

# **INTERIM RESULTS 2025**

19 August 2025 2509.HK



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A clinical-stage biotech company exclusively focused on biologic therapies for autoimmune and allergic diseases



#### **Exclusive Focus**

Focus on autoimmune and allergic disease therapies since our inception



#### **Full Coverage**

Cover **four major disease areas** in the fields of Skin, Rheumatic, Respiratory and Digestive diseases



#### **Huge Market**

Global market size of US\$187.5 billion in 2022 of autoimmune and allergic diseases, the secondlargest therapeutic area globally



#### **Comprehensive Pipeline**

1 product approved9 drug candidates21 IND approvalsMultiple ongoing clinical trials



#### **Advanced Development Status**

QX001S: 1st Ustekinumab biosimilar (SAILEXIN) in China (BLA approved) QX002N: for AS (Phase III) QX005N: for AD, PN (Phase III) QX004N: for Ps (Phase III)



#### In-house Manufacturing

Established commercial-scale
cGMP-standard
4 x 2,000L single-use bioreactors
~300 kg annual capacity



#### Strategic Partnership

Practical commercialization model to partner with Huadong Medicine,
Joincare and Hansoh Pharma.
Reached an agreement with Lilly Asia
Ventures and other funds for global
NewCo's cooperation



#### **Management Team**

Experienced and diverse management team led by a successful serial entrepreneur and industry veteran



# **Exclusive Focus** on Autoimmune and Allergic Disease Therapies, Covering Four Major Disease Areas And Key Therapeutic Pathways

#### mAbs bring commercial certainty; bsAbs boost efficacy and patient compliance



# Seasoned Management Team with Extensive Industry Experience And Successful Entrepreneurial Track Records





**Jiwan Qiu**Executive Director, Chairman, General Manager

**30 years of extensive R&D experience** in biotechnology industry with depth knowledge and understandings of innovation

Various entrepreneurial achievements, founded and led several antibody-focused biotech companies

**Previously founded Jiangsu T-mab,** developed 4 therapeutic biologic drugs, including LA-GCSF, anti-VEGF mAb, Denosumab biosimilar, GLP-1 analogue

Genetics and genetic engineering, Fudan University













Innovative R&D Capability: 01 Dual Engines Linking Past And Forging Future **Strategic Partnership Capability:** 02 **Future Commercialization Guarantee Self-Sustaining Operations:** 03 Stronger Financial Performance Insurance 04 **Financial Results** 

**Overview** 









### 2025H1 sales performance of SAILEXIN is encouraging

- On Oct 29, 2024, SAILEXIN, China's first ustekinumab biosimilar, was approved with rapid nationwide sales launch;
- As of June 30, 2025, Qyuns has shipped over **60,000** units to Zhongmei Huadong.



## Early stage bsAbs gradually form an innovative pipeline matrix

• As of the interim results announcement date, Qyuns has disclosed **4** innovative bsAbs, **3** of which are scheduled for IND filing within this year.



## First step for globalization: first NewCo deal, USD 555 mil in total

• In April 2025, Qyuns and Caldera have entered into an out-license agreement granting Caldera an exclusive right to develop and commercialize QX030N globally.

