Henlius 复宏汉霖

Henlius（2696.HK）
2022 Annual Results Investor Presentation

March 2023

超越 共同

01

2022 Business Highlights & Company Strategy

2022 Business Highlights： Revenue Tops 3.21B RMB

Revenue	BD	Pipeline	Commercial Capacity	Operating Cash Flow
3.2B RMB	9	50+	48KL	1B RMB

Commercialization

- Growing core capabilities of commercialization with steady team expansion
- HANSIZHUANG® launched successfully with strong sales beyond expectation
- HANQUYOU® maintained high growth with improving expense ratio, despite the impact of COVID pandemic

Business Development

- 5 global out-licensing deals with over 1.5 Billion RMB upfront payment
- Biosimilars out-licensed to global partners, such as Organon, Abbott, etc.
- Co-developed 2 first-in-class assets with Palleon (founded by Nobel Laureate Carolyn Bertozzi)

R&D

- ASTRUM-005 trial endorsed by FDA & EMA, MAA submitted in Europe, will file BLA in the US
- Multiple ADC assets entered IND-enabling phase; expand therapeutic area into metabolism, neurology besides oncology
- Established in-house clinical development and registration teams in the US, Australia, etc.

Manufacturing

- Songjiang 1st Plant's 24,000L capacity was approved, removing capacity bottleneck
- Songjiang 1st Plant received China GMP and EU QP certification
- Construction of Songjiang 2nd Plant is on track; total capacity expected to achieve 144,000L by 2026

Financial

- 2022 total revenue of 3.21 billion RMB, 91.1% YoY growth
- Net operating cash inflow of 0.98 billion RMB in 2022
- Net loss excl. extraordinary items further narrowed to 525 million RMB in 2022

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 areas

Globalization

Becoming a global and scale-up biopharma company

Leading Biosimilars Business in China with International Competitiveness

Biosimilars
Innovative Drugs
Globalization

1

Strong Competency of Biosimilars business in the

International Market

- Robust biosimilar pipeline
- Commercial capacity reached 48,000L, both China and EU GMP certified
- Achieved a number of global out-licensing deals for biosimilars
- Trastuzumab was approved in 30+ countries

A Pioneer Biosimilars Leader

in China

9

9 biosimilars products pipeline, including approved products and clinical assets

2.3

Sales revenue of biosimilars* in 2022 reached

2.34B

***Note: Referring revenue recognized by Henlius instead of Fosun Pharma**

The Global Antibody Biosimilar Market Promising Outlook

- Antibody biosimilars account for more than half of the entire biosimilar market. With high potential in regulated markets like EU and the U.S., registration and market access policies also encourage biosimilars
- Chinese biosimilar market is also growing rapidly. The biosimilar price reduction by VBP is expected to be mild after the provincial VBP pilot in 2022

	Market Size of Antibody Biosimilars (22Q3 MAT)	CAGR (Past 3 Years)	Market/Region Characteristics
China	0.9B USD	175%	Market Doubled with High Potential; Rapid Substitution of the Originator; NRDL Coverage Following the Originator; Expect Moderate VBP Price Reduction
U.S.	5.7B USD	56%	Large Market Size with High Growth; Encourage Biosimilars Grow; Large Room for Drug Pricing; Quickly Peak in 3 Years
EU	6.6B USD	22%	

Data source: IQVIA MIDAS 2022 Q3 MAT

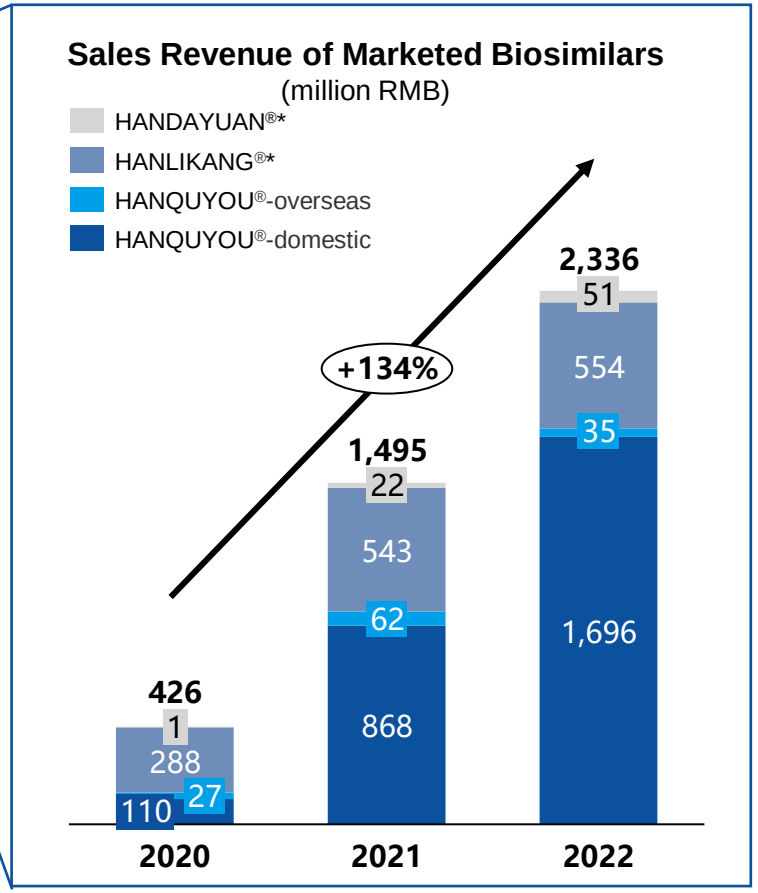
Sales Revenue of Henlius' Biosimilars Grew Rapidly

Biosimilars | Innovative Drugs | Globalization

- Successfully launched 4 biosimilars in China and abroad, sales revenue reached 2.34 billion RMB in 2022
- 5 biosimilars are in the clinical phase, mainly in oncology, osteology, and other therapeutic areas, covering targets such as HER2, RANKL, CTLA-4, etc.
- Multiple biosimilar products have been out-licensed to MNCs for overseas market development, a systematic approach to derisk R&D costs and expand brand awareness both in China and overseas

Pre-clinical	Clinical Trial	Marketed
1	5	4
HLX17-pembrolizumab	HLX05-cetuximab	HANLIKANG®--rituximab First biosimilars in China
	HLX11-pertuzumab	HANQUYOU®--trastuzumab First Trastuzumab biosimilars in China
	HLX13-ipilimumab	HANDAYUAN®--adalimumab
	HLX14-denosumab	HANBEITAI®--bevacizumab
	HLX15-daratumumab	

With overseas out-licensing



*Referring revenue recognized by Henlius instead of Fosun Pharma

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First Commercialized Innovative Drug — Serplulimab

Biosimilars
Innovative Drugs
Globalization

339M
RMB

Remarkable commercialization results —sales revenue of 339M RMB only 9 months after launch

1B
RMB

Out-licensing agreement with Fosun Pharma to grand exclusive commercialization rights of Serplulimab in the U.S., with 1 billion RMB upfront payment

Differentiated Indications

Approved Indications:

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

Applied indications:

- **ESCC**
- **ES-SCLC (EU,US)**
- **CRC**
- **GC**
- **LS-SCLC**

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

Biosimilars | Innovative Drugs | Globalization

Product Type & Introduction

- ✓ Total 57 molecules in pipeline with 48 innovative drugs
- ✓ Mainly focuses on oncology pipeline and started to explore around Autoimmune / Ophthalmology / Metabolic / Rare Disease…

81% **19%**

Oncology

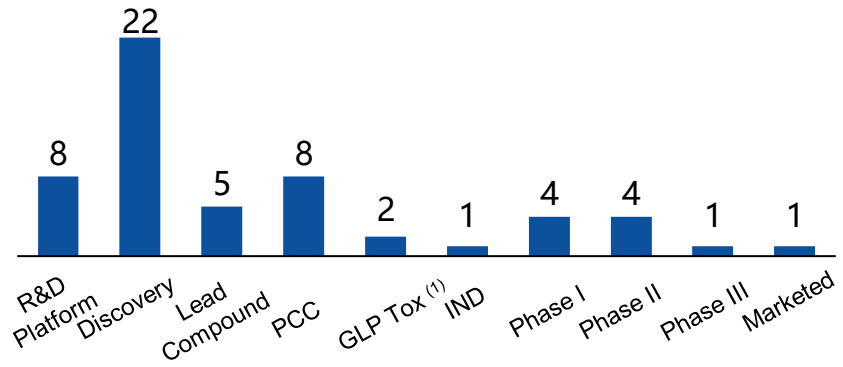
Solid Tumor
- Breast Cancer
- Lung Cancer
- MSI-H
- Gastric Cancer
- CRC
- ESSS
- HNSCC
- NPS
- NSCC
- HCC
- …

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

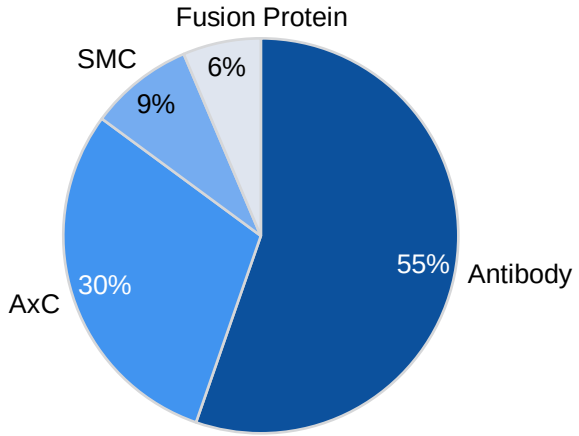
Non-oncology

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 (2)



(1) GLP Tox: Toxicological studies conducted in accordance with good practices for non-clinical research of drugs; (2) SMC: Small molecule conjugates; AxC: Antibody X conjugates, including AEC, AOC & ADC

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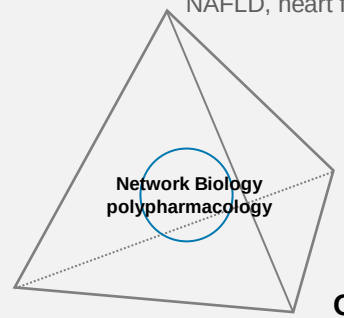
R&D Strategy: Breakthrough via Targeted Delivery and Conjugates Platform, Accelerate by Deep Data Driven and Biocomputation, and Focus on Metabolism, Immunity, Neurological, Oncology Areas

Biosimilars
Innovative Drugs
Globalization

Targeted Drug Delivery
Precision and Combo Therapy

Center around metabolism, Develop innovative drugs for complex diseases through network biology and polypharmacology



Metabolism
Diabetic nephropathy, obesity, ventilation, NAFLD, heart failure, etc.

