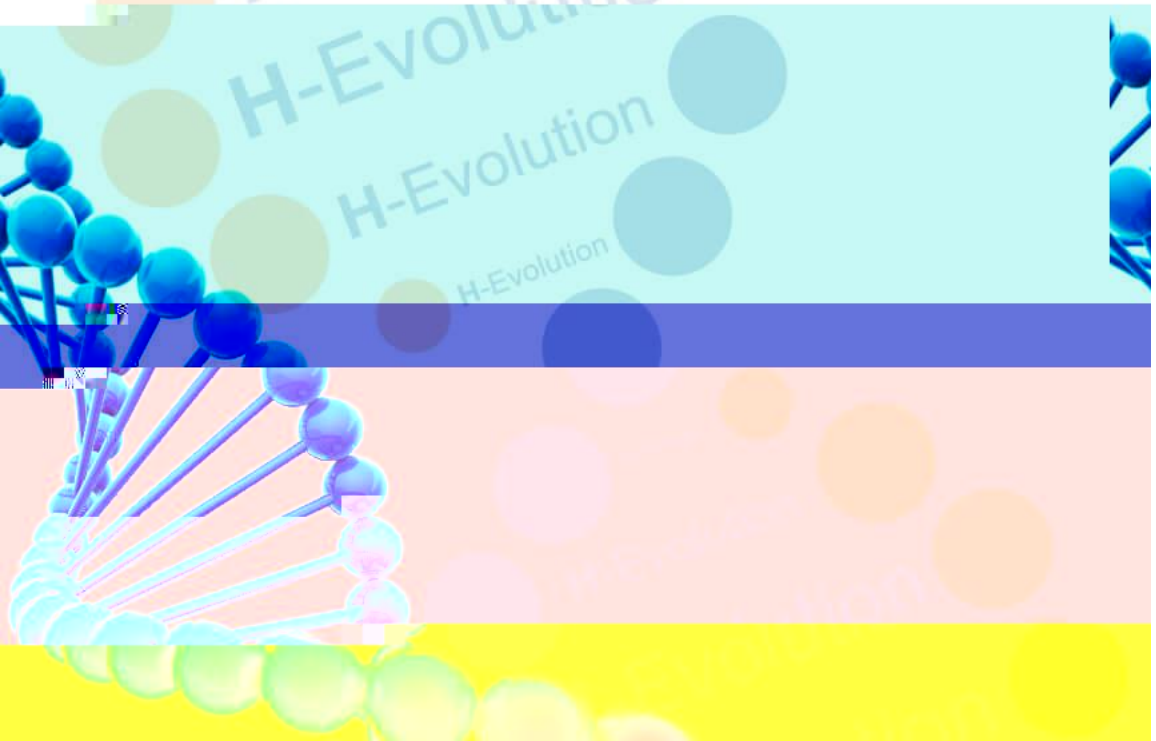
CONTENTS

01 Company Overview and Strategy

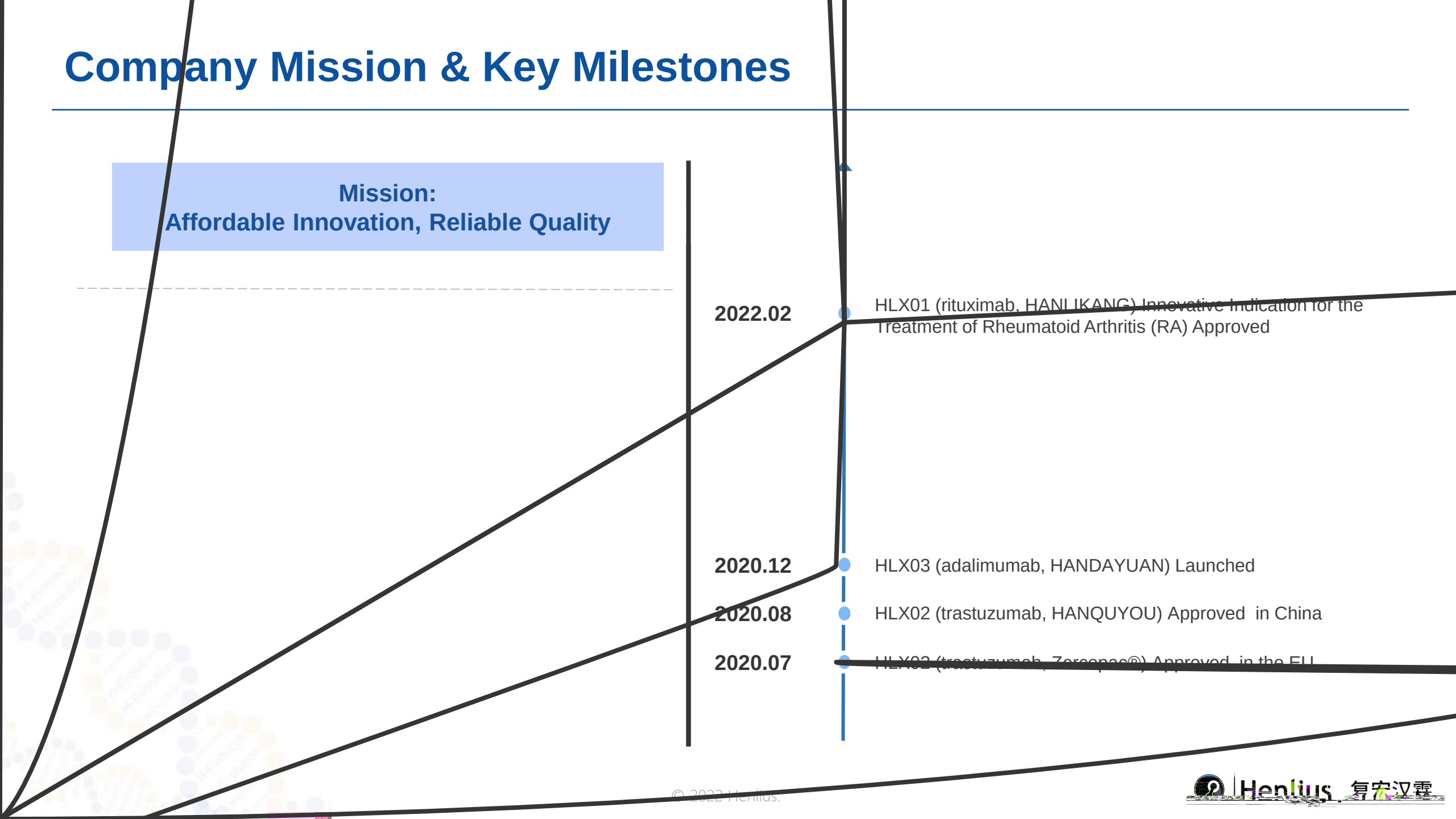
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Company Mission & Key Milestones

Mission:
Affordable Innovation, Reliable Quality



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H-evolution: From Biotech to Biopharma, Operational Enhancement

Biotech

- Partial function setup
- Singular/few products
- In-licensing dependent
- Thin revenue, cash burning
- Lack of system, highly rely on founder

H-evolution

Biopharma

- Full value chain
- Comprehensive portfolio
- Mostly organic, supplemented with external
- Sizable revenue, self financing
- Strategic/systematic governance

