

**HARBOUR**  
BIOMED

# FY2023 RESULTS

March 28, 2024

HBM HOLDINGS-B  
2142-HK





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Jingsong Wang MD PhD

# HBM Holdings: Value Creation through Globalization and Sustainable Growth

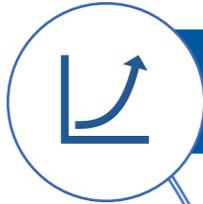
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## **Dr. Jingsong Wang**

Founder, Chairman of the Board and  
Chief Executive Officer



# HBM Holdings: Value Creation through Globalization and Sustainable Growth



## 1 Sustainable Growth: Focus on China with global perspective and steadily advance core pipeline assets

### 6 milestones from key clinical-stage assets:

- Batoclimab (HBM9161)
- Porustobart (HBM4003)
- HBM9378 (TSLP)
- HBM1020 (B7H7/HHLA2)
- .....

### 5 drugs obtained IND approval:

- HBM1020
- HBM1007
- HBM1022
- HBM9027
- HBM9033
- .....



### 7 milestones from collaboration assets:

- HBM7022 
- HBM7008 
- HBM9033 
- 4 collaborations  
- .....

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## 2 Globalization: Leading Chinese Biotech Going Global; Diversified Revenue Validates Business Model

- Completed **2** sizable BD deals with top overseas biotech companies in FY23
  - HBM7008 (B7H4x4-1BB)  **US\$600m+**
  - HBM9033 (MSLN ADC)  **US\$1bn+**
- Harbour/Nona partners: **50%+ from Top 10 Global Biotech/Pharmas**

### Remarkable results from Nona:

- Achieved net profits in FY23 <sup>1</sup>
- Quality revenue with orders mainly from **Top Global Biotech/Pharmas**



## 3 Value Creation: Sizable Net Profits Achieved for the First Time with Robust Cash Reserve

### Achieved Net Profits for the First Time:

- FY23 total revenue: US\$89.5m (~RMB640m), **+120%** vs. FY22
- FY23 net profits: US\$22.76m (~RMB160m)

### Value Creation:

- Group revenue from overseas **>85%**
- Robust Cash Reserve of **~US200m** <sup>2</sup>

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Note: USD/RMB = 7.1

1. As per FY23 Management accounts; 2. If including the upfront payment in relation to HBM9033 received in January 2024

## Harbour Therapeutics: Efficient and Synergized Pipeline Advancement

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**Dr. Xiaolu Tao**

President of Harbour Therapeutics



**Dr. Yiping Rong**

Executive Director,  
Chief Scientific Officer

# Harbour Therapeutics – FY23 Business Highlights

## Clinical Stage Assets

- ✓ **Batoclimab (HBM9161), gMG:** 
  - Completion of phase III clinical trial
  - Publication of Ph III study results in top medical journal *JAMA Neurology*
- ✓ **2 clinical data readouts for Porustobart (HBM4003)** 
- ✓ **2 clinical milestones**
  - Completion of HBM9378 Ph I study 
  - Conduction of HBM1020 Ph I study 
- ✓ **5 IND approvals from FDA** 
  - HBM1020, HBM1007, HBM1022, HBM9027, HBM9033

## Collaboration Assets

- ✓ **1 regional license-out to accelerate global R&D** 
- ✓ **5 preclinical collaboration assets/licenses advanced to clinical stage**
  - AstraZeneca: HBM7022/AZD5863
  - Hualan Bio: HBM7020, HBM7015, HBM1029
  - NK CellTech: NK-010

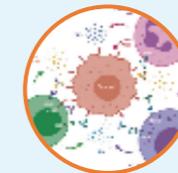


## Preclinical Stage Assets

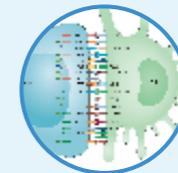
- ✓ **Advancing global pipeline of highly differentiated next-gen therapeutics**
- ✓ **Strategically promote the R&D of MULTIPLE immune cell engager bispecifics**



Direct Killing



Stimulate Immune Cells



Overcome Immune Suppression

**Focus on China with Global Perspective  
Rapidly Advance Next-Generation of Innovative Immunotherapy in Oncology**



# Highly Innovative and Differentiated Global Pipeline

Project	Target	Indication	Commercial Rights	Status						
				Discovery	Pre-Clinical	IND	Phase I	Phase II	Phase III	BLA
Batoclimab HBM9161	FcRn	Myasthenia Gravis	Greater China Rights Out-licensed <sup>1</sup>	Phase III 						
Porustobart HBM4003	CTLA-4 <sup>2</sup>	Solid Tumors <sup>a</sup>	Global	Monotherapy Ph 1b/2						
		Solid Tumors <sup>b</sup>		Combo with PD-1 Ph 1b/2						
		Solid Tumors <sup>c</sup>		Combo with PD-1/PD-1+Chemo Ph 1						
HBM7008	B7H4×4-1BB	Solid Tumors	Ex-U.S. <sup>3</sup>	Ph 1 						
HBM9378	TSLP	Asthma	Global	Ph 1 						
HBM1020	B7H7/HLA2	Solid Tumors	Global	Ph 1						
HBM7022	CLDN18.2×CD3	Solid Tumors	Global Out-license	Ph 1/2 						
HBM1007	CD73	Solid Tumors	Global	US IND clearance in January 2023						
HBM1022	CCR8	Solid Tumors	Global	US IND clearance in February 2023						
HBM9033	MSLN ADC	Solid Tumors	Global Out-license	US IND clearance in August 2023 						
HBM9027	PD-L1×CD40	Solid Tumors	Global	US IND clearance in January 2024						
HBM7004	B7H4×CD3	Solid Tumors	Global							
HBM1047	CD200R1	Solid Tumors	Global							
HBM9014	LIFR	Solid Tumors	Global							

1. HBM in-license the Greater China Rights of HBM9161 from HanAll in 2017, and the rights is out-license to CSPP in Oct 2022  
 2. HBM4003 is a next-gen anti-CTLA-4 antibody with enhanced ADCC for Treg depletion  
 3. The U.S. rights of HBM7008 is out-licensed to Cullinan in Feb 2023  
 \* MG: Myasthenia Gravis; TED: Thyroid Eye Disease;

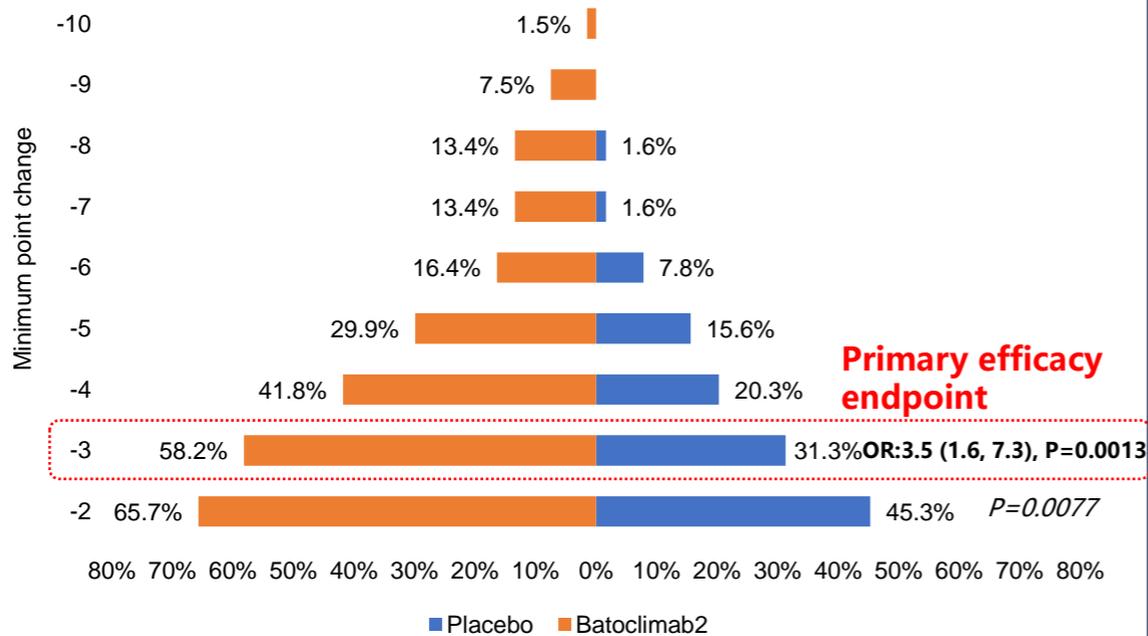
a. Melanoma, HCC, RCC and Other Advanced Solid Tumors  
 b. Melanoma, HCC, NEC/NET and Other Advanced Solid Tumors  
 c. NSCLC and Other Advanced Solid Tumors

