Henlius 复宏汉霖

Henlius（2696.HK）1H 2023 Results Investor Presentation

August 2023

超越 共同

01 1H 2023 Business Highlights & Company Strategy

Revenue Tops 2.50B RMB with Net Profit of 240M RMB

Revenue	BD	Pipeline	Commercial Capacity	Operating Cash Flow
2.5B RMB	3	60+	48KL	0.3B RMB

Commercialization

- Achieved sustainable and profitable growth from strong sales team & effective sales management
- Over RMB 100M monthly sales from HANSIZHUANG since March 2023
- HANQUYOU maintains outstanding monthly sales exceeding RMB 200M since Q2 2023 while improving expense ratio

Business Development

- HLX10 (HANSIZHUANG) out-licensed to Kalbe in the Middle East and North Africa, with upfront payment of USD 7M and a total amount of USD 665M
- Co-develop the innovative technology platform for the potential first-in-class new drugs with HanchorBio
- HLX01 (HANLIKANG) out-licensed to Boston Oncology in Middle East and North Africa

R&D

- The latest clinical data of HLX10, HLX07 (EGFR), HLX208 (BRAF V600E), HLX26 (LAG-3), were released at the ASCO
- NMPA grants Breakthrough Therapy Designation for HLX208 (BRAF V600E)
- HLX22 (innovative anti-HER2 mAb) Phase I clinical study data published on *Investigational New Drugs*

Manufacturing

- High utilization of 48,000L total capacity, completing over 700 commercial batches
- Songjiang 1st Plant received China GMP and the EU QP certification
- Construction of Songjiang 2nd Plant is on track; total capacity expected to reach 144,000L by 2026

Financial

- Total revenue reached RMB 2.50B in 1H 2023, 93.9% YoY growth
- Total product sales reached RMB 2.15B in 1H 2023, 82.2% YoY growth
- Net operating cash inflow of RMB 330M in 1H 2023
- Net profit excl. extraordinary items reached RMB 230M in 1H 2023

Our Mission and Vision

Affordable Innovation
Reliable Quality

Biosimilars

Maximize the commercialization value in China and international markets

Innovative Drugs

Explore new mechanisms, new technology platforms and expand the therapeutic area coverage

Globalization

Develop towards a biopharma with global presence & scale

The Sales Growth of Marketed Biosimilars Accelerated; Multiple Pipeline Products Planned for Global Presence

- 1H 2023 sales revenue of biosimilars reached ~1.6 billion RMB, 44% YoY growth, exceeding the sales revenue of biosimilars in the full year of 2021
- The biosimilar pipeline covered globally popular targets such as HER2, RANKL, CTLA-4, and conduct MRCT for global market expansion
- HANQUYOU BLA was under FDA review while working with business partners to expand global markets

Pre-clinical

1

HLX17-pembrolizumab

Multiple biosimilars are under development

Clinical Trial

5

HLX05-cetuximab

HLX11-pertuzumab

HLX13-ipilimumab

HLX14-denosumab

HLX15-daratumumab

Marketed

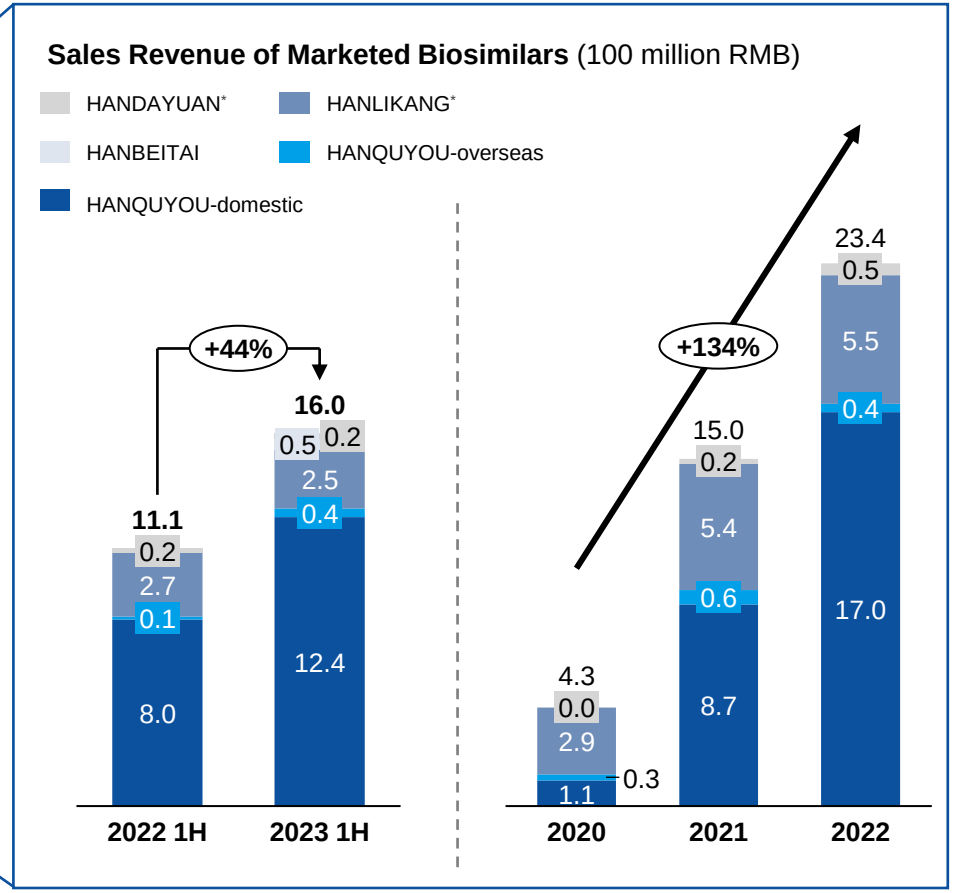
4

HANLIKANG--rituximab
First biosimilar in China

HANQUYOU--trastuzumab
First Chinese trastuzumab

HANDAYUAN--adalimumab

HANBEITAI--bevacizumab



*above are revenue reported by Henlius

With international out-licensing (ex China) and clinical trials

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HANSIZHUANG Entered into a New High-growth Stage of Commercialization with Differentiated Advantages

556M RMB

- In March 2023, HANSIZHUANG achieved over **RMB 100M monthly sales** in China for the first time, representing its commercialization stepping up into new stage
- By June 2023, HANSIZHUANG has completed tendering platform listing for **29 provinces** in China, covering about **1,500 hospitals** (focus on departments related to lung cancer, gastrointestinal cancer and etc.)

Differentiated Antibody

- HANSIZHUANG (Serplulimab) has shown a stronger affinity and slower dissociation rate[1] with PD-1, compared with peers
- HANSIZHUANG (Serplulimab) activates T cells with higher strength and longer duration through a unique molecular mechanism

Clinical Advantages

HANSIZHUANG recommended by 9 *Diagnosis and Treatment Guidelines of CSCO in 2023*

- Including *2023 CSCO Diagnosis and Treatment Guidelines* for SCLC, NSCLC, EC, CRC and Clinical Application Guideline for immune checkpoint Inhibitor etc., and brought more survival benefits to cancer patients

Differentiated Indications

ES-SCLC (marketed):

mOS: 15.8 months, a new global record

GC (Phase III):

Expected to be the world's first and the only perioperative immune drug in China for GC

LS-SCLC (Phase III):

Expected to be the world's first PD-1 for the treatment of LS-SCLC

1. Issafras H, Fan S, Tseng C-L, Cheng Y, Lin P, Xiao L, et al. (2021) Structural basis of HLX10 PD-1 receptor recognition, a promising anti-PD-1 antibody clinical candidate for cancer immunotherapy. PLoS ONE 16(12): e0257972.