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02 Organization Capability

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A Fully-Integrated Platform



Global R&D, RA, Clinical Development & Operation Platform



Commercial-scale Manufacturing Facilities



‡ Continuing its momentum for a diversified innovation by enhancing internal innovation capacities and reaching out to more strategic partners;

‡ Global regulatory filing capabilities with 4 products launched successfully and over 70 clinical approvals obtained worldwide

‡ Comprehensive Good Clinical Practice quality management system passing GCP on-site inspections conducted by the NMPA and EMA

‡ Manufacturing facility scaling up:

Xuhui Manufacturing Facility

Songjiang Manufacturing Facility (First Plant)

Songjiang Manufacturing Facility (Second Plant);

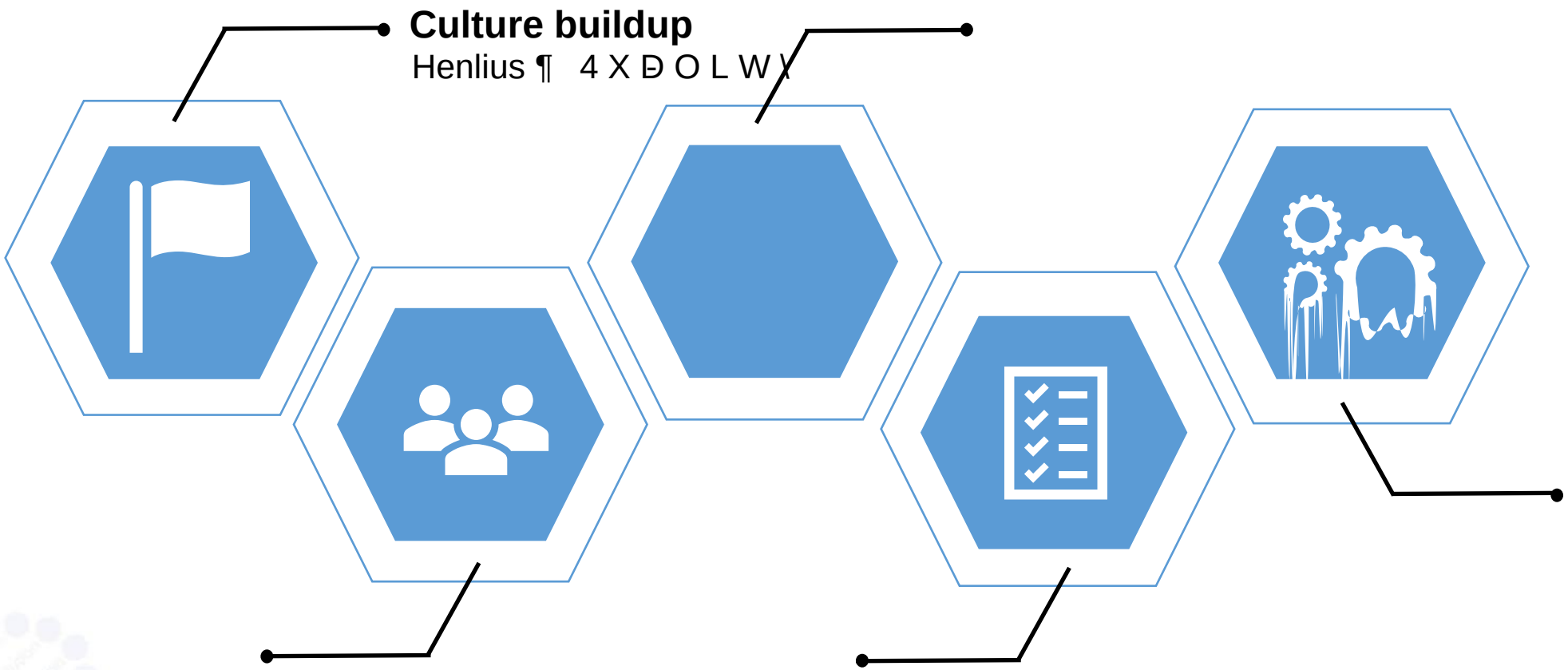
‡ Site and quality management system certificated by China and the EU GMP and covering the entire product

‡ Building top in-house commercial team in the industry through the implementation of innovative marketing, access and commercialisation strategies and the execution of highly-efficient sales

‡ Concluding partnerships with reputable global pharmaceutical companies and expanding presence in major and emerging markets

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All-Round Improvement, Casting Henlius-Quality



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Management Team: Solidarity, Stability, Innovation



Wenjie Zhang

Chairman

Executive Director and CEO

- Joined Henlius in Mar 2019
- Near 30 years of commercial operation experience in pharmaceutical industry
- Former business head, business vice president and general manager at Bayer China, Roche China and Amgen China
- MBA in Yale University and bachelor degree of microbiology in Shandong University