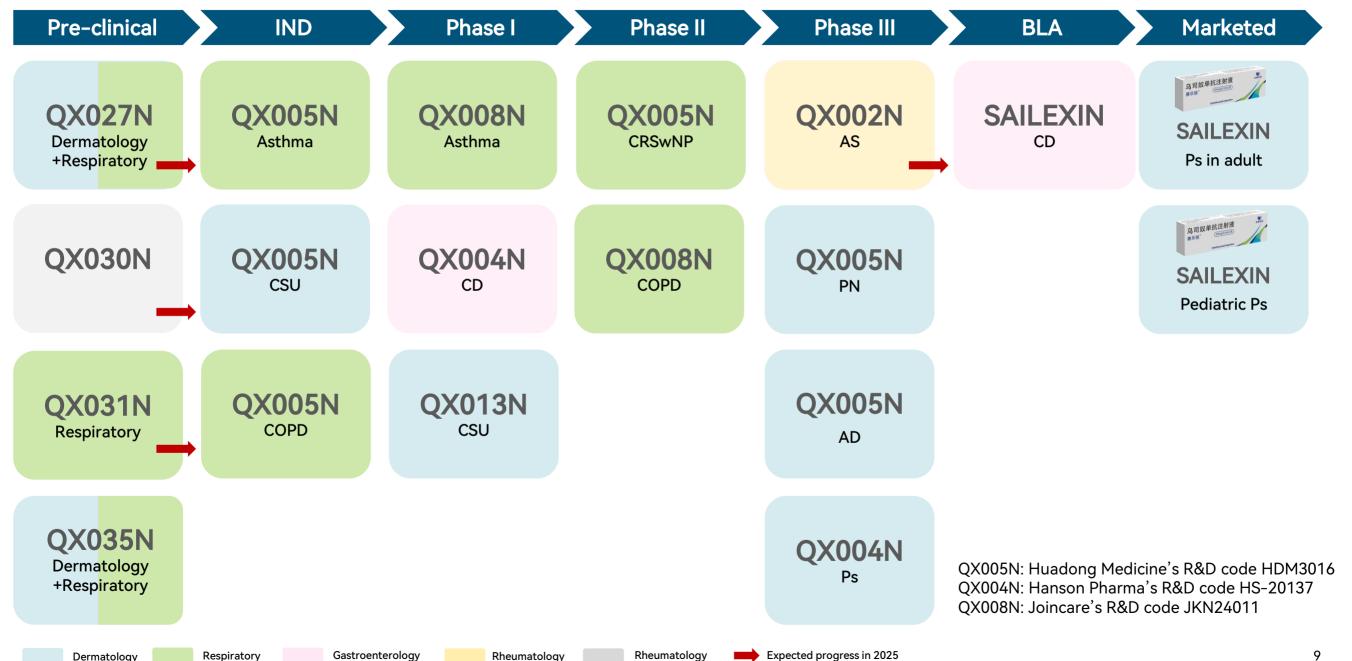


# **Comprehensive and Synergized Pipeline**





# Bridging Past & Future: MAbs for Strong Delivery; BsAbs for Innovative Portfolio





## **Expected Progress of Certain Products in The Next Three Years**

**QX002N** QX005N-PN **BLA Submission BLA Submission QX030N** QX005N-AD Phase III: Primary **CTN Submission** endpoint data (Australia) readout **QX031N QX030N IND Submission** Phase I: FPI (China and the U.S.) QX005N-PN **QX031N** QX005N-AD **QX002N** Phase III: Primary Phase I: FPI endpoint data **BLA Submission BLA Approval** readout **QX027N** QX008N-COPD **QX035N** QX005N-PN QX005N-AD **IND Submission** Phase I: FPI Phase III: FPI **BLA Approval BLA Approval** (China and the U.S.) H2 Q4 H1 H1 H2 2025 2026 2027

IND/CTN Clinical BLA BLA Submission Milestones Submission Approved

**QX027N** 

**IND Submission** 

(China and the U.S.)

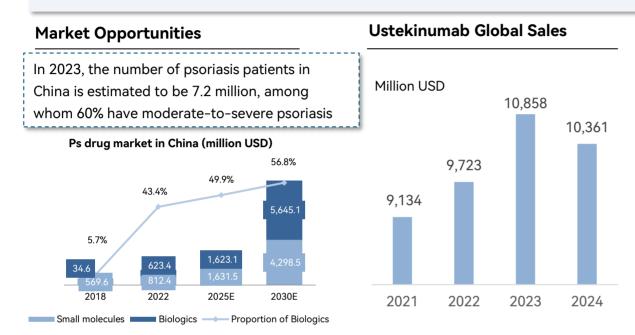
Q3

QX005N: Huadong Medicine's R&D code HDM3016 QX004N: Hanson Pharma's R&D code HS-20137 QX008N: Joincare's R&D code JKN24011

# SAILEXIN – 1st Ustekinumab Biosimilar Approved in China & Expected Blockbuster



#### **Market Opportunities and Competition**



#### **Cooperation with Huadong Medicine**





- In 2020, Zhongmei Huadong was granted the rights for joint development and exclusive commercialization of QX001S in mainland China
- We have received the upfront payment and milestone payments from Zhongmei Huadong, amounting to a total of RMB 50 million
- After offsetting the attributable loss from the commercialization of QX001S, the parties will share the cumulative pre-tax profits from QX001S on a 50:50 basis
- The strategic partnership with Zhongmei Huadong will ensure more efficient commercialization of QX001S

