

# Henlius (2696.HK)

## 1H22 Results Investor Presentation

August 2022

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## 1H22 Business Highlights

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## Financial Review & Outlook

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# 1H22 Business Highlights






# 1H22: The Pivotal 6 Months of Henlius Biotech to Biopharma

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- ✓ Sustained operations during Covid outbreaks and lockdowns
- ✓ Doubled production capacity, breaking through the bottleneck
- ✓ Received NMPA approval for the first innovative biological drug, *Serplulimab*
- ✓ Accelerated product sales growth (HANQUYOU & HANSIZHUANG)
- ✓ New license-out milestones (Organon)
- ✓ Innovative R&D transformation starts to bloom

# 1H22 Key Milestones

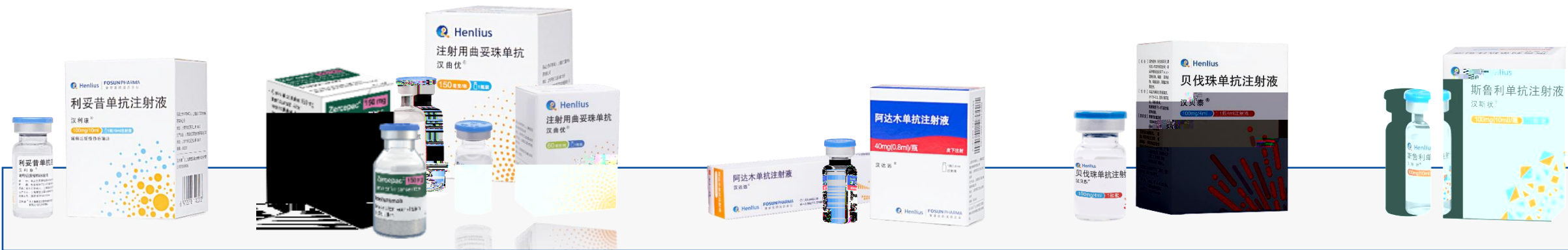
**Our Mission:  
Affordable Innovation, Reliable Quality**

	<b>Products Launched Domestically</b>	<b>5</b>
	<b>Products Launched Internationally</b>	<b>1</b>
	<b>NDA's Under NMPA Review*</b>	<b>3</b>
	<b>Phase 3 Trials*</b>	<b>8</b>
	<b>Total Commercial Production Capacity</b>	<b>48,000L</b>

- IND of HLX53 (anti-TIGIT Fc fusion protein) approved by NMPA
- Reached license agreement with Palleon for bifunctional sialidases
- Reached license agreement with Organon, with payments up to US\$541M on two mAbs products
- HLX35 (anti-EGFR 4-1BB BsAb) first patient dosing in a phase 1 clinical trial in China completed
- 2022.06** ● HANSIZHUANG's 1L ES-SCLC clinical data presented at 2022 ASCO
- 2022.05** ● Songjiang First Plant with a 24,000L capacity began commercial operation for HANQUYOU
- HANSIZHUANG granted orphan-drug designation for SCLC by FDA
- 2022.04** ● NDA for HANSIZHUANG for Extensive Stage Small Cell Lung Cancer (ES-SCLC) accepted by NMPA
- 2022.03** ● HANSIZHUANG (serplulimab) for MSI-H solid tumour indication treatment launched
- 2022.02** ● HANLIKANG (rituximab) for Rheumatoid Arthritis (RA) indication approved in China

\* Note: as of the latest practicable date

# 5 Products Launched: Revenue Tops 1.29 Billion RMB



First Chinese biosimilar

**HANLIKANG (rituximab)**

Approved in 2019.02

China's first self-developed mAbs approved in China and EU

**HANQUYOU (trastuzumab)**

Zercepac® in Europe

Tuzucip® & Trastucip® in Australia

Approved in 2020.08

Approved in 2020.07

Approved in 2022.07

First Chinese adalimumab manufactured in China and EU GMP-certificated production facilities

**HANDAYUAN (adalimumab)**

Approved in 2020.12

The only bevacizumab biosimilar with Phase 3 clinical data for mCRC in China

**HANBEITAI (bevacizumab)**

Approved in 2021.11

Our first self-developed innovative mAb drug

**HANSIZHUANG (serplulimab)**

Approved in 2022.03



**13+11**

Candidates/Combo Therapies under Clinical Studies



**20+**

Clinical Studies



**3**

NDA's under NMPA review

Note: All data as of the Latest Practicable Date

# High-performing Leadership Team with A Global Vision

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**Wenjie Zhang**  
Chairman  
Executive Director and CEO

- Joined Henlius in Mar 2019
- 

**Gino Li**  
Chief Financial Officer  
VP

**Arthur Sheng**  
GM of Global Strategy &  
PMO

**Jinzh Li**  
VP of Legal and  
Compliance

**Ming Yang**  
GM of Immune-Oncology  
Business Unit

**Kurt Yu**  
Chief Commercial Officer  
VP

# Enhance R&D and Commercialisation Capabilities, Evolving to Biopharma

While maximising the commercial value of biosimilars, we rely on our own R&D expertise, complemented by external collaborations and license-in, to accelerate our innovation.



Synergise **China and US** R&D centres, strengthen **translational medicine capability**, advance **differentiated innovation**, to address unmet medical needs

R&D



Assure **Henlius quality**, further improve **manufacturing capacity**, optimise **manufacturing technology**, in order to create competitive **economies of scale**

Manufacturing

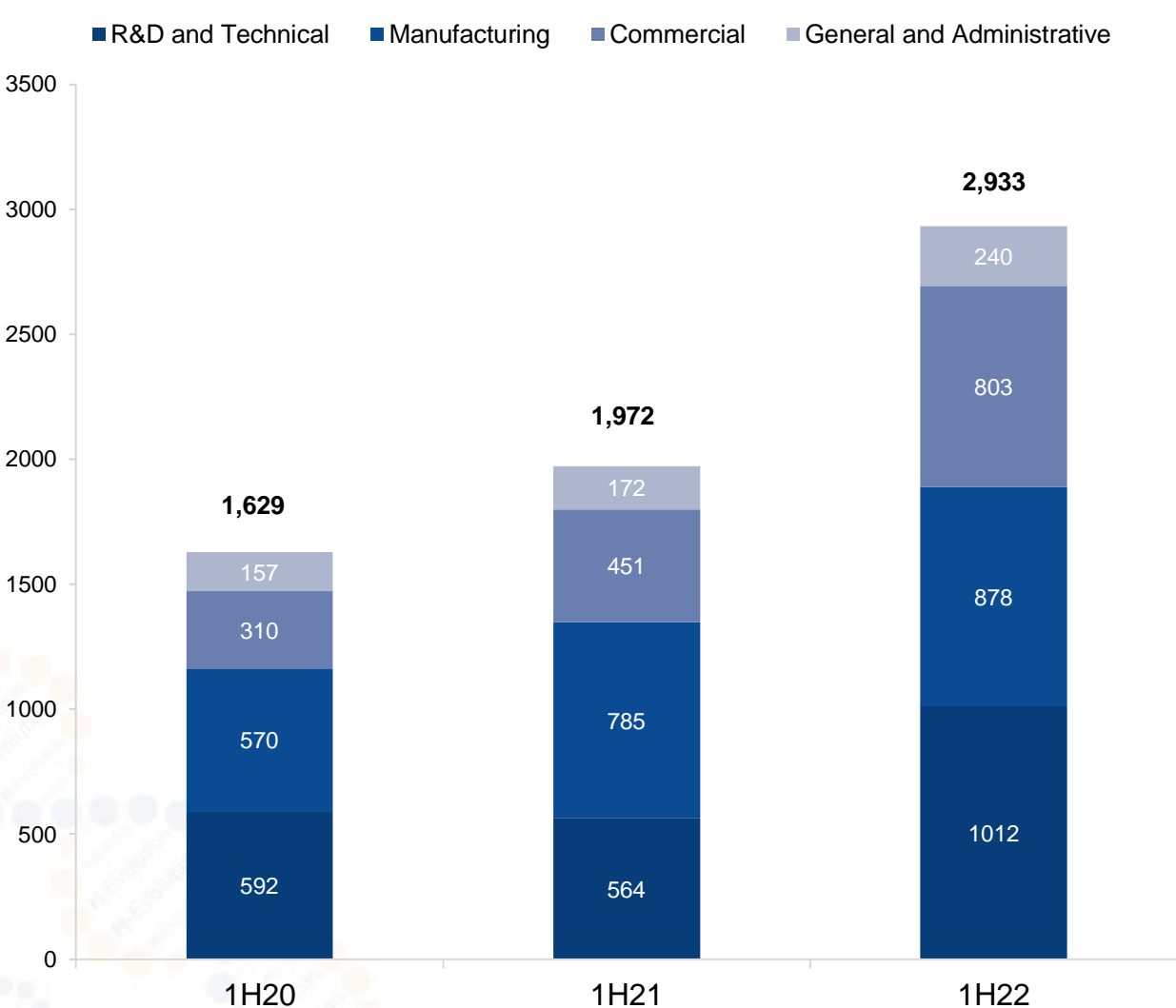


Aim to establish a first-class **commercial team** able to deliver **strong performance** through innovative marketing, access, channel and sales strategies

