2024 Interim Results
Corporate Presentation

14 August 2024

東曜藥業股份有限公司

TOT BIOPHARM International Company Limited

(於香港註冊成立的有限公司)

股份代號: 1875

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Performance Overview

Business Highlights

01

Performance Review in 1H 2024 – Turning Losses into Profits

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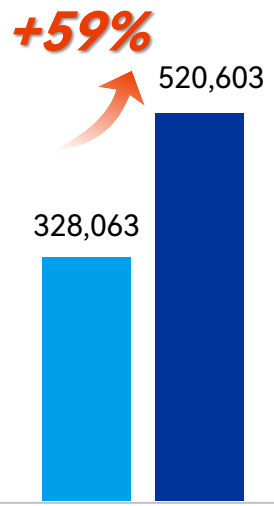
- Continuous significant revenue increase to RMB521 million, representing a YOY increase of 59%
- Remarkable results in its CDMO strategic transformation, turned from losses to profits, with a net profit reaching RMB31.56 million
- Adjusted EBITDA* amounted to RMB60.80 million. Net cash from operating activities amounted to RMB27.80 million 1H 2024 and remained positive for two and a half years

Rapid revenue growth

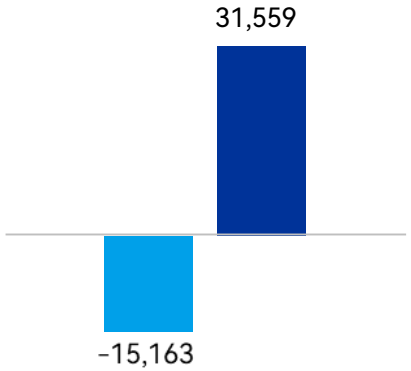
521 million



Unit: RMB'000

Turning losses into profits

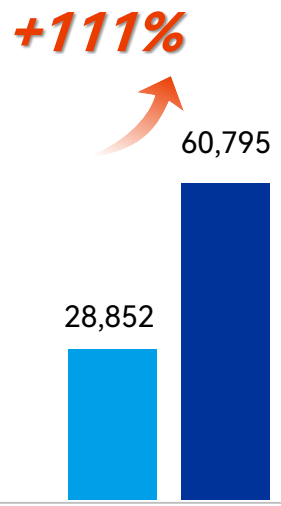
31.56 million



Unit: RMB'000

Adjusted. EBITDA*

60.80 million



Unit: RMB'000

*Adj.EBITDA excludes share-based compensation expenses, and one-time impairment loss related to the company's strategic transition

1 H 2024 Business Highlights

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01 Continued strengthening of the international quality system

- Maintain the CN/US/EU GMP standard quality management system, has been widely recognized
- Accumulated 60+ GMP audits, including passing the EU QP audit with zero defects and the official GMP audit directly on-site in Colombia, Indonesia, Egypt, and other countries

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02 Comprehensive R&D and production service platform

- Jointly developed the ADC site specific conjugation technology platform-GL-DisacLink ® with GlycanLink (糖岭生物) to deepen the exploration and expand the application
- Relying on the mature one-stop platform for XDC projects, take less than15 months on average from DNA to IND to accelerate drug entry to clinics
- Through strategic cooperation, expand full-service capabilities and build multi-service platforms

GL-DisacLink®

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GLYCANLINK 糖岭生物

03 Continuously enhance CDMO team capabilities

- To meet the rapid development of CDMO business, CDMO team members increased by 29% YOY to 492, representing 86% of the Group's total
- ADC CDMO team increased by 27%, strengthening business focus
- Senior management team had an average of 15+ years of work experiences in world renowned multinational companies

04 Further strengthen the position of Biopharmaceutical CDMO

- 20 newly added projects 1H 2024, accumulating to 115 projects
- 2 newly added ADC pre-BLA projects (total of 8), successfully locked future commercial production
- Multiple assistances with customers to complete overseas partner MNC pharmaceutical company inspection and successful authorization
- The number of visits by domestic and foreign customers has increased continuously, further expand the brand's influence

Pusintin® Sales Continue to Release and Stable

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Sales volume as compared with 1H 2023

+49%

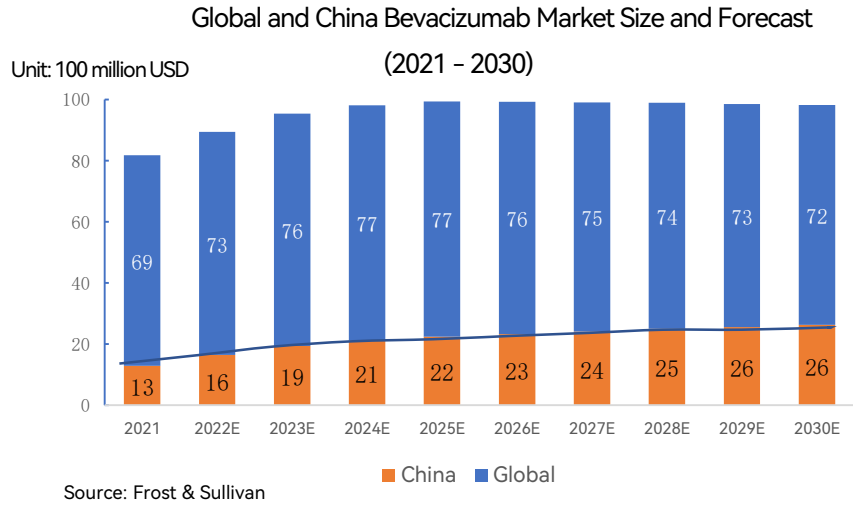
Chinese market

- Strong sales momentum, the sales volume in 1H 2024 increased by 49% as compared with 1H 2023
- Differentiated market strategy filling out the potential outside hospital market, expanding market share, and creating a good foundation for centralized procurement