# Batoclimab (HBM9161) Demonstrates Remarkable Therapeutic Benefits in gMG Patients

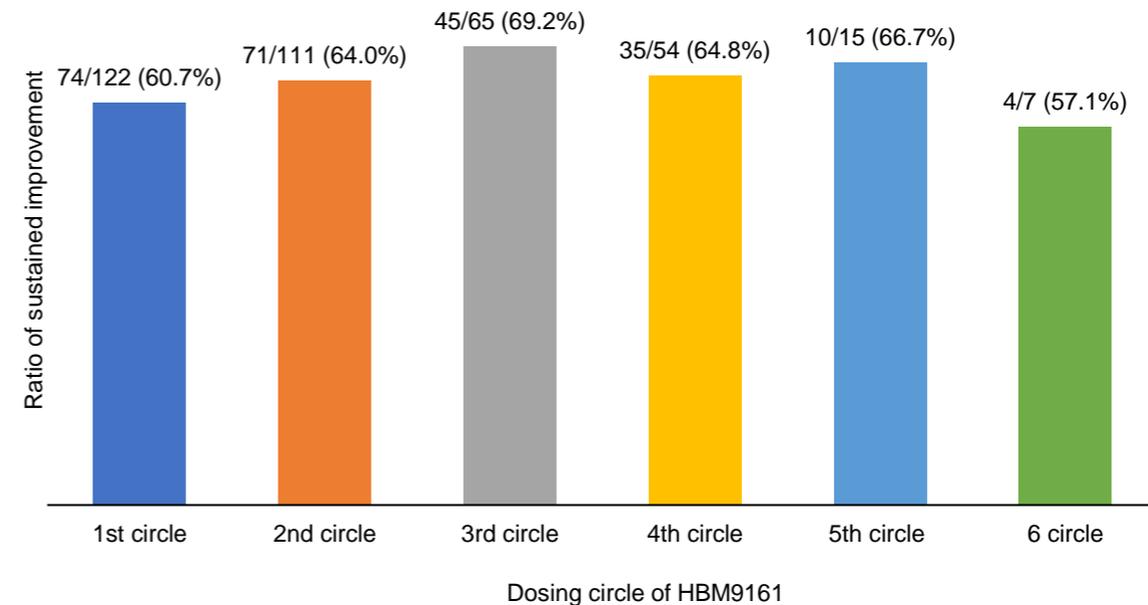


## Highlights

- First and only innovative drug targeting FcRn that has completed phase I,II and III clinical trials in China
- First innovative drug for gMG that has been granted breakthrough therapy designation by CDE
- First and only innovative drug that has achieved outstanding phase III positive results in China gMG patients
- First subcutaneous injection production for FcRn target in China, providing better convenience for gMG patients



## Efficacy: Consistency in the MG-ADL improvement, effect onset and duration for each treatment circle



Note: Sustained improvement was defined as a  $\geq 3$ -point reduction from baseline MG-ADL score from day 1 to day 64 that persisted for 4 weeks. The analysis of sustained improvement rates only included subjects who completed at least 6 visits between weeks 2 and 9 within each cycle

# Ph III Study Results of Batoclimab (HBM9161) Published in Top Medical Journal – JAMA Neurology



## JAMA Neurology (March 2024)

- Clinical Data demonstrate the **efficacy and safety** of Batoclimab in adult patients with generalized MG
- The MG-ADL score diverged between antibody-positive patient group and placebo group as early as week 2, suggesting Batoclimab is able to **take effect quickly** and **improve symptoms**
- The rate of sustained MG-ADL improvement in the first cycle in antibody-positive patients was 31.3% in placebo group vs 58.2% in the Batoclimab group, suggesting Batoclimab can **significantly improve patient symptoms** with **sustainable therapeutic effects**
- In the 1<sup>st</sup> treatment cycle, the proportion of patients in antibody-positive patient group reaching the mildest symptom manifestations was **25.4%**, much higher than the 4.7% in placebo group.

Research

JAMA Neurology | **Original Investigation**

### Batoclimab vs Placebo for Generalized Myasthenia Gravis A Randomized Clinical Trial

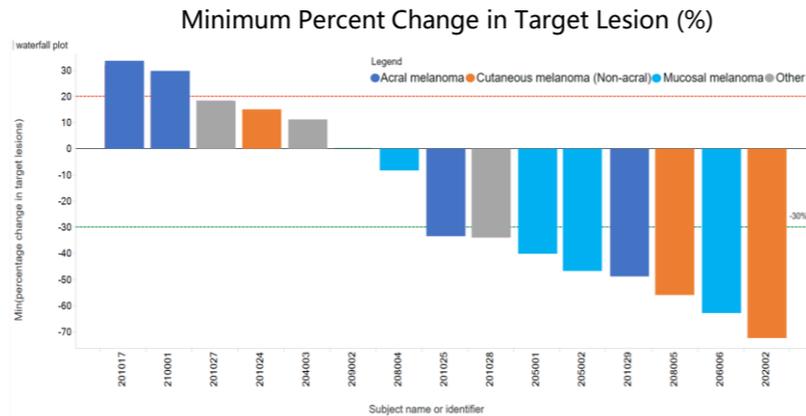
Chong Yan, MD; Yaoxian Yue, MD; Yuzhou Guan, MD; Bitao Bu, MD; Qing Ke, MD; Ruisheng Duan, MD; Hui Deng, MD; Qun Xue, MD; Haishan Jiang, MD; Fei Xiao, MD; Huan Yang, MD; Ting Chang, MD; Zhangyu Zou, MD; Haifeng Li, MD; Song Tan, MD; Haibing Xiao, MD; Hongyu Zhou, MD; Hua Zhang, MD; Qiang Meng, MD; Wenyu Li, MD; Wei Li, MD; Junhong Guo, MD; Yali Zhang, MD; Zunbo Li, MD; Jianglong Tu, MD; Jianquan Shi, MD; Wei Li, MD; Michael Lee, PhD; Yu Chen, MD; Xiaolu Tao, PhD; Shuai Zhao, MS; Ping Li, MS; Chongbo Zhao, MD; for the Batoclimab Study Team

# Porustobart (HBM4003) Clinical Benefit and Market Opportunities in Various Tumors

## Robust efficacy observed for HBM4003 + Toripalimab in PD-1 naïve melanoma cohort

### Best Overall Response by RECIST 1.1, N (%)

Pts with tumor assessments	15 (100%)
ORR (CR + PR)	5 (33.3%)
DCR (CR + PR +SD)	11 (73.3%)
Tumor reduction	9 (60.0%)



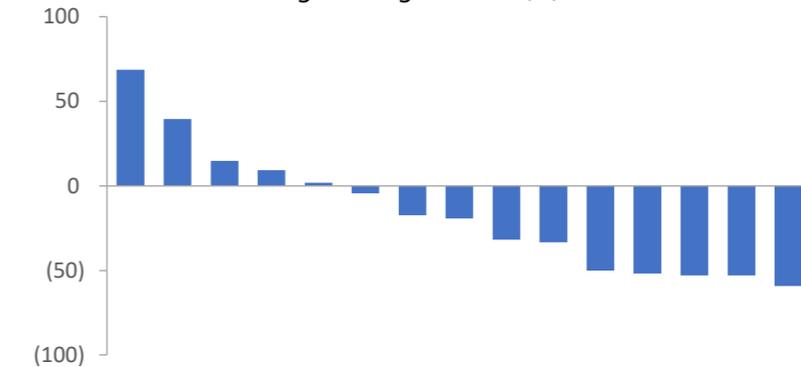
## Excellent therapeutic potential observed for HBM4003 in patients with HCC

- HBM4003 monotherapy has demonstrated **preliminary efficacy** in late-stage liver cancer patients resistant to PD-1 treatment
  - ✓ 0.45mg/kg Q3W dose group: 1CR, 1PR
- HBM4003 in combo with Toripalimab has shown **promising therapeutic efficacy** in patients with HCC who have been treated with TKI