Neural
Alzheimer's, Parkinson's, ALS, etc.

Immunity
Inflammatory bowel disease, lupus erythematosus, rheumatoid, cholangitis, etc.

Oncology
Lung cancer, breast cancer, liver cancer, colon cancer, pancreatic cancer, etc.

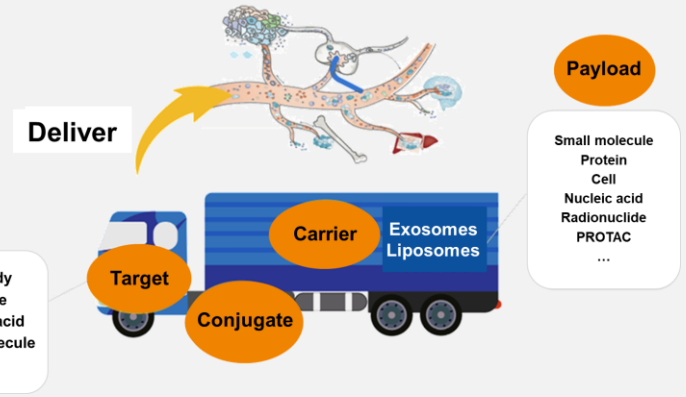
Core methodology

Deep Data Driven Drug Discovery (5D*)

&

Biocomputation Accelerated Molecule Design (BAMD*)

Linker-Centric Diversified Conjugates Platforms



* Deep Data Driven Drug Discovery (5D); Biocomputation Accelerated Molecule Design (BAMD)

Globalization: Enter into Commercialization Stage

Biosimilars
Innovative Drugs
Globalization

Europe

- Trastuzumab marketed in ~20 European countries
- MRCT phase III study of pertuzumab has been approved in Spain
- MRCT phase III study of serplulimab for LS-SCLC indication approved in EU
- MAA of Serplulimab (for ES-SCLC indication) has been submitted to EMA in 2023

US

- Trastuzumab BLA under FDA review
- Serplulimab bridging study in U.S. completed first patient dosing
- Expect to submit BLA of Serplulimab to FDA in early 2024
- MRCT phase III study for Bevacizumab (Ophthalmic indication) completed first patient dosing in the U.S.

Other Countries & Regions

- Trastuzumab approved in Australia, Argentina, Saudi Arabia and other countries
- Granted out-licensing for 4 biosimilars products in 18 Latin American countries
- Serplulimab out-licensed to KG Bio in 10 Southeast Asian countries
- Trastuzumab is expected to submit NDA applications in 14 countries in 2023

02

Commercialization

HANQUYOU®(Trastuzumab): Sales Growth 86.1% YoY, BLA Submitted to FDA

1.73B RMB

Revenue in 2022

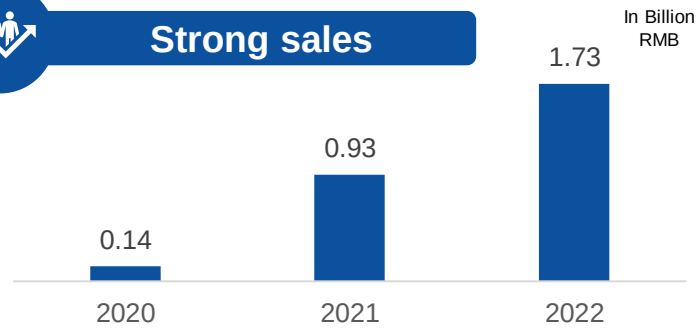
International quality

- First approved trastuzumab biosimilar in China
- First "Chinese nationality" mAb biosimilar approved in Europe
- BLA submitted to FDA; expected to be the first "Chinese nationality" biosimilar approved in China, Europe, and the US

Multiple specifications

- Designed for HER2-positive breast cancer patients in China, flexible spec combination can fit with personalized dose and reduce residual fluid waste
- No preservatives, solution preparation upon product usage to provide more safety
- Improved patient medication safety and good practice for drug administration

Strong sales



- Breaking production capacity bottleneck with the new capacity approved from Songjiang 1st plant in May 2022
- 150mg specification: completed NRDL and tendering platform listing for all provinces; access to more than 85% of Top 1,000 hospitals
- 60mg specification: since launched in April 2022, completed NRDL for all provinces and tendering platform listing in 29 provinces; access to more than 35% of Top 1,000 hospitals
- Commercial team with 560 professionals, covering 6 major sales regions and nearly 3,700 hospitals in China

Zercepac® in Europe

Tuzucip® & Trastucip ® in Australia

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)

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Excellent Performance of HANQUYOU®

Higher cost-effectiveness than domestic innovative biotech companies

Sales Per Capita

> 3.7M RMB

Industry Benchmark – Chinese Biotechs (~1.5M-2M RMB)

Sales Expenses Ratio

< 40%

Industry Benchmark – Chinese Biotechs (~57%-62%)

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

Sustained growth under COVID Pandemic

- Overcame challenges such as patient attrition and treatment delay caused by the pandemic and continued to build more market share in the trastuzumab market
- Patient enrolment of HANQUYOU increased rapidly, pt enrolled in 2H 2022 is 50% higher than 1H 2022

+50%

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

339M RMB

Revenue in 2022
(In market for 9 months)

Impressive R&D results

- Outstanding clinical data published in top medical journals, including JAMA, Nature Medicine, British Journal of Cancer

nature medicine | JAMA The Journal of the American Medical Association | BJC British Journal of Cancer

Multidimensional improvement on product accessibility

- Launched patient assistance programs to reduce the patient economic burden, improve medication adherence, and maximize treatment outcomes
- Proactively exploring Huiminbao(Urban-Customized Commercial Medical Insurance) and have been included in cities such as Zibo, Wuxi, Changzhou, Jinhua, Ningbo, etc.; greatly improved the accessibility of HANSIZHUANG for residents in these cities

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 value and expand overseas market

Acceleration on market access and penetration

- Completed tendering and procurement platform listing in 27 provinces, entered to 30% of the Top 110 hospitals
- Specialized commercial team of ~400 people with good communication skills and sales experience in oncology
- Built efficient distribution network of HANSIZHUANG®, maximizing patient accessibility through strengthening the coverage of DTP pharmacies and infusion centres

Target: PD-1

Indications:

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

Drug Specifications:

100mg/10ml/bottle

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HANSIZHUANG® Commercialization Highlights

First-class Commercialization Efficiency

339M RMB

In Market for 9 months

Outstanding Achievements

Sales outperformed most of the competing PD-1/PD-L1 launched since 2021

Sales Per Capita

~1.6M RMB

Launched for 9 months

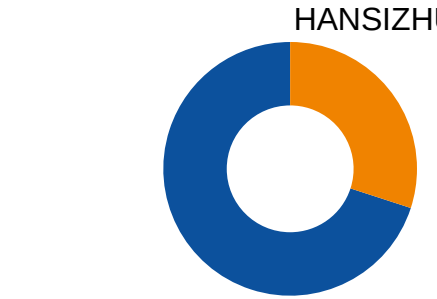
Industry Leading

Higher than all PD-1/PD-L1 products launched in the same period

Improve Market Share with Differentiation Strategy

Differentiation Strategy Focus on SCLC

(15-20% of total lung cancer patients)



~30%

Share of patients under 1L SCLC treatment in top leading accessible hospitals

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HANLIKANG®(Rituximab): Strengthen the Leading Market Position

554M RMB

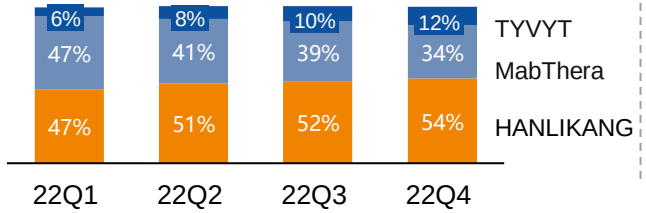
Revenue recognized by Henlius instead of Fosun Pharma

Acceleration on market access and penetration

- Approved in February 2019 as the first approved biosimilar in China as well as the first approved rituximab biosimilars in China
- Innovative indication was approved in March 2022; the only rituximab approved for Rheumatoid Arthritis (RA) indication in China

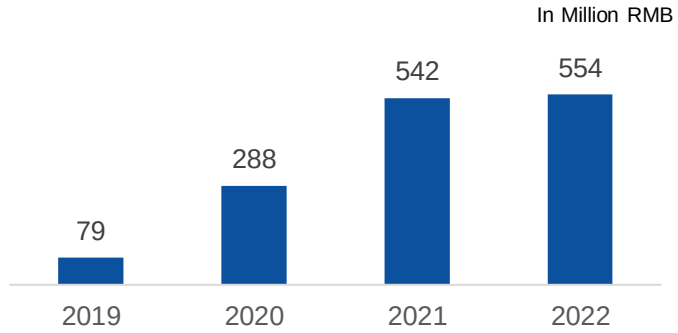
Market share leader

- Market share of HANLIKANG exceeds 50%



* Data source: IQVIA CHPA

Commercial Success



- Sales of HANLIKANG® in China executed by Jiangsu Fosun, a subsidiary of Fosun Pharma, and it has established a sizable professional sales team
- Listed on the procurement platform in most provinces by the end of 2022, and covered by NRDL in all provinces

Target: CD20

Indications:

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

Drug Specifications:

100mg/10ml/bottle

500mg/50ml/bottle

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HANDAYUAN® (Adalimumab): Entered Autoimmune Diseases Area