Global market

- Initiated registration application in 31 overseas countries, and 17 countries have accepted the application
- Passed GMP on-site inspections in Columbia, Egypt, Indonesia and other countries
- First overseas approval expected in 2H 2024 to penetrate overseas markets

Huge market potential



Source: Frost & Sullivan

The global market is expected to reach $7.2 billion by 2030, with China's market growing to $2.6 billion; China's compound annual growth rate will far exceed the global market

Target: VEGF

Indication:

Non-small cell lung cancer*
Colorectal cancer*
Glioblastoma*
Epithelial ovarian cancer*
Fallopian tube/peritoneal cancer
Cervical cancer
Hepatocellular carcinoma

Drug Specification: 100mg(4ml)/vial

Product: Pusintin®

- Six indications in total:
- Advanced, metastatic or recurrent non-squamous non-small cell lung cancer; metastatic colorectal cancer; recurrent glioblastoma; epithelial ovarian, fallopian tube or primary peritoneal cancer; cervical cancer; hepatocellular carcinoma

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Business Development

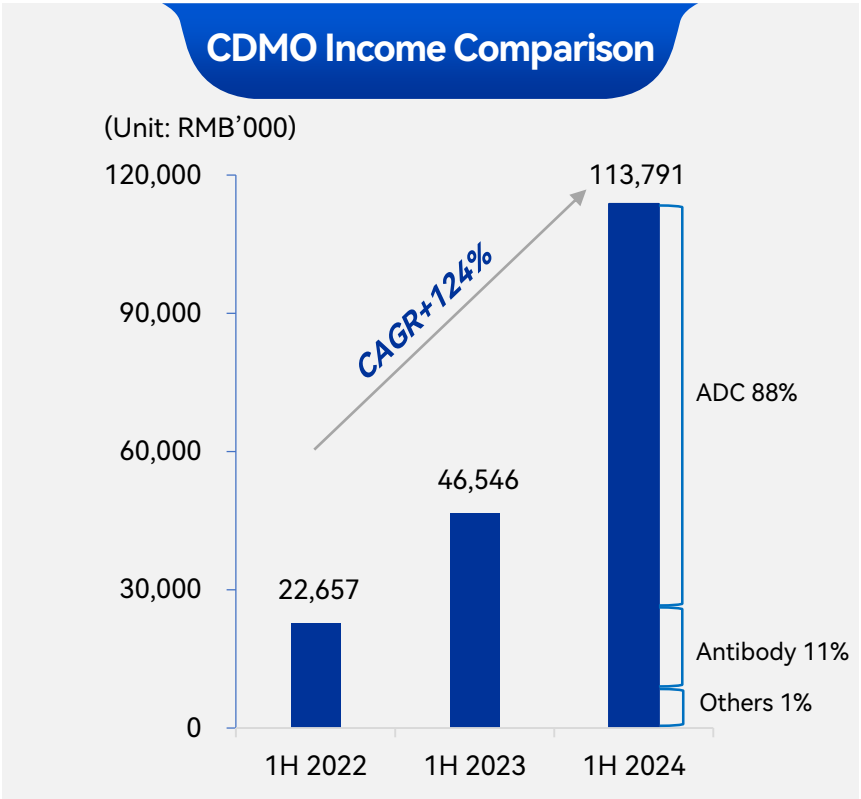
CDMO Highlights

02

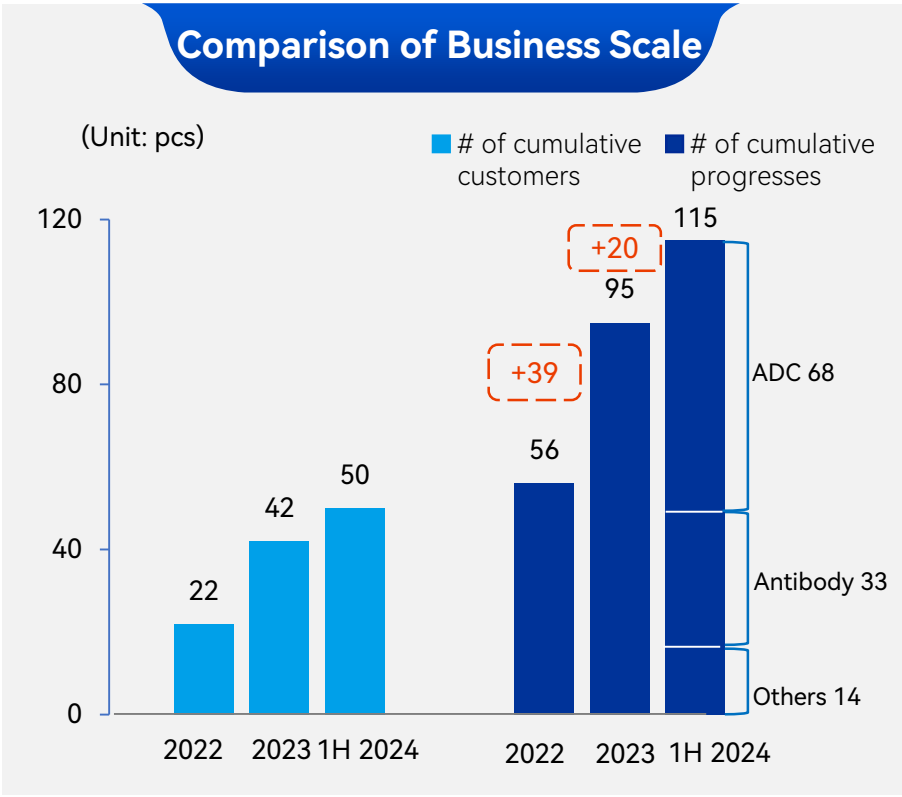
1H CDMO Highlights

- Revenue from CDMO was RMB114 million, representing a YoY increase of 144%, from ADC projects (including antibody production) accounted for 88%
