



Henlius 复宏汉霖

Henlius (2696.HK) 3Q 2023 Results Investor Presentation

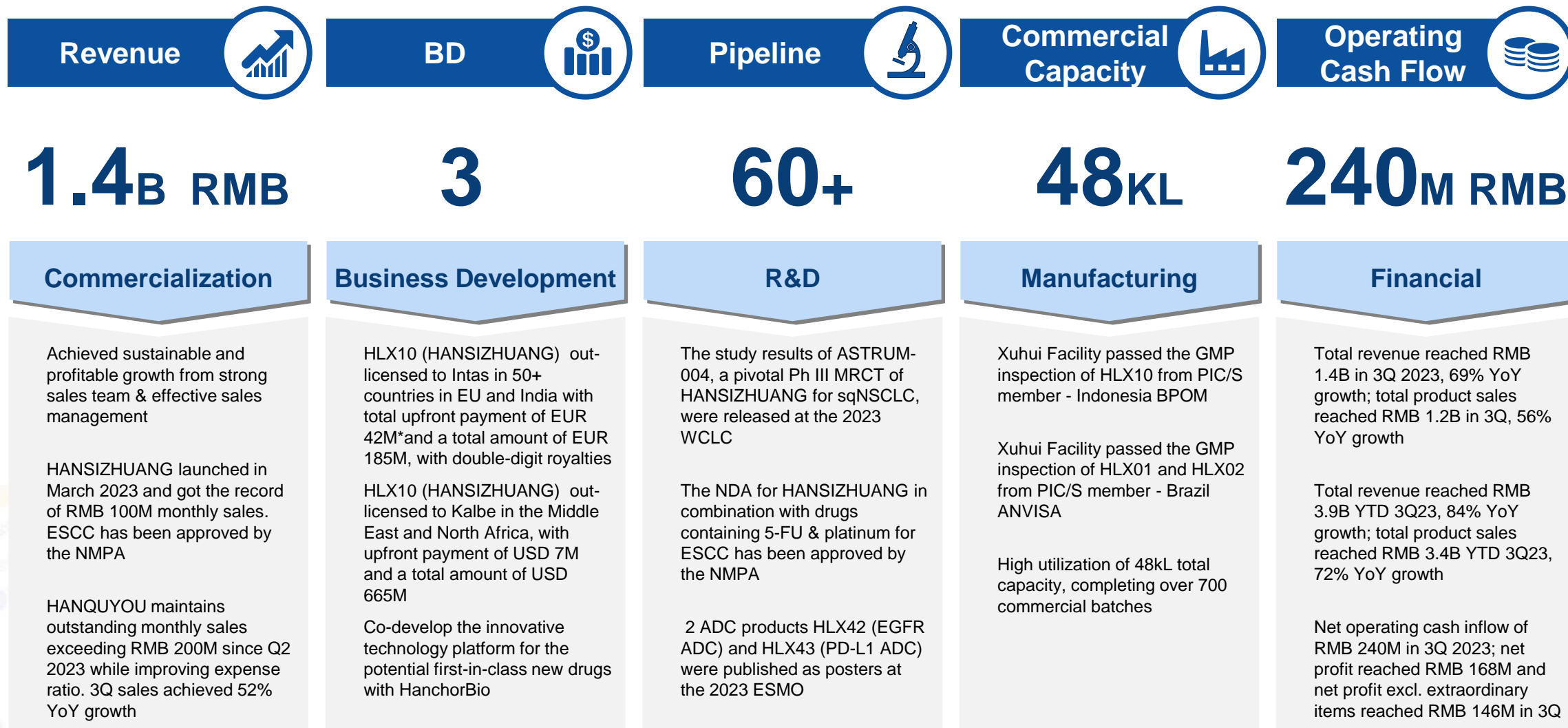
November 2023



01

3Q 2023 Business Highlights & Company Strategy

3Q23: Revenue Tops 1.4B RMB with Net Profit of 168M RMB



issuing a positive opinion (day 210 of the centralized procedure) for the licensed product to be used as a first-line treatment of extensive-stage small cell lung cancer (ES-SCLC)