Improve patients' availability and accessibility

51M RMB

Revenue recognized by Henlius instead of Fosun Pharma

- Henlius' First product for autoimmune diseases
- 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
- Established the *Dayuan Home*, a patient care platform for the whole disease cycle, cooperated with the *National Clinical Research Center for Skin and Immune Diseases* to launch the *ASSC Ankylosing Spondylitis Standardized Diagnosis and Treatment Project* to help standardize the diagnosis and treatment of ankylosing spondylitis in China

Work with partners to penetrate the market

- Sales of HANDAYUAN® in China executed by Jiangsu Wanbang, having a sizable rheumatic immunity business unit and experienced salesforces in RA as well as a mixed line sales team for the broad market
- Collaborated with Getz Pharma in February 2022 and out-licensed the commercialization rights of HANDAYUAN® in 11 countries, including Pakistan, the Philippines and Kenya, to promote the product in global markets

Target: TNF-α

Indications:

- Rheumatoid arthritis
- Ankylosing spondylitis
- Psoriasis
- Uveitis

Drug Specifications:

40mg/0.8ml/bottle

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HANBEITAI® (Bevacizumab): Commercialization Start in 2023

Acceleration on market access and penetration

- Covered by NRDL in 30 provinces, and completed tendering and procurement platform listing in 25 provinces
- Focus on the dual-channel markets and proactively seek opportunities for hospitals access in non dual-channel market
- Proactively participate in provincial VBP opportunities

Exploration for new medication methods

- The only bevacizumab biosimilars with phase III clinical data for metastatic colorectal cancer in China
- Combine with HANSIZHUANG (anti-PD-1 mAb) to develop combined immunotherapy for cancer, which can be widely used for various oncology therapies
- HANBEITAI® approved with sNDAs for more indications such as recurrent glioblastoma, cervical, ovarian, fallopian tube, or primary peritoneal cancer

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

03

Business Development

5 Out-licensing Deals with Total Upfront Payment of 1.5 Billion RMB

(NYSE: OGN)

Spin-off from MERCK on June 3, 2021

- **Business footprint:** 140+ countries & regions
- **Sustainable operation:** 100+ years
- **Market Cap:** US$5.4B

US$73M Upfront payment
US$541M In Total

- **HLX11 (Pertuzumab)**
- **HLX14 (Denosumab)**
- **Option to license HLX13 (Ipilimumab)**

Global
(except Mainland China, Hong Kong, Macau and Taiwan)

ORGANON

GETZ PHARMA

Upfront payment
US$0.5M
US$8M In Total

- **HANDAYUAN® (Adalimumab)**

11 emerging markets in Asia, Africa and Europe

EUROFARMA

Upfront payment
US$4.5M
US$50.5M In Total

- **HANLIKANG® (Rituximab)**
- **HANQUYOU® (Trastuzumab)**
- **HANBEITAI® (Bevacizumab)**

Covering 16 Latin America countries

FOSUN PHARMA

Fosun Pharma USA

- **Fosun Pharma:** global innovation-driven pharmaceutical and healthcare group
- **Fosun pharma USA:** established U.S. subsidiary in 2017 with a experienced commercialization team

1B RMB Upfront payment
US$700M Regulatory & Sales Milestones
US$850M In Total

- **HANSIZHUANG® (Serplulimab)**

Exclusive commercialization in the U.S.

ABBOTT

Upfront payment
US$3M
US$4.4M In Total

- **HANLIKANG® (Rituximab)**
- **HANQUYOU® (Trastuzumab)**

Brazil (semi-exclusive)

5 Out-licensing Deals

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In-licensing Innovative Products & Technology Platforms

In-licensing AXC Products & Platforms to Enrich Pipeline

Cooperation for CDx Development & Commercialization

PALLEON

- **Her2-Sialidase:** preclinical study shows therapeutic potential in both HER2-low and HER2-high tumors
- **TAA-Sialidase:** TAA target, combined with new technologies

Joint development, exclusive rights in China (including HK, Macao and Taiwan)

- ***Innovative bifunctional sialidases fusion protein therapy***
- ***Co-development, powerful alliance***
- ***Potentially first-in-class Oncology drugs***
- ***Co-founder of Palleon was the 2022 Nobel Laureate in Chemistry***

NOVACYTE

- Joint development of no more than 3 ADC products, global rights
- NC18: antibody supply, potential commercialization cooperation

Global Rights
Options on China Rights

- ***Zhongguancun innovation-driven enterprise***
- ***Safe & efficient high DAR value polymer linker techniques***
- ***High technical barriers, ADC platform with various proprietary IP***

MediLink

- Innovative platform to jointly develop two target ADC products

Global Rights

- ***Founded by Former Kelun R&D technical management team***
- ***New toxin linker technology platform with exclusive IP***
- ***MediLink ADC platform has entered clinical stage in the U.S., proving the safety of the platform***

MEDx

- Biomarker
- HANSIZHUANG® GC/EC CDx

- ***Chinese CDx leading innovator***
- ***Identify targeted patient groups to promote precision medicine***
- ***Accelerate patient benefits under new regulatory policy in China***

04

Research & Development

Product Pipeline

Pre-clinical	IND	Phase I	Phase II	Phase III	NDA	In-Market
HLX61 Undisclosed (tumor immunity) Solid tumors	HLX51 OX40 Solid tumors, lymphoma	HLX10[1] (serplulimab)+HLX26 PD-1+LAG-3 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	HLX10[1] (serplulimab)+HLX60[2] PD-1+GARP Solid tumors	HLX10[1] (serplulimab)+HLX07 PD-1+EGFR HNSCC, NPC, GC, ESCC, sq-NSCLC	HLX10[1] (serplulimab)+chemo PD-1 Neo/adjuvant treatment for GC	HLX10[1] (serplulimab)+chemo PD-1 ES-SCLC 1L	HANLIKANG (rituximab) [12] CD20 NHL, CLL, RA [13]
HLX41 LIV1 ADC Solid tumors		HLX26 LAG-3 Solid tumors, lymphoma	HLX07[6] EGFR Solid tumors (cSCC)	HLX10[1] (serplulimab)+chemo +radio PD-1 LS-SCLC 1L	HLX02 (trastuzumab) [11] HER2 Breast cancer, mGC	HANQUYOU (trastuzumab) [11] HER2 Breast cancer, mGC
HLX42 EGFR ADC Solid tumors		HLX60 GARP Solid tumors, lymphoma	HLX22+HANQUYOU HER2+HER2 GC	HLX10[1] (serplulimab)+HANBEITAI PD-1+VEGF nsNSCLC 1L		HANDAYUAN (adalimumab) [14] TNF-α RA, AS, psoriasis, uveitis
HLX43 PD-L1 ADC Solid tumors		HLX35[3] EGFR x 4-1BB Solid tumors	HLX208[7] BRAF V600E LCH/ECD, solid tumors (i.e. MEL, thyroid cancer, mCRC, NSCLC)	HLX04-O[8] VEGF Wet AMD		HANBEITAI (bevacizumab) [15] VEGF mCRC, advanced, metastatic or recurrent NSCLC, GBM, etc.
HLX44 Nectin4 ADC Solid tumors		HLX301[4] PD-L1 x TIGIT Solid tumors, lymphoma	HLX208[7]+HLX10[1] (serplulimab) BRAF V600E+PD-1 NSCLC	HLX11 (pertuzumab) [9] HER2 Neoadjuvant treatment of breast cancer		
HLX80 STEAP1 ADC Prostate cancer		HLX53 TIGIT Solid tumors, lymphoma		HLX14 (denosumab) [10] RANKL Osteoporosis		
HLX309 Nectin4 x 4-1BB Solid tumors		HLX05 (cetuximab) [5] EGFR mCRC, HNSCC				
HLX314 HER2xSialidase Solid tumors		HLX15 (daratumumab) CD38 Multiple myeloma				
HLX17 (pembrolizumab) PD-1 Solid tumors						

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

(1) IND approvals obtained in China/the U.S./EUUS countries/Australia, etc. Approved by the NMPA in March 2022. Business partners: KGbio/Fosun Pharma. (2) IND approvals obtained in Australia. (3) Business partner: Binacea. (4) IND approvals obtained in China/Australia. (5) Business partner: Shanghai Jingze. (6) IND approvals obtained in China/the U.S.. (7) Commercialization rights obtained for Mainland China, Hong Kong, Macao and Taiwan. (8) IND approvals obtained in China/Australia/the US/Singapore/EU countries, etc. Business partner: Essex. (9) IND approvals obtained in China/EU. Business partner: Organon. (10) IND approvals obtained in China/EU/Australia. Business partner: Organon. (11) Approved in 30+ 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/ mAbxience/ Eurofarma/ Abbott. (12) The first biosimilar approved in China. Business partners: Fosun Pharma/Farma de Colombia/Eurofarma/Abbott. (13) The first rituximab approved for the indication in China. (14) Business partners: Wanbang/Getz Pharma. (15) Business partner: Eurofarma.

