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

2024 Annual Results > Corporate Presentation

12 March 2025

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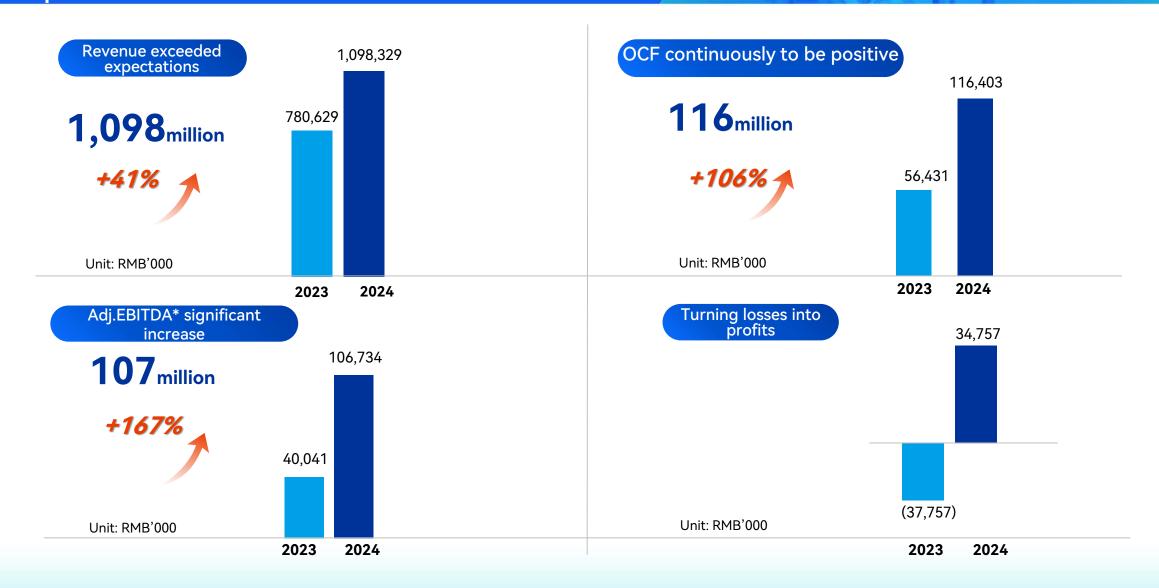


Performance > Review 2024 Business Highlights



Performance Review in 2024 - Revenue for the Year Exceeding
RMB1 Billion, Demonstrating Stable and Sustainable Cash-generating
Capabilities







Globally Recognized CDMO Service Provider







01 Continued strengthening of the international quality system

- Maintain the CN/US/EU GMP standard quality management system, has been widely recognized by the industry
- Obtained PMDA in Japan, marking a new milestone for its CDMO service in Japan
- In 2024 alone, received 38 GMP audits in total, including 7 official GMP audits and 2 EU QP audits



02 Committed to developing specialized technology platforms tailored to customers' needs

- Jointly developed the ADC site-specific conjugation technology platform-GL-DisacLink® with GlycanLink (糖 岭生物) to deepen the exploration, expand the application, and continue to enhance promotion
- Strategic cooperation with partners to introduce the "OS One-Step Conjugation" and HydroTrio technologies
- Self-developed BDKcellTM cell line platform significantly boosts the expression levels of bispecific antibodies, achieving levels of up to 12g/L, It has already supported the development of multiple antibodies
- Committed to build a comprehensive one-stop service platform for antibodies, proteins, and drug conjugates

03 Further strengthened capabilities of CDMO team

- To meet the rapid growth of CDMO business, 75% of the CDMO team members had a bachelor's degree or higher, reflecting our progress in upgrading the team's educational level
- ADC CDMO team members increased by 17% YoY, with 85% holding master's or doctoral degrees
- Senior management team had an average of 15⁺ years of work experiences in world renowned multinational companies