### Best Overall Response by RECIST 1.1, N (%)

Best Overall Response, n(%)	RECIST 1.1	mRECIST
Pts with tumor assessments	15 (100%)	15 (100%)
ORR (CR + PR)	6 (40.0%)	6 (40.0%)
DCR (CR + PR +SD)	11 (73.3%)	10 (66.7%)
Tumor reduction	10 (66.7%)	10 (66.7%)

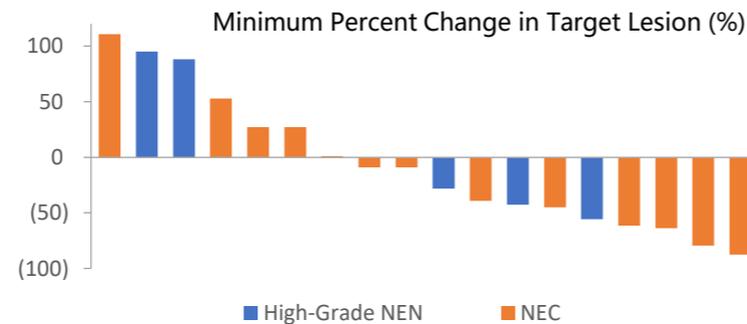
### Minimum Percent Change in Target Lesion (%)



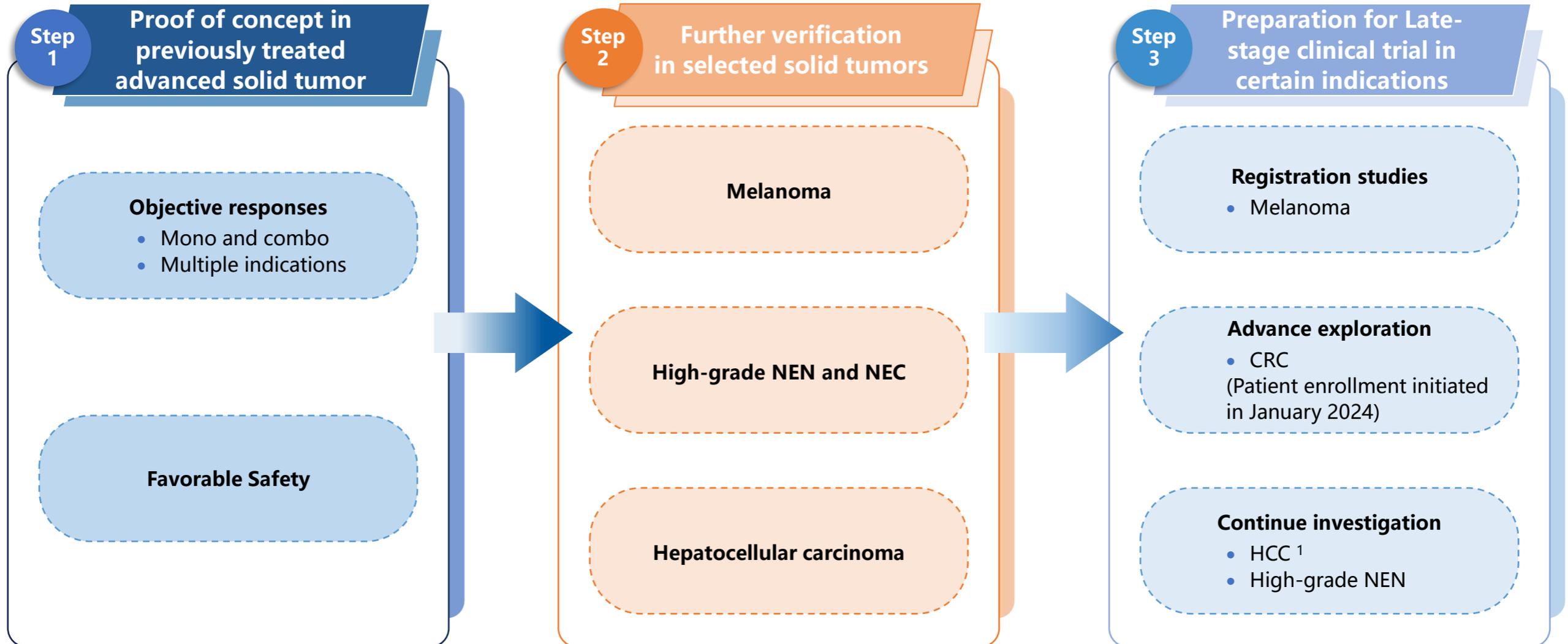
## HBM4003 + Toripalimab elicited significant efficacy improvement in high-grade NENs patients

### Best Overall Response by RECIST 1.1, N (%)

Pts with tumor assessments	19 (100%)
ORR (CR + PR)	7 (36.8%)
DCR (CR + PR +SD)	11 (57.9%)
Tumor reduction	12 (70.6%)



# Porustobart (HBM4003) – Pivotal Trial Preparations



**HBM4003 combination therapy with anti-PD-1**

# HBM1020 (B7H7/HHLA2)

## An Alternative Immune Escape Mechanism Beyond PD-L1

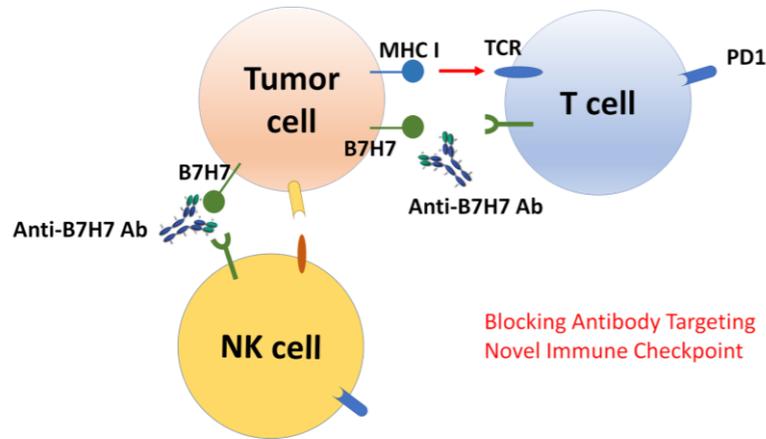


### Highlights

- T cell and NK cell activation activity and excellent in vivo efficacy in humanized tumor models
- Widely Expressed in Various Solid Tumors & Reciprocal to the Expression of PD-L1
- Huge potential to treat PD-L1 negative or anti-PD1/PD-L1 refractory cancer patients
- HBM1020 is the first and only mAb entering clinical development worldwide
- **Ph1 ongoing - multiple patients dosed in collaboration with top-tier US cancer centers**



