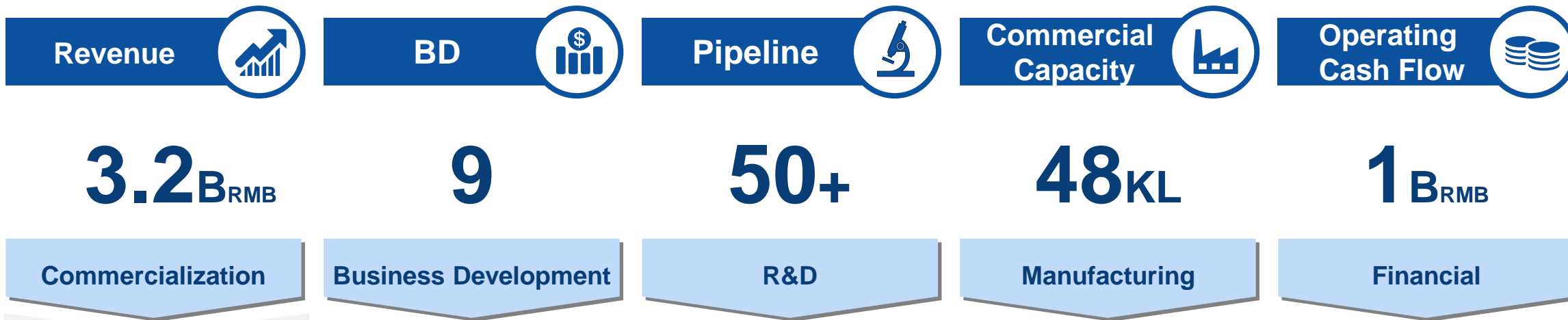




# 2022 Business Highlights & Company Strategy

# 2022 Business Highlights Revenue Tops 3.21B RMB



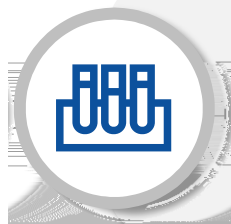
Growing core capabilities of commercialization with steady team expansion

HANSIZHUANG® launched successfully with strong sales beyond expectation

HANQUYOU® maintained high growth with improving expense ratio, despite the impact of

# 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

## Strong Competency of Biosimilars business in the International Market

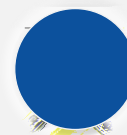
Robust biosimilar pipeline  
Commercial capacity reached  
48,000L, both China and EU GMP  
certified  
Achieved a number of global out-  
licensing deals for biosimilars  
Trastuzumab was approved in 30+  
countries



## A Pioneer Biosimilars Leader in China



**9** biosimilars products  
pipeline, including approved  
products and clinical assets



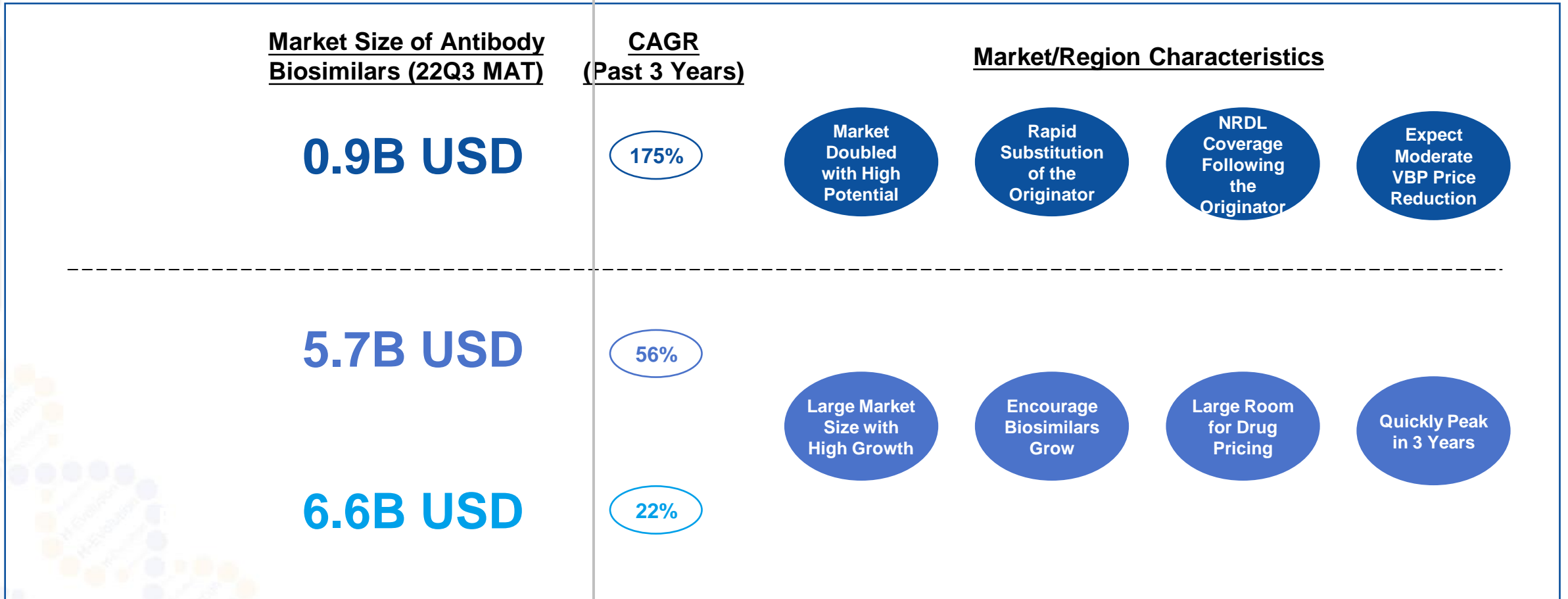
Sales revenue of  
biosimilars\* in 2022  
reached  
**2.34B**

