

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

东曜药业
TOT BIOPHARM

2023 Interim Results Corporate Presentation

14 August 2023



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Performance ➤
Overview
Business Highlights

01

Performance Review in 1H 2023—Significant improvement in major financial indicators

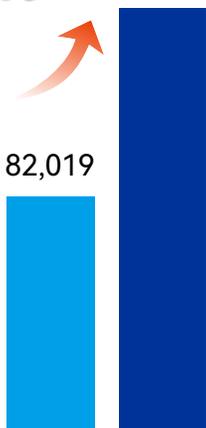
- Revenue reached to **RMB328 million**, representing an increase of **80%* YoY**, excluding the impact of revenue from licenses granted for 1H 2022, the YoY increase of revenue reached **147%**
- **Profitability improving continuously**, adjusted EBITDA reached to **RMB13.5 million**, representing an increase of **13%* YoY**, excluding the impact of revenue from licenses granted for the same period last year, the YoY increase of revenue reached **136%**
- Net operating cash flow (OCF) **continued to be positive**, and net OCF 1H 2023 was **RMB62.4 million**, representing an increase of **116% YoY**

Rapid revenue growth

328 million

+80%* 328,063

182,019



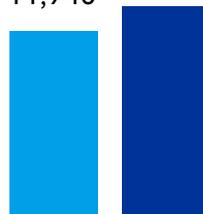
1H 2022 1H 2023

EBITDA turn positive*

13.5 million

+13%

11,940 13,504



1H 2022 1H 2023

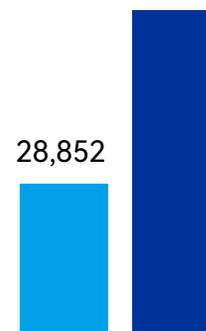
OCF continuously to be positive

62.4 million

+116%

62,413

28,852



1H 2022 1H 2023

Unit: RMB'000

Unit: RMB'000

Unit: RMB'000

*Excluding the impact of last year's licensing grant revenue, the year-on-year growth rate of revenue is **147%**

*Adj.EBITDA excludes share-based compensation expenses, and still remains positive without contribution from license grant rev. excluding license grant rev. in the same period last year, it was RMB-37.49 million, a year-on-year increase of **136%**



01 Innovative technology platform

- Reached a cooperation with GlycanLink (糖岭生物) to jointly develop ADC site-specific conjugation technology platform-DisacLink™, creating the world's **most valuable** site-specific conjugation technology and accelerating innovative ADC drugs' development.



02 Built the largest commercial ADC production line in China

- Company's 2nd, the **domestic largest** ADC commercial production workshop established, which can produce 2R-50 freeze-dried products with a maximum operating speed of **200 vials/min**.
- Built the 2nd & 3rd ADC substance manufacturing commercial line, scale up to **5kg/batch per line**



03 ADC CDMO strategic cooperation

- Achieved **multiple** long-term ADC CDMO strategic cooperation
- Successfully obtained **3 ADC pre-BLA** projects and locked for future commercial production
- Develop innovative conjugation drugs (XDC/AXC and etc.)



04 Continuous growth of CDMO Team

- Due to the increase of company's CDMO business, the number of CDMO people has increased by **13%** compared to the end of 2022, and accounting for **80%** of the company
- The total number of personnel in technology, production, and quality accounts for **83%** of the total number of CDMO personnel

Promote the market sales of launched drugs, and actively seek license out partners for R&D drugs

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)							
	TAC020 (new target)	Various solid tumors							

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; glioblastoma multiforme or anaplastic astrocytoma that recurs or progresses after conventional treatment.	20mgx5 capsules/bottle; 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	150mL/bottle	Approved for launch by NMPA on 13 May 2021 <i>(This product is imported from Taiwan; the Company owns the exclusive agency rights of this product in mainland China, Hong Kong and Macau)</i>



Bevacizumab's in-hospital drug market ranks first in domestic anti-tumor drugs

- In 2022, **in-hospital sales** of Bevacizumab reached **RMB 6.49 billion**, ranking **first** among the national anti-tumor drugs in China; The sales of Avastin continued to decline to **22.9%** of the national market share, while biosimilar accounted for **77.1%***
- In 2030, the market size of Bevacizumab in China is estimated to increase to **RMB 18.4 billion**, with a growth rate higher than that in the world
- Capable of combining with chemical drugs, double antibody, ADC and other kinds of drugs, which contains **potential market space**

Pusintin® Domestic Market

- Strong sales momentum, with sales growth rate exceeding **161%** in 1H 2023 compared to 1H 2022
- Differentiated market strategy, **filling out the gap of outside hospital market**, further **increasing market share**, and creating a good foundation for centralized procurement