#### **Competitive Advantages**

#### The first marketed Ustekinumab Biosimilar in China (SAILEXIN)

- ✓ The commercial collaboration with Huadong Medicine has ensured rapid commercialization. As of 2025H1, over **1,200** hospitals have prescribed the product, and Qyuns has shipped more than **60,000 units** by 2025H1.
- ✓ Expect better accessibility than Stelara® (annual cost ~RMB16,063 for maintenance treatment) given Qyuns' manufacturing capability

#### Ustekinumab: 10+ years clinical evidences on safety and efficacy

- ✓ Higher drug survival rate: more effective than TNF- $\alpha$  and IL-17 mAbs in long term
- ✓ Convenient treatment regimen: Q12W (QX001S) vs. Q4W (IL-17A mAb)
- ✓ In Phase III clinical trial for Ps, **QX001S demonstrated clinical equivalence to Ustekinumab** in terms of efficacy, safety, immunogenicity and PK profile

#### **Clinical Development and Commercialization Process**



Source: NMPA, CDE, Frost & Sullivan

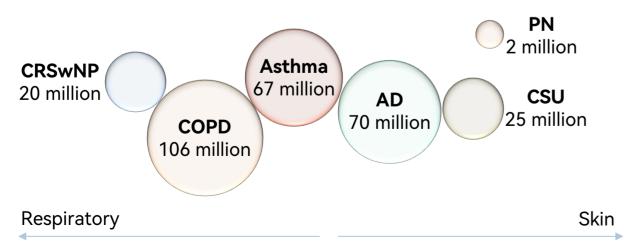
# QX005N – One of the Only Two IL-4R $\alpha$ mAbs with BTD in China



#### **QX005N**

- IL-4Rα controls the signaling of both IL-4 and IL-13, which is critical in the initiation of type 2 inflammation
- QX005N is designed to inhibit IL-4Rα, a well-validated, broad-acting target for a wide range of indications

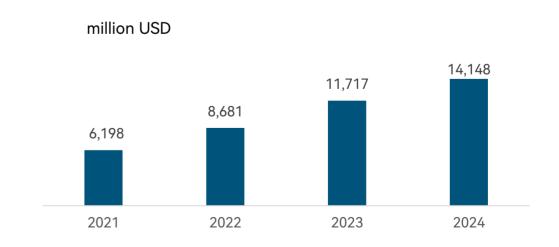
#### 2022 Prevalence of Covered Indications in China





- In July 2024, the exclusive joint development rights, exclusive commercialization options, and MAH transfer priority were granted to Zhongmei Huadong in the designated area
- Zhongmei Huadong will bear 50% of the Ph III clinical costs for the cooperative indications

#### Dupixent® Global Sales, 2021 - 2024



Source: Frost & Sullivan, Sanofi annual reports

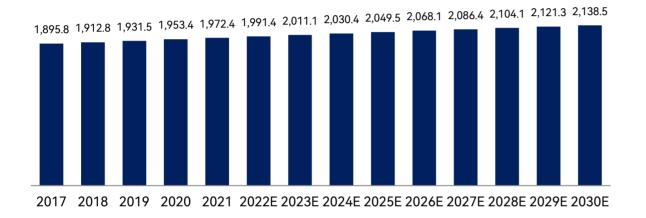
# QX005N - 1st Biologic Drug Candidate for PN Developed by Chinese Domestic Company



#### **Market Opportunities and Competition**

#### Prevalence of PN in China, 2017-2030E

Thousand



- Commonly associated with other skin diseases or underlying medical conditions that affect multiple body systems
- · Biologic drugs have become a guideline treatment option for PN

#### **Marketed Targeted Biologics for PN in China**

Brand Name	INN	Company	Target	NMPA Approval Time
Dupixent	Dupilumab	Sanofi	IL-4Ra	2023

#### **Unmet Medical Needs**

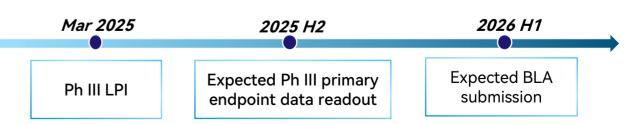
Limitation of current treatment

- Development of the PN drug market in China is still at an early stage
- Current treatment (topical steroids and topical anesthetics):
   only for limited duration due to side effects
- Lack of effective treatment
- Lack of biologic drug: **Dupixent**® is the only treatment approved by FDA and by NMPA for PN
- Dupixent® is the only biologic drug approved for PN in China

