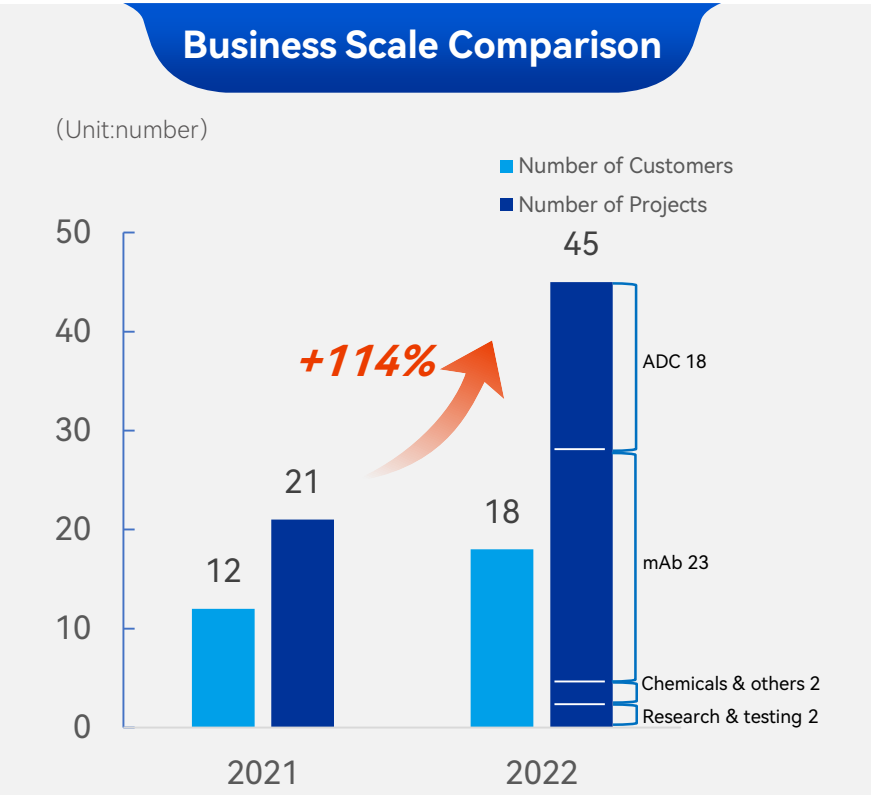
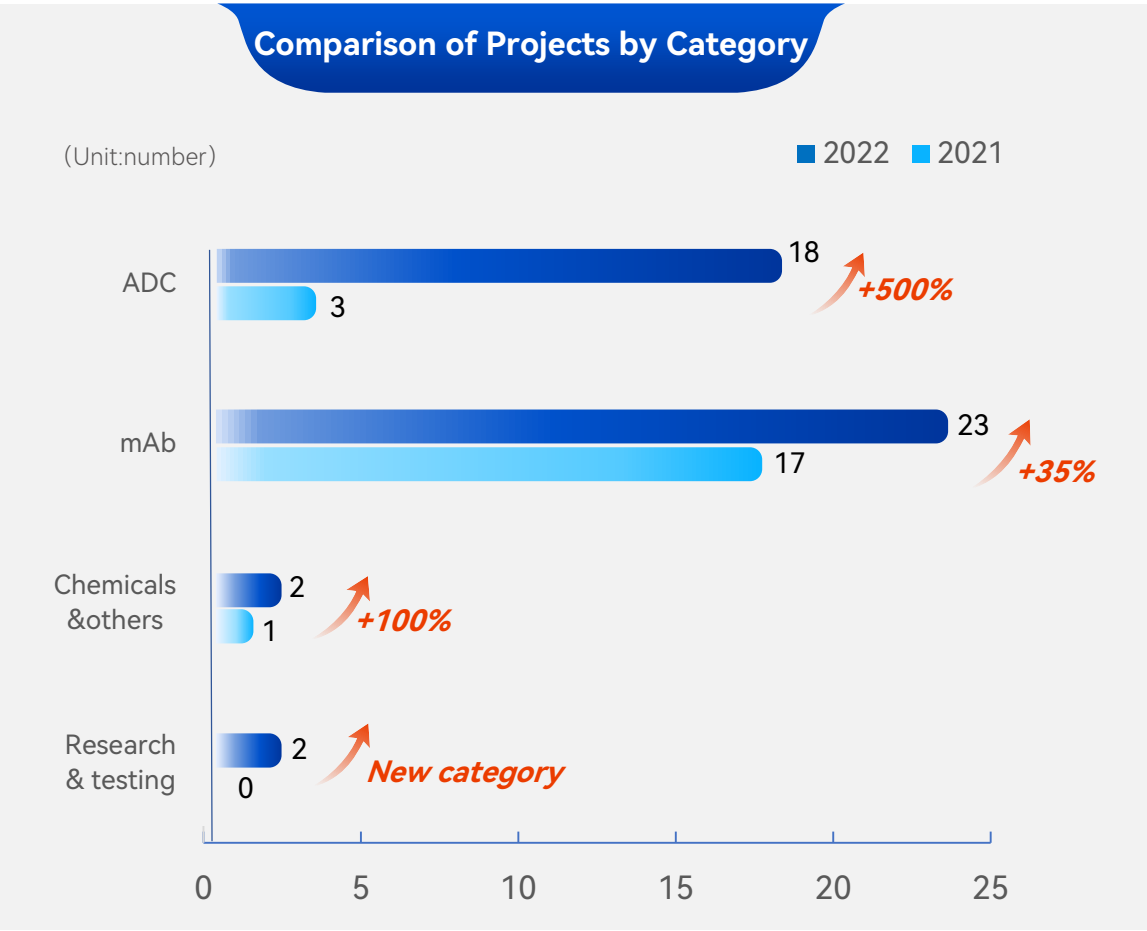
- As of December 2022, the revenue from CDMO/CMO business amounted to RMB 72.54 million， representing an increase of 35% YoY, of which the revenue reached RMB 49.88 million of 2H 2022, accounting for 69% of FY 2022;
- Market size of CDMO business continuous increased with a total of 45 projects, with 114% YoY growth, including 18 ADC projects, and 23 mAb projects
- Extended value chain service, 2 newly added projects in research and testing projects