Pusintin® Overseas Market

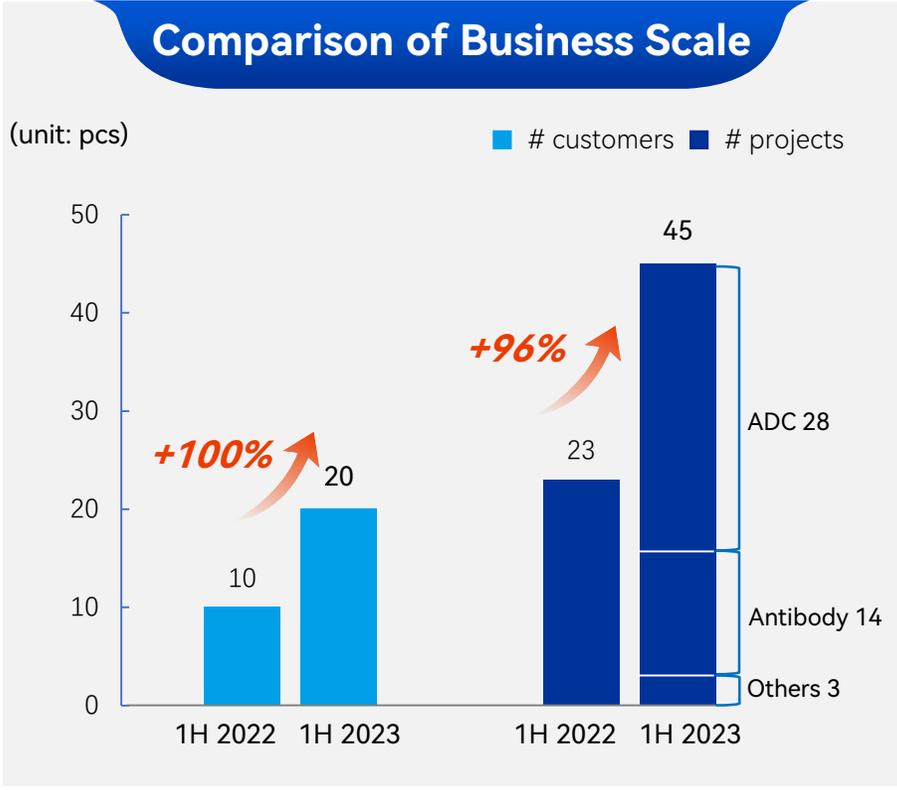
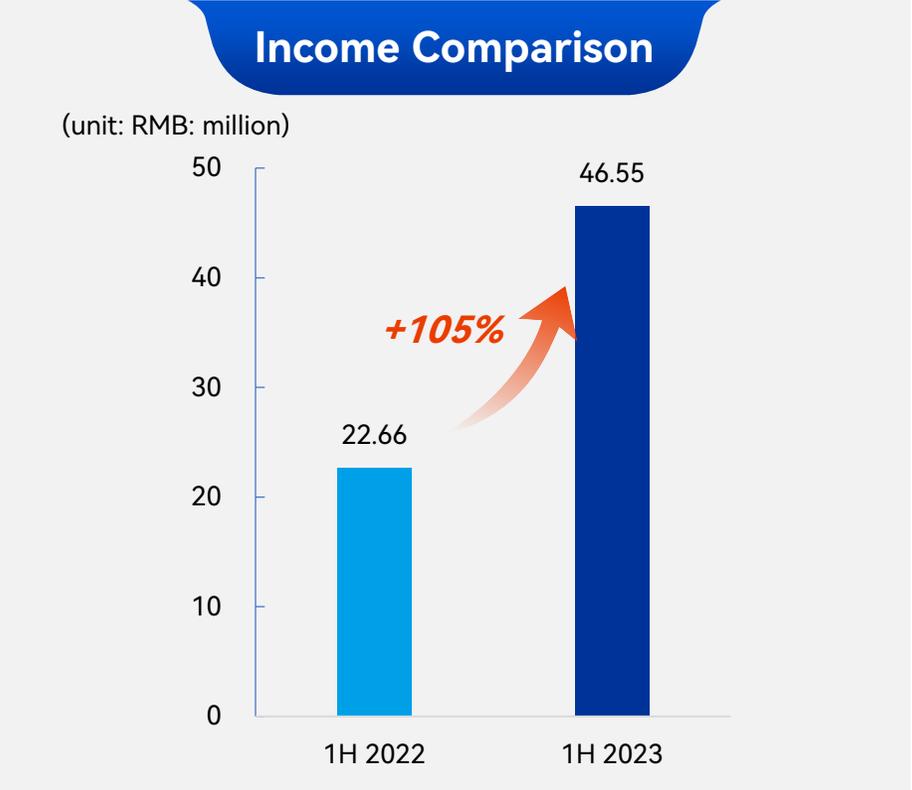
- Initiated the registration application in **20 overseas countries**, and the registration application documents have been accepted by **8 countries**
- Aim to obtain the **first approval** from an overseas country by the end of 2023 in order to **penetrate overseas markets**

Business 
Development
CDMO Highlights

02

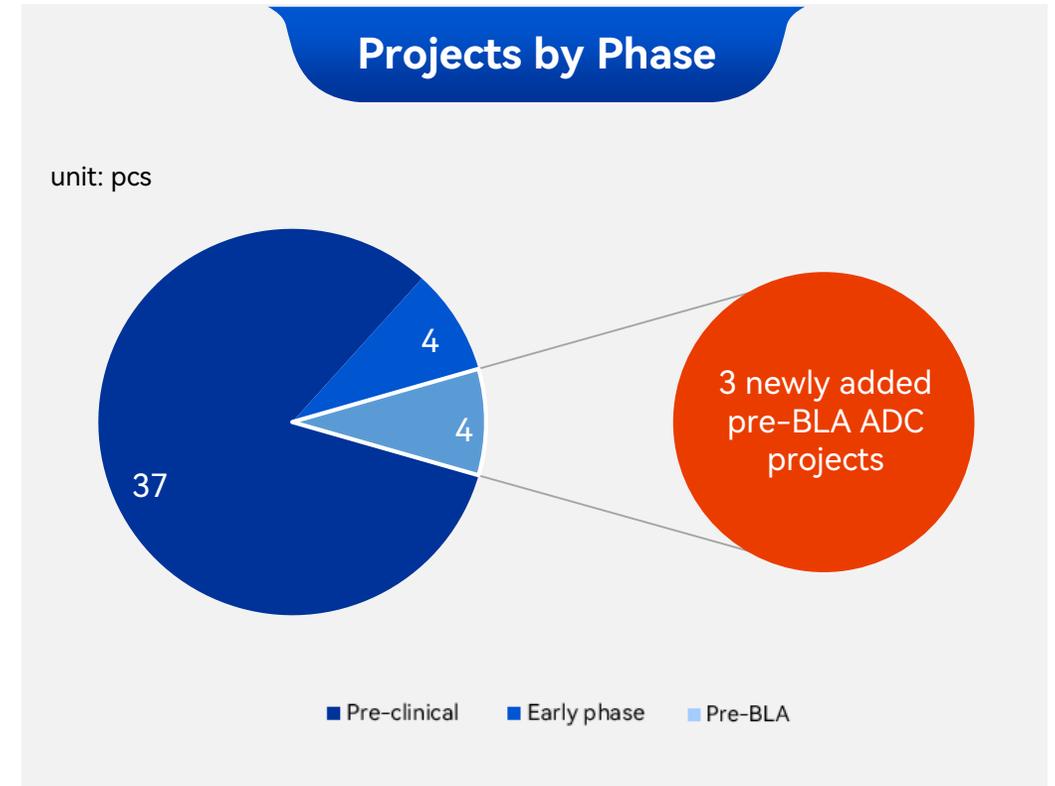
1H CDMO Highlights

- As of June 30, 2023, CDMO revenue reached **RMB 46.55 million**, representing a growth rate of **105% YoY**
- **45 CDMO** projects, with an increase of **96% YoY**; rocket increase of ADC projects, with **28 ADCs** accounting for 62% of the total
- BD strategy achieved remarkable results, number of customers doubled YoY; **20 newly added** projects, of which **15** are ADCs

