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TOT BIOPHARM

2022 Interim Results Corporate Presentation

15 August 2022

TOT BIOPHARM International Company Limited
Stock Code: 1875

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1 Performance Overview

1H Business Highlights

Business Highlights & Major Milestones-As at 1H 2022

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- Operating revenue achieved RMB182 million, increasing 687% year-on-year, mainly attributable to satisfactory sales performance of Pusintin®, fast-growing CDMO business, and revenue from grant of product license, net loss shrank by 86% to RMB15.72 million YoY

Major Revenue Contribution

Revenue from sales of products achieved RMB104 million

- Pusintin ®, the performance was in line with our expectations, achieved comprehensive coverage in all provinces and autonomous regions, except Tibet
- Tazian® has been selected as the product to participate in centralized procurement by Thirteen Provinces Alliance(1), Jiangsu Province, and Hebei Province
- Established partnership with Frontier Biotechnologies to carry out the marketing of Megaxia® in the AIDS field

Revenue from sales of CDMO achieved RMB22.66 million, increasing 94% yoy

- 23 projects in total, among which 10 projects have been delivered on schedule
- And including 14 backlogs projects and 9 newly added projects
- Signed CDMO strategic cooperate agreement with Jemincare

Revenue from royalties payment achieved RMB49.43 million

- Signed a commercialization license and cooperation agreement with Kexing Biophar of Pusintin® for overseas markets
- Authorized marketing rights of TAB014 in mainland China, Hong Kong and Macau to Zhaoke Ophthalmology

Milestones in Clinical Projects

➢ Two key clinical projects

- TAA013: Completed patient enrollment for Phase III clinical trial
- TAB014: Completed enrollment of the first patient for Phase III clinical trial, TOT BIOPHARM will continue to be responsible for the supply of clinical products and commercial production

Commercial Production Capacity

➢ Reinforce the capacity of ADC

- Promote the expansion of ADC pilot stock solution workshop, scheduled for completion in 2H 2022
- Promote the expansion of ADC commercialized preparation workshop, scheduled for completion in 1H 2023

(1) Thirteen Provinces Alliance: 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

Continuous Financing Capability and Shareholder Strategic Support

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- Have completed the first round of equity financing since IPO, fully backed by the major shareholders of Vivo Capital and Center Ventures, subscription completed on July 29 with net proceeds of approximately HK $470million (subscribed at HK $3.15 per share)
- Continued to optimize the capital structure, facilitated the company's strategic transformation and accelerated development of CDMO business through diversified financing access and strategic cooperation

VIVO CAPITAL

- World-leading investment institution focusing on health care
- Invested in more than 290 listed and unlisted companies worldwide
- With total assets of $6.4 billion by the end of 2021

晟德 CENTER VENTURES

- Taiwan's largest oral liquid manufacturer, with a 70 percent market share
- Incubated or funded several well-known biotechnology companies
- With total assets of about $1.1 billion by the end of 2021

Key Strategic Layout

- Construction of the Global R&D Centre and upgrade of ADC formulation production workshops to expand production capacity and to enhance production efficiency
- Accelerate CDMO/CMO business development and strengthen project-based collaboration with domestic and foreign pharmaceutical companies
- Promote the completion of Phase III clinical trial study and marketing process of TAA013
- Promote commercial production, marketing and sales activities for products launched

Note: the 150,000,000 shares they subscribed for account for (I) approximately 24.38% of the issued share capital of the company on the date of this announcement; and (II) approximately 19.60% of the issued share capital of the company expanded by the allotment and issuance of all shares subscribed for, and the price is 4.79% higher than the average closing stock price of the five days of trading before the date of the agreement

Main Product Pipeline Update

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- TAA013: completed patient enrollment for Phase III clinical trial, the patients follow-up works in process.
- TAB014: completed the enrollment of the first patient in the Phase III clinical trial, and TOT BIOPHARM will continue to be responsible for the supply of clinical products and commercial production

Type	Drug Candidate	Indication(s)	Preclinical	Clinical Phase I	Clinical Phase II	Clinical Phase III	NDA	Launched
Launched	TAB008 (anti-VEGF)	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)						
	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)						
	TAC020 (new target)	Various solid tumors						