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

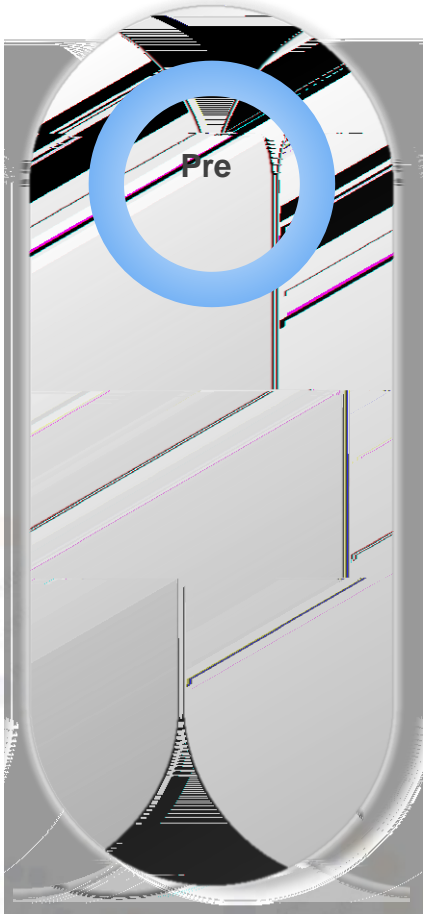


# The Global Antibody Biosimilar Market Promising Outlook

- 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



- 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



### Sales Revenue of Marketed Biosimilars (million RMB)

- HANLAYUAN®\*
- HANLIKANG®\*
- HANQUYOU®-overseas
- HANQUYOU®-domestic

# First Commercialized Innovative Drug

# Serplulimab



**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

## 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

## Innovative Pipeline Distribution By Stage (By Molecule)



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



Autoimmune

IBD  
PBC/PSC  
SLE  
RA



Metabolic

DKD  
NAFLD/NASH



Ophthalmology

Wet AMD



Cardiovascular

Heart Failure  
HLP



Rare Diseases

LCH/GBa

# 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

Globalization  
 Innovative Drugs  
 Biosimilars



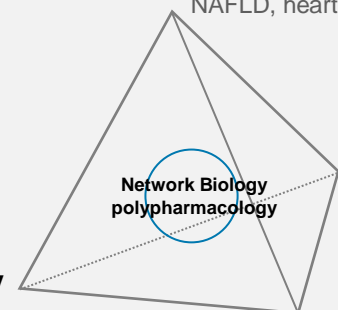
**Targeted Drug Delivery  
Precision and Combo Therapy**

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

*Core methodology*

**Linker-Centric Diversified Conjugates Platforms**

**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.

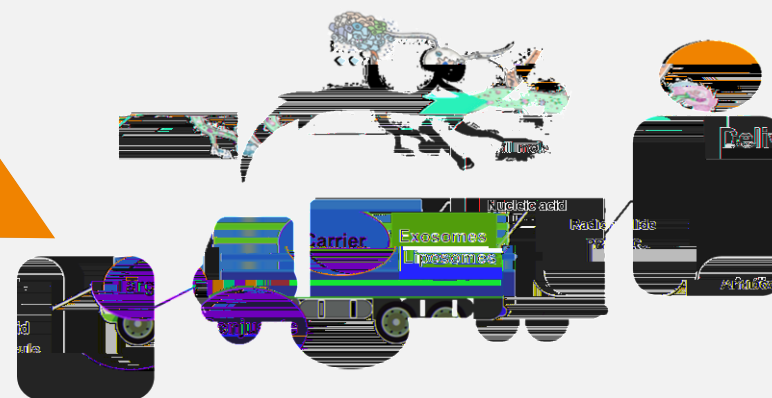
**Oncology**  
Lung cancer, breast cancer, liver cancer, colon cancer, pancreatic cancer, etc.



**Deep Data Driven Drug Discovery (5D\*)**



**Biocomputation Accelerated Molecule Design (BAMD\*)**



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

# Globalization: Enter into Commercialization Stage



## 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.

- ✓ 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

# 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

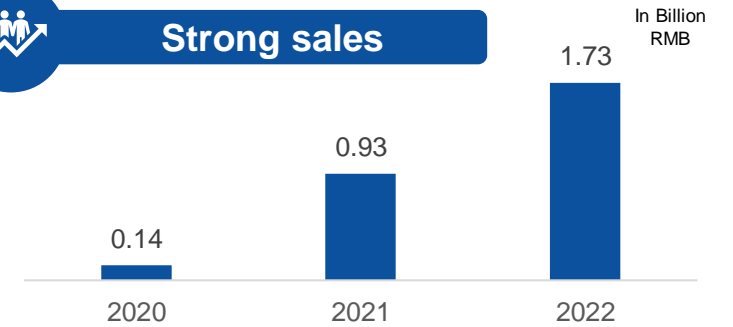
Designed for HER2-positive breast cancer patients in China, flexible spec combination can fit with personalized dose and reduce residual fluid waste

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 1<sup>st</sup> 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



### 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)



Zercepac® in Europe

Tuzucip® & Trastucip® in Australia

# Excellent Performance of HANQUYOU®

---

Higher cost-effectiveness than



**> 3.7M RMB**

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

Sales Expenses Ratio

**< 40%**

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



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

 Impressive R&D results

 **339M RMB**

Revenue in 2022  
(In market for 9 months)



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



 Target: PD-1

Indications:

MSI-H solid tumor  
sqNSCLC  
ES-SCLC

Drug Specifications:

100mg/10ml/bottle

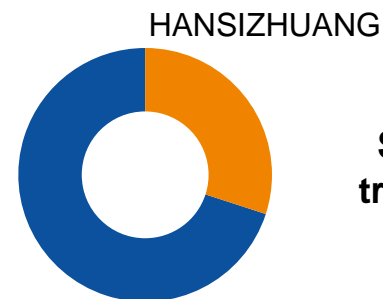
# HANSIZHUANG<sup>®</sup> Commercialization Highlights

## 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



**~30%**

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

# HANLIKANG®(Rituximab): Strengthen the Leading Market Position

Revenue recognized by Henlius instead of Fosun Pharma

## Acceleration on market access and penetration

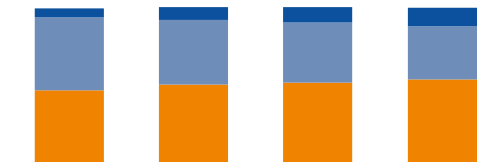
Approved in February 2019 as the first approved biosimilar in China as well as the first approved rituximab biosimilars in China

Innovative indication was approved in March 2022; the only rituximab approved for Rheumatoid Arthritis (RA) indication in China

## Commercial Success

## Market share leader

Market share of



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



Non-Hodgkin lymphoma

100mg/10ml/bottle

Chronic lymphocytic leukemia

500mg/50ml/bottle

Rheumatoid Arthritis (RA)