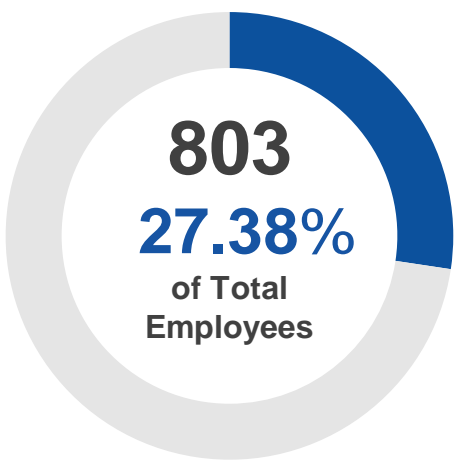
Commercialisation

# Company Scale: Rapid Team Expansion

Company Size and Composition\*



R&D and Technical	1012
Manufacturing	878
Commercial	803
General & Administrative	240



Commercial Team



R&D and Technical Team

Note: as of June 30, 2022  
 1H20 and 1H21 R&D Team only includes R&D and clinical teams;  
 1H22 R&D Team includes R&D, clinical and technical teams

# 2.1

# Commercial Operation





# HANQUYOU (trastuzumab): Outstanding Sales Performance



## Sales performance

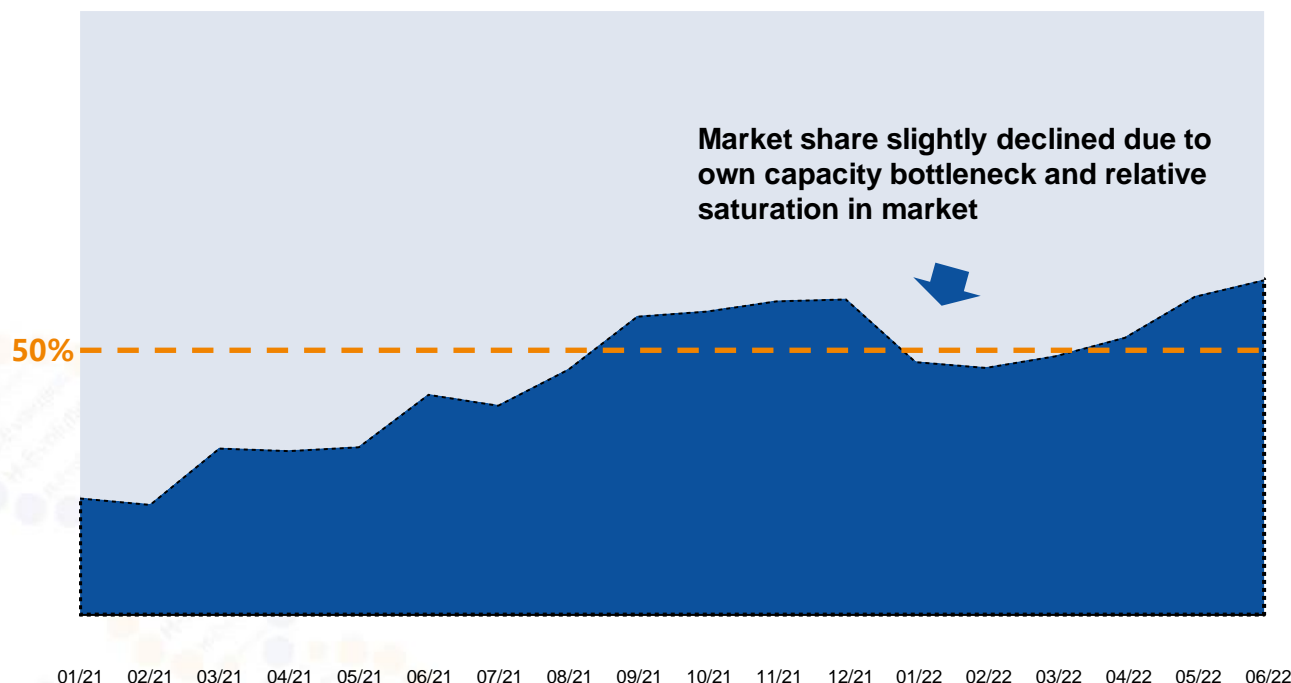
Total estimated accessed market rate reached 70% as of Jun 30, 2022, market share in accessed market reached 50%



## Efficient sales investment

Enhanced efficiency to achieve sustainable development and returns

Market Share



>3.16M  
RMB

## Sales per capita

Benchmark against domestic counterparts (~1.5M-2M) \*

<39%

## Sales Expenses as share of Revenue

Benchmark against domestic counterparts (~60%-80%) \*

Data source 1. internal sales data 2. IQVIA CHPA  
3. Accessed market rate=accessed market potential / total market potential  
4. Annual report of domestic innovative biopharma

# HANQUYOU: 60mg Specification Launched, Advanced Leading Position in the Trastuzumab Market



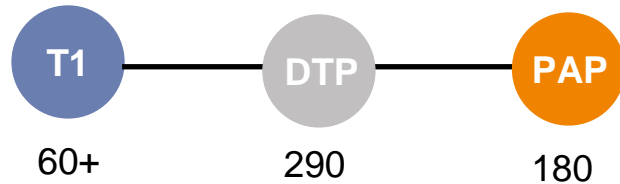
## Establishing new standard among peers

- 01 Adjustable Dosage**  
Suitable for Asian Female Patients
- 02 Dual Drug Specifications**  
Standardising Drug Adoption
- 03 Superior Formulation**  
No preservatives, fewer side effects

# HANSIZHUANG (serplulimab): Successful Launch in March

## DTP channel optimisation

- Pursued synergistic effect with HANQUYOU, established efficient distribution network
- Maximised access by leveraging DTP pharmacies and infusion centres



## Refined management

- Establish a field team of **200+** who have extraordinary communications skills and experience in the oncology drugs market
- Created a team culture of professionalism, efficiency and compliance

## Access and market penetration

### Accelerated bidding

Complied with national drug code system regulation, completed tenders on procurement platforms in 18 provinces

### Focus on core hospitals

Introduced to 21% of the Top 110 hospitals

## Henlius Speed: outstanding sales performance



Benefited  
**2,485**  
Patients

Within 3 month of first prescription

# HANSIZHUANG (serplulimab): Under China NDA Review for sqNSCLC and SCLC Indications



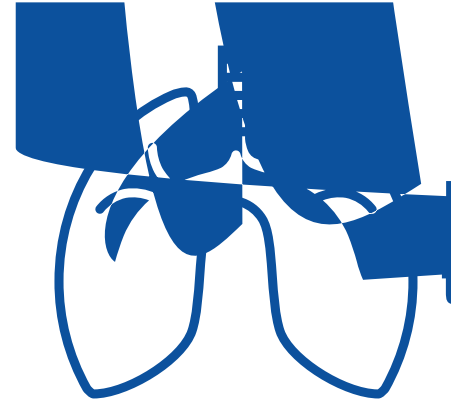
## Market prospects

- 800k+ new lung cancer patients every year (170k+ in sqNSCLC, 120k + in SCLC)
- HANSIZHUANG would potentially be the world's first PD-1 inhibitor for the first-line treatment of SCLC indication



## Clinical efficacy profile

- Significantly extended the mOS of patients with sqNSCLC
- Superior mOS among all anti-PD-1 mAb for first-line treatment of SCLC
- Lowest HR value among all registered treatments for SCLC, with better efficacy among Asian demographics



Exploring lung cancer treatment potential

**sqNSCLC expected to be approved in 2H22**

**ES-SCLC expected to be approved in 1H23**

# HANLIKANG (rituximab) :Market Leader amid Competition and COVID-19 Pandemic



## Market Access

### 100mg:

Listed on the procurement platform in **30 provinces and municipalities** except Yun Nan by the end of June; Covered by medical insurance schemes in **30 provinces and municipalities** except Tibet

### 500mg:

Listed on the procurement platform in **26 provinces and municipalities** by end of June; Covered by medical insurance schemes in **14 provinces and municipalities**

### Hospital listing:

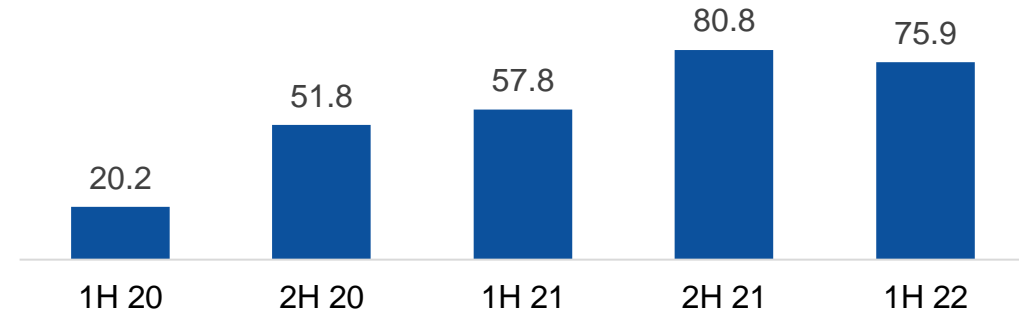
**74%** of Top300 hospitals have introduced the product