Jason Zhu
President



Wei Huang
Chief Operation Officer
SVP



James Guo
Chief Financial Officer
SVP



Jean-Michel Gries
President of Hengenix Biotech



Gino Li
Chief Financial Officer
VP



Kurt Yu
Chief Commercial Officer
VP



Ping Cao
VP of Business Development



Wallis Zeng
VP of Oncology Business Unit



James Liu
VP of Legal and Compliance



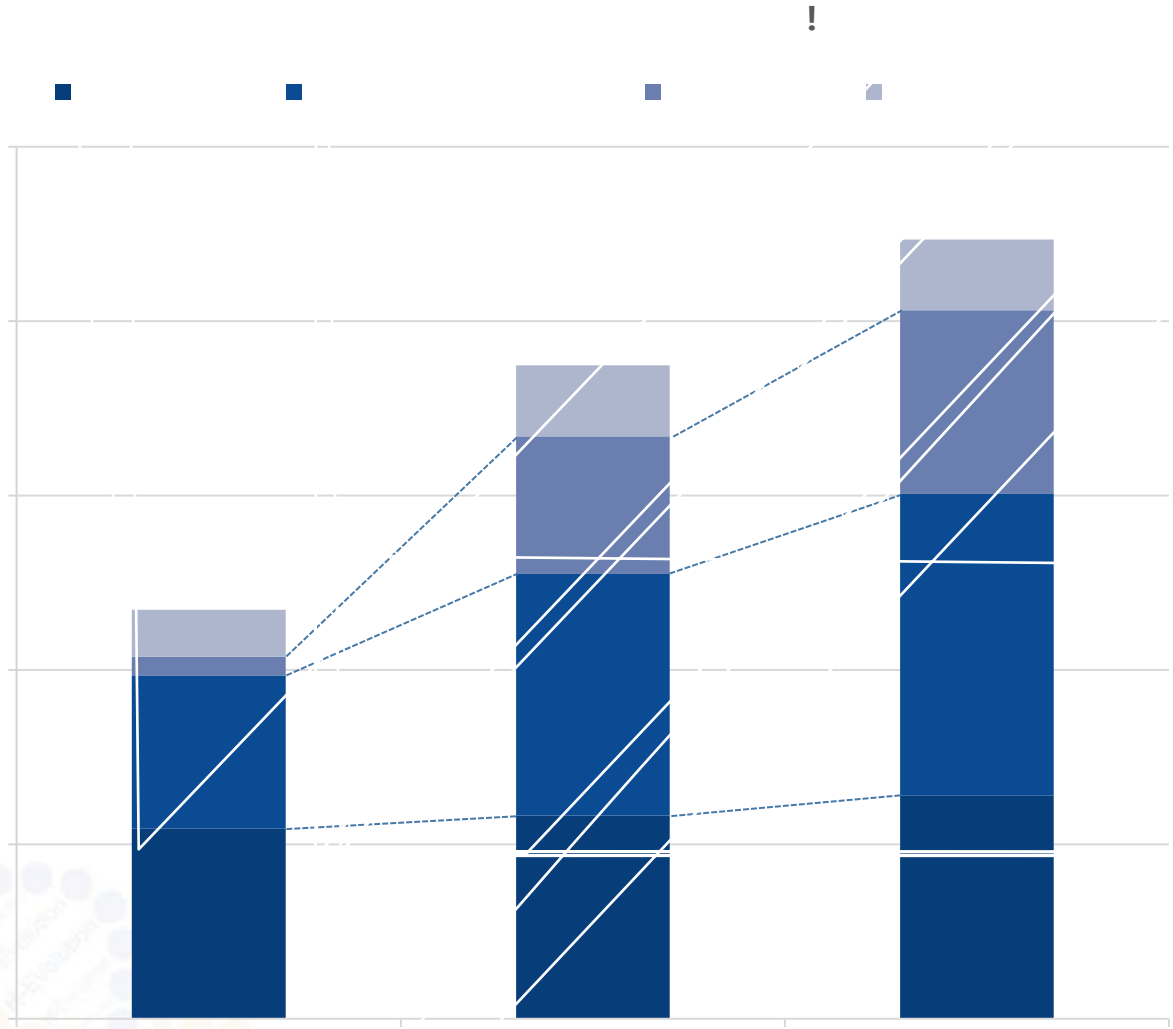


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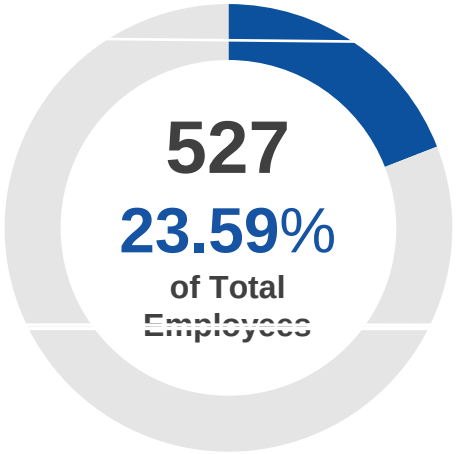
Alex Shen
GM of Global Strategy & PMO

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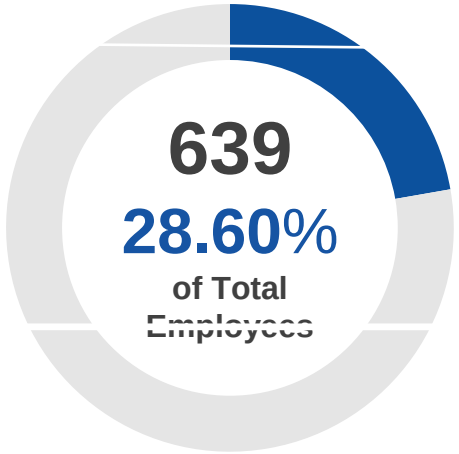
Company Size: the Number of Employees Rapidly Grew







Commercial Team



R&D/Clinical Team

* Note: as of December 31, 2021

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3.1 R&D

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Leader in China Biopharmaceutical Industry

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Diversified Product Pipelines Based on Fully-Integrated R&D Platform- Innovative Biologics

Products	Targets	Indications	Pre-clinical	IND	Phase 1	Phase 2	Phase 3	NDA	Launch	Business Partners
HLX10 (serplulimab										

Serplulimab (anti-PD1 mAb): All Tumor Targeting, Differentiate Competition, Empoweringa Ecosystem and Global Layout

Pave the Way for Globalization

Lung cancer

- SC-NSCLC
- SCLC



International Multicenter Clinical Trial Reach Primary Endpoint

‡ Multiple clinical trials of immuno-oncology combination therapy initiated in different countries and worldwide; about 2300 subjects enrolled in China, Turkey, Poland, Ukraine, Russia, etc., making Serplulimab a PD-1 product with one of the largest international clinical data pools

‡ A collaboration agreement reached with KG Bio in 2019, upon which KG Bio is granted exclusive rights to develop and commercialise Serplulimab in 10 Southeast Asian countries

All Tumor Targeting

- MSI-H solid tumors
- Head&Neck
- Esophageal
- Lung
- Gastric
- Hepato-cellular

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Diversified Product Pipelines Based on Fully-Integrated R&D Platform-Biosimilar

HANLIKANG (rituximab)[1]	**CD20**	**non-Hodgkin lymphoma, chronic lymphocytic leukemia rheumatoid arthritis[5]**								
HANQUYOU (trastuzumab)[2]	**HER2**	**breast cancer, metastatic gastric cancer**								
HANDAYUAN (adalimumab)[3]	**TNF-**	**rheumatoid arthritis, ankylosing spondylitis, plaque psoriasis, uveitis**								
HANBEITAI (bevacizumab)[4]	**VEGF**	**metastatic colorectal cancer, non-squamous non-small cell lung cancer**								
HLX11 (pertuzumab)	HER2	breast cancer								
HLX05 (cetuximab)[6]	EGFR	metastatic colorectal cancer, squamous cell carcinoma of the head and neck								
HLX12 (ramrcramab										

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Preclinical：Effectively Propel the IND Application for Preclinical Projects