- CDMO revenue grew much faster than overall revenue, increasing 8% to 22%
- Remarkable results in its CDMO strategic transformation, with a 3-year CAGR* of 124%, higher than the industry average. Backlog reached RMB184 million, representing a growth rate of 104% YoY

CDMO Income Comparison



Comparison of Business Scale



*CAGR: Compound annual growth rate

Further Consolidated the Position of Biological Drug CDMO

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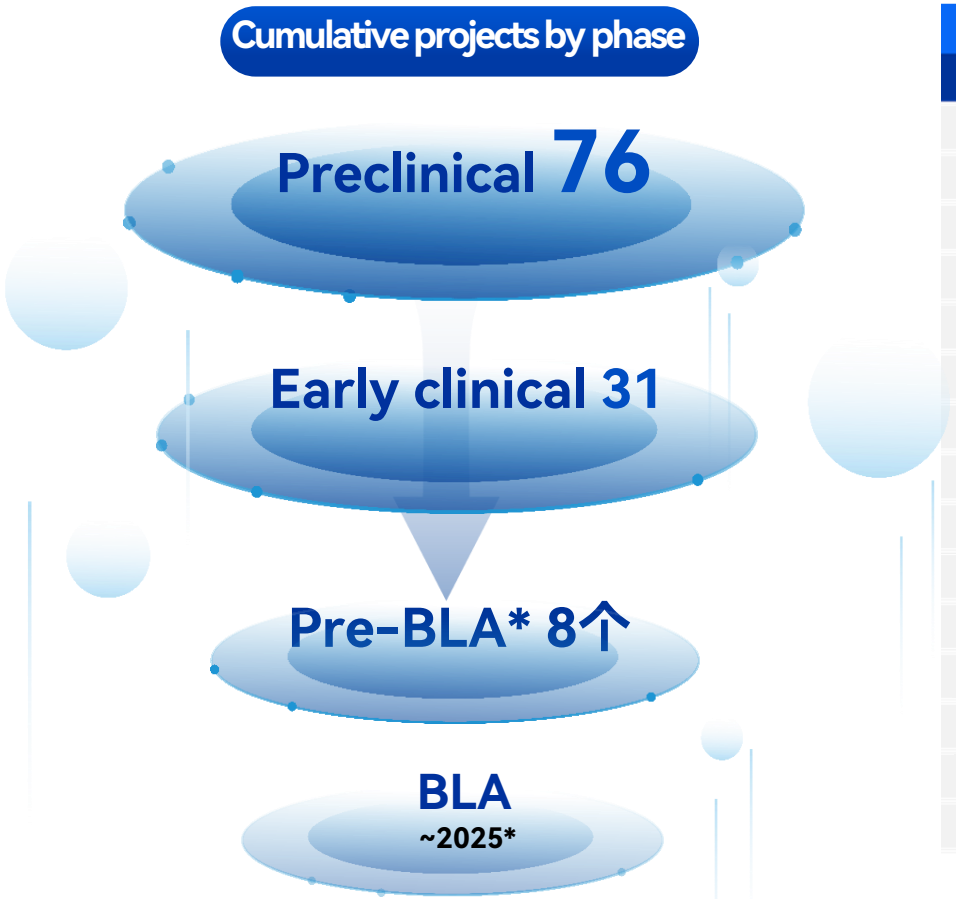
- 20 newly added projects in 1H 2024 (17 were ADCs), accumulating to 115 projects
- 2 newly added Pre-BLA projects, accumulating to 8 projects



Business Performance of Some ADCs

Product type	Project phase	Service content	File standards
ADC	Pre-BLA	Antibody + ADC DS/DP	
ADC	Pre-BLA	Antibody + ADC DS/DP	
ADC	Pre-BLA	Antibody + ADC DS/DP	
ADC	Pre-BLA	Antibody + ADC DS/DP	
ADC	Early clinical	Antibody + ADC DS/DP	
RDC	IND	RDC DS/DP	
ADC	Early clinical	ADC DS/DP	
ADC	Early clinical	Antibody + ADC DS/DP	
BsADC	Early clinical	Antibody + ADC DS/DP	
ADC	IND	Antibody + ADC DS/DP	
BsADC	IND	Antibody + ADC DS/DP	
BsADC	IND	Antibody + ADC DS/DP	
ADC	IND	Antibody + ADC DS/DP	
ADC	IND	Antibody + ADC DS/DP	
…	…	…	…