### MOA



### NCT05824663 Indicative Timeline





# Building The Technical Foundations on Immune Cell Engager Bispecifics

## Partnerships based on Immune Cell Engager Bispecifics

AstraZeneca

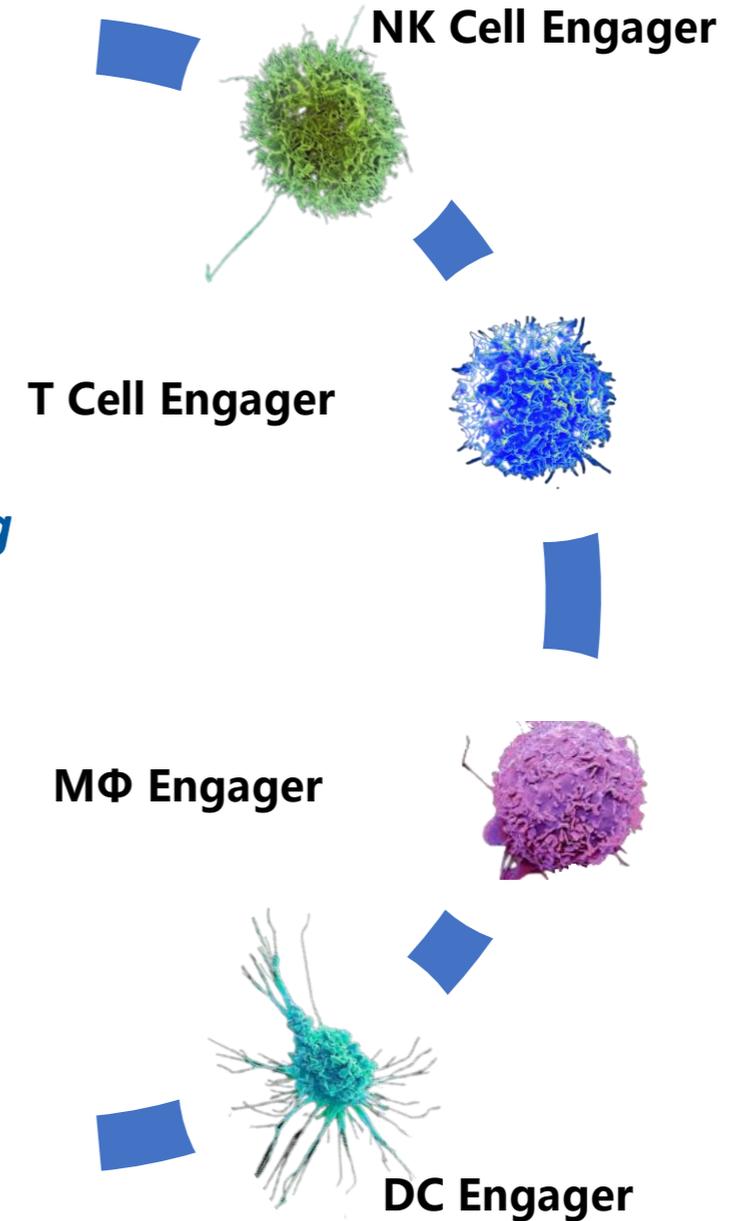
cullinan  
ONCOLOGY

Dragonfly

華蘭生物  
HUALAN BIO



*HBICE targeting  
four types of  
immune cells*



# HBM9027 (PD-L1xCD40)

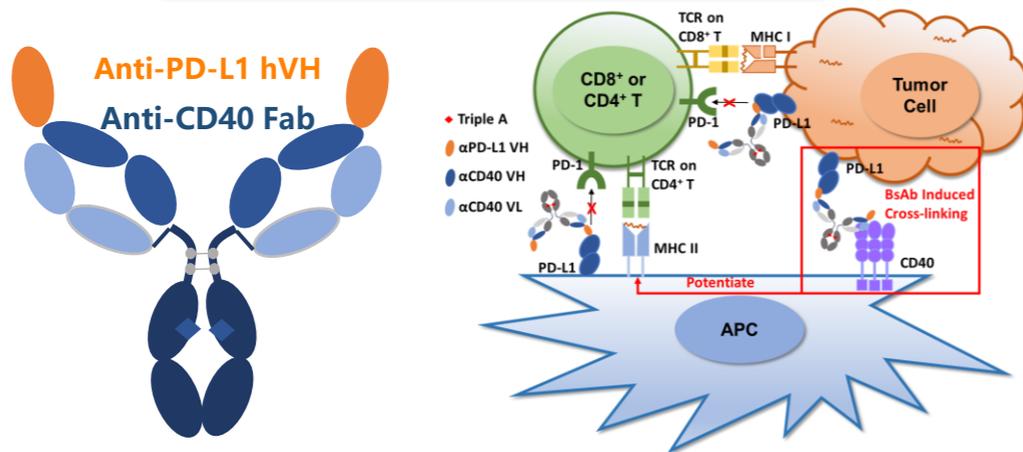
## Innovative Bispecific Antibody Activating APC/T Cells



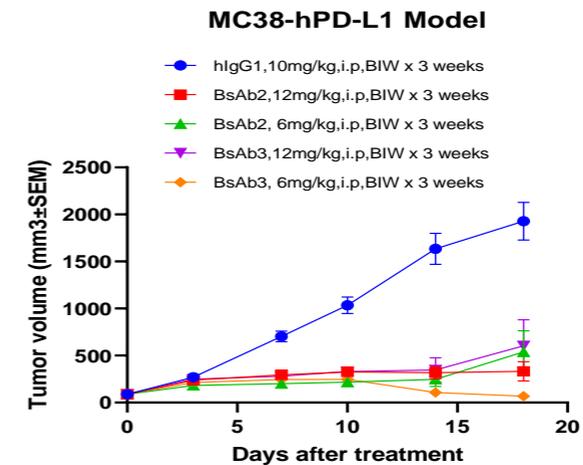
### Highlights

- Synergistically activating both myeloid/DC cells and T cells is critical for some solid tumor therapy considering the most abundant myeloid cell population in TME
- Well maintained  $\alpha$ PD-L1 arm and  $\alpha$ CD40 arm function activity with robust developability using fully human symmetrical HBICE® format
- Encouraging in vivo efficacy superior to Tecentriq and safety profile is much better than Selicrelumab
- **Obtained US IND approval in January 2024**

### Molecule Design and MOA



### Strong Anti-tumor Activity in hPD-1/hCD40 DKI Mice



# HBM7004 (B7H4xCD3)

## Unique “2+1” Asymmetric HBICE® Using Novel TAA and Safer Anti-CD3 Arm



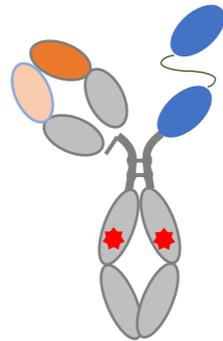
### Highlights

- HBICE® technology grants asymmetric structure but less light chain mispairings
- TAA is mainly expressed in low PD-L1 tumors, particularly in gynecological cancers and squamous cell lung cancer
- Potentially combine with PD1 therapy or in-house HBM7008 to overcome T cell engager challenges in solid tumor

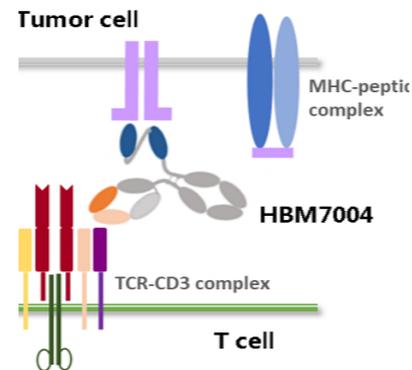
### Molecule Design and MOA

Optimized anti-CD3 arm, ~200-300nM

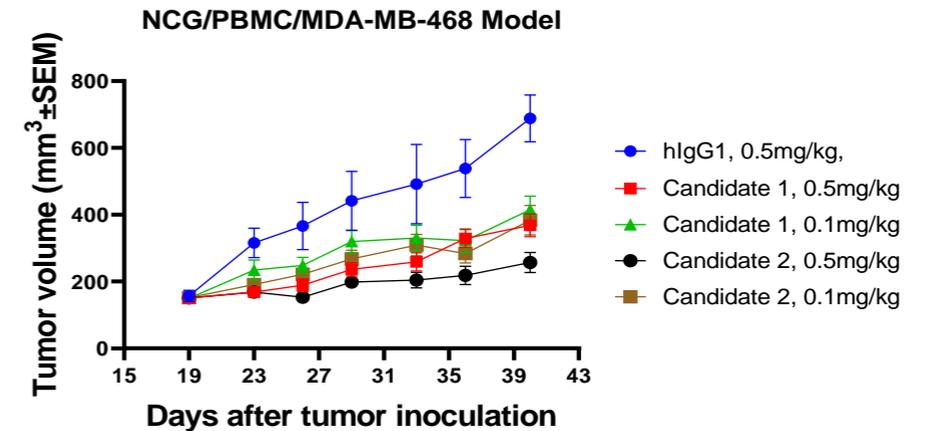
Strong bivalent binding to B7H4



Silenced Fc



### Strong Anti-tumor Activity in Mouse Tumor Model



# **Nona Biosciences: Strong Growth Empowered by Innovation**

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**Dr. Yun He**

Chief Technology Officer, Nona Biosciences



# Nona Biosciences Empowers Global Therapeutic Innovation



**Nona:**  
Roman Goddess  
Who Enables  
Others to Succeed

## Our Mission

Leveraging industrial leading technology platforms, Nona Biosciences is committed to provide integrated discovery solutions for biotech and pharmaceutical companies from **Idea to IND (I to I)**

We value our promise, we embrace diversity

## Leading Innovative Technology Platform

- The world's leading **fully human antibody platform**
- The **ONLY** open platform fully-protected by global IP
- Fully validation by **~20 projects in clinical stage**
- Successful application in GCT, ADC, AI and other fields