04 Extensive project experience recognized by the market

- 58 newly added projects in 2024, accumulating to 153 projects
- 2 newly added ADC pre-BLA projects (total of 8), successfully locked future commercial production
- GL-DisacLink * technology strengthened frontend project acquisition capabilities, enabling the signing of multiple overseas orders
- Volume of clinical-stage orders associated with overseas has shown sustained growth
- Multiple assistances with customers to complete overseas partner multinational pharmaceutical company inspection and successful authorization
- Number of visits by domestic and foreign customers increased continuously, further expand the brand's influence



















Pusintin® Sales Continue to Grow, Contributing Stable Cash Flow



Product: Pusintin®

Target: VEGF

Drug Specification: 100mg(4ml)/ vial

Indication

Annual sales volume as compared with 2023





Domestic: remarkable results achieved with differentiated marketing strategies

Addressing unmet market needs and expanding market share, thereby establishing a strong foundation for being included in centralized procurement catalogue

Overseas: steady expansion

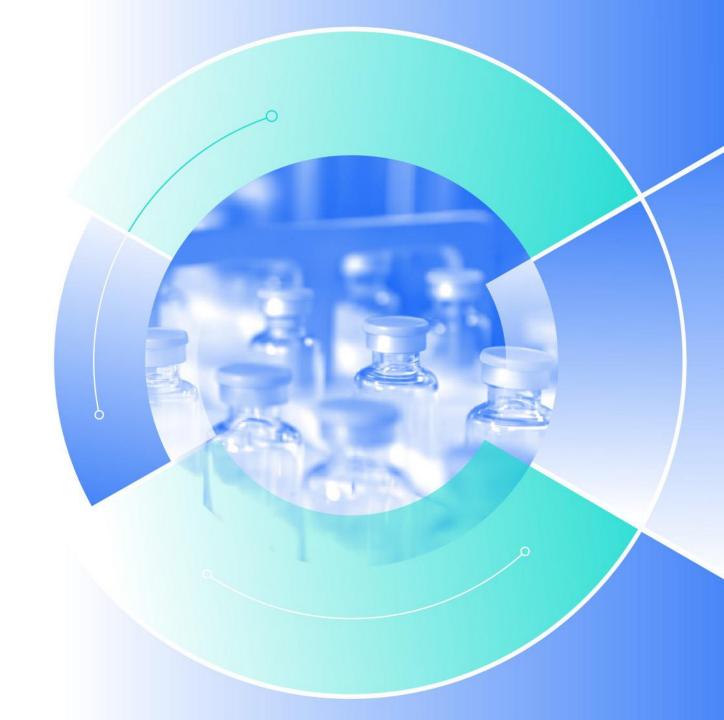
Initiated the registration application in 34 overseas countries, accepted by 20 countries
Products have obtained GMP certificates from countries including Colombia, Egypt, and Indonesia First overseas approval expected in 2025

Ten-Billion-Dollar Drug Market Potential

Global market size of bevacizumab is expected to reach USD7.2 billion by 2030 Market size of bevacizumab in China is expected to grow to USD2.6 billion CAGR in China will significantly outpace the global average



Business Development CDMO Performance Highlights



CDMO Segment Continued to Grow, and Revenue from ADC Projects Continued to Increase



- In 2024, revenue from CDMO was RMB207 million, representing a YoY increase of 47%, of which revenue from ADC projects (including antibody production) accounted for 86%
- Steady increase in overseas customers due to enhanced brand recognition
- 3-year CAGR reached 69%, higher than the industry average. Service backlog at hand reached RMB191 million, representing a YOY increase of 39%





- Leveraging cutting-edge technology platforms, resulting in a significant increase in early-stage projects
- 58 newly added projects in 2024 (48 were ADCs), accumulating to 153 projects
- 2 newly added Pre-BLA projects, accumulating to 8 projects