\* Fosun Pharma is responsible for the commercialisation of HANLIKANG

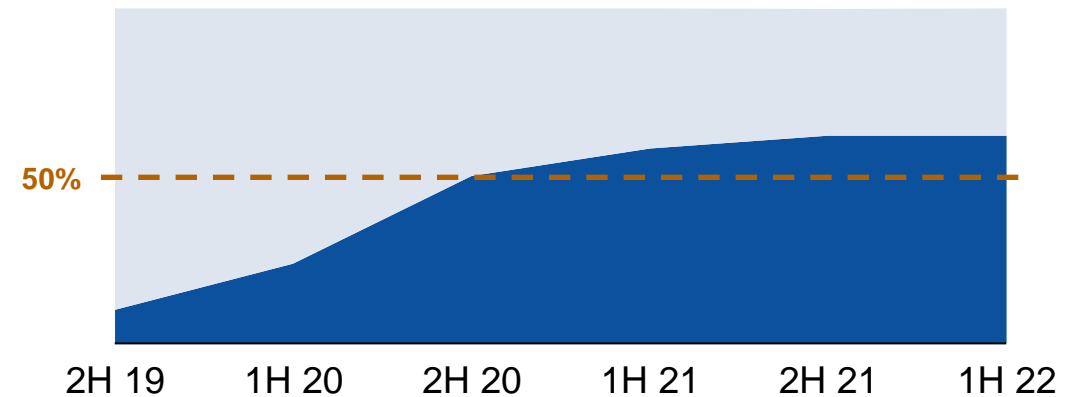


## Sales Performance\*

### Ex-factory Sales\* (Unit:10,000 vials)



### Market Share

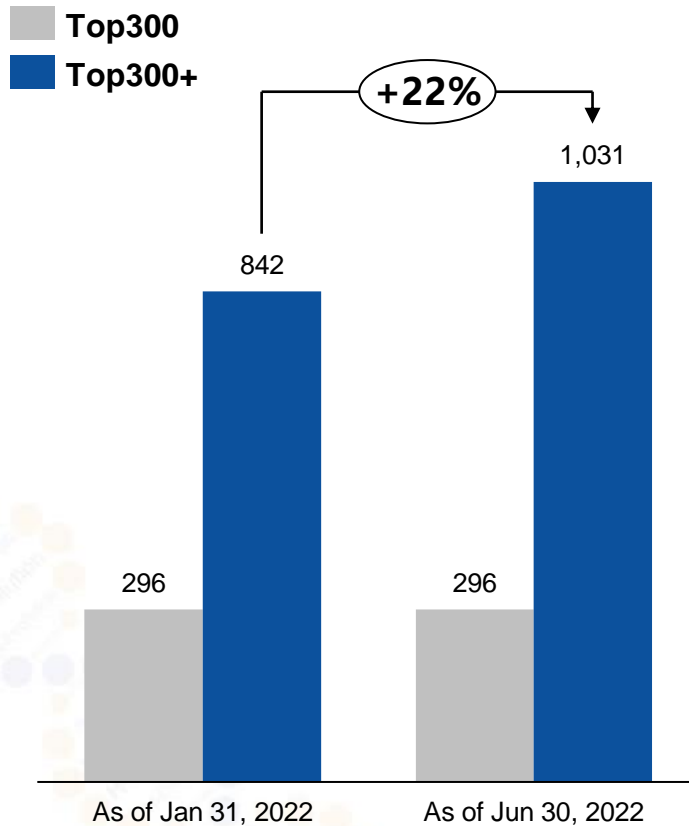


\* ex-factory sales volume based on 100mg for calculation

# HANLIKANG: Rapidly Claiming Market Share in RA Treatment

## Consolidated leadership in core market and expanded further

By June, the number of Top 300+ hospitals with HANLIKANG prescriptions has climbed 22% since the beginning of the year



Hospital no. by Tiers

## Approved for RA Indication, proactively preparing NRDL negotiations



### Expanding application scenarios

The originator drug has not approved for RA indication treatment by NMPA

Low dosing frequency, sustained efficacy

Combined treatment in full course with HANDAYUAN




# 2.2

## Innovative Biological Drugs R&D Milestones (Clinical Phase)

Products		Targets	Indications	Pre-clinical	IND	Phase 1	Phase 2	Phase 3	NDA	Launch	Business Partners
HANSIZHUANG (serplulimab) <sup>(1)</sup>		PD-1	MSI-H solid tumours								
HLX10 (serplulimab injection) <sup>(2)</sup>	+chemo	PD-1	squamous non-small cell lung cancer 1L	Global multi-centre clinical study							
			extensive-stage small cell lung cancer 1L								
HLX10 (serplulimab injection) <sup>(2)</sup>	+chemo	PD-1	metastatic esophageal squamous-cell carcinoma 1L								
			neo-/adjuvant treatment of gastric cancer								
	+chemo +radio	PD-1	limited-stage small cell lung cancer 1L								
			non-squamous non-small cell lung cancer 1L								
	+HANBEITAI	PD-1+VEGF	hepatocellular carcinoma 1L								
			metastatic colorectal cancer 1L								
	+HLX07	PD-1+EGFR	squamous cell carcinoma of head&neck 2L								
squamous non-small cell lung cancer 1L											
+HLX26	PD-1+LAG-3	solid tumours, lymphomas									
HLX04-O <sup>(3)</sup>	VEGF	wet age-related macular degeneration									ESSEX 亿健
HLX22 +HANQUYOU	HER2+HER2	gastric cancer									
HLX07 <sup>(4)</sup>	EGFR	solid tumours non-small cell lung cancer, esophageal carcinoma, etc.									
HLX208 <sup>(5)</sup>	BRAF V600E	Metastatic colorectal cancer, non-small cell lung cancer LCHand ECD									
HLX26	LAG-3	solid tumours, lymphomas									
HLX35 <sup>(6)</sup>	EGFR x 4-1BB	solid tumours									
HLX301 <sup>(7)</sup>	PD-L1 x TIGIT	solid tumours									
HLX23 <sup>(8)</sup>	CD73	solid tumours									
HLX53	TIGIT	solid tumours, lymphomas									

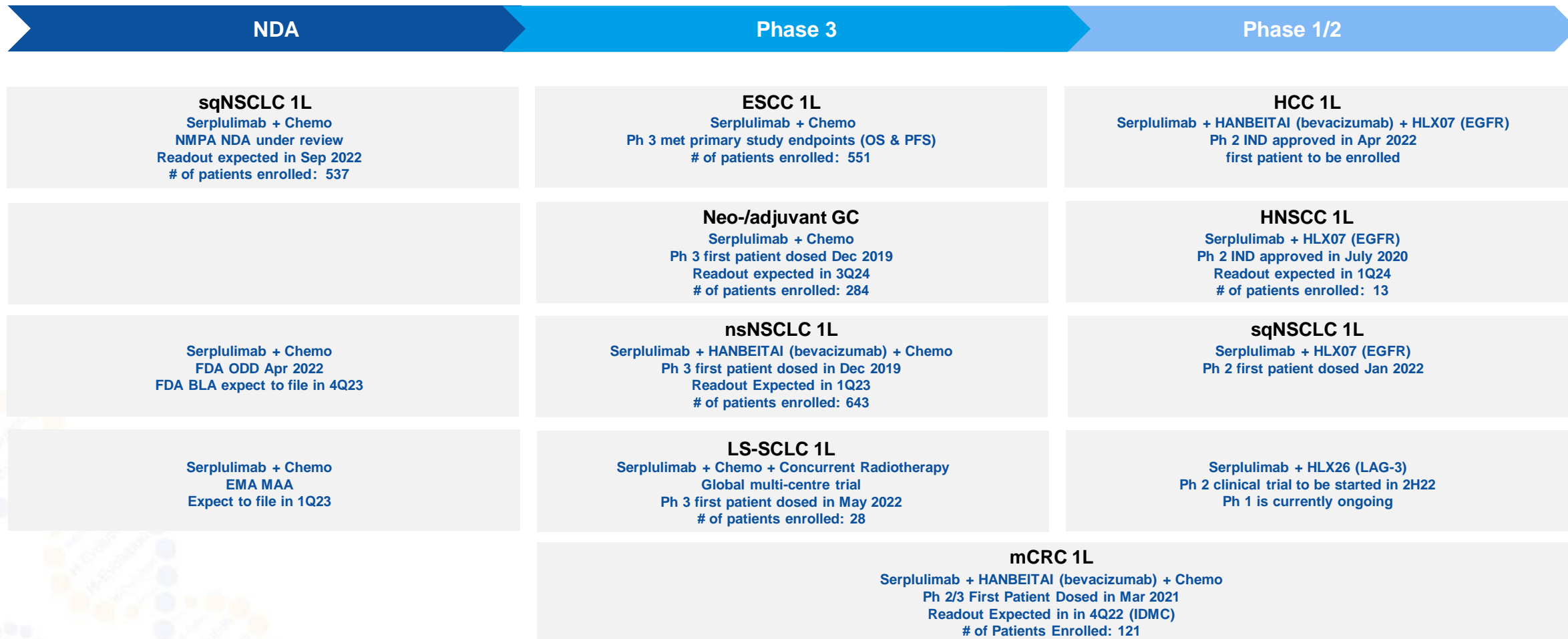
(1) Indication of MSI-H solid tumours approved in March 2022.