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4.1 R&D: Milestones for Clinical Pipeline

Clinical Pipeline Milestones - 2022 Review

	1H2022	2H2022	
NDA/BLA/MAA Submission	**HLX10** Extensive stage small cell lung cancer (ES-SCLC) 1L (CN)	**HLX10** Esophageal squamous cell carcinoma (ESCC) 1L (CN)	**HLX02** BLA Submission to FDA
Key Clinical Data Readouts	**HLX10** Esophageal squamous cell carcinoma (ESCC) 1L (Pivotal)	**HLX04-O** Wet Age-Related Macular Degeneration (Wet AMD) (PoC)	**HLX22** Gastric Cancer (GC) 1L (PoC)

Innovative mAb mAb biosimilar

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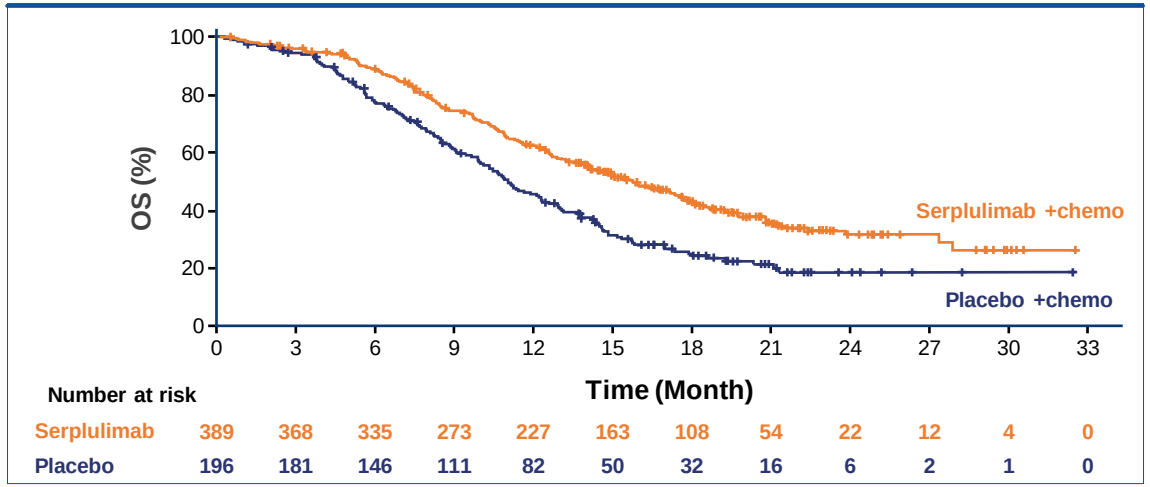
ASTRUM-005 & ASTRUM-007 were Published in JAMA and Nature Medicine Respectively

ASTRUM-005: Presented at 2022 ESMO Asia, updated data for 1L ES-SCLC

Data cut-off date: 2022-6-13



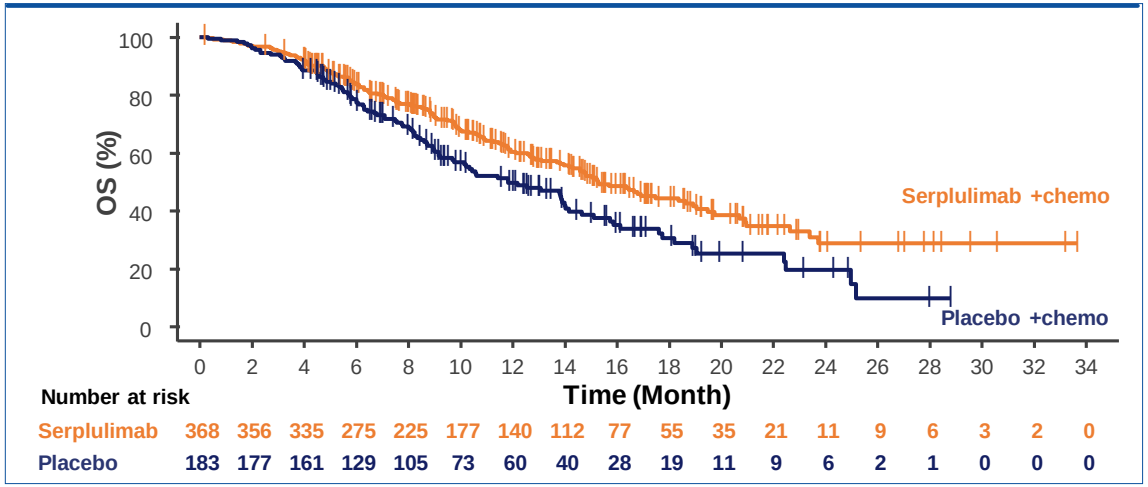
- After **19.75 months follow-up** (vs 12.3 months median follow-up for the previous ASCO presentation), the latest data show:

	Overall population	Asian: The absolute benefit was better than the overall population
Median OS	**15.8 months,** significantly extended 4.7 months (HR=0.62, 95%CI: 0.50-0.76)	**15.9 months,** significantly extended 4.8 months (HR=0.63, 95%CI: 0.49-0.81)
Median PFS	**5.8** vs 4.3 months (HR=0.47, 95%CI: 0.38~0.58)	**6.1** vs 4.3 months (HR=0.47, 95%CI: 0.37~0.61)

- **The study results were published in JAMA in 2022 (IF: 157.3)**
- **The world's first PD-1 mAb to achieve positive results in the 1L treatment of ES-SCLC**
- **Serplulimab combined with chemotherapy led to longer survival benefits compared with approved PD-L1 mAbs (not head-to-head studies)**

ASTRUM-007: Presented at 2022 CSCO, reported data for 1L EC

Data cut-off date: 2022-4-15



- After **14.9 months follow-up**, the latest data show:

	Overall population	Patients with PD-L1 CPS≥10
Median OS	**15.3 months,** significantly extended 3.5 months (HR=0.68, 95%CI: 0.53~0.87)	**18.6 months,** significantly extended 4.7 months (HR=0.59, 95%CI: 0.40~0.88)
Median PFS	**5.8** vs 5.3 months (HR=0.6, 95%CI: 0.48~0.75)	**7.1** vs 5.3 months (HR=0.48, 95%CI: 0.34~0.68)

- **The study results were published in Nature Medicine in 2023 (IF:87.2)**
- **Intensive chemotherapy was used in the study design**
- **The study showed that serplulimab combo with cisplatin and 5-FU had a consistent efficacy benefits and manageable safety profile for PD-L1-positive ESCC patients**

*HR, hazard ratio; CI, confidence interval; OS: overall survival; PFS, progression free survival

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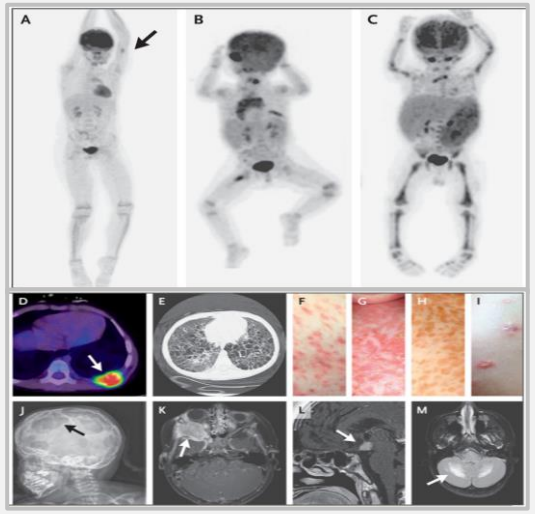
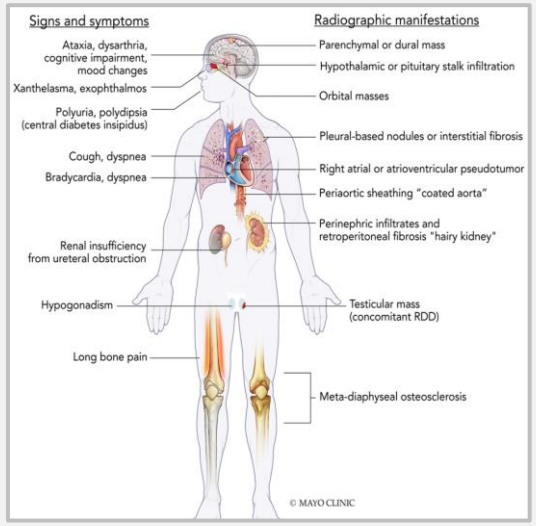
HLX208-LCH/ECD201 Studies Showed Promising Results



LCH/ECD is a clonal hematologic malignancy characterized by activating MAPK pathway, which belongs to inflammatory myeloproliferative neoplasm. About 50% of the the disease tissues of LCH/ECD patients have been identified BRAF V600E mutations.



LCH/ECD presents at various degrees of systemic involvement, so its clinical manifestations vary subject to affected systems, seriously affecting the quality of life of patients, such as:

- Skeletal system: ostealgia, pathological fractures, etc.;
- Central nervous system: diabetes insipidus, limb activity disorder, etc.;
- Cardiovascular system: pericardial effusion, chest discomfort, breathlessness, etc.;
- Skin: skin rash, etc.;
- Loose teeth, tooth loss;
- Ureteral obstruction;
- Unilateral or bilateral exophthalmos and even blindness, etc.

Challenges

- Adults LCH/ECD is a rare disease that can affect multiple systems of the whole body and seriously impact the life and living quality of patients
- Currently chemotherapy is the main treatment for adults LCH/ECD, which has severe side effects and is likely to relapse. There is no approved targeted drugs in China, indicating unmet medical needs

Study Results

- HLX208 has shown excellent efficacy and safety in adult LCH/ECD, better than chemotherapy
- CDE accepted a single-arm pivotal clinical trial and the pre-NDA can be conducted 6 months after the enrollment of the last patient
- LCH/ECD indication has applied Breakthrough Therapy Designation (BTD)

Exploration

- HLX208 will continue to explore in major oncology indications such as NSCLC, mCRC etc.

Gaurav Goyal et al. Blood. 2020 May 28;135(22):1929-1945
Carl E. Allen et al. N Engl J Med. 2018 August 30; 379(9): 856–868

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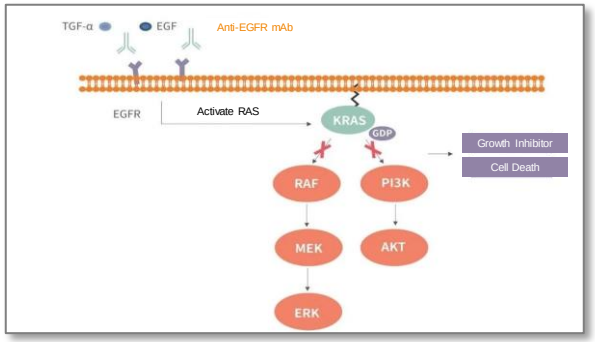
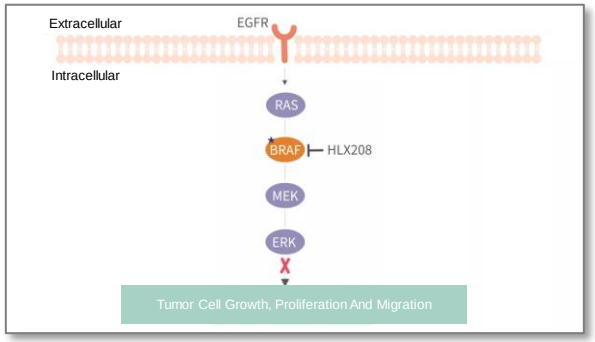
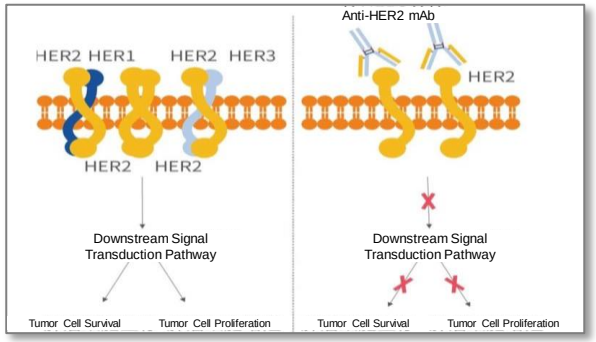
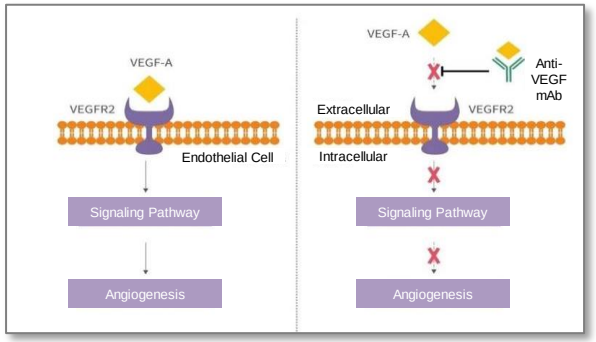
Advancement of Clinical Pipeline (Phase 2/3)