Insufficient study

- 2024.1 QX005N BTD received for PN
- In the Phase II trial, the proportions of patients achieving ≥4point improvement in WI-NRS score from baseline at Week 16
  were 76.7% (300mg), 83.3% (450mg), and 76.7% (600mg)
  respectively, all demonstrating statistically significant
  superiority over the placebo group (30%; P<0.0001)</li>

#### **Clinical Development**



Source: Company data, Frost & Sullivan

# QX005N - Treatment for Moderate-to-Severe AD

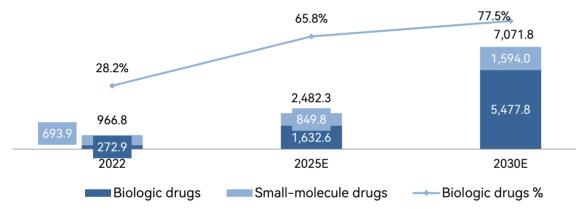


#### **Market Opportunities and Competition**

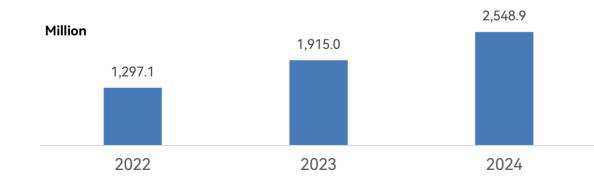
#### **Market Opportunities**

AD patients in China reached 70.3 million in 2022 and is anticipated to reach 78.5 million in 2030, 30% of which are suffered from moderate-to-severe AD.

#### AD drug market in China (million USD)



#### Sales volume of Dupilumab in China



Source: Company data, Frost & Sullivan, Menet

#### **Unmet Medical Needs**

- Systemic immunosuppressants face significant safety concerns and inadequate efficacy in the long-term treatment of moderateto-severe AD.
- Children above 6 months demand absolutely safe and effective treatment of AD

#### **Clinical Development and Commercialization**

Commercialization

- > Key products in the dermatology portfolio
- > It is expected to quickly realize its value through Huadong Medicine's channels

Phase III

- Adolescent (12-17 yrs old) and adult patients are enrolled simultaneously
- > Targeting a broader population

Phase I~II

> Good tolerability and safety, with significant efficacy

2025 Q3

2026 H1

Phase III LPI

Expected Ph III primary endpoint data readout

Expected BLA submission

2026 H2

# QX002N - IL-17A mAb for AS

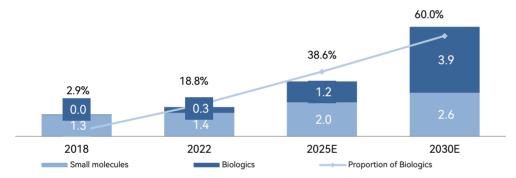


#### **Market Opportunities and Competition**

#### **Market Opportunities**

The AS patient population in China reached 3.9 million in 2022, mainly younger adults

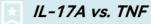
#### AS drug market in China (billion USD)



#### **Unmet Medical Needs**

- 40% of AS patients intolerant to / inadequate disease control with anti-TNF therapies
- Guided as 2L standalone treatment for AS (the same designation as TNF inhibitors) for AS patients with high disease activity after receiving first-line traditional treatments

#### **Competitive Advantages**



- ✓ Guided as 2L standalone treatment for AS, IL-17A inhibitors have shown clear clinical benefit in patients who are intolerant to or fail to achieve adequate disease with TNF- $\alpha$  inhibitors
- ✓ IL-17A inhibitors are more targeted and with generally fewer warnings and precautions
- Cost-effective in-house commercialization

#### **Clinical Development**

Phase III

> Ph III primary endpoint data read-out in Feb 2025

Data

- > **ASAS40 40.4% vs 18.9%** (QX002N vs Placebo)
- > **ASAS20 65.2% vs 41.3%** (QX002N vs Placebo)
- > Good safety



15

# QX004N - IL-23p19 mAb for Psoriasis and Crohn's Disease



IL-23p19 is currently a better target for psoriasis.

The treatment effect of psoriasis will be further improved, and it is conducive to long-term management.