# HANDAYUAN® (Adalimumab): Entered Autoimmune Diseases Area



## 51M RMB

Revenue recognized by Henlius instead of Fosun Pharma

Covered by NRDL in 30 provinces, and completed tendering and procurement platform listing in 31 provinces

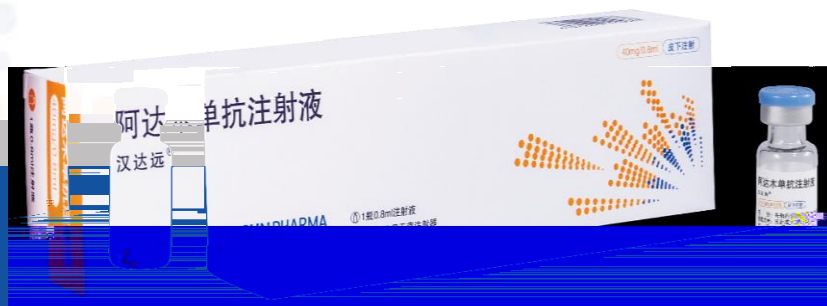
The first phase III clinical study of adalimumab biosimilar for psoriasis patients in China

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



### Target: TNF-

Indications:

- Rheumatoid arthritis
- Ankylosing spondylitis
- Psoriasis
- Uveitis

Drug Specifications:

40mg/0.8ml/bottle

# HANBEITAI<sup>®</sup> (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<sup>®</sup> 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

# 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

HLX11 (Pertuzumab)  
USA14 (Denosumab)  
Option to license HLX13  
(Ipilimumab)

**ORGANON**

**Fosun Pharma USA**

**USA Pharma:** global innovation-driven pharmaceutical and healthcare group

**Fosun Pharma USA:** established U.S. subsidiary in 2017 with a experienced commercialization team

**FOSUN PHARMA**



5 Out-licensing Deals  
USA

GETZ PHARMA

EUROFARMA

ABBOTT

# In-licensing Innovative Products & Technology Platforms

## In-licensing AXC Products & Platforms to Enrich Pipeline

## Cooperation for CDx Development & Commercialization



**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



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



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



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

# 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 <sup>(1)</sup> (serplulimab)+HLX26 PD-1+LAG-3 Solid tumors	HLX10 <sup>(1)</sup> (serplulimab)+HANBEITAI PD-1+VEGF mCRC 1L	HLX10 <sup>(1)</sup> (serplulimab)+chemo PD-1 ES-SCLC 1L	HLX10 <sup>(1)</sup> (serplulimab)+chemo PD-1 ESCC 1L	HANSIZHUANG (serplulimab) <sup>(1)</sup> PD-1 MSI-H solid tumors, sqNSCLC, ES-SCLC
HLX6018 GARP/TGF- Chronic inflammatory diseases	HLX13 (ipilimumab) CTLA-4 MEL, HCC, RCC, mCRC	HLX10 <sup>(1)</sup> (serplulimab)+HLX60 <sup>(2)</sup> PD-1+GARP Solid tumors	HLX10 <sup>(1)</sup> (serplulimab)+HLX07 PD-1+EGFR HNSCC, NPC, GC, ESCC, sq-NSCLC	HLX10 <sup>(1)</sup> (serplulimab)+chemo PD-1 Neo/adjuvant treatment for GC	HLX10 <sup>(1)</sup> (serplulimab)+chemo PD-1 ES-SCLC 1L	HANLIKANG (rituximab) <sup>(12)</sup> CD20 NHL, CLL, RA <sup>(13)</sup>
HLX41 LIV1 ADC Solid tumors		HLX26 LAG-3 Solid tumors, lymphoma	HLX07 <sup>(6)</sup> EGFR Solid tumors (cSCC)	HLX10 <sup>(1)</sup> (serplulimab)+chemo +radio PD-1 LS-SCLC 1L	HLX02 (trastuzumab) <sup>(11)</sup> HER2 Breast cancer, mGC	HANQUYOU (trastuzumab) <sup>(11)</sup> HER2 Breast cancer, mGC
HLX42 EGFR ADC Solid tumors		HLX60 GARP Solid tumors, lymphoma	HLX22+HANQUYOU HER2+HER2 GC	HLX10 <sup>(1)</sup> (serplulimab)+HANBEITAI PD-1+VEGF nsNSCLC 1L		HANDAYUAN (adalimumab) <sup>(14)</sup> TNF- RA, AS, psoriasis, uveitis
HLX43 PD-L1 ADC Solid tumors		HLX35 <sup>(3)</sup> EGFR x 4-1BB Solid tumors	HLX208 <sup>(7)</sup> BRAF V600E LCH/ECD, solid tumors (i.e. MEL, thyroid cancer, mCRC, NSCLC)	HLX04-O <sup>(8)</sup> VEGF Wet AMD		HANBEITAI (bevacizumab) <sup>(15)</sup> VEGF mCRC, advanced, metastatic or recurrent NSCLC, GBM, etc.
HLX44 Nectin4 ADC Solid tumors		HLX301 <sup>(4)</sup> PD-L1 x TIGIT Solid tumors, lymphoma	HLX208 <sup>(7)</sup> +HLX10 <sup>(1)</sup> (serplulimab) BRAF V600E+PD-1 NSCLC	HLX11 (pertuzumab) <sup>(9)</sup> HER2 Neoadjuvant treatment of breast cancer		
HLX80 STEAP1 ADC Prostate cancer		HLX53 TIGIT Solid tumors, lymphoma		HLX14 (denosumab) <sup>(10)</sup> RANKL Osteoporosis		
HLX309 Nectin4 x 4-1BB Solid tumors		HLX05 (cetuximab) <sup>(5)</sup> 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./EU/US 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/ mAbience/ 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.