R&D for Innovative Drugs: Beyond Oncology, Expanding into New TAs for UMN

Product Type & Introduction

- ✓ Total 63 molecules in pipeline with 49 innovative drugs and 14 biosimilars
- ✓ Pipeline focuses around oncology while starting to explore new TAs including Autoimmune / Ophthalmology / Metabolic / Rare Disease…

75% | **25%**

Oncology

Solid Tumor

- Breast Cancer
- Lung Cancer
- MSI-H
- Gastric Cancer
- CRC
- ESSS
- HNSCC
- NPS
- NSCC
- HCC
- …

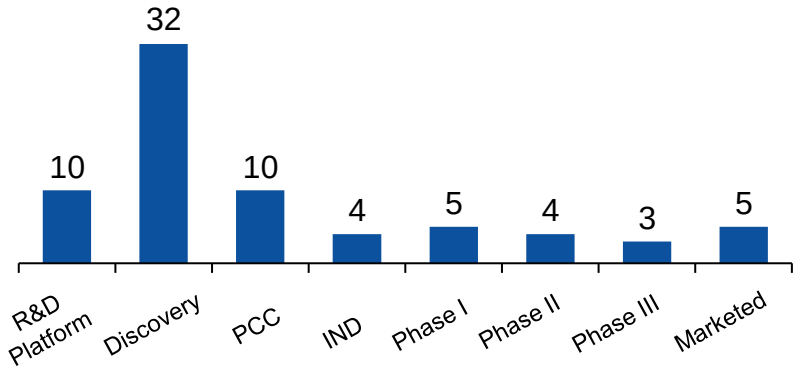
Hematology

- Non-Hodgkin Lymphoma
- Chronic Lymphocytic Leukemia
- Multiple Myeloma

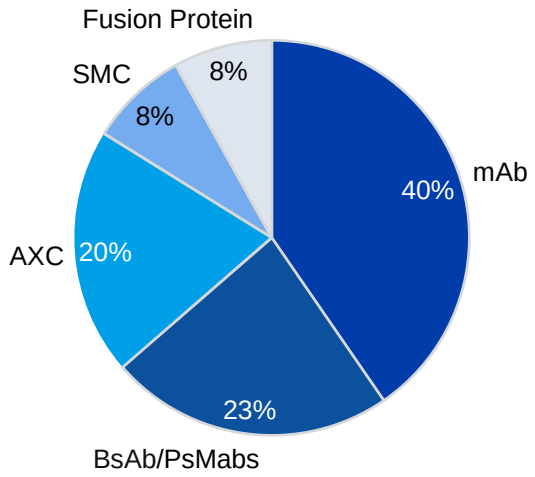
Non-oncology

Autoimmune	• IBD • PBC/PSC • SLE • RA
Metabolic	• DKD • NAFLD/NASH
Ophthalmology	• Wet AMD
Cardiovascular	• Heart Failure • HLP
CNS	• ALS/PD
Rare Diseases	• LCH/ECD • IPF

Innovative Pipeline Distribution by Stage (by Molecule)



Modality Distribution (1)



(1) SMC: Small molecule conjugates; AXC: Antibody X conjugates, including AEC, AOC & ADC

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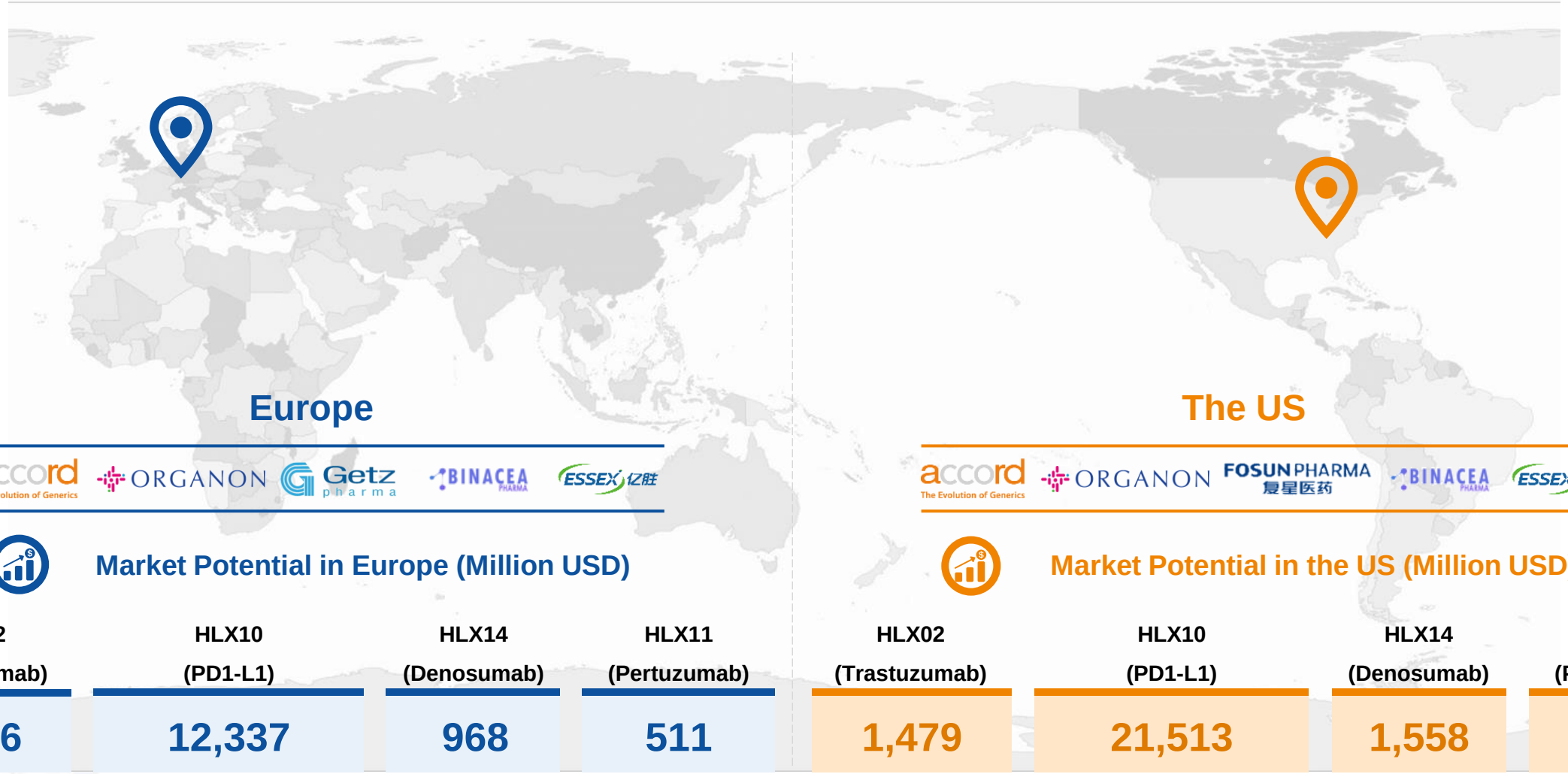
Expanding Footprints in Global Key Markets with Strategic Alliance Partners



Europe

accord The Evolution of Generics · ORGANON · Getz pharma · BINACEA PHARMA · ESSEX 亿胜

Market Potential in Europe (Million USD)

HLX02 (Trastuzumab)	HLX10 (PD1-L1)	HLX14 (Denosumab)	HLX11 (Pertuzumab)
1,146	12,337	968	511

The US

accord The Evolution of Generics · ORGANON · FOSUN PHARMA 复星医药 · BINACEA PHARMA · ESSEX 亿胜

Market Potential in the US (Million USD)

HLX02 (Trastuzumab)	HLX10 (PD1-L1)	HLX14 (Denosumab)	HLX11 (Pertuzumab)
1,479	21,513	1,558	2,554

Source: 2022 Sales revenue for the products sharing the same nonproprietary names calculated by IQVIA MIDAS

02 Commercialization

HANQUYOU (Trastuzumab): Sales Growth 57% YoY

1.28B RMB*

Revenue in 1H 2023

Zercepac® in Europe

Tuzucip® and Trastucip® in Australia

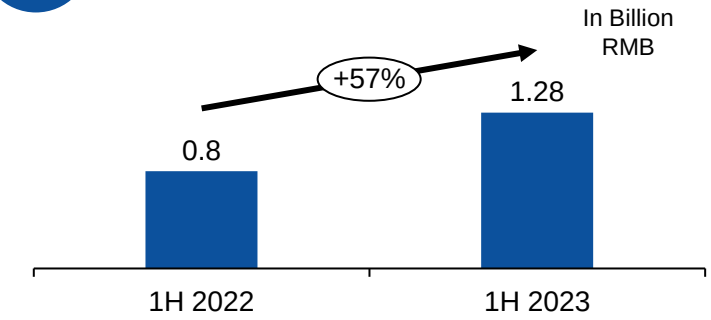
International quality

- First approved trastuzumab biosimilar in China
- First “Chinese nationality” mAb biosimilar approved in Europe
- BLA under FDA review; expected to be the first “Chinese nationality” biosimilar approved in China, Europe, and the US
- Launched in 41 countries and regions

Multiple specifications

- Tailored for HER2-positive breast cancer patients in China with flexible specs to fit with personalized dosage and reduce residual fluid waste
- No preservatives, solution preparation upon product usage to improve safety
- Improved patient medication safety and good practice for drug administration

Strong growth momentum



- 150mg specification: completed NRDL and tendering platform listing for all provinces; access to more than 87% of Top 1,000 hospitals
- 60mg specification: completed NRDL for all provinces and tendering platform listing in 29 provinces; access to more than 38% of Top 1,000 hospitals
- Commercial team with ~600 professionals, covering 6 major sales regions and ~3,700 hospitals in China

Target: HER2

Indications:

- Early stage breast cancer
- Metastatic breast cancer
- Metastatic gastric cancer