#### Strategic cooperation with Hansoh Pharma







- On 24 April, 2024, Qyuns and Hansoh Pharma reached a strategic cooperation
- Under the terms of the agreement, Hansoh Pharma has paid an upfront payment of RMB 75.0 million, and shall pay potential milestone payments of no more than RMB 1,032.0 million upon the achievement of development, regulatory and sales-based commercialization milestones, plus tiered royalties on future product sales
- Recently, Qyuns has received the Ph III milestone payment and other payments for Ps
   from Hansoh Pharma in accordance with the license agreement, totaling RMB 58M

#### Same target competitor

The global sales of Skyrizi®, the same target competitor, were \$1.59 billion in 2020, \$2.94 billion in 2021, \$5.17 billion in 2022, and \$7.76 billion in 2023, with an average annual growth rate of 70.3%. At the end of 2024, its global sales reached \$11.7 billion with the annual growth rate of 50.9%.

#### **Clinical Development**

> Dec 2024: Ph I data published in JAMA Dermatology

> Mar 2025: Hansoh presented Ph II data as a late-breaking oral presentation at the 2025 AAD Annual Meeting

> **92.3% PASI 75 and 76.9% PASI 90** response rates at 16 weeks (200mg dose)

> 2024.5 Ph la completed

Ps

May 2024

> Led by Hansoh subsequently

Aug 2024

CD Ph la completed

Ph II primary endpoint data read-out for Ps

Ph III initiated

2025 Q2

# QX008N - TSLP mAb for Respiratory Diseases



- TSLP is a cytokine expressed by the airway epithelium and sits at the top of multiple inflammatory cascades
- TSLP monoclonal antibody is the only biologic drug that is independent of eosinophilic levels and reduces the exacerbation of severe asthma in a broad population

#### Same target competitor

The global sales of Tezspire®, a competitor with the same target, were \$174 million in 2022 and \$653 million in 2023, with an annual increase of 275.3%. At the end of 2024, its global sales reached \$1.219 billion with the annual growth rate of 86.7%.

Tezspire® recently received **breakthrough therapy designation** from the FDA as an additional maintenance therapy for patients with moderate-to-severe COPD.

#### **Strategic Cooperation with Joincare**



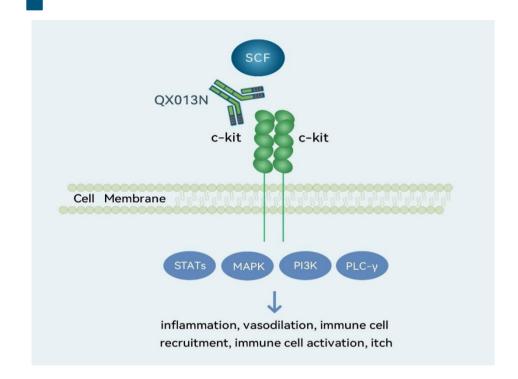




- In January 2024, we entered into a technology transfer agreement with Joincare to grant Joincare an exclusive license to develop, manufacture and commercialize QX008N in China, Hong Kong and Macau. Joincare will be responsible for the BLA application and will be the MAH of QX008N in the aforementioned area, once approved. We retain the exclusive rights to develop, manufacture and commercialize QX008N outside China, Hong Kong and Macau
- · Joincare has completed Phase II patient enrollment for COPD in China as the leading player in this field, and is expected to initiate Ph III trial in 2026H1

# QX013N - First Biologic Drug Candidate Targeting c-kit in China





QX013N is a humanized IgG1 mAb independently developed by Qyuns and is the first biologic drug candidate targeting c-kit in China. Used for the treatment of chronic spontaneous urticaria (CSU).

Mast cells are a key driver of the inflammatory response, yet current therapies focus on blocking mast cells and releasing medium, not the source.

Direct inhibition of mast cell activation and degranulation is an innovative therapy for the treatment of a variety of allergic diseases.

Potential future indications include atopic dermatitis, asthma, allergic rhinitis, etc.

#### Indication Introduction

CSU is a common chronic inflammatory skin disease characterized by the spontaneous appearance of wind masses and/or angioedema on the skin, lasting more than 6 weeks. The disease is prone to relapse and is often accompanied by a persistent itching or burning sensation, seriously affecting patients' quality of life and physical and mental health. Public information shows that 5.1 million patients in China are receiving treatment and 2 million are not under control.