Product（Reference）	Target	Indication	1Q21	2Q21	3Q21	4Q21



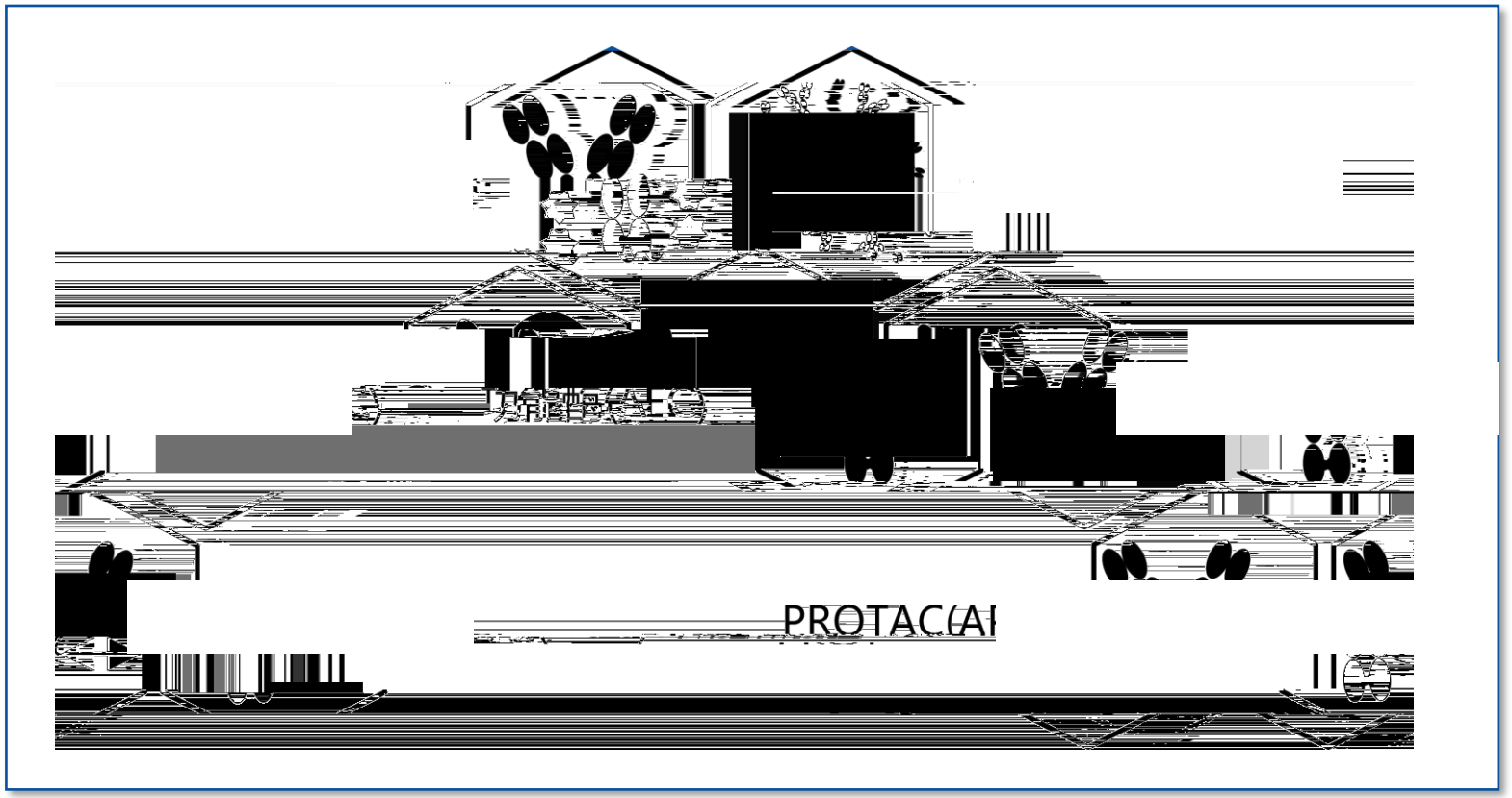
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Pre-Clinical Build Proprietary AXC Technology Platform

Antibody-Centric, Evolved Modality (AXC: Antibody X-molecule Conjugate)

Based on antibody and novel conjugating technologies, expand different forms of antibody conjugates to address unmet clinical needs.



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3.2 Manufacturing

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Integrated Platform Advantage: Manufacturing Bases Construction Will Further Increase Integrated Platform Advantage

Continuous Improvement of Quality Management System In Compliance with Global GMP Standard

‡ **NMPA & EMA certified FDA to be certified next**

‡ **Continue to improve the quality management system through audits from clients and regulatory agencies**

Leading Commercial Manufacturing Capacity

‡ **Successful commercial manufacturing batches: 350+**

‡ **Production successful rate::**

‡ **Overall manufacturing related employees: 900+**

‡ **Production intensity Industry Leading**

Creating a Commercial Manufacturing Platform with Cost Advantages

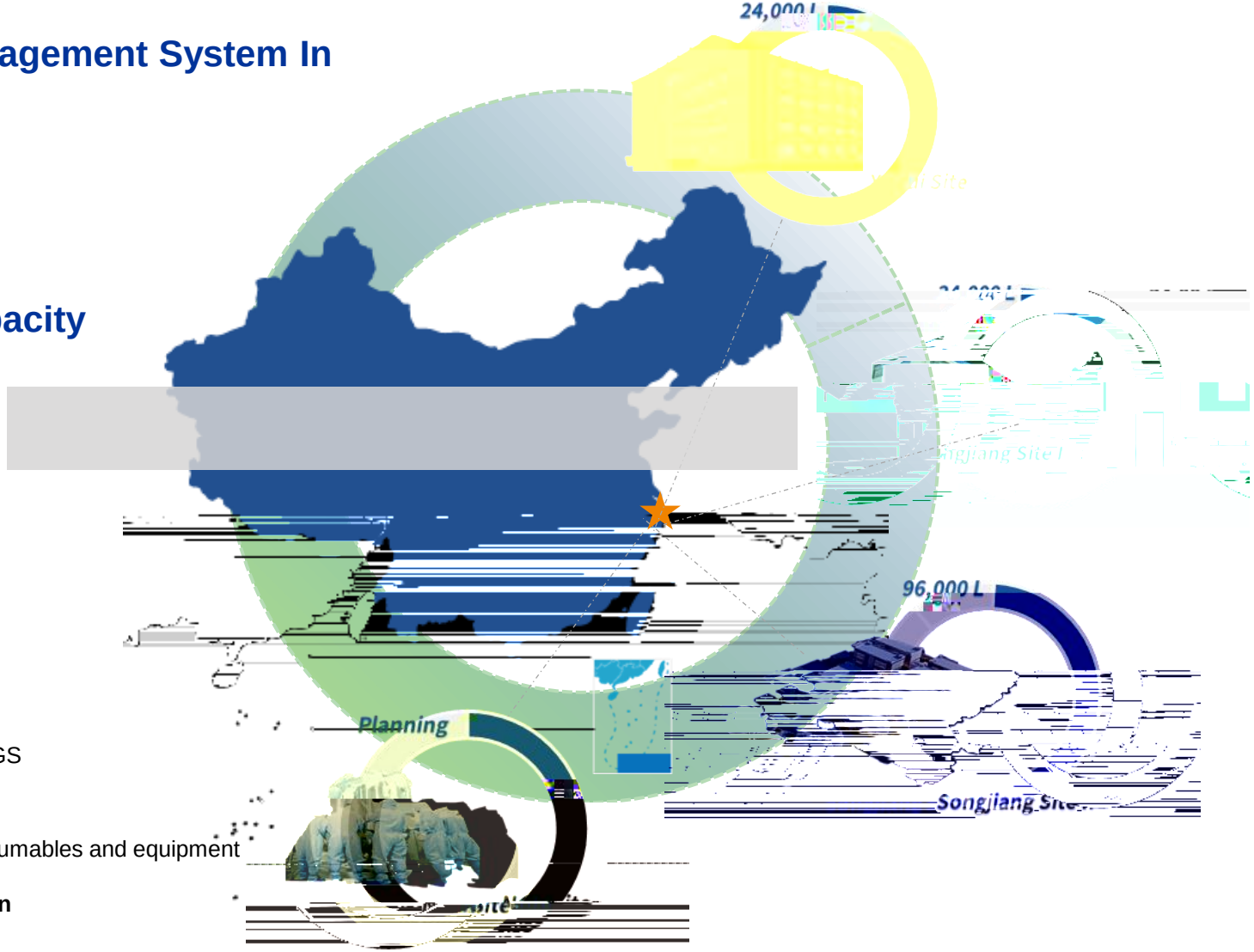
‡ **Lead the innovation in manufacturing technology:**

- Single-use technology combined with Stainless steel technology
- Large-scale stainless steel technology is introduced to reduce GOGS

‡ **Advance the localization process**

- Facilitate the localization process of manufacturing materials, consumables and equipment

‡ **Insist on lean production, lean management and lean operation**



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Songjiang Site I: Completed the Construction of Commercial Scale Manufacturing Plant and Pilot Scale Continuous Manufacturing Plant, and Commenced Manufacturing Successfully