Drug Specifications:

150mg/bottle (China, Europe, Australia)

60mg/bottle (China, Europe)

420mg/bottle (Europe)

* Sum of sales revenue of HANQUYOU, drug substance of trastuzumab and Zercepac®

Excellent Performance of HANQUYOU

Higher sales per capita than domestic peers

Sales Per Capita[1] (1H 2023)

>400K RMB per month

Industry Benchmark China-based innovative biotech (~120-180K RMB per month)

The only Trastuzumab with two specifications

- 2 specifications were customized to address HER2-positive breast cancer patients medical needs in China
- Solved the issue of residual liquid storage, improving drug use safety and honing product differentiation advantage

Fast-growing market share

- Achieved ~50% of Trastuzumab market share by June 2023 in existing market in China[2]

50%

market share of Trastuzumab in China

Monthly sales over 200M RMB

- Monthly sales over 200M RMB for 4 consecutive months since March 2023:

>200M RMB per month

With steady growth

1. Sales per capita =Product sales / # of salesforce / 6 months
2. Source: Henlius internal analysis

HANSIZHUANG (Serplulimab): First Global PD-1 mAb for SCLC 1L Treatment

556M RMB

Revenue in 1H 2023

Widespread recognition

- MAA for 1L ES-SCLC indication is under EMA review
- Recommended in 2023 CSCO treatment guidelines for SCLC, NSCLC, EC etc.
- Released 1L ESCC Phase III clinical data at the ASCO Annual Meeting

Efforts to product accessibility

- Launched patient assistance programs to optimize treatment outcomes, with reduced economic burden and improved medication adherence for patients
- Has been covered in Huiminbao (Regional Commercial Health Insurance) of 17 regions incl. Shanghai, Fujian, Chengdu, Kunming

Differentiated strategies to seize the market

- Developed differentiated marketing strategies and focused on SCLC to rapidly increase market share and gain customer trust
- Working with business partners to create more commercial value and expand overseas market

Acceleration on market access and penetration

- Completed tendering and procurement platform listing in 29 provinces, access to 35% of 110 major hospitals
- ~550 people specialized commercial team with strong sales experience in oncology
- Built efficient distribution network, strengthening the coverage of DTP pharmacies and infusion centers

Target: PD-1

Indications:

- MSI-H solid tumor
- sqNSCLC
- ES-SCLC

Drug Specifications:

100mg/10ml/bottle

HANSIZHUANG Commercialization Highlights

First-class Commercialization Efficiency

556M RMB
1H 2023

Outstanding Achievements

- Sales outperformed most of the competing PD-1/PD-L1 since its launch in 2021
- Expected to be Tier-1 PD-1 /PD-L1 products by 2023

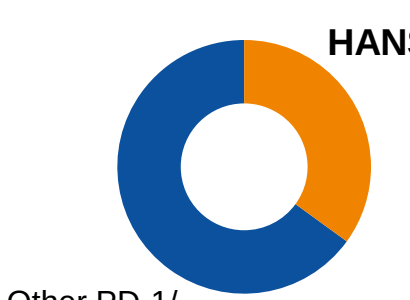
>100M RMB per month
Since March 2023
Excellent Sales

1H 2023 Sales Per Capita[1]
~210K RMB per month
Industry Leading

High Market Share Driven by Differentiation Strategy

Differentiation Strategy Focus on SCLC

(15-20% of total lung cancer patients)



~35%

patients under 1L SCLC treatment in top accessible hospitals

1. Sales per capita =Product sales / # of salesforce / 6 months

HANBEITAI (Bevacizumab): Commercialization Acceleration in 2023

45M RMB

Revenue in 1H 2023

Acceleration on market access and penetration

- Covered by NRDL in 31 provinces, and completed tendering and procurement platform listing in 28 provinces
- Focus on the dual-channel markets, and enhance market recognition to drive sales growth
- Proactively seek for hospitals access in non dual-channel markets
- Proactively participate in provincial VBP programs

Exploration for new medication methods

- The only bevacizumab biosimilars with phase III clinical data on metastatic colorectal cancer in China
- Combine with HANSIZHUANG (anti-PD-1 mAb), treating on multiple tumor types in a combo therapy

Target: VEGF

Indications:

- Metastatic colorectal cancer
- Advanced, metastatic or recurrent NSCLC
- Recurrent glioblastoma
- Cervical cancer
- Epithelial ovarian, fallopian tube, or primary peritoneal cancer

Drug Specifications:

100mg/4ml/bottle

HANLIKANG (Rituximab): Strengthen the Market Leader Position

254M RMB

1H 2023 revenue recognized by Henlius

Acceleration on market access and penetration

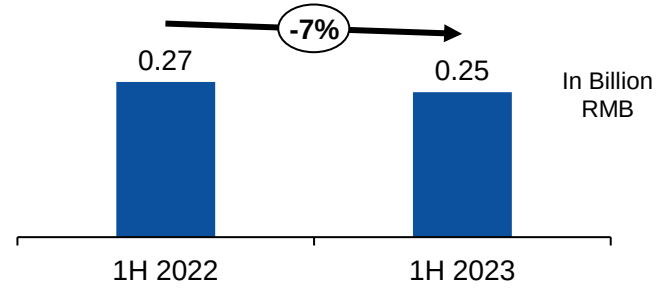
- Approved in February 2019 as the first approved biosimilar in China, the first approved rituximab biosimilar in China
- New indication approved in March 2022: the first rituximab approved for Rheumatoid Arthritis indication in China

Solid market leader position

- Market leader for rituximab in China with speedy share growth since launch
- Gained the largest market share for consecutive quarters , 47% in 1Q 2023*

Commercialization Progress

- Jiangsu Fosun, a subsidiary of Fosun Pharma, is responsible for HANLIKANG's commercialization in China
- Listed on the procurement platform in most provinces by the end of June 2023, and covered by NRDL in all provinces
- Completed in-hospital sales in 241 hospitals of the Top 300 hospitals in China by the end of June, 2023



Target: CD20

Indications:

- Non-Hodgkin lymphoma
- Chronic lymphocytic leukemia
- Rheumatoid Arthritis (RA)

Drug Specifications:

100mg/10ml/bottle

500mg/50ml/bottle

* Source: Henlius internal analysis

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HANDAYUAN (Adalimumab): Entered Autoimmune Disease Area

21M RMB

1H 2023 revenue recognized by Henlius

Improve patients' availability and accessibility

- Henlius' first autoimmune disease product
- Covered by NRDL in 30 provinces, and completed tendering and procurement platform listing in 31 provinces
- The first phase III clinical study of adalimumab biosimilar for psoriasis patients in China
- ~67,000 patients benefited since launch
- Contributed to standardize the diagnosis and treatment on ankylosing spondylitis in China through:
  - Established the *Da En Home*, a full cycle patient care platform
  - Launched *ASSC Ankylosing Spondylitis Standardized Diagnosis and Treatment Project*

Work with partners to penetrate the market

- Jiangsu Wanbang is responsible for China-region sales of HANDAYUAN. It has a sizable rheumatic immunity business unit and experienced salesforces in RA as well as a mixed line sales team
- Out-licensed the commercialization rights of HANDAYUAN to Getz Pharma in February 2022 in 11 countries, including Pakistan, the Philippines and Kenya

Target: TNF-α

Indications:

- Rheumatoid arthritis
- Ankylosing spondylitis
- Psoriasis
- Uveitis

Drug Specifications:

40mg/0.8ml/bottle

03 Business Development

HLX10 Out-licensing in the Middle East and North Africa

PT Kalbe Genexine Biologics

US$7M Upfront Payment

US$665M in Total*

HANSIZHUANG (Serplulimab)

Covering 12 countries in the Middle East and North Africa

* Included the sales milestones from the previous deal with Kalbe covering Southeast Asia regions. Total sales milestone are up to US$650M

Alliance with Strong Partner to Develop Potential FIC Products

FBD Biologics Limited[1]

Win-Win Collaboration

Co-develop innovative drugs by the new FBDB™[2] platform

Innovative Platform

Unique biologics with multiple targeting modes

Unlock the innate and adaptive immune systems to kill tumors

Improve innovative drug R&D methodology and roadmap

Global Licensing

Synergistic combination of traditional mAb and the new FBDB platform

Multi-target is more suitable for pan-tumor treatments

Overcome the pain points of traditional CPI[3] therapies

Global exclusive collaboration with high commercial potential

A potential first-in-class product

1. Hong Kong company of HanchorBio Inc.; 2. IgG Fc-Based Designer Biologics (FBDB™), biopharmaceutical platform based on Fc; 3. Checkpoint inhibitors