# Pipeline Catalysts in 2H22 and 2023

	2H2022	1H2023	2H2023
 <p><b>NDA/BLA/MAA Submission</b></p>	HLX10 – Esophageal squamous cell carcinoma (ESCC) 1L (CN)	HLX10 – Extensive Stage Small Cell Lung Cancer (ES-SCLC) 1L (EU)	<p>HLX10 – Non-squamous Non-Small Cell Lung Cancer (nsNSCLC) 1L (CN)</p> <p>HLX10 – Extensive Stage Small Cell Lung Cancer (ES-SCLC) 1L (US)</p>
	 <p><b>Key Study Clinical Data Readouts</b></p>	<p>HLX07 – Cutaneous squamous cell carcinoma (CSCC)</p> <p>HLX10 – squamous Non-Small Cell Lung Cancer (sqNSCLC) 1L (Pivotal)</p> <p>HLX10 – metastatic Colorectal Cancer (mCRC) 1L (PoC)</p> <p>HLX22 – Gastric Cancer (GC) 1L (PoC)</p> <p>HLX04-O – wet age-related Macular Degeneration (wAMD) PoC</p>	<p>HLX10 – Non-squamous Non-Small Cell Lung Cancer (nsNSCLC) 1L (Pivotal)</p> <p>HLX208 – metastatic Colorectal Cancer (mCRC) (PoC)</p>
 <p><b>New Phase 3</b></p>		HLX10 – metastatic Colorectal Cancer (mCRC) 1L	<p>HLX22 – Gastric &amp; Gastroesophageal junction cancer (GC&amp;GEJ) 1L</p> <p>HLX301 – Non-Small Cell Lung Cancer (NSCLC) 1L</p>

# Serplulimab: Clinical Trials on Major Oncology Indications

Serplulimab approved for 10+ clinical trial projects in China, the US, the EU, etc.



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MSI-H  
Solid Tumour

Esophageal  
Squamous-cell

Lung Cancer

Hepatocellular  
Carcinoma  
(HCC)

# Serplulimab: Presented Orally at ASCO, Shows Extraordinary Clinical Data for 1L ES-SCLC

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- Serplulimab combo with chemotherapy showed **consistent benefits** in OS, PFS, ORR and DOR. Long-term efficacy benefits were also observed;
  - **mOS: 15.4** vs 10.9 months, HR=0.63, p <0.001
  - **mPFS: 5.7** vs 4.3 months, HR=0.48
-

# Serplulimab: Better mOS and HR Results

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# Advancement of Clinical Pipeline (Ph 2/Ph 3)

## HLX07

(EGFR)

- A recombinant **humanised** anti-EGFR monoclonal antibody, with a **LONGER half-life** compared with Cetuximab
- Showed higher safety and antitumour activity in phase 2 clinical trial. The ORR confirmed by IRRC and INV was 38.5%, better than the historical data of 23% (Pembrolizumab)

## HLX208

(BRAF  
V600E)

- Has strong oral bioavailability and safety profile. Expected to be the world's **first BRAF inhibitor** approved in adult LCH indication treatment
- Now in phase 2. Expected to be the **first BRAF inhibitor** to be combined with immunotherapy in China

## HLX22

(HER2)

- Targeting distinct epitopes within **domain IV** of Her2. PDx data demonstrates the combo of HLX22 and Trastuzumab (also target epitope domain IV) excels the combo of Trastuzumab and Pertuzumab in GC
- Shows big potential for upgrading SoC of 1L metastatic GC/GJC treatment, with a predicted ORR of 85+%, based on current phase 2 data unblind in Oct.

## HLX04-O

(VEGF)

- Showed significant BCVA improvement in phase 1/2 trial and high success rate in phase 3 trial
- Expected to become the **first batch** of domestic ophthalmic mAb to go overseas, through two head-to-head controlled phase 3 trials with LUCENTIS conducted in China and worldwide

# HLX22: Great Efficacy in Ph 2 Clinical Trial

## A candidate of 1L HER2+ gastric cancer treatment with great potential

1. HLX22 emerges as a strong candidate with an expected ORR of 85% in HER2+ locally advanced/metastatic GC, based on the efficacy data from a double-blind, randomized, multi-centre Ph 2 study. The subsequent study will continue exploring the synergistic efficacy of HLX22 and Serplulimab
2. A global pivotal study for HLX22 in treatment of HER2+ GC 1L is planned in 2023
3. Enhertu has yet to initiate Ph 2/3 study in 1L GC. It was approved by FDA for the treatment of patients with HER2+ locally advanced or metastatic GC who have received a prior anti-HER2-based regimen (DESTINY-Gastric01) with ORR at 51% vs. 14% (Enhertu 125pts vs. Chemo 62pts)

Clinical Trial	Regimen	Sample Size	Primary Endpoint	ORR
HLX22	HLX22-GC-201 Ph 2 HLX22(25mg/kg)+Trastuzumab+XELOX vs HLX22(15mg/kg)+Trastuzumab+XELOX vs Trastuzumab+XELOX	54+128	PFS/ORR	INV : • HLX22 15mg cORR 100%(2/2) • Blind data cORR 77.3% (17/22)  Predicted unblind ORR of HLX22 cohorts reaches 85+%
Pembrolizumab	KN811 Ph 3 Pembrolizumab + Trastuzumab + CF/XELOX vs Trastuzumab + CF/XELOX	732 (1:1) Efficacy based on first 264 pts	PFS/OS	IRRC cORR: 74.4% vs 51.7% (N= 133 vs 131) P = 0.00006
ZW25	NCT04276439 Ph 2 Tislelizumab+ZW25+Chemo	33	ORR	INV: cORR 75.8%
SOC	ToGA Ph 3 Trastuzumab+CF/CX vs CF/CX	584 (1:1)	OS	47.3% vs 34.5% P = 0.0017



# HLX208 (BRAf V600E Inhibitor): Ongoing Clinical Trials

## Indications

- Non-Small Cell Lung Cancer (NSCLC)
- Eangenhans cell histiocytosis (LCH) and Erdheim-Chester Disease (ECD)
- Metastatic colorectal cancer (mCRC Mono and Combo)
- Anaplastic Thyroid Cancer (ATC)
- Melanoma (Mel)
- Brain tumour (BT)
- Other solid tumour

## Strategic Significance

- Fast to Market Scheme
- Expected to be the second approved domestic BRAf inhibitor in lung cancer treatment
- Fast to Market Scheme
- Expected to be the only approved BRAf product (LCH) in the medium and long term
- Efficacy w-8(l)5(o1dp]TJETQ EMCVP < MCID 100>BDC 834.96 57.84 72.96 42.96 ref\* E
- Quickly start the first-line Phase 3 clinical trial after getting the efficacy data of HLX208
- One of the strongest players in terms of development speed
- Expected to be the only approved BRAf inhibitor in the medium and long term (ATC)
- Explore the other potential indications

Ph 2

Ph 2

Ph 1b/2

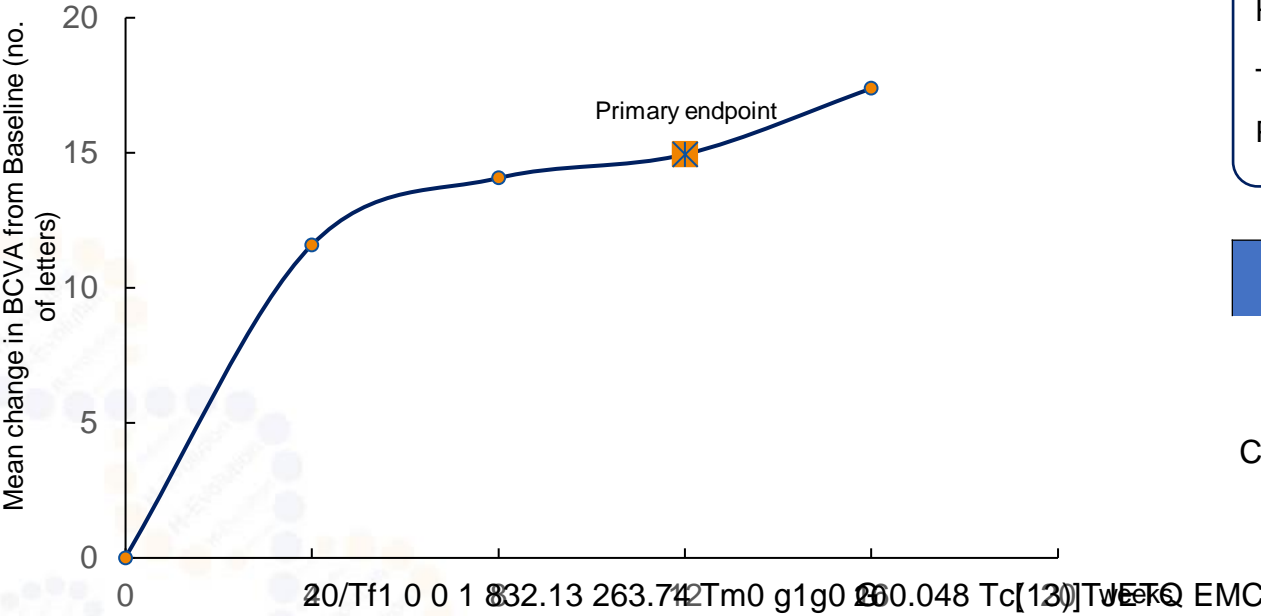
Ph 2

Langenhan

# HLX04-O: Ph 1/2 Showed Safety and Preliminary Efficacy

Clinical Trials	Ph 1	Ph 2	Ph 3
HLX04-O-wAMD-CN01	[Progress bar]		
HLX04-O-wAMD-CN	[Progress bar]		
HLX04-O-wAMD-Global	[Progress bar]		

The mean changes from baseline in BCVA of HLX04-O (HLX04-O-wAMD-CN01 cutoff date: July 7, 2022)



HLX04-O-wAMD-CN01: The results indicated the safety and preliminary efficacy of HLX04-O among patients with wet Age-related Macular Degeneration (wAMD). The mean improvements of BCVA was 6.6 and 10.7 respectively in the two pivotal Phase 3 trials of Lucentis.