HLX07(EGFR)

- HLX07 is a **humanized** monoclonal antibody, with a **longer half-life** compared with Cetuximab
- Observed higher safety and antitumor activity in phase 2 clinical trial
- **Showed synergistic efficacy in multiple types of tumors combined with serplulimab**
- HLX07 monotherapy has shown preliminary efficacy in late-line treatment of esophageal cancer and advanced cutaneous squamous cell carcinoma

HLX208(BRAF V600E)

- Compelling safety and oral bioavailability profile
- Potentially to be **the first** BRAF product combined with immunotherapy **in China**
- Promising clinical study data for LCH/ECD indications
- Received positive registration feedback from regulator based on the single-arm trial for LCH/ECD indication
- Expected to be the world's **first** BRAF inhibitor approved for adult LCH indication
- Showed preliminary efficacy in colorectal cancer, melanoma, etc.

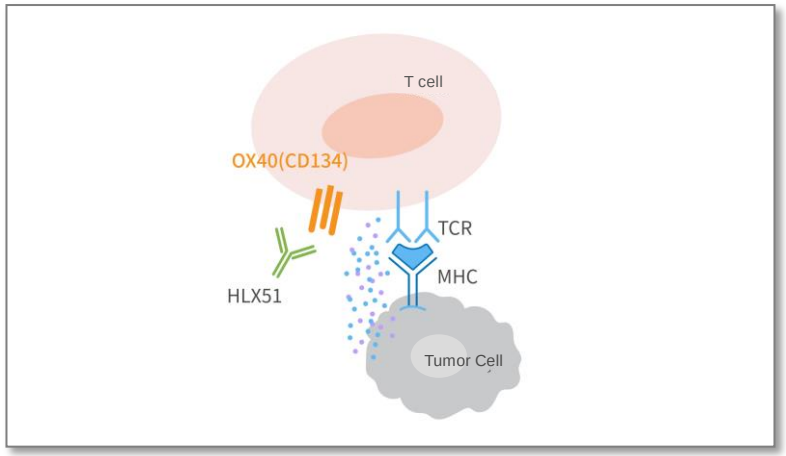
HLX22(HER2)

- HLX22 targets at **different** epitopes within domain IV of Her2.
- PDx data demonstrated the combo of HLX22 and Trastuzumab (also targeting Her2 domain IV) outperformed the combo of Trastuzumab and Pertuzumab in gastric cancer
- In phase II study data, compared to current SOC of 1L metastatic GC/GJC treatment, there will be clear benefits for patients, leading to great potential to change the SOC

HLX04-O(VEGF)

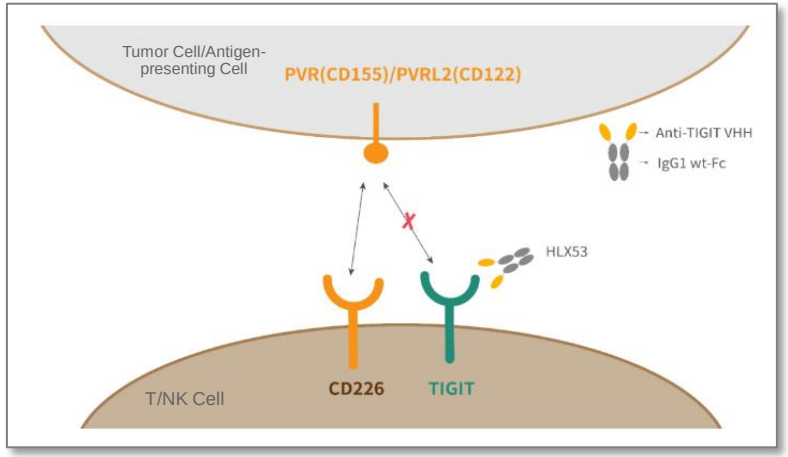
- Phase I & II studies showed significant BCVA improvement and high likelihood for phase III trial to succeed
- Expected to become **the first batch** of Chinese ophthalmic mAb to market overseas, through two head-to-head controlled phase III trials with Ranibizumab conducted in China and worldwide

Early-Stage Assets (Clinical IND/Phase 1) (1/2)



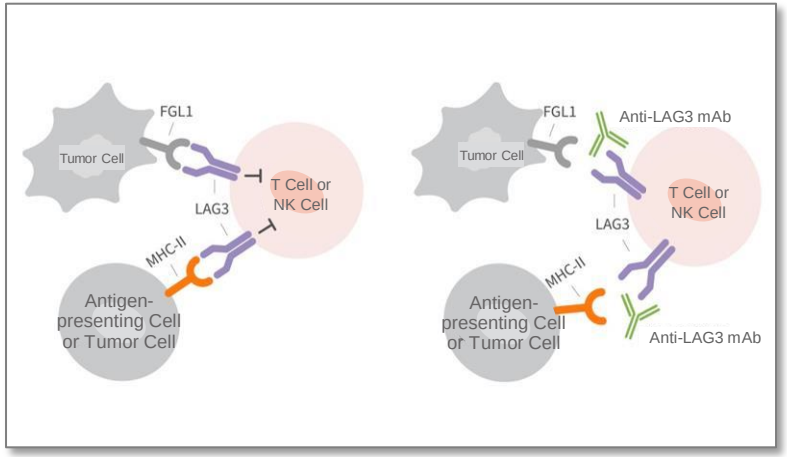
HLX51(OX40)

- Through quadrivalent binding, induce clustering of OX40 and exert immune activation
- Showed a dose-dependent tumor killing effect in many tumor models
- Combo with PD1/PDL1 antibody demonstrated a significant efficacy
- HLX51 outperforms peers no matter mono or combo with PD1/PDL1 antibodies
- Submitted IND application (monotherapy) in Nov. 2022



HLX53(TIGIT)

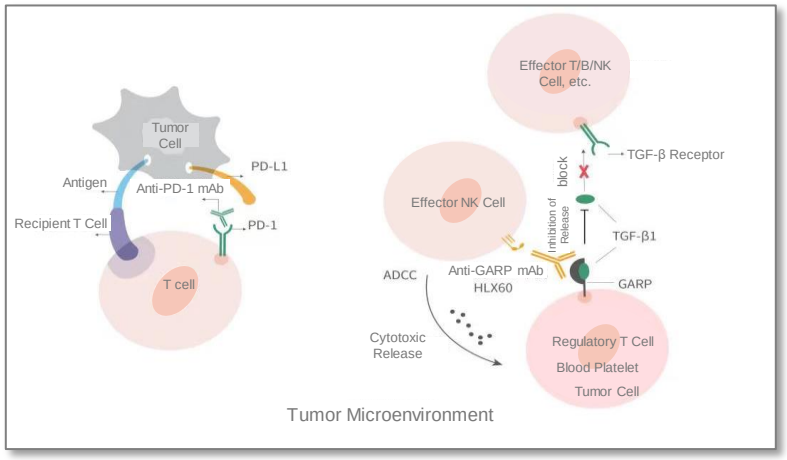
- Notable immune regulation in tumor microenvironment
- HLX53 combo with Serplulimab has observed superior efficacy to Tiragolumab combo with Atezolizumab
- Demonstrated good safety profile in monotherapy dose escalation

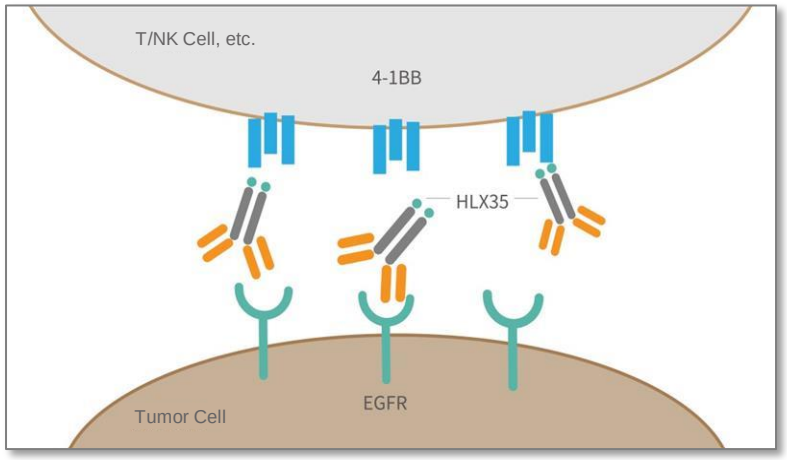


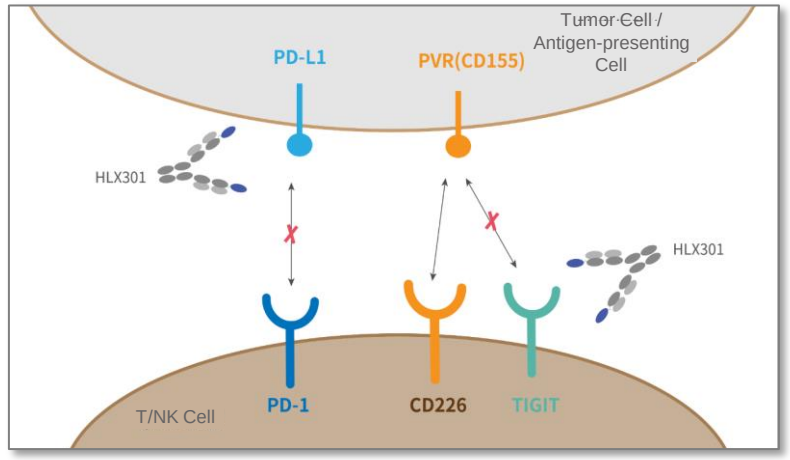
HLX26(LAG-3)