‡ **2021.03**
Completed the construction and qualification of DP filling line

‡ **2021.04**
Completed the validation of 2nd generation process of DS for HLX02

‡ **2021.05**
Completed the validation of 2nd generation process of DP for HLX02

‡ **2021.08**
Songjiang Site I was licensed for production

‡ **2021.09**
Submitted sNDA for HLX02 2nd generation process

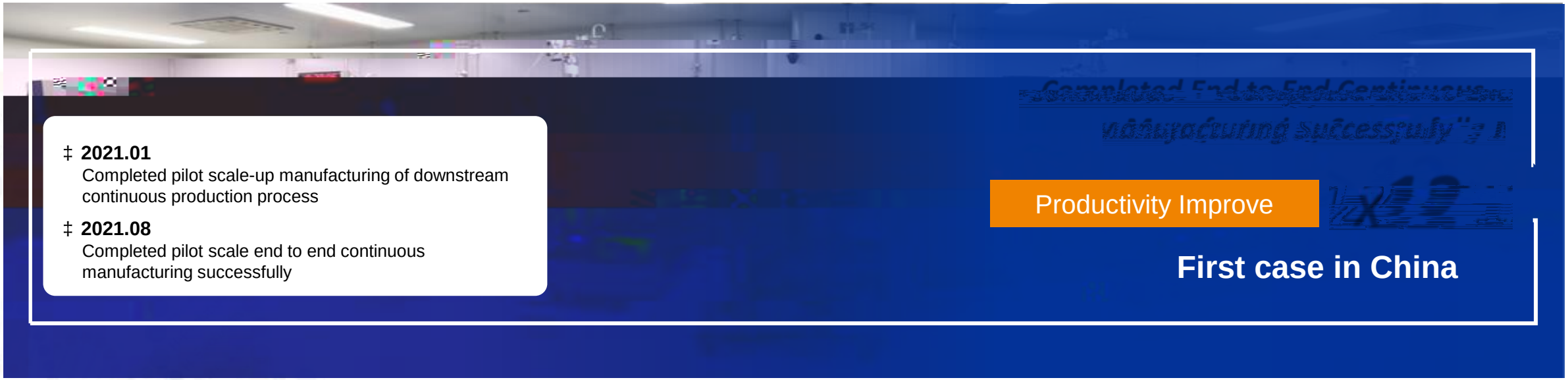




Total capacity increase

The capacity will no longer be a bottleneck for commercial product supply

Productivity Improve



‡ **2021.01**
Completed pilot scale-up manufacturing of downstream continuous production process

‡ **2021.08**
Completed pilot scale end to end continuous manufacturing successfully

Productivity Improve

First case in China

‡ Completed the main structure and secondary structure of the two main production buildings as well as the supporting public utilities and

The total designed capacity up to:



© 2

3.3 Commercial Operation

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Upgrade Commercialization by Enhancing Core Capabilities

Access

- NRDL & PRDL
- Tendering
- Hospital listing

Sales

- Professional
- Customer-oriented
- Efficient implementation

Channel

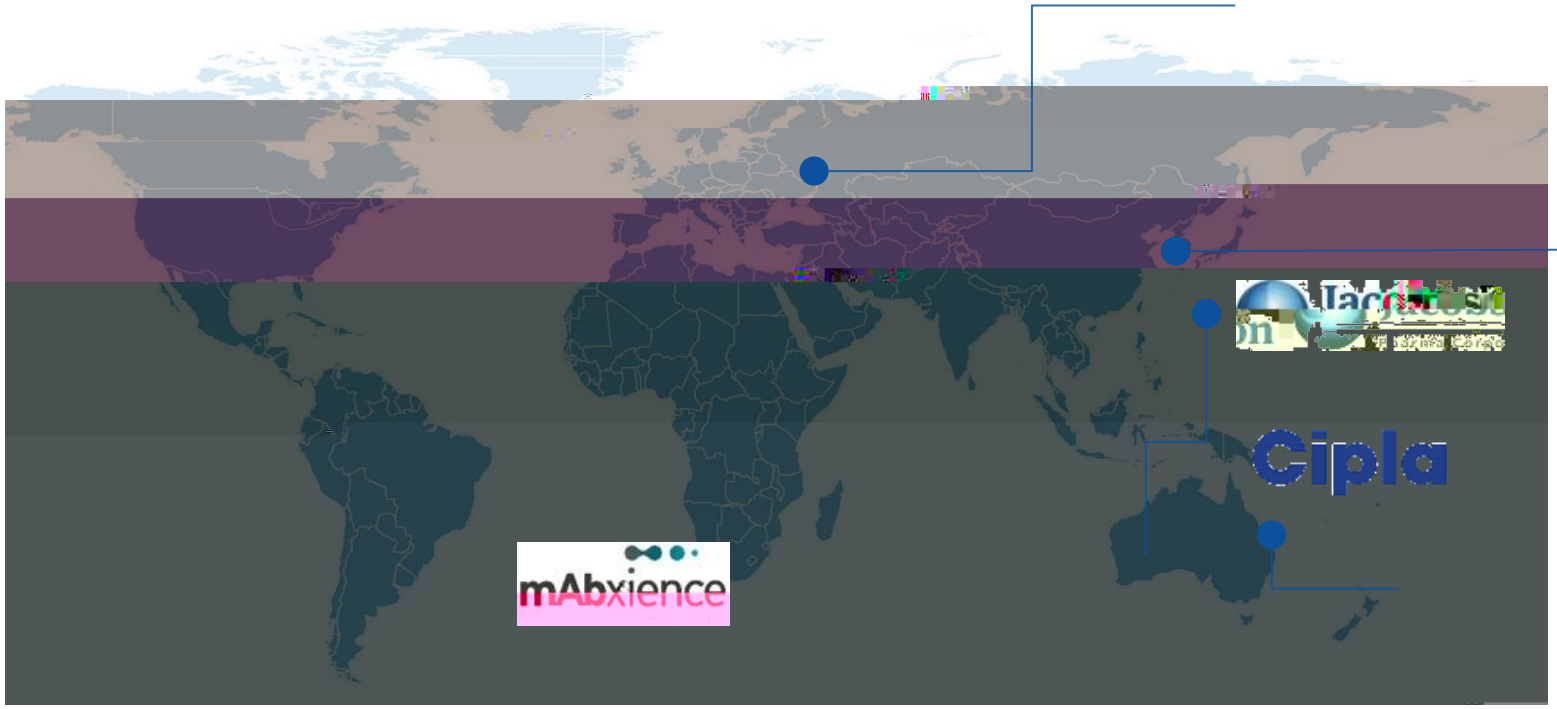
- Distribution network
- DTP pharmacy
- Patient accessibility

Marketing

- Comprehensive and sustainable commercial strategy
- Strong KOL support
- Commercial Innovation



To achieve healthy and sustainable development through patient-centric partnership strategy & cost-effectiveness management



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HANQUYOU® (

Collaboration on Physician Education

- Collaborate with medical societies, facilitate at community level
- Empower innovative academic communication platforms and online activities