# R&D: Milestones for Clinical Pipeline

# Clinical Pipeline Milestones - 2022 Review

  
NDA/BLA/MAA  
Submission




1H2022

**HLX10**  
Extensive stage small cell lung  
cancer (ES-SCLC)  
1L (CN)

2H2022

**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)

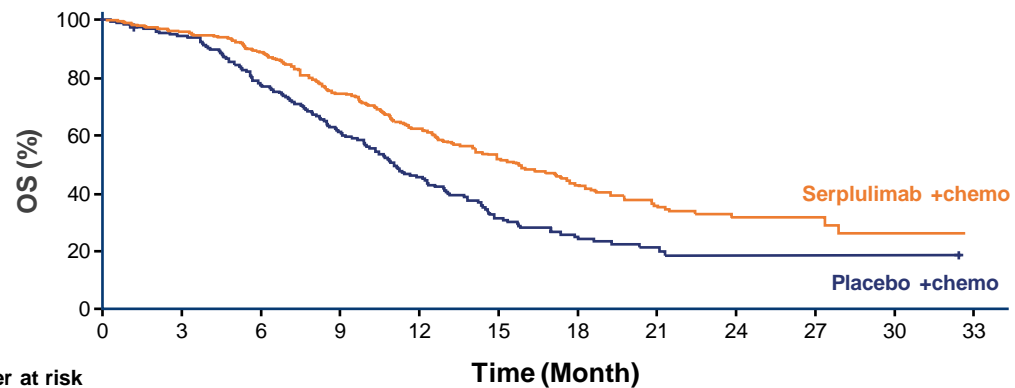
**HLX04-O**  
Wet Age-Related Macular  
Degeneration (Wet AMD)  
(PoC)

**HLX22**  
Gastric Cancer (GC)  
1L (PoC)

 Innovative mAb  mAb biosimilar

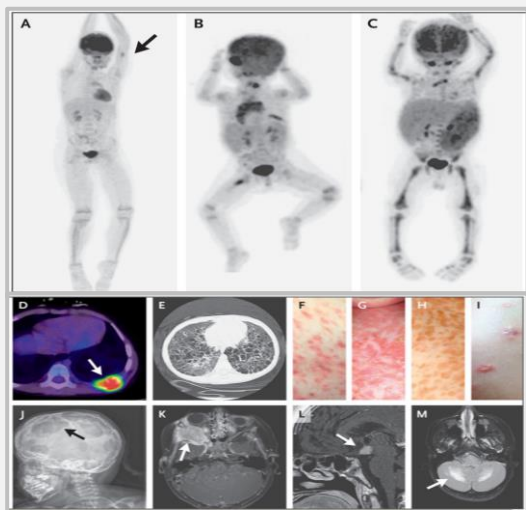
## ASTRUM-005: Presented at 2022 ESMO Asia, updated data for 1L ES-SCLC

Data cut-off date: 2022-6-13

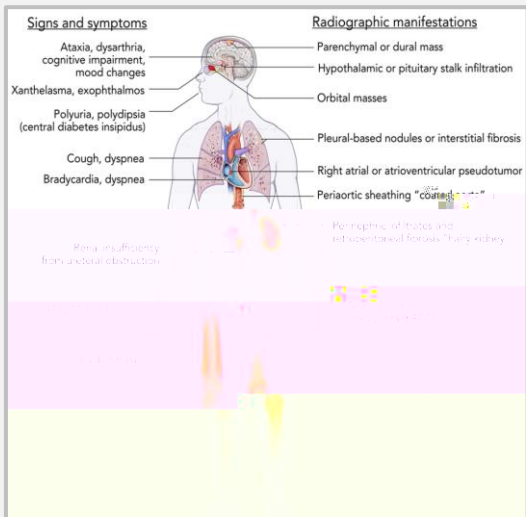


	Number at risk											
	Time (Month)											
Serplulimab	389	368	335	273	227	163	108	54	22	12	4	0
Placebo	196	181	146	111	82	50	32	16	6	2	1	0

# 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 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

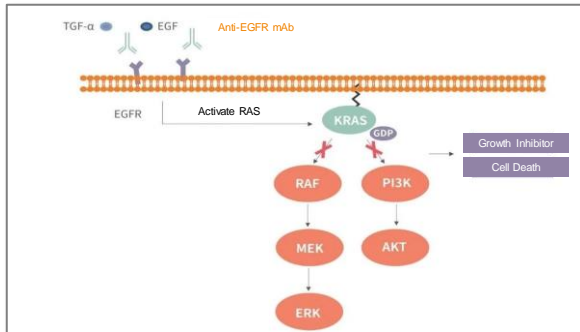
CDE accepted a **single-arm** pivotal clinical trial and the pre-NDA can be conducted 6 months after the enrollment of the last patient

LCH/ECD indication has applied Breakthrough Therapy Designation (BTD)

## Exploration

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

# Advancement of Clinical Pipeline (Phase 2/3)



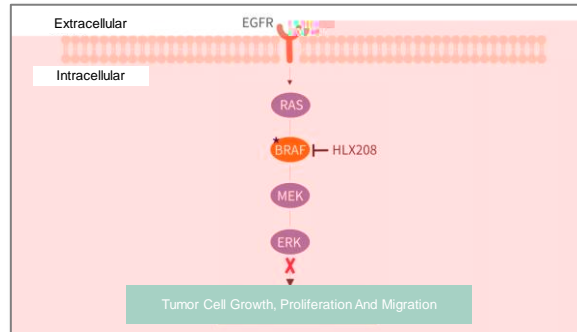
## HLX07(EGFR)

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

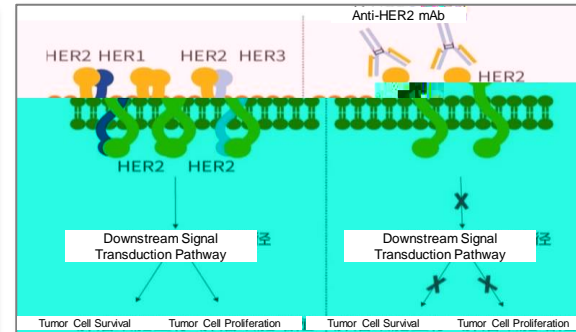
Potentially to be **the first** BRAF product combined with immunotherapy **in China**

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.