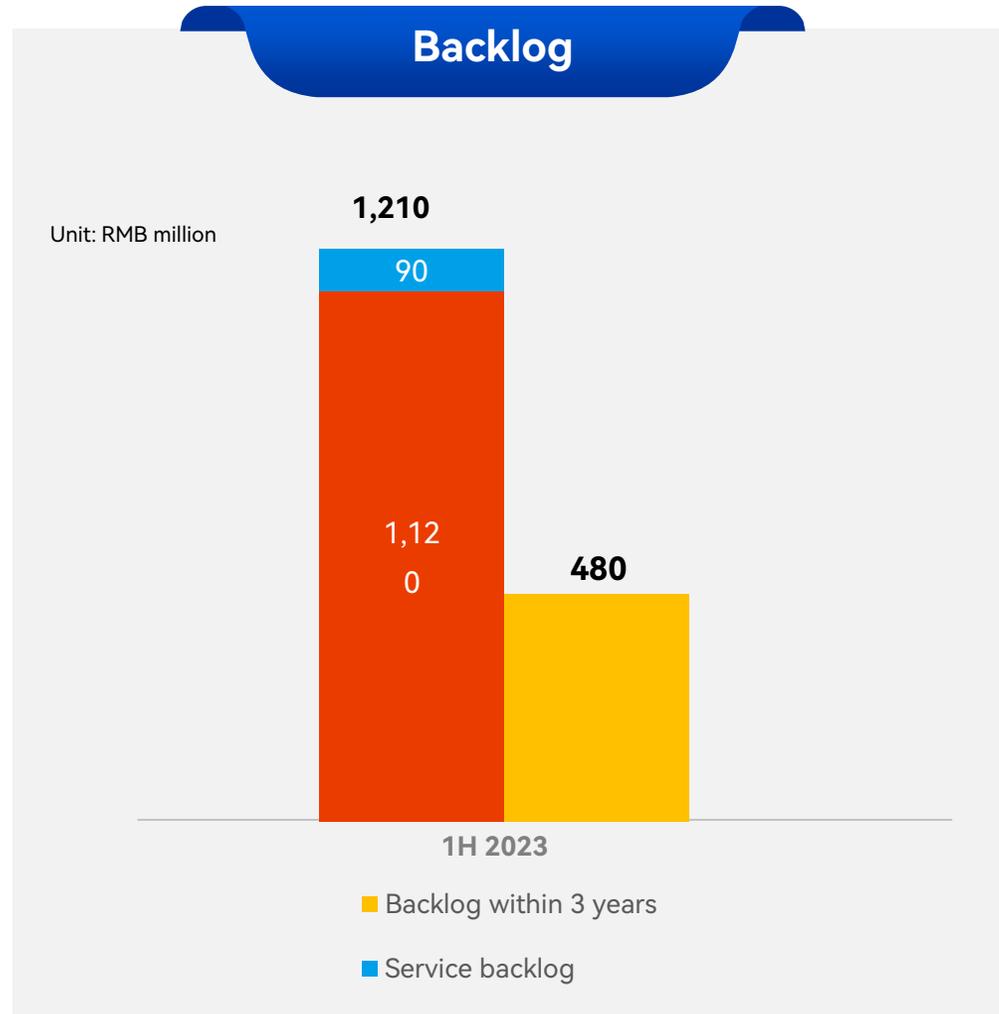


Significant Effectiveness of CDMO Market Strategy

- 1 Focus on ADC CDMO, leveraging our outstanding CMC development and successful commercial projects experiences, won high recognition from customers
- 2 Quickly lock the potential commercialization order, accelerate the cash flow conversion
- 3 Accurately target customer groups, 3 newly added pre-BLA ADC projects, of which 2 are external transfer projects
- 4 Accelerate market expansion and increase market share. Among the 37 IND projects, 17 are new added projects, including 2 early R&D/testing projects



Backlog Continue To Drive Future Revenue Growth



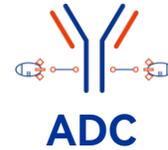
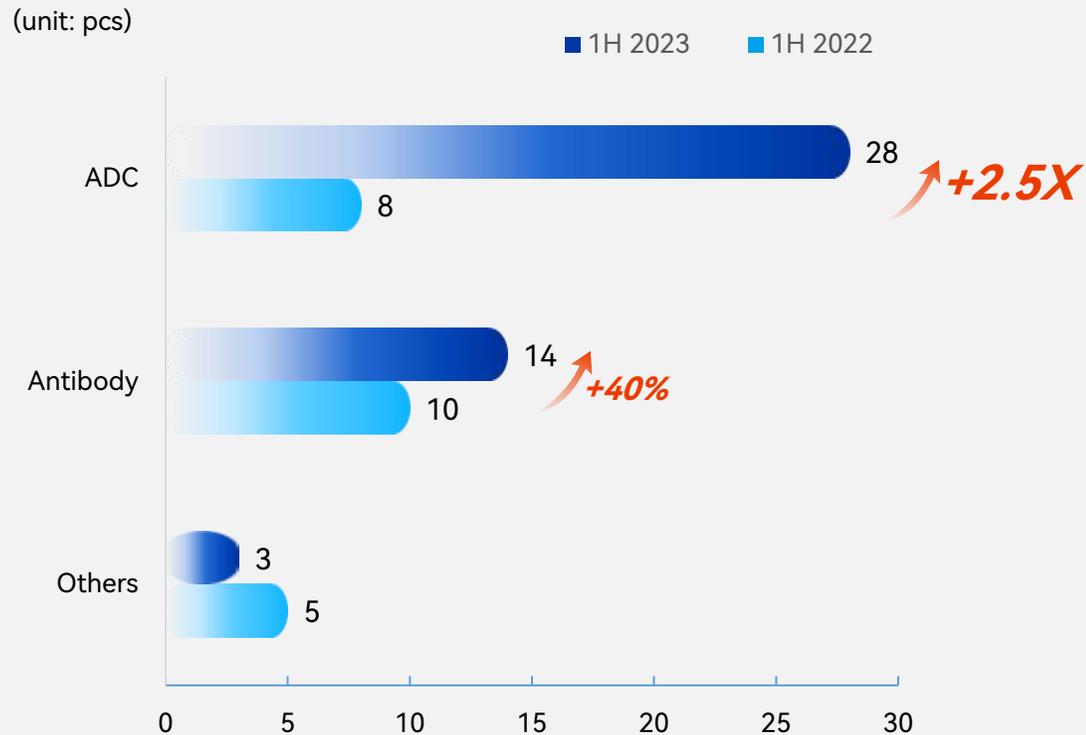
- Attribute to TOT's complete experience from development to commercial production, as of 30th June, 2023, the total backlog amount increased to **RMB1,210 million** with strong growth momentum in performance
- The differentiated advantage of the ADC CDMO industry platform have been highly recognized by customers. As of June 30, 2023, the backlog within 3 years has increased to **RMB480 million**, providing high visibility of strong short-term growth
- For upcoming potential milestone fees, backlog within 3 years highly accounts for **40%**, and backlog over 3 years for **60%**
- Upcoming potential milestone backlog are all projects after pre-BLA, with **high revenue conversion**, providing strong support for future business growth
- High-end and flexible production line configuration matching diverse project requirements