04 Research & Development

Product Pipeline

Pre-clinical	IND	Phase I	Phase II	Phase III	NDA	Marketed
HLX61 Undisclosed (tumor immunity) Solid tumors	HLX51 OX40 Solid tumors, lymphoma	HLX10[1] (serplulimab)+HLX60[2] PD-1+GARP Solid tumors	HLX10[1](serplulimab)+HANBEITAI PD-1+VEGF mCRC 1L	HLX10[1] (serplulimab)+chemo PD-1 ES-SCLC 1L	HLX10[1] (serplulimab)+chemo PD-1 ESCC 1L	HANSIZHUANG (serplulimab)[1] PD-1 MSI-H solid tumors, sqNSCLC, ES-SCLC
HLX6018 GARP/TGF-β1 Chronic inflammatory diseases	HLX13 (ipilimumab) CTLA-4 MEL, HCC, RCC, mCRC	HLX60 GARP Solid tumors, lymphoma	HLX10[1] (serplulimab)+HLX07 PD-1+EGFR HNSCC, NPC, GC, ESCC, sqNSCLC	HLX10[1] (serplulimab) +chemo PD-1 Neo/adjuvant treatment for GC	HLX10[1] (serplulimab)+chemo PD-1 ES-SCLC 1L	HANLIKANG (rituximab)[11] CD20 NHL, CLL, RA[12]
HLX41 LIV1 ADC Solid tumors	HLX42 EGFR ADC Solid tumors	HLX301[3] PD-L1 x TIGIT Solid tumors, lymphoma	HLX10[1] (serplulimab)+HLX26 PD-1+LAG-3 mCRC 3L+	HLX10[1] (serplulimab) +chemo +radio PD-1 LS-SCLC 1L	HLX02 (trastuzumab)[10] HER2 Breast cancer, mGC	HANQUYOU (trastuzumab)[10] HER2 Breast cancer, mGC
HLX44 Nectin4 ADC Solid tumors	HLX43 PD-L1 ADC Solid tumors	HLX53 TIGIT Solid tumors, lymphoma	HLX07[5] EGFR Solid tumors (cSCC)	HLX10[1] (serplulimab)+HANBEITAI PD-1+VEGF nsNSCLC 1L		HANDAYUAN (adalimumab)[13] TNF-α RA, AS, psoriasis, uveitis
HLX80 STEAP1 ADC Prostate cancer		HLX05 (cetuximab)[4] EGFR mCRC, HNSCC	HLX22+HANQUYOU HER2+HER2 GC	HLX04-O[7] VEGF WetAMD		HANBEITAI (bevacizumab)[14] VEGF mCRC, advanced, metastatic or recurrent NSCLC, GBM, etc.
HLX309 Nectin4 x 4-1BB Solid tumors		HLX15 (daratumumab) CD38 Multiple myeloma	HLX208[6] BRAF V600E LCH/ECD, solid tumors (i.e. MEL, thyroid cancer, mCRC, NSCLC)	HLX11 (pertuzumab)[8] HER2 Neoadjuvant treatment of breast cancer		
HLX17 (pembrolizumab) PD-1 Solid tumors			HLX208[6]+HLX10[1] (serplulimab) BRAF V600E+PD-1 NSCLC	HLX14 (denosumab)[9] RANKL Osteoporosis		
HLX314 HER2 x Sialidase Solid tumors						
HLX92 Polypharmacology Primary sclerosing cholangitis, Primary biliary cholangitis						
HLX94 Polypharmacology Amyotrophic lateral sclerosis, Parkinson's disease						

Innovative mAb | Innovative BsAb | Innovative fusion protein
mAb biosimilar | Innovative ADC | Innovative small molecule
Bridging study in the US | BLA under FDA review | MAA application in the EU
MRCT | The first Chinese mAb approved both in Mainland China and the EU

(1) IND approvals obtained in China/the US/the EU countries/Australia, etc. Approved by the NMPA in March 2022. Business partners: KGbio/Fosun Pharma. (2) IND approvals obtained in Australia. (3) IND approvals obtained in China/Australia. (4) Business partner: Shanghai Jingze. (5) IND approvals obtained in China/the US (6) Commercialization rights obtained for Mainland China, Hong Kong, Macao and Taiwan. (7) IND approvals obtained in China/Australia/the US/Singapore/the EU countries, etc. Business partner: Essex. (8) IND approvals obtained in China/the EU. Business partner: Organon. (9) IND approvals obtained in China/the EU/Australia. Business partner: Organon. (10) Approved in 40+ countries, including China, the UK, Germany, France and Australia, trade name registered in Europe: Zercepac®, trade name registered in Australia: Tuzucip® and Trastucip®. Business partners: Accord/ Cipla/ Jacobson/ mAbxi/ Eurofarma/ Abbott. (11) The first biosimilar approved in China. Business partners: Fosun Pharma/FARMA DE COLOMBIA/Eurofarma/Abbott/Boston Oncology. (12) The first rituximab approved for the indication in China. (13) Business partners: Wanbang/Getz Pharma. (14) Business partner: Eurofarma.

Clinical Pipeline Milestones: 1H 2023 Review

1H2023

NDA/BLA/MAA Submission

HLX10
ES-SCLC[1]
1L (EU)

Key Clinical Data Readouts

HLX10
sqNSCLC[2]
Final OS results
1L (Pivotal)

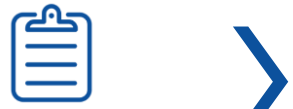
HLX07+HLX10
ESCC[3]
1L, 2L and late-line (PoC)

HLX208
BRAF V600E
LCH/ECD[4] - 22pts

Innovative mAb
Innovative small molecule

1. Extensive stage small cell lung cancer
2. Squamous non-small cell lung cancer
3. Esophageal squamous cell carcinoma
4. Langerhans cell histiocytosis (LCH) and Erdheim-Chester disease (ECD)

Clinical Pipeline Milestones: 2023-2024 (expected)



NDA/BLA/MAA Submission

Key Clinical Data Readouts

	2H2023	2024
NDA/BLA/MAA Submission	**HLX10** nsNSCLC[1] 1L (CN)	**HLX10** ES-SCLC[2] 1L (US) **HLX04-O** Wet AMD[3] 1L (CN) **HLX11** Breast cancer Neoadjuvant therapy (US) **HLX14** PMOP[4] (EU & US)
Key Clinical Data Readouts	**HLX10** nsNSCLC 1L (Pivotal) **HLX07+HLX10** sqNSCLC[5] (Stage 3) 1L (PoC in CN) **HLX10** nsNSCLC 1L- Final OS results (Pivotal) **HLX208** BRAF V600E LCH/ECD[6] - 30pts **HLX22+HLX02** GC[7] 1L- Part B mPFS (PoC) **HLX07+HLX10** ESCC[8] 1L, 2L and late-line (PoC) **HLX10** mCRC[9] 1L (PoC) **HLX07** ESCC 1L and late-line	**HLX10** ES-SCLC 1L (US bridging study) **HLX208** BRAF V600E LCH/ECD - 30pts **HLX07+HLX10** NPC[10] 1L (PoC in CN) **HLX11** Breast cancer Neoadjuvant therapy (Pivotal) **HLX04-O** Wet AMD 1L (Pivotal in CN) **HLX14** PMOP (Pivotal)

1. Non-squamous non-small cell lung cancer
2. Extensive stage small cell lung cancer
3. Age-related macular degeneration
4. Postmenopausal osteoporosis
5. Squamous non-small cell lung cancer
6. Langerhans cell histiocytosis (LCH) and Erdheim-Chester disease (ECD)
7. Gastric cancer
8. Esophageal squamous cell carcinoma
9. Metastatic colorectal cancer
10. Nasopharyngeal carcinoma

Innovative mAb | Innovative small molecule | mAb biosimilar

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HLX11 and HLX14: Multi-Regional Phase III Clinical Trials Ongoing

HLX11 – Pertuzumab Biosimilar

- Focusing on China, the US and Europe, the MRCT[1] plans to enrol 900 patients globally, expected to be the first globally approved Pertuzumab biosimilar
- As the sales of the originator drug was over US$4.4B[2] in 2022, HLX11 would have a considerable sales potential if globally approved as the first biosimilar

	NDA/BLA/MAA Submission[3]	NDA/BLA/MAA Approval[3]
US	2H 2024	2H 2025
EU	1H 2025	1H 2026
China	1H 2025	2H 2026

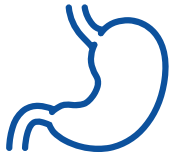
HLX14 – Denosumab Biosimilar

- As the first China-made Denosumab biosimilar aiming to be approved globally, the MRCT[1] which focuses on the US and Europe has enrolled 514 patients
- As the originator drug achieved over US$3.6B[2] sales in 2022, HLX14 will have a promising global market prospect by licensing collaboration with global MNCs

	NDA/BLA/MAA Submission[3]	NDA/BLA/MAA Approval[3]
US	2H 2024	2H 2025
EU	2H 2024	2H 2025
China	1H 2025	2H 2026