Our Mission and Vision

Affordable Innovation
Reliable Quality



Biosimilars

Maximize the commercialization value in China and international markets



Innovative Drugs

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



Globalization

Develop towards a biopharma with global presence & scale

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

By 3Q 2023 sales revenue of biosimilars reached ~2.5 billion RMB, 43% YoY growth, exceeding the sales revenue of biosimilars in the full year of 2022
The biosimilar pipeline covered globally popular targets such as HER2, RANKL, CTLA-4, and conduct MRCT for global market expansion
HANQUYOU BLA was under FDA review while working with business partners to expand global markets



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



865M RMB

In March 2023, HANSIZHUANG achieved over **RMB 100M monthly sales** in China for the first time, representing its commercialization stepping up into new stage

By June 2023, HANSIZHUANG has completed tendering platform listing for **30 provinces** in China, covering about **1,500 hospitals** (focus on departments related to lung cancer, gastrointestinal cancer and etc.)



Differentiated Antibody

HANSIZHUANG (serplulimab) has shown a stronger affinity and slower dissociation rate¹ with PD-1, compared with peers

HANSIZHUANG (serplulimab) activates T cells with higher strength and longer duration through a unique molecular mechanism¹



Clinical Advantages

HANSIZHUANG recommended by 9 CSCO Guidelines for Diagnosis and Treatment

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



Differentiated Indications

ES-SCLC (Marketed):

mOS: 15.8 months, the globally first approved PD-1 for ES-SCLC

ESCC (New Indication) :

mOS: 18.6 months, HR 59% (PD-

GC (Phase III):

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

LS-SCLC (Phase III):

PD-1 for the treatment of LS-SCLC

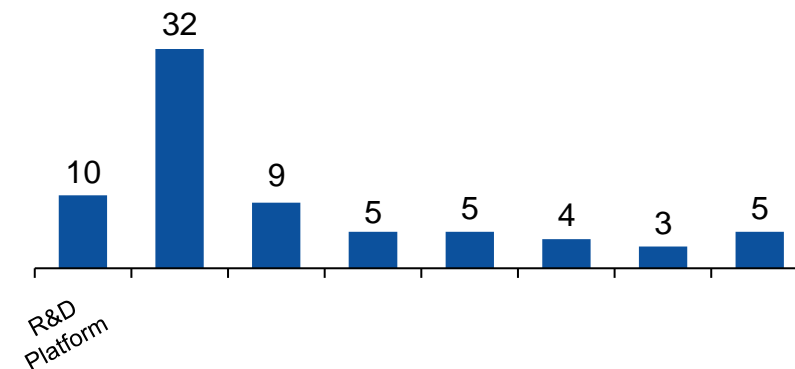
1. Issafras H, Fan S, Tseng C-L, Cheng Y, Lin P, Xiao L, et al. (2021) Structural basis of HLX10 PD-1 receptor recognition, a promising anti-PD-1 antibody clinical candidate for cancer immunotherapy. PLoS ONE 16(12): e0257972.

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

Product Type & Introduction

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

Innovative Pipeline Distribution by Stage (by Molecule)



Modality Distribution ⁽¹⁾

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

02

Commercialization

HANQUYOU (Trastuzumab): 3Q23 Sales Growth 52% YoY



738M RMB*

3Q 2023 Revenue

2.01B RMB*

YTD 3Q 2023 Revenue



International quality

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

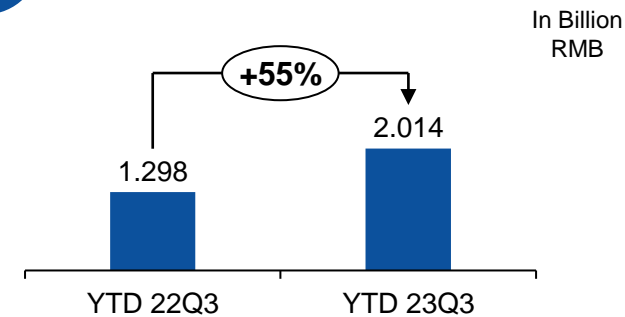


Multiple specifications

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



Strong growth momentum



150mg specification: completed NRDL and tendering platform listing for all provinces; access to more than 87% of Top 1,000 hospitals

60mg specification: completed NRDL for all provinces and tendering platform listing in 29 provinces; access to more than 60% of Top 1,000 hospitals