*The progress and revenue recognition of upcoming potential milestone fees depend on customers' projects progress

1H CDMO Highlights

- Focus on biologics CDMO, expand early stage projects, and enhance **customer stickiness**
- ADC business has significantly improved with an increase of **2.5X YoY**, ranking among the top of the industry

Comparison of Business Scale



- Includes early R&D, comprehensive projects and preparation filling
- Total 28 projects, including 32 orders, and 7 projects completed



- Includes early antibody R&D, comprehensive projects and antibody preparation filling
- **Newly added bispecific & trispecific antibody**
- Total 14 projects, including 22 orders, and 12 projects completed



- Tighten non-core track projects
- Total 3 projects, including 2 R&D testing projects, both are regular customer's new projects

Continuously Growing of CDMO Team

In order to meet the rapid growth of CDMO business, we focus on introducing **key CDMO talents** of technology, production, and quality



Optimize the allocation of talent structure, with CDMO personnel accounting for **80%*** of the group, an increase of **13%** compared to the end of 2022



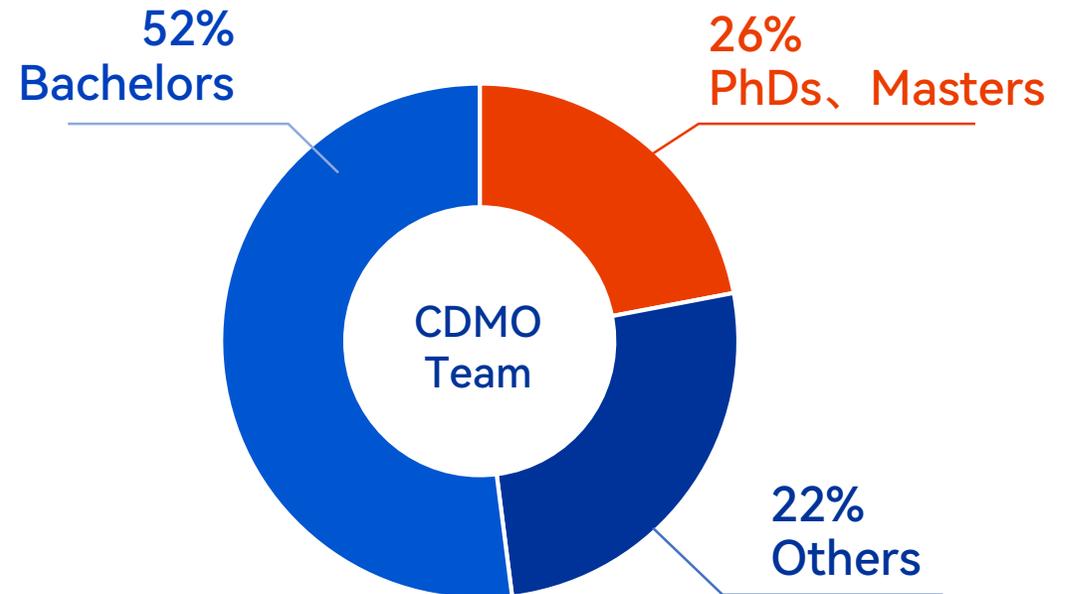
The total number of personnel in technology, production, and quality accounts for **83%** of the total number of CDMO personnel



The core team has an average of **12 years** in biopharmaceutical industry, rich experiences in projects has earned customers' trust



Bachelor's degree or above accounts for to **78%**, with master's, doctoral, or above degrees accounting for **26%** of the CDMO team



“One-Base· End-to-End” ADC Industrialization Platform



- Own an **ADC integrated platform** that integrates antibodies, ADC drug substances and ADC drug products, which can meet the **full process requirements** of ADC drugs from development to commercial production and ensure stable supply

- Provide customers with one-stop ADC CDMO services through a **comprehensive quality management system** and **an experienced technical team**

- **Completely avoiding** the compliance regulatory risks brought by segmented production faced by domestic peers

Branding

- Aim to build a leading ADC/XDC CDMO company, empowering the rapid development of industry
- Continuously improving brand awareness, strengthening brand image, precise positioning, and highlighting ADC's differentiated competitive advantages



— Industry Leading, Best Customer-trusted Partner in Biopharmaceuticals—



- **Delivery rate 100%**
- A professional, stable, and experienced technical team provides full support throughout the entire process
- High recognition from customers with the company's best delivery results and excellent delivery records
- **High customer recognition**
- Regularly conduct customer surveys to continuously improve service quality, technical capabilities, and empower customers
- Continuous improvement to create high-quality and efficient services
- **Regular customers related signed amount account for 97%**
- Industry reputation continues to improve, with an increase in customer referral projects. The signing amount brought by regular customers accounts for 97% of the total new signing amount in 1H 2023
- Continuously expanding new customers to regular customers

Achieved Multiple ADC CDMO Collaborations

- Promote innovation through quality
- Establishing steady and sustainable cooperative relationships with partners



Both parties have reached a deep strategic cooperation of ADC drugs from late clinical stage to commercialization



TOT BIOPHARM has established a long-term cooperation with LEPU BIOPHARMA for ADC drugs from research and development to clinical and commercialization



TOT BIOPHARM will provide comprehensive support for various R&D project for BioRay's ADC drug through a "one-base, end-to-end" CDMO service platform



Both sides will rapidly promote the development of innovative radionuclide drug conjugates (RDCs) based on conjugation technology.