- Revealed synergistic effects when combined with PD-1 antibody in various tumor types (mCRC, NSCLC, etc.)
- Good drug tolerance and safety profile

Early-Stage Assets (Clinical IND/Phase 1) (2/2)







HLX60(GARP)

- Potentially a First-in-Class innovative drug, the first IND in China and the third globally
- Inhibits TGFβ maturation and release, regulates tumor inflammation and immune microenvironment
- ADCC effects to remove GARP-positive tumor cells and Treg cells
- Used as single agent or combo with immune checkpoint inhibitors all showed good efficacy in different tumor models

HLX35(EGFR x 4-1BB)

- Potentially a First-in-Class innovative drug and the first to enter clinical trial globally
- Stronger tumor killing effects that simultaneously blocking EGFR signaling and activating T cells and NK cells, and potentially improve the respond rate of tumor cells insensitive to EGFR antibody
- Current phase 1 clinical data showed good drug tolerance and safety profile

HLX301(PD-L1 x TIGIT)

- HLX301 has differentiated molecule design comparing to other competing molecules
- Superior efficacy to Tiragolumab combo with Atezolizumab in animal models for multiple tumors
- Two parallel dose escalation trials conducted in Australia and China showed good tolerance and safety profile

Clinical Pipeline Milestones in 2023

NDA/BLA/MAA Submission

Key Clinical Data Readouts

1H2023	2H2023
NDA/BLA/MAA Submission	
HLX10 Extensive stage small cell lung cancer (ES-SCLC) 1L (EU)	**HLX10** Non-squamous non-small cell lung cancer (nsNSCLC) 1L (CN)
Key Clinical Data Readouts	
HLX10 Non-squamous non-small cell lung cancer (nsNSCLC) 1L (Pivotal)	**HLX07** Esophageal squamous cell carcinoma (ESCC) (PoC)
HLX208 Metastatic colorectal cancer (mCRC) (PoC)	**HLX208** Solid tumor (PoC)
HLX10 Metastatic colorectal cancer (mCRC) 1L (PoC)	**HLX07** Cutaneous squamous cell carcinoma (CSCC) (PoC)
HLX10 Squamous non-small cell lung cancer (sqNSCLC) – report final OS results 1L (Pivotal)	**HLX208** Melanoma (MEL) (PoC)
	HLX22+HLX10 Gastric cancer (GC) 1L (PoC)
	HLX208+HLX10 Non-small cell lung cancer (NSCLC) (PoC)
	HLX26+HLX10 MSS metastatic colorectal cancer (mCRC) 3L+ (PoC)
	HLX208 BRAF V600E mutation Langerhans Cell Histiocytosis (LCH) and Erdheim-Chester Disease (ECD) (Pivotal)
	HLX301 Non-small cell lung cancer (NSCLC) 1L (PoC)

Innovative mAb Innovative bsAb Innovative small molecules

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4.2 R&D: Pre-clinical Progress

Targeting Clinical Benefits for Unmet Medical Needs, Focus on Tumors, Metabolic, Cardiovascular, Renal and Neurological Disorders

Clinical Value-oriented New Drug R&D

Focus on solid tumors to meet the unmet clinical needs

- For metastatic and drug resistant tumors, develop antibody-drug conjugate (ADC)
- Coupling with immuno agonist and cytokine, develop new BsAb, T cell engager, and NK cell engager to treat tumors insensitive and resistant to PD-1/PD-L1
- To improve targeted therapy and combination therapy of anti-tumor drugs, keep iterating new targeted drug delivery system (XXC) centered around linkers, based on the AXC platform

Expand into non-oncology TAs such as metabolism, cardiovascular, nephrology and neurology

- Through conjugating with immunomodulator, metabolic regulator, etc., exploit new recombinant protein, antibody, etc.
- To improve the efficacy of neurological diseases drugs, establish blood-brain barrier penetration drug delivery platform

Extend novel drug development area for rare disease

- Leveraging RNAi (RNA interference) drugs, mRNA meditated protein replacement therapy, and gene-editing therapy to develop innovative drugs for rare diseases

Technologies for New Drug R&D: Deep Data Driven Drug Discovery and Biocomputation Accelerated Drug Molecule Design (BAMD)

- Based on the Deep Data Driven Drug Discovery (5D) platform, integrate medical information data, to discover new targets, mechanisms and drugs for inflammatory, immune, and metabolic intervention
- Driven by the BAMD platform, design new drug molecules,e.g. peptides and nucleic acids, and optimize antibodies, small molecule drugs, ADC payloads, etc.

Proprietary Innovation Supplemented by External Innovation to Maximize the Quality, Efficiency and R&D

- China-US dual R&D centers driven: US center focuses on 0-to-1 high quality original innovation while China center continues on 1-to-10 high efficiency development
- Conducting break-border research with external leading scientists and institutions, enhance the strength of in-house innovation, and incubate early stage cutting-edge breakthrough technology

Antibody Drug Conjugate (ADC) R&D Strategy

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 (CRPL) platform**
4. **Enhance the selectivity of ADCs: build Tumor microenvironment (TME) Conditionally Activated Antibody (CAA) platform**
5. **Expand the application scenarios of ADCs: discover new toxin and non-toxin payloads**

HLX42 (EGFR ADC)

- Potential **first-in-class ADC product**
- TME-dependent activation and release of payload
- Good tumor killing effect against multiple solid tumors with mutation and resistance to EGFR Ab or TKI
- Excellent therapeutic window

HLX43 (PD-L1 ADC)

- Potential **first-in-class ADC product**
- TME-dependent activation and release of payload
- Good tumor killing effect against multiple solid tumors non-responsive or resistant to PD1/PDL1
- Excellent therapeutic window

Deep Data and Computation Driven Innovative Drug Development Targeting Inflammation, Autoimmunity, and Metabolism

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

Driven by the BAMD platform, design new drug molecules such as peptides and nucleic acids, and optimize antibodies, small molecule drugs, ADC payloads, etc.

Focusing on Metabolism, develop innovative drugs for complex diseases through network biology and polypharmacology

HLX94 (SMC)

- **First-in-class small molecule drug conjugates**
- Polypharmacology with a unique MOA
- Address unmet needs in the field of ALS 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 diabetic kidney disease (DKD) models
- Large patient population with huge unmet needs

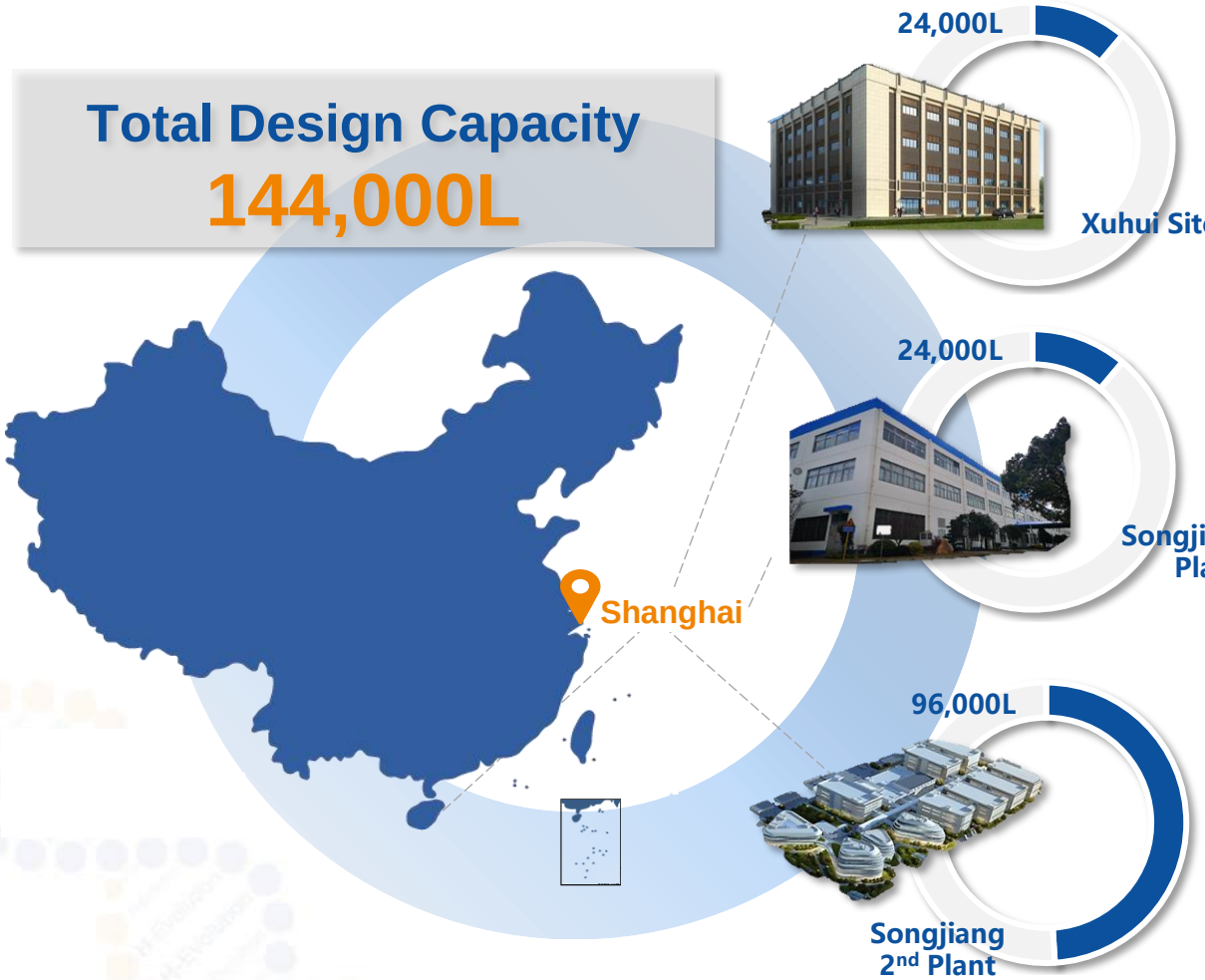
05

Manufacturing: Capacity Breakthroughs

(Strengthen Market Leading Position in Manufacturing Technology & Quality)

Songjiang 1st Plant: 24,000L Capacity Approved for HANQUYOU

Total Design Capacity
144,000L



Leading Commercial Manufacturing Capability In China

- Total commercial production capacity of Songjiang 1st Plant & Xuhui Facility in 2022: **48,000L**
- Commercial GMP batches: **582+** (since 2019)
- Manufacturing success rate: **≥98%**
- Manufacturing and quality employees: **1200+**
- Production strength & intensity: **globally leading**

Songjiang 1st Plant Approved for Commercial Operation in May 2022

- Manufacturing capacity: **24,000L**
- Commercial production approved for **HANQUYOU (Trastuzumab)**
- Products for clinical trials in EU: HLX04-O, HLX11, HLX14, etc.