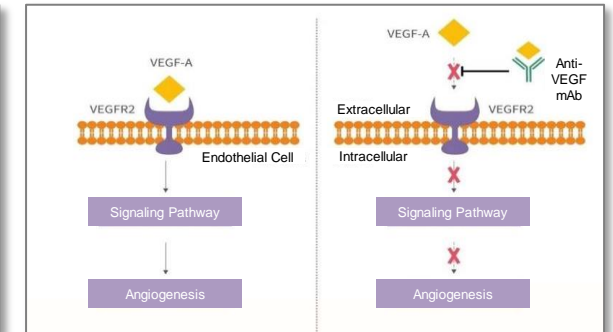


## HLX22(HER2)

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

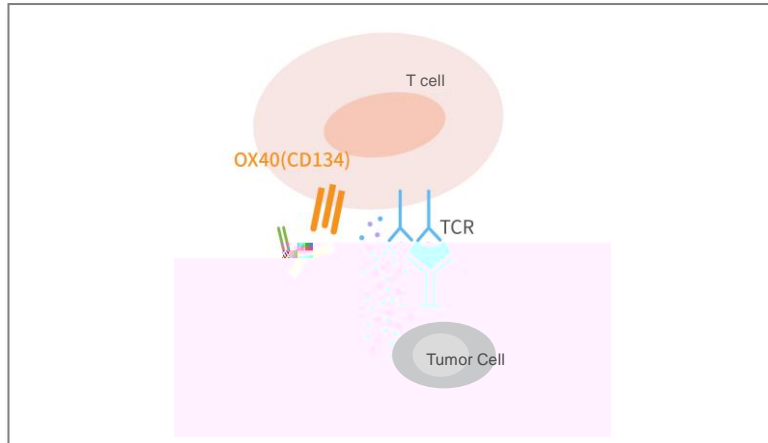


## HLX04-O(VEGF)

Phase I & II studies showed significant BCVA improvement and high likelihood for phase III trial to succeed

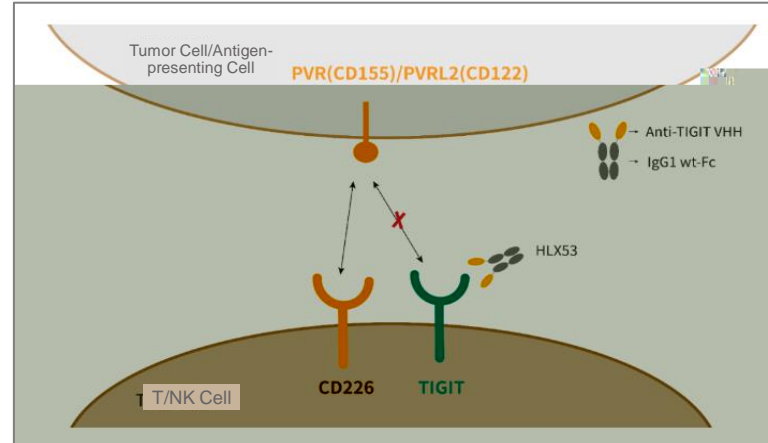
Expected to become **the first batch** of Chinese ophthalmic mAb to market overseas, through two head-to-head controlled phase III trials with Ranibizumab conducted in China and worldwide

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



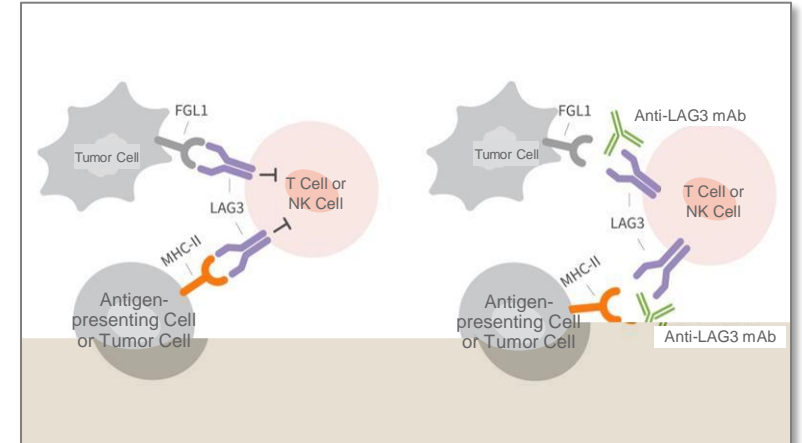
## HLX51(OX40)

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)

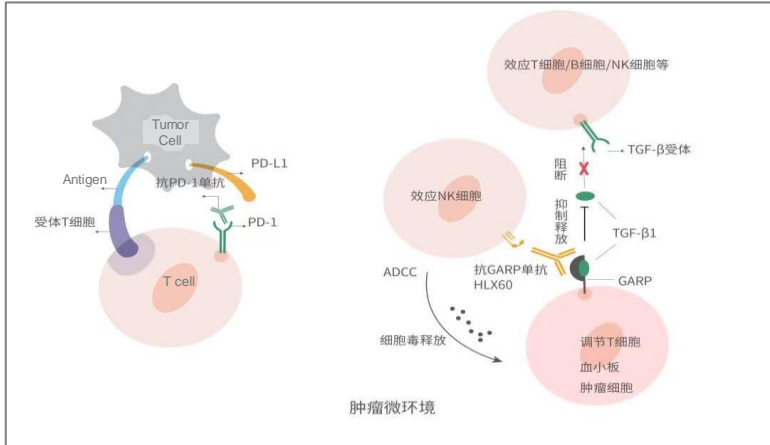
Notable immune regulation in tumor microenvironment  
 HLX53 combo with Serplulimab has observed superior efficacy to Tiragolumab combo with Atezolizumab  
 Demonstrated good safety profile in monotherapy dose escalation



## 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)



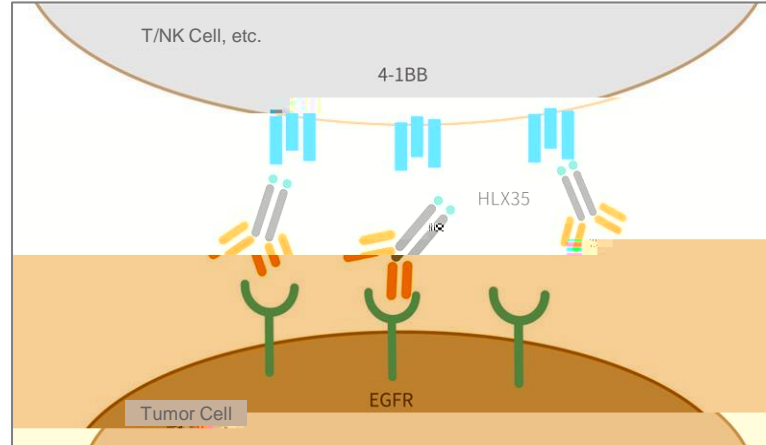
## HLX60(GARP)