	Baseline	4W	8W	12W	16W
Pts Num.	20	19	17	18	13
Mean Change from Baseline	0.0	6.6	10.7	10.7	10.7

# Highlights of Early-Stage Clinical Assets (Ph 1/2)

## HLX23 (CD73)

- With differentiated mechanism, no hook effect compared to previous CD73 inhibitors
- More significantly and persistently inhibit CD73 activity and induce CD73 internalisation

## HLX53 (TIGIT)

- Strong immune regulating effects in TME
- HLX53 combo with Serplulimab was observed significantly superior to Tiragolumab combo with Atezolizumab

## HLX26 (LAG-3)

- Significant synergy in virous xenograft models (mCRC, NSCLC) in combination with anti-PD-1 antibody
- Good tolerability and safety profile

## HLX60 (GARP)

- **Potentially a first-in-class innovative drug**
- **The first IND in China and the third globally**
- Single agent or combo with ICI showed good efficacy in different tumour model

## HLX35 (EGFRx 4-1BB)

- **Potentially a first-in-class innovative drug** and the first IND globally
- Potent efficacy by simultaneously blocking EGFR signaling and activating T effector cells and NK cells, and is effective for EGFR antibody insensitive tumours

## HLX301 (PD-L1 x TIGIT)

- Differentiated molecule design from other competitors
- Significantly superior to Tiragolumab combo with Atezolizumab in different animal models in cancer research

# 2.3

## Early Stage R&D Strategies (Pre-clinical Phase)

# R&D Goal: Antibody-centric approach with further innovation to be the backbone of innovative drug ecosystem

**10  
Years**

**2010-2020**

**Leader in biosimilars**

**Start with Biosimilars, entered innovative drugs:**

- HLX01/ 02/ 03/ 04<sup>1</sup> and other biosimilars as an initial focus
- Innovative drugs (e.g.HLX10 (PD-1)) entered late clinical stage.

- **Antibody production with internationally recognised quality and reasonable cost**

**Accomplished**

**Key  
Features**

**Core  
Ability**

**5  
Years**

**2020-2025**

**Benchmark in innovative biologics**

**Focus on major cancer types, expand non-oncology, evolve new modalities:**

- Capitalise fully on marketed and existing late-stage clinical assets (PD-1, HER2).
- Address unmet clinical needs with innovative antibody design with AXC, small antibodies and bispecific antibodies
- Develop new drug modalities such as nucleic acid and iPS cell therapy.

- **R&D system for innovative antibody drugs such as small antibodies and transmembrane antibodies**
- **AXC innovative technology platform**
- **New drug modalities, e.g. nucleic acid, iPS cell**
- **Rely on in-house R&D, complemented by external in-licensing and co-de**

**Accelerating innovation**

**5  
Years**

**2025-2030**

**Backbone of innovative drug ecosystem**

**Further Innovation with data-driven pharmaceuticals and diagnostics:**

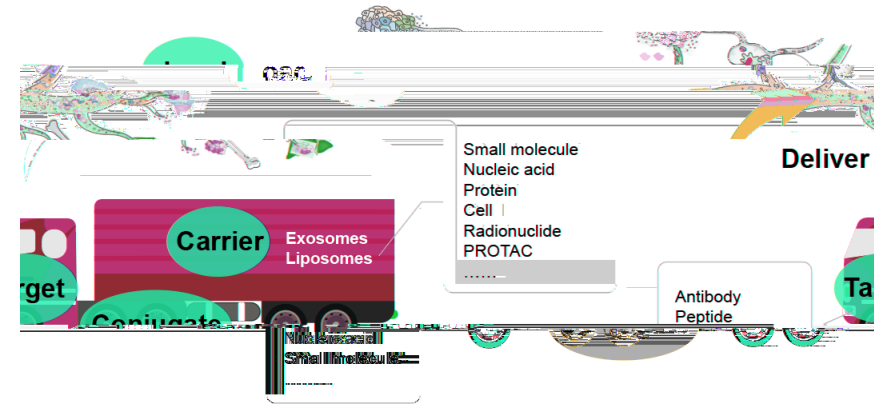
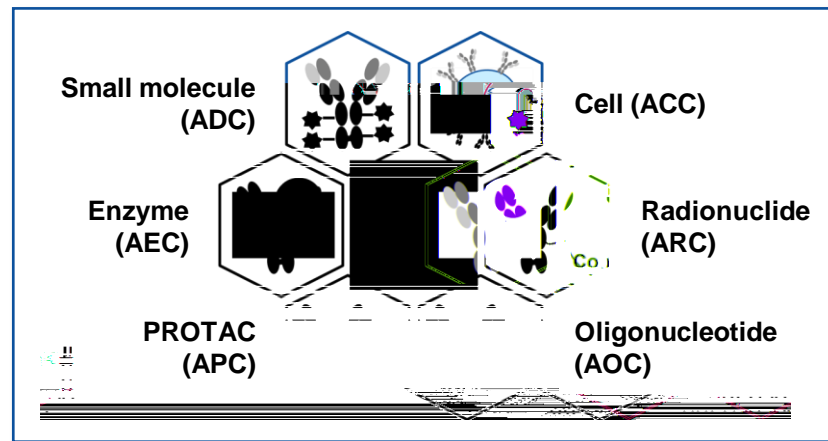
- **Medical data + Bioinformatics:** First-in-indication, or best-in-indication targets
- **Molecular engineering + Bio-computation:** Dynamic molecule design and combo development.
- **Precise diagnostics + Optimised therapy:** Highly precise and personalised medication solutions.

- **Discovery and validation of innovative targets**
- **Diversified platforms for drug development:** antibody, peptide, nucleic acid, cell, XXC, etc.
- **Pan-ecosystem collaboration:** universities, hospitals, research institutes, biopharma/biotechs, etc.
- **A powerful translational science platform**

# R&D Strategy: Build up AXC Platform, Empower Further Innovation

Within 1 Year

1-3 Years



- Antibody-centric, Evolved Modality (AXC: Antibody X-molecule conjugate)
- **Expected IND:** 4-5 ADC and AXC products, including 2 potential first-in-class ADC products, which are expected to be submitted for an IND in June 2023
- Completed ADC pilot production workshop construction, will adopt Payload (with intellectual property rights) to develop ADC products
- **IND enabling stage:** 4 potential first-in-concept products will start IND enabling, as well as 6 potential differentiated innovative Best-in-class products
- Several products for non-oncology indications entered preclinical development stage

- Expand R&D of XXC products, focusing on developing targeted delivery and blood-brain barrier drugs coupled with exosomes;
- Further develop CAMD (Computation Accelerated Molecule Design) platform to improve molecular design and R&D capabilities
- Focus on nucleic acid drug design and development, iPS cell induction and differentiation technology
- Conduct translational medicine research, improve R&D efficiency through in-depth exploration of biological networks and biomarker discovery
- Accelerate the integration and differentiated innovation of China and US R&D centres, push forward talent recruitment schemes, and strengthen methods to introduce outside intelligence

# Pre-Clinical Pipeline: Aim to Solve Unmet Medical Needs

## HLX51 (mAb)

- Induces **OX40** clustering through tetravalent binding and exerts immune activation
- Exhibits dose-dependent tumour-killing effect in multiple tumour models
- Significant synergistic effect with PD1/PDL1 antibodies
- Significantly outperforms competing molecules, both single and in combination with PD1/PDL1 antibodies

## HLXD6018 (mAb)

- Potential **first-in-class monoclonal antibody**
- Clear MOA, unique immune microenvironment modulation effect
- Exhibits good efficacy in a variety of tumour models both single and in combination with immune checkpoint inhibitors
- Can also develop indications of fibrotic diseases

## HLXD42 (ADC)

- Potential **first-in-class ADC product**
- TME-dependent activation and release of payload
- Good tumour-killing effect against multiple EGFR inhibitor resistant or mutated solid tumours
- Excellent therapeutic window