## Decades of Experience with MNC Endorsement

- Management experience from **top MNCs**
- Strong scientific background from **top academics and industry**
- Rich academic resources and MNC endorsement
- **70+** scientists with ample research and development experience in innovative medicine

## Extensive Global Collaborations



**>50** partners including MNC, biotech and academic institutions, forming a large innovative network

# Nona's Technology Platform Contributes to the Rapid Business Growth Achieved in FY23

## Platform-based Research Services

50+ partners  
30+ collaborations in progress

19+ projects entered into clinical stage



Protein Engineering



Conjugation Technology



Delivery Technology



Cell Therapy Technology



## Technology Licensing

> US\$60m revenue

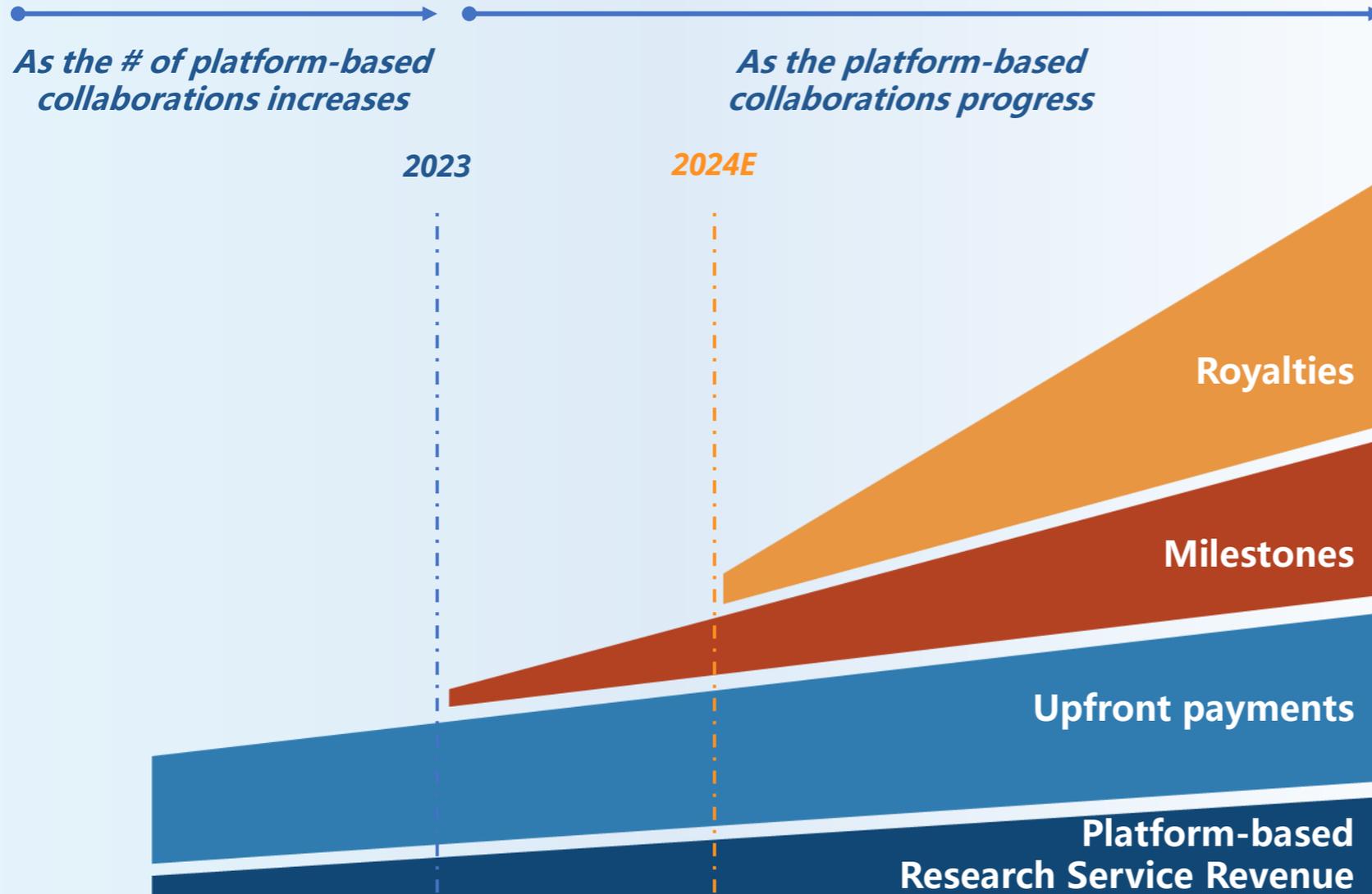
- ✓ Antibody depot is set up after 8 years of preparation
- ✓ Partnerships with top biotech / biopharmas



Focusing on 4 application areas.....

FY23 Witnesses the Commercialization of Nona with Sizable Profits

# Nona's Unique Growth Model Based on Platform Technology



# Harbour Mice<sup>®</sup> - New Generation of Fully Human Antibody Platforms

## Harbour Mice<sup>®</sup> Fully Human Antibody Transgenic Mice

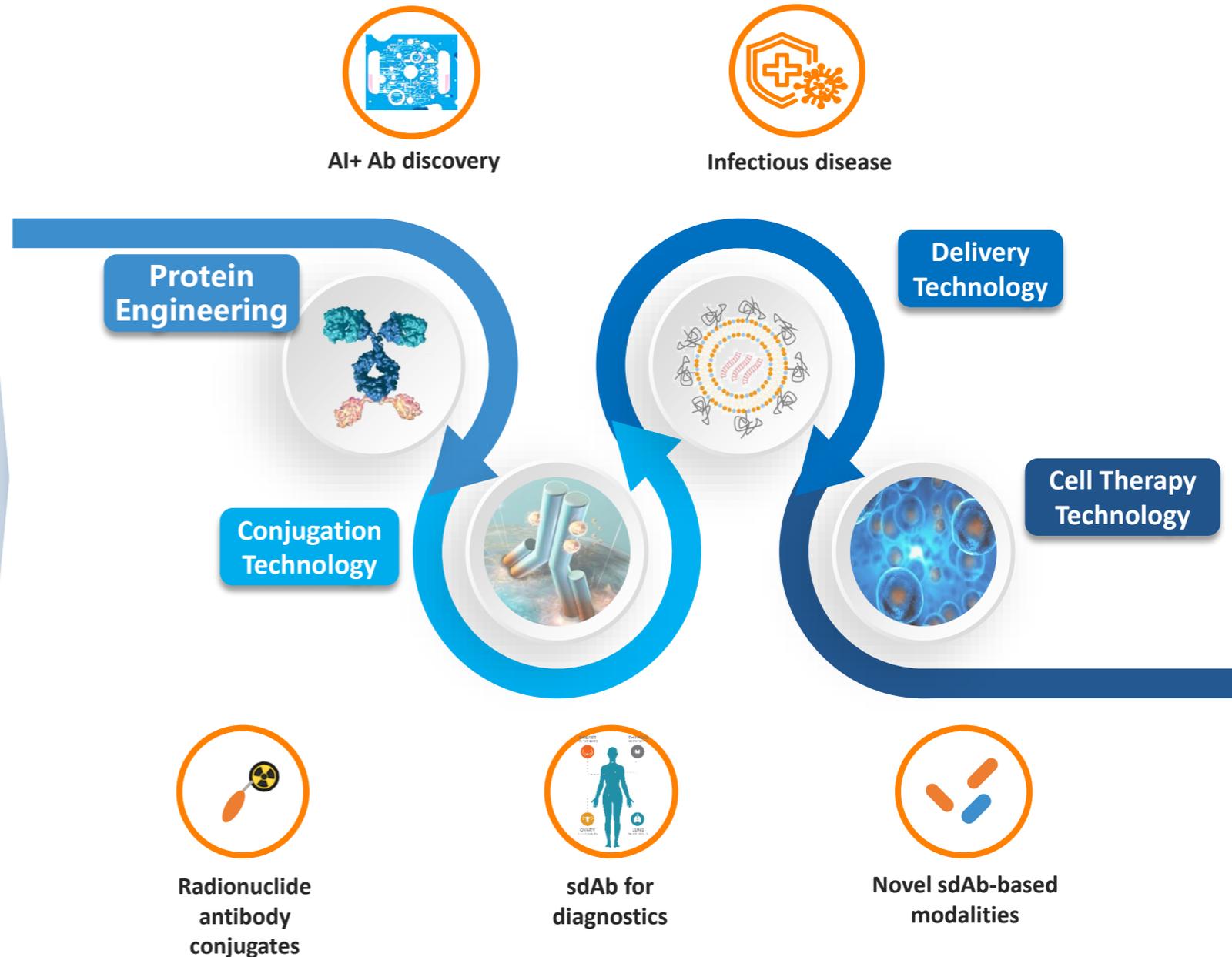
H2L2



HCAb



- ✓ Human
- ✓ Natural
- ✓ Optimized
- ✓ Validated



# Extend Antibody Discovery Platform to Integrated ADC Discovery Platform

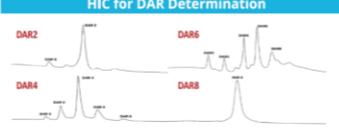


**H2L2**      **HCab**      **BsAb**

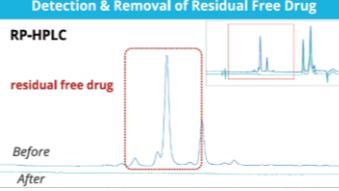
**Clinically validated fully human antibody platform**