Cumulative projects by phase

Preclinical 107

Clinical 38

Pre-BLA* 8

Commercialization ~2025*

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	Clinical phase	Antibody + ADC DS/DP	*3	
RDC	IND	RDC DS/DP	*3	
ADC	Clinical phase	ADC DS/DP	*	
ADC	Clinical phase	Antibody + ADC DS/DP	*)	
BsADC	Clinical phase	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		
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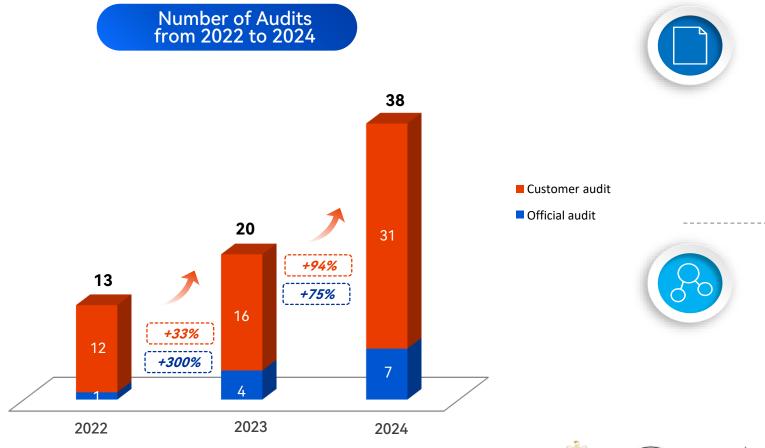






International Quality Management System, Validated through Multiple Audits, Lays a Solid Foundation for Customer Projects





A reliable quality system is a cornerstone of customer project success

- Positive audit outcomes from both customers and regulatory authorities bolstered the success of customer projects
- In 2024 alone, the Company received 38 GMP audits in total, representing a YOY increase of 90%

Positive feedback from multiple multinational pharmaceutical companies

- The Company has collaborated with customers in a number of inspections by partnering overseas multinational pharmaceutical companies and audits by institutions
- The Company has successfully collaborated with customers to secure authorizations and earned high levels of recognition















Company
Highlights
Competitive
Advantages and
Commercial Production





Biological Drug CDMO Business with Industry Barriers and Competitive Advantages



One-Stop, One-Base, End-to-End antibodies/ADC solutions with experience in commercial product production

- Continuous commercial product production experience
- 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

- Competitive advantages driven by core conjugation technology and a robust ADC analysis platform
 - A complete commercial production workshop integrating antibodies, ADC substances and drug products

04 High-end talent team

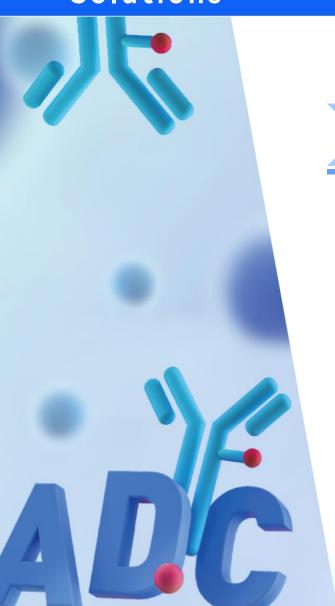
- CDMO team members accounting for 86% of the Group' workforce, and 75% hold bachelor's degrees or higher
- 85% of ADC R&D members hold master's or doctoral degrees, highlighting the Company's significant achievements in attracting and cultivating high-end R&D talents

05 Corporate reputation

High standard service, good communication and well-established project₁₂
 management system won high recognition from customers

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





- Quality system meeting GMP standards (China/US/EU)
- Passing manufacturing and GMP inspections by national 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 **Commerc** ialization

From Non-GMP to GMP production

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Antibody Modification

Cell line construction

Antibodies

- Cell bank construction
- Upstream and downstream process development/validation
- Formulation and process development/validation
- Antibody drug substances manufacturing
- Drug products filling production (including freeze-drying)

Naked antibody activation modification

Antibody intermediates

Payload and linker process research, development and production

Load linkers

(Strategic

cooperation)

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

Meeting China/US/EU quality system standards

ADC Conjugation

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

ADC Analysis and Characteriza tion

- 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



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

Domestic large-scale production lines for ADC drug substances and drug products



- 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 product: 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 5.30 million vials