宜联生物 MediLink Therapeutics　DualityBio 映恩生物　乐普生物 LEPU BIOPHARMA　诗健生物 Escugen　Akesobio 康方生物　BioRay 博锐生物　智核生物 SmartNuclide　……

*Pre-BLA refers to pre-NDA filing projects
*It is expected that there will be projects for BLA filing in 2025, depending on the actual progress of the projects

Customer Visits and Audits Continue to Increase Further Shows Brand Influence and Quality System

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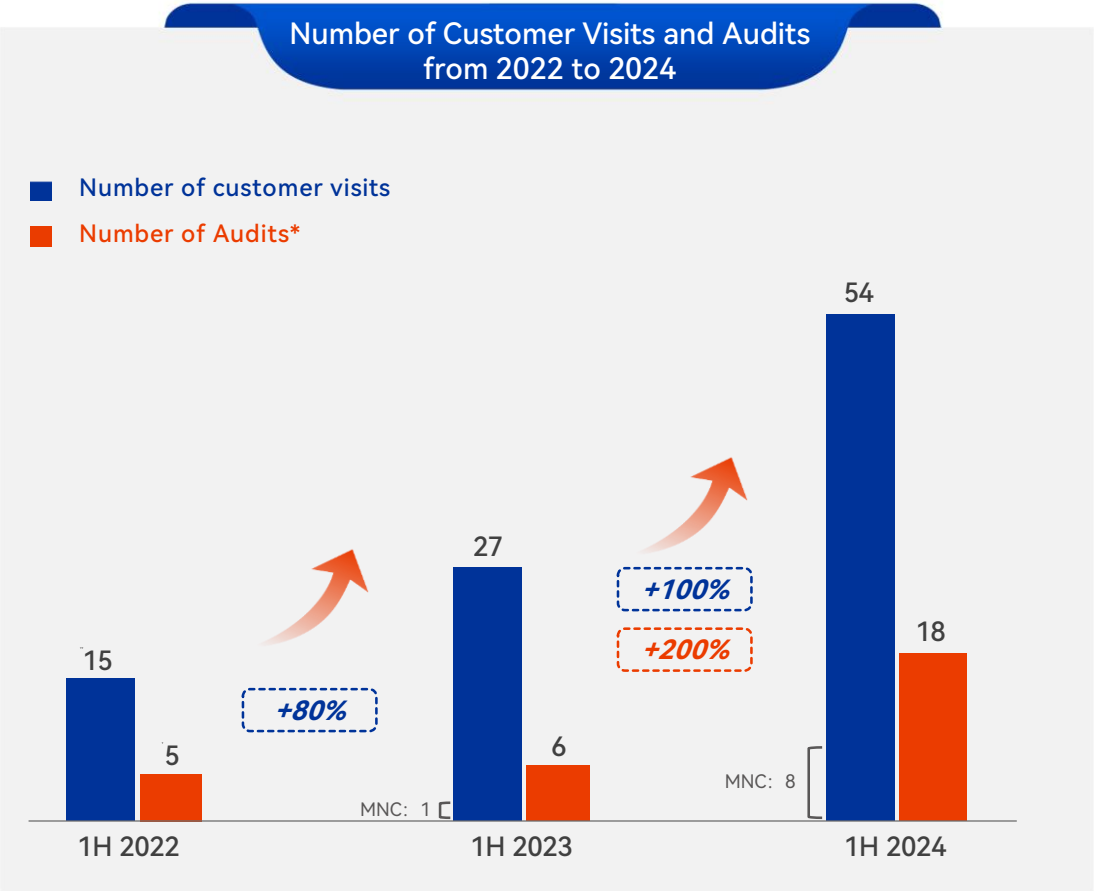

- With high-quality project delivery, the number of customer visits continued to increase with 100% YOY 1H 2024. Multinational pharmaceutical companies have all given positive feedback regarding Company's quality system
- Positive customer and regulatory audit results have validated the Company's service capability from clinical to commercial production, the number of audits increased by 200% YOY

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*Audits include customer and official audits; Customer visits excludes regulatory audits

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Company Highlights

Competitive advantages and Commercial production

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CDMO Business with Industry Barriers and Competitive Advantages

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01 One-Stop, One-Base, End-to-End Antibodies/ADC Solutions

- Comprehensive services from antibody/conjugation/drug product process development, analytical method development and validation, R&D and pilot production to commercial-scale production

02 High standard quality system and capacity allocation

- Domestic high-end one-stop commercialization platform for antibody and ADC drug development, flexible and diversified capacity to meet varied needs
- Quality management system meeting China/US/EU GMP standards

03 High technology barrier

- Advanced core conjugation technology and ADC analysis platform
- A complete commercial production workshop integrating antibodies, ADC substance and drug products