Commercial team with ~600 professionals, covering 6 major sales regions and ~3,700 hospitals in China



Zercepac® in Europe

Trastucip



Target: HER2 Indications:

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

Drug Specifications:

- 150mg/vial (China, Europe, Australia)
- 60mg/vial (China, Europe)
- 420mg/vial (Europe)

Excellent Performance of HANQUYOU

Higher sales per capita than domestic peers

Sales Per Capita*
(YTD 3Q 2023)

>400K RMB
per month

The only trastuzumab with two specifications

2 specifications were customized to address HER2-positive breast cancer patients medical needs in China

Solved the issue of residual liquid storage, improving drug use safety and honing product differentiation advantage



Strengthen product advantage to build competition advantage

As more local trastuzumab products launched in 2023, the competition situation is increasingly complicated. HANQUYOU made strategy and comprehensive preparations in advance, kept strengthening international quality and two specifications advantage to increase market awareness and acceptance.

Develop Broad market

Trastuzumab is widely used across China, hospitals in small towns and rural area have been growing fast and gaining share

HANQUYOU has expanded coverage, deepened promotion activities to develop the broad market in small towns and rural area

* Sales per capita = Product sales / # of salesforce / 9 months

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

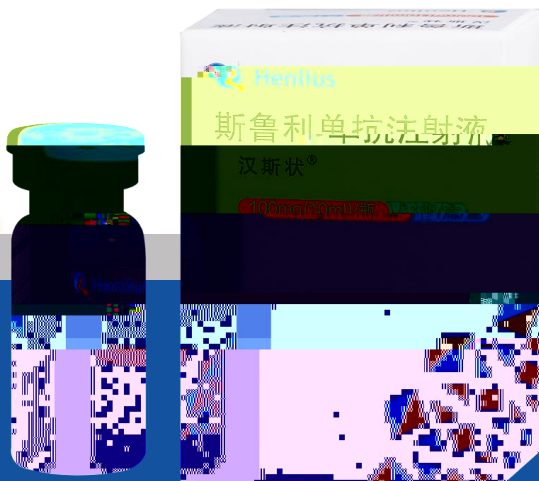


309M RMB

3Q 2023 Revenue

865M RMB

YTD 3Q 2023 Revenue



Widespread recognition

MAA for 1L ES-SCLC indication is under EMA review

Recommended in 2023 CSCO treatment guidelines for SCLC, NSCLC, EC etc.

1L ESCC indication newly approved in China



Efforts to product accessibility

Launched patient assistance programs to optimize treatment outcomes, with reduced economic burden and improved medication adherence for patients

Has been covered in Huiminbao (Regional Commercial Health Insurance) of 44 regions incl. Shanghai, Fujian, Chengdu, Shaanxi Chongqing Nanjing Suzhou Jinan Xiamen



Differentiated strategies to seize the market

Developed differentiated marketing strategies and focused on SCLC to rapidly increase market share and gain customer trust

Working with business partners to create more commercial value and expand overseas market



Acceleration on market access and penetration

Completed tendering and procurement platform listing in 30 provinces, access to over 50 hospitals of 365 major hospitals

~580 people specialized commercial team with strong sales experience in oncology

Built efficient distribution network, strengthening the coverage of DTP pharmacies and infusion centers



Target: PD-1

Indications:

MSI-H solid tumor
sqNSCLC
ES-SCLC
ESCC

Drug Specifications:

100mg/10ml/vial

HANSIZHUANG Commercialization Highlights

First-class Commercialization Efficiency

Outstanding Achievements

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

YTD 3Q 2023
Sales Per Capita¹
~180K RMB
per month
Industry
Leading in China

High Market Share Driven by Differentiation Strategy

Differentiation Strategy
Focus on **SS1B Sales**

HANBEITAI (Bevacizumab): Commercialization Acceleration in 2023

Acceleration on market access and penetration

Covered by NRDL in 31 provinces, and completed tendering and procurement platform listing in 28 provinces

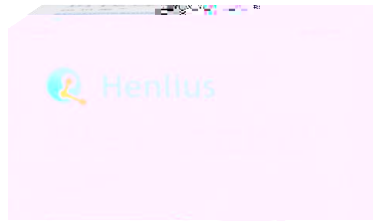
Focus on the dual-channel markets, and enhance market recognition to drive sales growth