‡

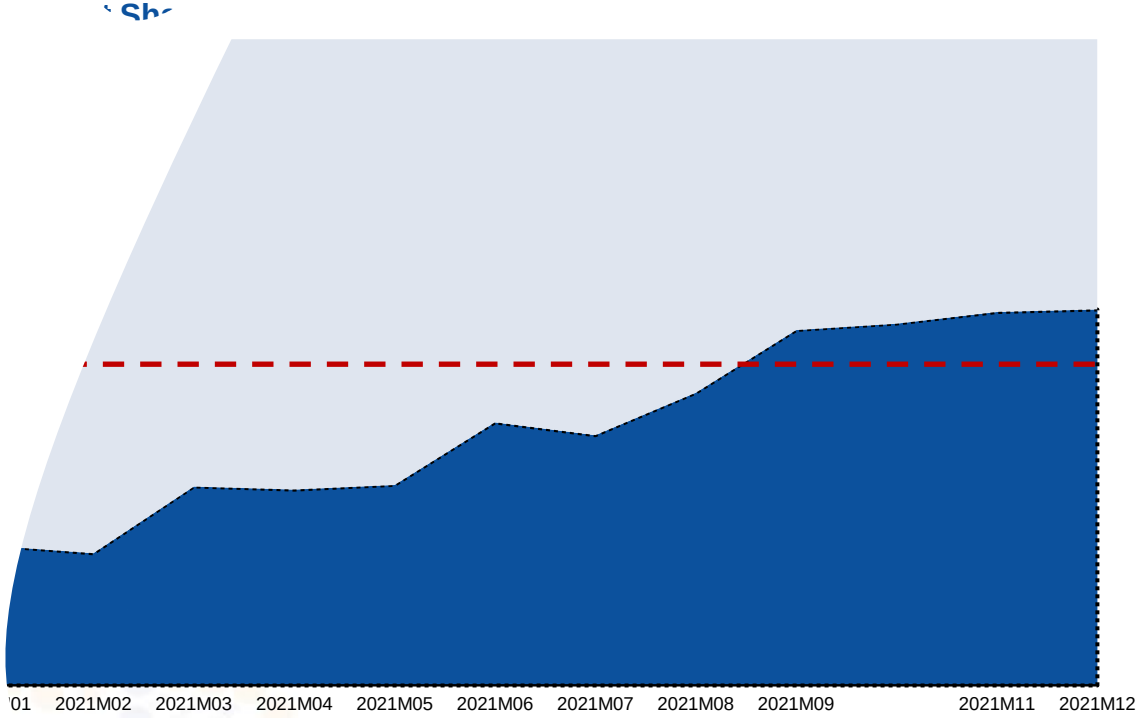
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ANQUYOU® (trastuzumab) : Excellent Sales Performance to Lead a Healthy and Sustainable Development

Sales Performance

Investment-Effectiveness



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HANQUYOU® (trastuzumab) Outlook : Become Market Leader by Seizing Opportunities to Increase Sales Volume Quickly

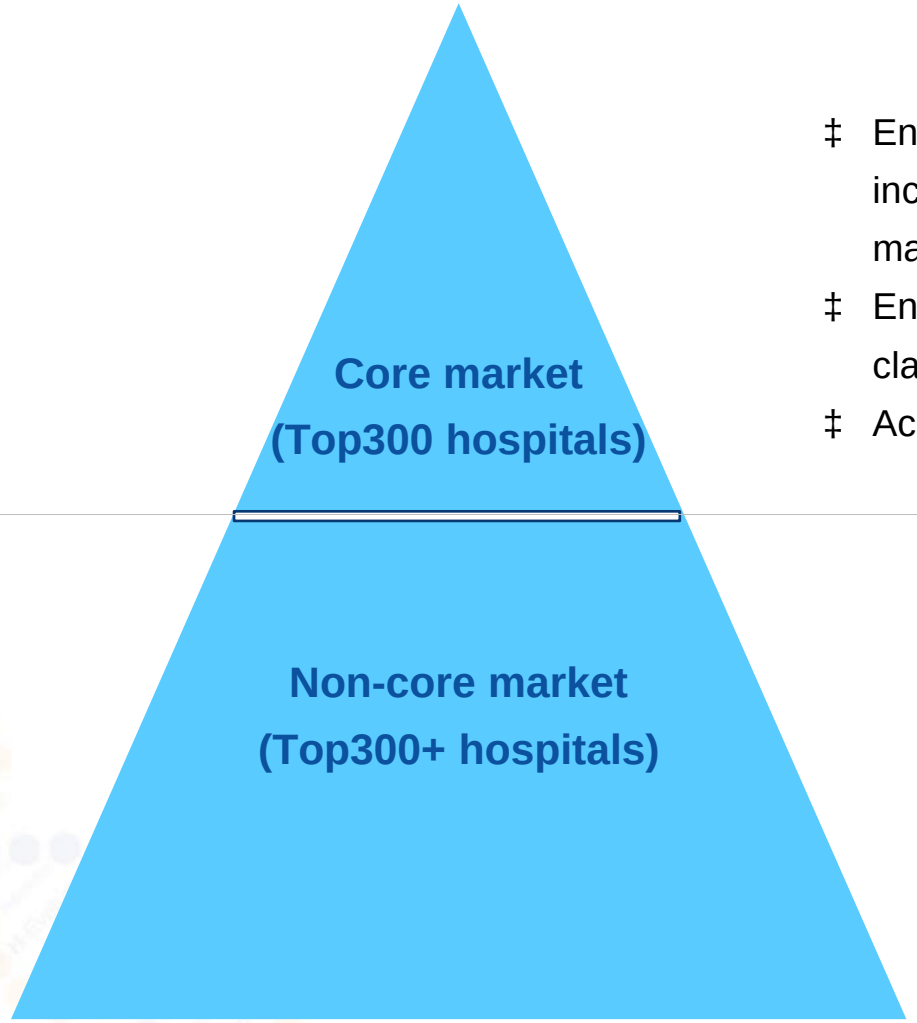
Expand Production Capacity, which will no longer be a bottleneck **in mid of 2022** once SJ1 steps into commercial

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HANLIKANG® (rituximab) :Continue to Increase Volume and Become the Market Leader

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HANLIKANG® (rituximab) : Take Advantage of First Entrant and Market Segmentation Differentiation



- ‡ Enhance the brand awareness of HANLIKANG® among doctors and the public, and increase the patient share and the DOT by initiating the patient journey management project for lymphoma patients
- ‡ Enhance the influence of hospitals by conducting academic exchanges with world-class lymphoma centers through the "zero-lymphoma" project
- ‡ Accumulate medical evidence for clinical practice by deepening the real world study

- ‡ Increase market penetration rate by integrating various resources to accelerate hospital listing
- ‡ Expand the coverage of hospitals and customers to realize brand switch.
- ‡ Standardize the diagnosis and treatment of lymphoma in subordinate hospitals through collaboration with medical treatment alliance

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HANLIKANG® (rituximab) Outlook: Strengthen Brand Penetration and Consolidate Leading Market Position

Improvement on hospital listing in Top 300+ hospitals with low market penetration rate

Improvement on diagnosis and treatment rate of lymphoma in primary hospitals by public-benefit activities, physician education etc.