## HLXD72 (rPro)

- Pioneering **first-in-concept new drug**
- Unique MOA, can simultaneously inhibit inflammatory response and promote damage repair
- Exhibits good efficacy in a variety of inflammatory disease models
- Vast disease population, huge unmet clinical needs

## HLXD43 (ADC)

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

## HLXD307 (rPro)

- Pioneering **first-in-concept new drug**
- Unique MOA, can simultaneously lower blood sugar and promote kidney damage repair
- Exhibits good efficacy in DKD models
- Vast disease population, huge unmet clinical needs

# 2.4

## Biosimilar Milestones

# Product Pipeline - Biosimilars

	Products	Targets	Indications	Pre-IND	IND	Phase 1	Phase 2	Phase 3	NDA	Launch	Business Partners	
Launched	HANLIKANG (rituximab) <sup>(1)</sup>	CD20	non-Hodgkin lymphoma, chronic lymphocytic leukemia and rheumatoid arthritis <sup>(2)</sup>	[Progress bar]								FOSUN PHARMA 复星医药, FARMALIA, Abbott
	HANQUYOU (trastuzumab) <sup>(3)</sup>	HER2	breast cancer, metastatic gastric cancer	The first Chinese mAb biosimilar approved both in China and the EU								accord, Cipla, Jacobson, mAbxience, eurofarma, Abbott
	HANDAYUAN (adalimumab) <sup>(4)</sup>	TNF-	rheumatoid arthritis, ankylosing spondylitis, plaque psoriasis, uveitis	[Progress bar]								万邦医药, FOSUN PHARMA 复星医药, Getz
	HANBEITAI (bevacizumab) <sup>(5)</sup>	VEGF	metastatic colorectal cancer, non-squamous non-small cell lung cancer	[Progress bar]								eurofarma
Under Clinical Studies	HANBEITAI (bevacizumab)	VEGF	glioblastoma	[Progress bar]								eurofarma
	HLX11 (pertuzumab) <sup>(6)</sup>	HER2	neoadjuvant treatment of breast cancer	[Progress bar]								Organon
	HLX14 (denosumab) <sup>(7)</sup>	RANKL	osteoporosis	Global multi-centre clinical study								Organon
	HLX05 (cetuximab) <sup>(8)</sup>	EGFR	metastatic colorectal cancer, squamous cell carcinoma of the head and neck	[Progress bar]								Jingze
	HLX12 (ramucirumab)	VEGFR2	gastric cancer, non-small cell lung cancer, metastatic colorectal cancer	[Progress bar]								
	HLX13 (ipilimumab)	CTLA-4	melanoma, renal cell carcinoma, metastatic colorectal cancer	[Progress bar]								
	HLX15 (daratumumab)	CD38	multiple myeloma	[Progress bar]								

(1) Approved by the NMPA in February 2019, being the first Chinese biosimilar.

(2) The only rituximab approved for the treatment of rheumatoid arthritis in China.

(3) Approved in nearly 30 countries, including China, the UK, Germany, France and Australia, trade name registered in Europe: Zercepac®, trade name registered in Australia: Tuzucip® and Trastucip®.

(4) Approved by the NMPA in December 2020.

(5) Approved by the NMPA in November 2021.

(6) Global commercialisation rights excluding Chinese mainland, Hong Kong, Macao and Taiwan region granted to Organon.

(7) Global commercialisation rights excluding Chinese mainland, Hong Kong, Macao and Taiwan region granted to Organon. Clinical Trial Notification has been acknowledged by the Therapeutic Goods Administration in China and Australia.

(8) Commercialisation rights in China have been granted to Shanghai Jingze.

# Globalisation: Out-Licensing in 100+ Countries / Regions

## Out-licensed products:

- **7 biosimilars:** HANLIKANG, HANQUYOU, HANDAYUAN, HANBEITAI, HLX05, HLX11, HLX14
- **3 innovative biological drugs:** HANSIZHUANG, HLX04-O, HLX35 (EGFRx4-1BB)

## Business Partners



## 1H22 Biosimilars license-out overseas:

**Organon US\$541M** (upfront US\$73M)

HLX11 (Pertuzumab), HLX14 (Denosumab)

Including US\$3M for the exclusive license option for HLX13 (Ipilimumab)

**Global (ex-China)**

**Abbott US\$4.4M** (upfront US\$3M)

HANLIKANG (Rituximab), HANQUYOU (Trastuzumab)

**Brazil (semi-exclusive)**

**Eurofarma US\$50.5M** (upfront US\$4.5M)

HANLIKANG (Rituximab), HANQUYOU (Trastuzumab), HANBEITAI (Bevacizumab)

**16 Latin American countries including Brazil (semi-exclusive)**

**Getz Pharma US\$8M** (upfront US\$0.5M)

HANDAYUAN (Adalimumab)

**11 emerging markets in Asia, Africa and Europe**

Sustainable cash flow from upfront fees, milestone payments and royalties ensure long-term organic growth

# Blockbuster Out-licensing Deal

## ORGANON

(NYSE: OGN)



MERCK

spinoff in June 2021



International footprint

Global **140+** markets



History **~100 years**

Founded in 1923



2021 Performance

Revenue **US\$6.3B**

Net profit **US\$1.5B**



Market Cap

**~ US\$8.3B**

### HLX11 (Pertuzumab)

Ph 3 neoadjuvant treatment for breast cancer (BC)

### HLX14 (Denosumab)

Ph 3 postmenopausal women with osteoporosis (OP)

- Up to a total of **US\$541M** in potential revenue
- Upfront payment of **US\$73M** (70+3)
- Granting of license:
  - ✓ Exclusive commercialisation of HLX11 & HLX14 in ex-China countries, covering mature markets such as the US, the EU and Japan, as well as a number of emerging markets
  - ✓ Option to negotiate an exclusive license for HLX13 (Ipilimumab) (US\$3M)



- **Biosimilar assets cash flow**




**the largest biosimilar deal in the past 5 years**



**international markets**

# A Leading Global Technology Platform for Biologics: Flexible and Efficient to FIH and Commercialisation

- **High throughout developability: selection of robust molecules**
- **Upstream**
  - Stable cell line with high titer
  - Proprietary cell culture media development
  - Intensified process
- **Downstream**
  - Superior bispecific antibody purification platform
  - Highly concentrated UF/DF process
  - Resin/filter sourcing fully localised, cost saving 50%
- **Drug product**
  - Liquid: high concentration & subcutaneous formulation
  - Drug product differentiation: combination product
  - Visible/subvisible particle characterisation and identification
- **Commercial process, product optimisation and characterisation**



**State-of-art analytical technologies**  
**Critical quality attribute dataset**  
**Process and product control strategy**

# 2.5

## Manufacturing Capacity Breakthroughs

(Strengthen Market Leading Position in Manufacturing Technology & Quality)

# Songjiang First Plant: 24,000L Additional Capacity Approved for HANQUYOU

## Leading commercial manufacturing capacity

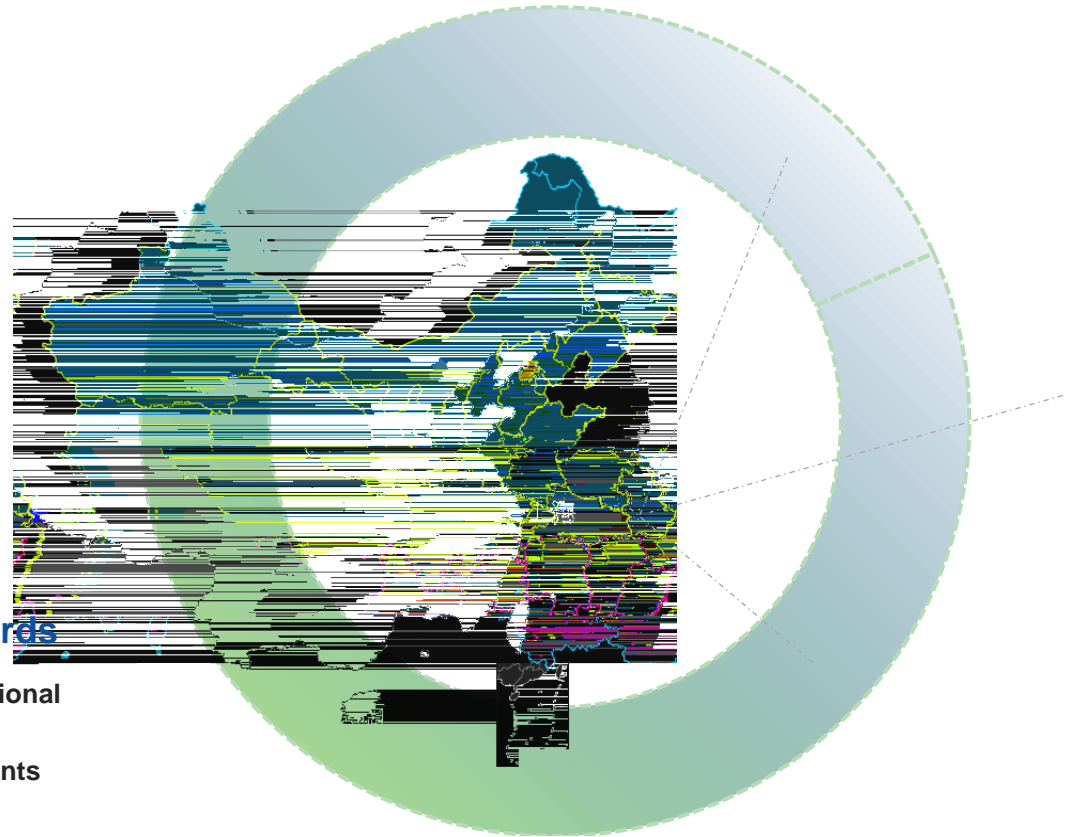
- Total manufacturing capability (SJ1&Xuhui): 48,000L
- Commercial GMP batches: 450+ (2019~)
- Manufacturing success rate:
- Manufacturing and quality related employees: 878
- Production intensity: globally leading