1. MRCT = Multi-Regional Clinical Trial
2. Date sources: Financial reports of the companies of the originator drugs
3. Expected timeline. The Company cannot guarantee the successful development and commercialization of HLX11 and HLX14. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

Serplulimab: Targeting Differentiated Indications



Gastric Cancer (GC)

Neoadjuvant treatment in combination with Chemotherapy / Adjuvant with Serplulimab only

Phase III clinical data readout: Q2 2025

1. According to the baseline data analysis of 649 subjects in the Checkmate, 60% advanced GC patients had CPS ≥ 5. The trial design had focused on PD-L1-positive patients (CPS ≥ 5) from the very beginning. Serplulimab aims to be **first perioperative I/O treatment in China for GC**
2. Around 2/3 of 300,000 new GC cases in China every year[1,2] were suitable for perioperative treatments. With the increasing penetration of gastroscopy examinations, more GC cases will be detected
3. Currently, the median EFS of perioperative SoC for GC is ~3 years. It is estimated that most patients can be treated with Serplulimab for up to 20 treatment cycles (the maximum duration set by the trial protocol) if the trial succeeds

Limited Stage Small Cell Lung Cancer (LS-SCLC)

Serplulimab combined with Concurrent Chemoradiotherapy (CCRT)

Phase III clinical data readout: Q1 2025

1. Globally, the incidence for lung cancer ranks #2 and the mortality ranks #1. In China, both incidence and mortality of lung cancers ranks #1. Among 820K new cases of lung cancers in China every year, 15% is SCLC. Among SCLC patents, about 30%-40% are LS-SCLC[3]
2. Phase III MRCT has begun with 222 enrolled patients, including 9 in the US, and the enrolment in Europe will start soon
3. Concurrent chemoradiotherapy (CCRT) is the SoC for LS-SCLC and globally no PD-1/PD-L1 was approved yet for this indication. **Serplulimab can potentially become the world's first PD-1 for LS-SCLC treatment** if the trial succeeds

1. Zheng RS et al. 2016 China cancer prevalence analysis. Chinese Journal of Oncololgy, 2023, 45(3): 212-220. DOI: 10.3760/cma.j.cn112152-20220922-00647
2. Strong, Vivian E et al. "Differences in gastric cancer survival between the U.S. and China." Journal of surgical oncology vol. 112,1 (2015): 31-7. doi:10.1002/jso.23940
3. Ha IB, Jeong BK, Jeong H, et al. Effect of early chemoradiotherapy in patients with limited stage small cell lung cancer. Radiat Oncol J. 2013 Dec;31(4):185-90.

HLX07: Address Unmet Medical Needs of High EGFR Expression Patients

ESCC Study Design (Phase II)

Inclusion Criteria:

- Age 18-75 years; ECOG PS 0 or 1
- ESCC or esophageal adenosquamous carcinoma
- Group A: no prior systemic antitumor therapy;
- Group B: failed first-line immuno-chemotherapy combination; ≥ 2 lines of other systemic antitumor therapy
- No prior therapy with systemic anti-EGFR antibody

Group A (1L)
HLX07, 1000 mg; Serplulimab, 200 mg; Chemotherapy
Q2W IV

Group B (≥2L)
HLX07, 1000 mg
Q2W IV

Primary Endpoints:
ORR and PFS (RECIST v1.1)

ESCC Efficacy Summary

Tumor Response[a] in Efficacy Evaluable Patients

	Group A (n=29)	Group B (n=13)
ORR, % (95% CI)	55.2 (35.7-73.6)	23.1 (5.0-53.8)
DCR, % (95% CI)	72.4 (52.8-87.3)	38.5 (13.9-68.4)

VS

SOC Efficacy Summary

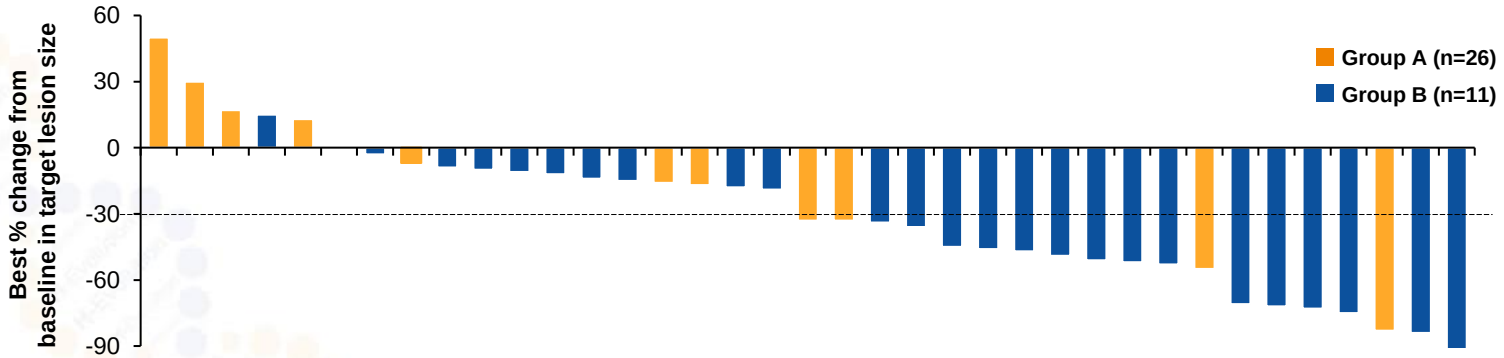
ESCC ≥2L ORR[b]:

- ICIs: 16.7%-20.2%
- CT: 21.5%

ESCC 1L ORR[c]:

- ICIs+CT: 45.0%-72.1%

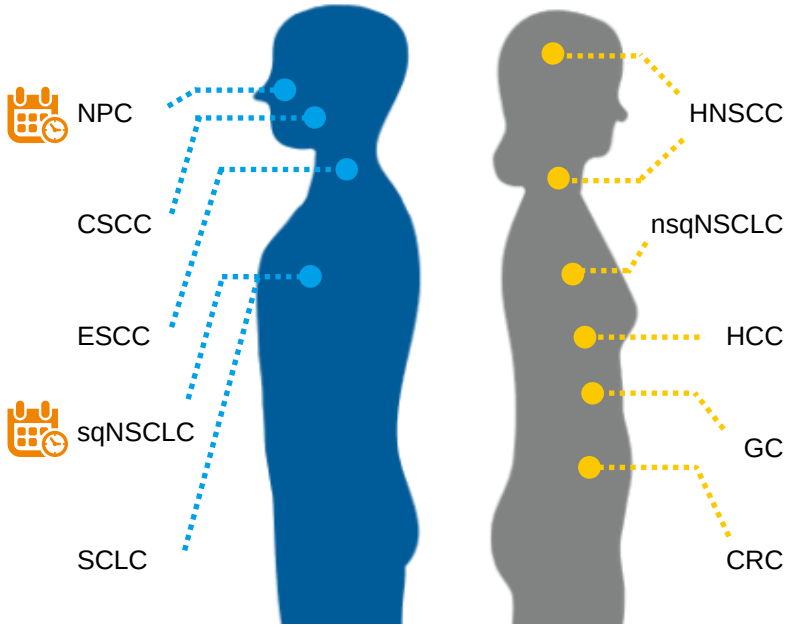
Best percentage change from baseline in target lesion size assessed by investigators



2023 American Society of Clinical Oncology (ASCO) Annual Meeting, June 2 – June 6, 2023ASCO; Data cutoff: February 4, 2023

HLX07 Indication Profile (Phase II)

10 indications have been planned:

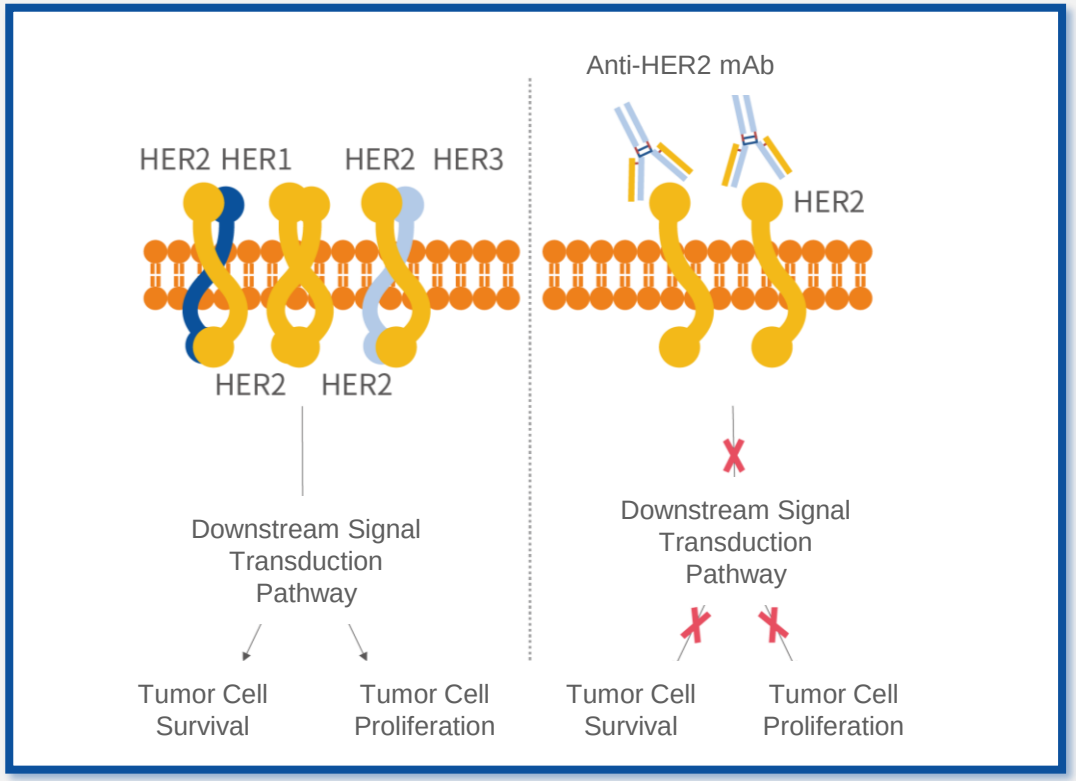


Readout date (expected): 2024 Q1

a: Unconfirmed tumor response assessed by investigators per RECIST v1.1 median follow-up duration was 2.9 months in group A and 4.0 months in group B median PFS was not reached in group A; it was 1.5 months in group B; **b**: KEYNOTE-181, ATTRACTION-3, ESCORT, ESWN 01; **c**: KEYNOTE-590, CheckMate-648, ESCORT

HLX22: Potential to Change the SOC of 1L GC

HLX22 (HER2)



- HLX22 targets at **different** epitopes within domain IV of Her2
- PDx data shows HLX22 & Trastuzumab combo has more advantages than Trastuzumab & Pertuzumab combo in GC

- Current **SOC** of 1L mGC/GJC treatment Trastuzumab + chemo approved in 2010: mPFS 6.7 months, mOS 13.8 months, and mDoR 6.9 months[1]
- Phase II study data shows HLX 22 has clear benefits for patients, leading to great potential to change the SOC

- HLX22 has shown better efficacy and safety
- Efficacy will not be affected by the expression level of PD-L1
- **No observation of severe diarrhea** which was observed in similar trials of competing products

1. Bang, Yung-Jue et al. "Trastuzumab in combination with chemotherapy versus chemotherapy alone for treatment of HER2-positive advanced gastric or gastro-oesophageal junction cancer (ToGA): a phase 3, open-label, randomised controlled trial." Lancet (London, England) vol. 376,9742 (2010): 687-97. doi:10.1016/S0140-6736(10)61121-X
2. Janjigian, Yelena Y et al. "The KEYNOTE-811 trial of dual PD-1 and HER2 blockade in HER2-positive gastric cancer." *Nature* vol. 600,7890 (2021): 727-730. doi:10.1038/s41586-021-04161-3
3. Zanidatamab (zani), a HER2-targeted bispecific antibody, in combination with chemotherapy (chemo) and tislelizumab (TIS) as first-line (1L) therapy for patients (pts) with advanced HER2-positive gastric/gastroesophageal junction adenocarcinoma (G/GEJC): Preliminary results from a phase 1b/2 study. Keun Wook Lee, Li-Yuan Bai, et al Journal of Clinical Oncology 2022 40:16_suppl, 4032-4032

4.1 R&D: Pre-clinical Assets

Antibody Drug Conjugate (ADC) R&D Platform: Hanjugator™

1. Develop differentiated ADC products: establish a new payload-linker and conjugate technology platform with proprietary IP rights
2. Increase the efficacy of ADCs: develop Multiple-Payloads ADC (MP-ADC)
3. Improve safety and therapeutic window of ADCs: build Tumor microenvironment (TME) Conditionally Released Payload-Linker (CPRL) platform
4. Enhance the selectivity of ADCs: build Tumor microenvironment (TME) Conditionally Activated Antibody (CAAb) platform
5. Expand the application scenarios of ADCs: discover new toxin and non-toxin payloads

Innovative Antibody Drug Conjugate (ADC)

HLX42 EGFR ADC

Molecular Design

- HLX42 EGFR ADC utilizes the properties of tumor tissues, and its payload-linker can be specifically released in the tumor microenvironment
- It is able to release payload extracellularly, not fully rely on endocytosis, and thus has strong bystander killing effect
- Unmet clinical needs are mainly for EGFR-positive patients who lack responses to EGFR mAb or TKIs drugs
- Potential FIC/BIC EGFR ADC drugs

Competitive Landscape

- There are currently 6 EGFR ADC-related drugs globally, most of them just entered the clinical stage (Phase I)
- Lepu Biopharma's MRG003 is the fastest in the clinical stage, and has begun the recruitment of patients of Phase II clinical trial

Key Data and Plans

- HLX42 has exhibited its strong tumor-suppressor activity and also good tolerance in multiple CDX/PDX models that are resistant to EGFR antibodies or TKIs
- Toxicology studies in rhesus monkeys have shown that HLX42 has a good therapeutic window, which is superior to previous ADC products with vcMMAE and DXD as payloads
- The IND application was accepted by NMPA in August 2023. The IND application to the FDA is expected in 2023

HLX43 PD-L1 ADC

Molecular Design

- HLX43 PD-L1 ADC utilizes the properties of tumor tissues, and its payload-liker can be specifically released in the tumor microenvironment
- It is able to release payload extracellularly, not fully rely on endocytosis, and thus has strong bystander killing effect
- Unmet clinical needs are mainly for patients with PD-1/PD-L1 non-response or drug resistance
- Potential FIC/BIC PD-L1 ADC drugs

Competitive Landscape

- Only Seagen's PD-L1 ADC has entered the clinical stage (phase I) all around the world, and its Phase I clinical trial started in Feb. 2022 for 1L patients with advanced NSCLC, HNSCC, ESCC, MEL and OC
- No IND-approved competing drug in China, HLX43 is very likely to be the first product

Key Data and Plans

- HLX43 PD-L1 ADC does not kill immune cells in blood and normal tissues
- HLX43 has exhibited outstanding antitumor efficacy in vivo models (including the models with low levels of PD-L1 expression, high heterogeneity, and non-response to PD-1/PD-L1 inhibitors) and also showed good tolerance
- Toxicology studies in rhesus monkeys have shown that HLX43 has a good therapeutic window, which is superior to previous ADC products with vcMMAE and DXD as payloads
- The IND application was accepted by NMPA in August 2023. The IND application to the FDA is expected in 2023

5D Platform Targeting Oncology, Metabolism, Immunity and Neurology

Based on the Deep Data Driven Drug Discovery (5D) platform, integrate medical informatic data to discover new targets, mechanisms and drugs targeting metabolism, inflammation, and Immune Intervention

Driven by the Biocomputing Accelerated Molecule Design (BAMD) platform, design new drug molecules such as peptides, nucleic acids, and optimize antibodies, small molecule drugs, ADC payload-linkers, etc.

Develop innovative drugs for complex diseases through network biology and polypharmacology

HLX92 (SMC)

- **First-in-class small molecule drug conjugates**
- Polypharmacology with a unique MOA
- Address unmet needs in the fields of **PSC**[1] and **PBC**[2]
- Potential breakthrough innovative drugs

HLX94 (SMC)

- **First-in-class small molecule drug conjugates**
- Polypharmacology with a unique MOA
- Address unmet needs in the fields of **ALS**[3] and **Parkinson's Disease**
- Potential breakthrough innovative drugs

HLX307 (rPro)

- **First-in-class recombinant protein products**
- Unique MOA, simultaneously lower blood glucose and improve kidney damage repair
- Good efficacy in **DKD**[4] models
- Large patient population with huge unmet needs

1. PSC = primary sclerosing cholangitis
2. PBC = primary biliary cholangitis
3. ALS = amyotrophic lateral sclerosis
4. DKD = diabetic kidney disease

05 Manufacturing

International Leading Capabilities on Manufacturing and Quality Management

- **Manufacturing capacity optimization:** The scale of commercial GMP batches has **reached a new high**
- **GMP certified in both China and the EU:** **Implement "Henlius Quality"** with international standards
- **Global expansion:** Products available in **Europe, Australia, South America and Southeast Asia**