# CDMO Business Performance in 2022

- ADC business expanded rapidly with prominent competitiveness
- Value chain services extension could be create potential cooperation opportunities from newly added research and testing projects




**ADC**

- Includes early R&D, comprehensive projects and preparation filling
- Total 18 projects, including 22 orders, and 6 projects completed

**mAb**

- Includes early antibody R&D, comprehensive projects and antibody preparation filling
- Total 23 projects, including 30 orders, and 18 projects completed

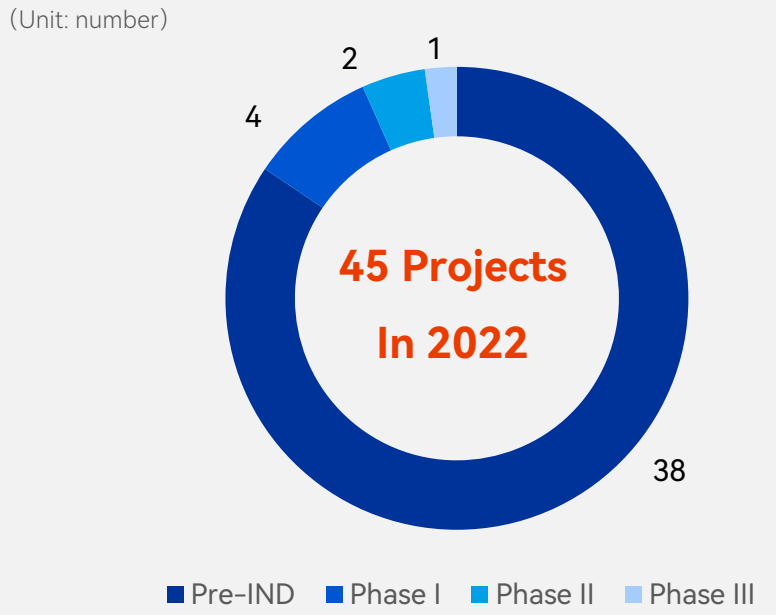
**Research & Testing**

- 2 newly added testing projects, of which 1 project has completed, and 1 was converted into a long-term cooperation project
- Consolidated and expanded the scope of cooperation with existing customers, and actively explored cooperation opportunities with new customers