Proactively seek for hospitals access in non

Exploration for new medication methods

The only bevacizumab biosimilars with phase III clinical data on metastatic colorectal cancer in China

Combine with HANSIZHUANG (anti-PD-1 mAb), treating on multiple tumor types in a combo therapy



 Target: VEGF

HANLIKANG (Rituximab): Strengthen the Market Leader Position



Jiangsu Fosun, a subsidiary of Fosun Pharma, is commercialization in China



HANDAYUAN (Adalimumab): Entered Autoimmune Disease Area



32M RMB

autoimmune disease product

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

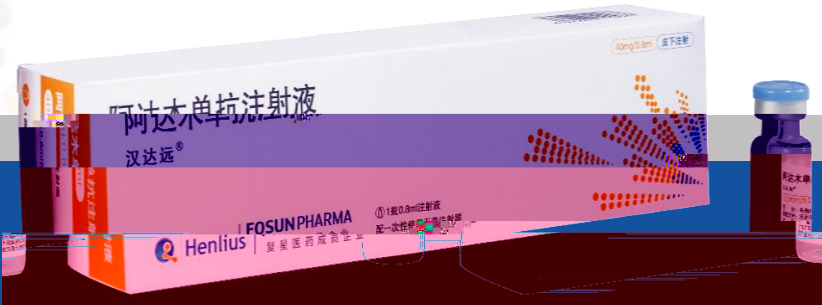
The first phase III clinical study of adalimumab biosimilar for psoriasis patients in China

~79,000 patients benefited since launch

Contributed to standardize the diagnosis and treatment on ankylosing spondylitis in China through:

Jiangsu Wanbang is responsible for China-region sales of HANDAYUAN. It has a sizable rheumatic immunity business unit and experienced salesforces in RA as well as a mixed line sales team

Out-licensed the commercialization rights of HANDAYUAN to Getz Pharma in February 2022 in 11 countries, including Pakistan, the Philippines and Kenya



Target: TNF-

03

Business Development

Collaboration Expansion with Existing Partner about HLX10 EU & India



Intas Pharmaceuticals Limited¹



1. Accord is a fully owned subsidiary of Intas
2. Source: Intas homepage

Collaboration Expansion with Existing Partner about HLX10 EU & India



Upfronts up to **& 42 million***
> f m t & +2/ g d f c h



HANSIZHUANG (serplulimab)

Covering EU & India 50+ countries

Since 2018, Intas/Accord started cooperation with Henlius on the registration, technology transfer and commercial launch of HLX02 in more than 70 countries and regions, including the EU (2018), the United States & Canada (2021).

Through this cooperation, Henlius has a royalty up to 27% , with the right to supply at premium pricing, contributing to a long-term stable growth of cashflow.





The deal of HLX10 EU could also strengthen the HLX02 EU deal to further maximize the commercial benefits of the company and strengthen the overseas promotion of the brand.

The leading position of Intas/Accord in the European market can further promote oversea marketing of HLX10 product.