ZHAOKE 兆科

IND authorized by FDA to directly enter Clinical Phase III

Co-development

TAA013: Completed Phase III Clinical Trial Enrollment

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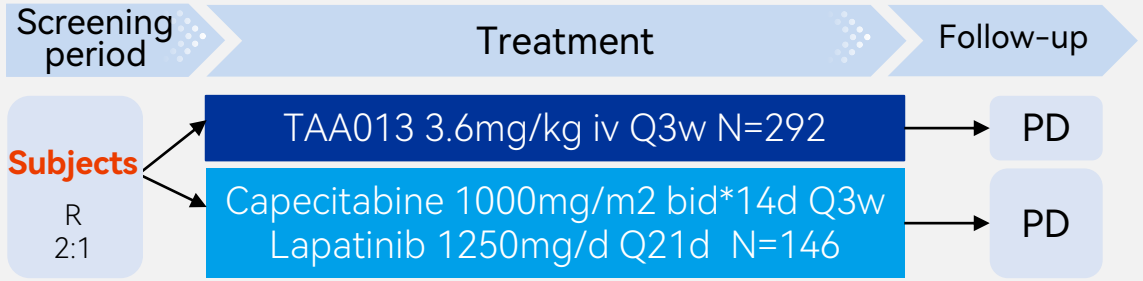
➢ **Phase III clinical research:** randomized, open-label, multicenter

- Subjects: HER2-positive advanced breast cancer patients with documented progression, previously treated with trastuzumab-based therapy
- Stratification factors: brain metastasis
  visceral metastasis



➢ Primary Endpoint

- Progression-free survival (PFS) evaluated by the independent review committee (a third party)

➢ Second Endpoint

- PFS evaluated by researchers
- ORR、DoR、DCR、OS

Evaluated by a third-party independent review committee and researchers

Study Plan

Interim Analysis

Start interim analysis when the evaluated PFS case reached 215 by the independent review committee

Quality Control

Quality Control of the clinical trial centers that have enrolled patients

Follow-up Supervision

Follow up and monitor of enrolled patients

Data Cleaning

Clean up the data of enrolled patients at the end-of-treatment (EOT)

2 Business Development

Marketing Highlights of Our Products

Pusintin® (Bevacizumab Injection)

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- The sales performance of Pusintin® mainly attributed from Q2 of 2022, higher growth expectation to be achieved in 2H than 1H

Market coverage

- have covered all provinces and autonomous regions except Tibet

Sufficient capacity

- 20,000L disposable bioreactor meets the stable market supply of the

Product quality

- 100% qualification rate of the product

Huge potential market in China

- Will become a next 10 billion product in the Chinese market, and it is expected to exceed RMB 6 billion in 2022

Six Indications

- nsNSCLC, mCRC, glioblastoma multiforme (GBM), ovarian cancer, cervical cancer *(hepatocellular carcinoma (HCC) launched)*

Exclusive Marketing Cooperation in mainland China

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

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

Jemincare 济民可信

Exclusive Commercial License in Overseas Countries

Progress of overseas approval: Reached preliminary cooperation intention with more than ten countries, and completed the materials collection of registration and application in several countries

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

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

科兴制药 Kexing Biopharm

Tazian® (Temozolomide Capsule)

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- Take effort on both centralized purchase and non-centralized purchase channels

Provincial gathering market expansion

13 Provinces Alliance

Jiangsu

Hebei

- successfully selected as the supplier for the renewal of centralized procurement in Thirteen Allied Provinces, Jiangsu Province and Hebei Province
- Actively prepare for the renewal of contracts in other provinces, and continue to improve the market share of collective-sourcing channels

Non-collection market development

- Cooperate with Jemincare, focusing on 2A/3A grade hospitals
- Promote brand awareness through flexible and diversified marketing activities

Jemincare 济民可信

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

美适亚®（Megestrol Acetate Oral Suspension）

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- Give play to the advantages of both parties in products and channels, and improve the quality of life of AIDS patients and product accessibility with innovative technology

Precise positioning of patient groups, segmentation of market promotion channels

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(Specialized in fighting AIDS)

Indication

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

Product Advantages:

- The **first** high concentration Megestrol Acetate Oral Suspension approved for marketing in mainland China
- The **only** drug with a clear oral dose for the treatment of cachexia fills the gap in clinical demand in this indication field in China
- The **nanocrystal technology** adopted has the advantages of high bioavailability, absorption is not affected by fasting, and high patient compliance, effectively improve patients's appetite, food intake, weight, as well as nausea and vomiting that sometimes occur