Attribute	Analytical Methods
DAR	HIC
	UV
	mass spec
	RP-HPLC
Purity	SEC (HMW & LMW species)
	HIC (DAR0 content)
Residual free drugs	RP-HPLC (DAR0 content)
	RP-HPLC
Endotoxin	Chromogenic LAL assay
	Recombinant Factor C assay

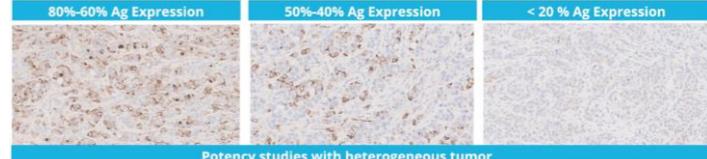
**HIC for DAR Determination**



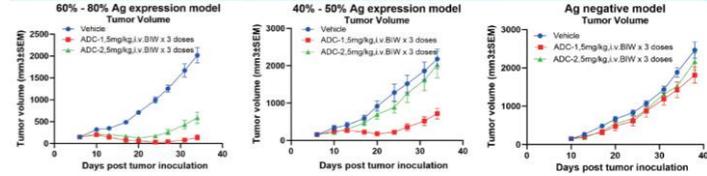
**Detection & Removal of Residual Free Drug**



**Comprehensive physicochemical characterization of ADC molecules**



**Potency studies with heterogeneous tumor**

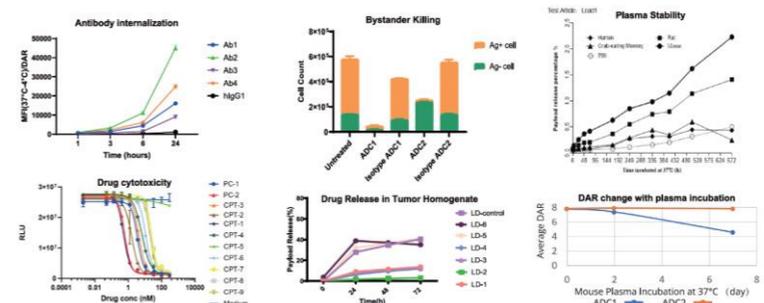


**Efficacy studies in various tumor models; PK studies; Preliminary toxicities.**



Conjugate Unite	Linker	Payload
<ul style="list-style-type: none"> <li>Cys-based</li> <li>Mal-based</li> <li>Non-Mal-based</li> <li>Lys-based</li> </ul>	<p><b>Commercialized Linkers</b></p> <ul style="list-style-type: none"> <li>Cleavable: vc-PABC, hydrazine, disulfide, GGFG, <math>\beta</math>-galactoside</li> <li>Uncleavable: MCC, PEG-link</li> </ul> <p><b>Novel Linkers</b></p> <ul style="list-style-type: none"> <li>Tuning cleavage efficiency/MoA</li> <li>Tuning hydrophobicity</li> <li>Tuning drug loading capacity</li> <li>PEG in side chain</li> <li>PEG in backbone</li> <li>Recognized by different peptidase</li> </ul>	<p><b>Classic Payloads</b></p> <ul style="list-style-type: none"> <li>MMAE/MMAF</li> <li>DM1-4</li> <li>Eribulin</li> <li>Doc/Exatecan</li> <li>SN38</li> </ul> <p><b>Novel Payloads</b></p> <ul style="list-style-type: none"> <li>Other Chemo drugs</li> <li>Immune Modulators</li> <li>Desamethazone or derivatives</li> <li>Paclitaxel</li> <li>CPT derivatives</li> <li>STING Agonist</li> </ul>

**Extensive experience and a variety of established bioconjugation technologies**



**Antibody internalization**

**Drug cytotoxicity**

**Bystander Killing**

**Drug Release in Tumor Homogenate**

**Plasma Stability**

**DAR change with plasma incubation**

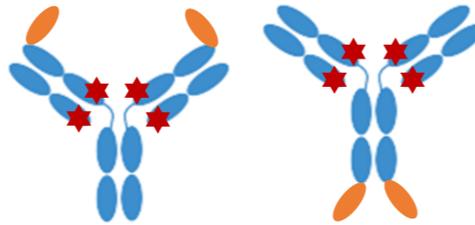
**Full range in vitro evaluation**

# Explore Frontiers in ADC Field

Collaborate with global ADC experts to build ADC ecosystem

Unveil the advantages of bispecific / biparatopic ADC

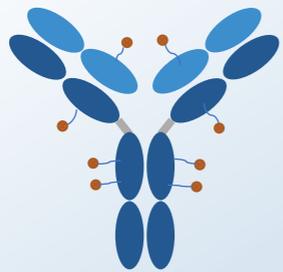
Application of HCAb in XDC for Diagnosis & Therapy



Radiolabeled anti-MSLN HCAb can quickly penetrate into tumors



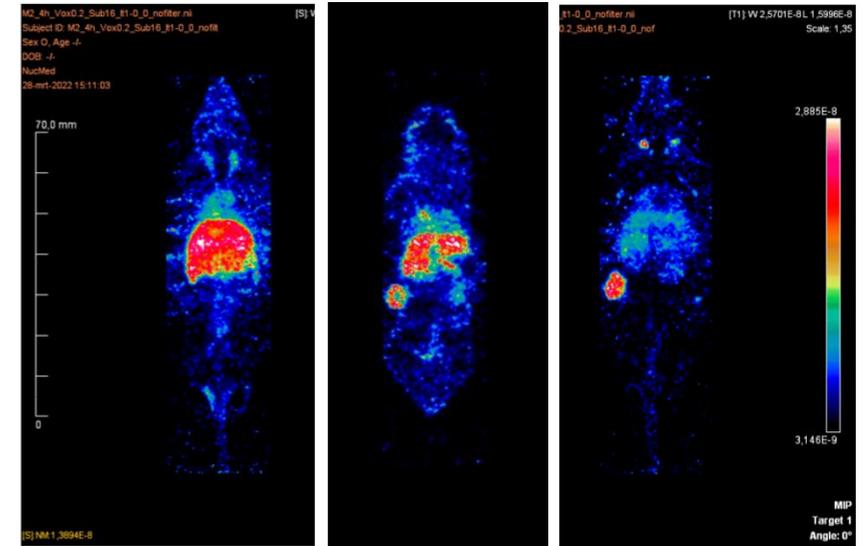
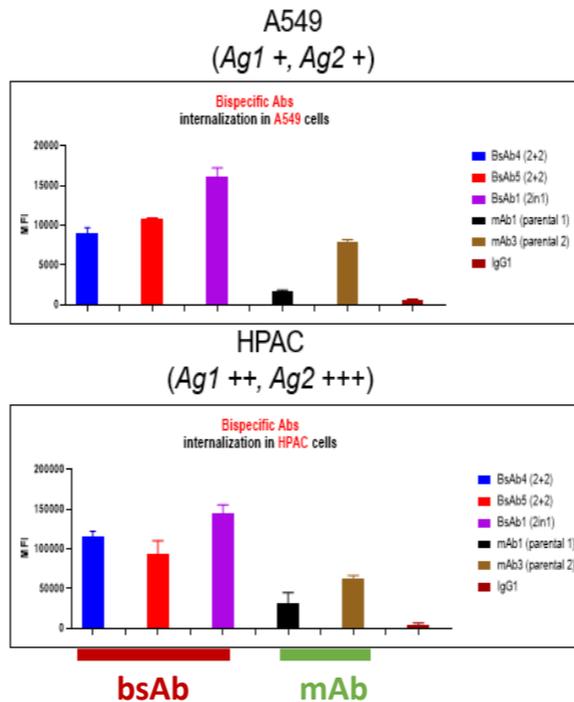
*bsAb showed stronger internalization*