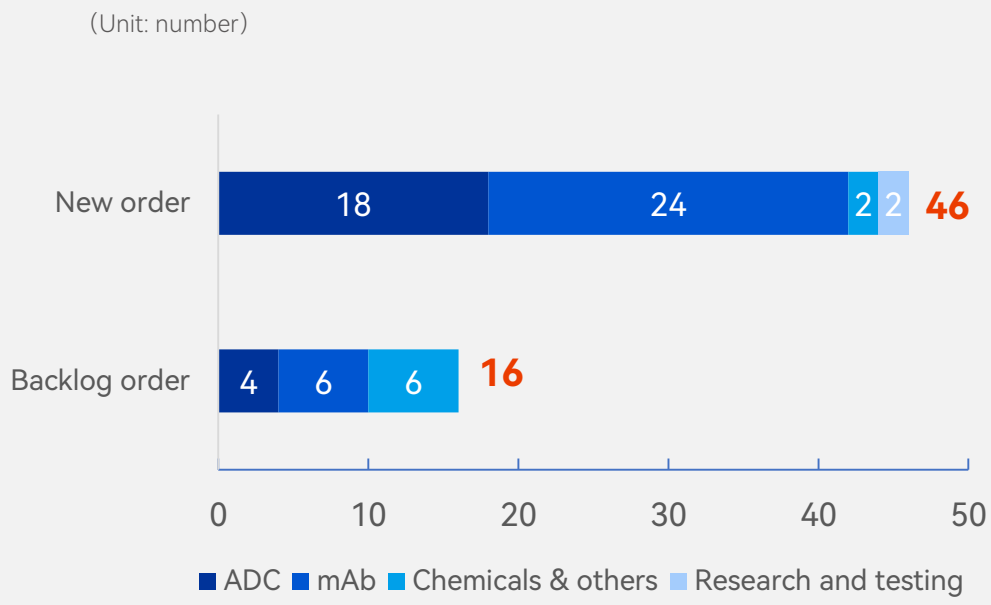
# CDMO Performance in 2022

- The phased projects were mainly pre-clinical projects, accounting for 84% of all projects, and the Phase I to Phase III clinical projects were 7 in total
- The total number of CDMO orders reached 62 ( including 46 new orders), of which 31 new orders from 2H of 2022

## By Project Phase




## Order Distribution



# CDMO Team Expansion

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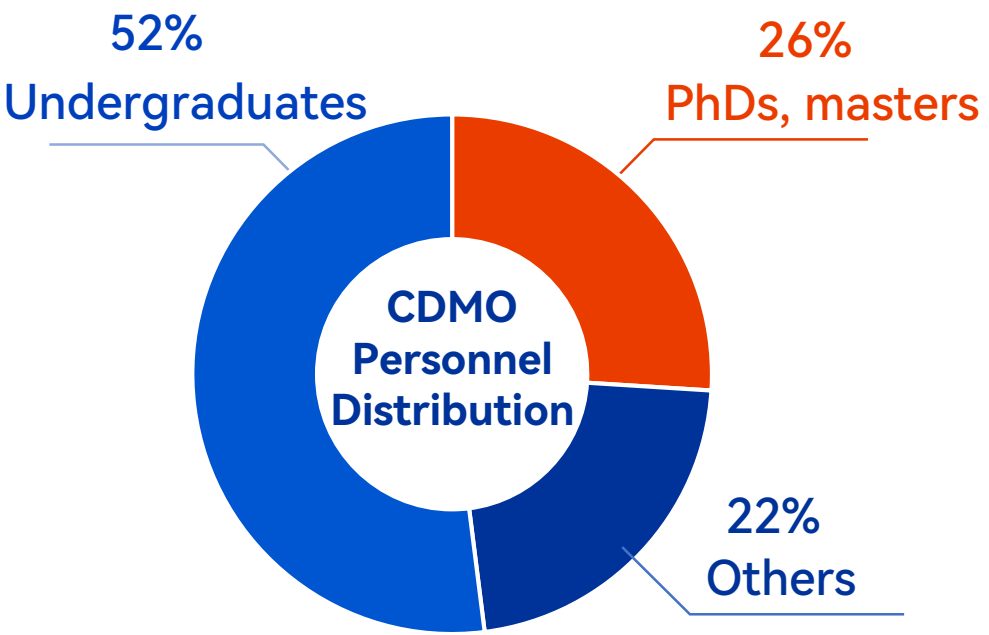
**In 2022, we continued to introduce CDMO key professionals, accounting for 77% of the Group's total employees, including 11 PhDs and 75 masters**