Launch HANLIKANG®RA indication with huge market potential, bring unique competitive advantage in China marketplace

‡ Accelerate hospital listing by resources integration and formulation of hospital listing plan that is unique strategy to unique hospital

‡ Standardize diagnosis and treatment of lymphoma, improve corporate image, market penetration and coverage further by **FTE expanding**, **enhancing delicacy operation**

‡ With a low frequency of administration, HANLIKANG® have an obvious advantage of patient compliance, which provides a new clinical option for posterior line treatment when TNFi fails. Accelerate the expansion to the field of rheumatism from top hospitals as starting point

Consolidate

patient share as well as leading market position

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HANSIZHUANG

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HANSIZHUANG® (serplulimab) : Tap Market Potential through Ecosystem Establishment

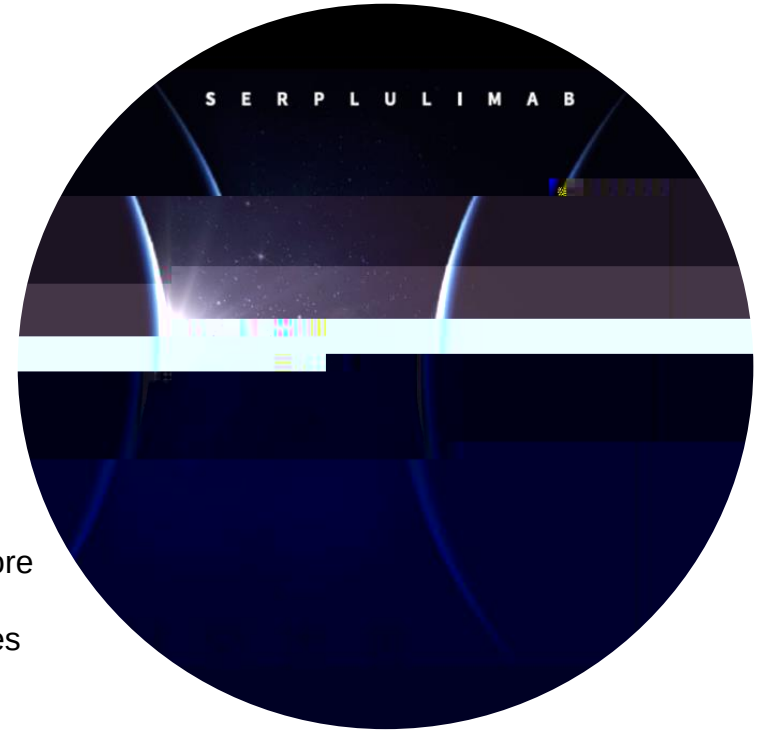
Ecosystem Empowerment

Physician Education

Empower innovative academic communication platforms through collaboration with medical societies

Collaboration on Testing & Diagnosis

Improve MSI screening standard and explore innovative patient service modes through collaboration with genetic testing companies



Market Access

Improve patient affordability through PAP initiated by charity foundations and collaboration with the government and commercial insurance to benefit more patients

Patient Education

Increase patient compliance by establishing digital patient education platforms in flagship hospitals based on the collaboration of medical societies.

Market Selection

Focus on core market, classify target hospitals and target customers precisely, differentiate promotion activities, and improve ROI

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Market Prospects

‡ 800k+ patients of Lung Cancer newly diagnosed per year (170k+ in sqNSCLC 120k + in SCLC)

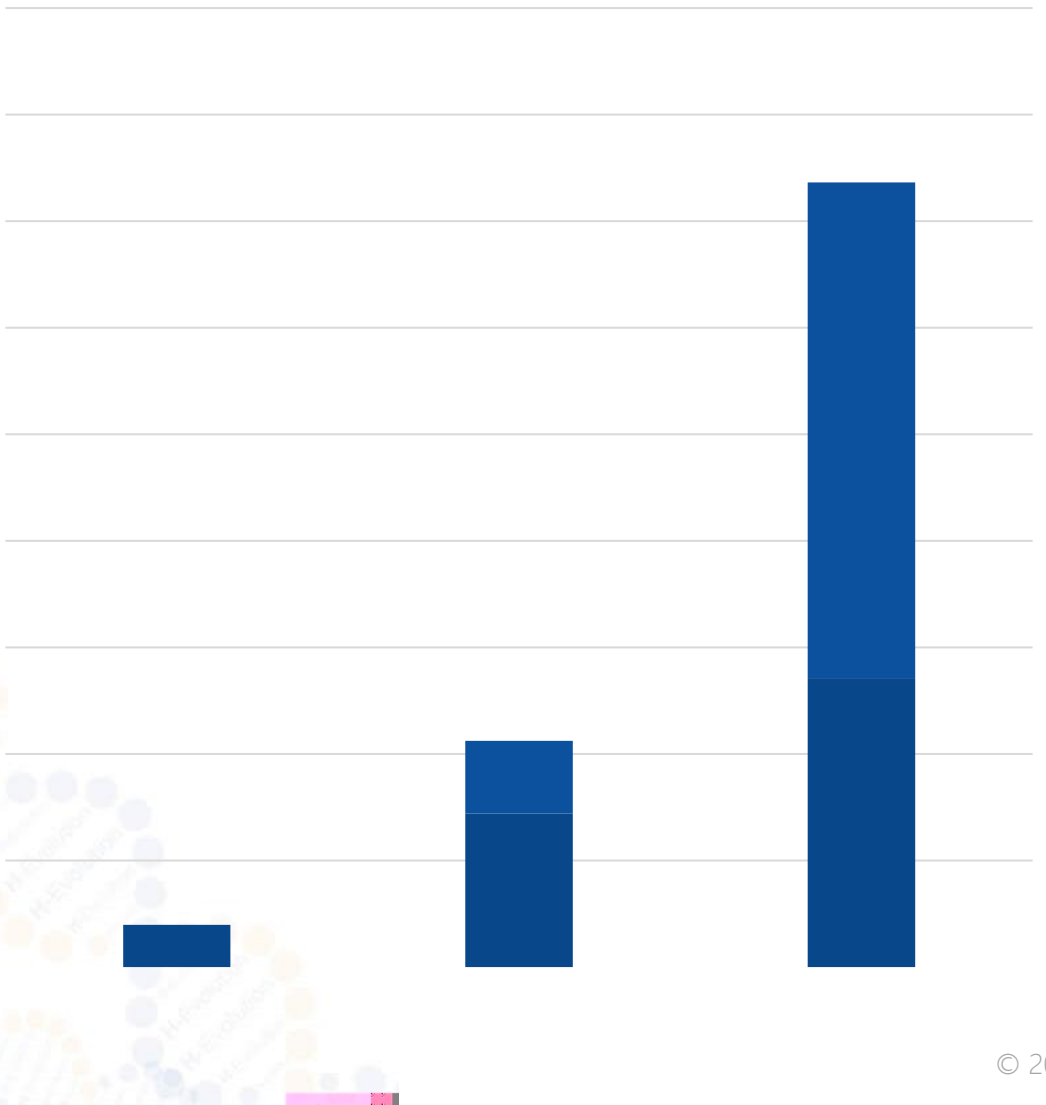
‡ First anti-PD-1 mAb for first-line treatment ofen-US