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)+HLX60 ⁽²⁾ PD-1+GARP Solid tumors	HLX10 ⁽¹⁾ (serplulimab)+HANBEITAI PD-1+VEGF mCRC 1L	HLX10 ⁽¹⁾ (serplulimab)+chemo PD-1 ES-SCLC 1L		HANSIZHUANG (serplulimab) ⁽¹⁾ PD-1 MSI-H solid tumors, sqNSCLC, ES-SCLC, ESCC
HLX6018 GARP/TGF- Chronic inflammatory diseases	HLX13 (ipilimumab) CTLA-4 Solid tumors	HLX60 GARP Solid tumors, lymphoma	HLX10 ⁽¹⁾ (serplulimab)+HLX07 PD-1+EGFR HNSCC, NPC, GC, ESCC, sq-NSCLC	HLX10 ⁽¹⁾ (serplulimab)+chemo PD-1 Neo/adjuvant treatment for GC	HLX02 (trastuzumab) ⁽¹⁰⁾ HER2 Breast cancer, mGC	HANLIKANG (rituximab) ⁽¹¹⁾ CD20 NHL, CLL, RA ⁽¹²⁾
HLX41 LIV1 ADC Solid tumors	HLX42 EGFR ADC Solid tumors	HLX301 ⁽³⁾ PD-L1 x TIGIT Solid tumors, lymphoma	HLX10 ⁽¹⁾ (serplulimab)+HLX26+	HLX10 ⁽¹⁾ (serplulimab)+chemo +radio PD-1 LS-SCLC 1L 		
HLX44 Nectin4 ADC Solid tumors	HLX43 PD-L1 ADC Solid tumors	HLX53 TIGIT Solid tumors, lymphoma		HLX10 ⁽¹⁾ (serplulimab)+HANBEITAI PD-1+VEGF nsNSCLC 1L		
HLX80 STEAP1 ADC Prostate cancer	HLX17 (pembrolizumab) PD-1 Solid tumors	HLX05 (cetuximab) ⁽⁴⁾ EGFR mCRC, HNSCC		HLX04-O ⁽⁷⁾ VEGF Wet AMD 		
HLX309 Nectin4 x 4-1BB Solid tumors		HLX15 (daratumumab) CD38 Multiple myeloma		HLX11 (pertuzumab) ⁽⁸⁾ HER2 Neoadjuvant treatment of breast cancer 		
HLX314 HER2xSialidase Solid tumors				HLX14 (denosumab) ⁽⁹⁾ RANKL Osteoporosis 		

Bridging study in U.S.

BLA under FDA review



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



Clinical Pipeline Milestones: YTD 3Q 2023 Review

YTD 3Q 2023



NDA/BLA/MAA
Submission



HLX10
ES-SCLC¹
1L (EU)

HLX10
ES-SCLC
1L (Indonesia, Myanmar, Cambodia)



Key Clinical Data
Readouts





HLX10
sqNSCLC²
Final OS results
1L (Pivotal)

HLX07+HLX10
ESCC³
1L, 2L and late-line (PoC)

HLX208
BRAF V600E
LCH/ECD⁴ - 22pts

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

 Innovative mAb
 Innovative small molecule

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

Focusing on China, the US and Europe, the **MRCT**¹

Serplulimab: Targeting Differentiated Indications



Gastric Cancer (GC)

Neoadjuvant treatment in combination with Chemotherapy / Adjuvant with Serplulimab only

According to the baseline data analysis of 649 subjects in the Checkmate, 60% advanced GC patients had CPS ≥ 5 . The trial design had focused on PD-L1-positive patients (CPS ≥ 5) from the very beginning. Serplulimab aims to be **first perioperative I/O treatment in China for GC**

Around 2/3 of 300,000 new GC cases in China every year^{1,2} were suitable for perioperative treatments. With the increasing penetration of gastroscopy examinations, more GC cases will be detected

Currently, the median EFS of perioperative SoC 0 0 1 0 0358.46 Tm0 g0 G 06an t8a1 725.95 34f1i 6 06ar

Limited Stage Small Cell Lung Cancer (LS-SCLC)

Serplulimab combined with Concurrent Chemoradiotherapy (CCRT)

Globally, the incidence for lung cancer ranks #2 and the mortality ranks #1. In China, both incidence and mortality of lung cancers ranks #1. Among 820K new cases of lung cancers in China every year, 15% is SCLC. Among SCLC patients, about 30%-40% are LS-SCLC³

HLX07: Address Unmet Medical Needs of High EGFR Expression Patients

ESCC Study Design (Phase II)

Inclusion Criteria:

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

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

Group B (2L)
 HLX07, 1000 mg
 Q2W IV

Primary Endpoints:

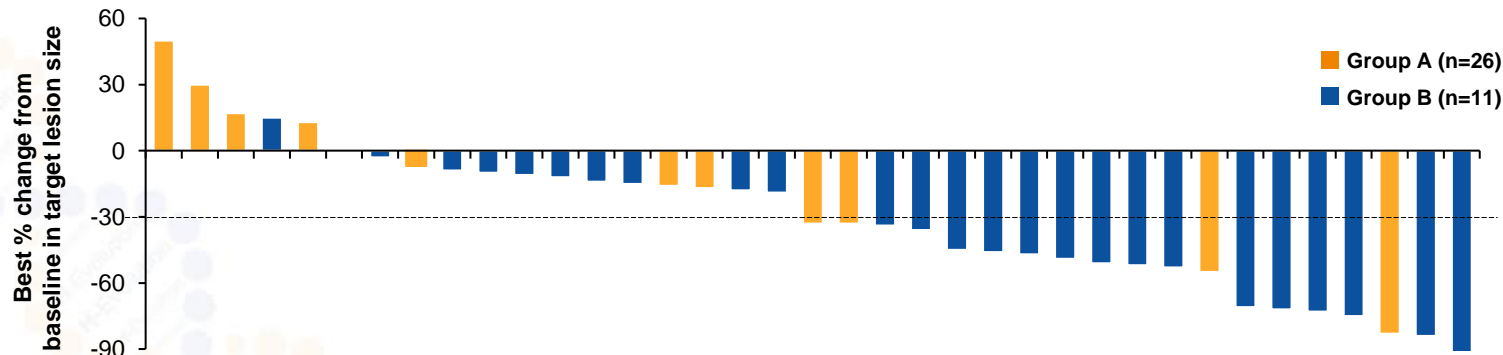
ORR and PFS
 (RECIST v1.1)

ESCC Efficacy Summary

Tumor Response^a in Efficacy Evaluable Patients

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

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



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



HLX22: Potential to Change the SOC of 1L GC

HLX22 (HER2)

HLX22 targets at **different** epitopes within domain IV of HER2

PDx data shows HLX22 & trastuzumab combo has more advantages than trastuzumab & pertuzumab combo in GC

4.1

R&D: Pre-clinical Assets

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



5D Platform Targeting Oncology, Metabolism, Immunity and Neurology

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



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

Develop innovative drugs for complex diseases through network biology and polypharmacology

HLX307 (rPro)

First-in-class recombinant protein products

Unique MOA, simultaneously lower blood glucose and improve kidney damage repair

Good efficacy in **DKD**⁴ models

Large patient population with huge unmet needs

HLX30 (bisAb)

First-in-class bi-specific antibody

Differentiated molecule design with better tumor selectivity

Address unmet clinical needs in the field of **advanced or metastatic tumors with EGFR mutations**

Potential breakthrough innovative drugs

HLX92 (SMC)

First-in-class small molecule drug conjugates

Polypharmacology with a unique MOA

Address unmet needs in the fields of **PSC**¹ and **PBC**²

Potential breakthrough innovative drugs

HLX94 (SMC)

First-in-class small molecule drug conjugates

Polypharmacology with a unique MOA

Address unmet needs in the fields of **ALS**³ and **J**

Potential breakthrough innovative drugs

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

05

Manufacturing

International Leading Capabilities on Manufacturing and Quality Management



24,000L

Manufacturing capacity optimization:

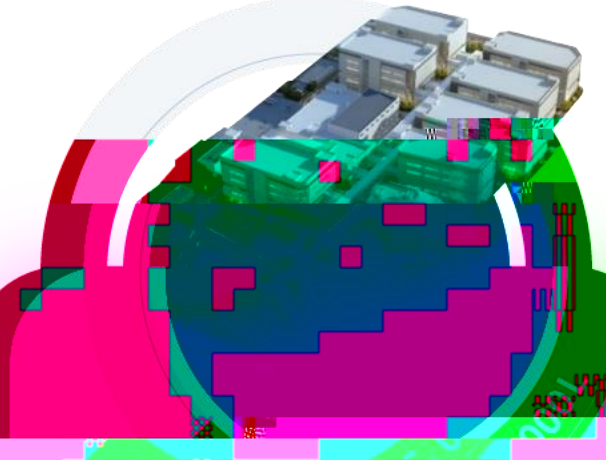
The scale of commercial GMP batches has **reached a new high**

Compliance with international standards: as of Oct 2023, GMP certified by **NMPA, EMA and PIC/S members (Indonesia and Brazil)**

Global expansion: Products available in **Europe, Australia, South America and Southeast Asia**



24,000L



Plant construction for Phase I & II trials:

Acceleration of the plant validation

The improved application of stainless steel equipment: Costs reduction by

Operation Excellence and Continuous Innovation

Technical Innovation

Reached key milestone of using domestic production consumables and completed **commercial scale process validation**