2 Business Development

CDMO Business Highlights

1H CDMO Business Highlights

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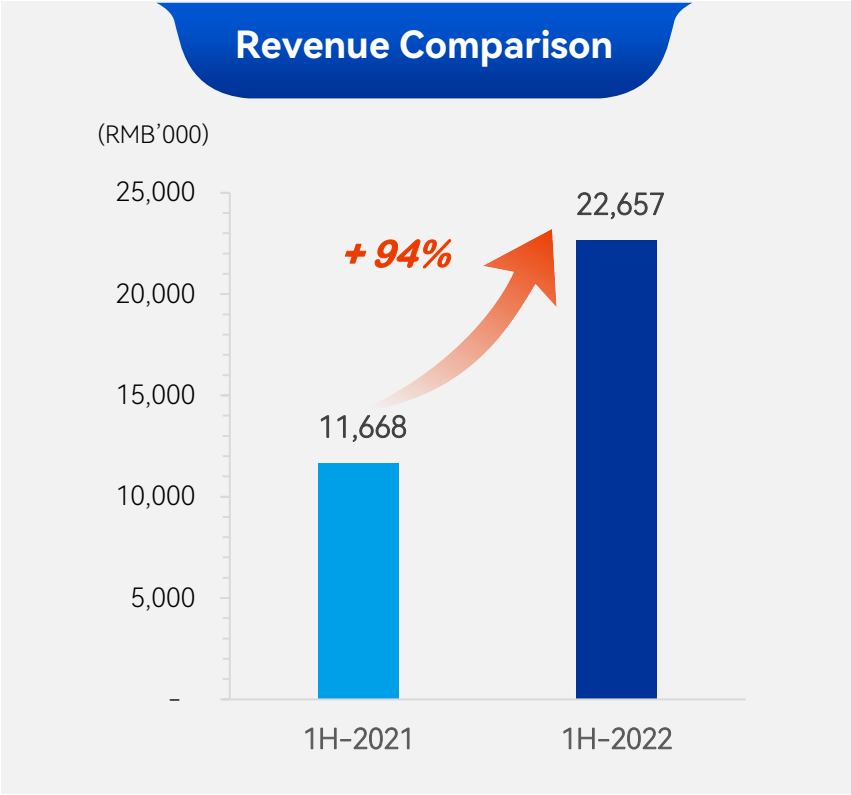
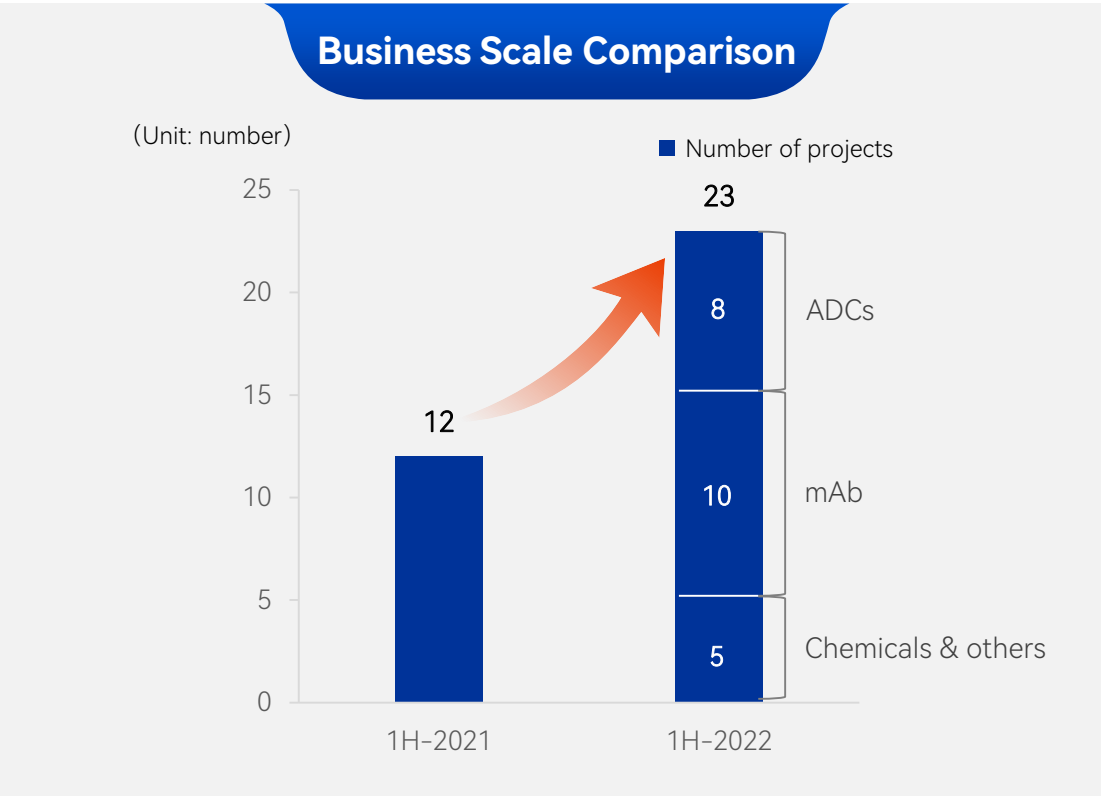
- In 1H, CDMO business revenue reached RMB 22.66 million, representing an growth rate of 94% yoy, available orders exceeded RMB 85 million
- 23 projects as at 1H, 10 of which have been completed as scheduled, 100% deliver rate
- Affected by the COVID-19 in 1H, some of newly added projects/ orders have been postponed to 2H