济民可信



宜联生物
MediLink Therapeutics



KINTOR

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Company Highlights ➤
**Competitive advantage and
commercial production**

03

Top-notch in Domestic With Outstanding Development and Commercialization Ability

- Top ADC CDMO company in China
- The only CDMO in Yangtze River Delta that capable of providing “one-base · end-to-end” services throughout the entire ADC R&D and production process

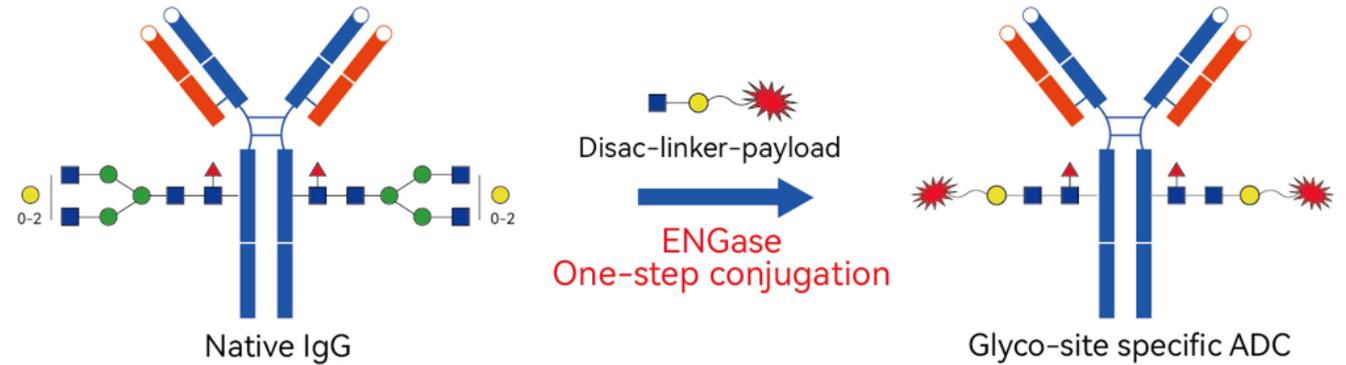
Comparison of the Capabilities of Top ADC CDMO in China

Company	R&D process			Production process			On-going phase III	One-base End-to- end
	Monoclonal antibody	Conjugation	Formulation and Process	Research	Development	Production		
东曜药业 TOT BIOPHARM	✓	✓	✓	✓	✓	✓	✓	✓
公司A	✓	✓	✓	✓	✓	✓	✓	✗
公司B	✓	✓	✓	✓	✓	✓	N.A	✓
公司C	✗	✓	✗	✓	✗	✗	✗	✗

The Most Valuable Site-specific Conjugation Technology Platform—DisacLink™

- The **most valuable** site-specific conjugation technology in China and one of the **most advanced** independent patented technologies **worldwide**
- **Enhance** the overall R&D level and **accelerate** the development of domestic ADC industry

✓ New generation of
“single enzyme **one-step**” method

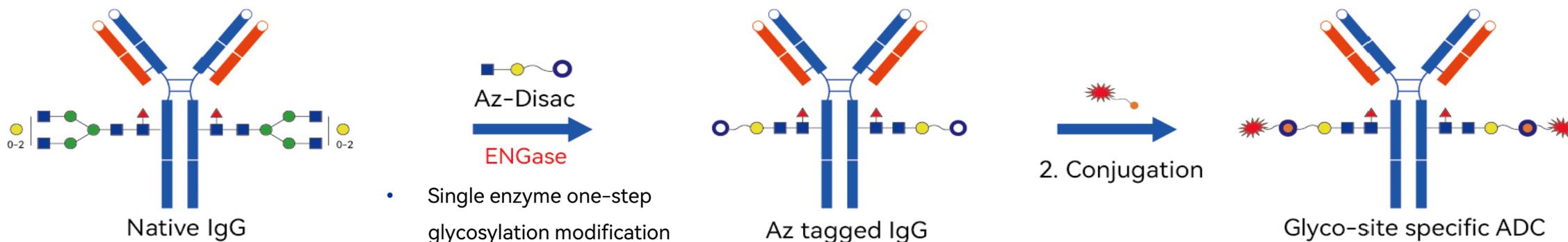
- No need to modify antibodies, no damage to structure
- Single enzyme, one-step, efficient (1-4h)
- Compatible with diverse linkers, and drugs
- Enzyme: expressed in Escherichia coli, high quantity, stable, and affordable



- ✓ Site-specific, uniform
- ✓ Better hydrophilicity and stability
- ✓ Better in-vivo activity, PK and safety

The Most Valuable Site-specific Conjugation Technology Platform—DisacLink™

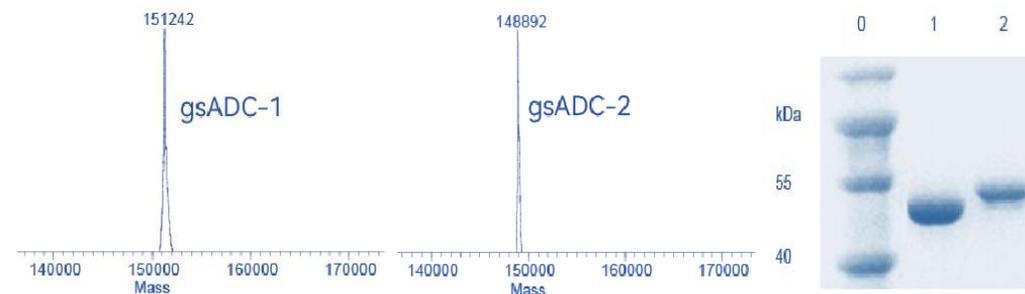
✓ New generation of “single enzyme **two-steps**” method , wider DAR values



Agile
development

- One enzyme only, with short reaction time, high conjugation rate, and stable
- Mild reaction condition, temperature friendly, no need organic solvents
- Simple purification steps