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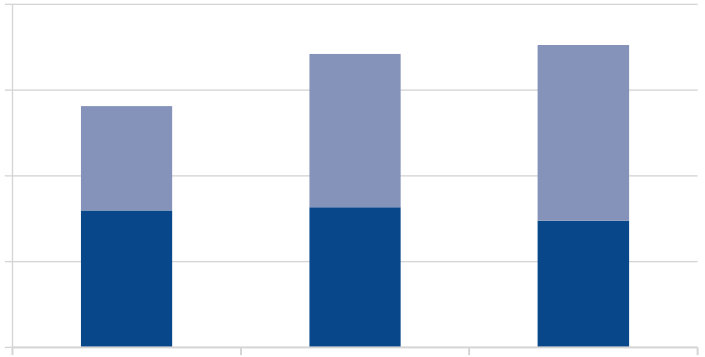
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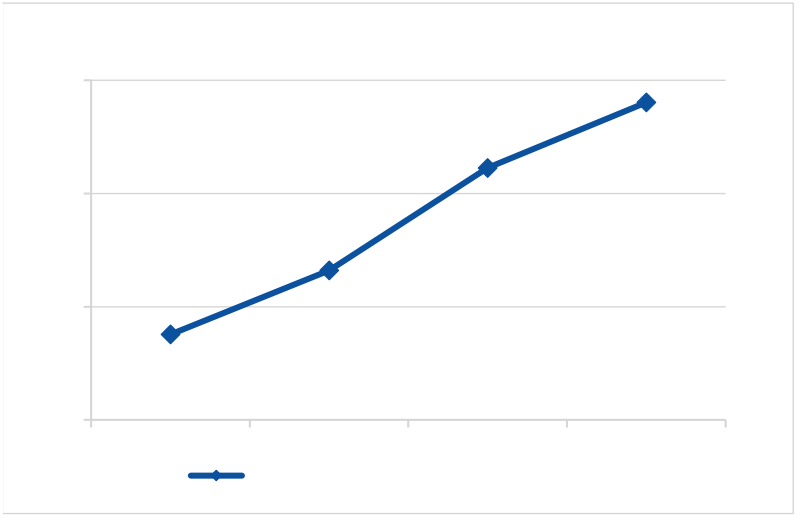
2021 Financial Review & 2022 Outlook

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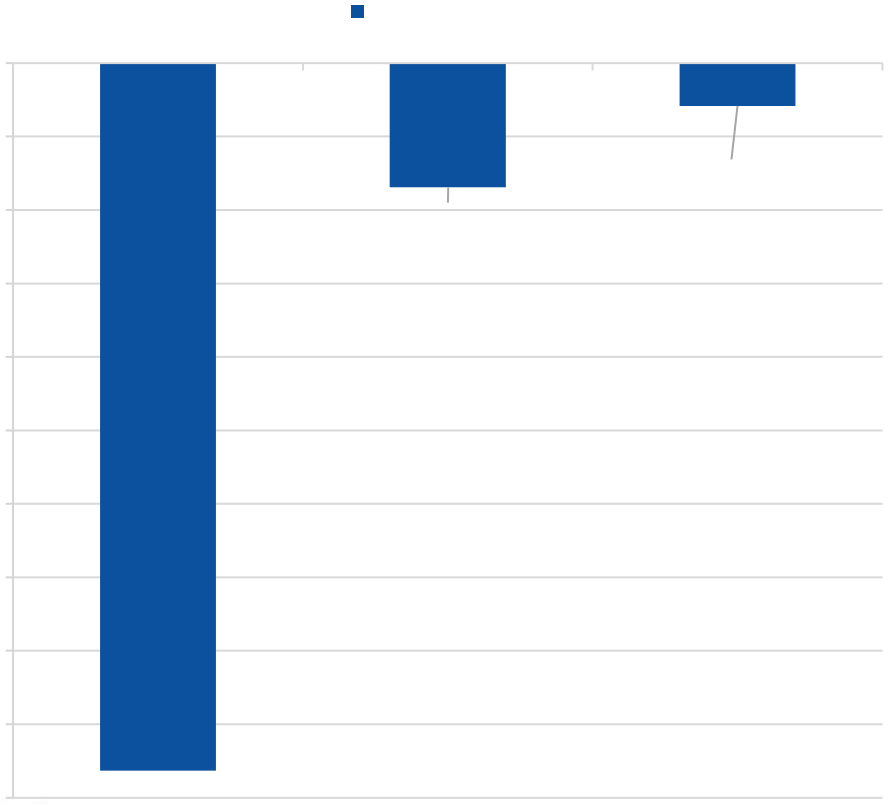
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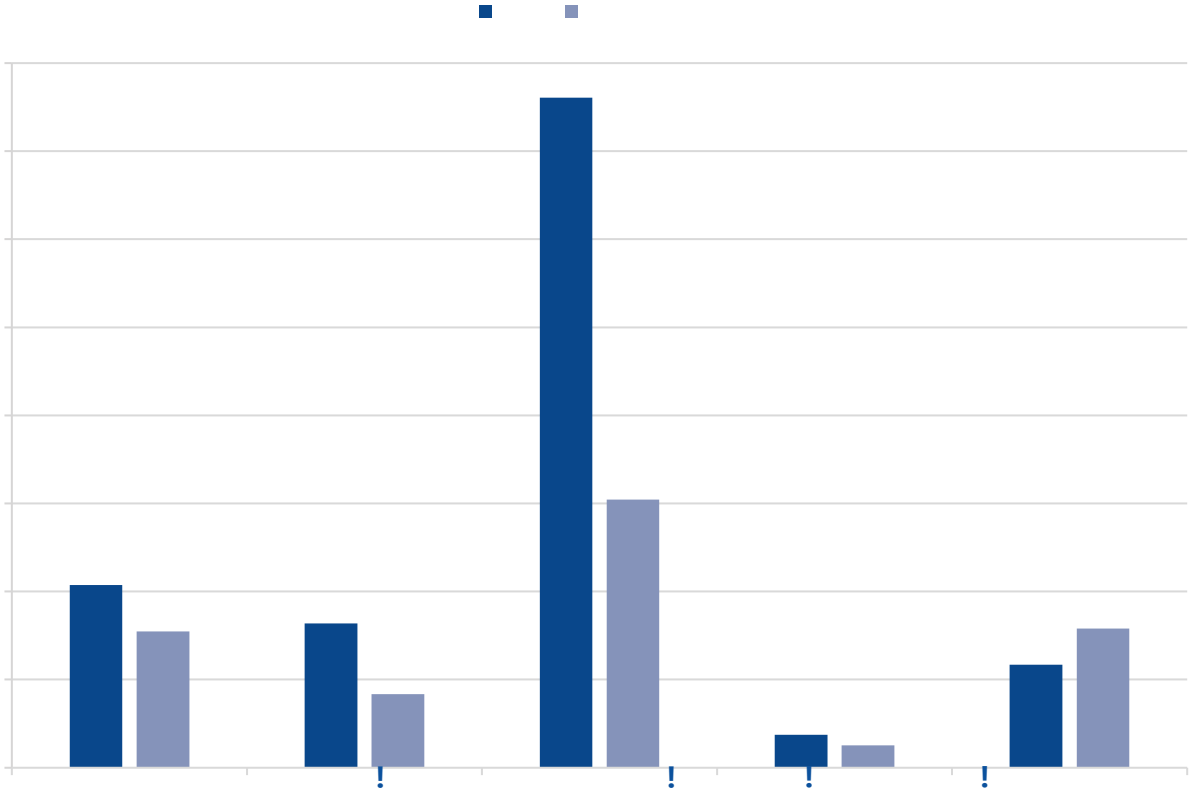




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2021 Loss Ratio & Expense Ratio: Largely Decreased





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2022 Outlook

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‡

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