1. Introduced key professionals in the fields of technology, business expansion and production at home and abroad to improve the comprehensive strength of CDMO business in line with business development
2. Optimized the organizational structure, strengthened internal and external collaboration and brand image promotion, and enhanced the quality management system and the capabilities of functional departments
3. Strengthened R&D and production capacities of ADC to effectively promote the development and production of ADC projects
4. Motivated the team's continuous innovation and breakthroughs and employee engagement via an innovative incentive performance system and a comprehensive training and development mechanism focusing on performance and results




*Note: As of December 31, 2022, the total number of employees of the Group was 431*

# CDMO Business with Industry Barriers and Competitive Advantages

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## 01 Stable and in-depth cooperative relationship

- Give full play to the first-mover advantage in the field of biological drug CDMO business, to expand early-stage R&D projects, and establish stable cooperative relationship with customers through long-term project cultivation to enhance customer stickiness

## 02 Quality system and capacity allocation that complied with industry regulations

- One of the few one-stop commercialization industrial platforms for antibody and ADC drug development in China, with flexible allocation of production lines to meet diversified needs
- Quality management system complies the EU GMP standards, to meet the filing of approval application in both China, the U.S. and the EU, as well as the regulatory consultation and application support

## 03 High-tech barriers

- Advantages in advanced coupling core technology and ADC analysis platform, with rich project experience covering all stages from drug development to launch
- A complete commercialization production workshop that can produce ADC naked antibodies, ADC drug substances and drug products

## 04 Corporate reputation

- Win high customer recognition with high standards of service, good customer communication and a comprehensive project management system

## 05 Funding security

- Continuous financing capacity and stable cash flow to support the on-going development and sustainable operation of CDMO business

# 2 Business Development

## Commercial Production Advantages

# Production Capacity of GMP-compliant Drug Substances

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- Have a commercial production base of biological drugs meet GMP requirements with a total production capacity of 20,000L
- Have 5 independent production workshops for drug substances, which can meet the production needs for both ADC and antibody drugs

**20,000 L**
Production capacity

**150 bathes**
Designed annual production capacity

**300 L'000**
Designed annual production capacity

**10+**
Production projects of over 500L

**7 Year**
Core team, everage term of service

- Different scale of drug substances production facilities, including **200L, 500L, 2,000L**
- **International leading brand** of disposable bioreactors with continuous production capability

Preparation of antibody stoste

Production of ADC drug substances

# Production Capacity of GMP-compliant Drug Products

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- **4 filling lines** (3 isolator freeze-drying lines, 1 O-RABS aqueous injection line), providing injection and freeze-drying filling and packaging services at different stages from development to commercialization, and enabling automatic switching

**Injection production line**

- Have successfully operated for 4 years, providing tox batch/IND batch/clinical batch sample/launched product filling services for various projects
- International leading brand of fully automatic preparation filling production line, suitable for GMP-compliant aseptic filling of 2R-20R standard vials, with an operating speed of up to 300 Vials/Min

**18,000 vials/h**
Production capacity of preparation production line

**250 batches**
Annual production capacity

**Freeze-drying production line**

- Have production workshops for pilot drug products and commercialization drug products, equipped with OEB5 grade isolators
- Adopt isolator filling linkage line, automatic feeding and discharging freeze-drying system and disposable filling system