Best-in-class ADC Project Timeline Shorter than the Project Plan

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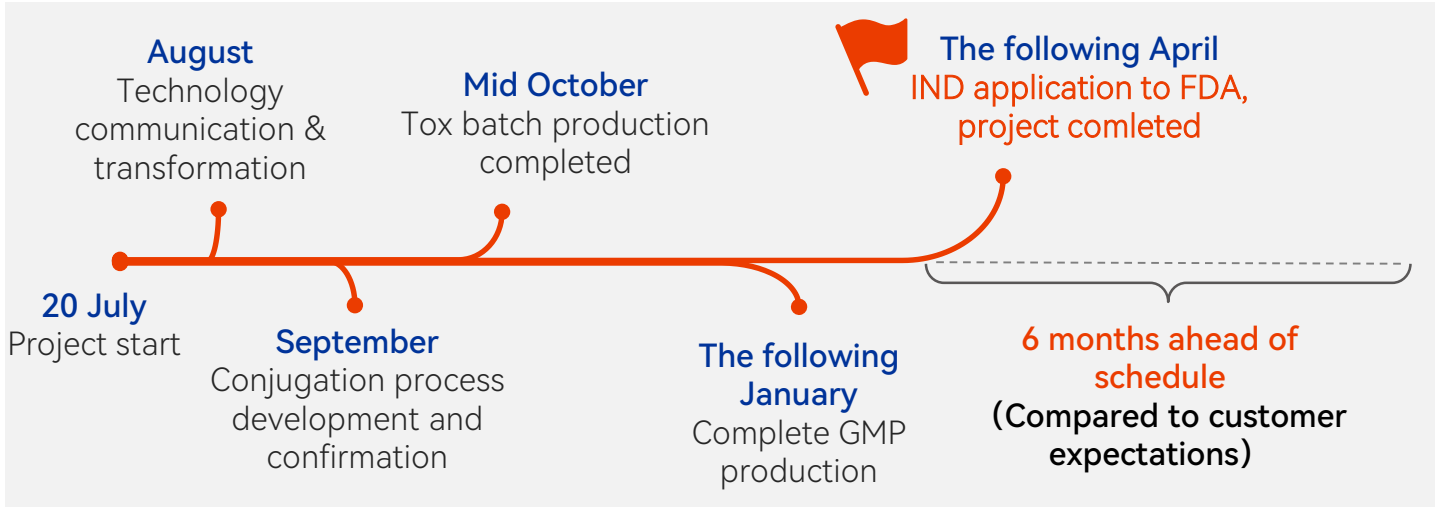
- From project start to complete pilot-level GMP production and submitted IND application, the product was delivered 6 months ahead of the customer's expectation, and highly recognized by customers



The Project Highlights

- Good communication with client, greatly shortened project timeline, better than the project plan
- Innovative ADC project from Lead Candidate development to IND application, Broke through the difficulties from Lead candidate develop to IND, displayed the advantages of CMC

Accurate Solution

Efficient Execution
From the pilot process development, quickly completed the target quality profile research and process development risk assessment

Lower Cost & Higher Efficiency
Developed an innovative process development plan, effectively shorten the timeline and save the costs

Mature CMC Capacity
Through co-work of conjugation process development and quality analysis, solved the difficulties in process and quality control

Stable Amplification Process
One-time success completing from process locked to 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

- *Capacity of DS: 1,000g / Batch*
- *Capacity of Preparation: 6,000 Vials / Batch*

Commercial GMP manufacturing facility for ADC

- *Capacity of DS: about 3,000g / Batch*
- *Capacity of Preparation: 50,000 Vials/ Batch*