Consistent quality management with global GMP standards

- GMP certified by China and EU and capable of manufacturing products for international markets
- Improve the quality management system through audits by regulatory agencies as well as domestic & overseas clients
- Proactively prepare for on-site inspections by **FDA, EMA**

Ensure high quality and sustainable manufacturing to implement "Henlius Quality" with international standards

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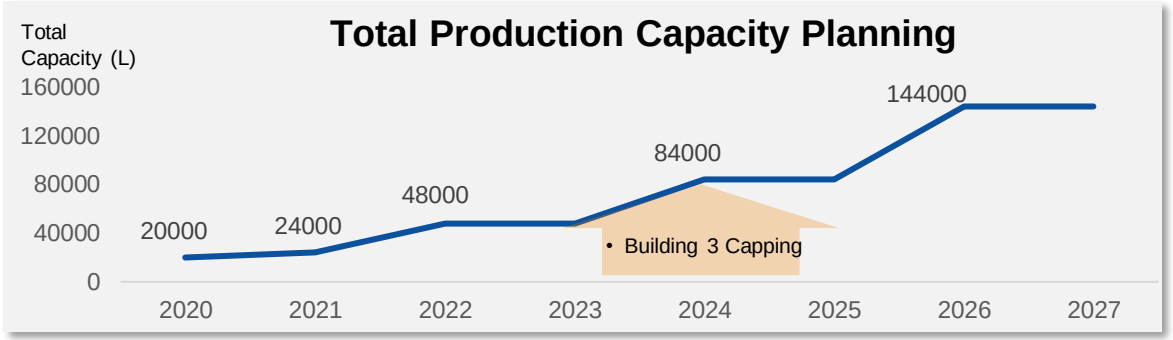
Total Capacity Estimated to Reach 144,000L by 2026



Xuhui Facility		Songjiang 1st Plant		Songjiang 2nd Plant
N: (5+1)*2 KL **S:** (5+1)*2 KL	+	(6*2KL)*2	+	(6*2 KL)*3 4*15 KL

Accelerating Construction

- The first and second stage of Songjiang 2nd Plant Phase I project are expected to complete for production by the end of 2023
- Accelerating the construction for PFS and ADC to enrich the production line portfolio
- Expand into CDMO business

Intelligent Drug Manufacturing

- Complete the construction of new technology platforms to upgrade the bioreactor
- Proprietary development of **15,000L** stainless steel bioreactor to enlarge the cost advantages of commercial production
- Process Analytical Technologies (PAT) Raman Spectrometer

Manufacturing Advantage

- Scientific capacity planning to meet production needs
- Develop production technologies in advance based on industry mainstream product types
- Establish a leading position in China leveraging production capacity and process technologies advantages

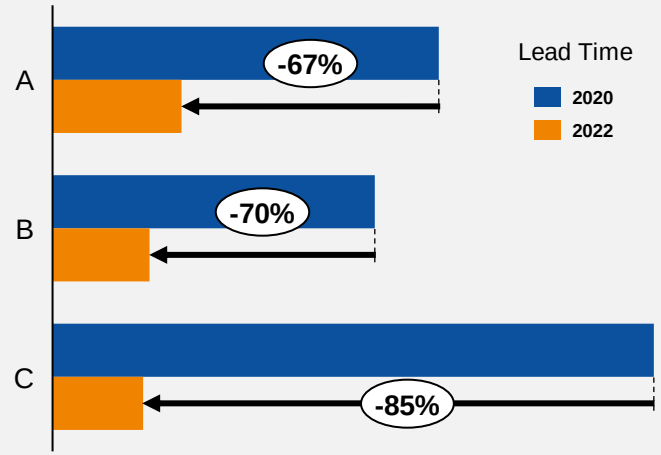
Design Capacity of Songjiang 2nd Plant Phase 1: 96,000L

Operation Excellence to Improve Efficiency and Reduce Costs

Lean Operations

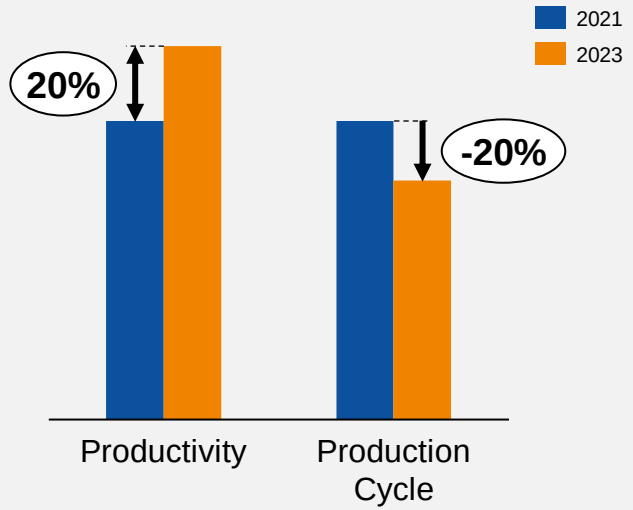
- Improve company policies, establishing culture of excellence
- Focusing on key businesses, the annualized income of projects exceeds 10 million RMB
- Optimze the overall management to implement digital transformation

Localization



- High efficiency and stable domestic raw material supply platform to realize higher productivity
- Proprietary culture medium and critical materials to achieve lower cost
- Multi-source management of supply chain, flexible response to supply crisis

Continuous Process Improvement



- Optimize the technology and the process to improve the productivity
- Keep improving, and shorten the production cycle

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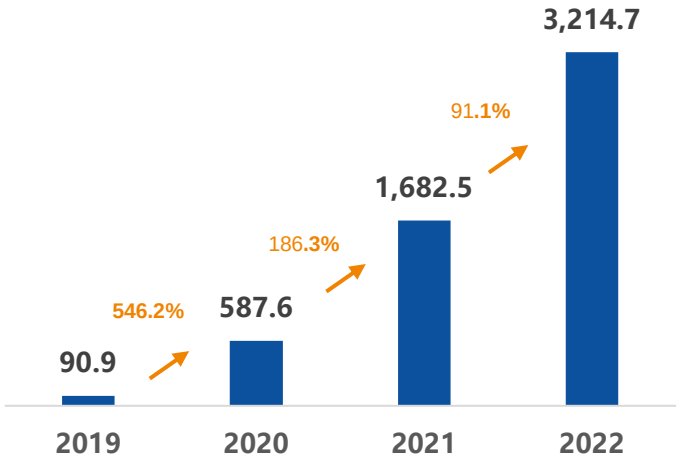
06

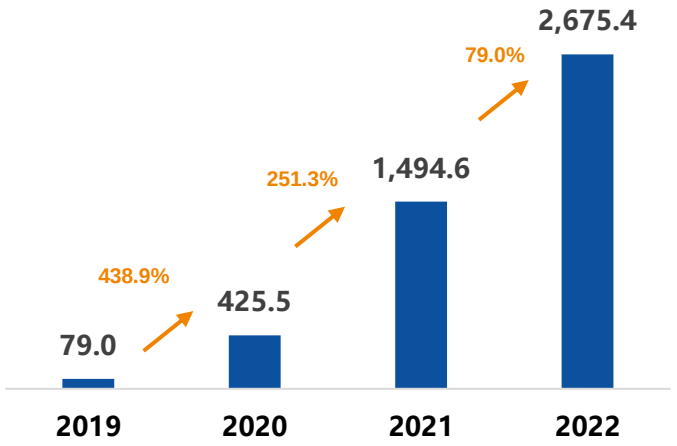
2022 Financial Review

2022 Fiscal Year Revenue Tops RMB 3.21B, YoY Growth 91.1%

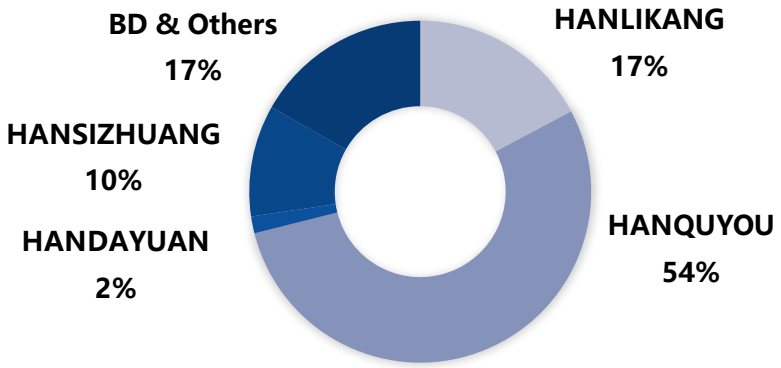
Revenue
(in Million RMB)



Product Income
(in Million RMB)