Efficient and
uniform



● Antibody substance manufacturing

20,000 L
Capacity

2
Independent workshop

150 batch
Annual designed capacity

30 '0000L
Annual designed capacity

- 200L to 2,000L drug substance production facilities with different scale
- International leading brand of disposable bioreactors with continuous production capability

Antibody substance manufacturing



● ADC substance manufacturing

5kg batch
Conjugation scale

3
Independent workshop

150 batch
Annual designed capacity

600 kg
Annual designed capacity

- International leading brand of reaction kettles with different scale from 5L to 500L
- Equipped with a non-toxic conjugation workshop to support non-toxic conjugation projects

ADC substance manufacturing

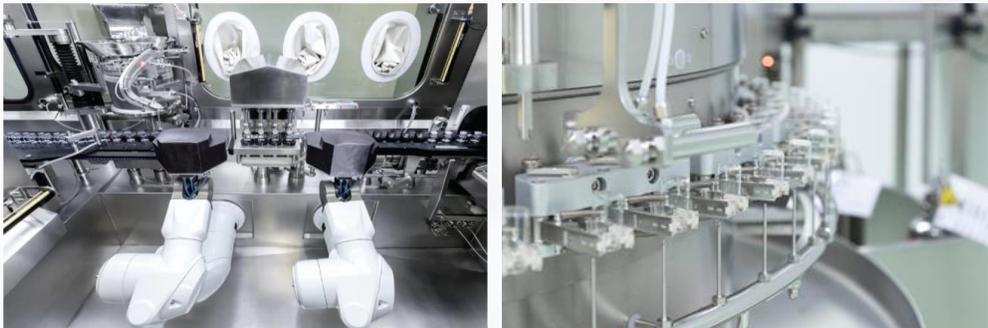


● Antibody product manufacturing



- 2 filling lines (including 1 freezing line and 1 injection line)
- International leading brand of **Steriline's** isolator filling linkage production line and **Bosch's** automatic filling injection production line
- Capable of GMP-compliant aseptic filling of 2R-20R standard vials, with an operating speed of up to 300 Vials/Min

Injection
production line



● ADC product manufacturing



- 2 filling lines (all freezing line)
- International leading brand of **Syntegon's** isolator filling linkage production line, and **Kyowac's** freeze-drying machine
- One 5m² and two 20m² freeze-drying machines, all equipped with automatic feeding and discharging systems

Freeze drying
production line



"One Base, End-to-End" ADC Platform

One-stop CDMO Service

- Complete ADC analysis technology platform and independent quality analysis capability to ensure high-quality product development
- Critical process in one place to achieve more efficient, optimal cost, and lower risk control

The Largest ADC Substance & Product Manufacturing Line



Antibody production



Drug substance production



Product manufacturing production

- **Antibody:** equipped with 2 independent substance production workshops, 2 production lines, up to 20,000L production capacity
- **ADC substance:** equipped with 3 independent substance production workshops, annual capacity reaches 600kg; Simultaneously equipped with a non-toxic conjugation workshop (DS05) to support non-toxic conjugation projects
- **ADC product manufacturing:** maintain 2 filling lines (2 freezing lines), Provide filling and packaging services for injections and freeze-drying at different stages, with an annual production capacity of 5.3 million vials

— Over 100+ Projects Produced, 100% Success Rate —

Expectation ➤
Outlook for 2023

04

01

Product strategy

- Further enhance market share of Pusintin®, generate abundant cash flow to the company
- Seeking for clinical partners to accelerate commercialization

02

Seize the ADC market

- Focus on ADC CDMO, continuously expand customer numbers and projects pool
- Enhance customer stickiness and increase market share with excellent service quality and full lifecycle regulatory support services

03

Expand XDC emerging fields

- Build a cutting-edge innovative technology platform, continuously accumulate rich project experience, and actively explore more innovative emerging fields such as **XDC, AXC and other broader bioconjugates drugs**
- Provide sustained growth momentum into the company's development

04

Gradually expanding overseas markets

Actively expanding overseas business, deeply understanding of international market needs to explore overseas market

Corporate Vision, Mission, and Values

Vision: Empowering pharmaceutical innovation to improve the quality of life and safeguard human health

Mission: To be the industry-leading and the best customer-trusted partner in biopharmaceuticals



Strive for Better Life !

Financial Review



Financial analysis of 1H 2023

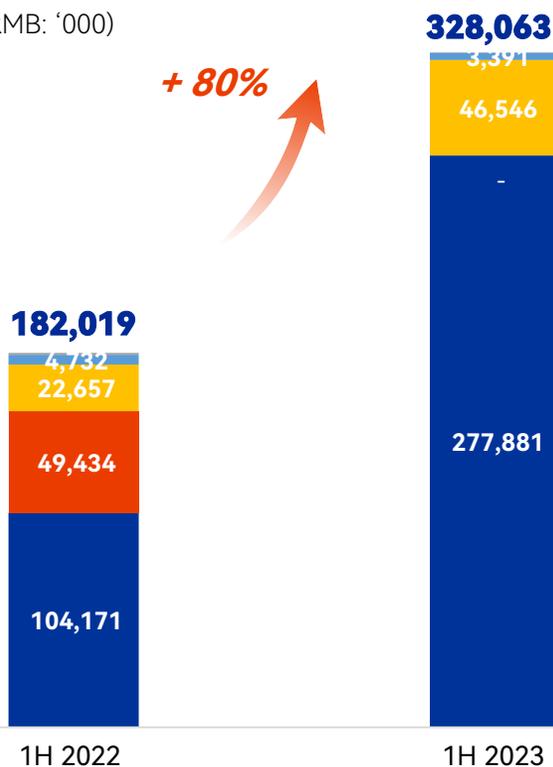
05

Maintain a 3-Digits Growth Rate in Revenue

- 1H 2023 Revenue reached to RMB328 million, representing an increase of **80% YoY**
- **Excluding the impact of revenue from licenses granted for 1H 2022**, the YoY increase of revenue reached **147%**
- Sales revenue reached RMB278 million, representing an increase of **167% YoY**, mainly due to the continuous growth of core product Pusintin®
- CDMO/CMO revenue reached to RMB 46.55million, representing an increase of **105%**, newly added projects will contribute more revenue in 2H 2023