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
- GMP 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 Business Development

Commercial Production Advantages

Commercial Production Capacity Advantage

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1. Have a one-stop large-scale commercial production base of biological drugs in line with GMP specifications, and have rich experience in commercial production. The total production capacity of stock solution reached 20,000L

2. Built a "One-Base, End to End" ADC commercial production platform, which integrated ADC DS, preparation and ADC naked antibody, successful experience of different types projects, covering phase I to phase III clinical projects

3. With a quality team of more than 120 people, establishing quality management system from R&D to commercialization, offering quality assurance for R&D and commercial production

4. One commercial production program (Bevacizumab injection) and one ADC program in phase III with 100% success rate of production batch under the compliance of regulators

mAb Drug Stock Solution and Preparation Workshop

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- The pilot and commercial production lines gained GMP certification by NMPA, including stock solution, injection and frozen trunk lines, to meet the production needs of different stages and projects

McAb DS

Workshop for mAb drug substances

- Gained GMP certification by NMPA
- Production capacity reached 20,000L for the different scale production, such as commercialization projects, pilot tests and small trials
- Continuous and flexible production capability of the international leading brand disposable bioreactors

McAb DP

Workshop for mAb commercialization drug products

- Gained GMP certification by NMPA
- The international leading brand of automatic filling injection production line

Workshop for mAb pilot drug products *(planned for production in 1H 2023)*

- The international leading brand of isolator filling linkage production line, which can realize freeze-drying, injection switching and continuous with the functionalities of automatic filling line, automatic feeding and discharging as well as capping

ADC Drug Stock Solution and Preparation Workshop

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- ADC drug production lines compliance the GMP standards, including internationally advanced pilot and commercial production facilities for the needs of different types production

ADC DS

Workshop for ADC commercialization drug substances

- Up to 500L ADC stock solution production scale
- Completed clinical production and process validation of multiple batches of ADC drugs
- GMP standard compliant, meeting flexible and diverse commercial production needs

workshop for ADC pilot drug substances *(planned for production in 2H 2022)*

- Design with 100L, 200L, 500L ADC stock solution production scale

ADC DP

workshop for ADC commercialization drug products

(planned for production in 1H 2023)

- The international leading brand of high-activity isolator filling linkage production line
- Specially designed for the production of scarce high-activity products to ensure aseptic production while meeting the needs of personnel safety protection

workshop for ADC pilot drug products

- High-activity isolator filling linkage production line, which has successfully completed clinical production and process validation of multiple batches of ADC projects

3 Expectation

Outlook for 2022

Outlook for 2022

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1. Marketing and Clinical Process

- Continuously increase the market share of the products for better performance
- Accelerate the phase III clinical analysis and commercialization license of ADC drug TAA013

2. CDMO Business Strategy Development

- Expand the overseas and domestic market scale with high growth rate
- Leverage the competitive edges of ADC CDMO business to reinforce the market position
- Build efficient and professional CDMO business as the core assets of the company

3. Production Capacity Layout

- Complete the expansion of the ADC pilot solution workshop
- Continue to expand the second commercialized ADC preparation production line
- Complete the construction of the global R&D center, as well as strengthen the CDMO research and development platform

4. Organizational Structure Adjustment

- According to business category, improve the organizational structure and financial system around CDMO business, focus on resources
- Strengthen talent introduction and team building
- Continuously improve operational efficiency and optimize cost control