Continuous Improvement

- **Increasing supply of HANQUYOU (Trastuzumab):** **Over 100 batches in total,** manufacturing successful rate > **98%**
- **Global GMP standards:** Well prepared for audit and inspection by **regulatory agencies across the globe**
- **Improving the laboratory infrastructure:** **Strengthen** downstream and formulation process optimization and scale-up capabilities

Scientific Optimization

- **Plant construction for Phase I & II trials:** **Acceleration** of the plant validation
- **The improved application of stainless steel equipment**: Costs reduction by process automation

Intelligent Drug Manufacturing

Operation Excellence and Continuous Innovation

Technical Innovation

- Reached key milestone of using domestic production consumables and completed **commercial scale process validation**
- Achieved the **automatic control** of cell culture in bioreactor by **Raman Spectroscopy**

Platform Construction

- **Adopted SCADA system for real-time production monitoring to achieve lean digital production**
- Optimized the satellite tank and scale-down models

Lean Operations

- **34 on-going lean operations projects** with ~10M RMB expected annualized returns
- **The batch output increased 10% compared with 2022** for Serplulimab

Supply Chain Excellence

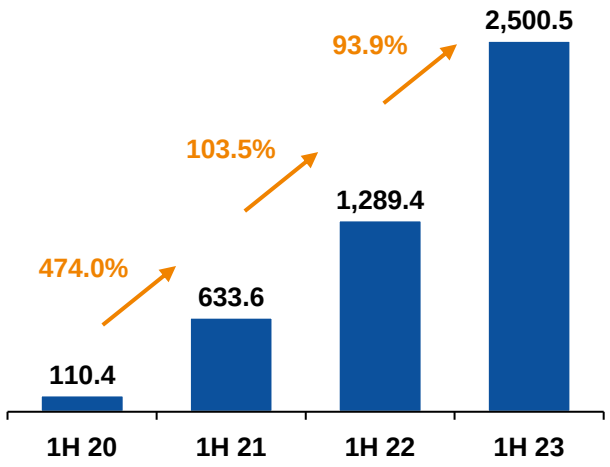
- The direct material cost was **11.4% lower than that in 2022**
- Completed the sustainability process design for supply chain and implemented risk-warning mechanism

06

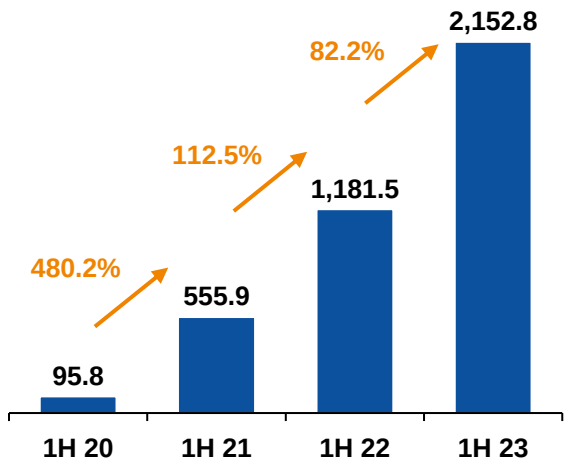
1H 2023 Financial Review

1H 2023 Revenue of RMB 2.50 Billion with 93.9% YoY

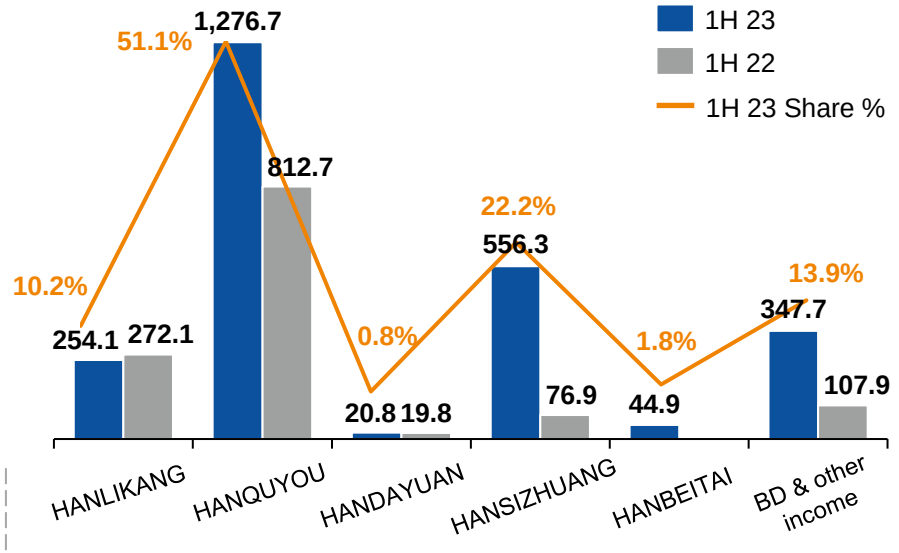
Revenue
(in Million RMB)



Product Sales
(in Million RMB)



1H 2023 Revenue Breakdown



Revenue Growth

- Revenue of RMB 2.50B in 1H 2023, 93.9% YoY growth
- Revenue growth mainly driven by: outperformed sales ramp-up of HANQUYOU and HANSIZHUANG
- Gross profit of RMB 1.78B in 1H 2023, 80.8% YoY growth

Product Sales

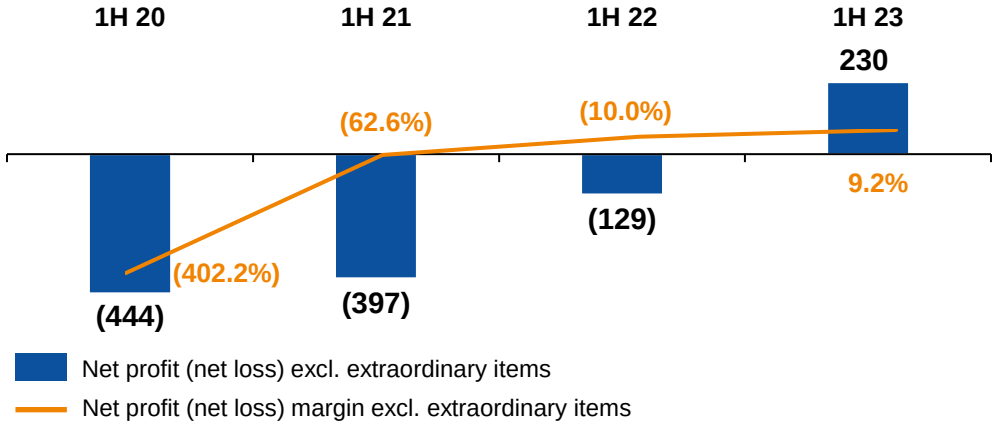
- Product sales of RMB 2.15B in 1H 2023, 82.2% YoY growth
- Product sales growth mainly from HANQUYOU sales volume open-up with additional capacity released after Songjiang 1st Plant being approved; HANSIZHUANG ES-SCLC 1L treatment was approved

Revenue Breakdown

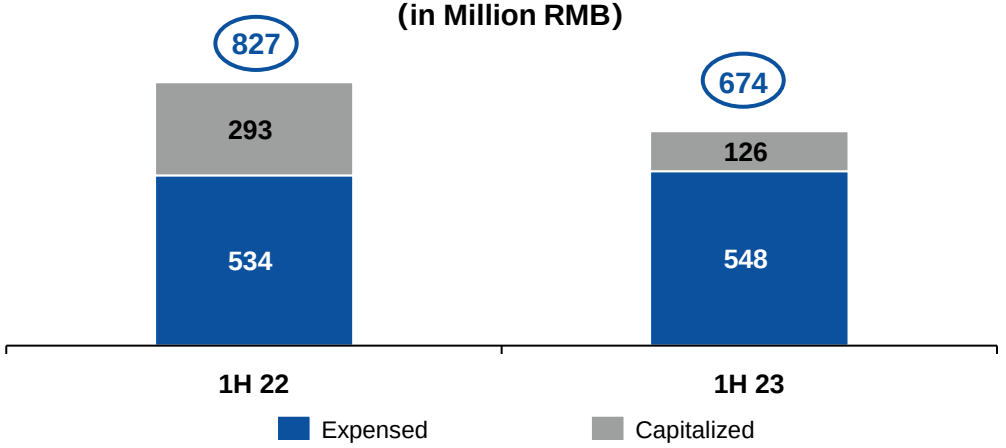
- HANQUYOU: RMB 1.28B sales in 1H 2023, 57.1% YoY growth
- HANSIZHUANG: RMB 556M sales in 1H 2023, 623.0% YoY growth
- HANLIKANG: RMB 254M sales in 1H 2023, -6.6% YoY
- HANDAYUAN: RMB 21M sales in 1H 2023, 5.1% YoY growth
- HANBEITAI: RMB 45M sales in 1H 2023
- BD and other income: RMB 348M in 1H 2023, 222.5% YoY growth