Income Distribution

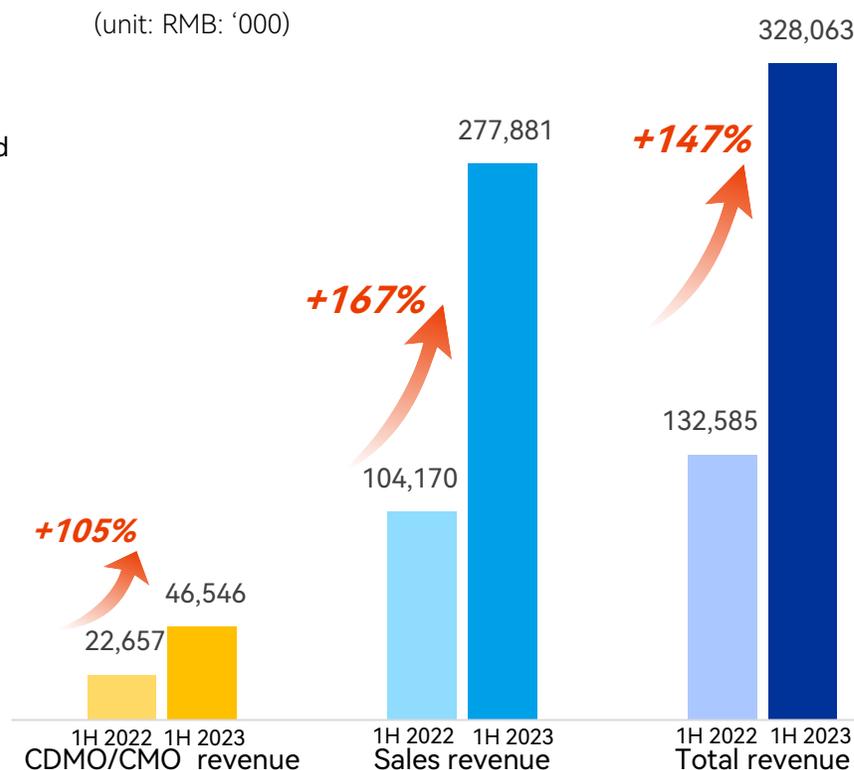
(unit: RMB: '000)



- Sales revenue
- Revenue from license granted
- CDMO/CMO revenue
- Commissions
- Others

Revenue Distribution

(unit: RMB: '000)



Note: 1H 2022 total revenue excludes revenue from license granted

Key Financial Data – P&L Statement

(Unit: RMB'000)

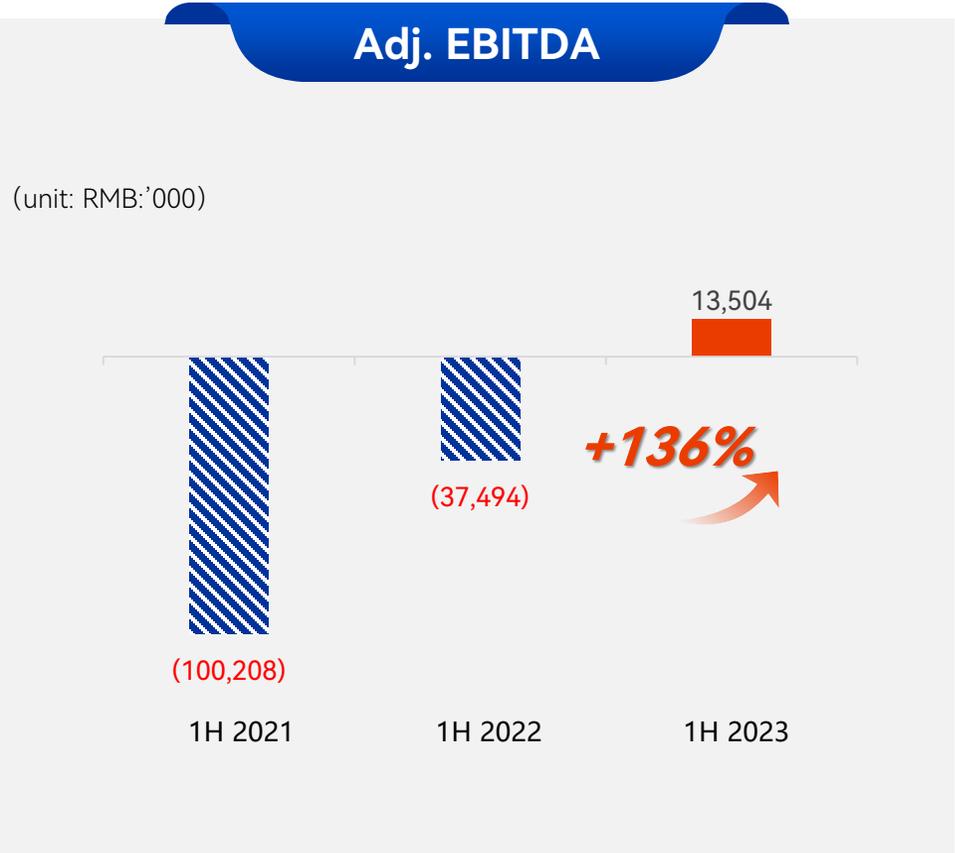
Items	1H 2023	1H 2022	+/-
Revenue	328,063	182,019	80%
Cost of revenue	(78,060)	(23,478)	232%
R&D expense	(49,969)	(70,268)	-29%
Selling expense	(197,376)	(70,091)	182%
General and administrative expenses	(31,104)	(25,698)	21%
Impairment losses	480	(923)	-152%
Other income and expenses	13,390	1,491	798%
Operating profit (loss)	(14,576)	(6,948)	110%
Net financial income and expenditure and investment gains and losses	(587)	(8,776)	93%
Net profit (loss)	(15,163)	(15,724)	-4%

- **Revenue:** an increase of 80% YoY, mainly due to a significant growth in revenue from self-developed products and CDMO/CMO
- **Cost of Revenue:** an increase of 232% YoY, mainly due to the increase of CDMO/CMO projects and corresponding investment; as well as the increase in sales of self-developed products and the consequent increase in costs
- **R&D expense:** a decrease of 29% YoY, mainly attributable to pipeline optimization, resource focus, and TAA013 settlement progress
- **Selling expense:** an increase of 182% YoY, mainly due to the increase in sales of self-developed products and corresponding increase in marketing and promotion expenses
- **General and administrative expenses:** an increase of 21% YoY, which was mainly attributable to the increase in taxation resulting from the increase in sales of self-developed products, and the increase in provision for share-based compensation expenses.
- **Other income and expenditure:** Mainly due to the exchange rate fluctuations and increase in government subsidies
- **Financial income and expenditure and investment gains and losses:** Mainly due to a decrease in financial costs and a narrowing of losses for joint ventures