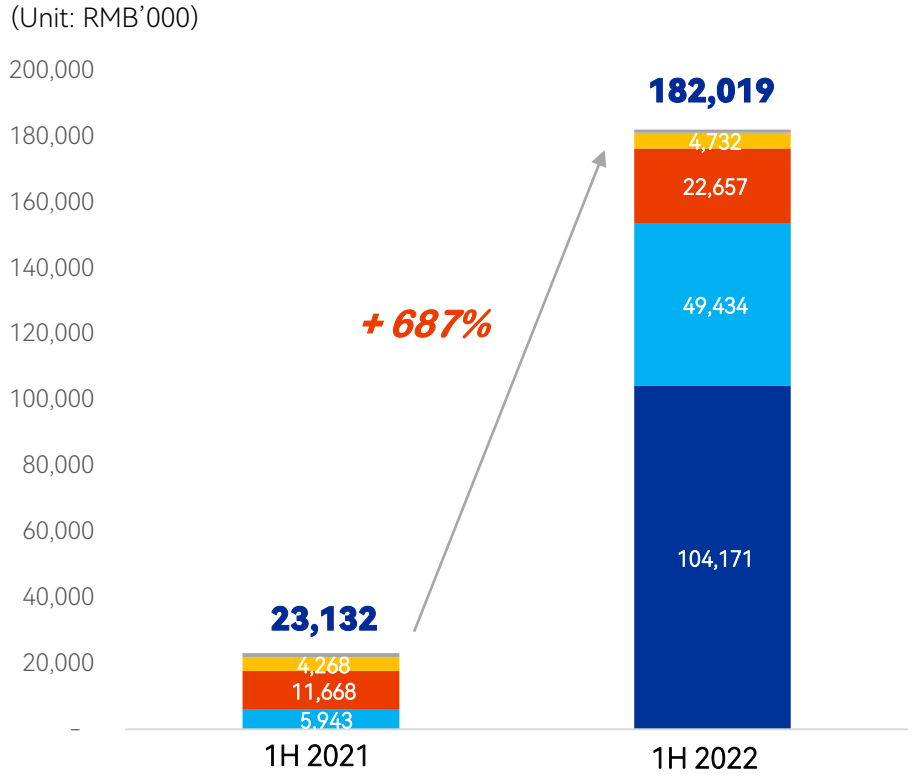
4 Financial Review

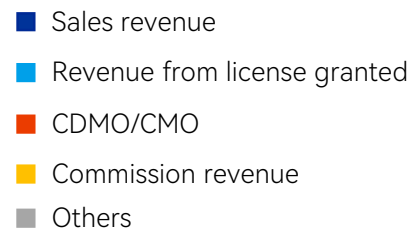
1H Financial Analysis

Key Financial Data – Revenue

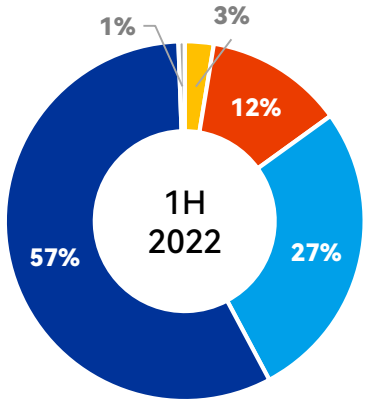
- In 1H 2022, the revenue reached RMB182 million, representing an increase of 687% YoY
- Revenue from sales of products achieved RMB104 million（the main contribution from the sales of Pusintin®）
- The revenue from CDMO/CMO business reached RMB22.66 million, representing an increase of 94% YoY

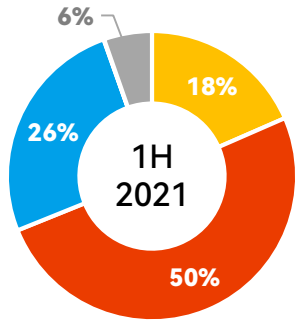
Income Distribution





% Income by Each Category





Key Financial Data – P&L Statement

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(Unit: RMB'000)

Items	1H 2021	1H 2022	+/-
Revenue	23,132	182,019	687%
Cost of revenue	(9,143)	(23,478)	157%
R&D expense	(88,749)	(70,268)	-21%
Cost of sales	(11,202)	(70,091)	526%
Management fees	(26,823)	(25,698)	-4%
Other income and expenditure (net)	(2,660)	568	121%
Operating profit (loss)	**(115,445)**	**(6,948)**	**-94%**
Net financial income and expenditure & others	440	(8,776)	NA
Net profit (loss)	**(115,005)**	**(15,724)**	**-86%**

- **Revenue:** an increase of 687% yoy, mainly due to a significant increase from our self-developed products
- **Cost of revenue:** an increase of 157% yoy, mainly due to some CDMO projects costs to be recognized according to the implementation schedule input method; and self-developed products sales increase, resulting in increased costs
- **R&D expense:** a decrease of 21% yoy, mainly due to pipeline optimization and the synergies from clinical cooperation, R&D material costs and clinical trial costs were effectively controlled during the period
- **Selling expenses:** an increase of 526% yoy, mainly due to the sales revenue increased, marketing consultant expenses increased accordingly

- On 29 July, the Company successfully completed the subscription by top two investors for new shares to be issued under specific mandate, resulting in approximately HK $470 million of capital.
- In 1H 2022, cash flow from operating activities was RMB 24.24 million.