Achieved the **automatic control** of cell culture in bioreactor by **Raman Spectroscopy**

Platform Construction

Adopted **SCADA system** for real-time production monitoring to achieve **lean digital production**

Optimized the satellite tank and scale-down models



Lean Operations

34 on-going lean operations projects with ~10M RMB expected annualized returns

The batch output increased 10% compared with 2022 for serplulimab

Supply Chain Excellence

The direct material cost was **11.4% lower than that in 2022**

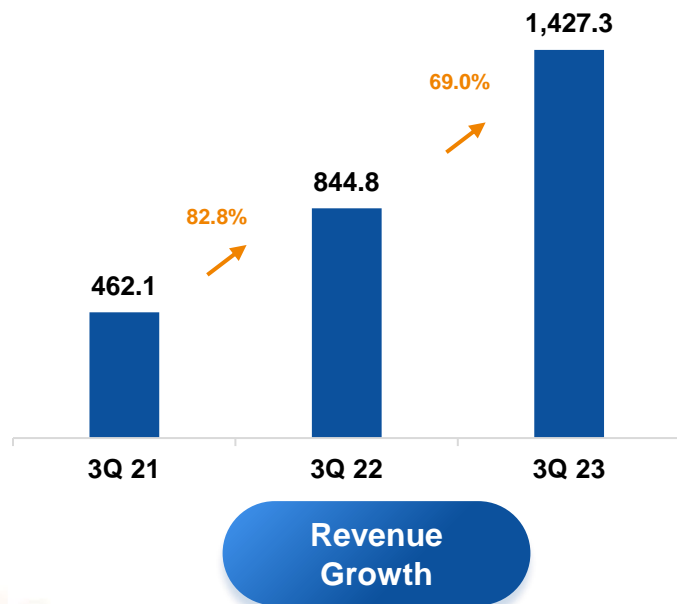
Completed the sustainability process design for supply chain and implemented risk-warning mechanism

06

3Q 2023 Financial Review

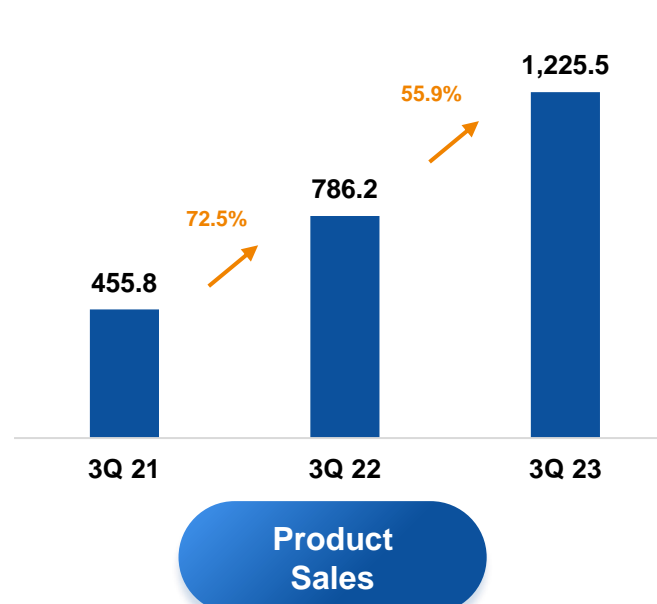
3Q 2023 Revenue of RMB 1.43 Billion with 69.0% YoY

Revenue
(in Million RMB)