# May 2024 Apr 2025 IND Clearance for CSU Ph la completed for CSU CSU

# Innovative BsAbs Portfolio: Delivering Superior Solutions for Chronic Disease Management and Marking a New Era of Company Pipeline





# **QX027N**

- Focusing on respiratory and skin diseases
- Planned IND filings in China and US in Q3 2025



# **QX031N**

- Focusing on respiratory diseases
- Planned IND filings in China and US in Q4 2025



# **QX030N**



- Undisclosed indication area
- Planned CTN submission in Australia in Q4 2025



# **QX035N**

- Focusing on respiratory and skin diseases
- Planned IND filings in China and US in Q4 2026

# Dermatology

- For AD, immediate relief of itching and skin lesions, reduction of recurrence risk, and significant prolongation of recurrence interval
- For CSU, immediate symptom relief to meet the needs of refractory patients

## Respiratory

- Strengthen disease-modifying therapy
- Delay, prevent and even reverse disease progression
- Maintain long-term efficacy and achieve the goal of clinical cure

**IBD** 

- Improve clinical and endoscopic remission rates
- Meet the needs of alternative treatment for patients who have received biologic therapies



# **R&D-Production-Commercialization Integrated Strategic Alliance**



**Early Research** 







**Clinical Development** 



**Production** 



Commercialization





Innovative structural platform for rabbit mAbs & BsAbs development



Integrated antibody structural characterization and analytical profiling platform



Ultra-sensitive PK/PD platform



10 self-developed product pipelines



21 IND approvals



Multiple therapeutic pipelines with reserve indications



Process development & pilot platform



Drug formulation screening platform



GMP production platform







#### **High Quality Antibody**

Innovative screening technology with high efficiency and success rates

Optimized antibodies with high affinity and low immunogenicity

# Comprehensive Coverage for Unmet Needs

Comprehensive multi-indications and multi-target drug therapy platform

#### **Lower Medication Costs**

High-quality, low-cost, and stable commercial production capability

#### **Higher Drug Accessibility**

Experiences in patient education, market access and academic promotion

# Strategic Cooperation: Verify Pipeline Value, Generate Cash Income, Accelerate Clinical Progress, Enhance Commercial Certainty





QX001S: strategic cooperation in Aug 2020

QX005N: strategic cooperation in Jul 2024



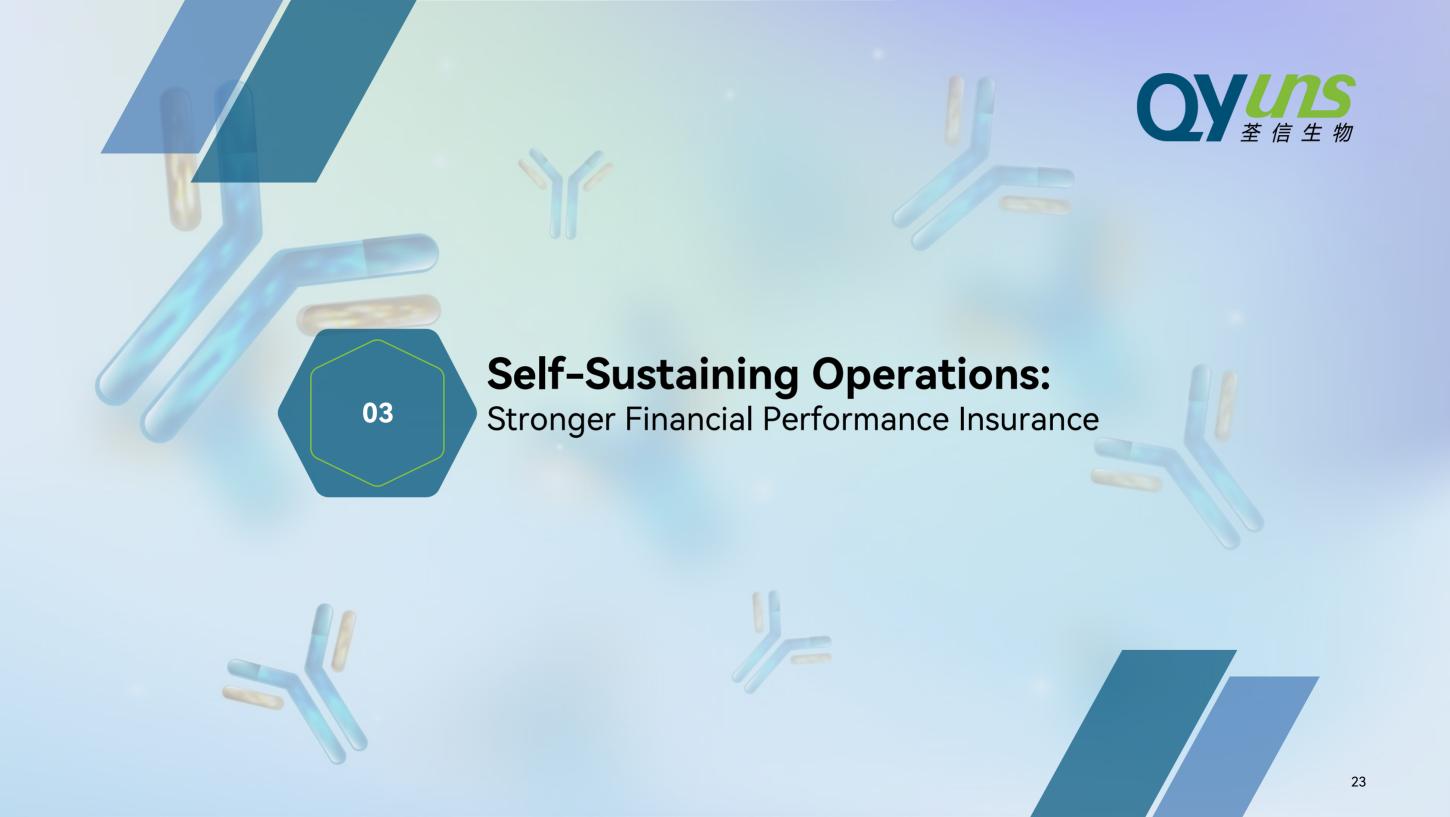
QX004N: strategic cooperation in Apr 2024