Key Financial Data – R&D Expenses

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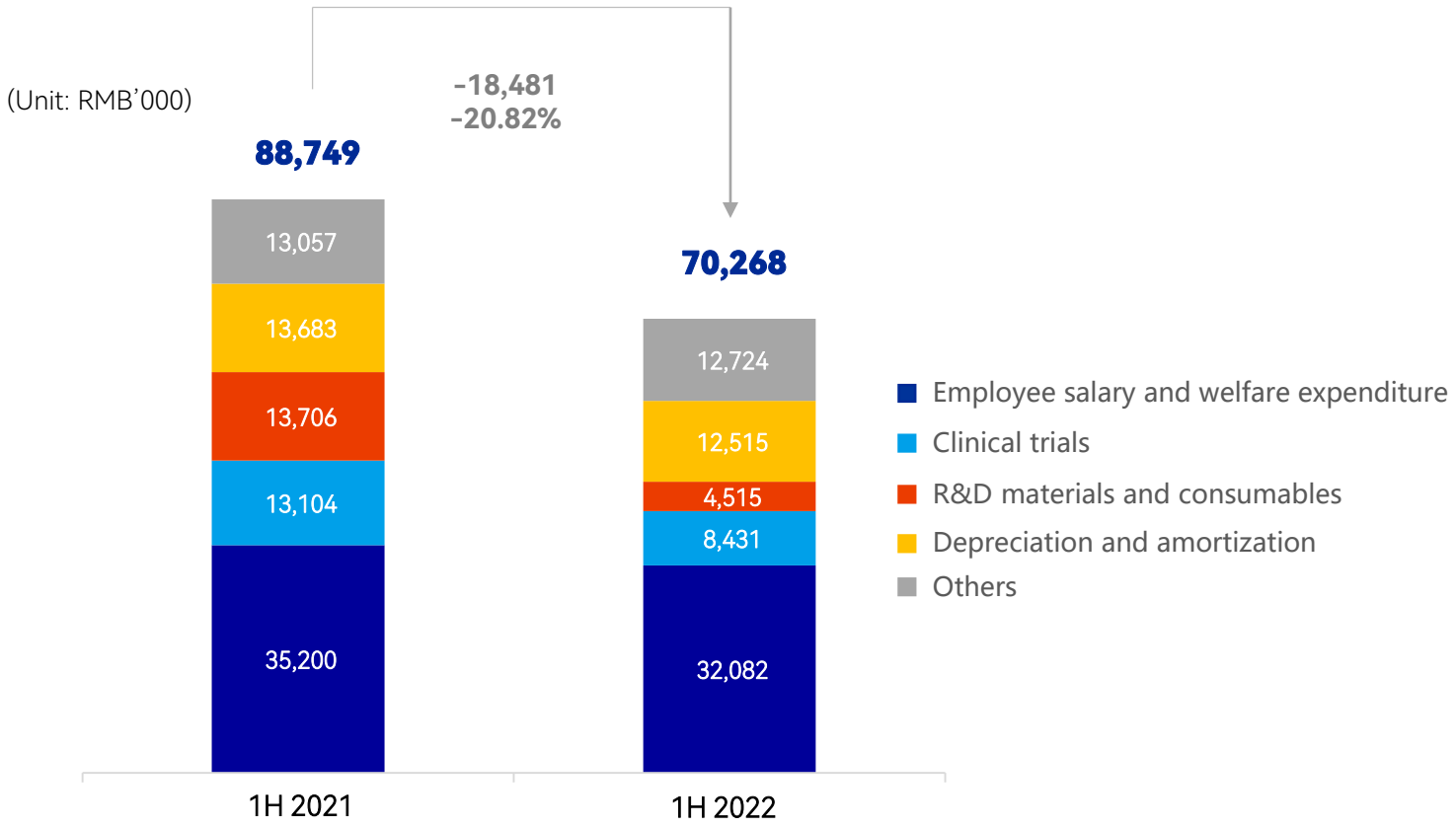
- In 1H 2022, R&D expenses were RMB70.268 million, representing a decrease of 20.82% YoY



Mainly Attributable to:

- **Clinical trials:** The costs of clinical trials was effectively controlled, mainly due to the product pipeline optimization and the synergies from clinical cooperation
- **R&D materials:** Due to the completion of the phase III clinical trial enrollment of TAA013, the relevant R&D materials have been significantly reduced

THANK YOU!