04 High-end talent team

- Focused on the core business, CDMO team members accounting for 86% of the Group, representing a YoY increase of 29%
- Among the CDMO team, 74% are Bachelors or above

05 Corporate reputation

- High standard service, good customer communication and well-established project management system have won high recognition from customers

One – Stop, One-Base, End-to-End Antibodies/ADC Solutions

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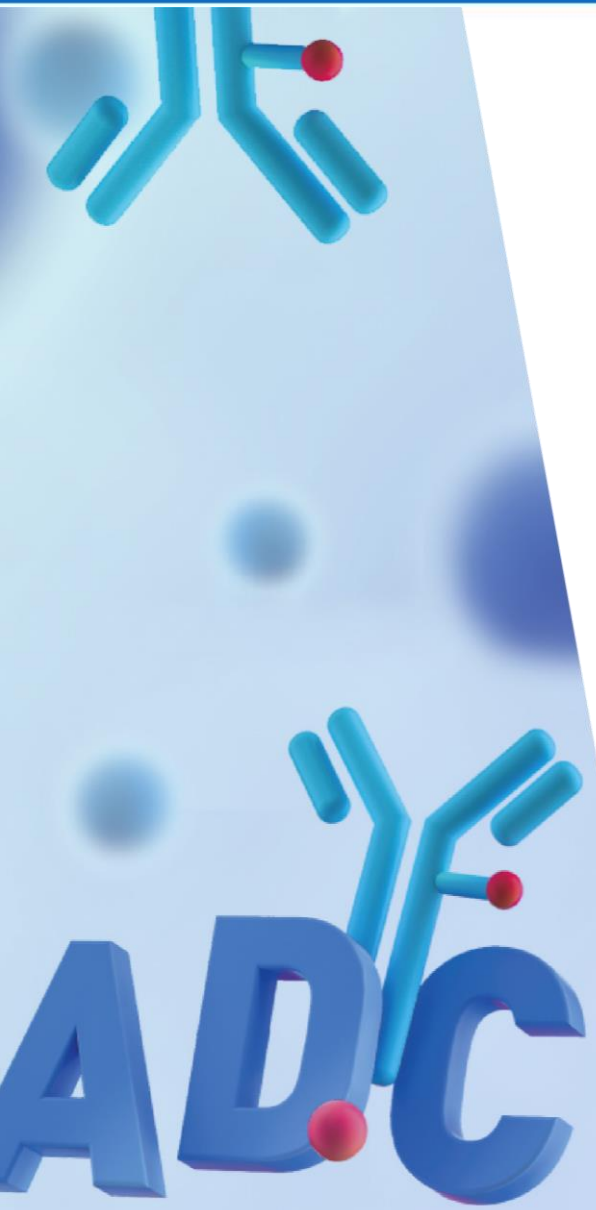

- Quality system meeting GMP standards (China/US/EU)
- Manufacturing and GMP inspection by Chinese regulatory bodies
- Key clinical medication and in-process manufacture of commercialized products

Drug screening → Drug study → Drug evaluation → Clinical Phase I → Clinical Phase II → Clinical Phase III → Commercialization

- From Non-GMP to GMP production
- China/US/EU quality system standards

Antibodies

- Cell line construction
- Cell Bank Construction
- Upstream and downstream process development/validation
- Formulation and process development/validation
- Antibody and drug substance production
- Drug products filling production (including freeze-drying)

Antibody modification

- Naked antibody activation modification
- Antibody intermediates

Load linkers (Strategic cooperation)

- Payload and linker process research, development and production
- Highly activated compound preparation, separation and purification
- 80+ payloads in stock, 400+ linkers in stock
- Stable supply at milligram - hundred-kilogram-level (GMP)

ADC Conjugation

- Conjugation process development/validation
- ADC formulation and process development/validation
- ADC drug substance production
- Drug products filling production (including freeze-drying)

ADC Analysis and Characterization

- Analytical method development/validation
- Physical and chemical analysis (purity, DAR, etc.)
- Characterization analysis (LC-MS)
- Biochemical analysis
- Biological analysis (cytotoxicity assays, etc.)

“One-Base, End-to-End Antibody/ADC Industrialization Platform

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One-stop CDMO Service

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

The Large-scale ADC Substance & Product Manufacturing Line


Antibody production


Drug substance production


Drug products manufacturing

- **Antibody:** 2 independent substance production workshops, 2 production lines, up to 20,000L production capacity
- **ADC substance:** 3 independent substance production workshops, annual capacity reaches 960kg; a non-toxic conjugation workshop to support non-toxic conjugation projects
- **ADC drug products:** 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