Potentially a First-in-Class innovative drug, the first IND in China and the third globally

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

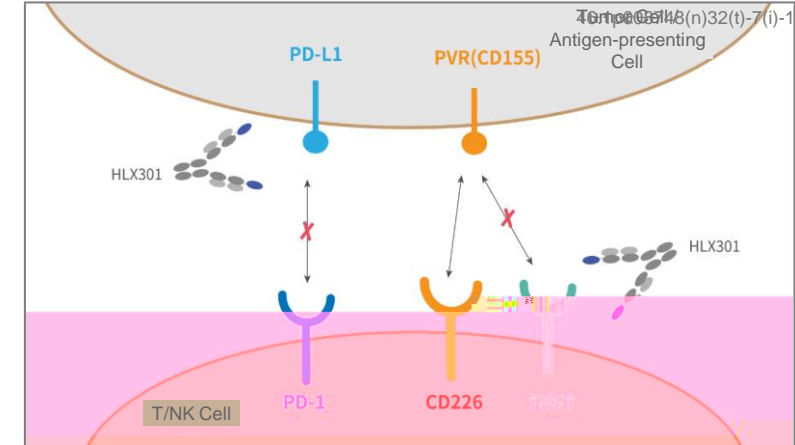


## HLX35(EGFR x 4-1BB)

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



1H2023

**HLX10**

Extensive stage small cell lung cancer (ES-SCLC)  
1L (EU)

2H2023

**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)

**HLX208**

Metastatic colorectal cancer (mCRC)  
(PoC)

**HLX10**

Metastatic colorectal cancer (mCRC)  
1L (PoC)

**HLX10**

Squamous non-small cell lung cancer (sqNSCLC)  
report final OS results  
1L (Pivotal)

**HLX07**

Esophageal squamous cell carcinoma (ESCC)  
(PoC)

**HLX208**

Solid tumor  
(PoC)

**HLX301**

Non-small cell lung cancer (NSCLC)  
1L (PoC)

**HLX07**

Cutaneous squamous cell carcinoma (CSCC)  
(PoC)

**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)

■ Innovative mAb   ■ Innovative bsAb   ■ Innovative small molecules

# 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

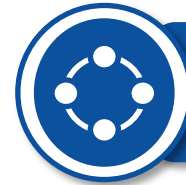
Leveraging RNAi (RNA interference) drugs, mRNA mediated protein replacement therapy, and gene-editing therapy to develop innovative drugs for rare diseases



## 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

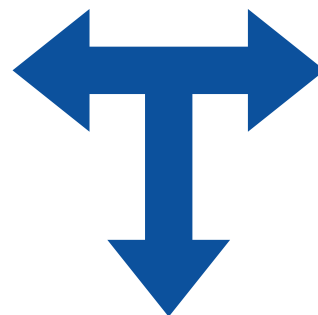
**HLX43  
(PD-L1  
ADC)**

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

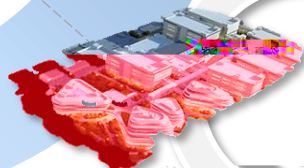
# Manufacturing: Capacity Breakthroughs

(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 1<sup>st</sup> Plant & Xuhui Facility in 2022: **48,000L**

Commercial GMP batches: **582+** since 2019

Manufacturing success rate:

Manufacturing and quality employees: **1200+**

Production strength & intensity **globally leading**



## Songjiang 1<sup>st</sup> 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

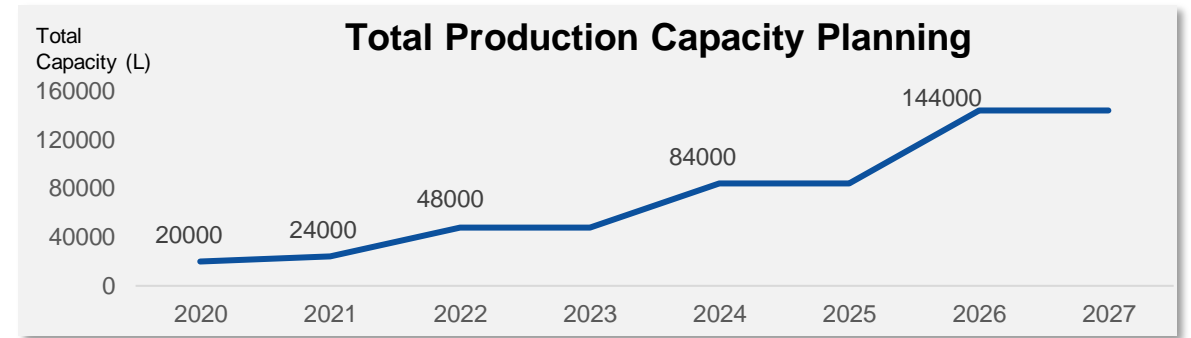
GMP certified by China and EU and capable of manufacturing products for international markets

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

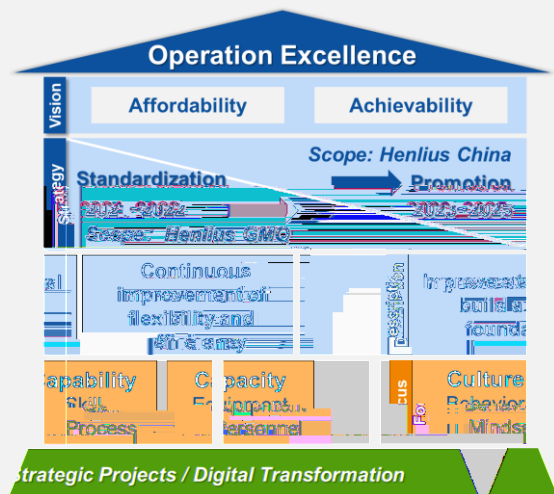
# Total Capacity Estimated to Reach 144,000L by 2026