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Appendix

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

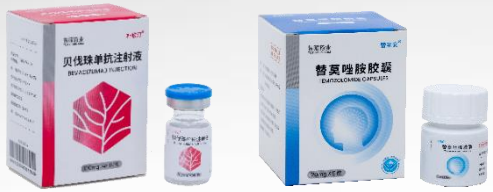
- Listed on the Main Board of the HKEX in November
- ADC drugs TAA013: completed phase I clinical trial
- TAB014: gained the National Science & Technology Major Project 'Creation of Major New Drugs'

2019

Listed on HKEX

2022 (1H)

- 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
- Phase III clinical trial of TAA013 completed patient enrollment



- 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

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

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

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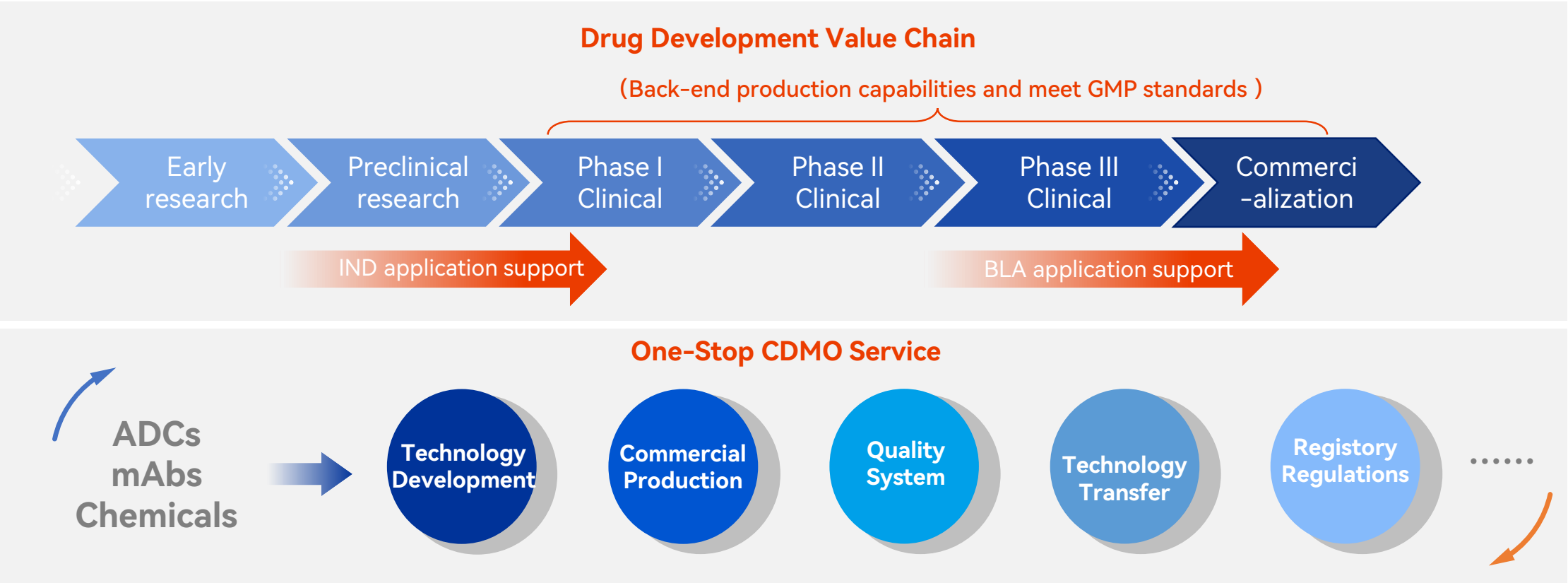
- Comprehensive industrial value chain that further binds customers with the Company and brings long-term value, creating sustainable business growth
- With the changes in the industry, early-stage drug discovery companies are increasingly dependent on the back-end resources of the clinical and commercialization 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.



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

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/Q9/Q10 Pharmaceutical Quality System Lifecycle Management

Pharmaceutical development → Technology Transfer → Commercial Manufacturing → Product Discontinuation

Investigational Products — GMP product lifecycle management

Management Responsibilities

PQS elements

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

Enabling CI

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

Why Choose US

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- ADC one-stop industrialization platform with core R&D technology advantages; enable to complete key production links in one production base
- Large-scale biological pharmaceutical commercial production base complying with GMP standard，having a leading and flexible commercial capacity to meet diverse and customized project requirements
- Clinical and commercial quality management system approved by industry regulators, throughout the whole process from research and development to commercialization
- Owning a sophisticated and stable core technology team with rich experience in biopharmaceutical process development, commercial production, quality and compliance, regulatory application
- Trusted and recognized by industry partners with a good reputation and track record