Site-specific Conjugation Technology Platform — GL-DisacLink ®

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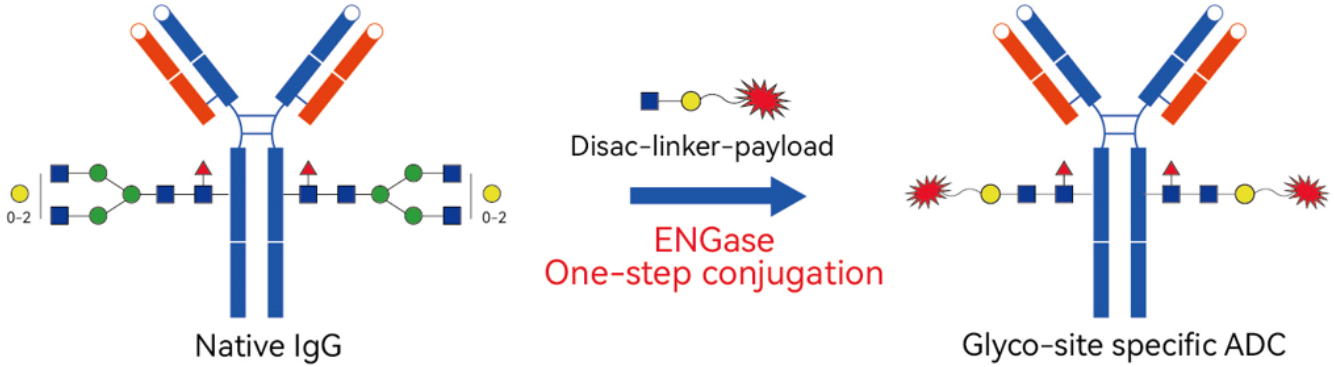
- Cooperate with GlycanLink (糖岭生物) to promote industrial-grade development and commercialization of the technology
- Accelerate the overall R&D level and the development of domestic ADC industry

✓ **New generation of "single enzyme one step" method**

GLYCANLINK 糖岭生物 × 东曜药业 TOT BIOPHARM



- ✓ Simple and efficient: single enzyme one step reaction, short reaction time, complete reaction
- ✓ Compatible: no preconditional antibody sequence, applicable to all antibodies and fusion proteins with antibody Fc segment structure

- GL-DisacLink ® technology is similar to Synaffix's GlycoConnect technology, but simpler to implement
- GlycoConnect has a cumulative license revenue of $4.75B
- Lonza acquires Synaffix to further enhance capabilities in ADC field service

Continuously Enhance the Capabilities of the CDMO Team

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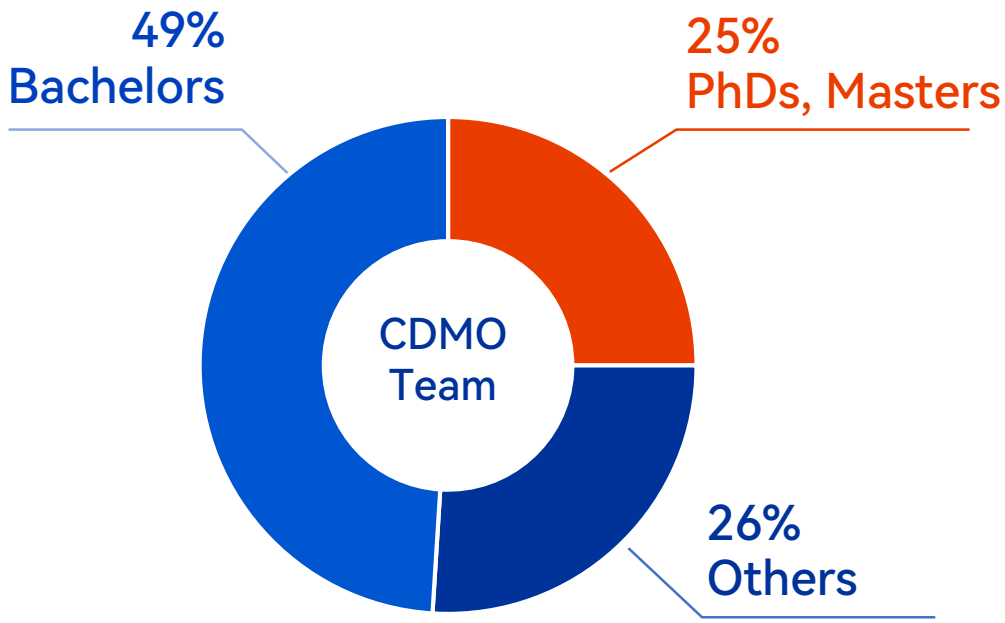
Continue to build a core talent team and optimize the organizational structure to meet the rapid development needs of the CDMO business

- CDMO team members accounting for 86% of the Group, representing a YoY increase of 29%
- ADC CDMO team members increased by 27% as compared with 2023
- 84% of ADC R&D hold master or above, highlighting remarkable results in gathering and cultivating high-end R&D talents
- Core senior management team had an average of 15+ years of work experiences in world renowned multinational companies
- Team's project experience continues to grow, with an average of 30+ projects per core member of the ADC team



- Core technical team refers to CDMO team members at manager level or above
- Senior management team refers to director and above

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Future Prospects

04

Future Prospects

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1. Focus on the core business

- Focus on biological drug CDMO business to promote more projects
- Continuously enhance Pusintin® market share and expand international influence

2. Accelerate the expansion of overseas business

- Further penetrate overseas markets
- Practice “TOT Quality” with international standards, deepen cooperation with international leading pharmaceutical companies to help expand overseas markets

3. Strengthen the position of biological drug CDMO

- Continue strengthening international quality system
- Deepen cutting-edge technology platforms to expand competitive advantage
- Continuous talent introduction and cultivation to enhance the team's ability to undertake projects