Design Capacity of Songjiang 2<sup>nd</sup> Plant Phase 1: **96,000L**

# Operation Excellence to Improve Efficiency and Reduce Costs

## Lean Operations

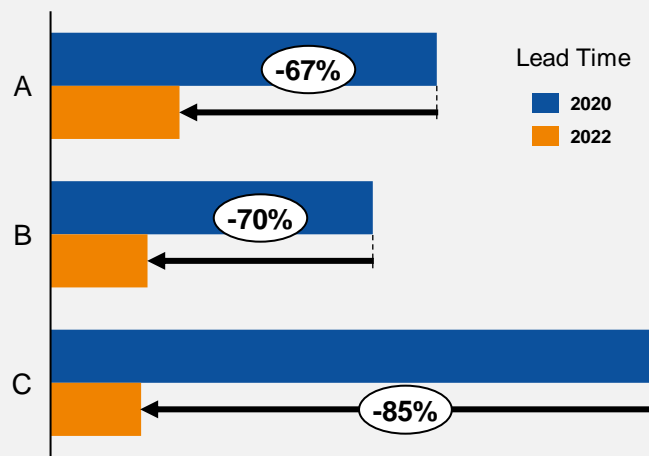


Improve company policies, establishing culture of excellence

Focusing on key businesses, the annualized income of projects exceeds 10 million RMB

Optimize the overall management to implement digital transformation

## Localization

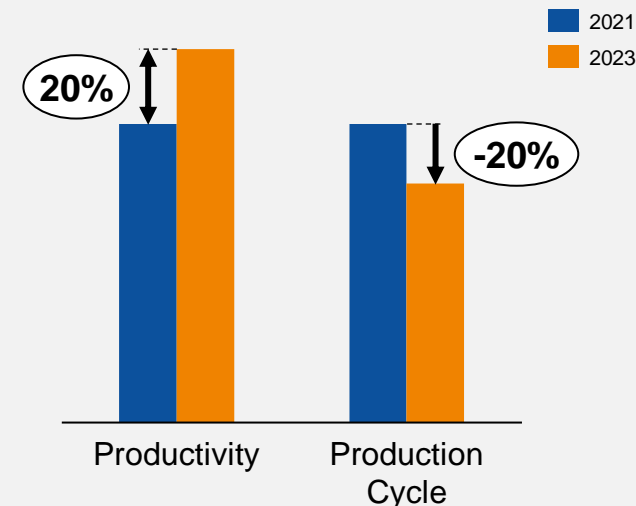


High efficiency and stable domestic raw material supply platform to realize higher productivity

Proprietary culture medium and critical materials to achieve lower cost

Multi-source management of supply chain, flexible response to supply crisis

## Continuous Process Improvement



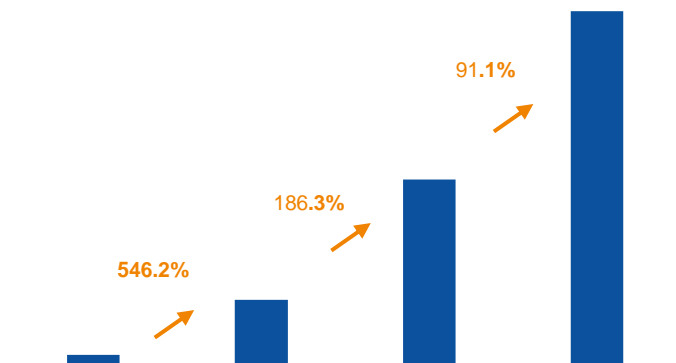
Optimize the technology and the process to improve the productivity

Keep improving, and shorten the production cycle



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

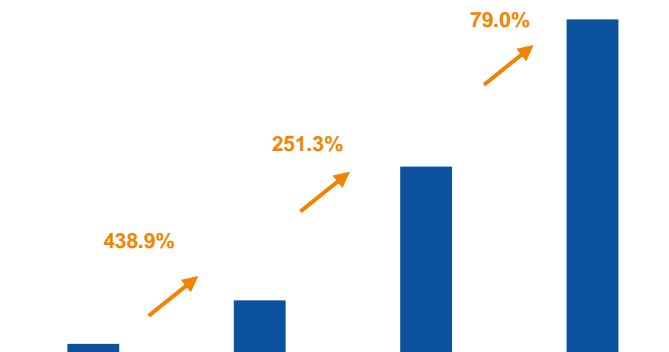
Revenue  
(in Million RMB)



## 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

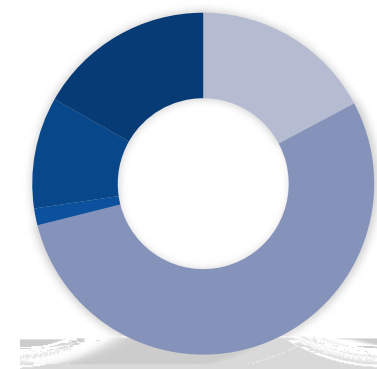
Product Income  
(in Million RMB)



## 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 1<sup>st</sup> Plant being approved; HANSIZHUANG expanded market share quickly to realize revenue driven by early commercialization approval