## Songjiang First Plant approved for commercial operation in May 2022

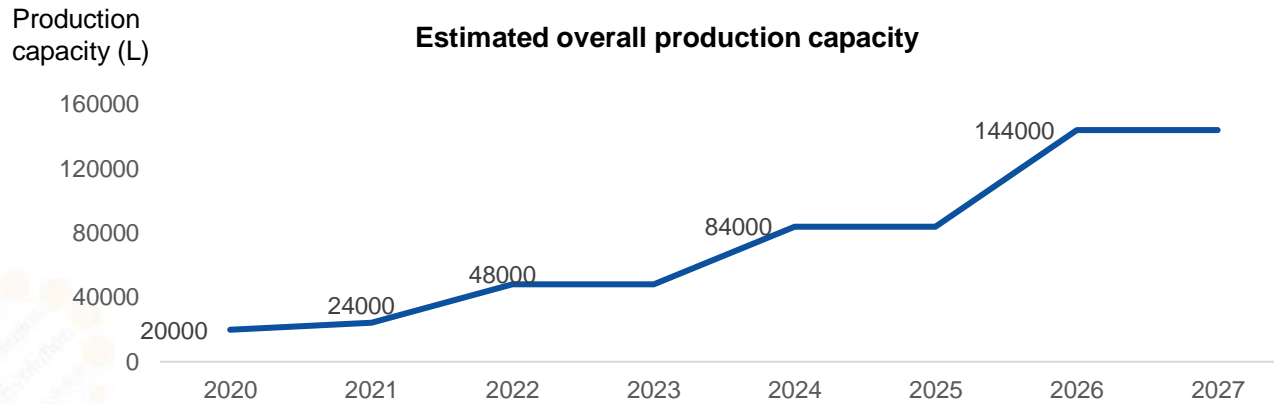
- Manufacturing capacity: 24,000L
- 

## Consistent quality management with global GMP standards

- GMP certified in China and the EU, conducive to be recognised by international audiences in different markets
- Constantly improve the quality management system through audits by clients and regulatory agencies
- Actively prepare for on-site inspections by FDA, EMA



# Production Capacity to Reach 144,000L by 2026



Xuhui

N: (5+1)\*2 KL  
S: (5+1)\*2 KL



SJ(I)

(6\*2KL)\*2



SJ(II)

(6\*2 KL)\*3

4\*15 KL



## Technology upgrade and innovation

- Established new technology platform
- Expanded the cost advantages of commercial production with **15,000L** stainless steel bioreactor system
- Optimised process to increase efficiency



## Production capacity & business improvement

- Accelerate **Songjiang Second Plant** construction to create global leading capacity advantage
- Reasonable layout of production capacity to achieve resource optimisation
- Expand CDMO business segment



## Lean operations drive manufacturing efficiency and cost reduction

- Materials and consumables localisation
- Localised multi-source supply chain management
- Lean operation, annual revenue 10 million

Estimated Songjiang Second Plant phase 1 production capacity up to **96,000 L**

# 3

# Financial Review & Outlook

# Financial Highlights

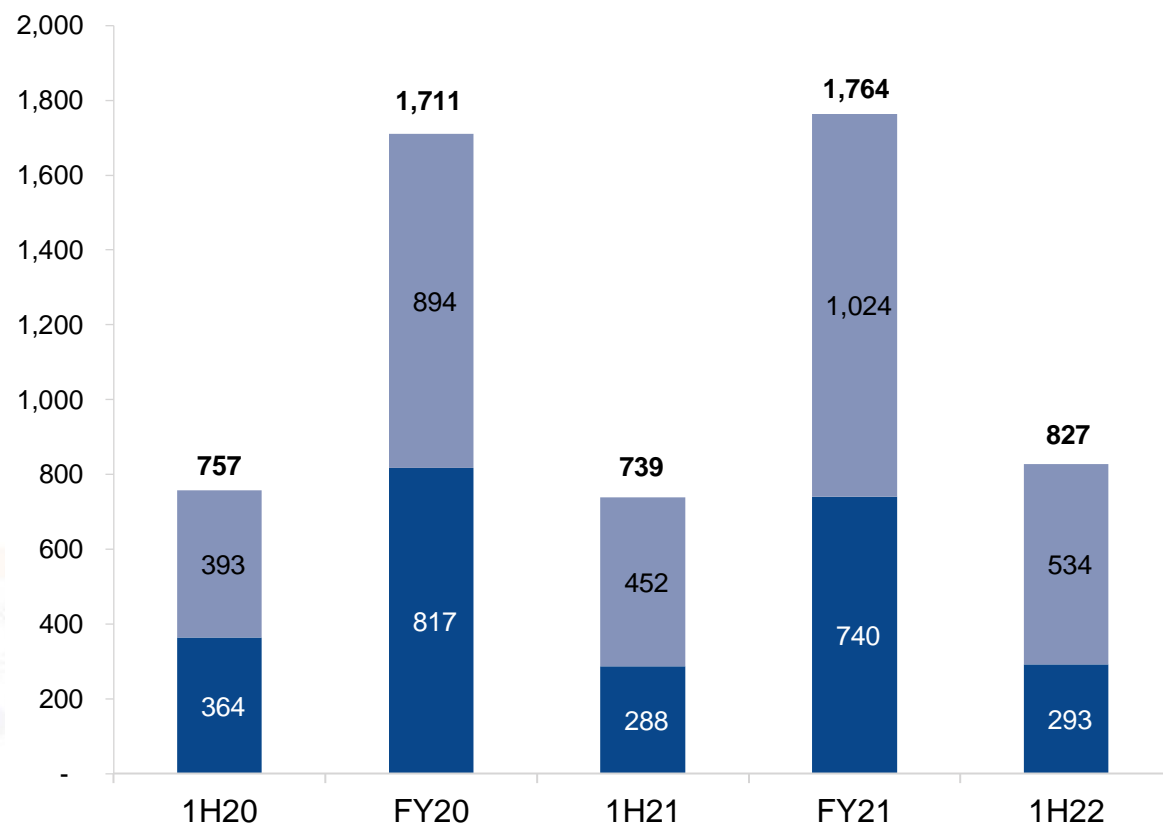
	1H22 In million RMB	1H21 In million RMB	Growth YOY
Revenue	1,289.4	633.6	103.5%
Gross Profit	983.8	412.2	138.7%
Gross Margin	76.3%	65.1%	11.2%
Operating Expenses*	1,073.7	767.4	39.9%
Net Loss	(252.1)	(393.8)	36.0%
CAPEX	472.7	189.8	149.1%

- **Rapid growth of total revenue:** mainly resulted from the increase of sales volumes of our core products

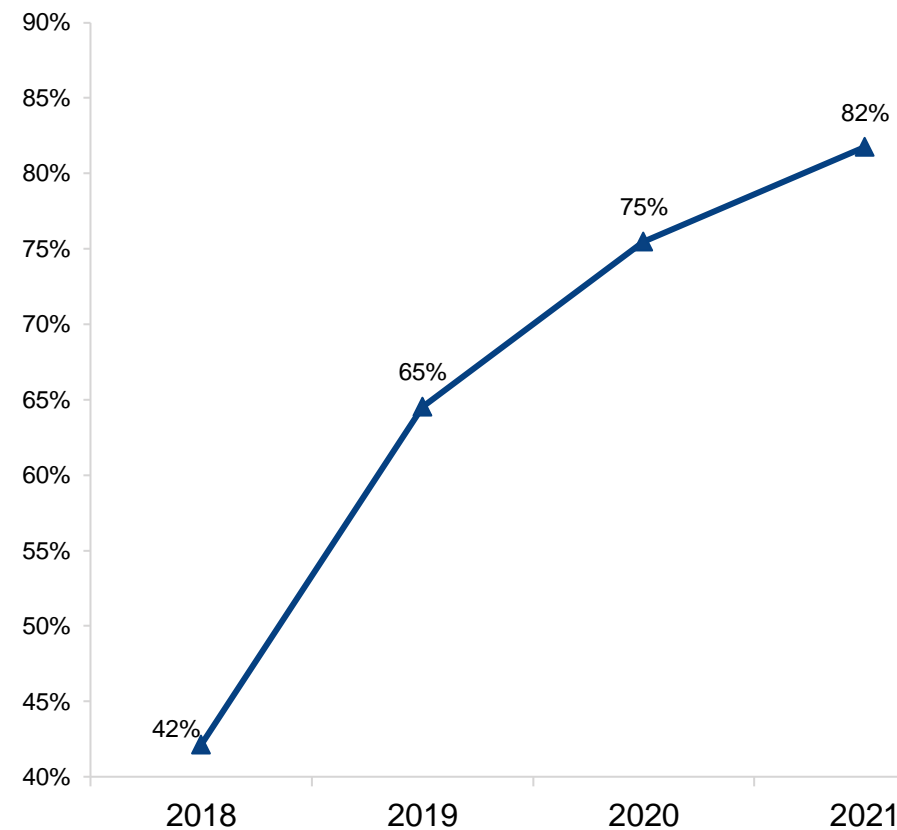
# 1H22 R&D: Invest in Innovative Drugs and Improve Efficiency