**150 batches**
Designed annual production capacity of freeze-dried drugs

**50,000 vials**
Designed production capacity of freeze-dried drugs in Vials/Batch

# “One-Base, End-to-End”ADC Industrialization Platform

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- Become one of the few ADC commercial production workshops in China that integrate antibodies, ADC drug substances and ADC drug products in the same factory to avoid the compliance uncertainty caused by staged production
- Advanced coupling core technology and ADC analysis technology advantages, successfully completed the development of more than 20 different coupling processes and ADC projects

**Production of naked antibodies**

- Have flexible and independent antibody stoste production lines with a total production capacity of 20,000L
- Equipped with drug substances production facilities of 200L, 500L, 2,000L scales

**Production of ADC drug substances**

- The workshop for ADC drug substances is equipped with OEB5 grade isolators for weighing active small molecules, and is also equipped with 100L, 200L, and 500L disposable coupling reactors, with a coupling scale of 5kg/batch

**60,000 g**
Designed annual production capacity

**500 L**
Maximum response scale per batch

**Production of freeze-dried formulation**

- Can produce freeze-dried products of 2R-20R specifications, with a maximum operating speed of 200 Vials/Min
- Have 5m² and 20m² freeze-drying machines, all equipped with automatic feeding and discharging systems
- Completed more than 20 batches of production tasks

# 3 Expectation

## Outlook for 2023

# Outlook for 2023

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## 1. Product Marketing

- Further improve the market share of Pusintin® and make full preparations for the centralized procurement of biological drugs
- Accelerate the sales growth rate of Tazian® via centralized procurement channel

## 2. CDMO Business Strategy

- Build a differentiated CDMO brand image to enhance market competitiveness
- Extend the CDMO industry value chain to create profit growth points

## 3. Production Capacity Layout and projects under construction

- Fully launch the production workshops for ADC pilot drug substances and the second production line for large-scale commercial production of ADC drug products to improve the utilization rate of production capacity
- Start to operate the Global R&D Center

## 4. Continuous Optimization and Improvement of Capital Structure

- Expand business scale, reduce cost and increase efficiency to improve profitability continuously
- In line with the company's strategic development, strengthening communication in the capital market and promote strategic cooperation