2022 Revenue Breakdown



Revenue Growth

- Annual revenue of RMB 3.21B in 2022, 91.1% YoY growth
- Revenue growth mainly driven by: sales volume increased; BD & other income achieving 187.2% YoY (jointly development, technology transfer, and commercialization licensing with partners)
- Annual gross profit of 2.37 billion in RMB in 2022, 104.4% YoY growth

Product Sales

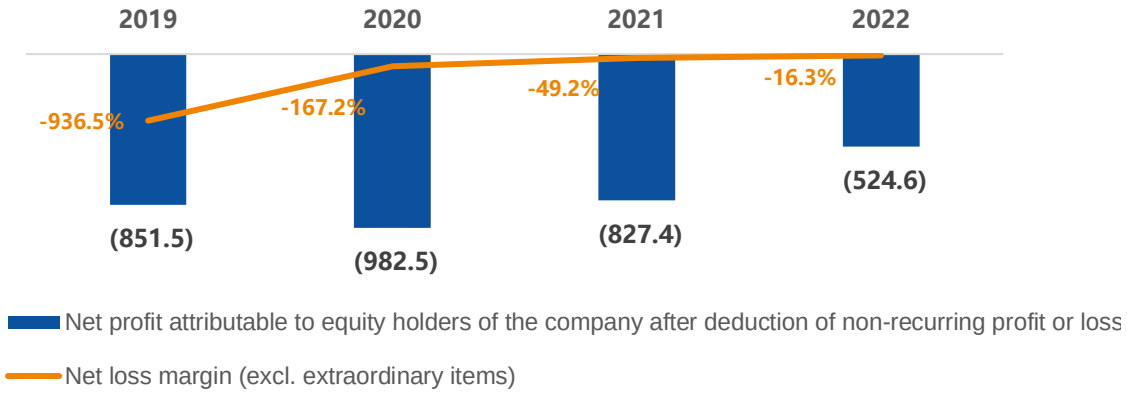
- Annual product sales of RMB 2.68B, 79.0% YoY growth
- Product sales growth mainly from HANQUYOU sales volume open-up with additional capacity released after Songjiang 1st Plant being approved; HANSIZHUANG expanded market share quickly to realize revenue driven by early commercialization approval

Revenue Breakdown

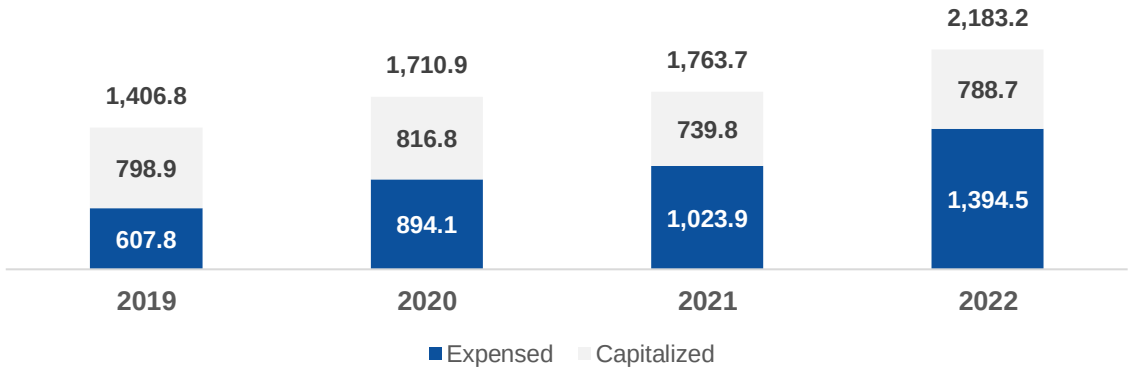
- HANQUYOU: 2022 annual sales of RMB 1.73B, 86.1% YoY growth
- HANSIZHUANG: approved in March 2022, revenue of RMB 339M for 9 months after launch
- HANLIKANG: 2022 annual sales of RMB 554M, 2.1% YoY growth
- HANDAYUAN: 2022 annual sales of RMB 51M, 134.5% YoY growth
- BD & others: 2022 total income of RMB 539M, 187.2% YoY growth

2022 Net Loss Narrowed; Positive Operating CF Generated

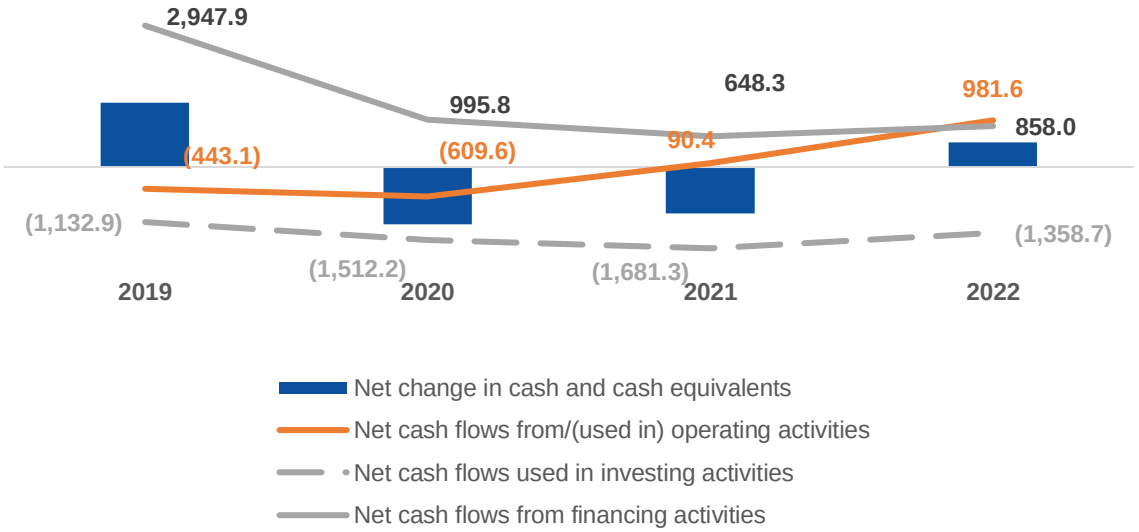
Net Loss Excl. Extraordinary Items Narrowed
(in Million RMB)



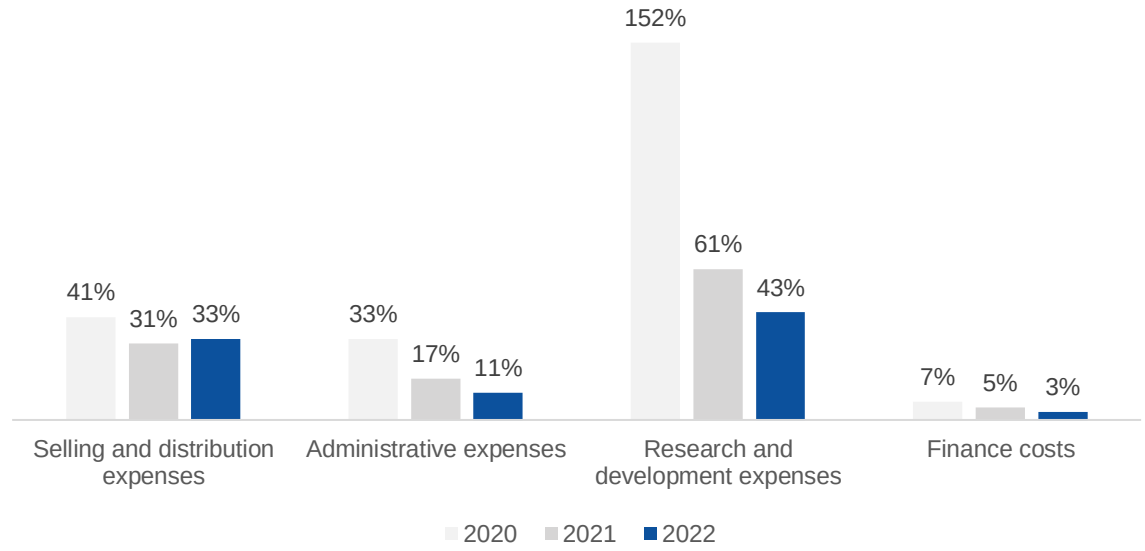
Total R&D Costs: the portion of R&D costs expensed increased on income statement
(in Million RMB)



Net change in cash and cash equivalents: positive OCF generated for 2 year
(in Million RMB)



Expense to revenue ratios steadily decreased



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Financial Highlights

Financial Data (Selected)	2022		2021		YOY Growth
Unit:	In million RMB	% of revenue	In million RMB	% of revenue	%
Revenue	3,214.7	100.0%	1,682.5	100.0%	91.1%
Product sales	2,675.4	83.2%	1,494.6	88.8%	79.0%
BD and other revenue	539.4	16.8%	187.8	11.2%	187.2%
Cost of sales	(844.6)	(26.3%)	(522.7)	(31.1%)	61.6%
Selling and distribution expenses	(1,049.3)	(32.6%)	(520.3)	(30.9%)	101.7%
Administration expenses	(354.0)	(11.0%)	(280.6)	(16.7%)	26.2%
R&D expenses	(1,394.5)	(43.4%)	(1,023.9)	(60.9%)	36.2%
Finance costs	(105.7)	(3.3%)	(84.8)	(5.0%)	24.6%
Loss before tax	(693.9)	(21.6%)	(956.7)	(56.9%)	(27.5%)
Loss for the year	(695.3)	(21.6%)	(984.1)	(58.5%)	(29.3%)

07

2023 Performance Outlook

Our Goals for 2023

- **Revenue:** rapid growth driven by strong market demands of HANSIZHUANG® and HANQUYOU®
- **Profitability:** improve P&L level and maximize growth from within
- **Cashflow:** positive OCF generated for the past two years; strengthen organic growth in 2023 and build strong and healthy cash flows
- **R&D:** 1 clinical asset aim for Breakthrough Therapy Designation; advance early-stage pipeline with differentiation and high efficiency; multiple ADC, BsAb, and fusion protein assets enter clinical stage
- **Overseas Market:** HANQUYOU® is expected to be approved in the U.S. by the end of 2023 and submit NDA in 14 countries globally; HANSIZHUANG® file MAA in Europe
- **Resource Allocation:** optimize resource allocation to improve return on investment; build competitive R&D pipeline to support long-term sustainable growth

声 明

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