Achieved Profitability in 1H 2023 with RMB ~330M Operating CF

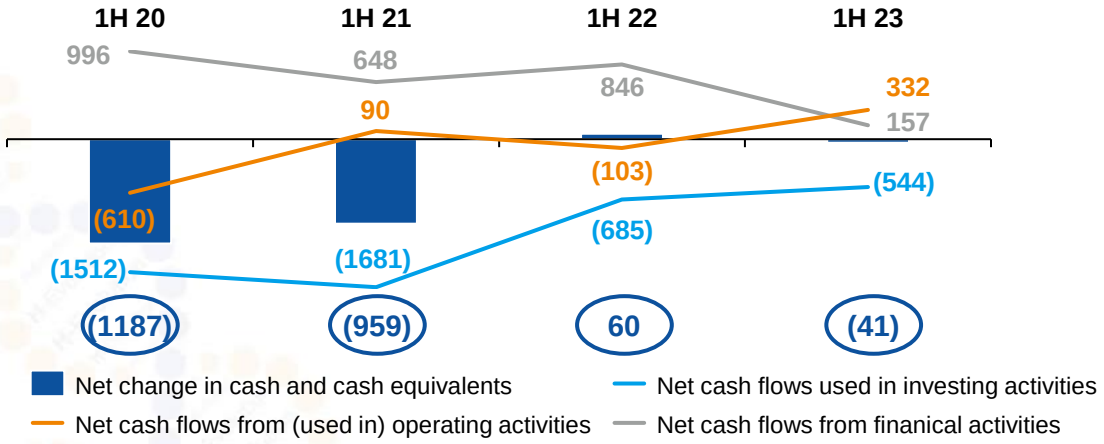
Net profit (net loss) excl. extraordinary items
(in Million RMB)



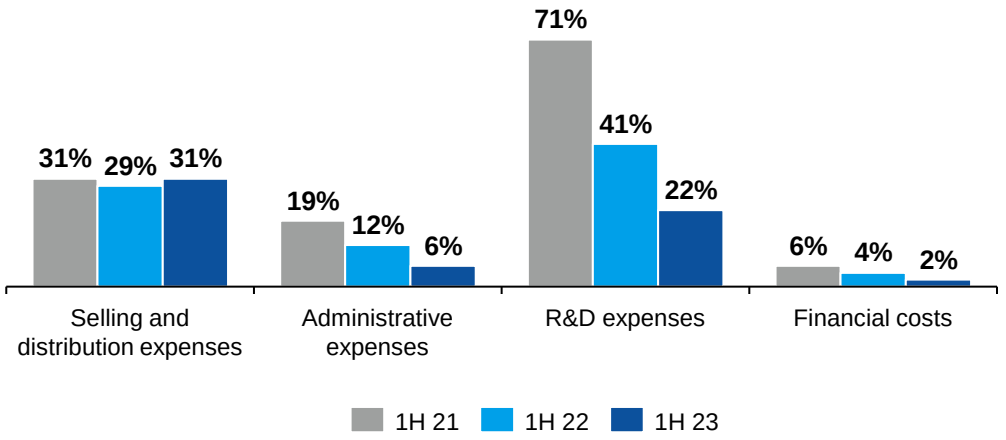
R&D investment
(in Million RMB)



Net change in cash and cash equivalents: positive OCF with RMB 332M
(in Million RMB)



Expense to revenue ratios steadily decreased

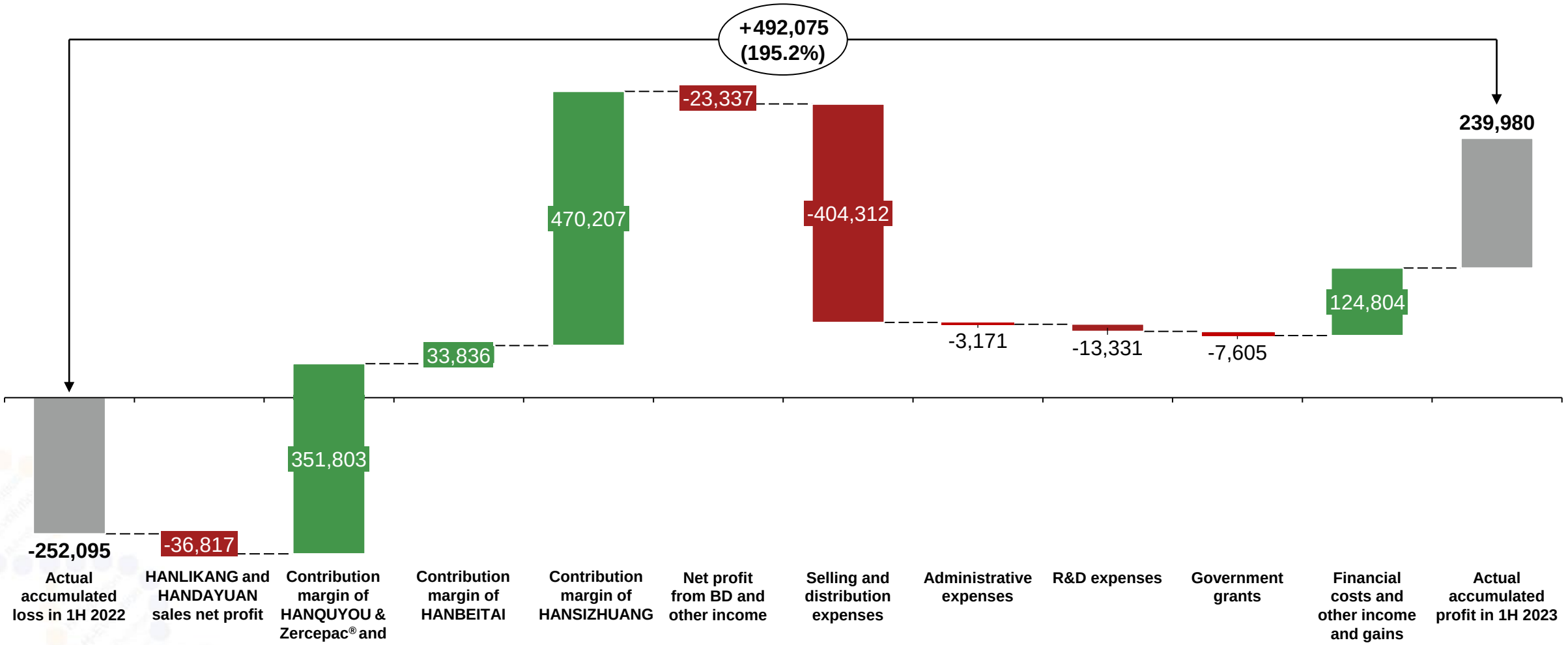


Financial Highlights

Financial Data (selected)	1H 23		1H 22		YoY Growth
Unit	In Million RMB	% of revenue	In Million RMB	% of revenue	%
Revenue	2,500.5	100.0%	1,289.4	100.0%	93.9%
Product sales	2,152.9	86.1%	1,181.6	91.6%	82.2%
BD and other revenue	347.6	13.9%	107.8	8.4%	222.4%
Cost of sales	(721.6)	(28.9%)	(305.6)	(23.7%)	136.1%
Selling and distribution expenses	(783.0)	(31.3%)	(378.6)	(29.4%)	106.8%
Administrative expenses	(163.7)	(6.5%)	(160.5)	(12.4%)	2.0%
R&D expenses	(547.8)	(21.9%)	(534.5)	(41.5%)	2.5%
Financial costs	(54.1)	(2.2%)	(51.3)	(4.0%)	5.5%
Net profit (net loss) excl. extraordinary item	229.6	10.7%	(129.2)	(10.9%)	277.8%
Net profit (net loss)	240.0	9.6%	(252.1)	(19.6%)	195.2%
Cash and bank balances	759.2	30.4%	794.7	61.6%	(4.6%)
Net cash flows from operating activities	332.5	13.3%	(103.1)	(8.0%)	422.5%

Net Profit: Turned into Profit in 1H 2023

In Thousand RMB



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07

2023 Performance Outlook

Our Goals for 2023

- **Revenue**: rapid growth driven by promoting clinical advantage of HANSIZHUANG and HANQUYOU
- **Profitability**: improve P&L level, and improve profits from internal operation
- **Cashflow:** positive OCF generated for the past two years; strengthen organic growth in 2023 and build strong and health cash flows
- **R&D**: advance late-stage pipeline faster, develop early-stage pipeline with differentiation, and introduce multiple modality assets to enter clinical stage
- **Overseas Markets**: accelerate HANQUYOU approval in the US and NDA submissions in multiple countries; advance HANSIZHUANG MAA filing in Europe
- **Resource Allocation**: optimize resource allocation, and improve return on investment of R&D, manufacturing and commercialization, to assure long-term sustainable growth

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Affordable Innovation