4. Financial goals

- Lean management and expand scale effect
- Profitability and cash-generating capacity continue to improve
- Annual operating income exceeds RMB1 billion
- Achieve full-year profitability

Corporate Vision, Mission, and Values

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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

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Financial Review

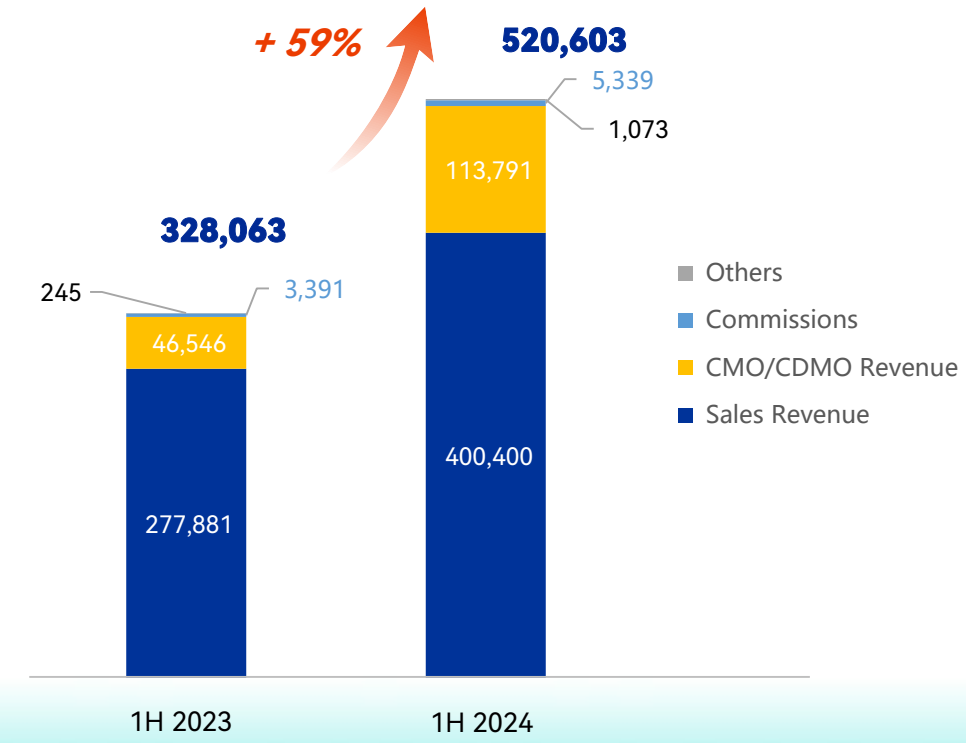
Financial analysis of 1H 2024

05

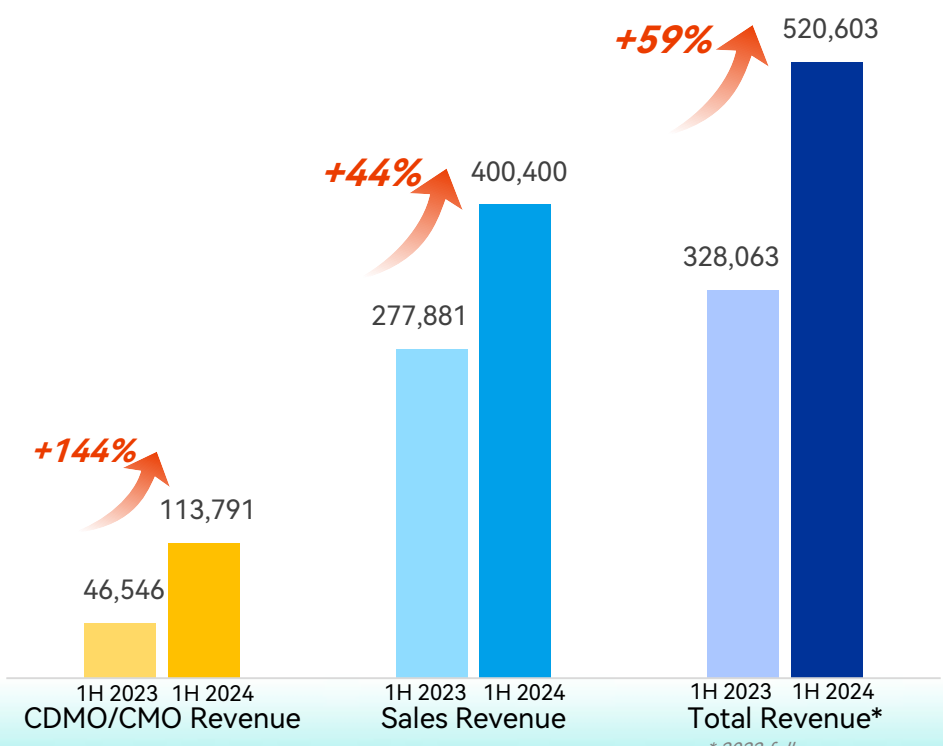
Continuous Significant Revenue Increased and Profitable

- Revenue amounted to RMB 521 million, representing a YoY increase of 59%
- CDMO/CMO revenue was RMB 114million, representing a YoY increase of 144%
- Revenue from sales of products was RMB400 million, representing a YoY increase of 44%, mainly due to the continuous increase in the sales volume of our core product Pusintin®