### R&D Expenditure (in million RMB)

■ Capitalised ■ Expensed



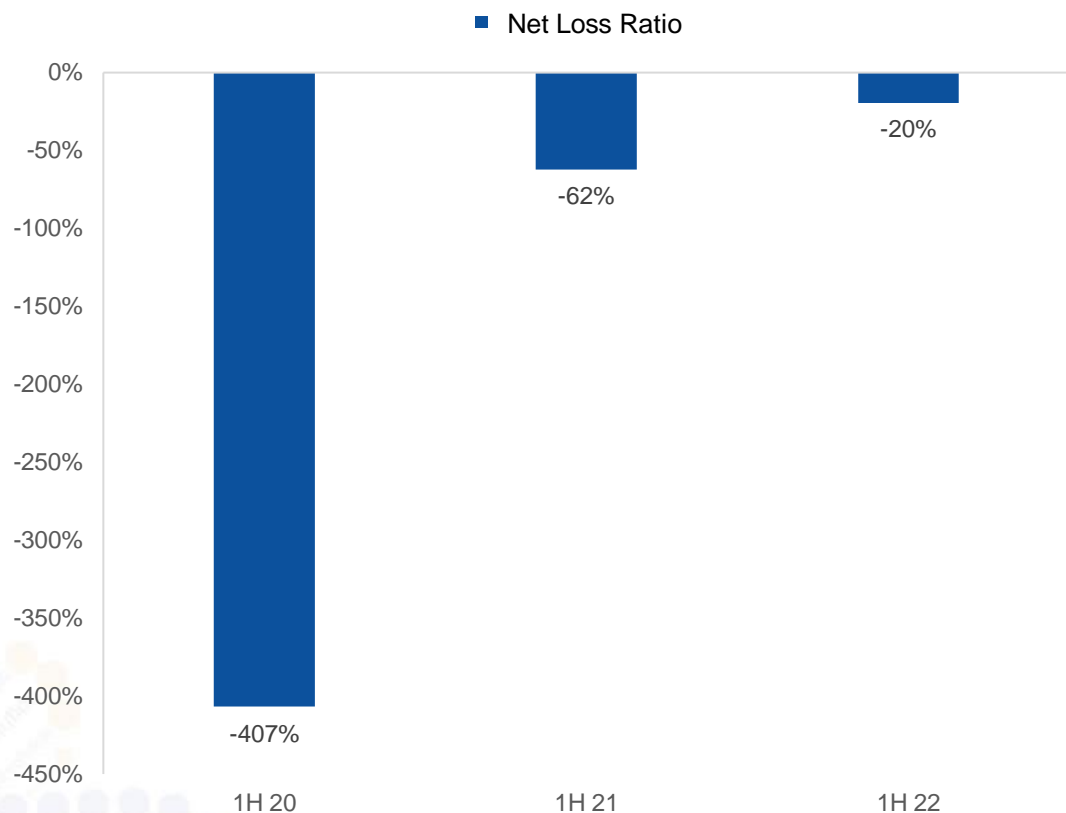
### Ratio of Innovative Biological Drugs Expenses



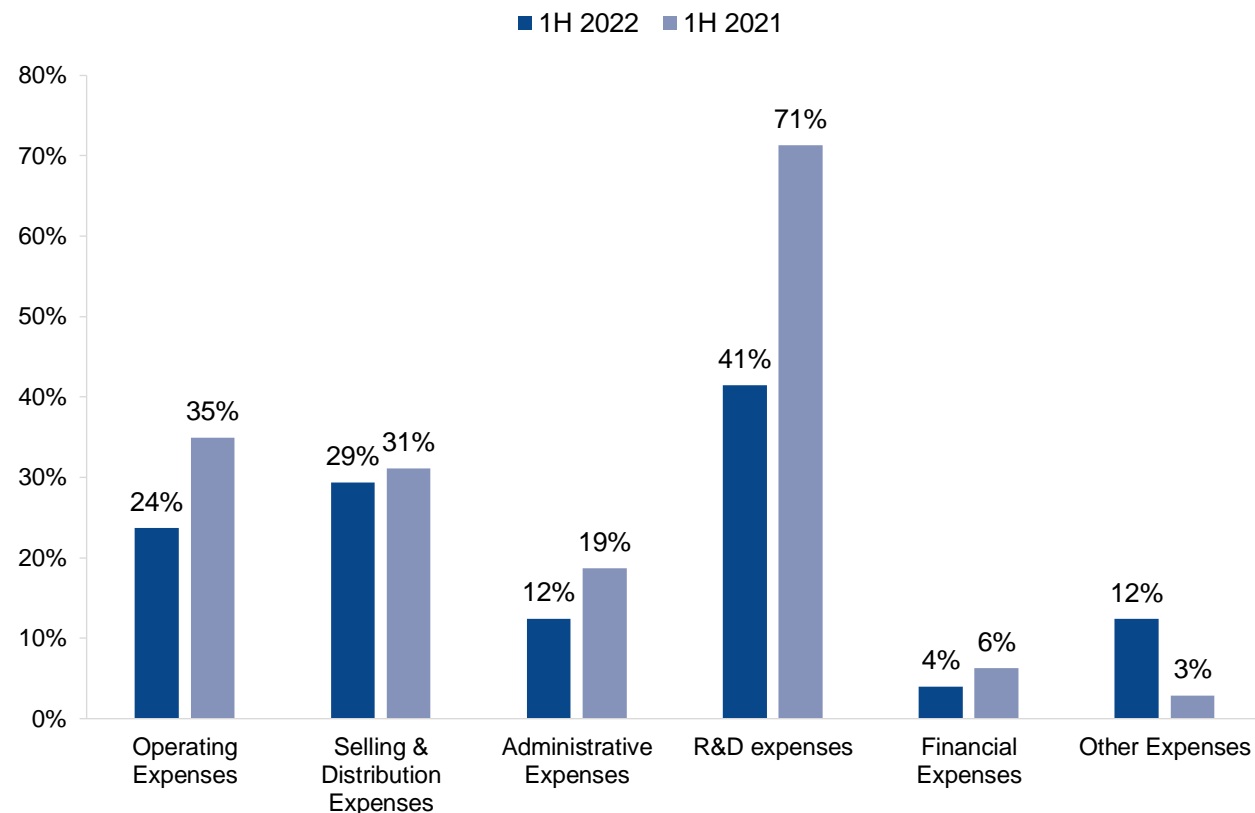
Note: Internal Data

# 1H22 Profitability: Net Loss Ratio & Expense Ratio Decreased

## The Ratio of Loss to Total Revenue Narrowed Down



## The Ratios of Expense to Total Revenue Decreased



- **Losses gradually narrowed and the ratio of loss to total revenue decreased significantly:** net loss in 1H22 decreased by RMB 141.7 million to RMB 252.1 million compared with that of 1H21. As revenues rose sharply, the net loss ratio in 1H22 dropped significantly to only 20%.

# 2H22 Top Priorities for Henlius



## Registration, R&D and BD

- Well prepared for FDA BLA submissions of HLX02 and HLX10 in 2023
- Global positioning: accelerate clinical trial progresses of HLX10, HLX208, HLX07, HLX22, HLX11/14, HLX04-O across the globe
- Efficient/differentiated early-stage R&D strategy including ADC, multi-specific antibody, and bispecific antibody
- Further optimise R&D strategy, continuously improve mechanisms and capabilities
- BD: Actively seeking license-in to improve company portfolio, keeping up with license-out for global deployment in the meantime



## Manufacturing, Quality and Technical

### Speed up SJ2 Construction; Optimise the efficiency of Xuhui&SJ1

- Speed up SJ2 construction progress to ensure entering commercial production phase in 2024
- Further apply lean management method to maximise the capacity of SJ1
- Optimise overall arrangement of production capacity to improve capital return
- Promote the development of next-generation technology to improve efficiency
- Promote local sourcing of key materials



## Commercialisation

### HANQUYOU becomes a market leader HANSIZHUANG exceeds the targets

- HANQUYOU
  - Leads the market in HER2 + BC
  - Gains full market access for different specifications (150mg/60mg)
- HANSIZHUANG
  - Plans ahead for 2023 to become a top-tier player of IO
  - Aims to become China's SCLC market leader in 2023

## Rapidly Evolving from *Biotech* to

2H22 Performance Guidance



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Affordable Innovation