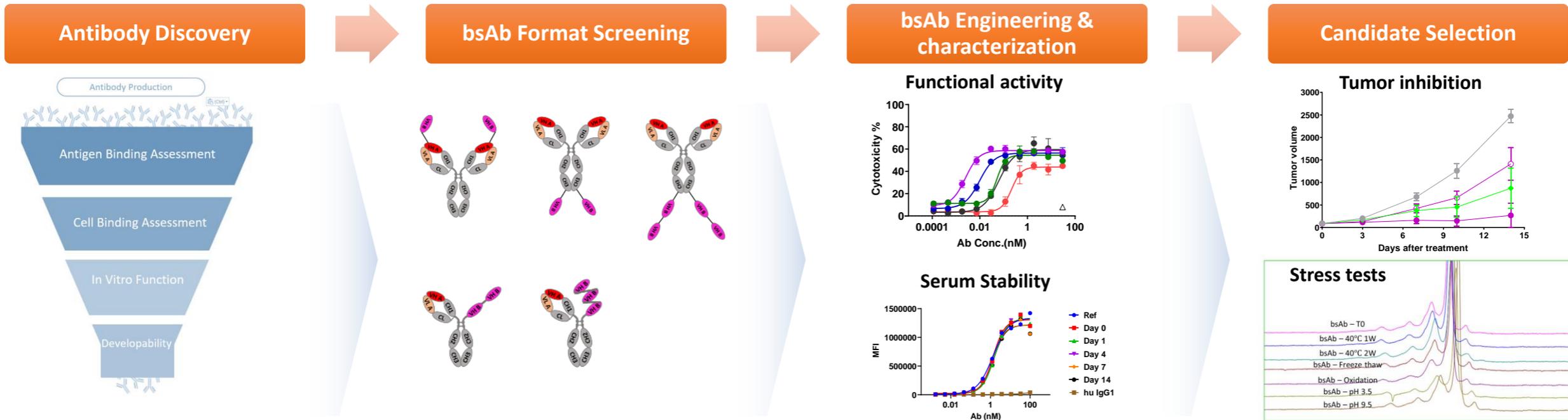
H2L2-ADC to MSLN

- ✓ fully human antibody with unique binding epitope
- ✓ Tumor specific cleavable linker with improved stability
- ✓ Superior in vivo potency and promising safety profile

**US IND clearance in Aug 2023**



# Comprehensive Bispecific Antibody Discovery Workflow to Reinforce Industry-leading HBICE® Platform (HCAb Based Immune Cell Engagers)



HBICE® Platform Has Been Endorsed by Global Partners

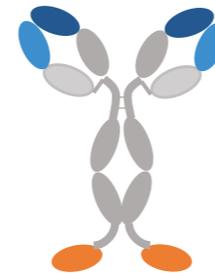


## HBM7022 (CLDN18.2×CD3)

Unique 2+1 format with better activity and potential larger therapeutic window.



1<sup>st</sup> Chinese bispecific antibody to "go global"



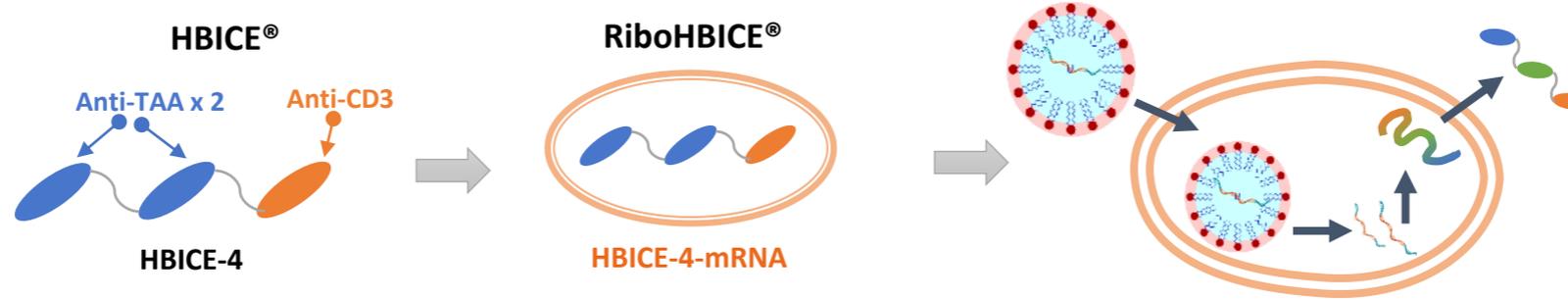
## HBM7008 (B7H4×4-1BB)

First-in-class B7H4 ×4-1BB with excellent anti-tumor efficacy and safety profile.

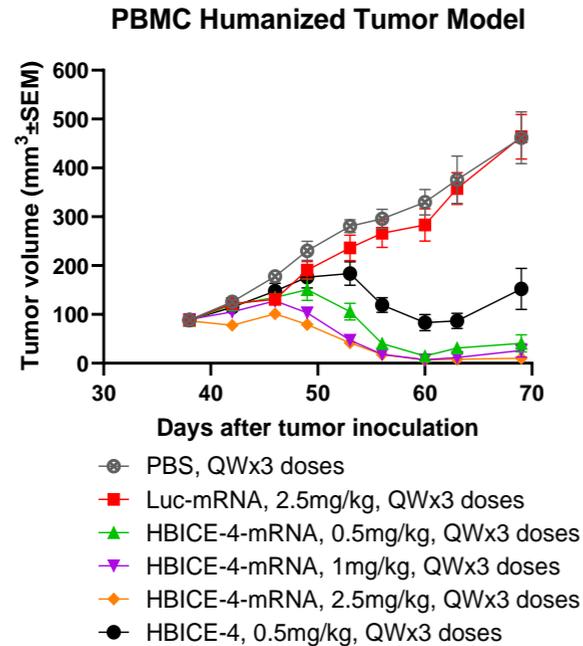




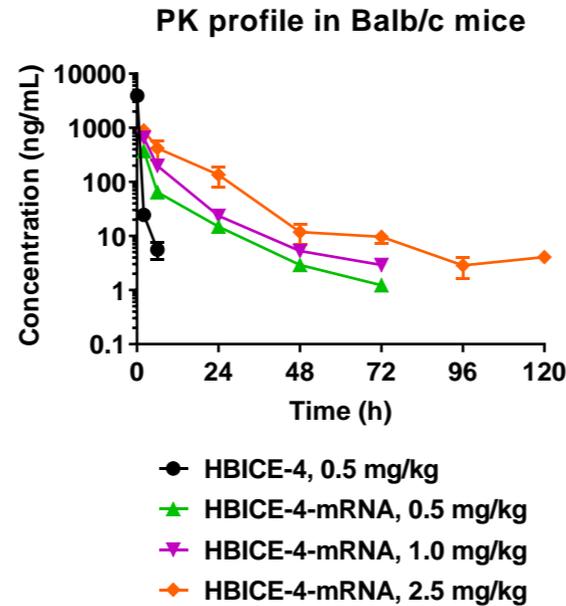
# Combine mRNA & HBICE® Technologies to Create Next-Gen Therapeutics



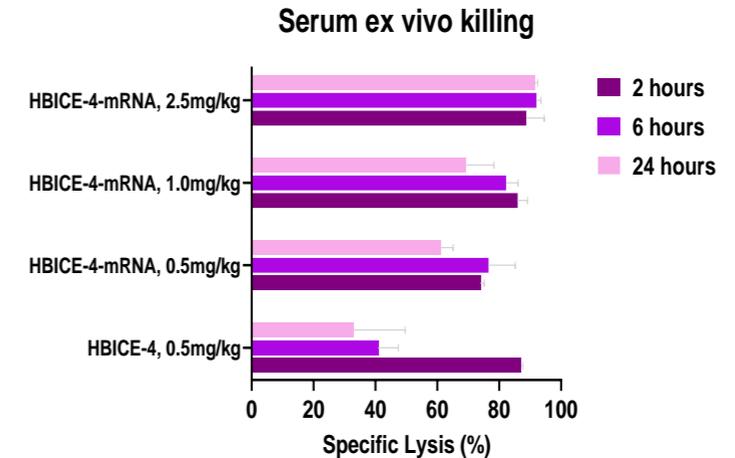
**RiboHBICE® demonstrates stronger tumor inhibition and longer duration**