QX008N: strategic cooperation in Jan 2024



QX030N: strategic cooperation in Apr 2025



# Cellularforce:



## Commercial Scale Production Capacity Supporting CDMO Business Transformation

One of only a few Chinese biotech companies that are focused on autoimmune and allergic diseases have established **commercial-scale in-house manufacturing capability** 

cGMP-standard manufacturing facility with excelled CMC capability and quality management will secure **high quality**, **cost controllable and reliable supply of products** for clinical study and commercialization

#### Manufacturing facility

CMC capability and quality management

- 4 x 2,000L single-use bioreactors
- Approximately 300 kg annual capacity of therapeutic antibodies
- CELLULARYORGS
- Strong CMC capability to improve production efficiency
- Excelled quality management through QA and QC









# Strong Operational Cash-generating Capability Delivering Sustained Capital Reserves





**Income from BD** 

RMB 180M +

**Income from CDMO & R&D services** 

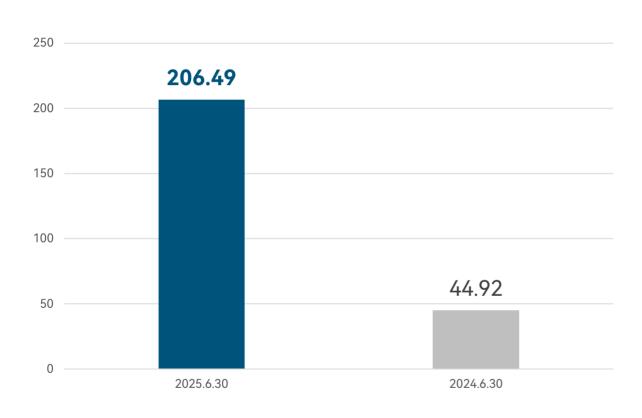
**RMB 22M +** 



# Significant Operating Income Increase further Strengthened Capital Reserves







Total Revenue in 2024 H1 and 2025 H1

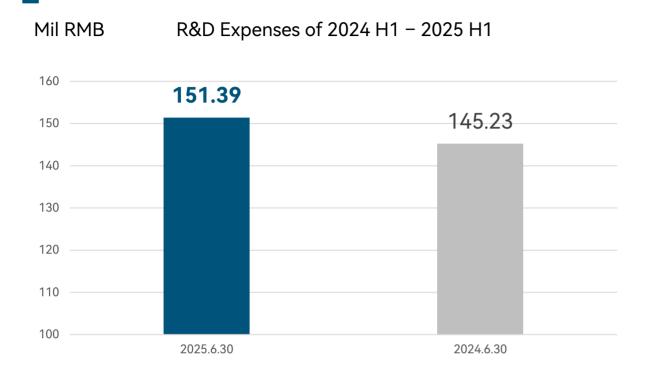
In 2025 H1, Qyuns recorded a total revenue of **RMB 206.49 million, representing 359.7% increase period-to-period.** 

In 2025 H1, company's revenue mainly derived from upfront and milestone payments from licensing agreements, provision of R&D services, and CDMO services and supply of SAILEXIN.