Continuous Improvement in Profitability

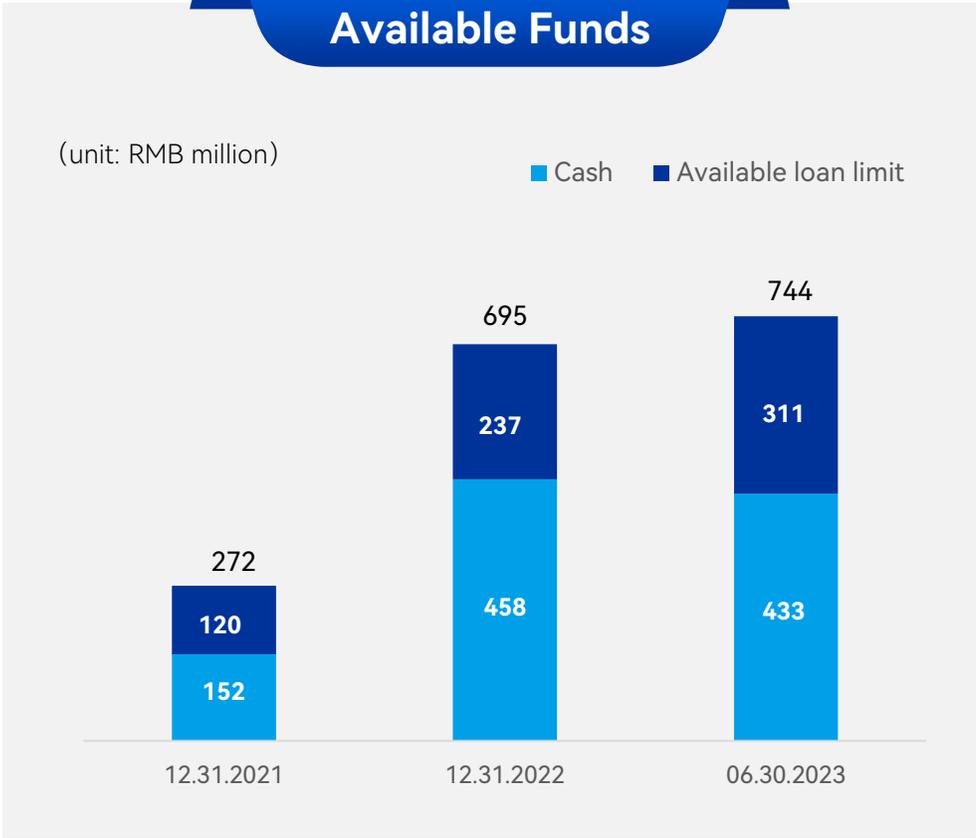
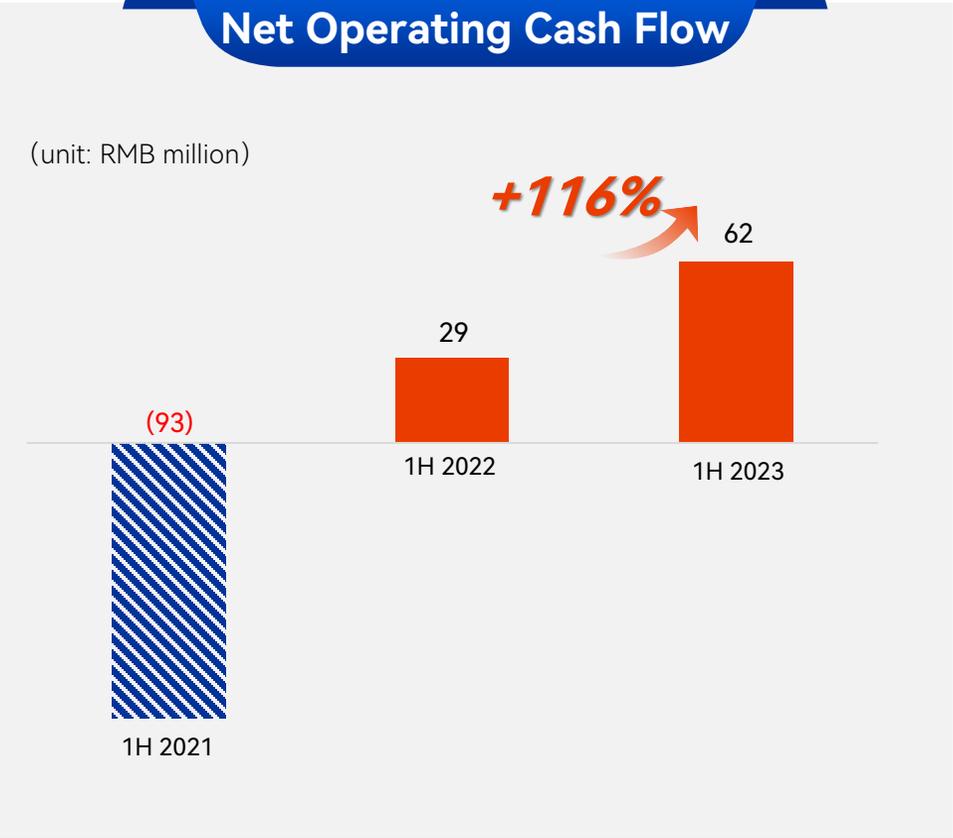
Excluding income from licensing granted for the same period in 2022

- Adj. EBITDA **turned positive for the first time**, to RMB 13.50 million, representing an increase of **136% YoY**, entering a new stage of stable development
- The strategic transformation has achieved significant results, with the adj. net loss continued to narrow to RMB 7.43 million, representing a decline of **88% YoY**



Continuously Stable Cash Movement

- Cash generating capability continues to enhance, and the net operating cash flow **continues to be positive**, reaching **RMB62 million**, representing an increase of **116% YoY**
- The abundant cash and the total amount of available funds are continuously increasing, laying the solid foundation for the sustainable development of the company



Thank you !
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