A Comprehensive Service Platform that Accelerates Customer R&D Projects

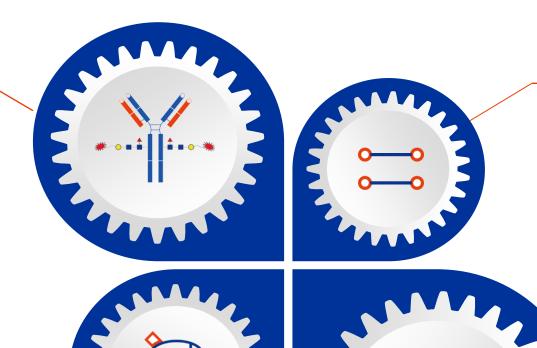


Site-specific Conjugation Technology Platform -GL-DisacLink®

- A single-enzyme, one-step reaction process that is simple, efficient, and highly controllable
- No antibody engineering required, making it applicable to various antibodies and Fc-fusion proteins

Multi-targeting Capability: HydroTrio Technology

- Introducing HydroTrio Technology: A holistic design integrating the linker + n toxins
- Compatible with site-specific conjugation technology, can be used for the preparation of ADCs with uniform and high DAR values



OS One-Step Conjugation Platform

- Exclusively introducing "OS One-Step Conjugation" site-specific conjugation technology
- Delivering fast and efficient services for early-stage research

Cell Line Platform - BDKcell™

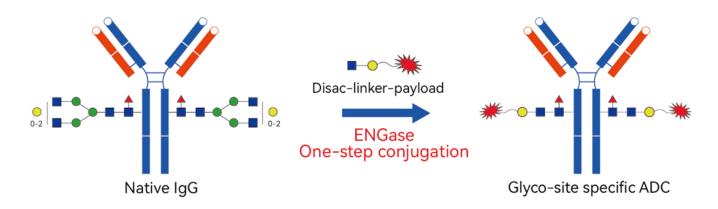
- A proprietary platform capable of delivering DNA to PCB in 10-12 weeks
- Able to provide high-yield, high-quality, and stable cell lines, with antibody expression levels reaching up to 12q/L, It has already supported the development of multiple antibodies

Site-specific Conjugation Technology Platform - GL-DisacLink®



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





- ✓ Simple and efficient: single enzyme one step reaction, complete reaction
- ✓ Compatible: no pre-conditional 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 USD7.3 billion
- Lonza acquired Synaffix to further enhance service capabilities in ADC field

Capabilities of the CDMO Talent Team were Further Strengthened



- Continued to build a core talent team and optimize the organizational structure to meet the rapid development needs of the CDMO business
- Steadily advanced the educational qualifications of team members to higher levels with a focus on building the core competencies of the team

CDMO team members accounting for 86% of the Group and 75% hold bachelor's degrees or higher



Number of ADC CDMO team members increased by 17% YoY to strengthen the business focus

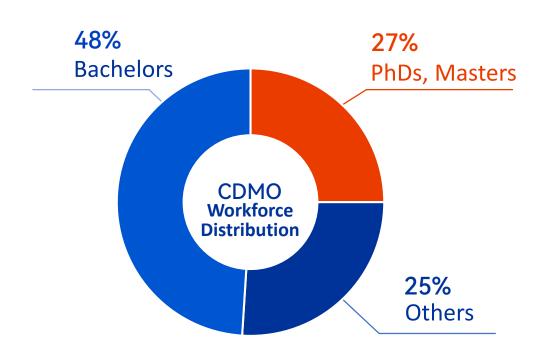


85% of ADC R&D members hold master's or doctoral degrees



Core senior management team* had an average of 15+ years of work experiences in world renowned multinational companies







Financial > Review
Financial analysis of 2024



Sustained Significant Revenue Increase and Achieving Full Profitability



- Total revenue for 2024 was RMB1,098 million, representing a YoY increase of 41%
- Revenue from CDMO/CMO was RMB207 million, representing a YoY increase of 47%