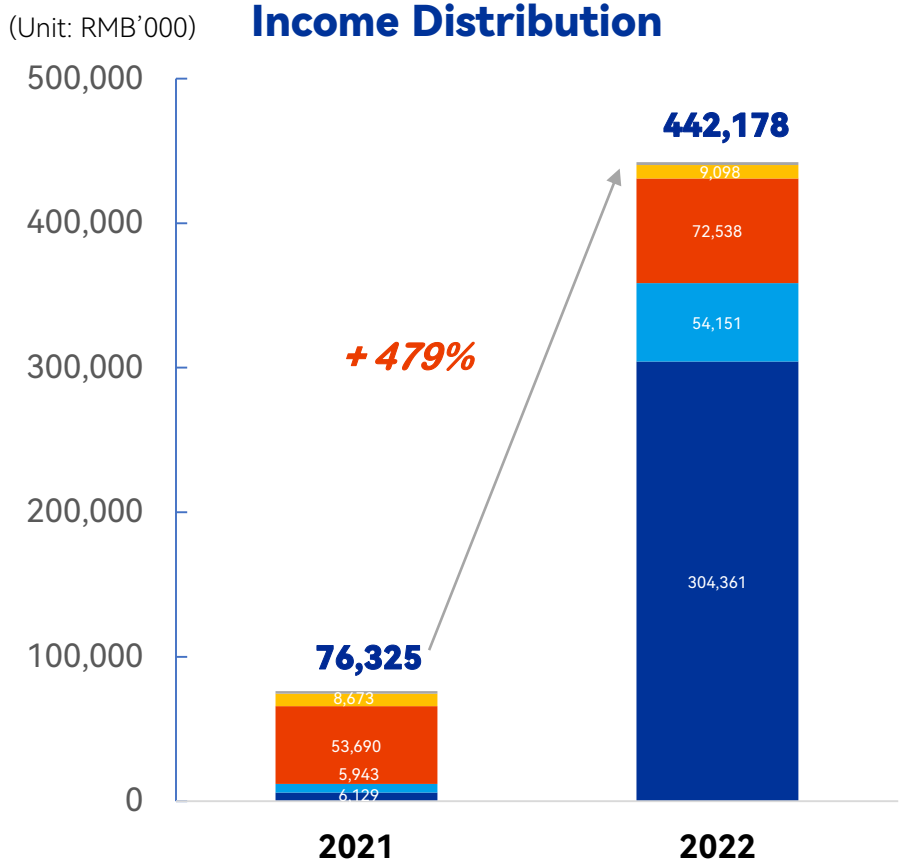
# 4 Financial Review

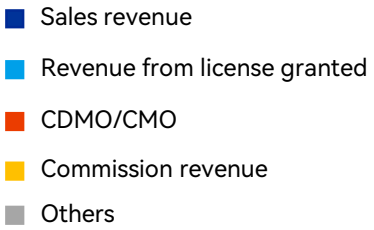
## Financial Analysis of 2022

# Key Financial Data – Revenue

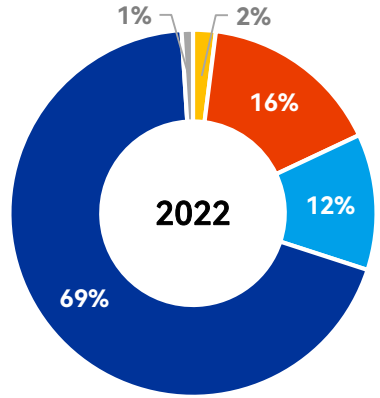
- As of December 31, 2022, the revenue reached RMB442 million, representing an increase of 479% YoY
- Revenue from sales of products achieved RMB304 million
- The revenue from CDMO/CMO business reached RMB72.54 million, representing an increase of 35% YoY
- The revenue from license granted reached RMB54.15 million

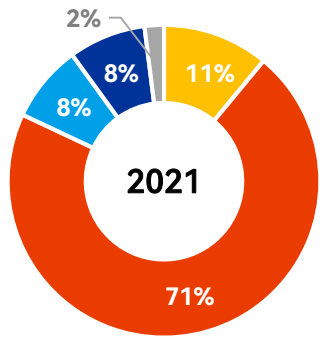
## Income Distribution




## % Income by Each Category



# Key Financial Data – P&L Statement

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## Substantial improvement in financial indicators:

- The net loss narrowed by 81% to RMB50,05 million
- The cash flow from operating activities was RMB59.93 million
- Cash and cash equivalents at end of the year was RMB418 million
- The total equity was RMB 715 million

(Unit: RMB'000)

| Items | 2021 | 2022 | +/- |
|---|---|---|---|
| Revenue | 76,325 | 442,178 | 479% |
| Cost of revenue | (48,851) | (71,563) | 46% |
| R&D expense | (214,699) | (151,168) | -30% |
| Cost of sales | (22,849) | (203,954) | 793% |
| Management fees | (56,336) | (62,587) | 11% |
| **Operating profit (loss)** | **(259,700)** | **(39,076)** | **-85%** |
| **Net profit (loss)** | **(261,216)** | **(50,046)** | **-81%** |

- **Revenue:** an increase of 479 % yoy, mainly due to a significant increase from self- developed products, as well as increased revenue from CDMO/CMO and license granted
- **Cost of revenue:** an increase of 46 % yoy, mainly due to the increase in sales of self- developed products and the consequent increase in costs
- **R&D expense:** a decrease of 30 % yoy, mainly attributable to the reduction of clinical expenses and raw material procurement as a result of the completion of patient enrollment for the TAA013 project, and the optimization of product pipelines that resulted in a convergence of R&D resources
- **Selling expenses:** an increase of 793 % yoy, mainly due to the increase in sales of self-developed products and the increase in marketing and promotion expenses resulting therefrom

# THANK YOU!

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