(million RMB)	2025.6.30	2024.6.30
Revenue	206.49	44.92

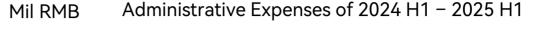
# Effective Expense Management Improves Operational Efficiency

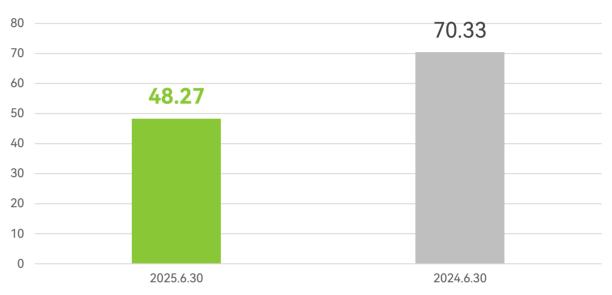




In 2025 H1, Qyuns R&D expenses amounted to RMB 151.39 million, a net effect of decrease of RMB 5.87 million in amortization of equitysettled share-based payment and increase of RMB 12.04 million in R&D expenses primarily attributable to the increase in clinical trial costs resulting from advancement of clinical trials.

(Mil RMB)	2025.6.30	2024.6.30
R&D Expenses	151.39	145.23





In 2025 H1, Qyuns incurred administrative expenses of RMB 48.27 million, 31.36% lower than RMB 70.33 million in the prior-year period, primarily attributable to a decrease in equity-settled share-based payment expenses.

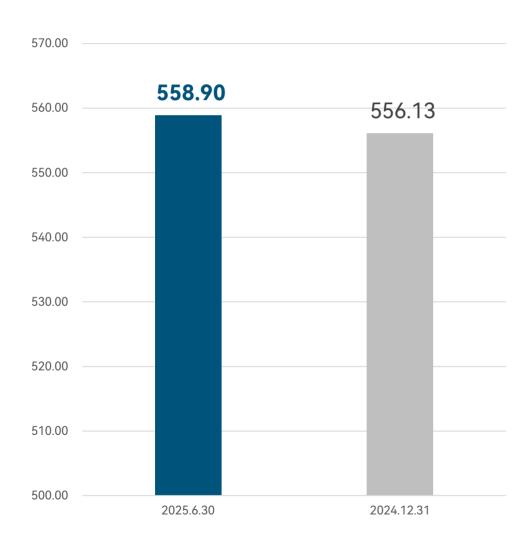
(Mil RMB)	2025.6.30	2024.6.30
Administrative Expenses	48.27	70.33

## Cash Reserves Remain Stable with Optimized Loan Structure



Cash and cash equivalents, time deposits, and financial assets at fair value through profit or loss

#### Mil RMB



**Stable cash reserves:** As of June 30, 2025, Cash and cash equivalents, time deposits, and financial assets at fair value through profit or loss amounted to **RMB 558.90 million**, an increase of **RMB 2.77 million** compared to **RMB 556.13 million** as of December 31, 2024, **indicating stable cash reserves**.

**Sufficient credit lines and optimized loan structure:** As of June 30, 2025, the unutilized credit facility for working capital use available to the Company amounted to RMB180.73 million; as of June 30, 2025, the balance of working capital loan with terms of 2 to 3 years accounted for 74.9% of the total working capital loan balance (December 31, 2024: 39.1%).

(Mil RMB)	2025.6.30	2024.12.31
Cash and cash equivalents, time deposits, and financial assets at fair value through profit or loss	558.90	556.13
Total non-current assets	453.09	367.15
Total current assets	679.06	616.73
Total non-current liabilities	465.28	332.67
Total current liabilities	451.02	430.16
Net current assets	228.02	186.56
Total equity	215.83	221.05