Income Distribution



Revenue Distribution



** 2022 full year revenue excludes revenue from license granted*

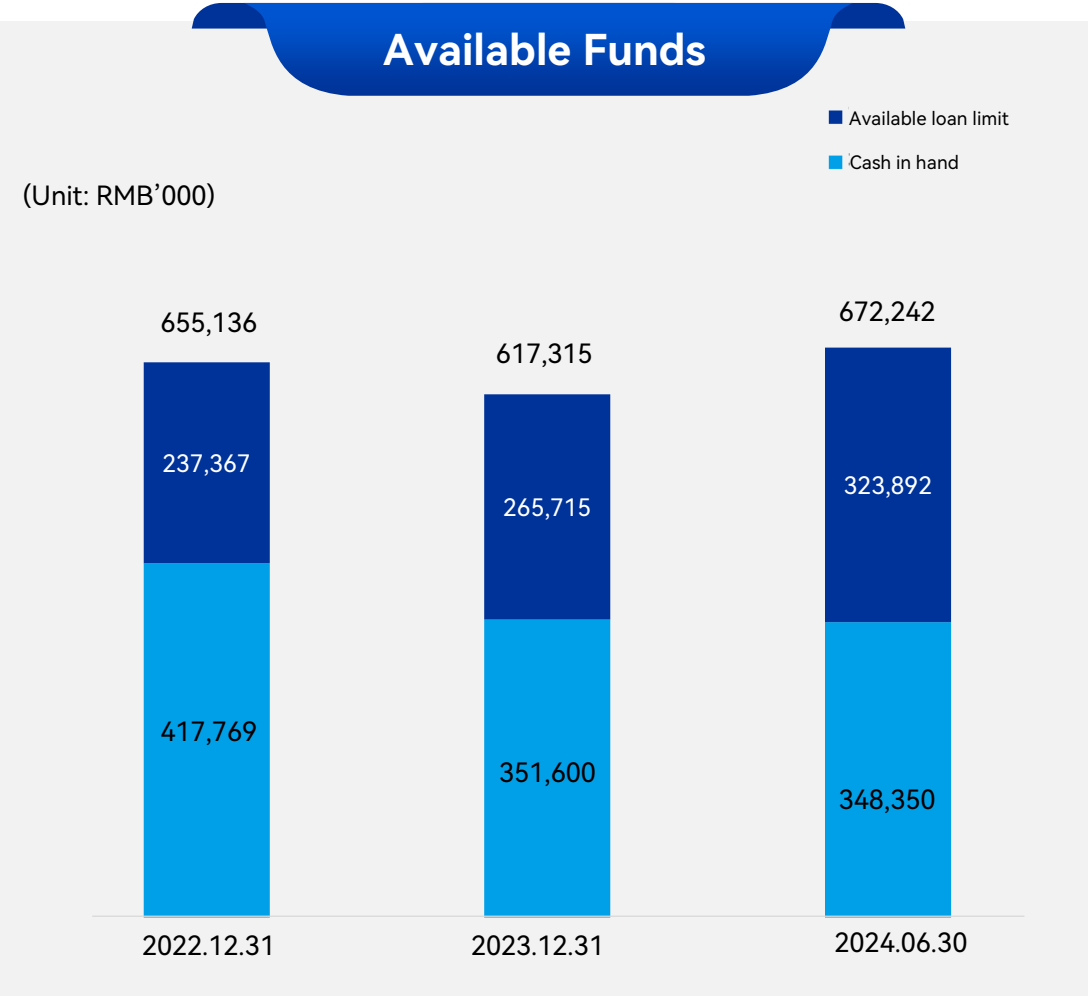
Key Financial Data_Statement of Profit or Loss

(Unit: RMB'000)

Item	1H 2024	1H 2023	+/−
Revenue	520,603	328,063	59%
Cost of revenue	(143,695)	(78,060)	84%
R&D expense	(46,059)	(49,969)	-8%
Selling expense	(276,482)	(197,376)	40%
General and administrative expenses	(32,105)	(31,104)	-
Impairment write-backs on financial assets	9,451	480	1869%
Other income and expenses	1,545	13,390	-88%
Operating profit (loss)	**33,258**	**(14,576)**	**NA**
Net financial income and expenditure and investment gains and losses	(1,699)	(587)	189%
Net profit (loss)	**31,559**	**(15,163)**	**NA**

- **Revenue:** primarily attributable to the significant increase of CDMO/CMO business segment; and the steady increase in the sales volume of our core self-developed product
- **Cost of revenue:** the expansion of CDMO/CMO business; and the corresponding operating costs along with the increase of product sales
- **Selling expense:** mainly attributable to the increase in sales of self-developed products, the increase in marketing and promotion expenses resulting therefrom, and the increase in CDMO business development personnel.
- **Impairment write-backs on financial assets:** mainly attributable to the recovery of amounts from previous years, which led to the reversal of impairment losses provided.
- **Financial income and losses:** mainly attributable to government grants and the impact of fluctuations in foreign currency.

Continuous Solid Cash Security



- Benefit from the strategic transformation and efficient cost management, the available funds are in a good position
- Balancing capital expenditures with available funds to lay the solid foundation for company's sustainability

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Thank you!

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