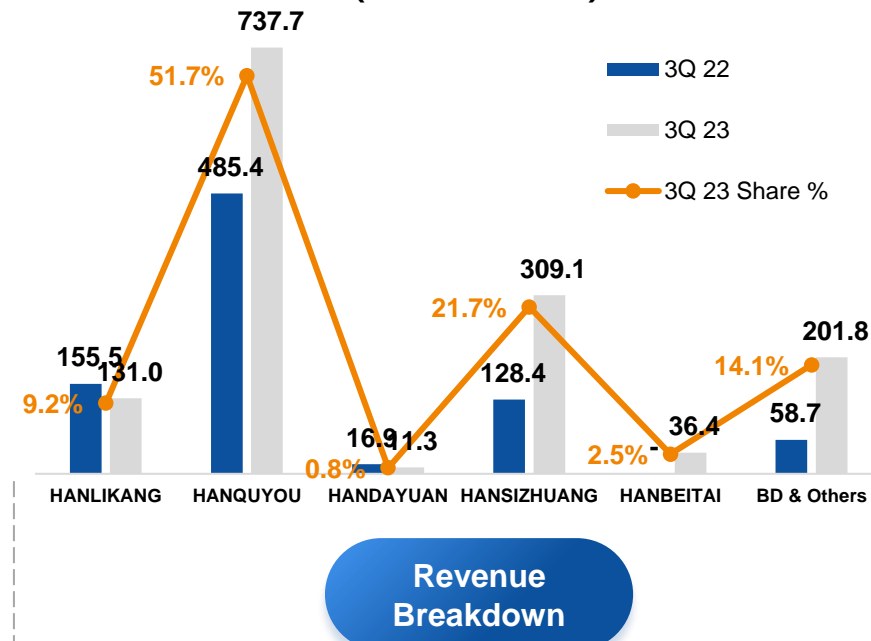
Revenue of RMB 1.43B in 3Q 2023, 69.0% YoY growth. Revenue of RMB 3.93B in YTD 3Q 2023, 84.0% YoY growth
Revenue growth mainly driven by: outperformed sales ramp-up of HANQUYOU and HANSIZHUANG

Product Sales
(in Million RMB)



Product sales of RMB 1.23B in 3Q 2023, 55.9% YoY growth. Product sales of RMB 3.38B in YTD 3Q 2023, 71.7% YoY growth
Product sales growth mainly from HANQUYOU sales volume open-up with additional capacity released after Songjiang 1st Plant being approved; HANSIZHUANG ES-SCLC 1L treatment was approved

3Q 2023 Revenue Breakdown
(in Million RMB)



HANQUYOU*: RMB 738M sales in 3Q23, 52.0% YoY growth; RMB 2.01B sales in YTD 3Q23, 55.2% YoY growth
HANSIZHUANG: RMB 309M sales in 3Q23, 140.7% YoY growth; RMB 865M sales in YTD 3Q23, 321.4% YoY growth
HANLIKANG: RMB 131M sales in 3Q23, -15.7% YoY growth; RMB 385M sales in YTD 3Q23, -9.9% YoY
HANDAYUAN: RMB 11M sales in 3Q23, -33.2% YoY growth; RMB 32M sales in YTD 3Q23, -12.6% YoY growth
HANBEITAI: RMB 36M sales in 3Q23; RMB 81M sales in YTD 3Q23
BD and other income: RMB 202M in 3Q23, 244.1% YoY growth; RMB 549M in YTD 3Q23, 230.1% YoY growth



Financial Highlights

Financial Data (selected)	3Q 23		3Q 22		YoY Growth	YTD 3Q 23		
	Unit	In Million RMB	% of revenue	In Million RMB	% of revenue	%	In Million RMB	% of revenue
Revenue		1,427.34	100.00%	844.83	100.00%	68.95%	3,927.81	100.00%
Product sales		1,225.50	85.86%	786.17	93.06%	55.88%	3,378.41	86.01%
BD and other revenue		201.83	14.14%	58.66	6.94%	244.09%	549.40	13.99%
Cost of sales		406.88	28.51%	209.07	24.75%	94.62%	1,128.52	28.73%
Selling and distribution expenses		449.26	31.48%	282.39	33.43%	59.09%	1,232.21	31.37%
Administrative expenses		96.46	6.76%	82.34	9.75%	17.16%	260.17	6.62%
R&D expenses		269.77	18.90%	368.79	43.65%	-26.85%	817.60	20.82%
Financial costs		28.46	1.99%	27.80	3.29%	2.40%	82.55	2.10%
Net profit (net loss) excl. extraordinary item		145.96	10.23%	(192.89)	-22.83%	/	375.58	9.56%
Net profit (net loss)		167.82	11.76%	(90.40)	-10.70%	/	407.80	10.38%
Cash and bank balances		586.12	41.06%	704.79	83.42%	-16.84%	586.12	14.92%
Net cash flows from operating activities		239.62	16.79%	711.95	84.27%	-66.34%	572.08	14.56%



Our Goals for 2023

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

声明

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