• Revenue from sales of products was RMB877 million, representing a YoY increase of 39%, mainly due to the

continuous increase in the sales volume of our core product Pusintin®







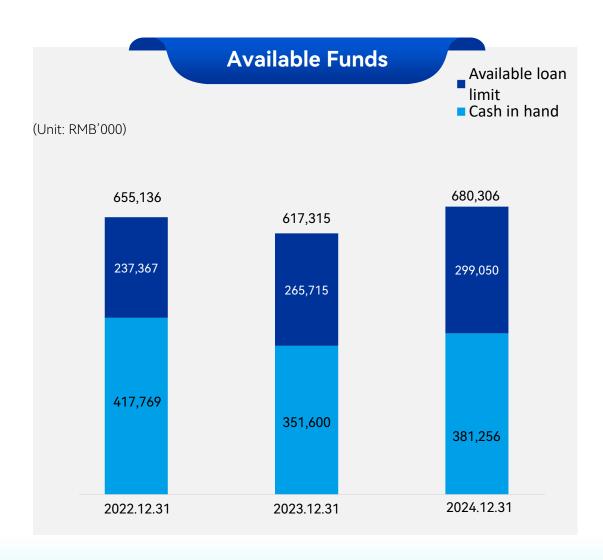
(Unit: RMB'000)

ltem	2024	2023	+/-
Revenue	1,098,329	780,629	41%
Cost of revenue	(315,897)	(206,643)	53%
Research and development expenses	(79,313)	(103,890)	-24%
Selling expenses	(606,711)	(441,019)	38%
Administrative expenses	(81,375)	(68,310)	19%
Net impairment gains/(losses) on financial and contract assets	8,005	(11,481)	-170%
Other income – net	18,216	17,654	3%
Operating profit (loss)	41,254	(33,060)	-225%
Net financial income and expenditure and investment gains and losses	(6,497)	(4,697)	38%
Net profit (loss)	34,757	(37,757)	-192%

- Revenue: mainly attributable to the steady increase of CDMO/CMO business and the sales volume of our core selfdeveloped products
- Cost of revenue: mainly attributable to the corresponding increase in costs in line with increased revenue
- Research and development expenses: mainly attributable to the streamlining of product pipelines and allocation of R&D resources to ADC CDMO process development and technological innovation
- Selling expenses: mainly attributable to higher personnel and operational costs associated for expanding market, as well as increased marketing and promotion expenses in line with the increase in sales of self-developed products
- Administrative expenses: mainly attributable to the expansion of the Company's scale and the enhancement of its management system
- Net impairment gains/(losses) on financial and contract assets: mainly attributable to the reversal of impairment on other receivables and other assets from previous years

Continuous Solid Cash Security





- Leveraging a mature business model and lean cost operations to maintain a robust available funding position
- By strategically managing capital expenditures, allocating significant resources to develop core business, and aligning investments with available funds, the Company has established a strong foundation for its long-term and sustainable development



Future > Prospects





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1. Developing multidimensional global competitiveness

- Expand overseas market
- Elevating service quality, fortify international quality management systems
- Strengthen cooperation with leading global pharmaceutical companies, and enhance international operational capabilities and market share

2. Committed to developing specialized technology platforms

- Deepen cutting-edge technology platforms to expand differentiated competitiveness
- Provide diversified technical support for customer projects

3. Committed to excellence, optimize service quality

- Optimize resource allocation, thereby enhancing market competitiveness
- Continuously attract talent, leveraging exceptional execution capabilities and extensive project experience to drive more projects to success
- Digital empowerment to improve efficiency and upgrade services

4. Lean management to improve financial performance

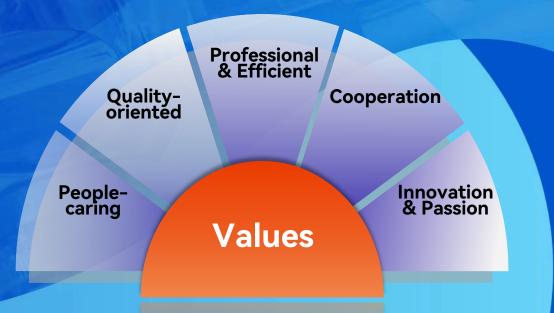
- Maintain stable and sustainable cash-generating capabilities while balancing strategic development investments
- Refine internal management processes to improve efficiency and enhance profitability





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 一奋斗成就更好的你!

Thank you! ir@totbiopharm.com