2022 Revenue Breakdown

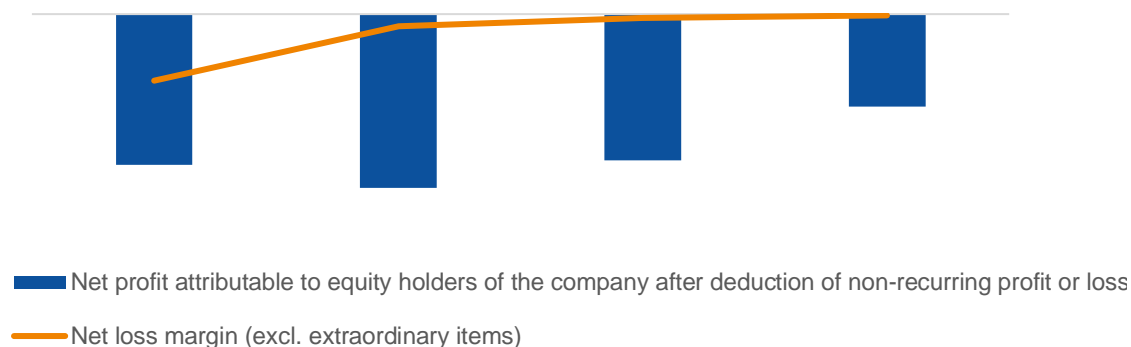


## Revenue Breakdown

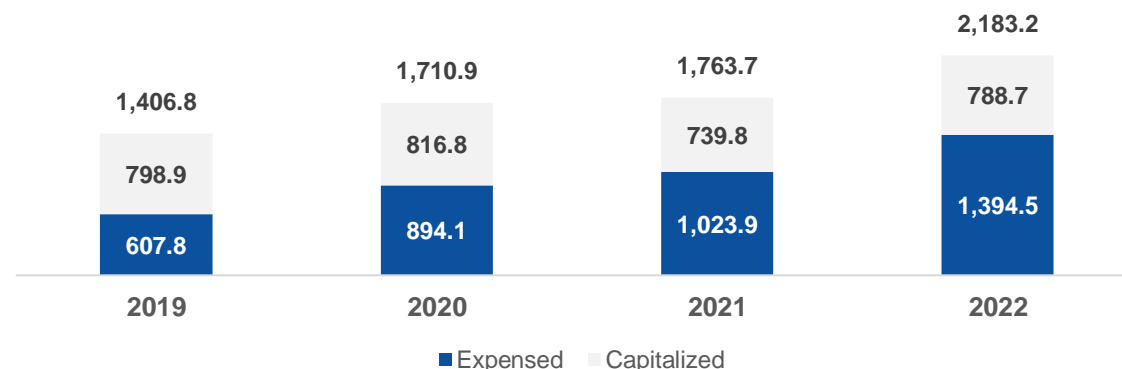
HANQUYOU: 2022 annual sales of RMB 1.73B, 86.1% YoY growth  
HANSIZHUANG: approved in March 2022, revenue of RMB 339M for 9 months after launch  
HANLIKANG: 2022 annual sales of RMB 554M, 2.1% YoY growth  
HANDAYUAN: 2022 annual sales of RMB 51M, 134.5% YoY growth  
BD & others: 2022 total income of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

# 2022 Net Loss Narrowed; Positive Operating CF Generated

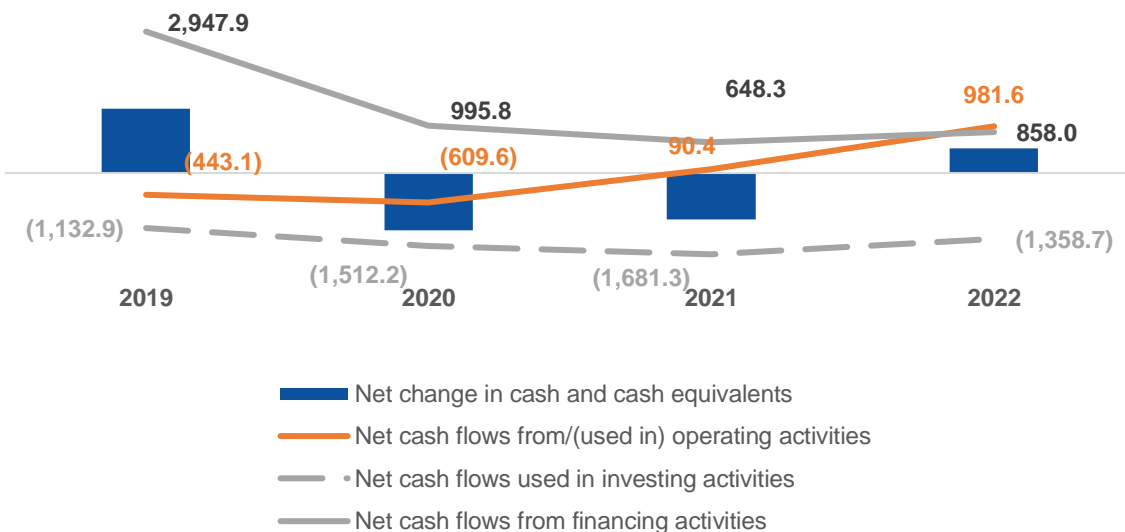
**Net Loss Excl. Extraordinary Items Narrowed**  
in Million RMB)



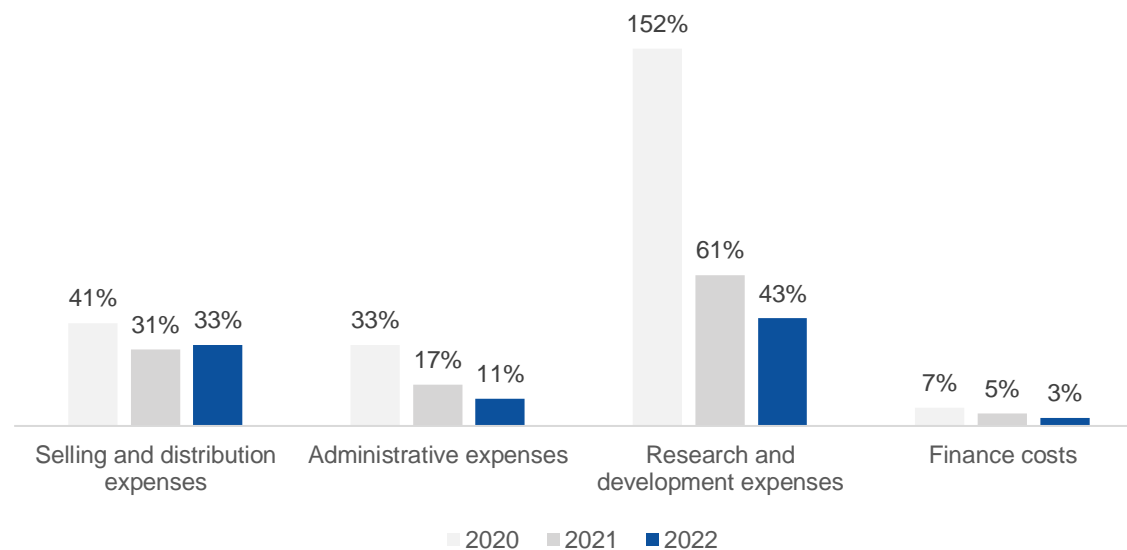
**Total R&D Costs: the portion of R&D costs expensed increased on income statement**  
(in Million RMB)



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



**Expense to revenue ratios steadily decreased**



# 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%)



# Our Goals for 2023

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- ✓ **Revenue:** rapid growth driven by strong market demands of HANSIZHUANG<sup>®</sup> and HANQUYOU<sup>®</sup>
- ✓ **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<sup>®</sup> is expected to be approved in the U.S. by the end of 2023 and submit NDA in 14 countries globally; HANSIZHUANG<sup>®</sup> 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

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