**RiboHBICE® shows longer serum half-life than recombinant protein HBICE®**

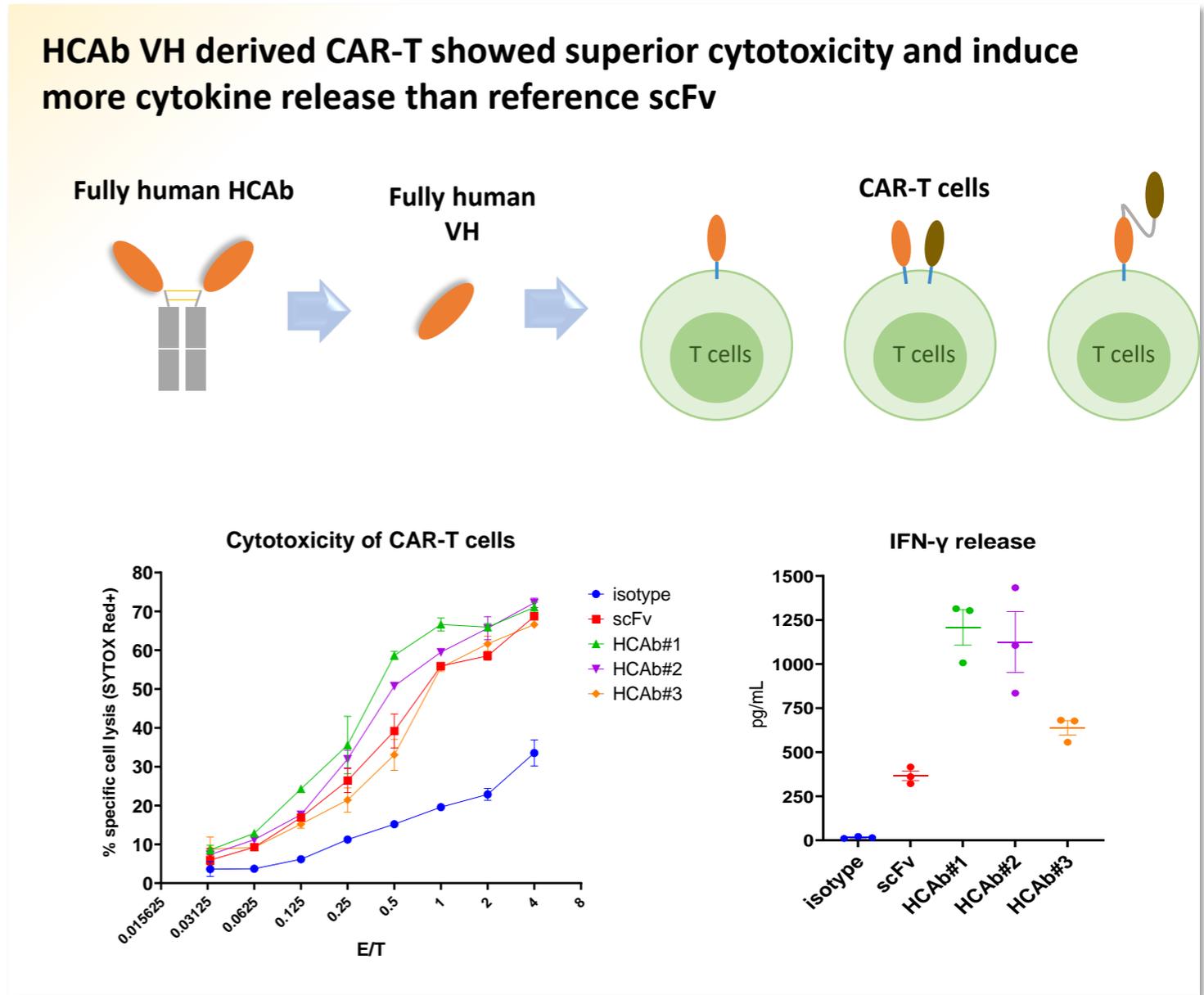
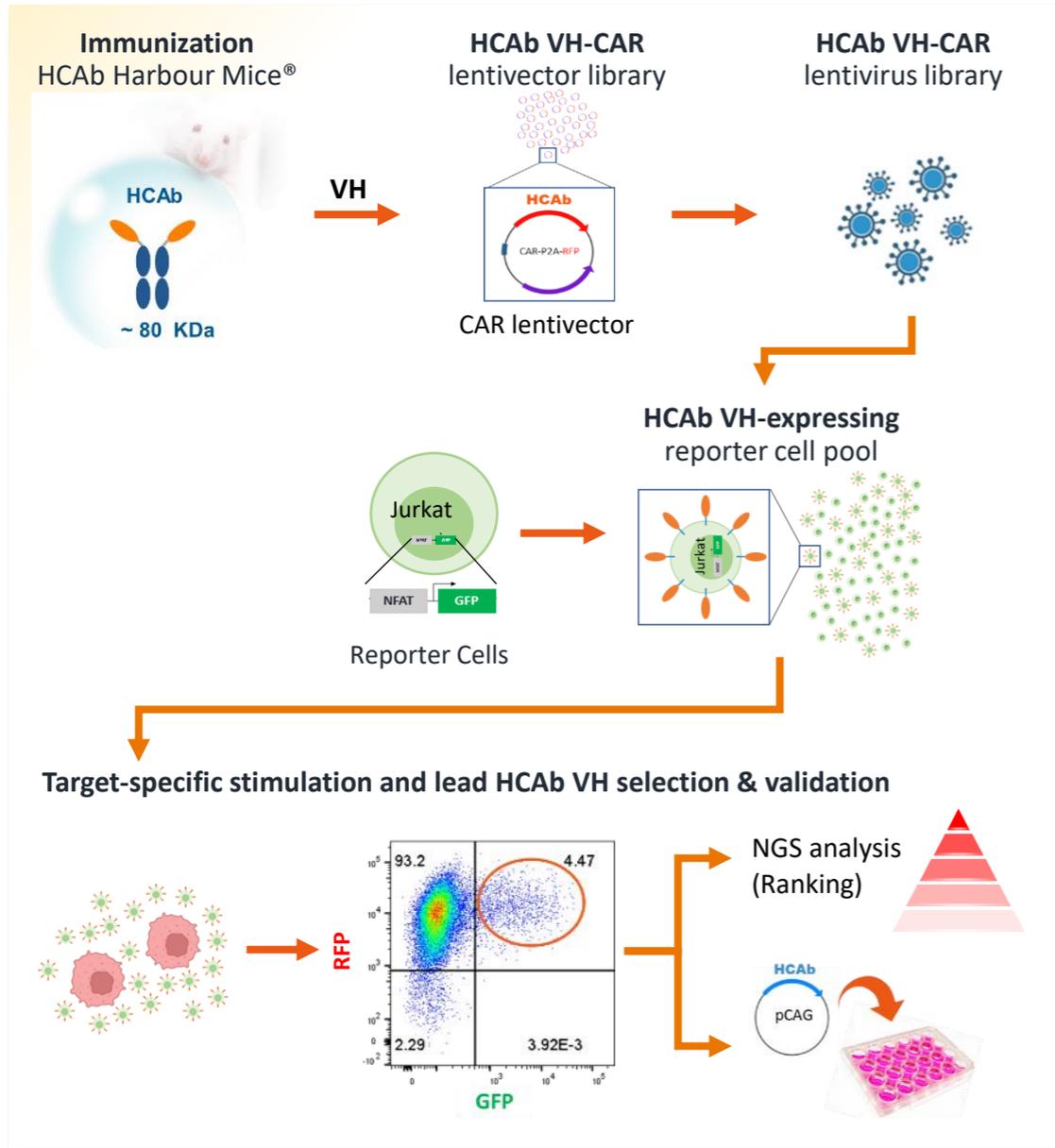


**Longer serum half-life translates to durable cytotoxicity and response**



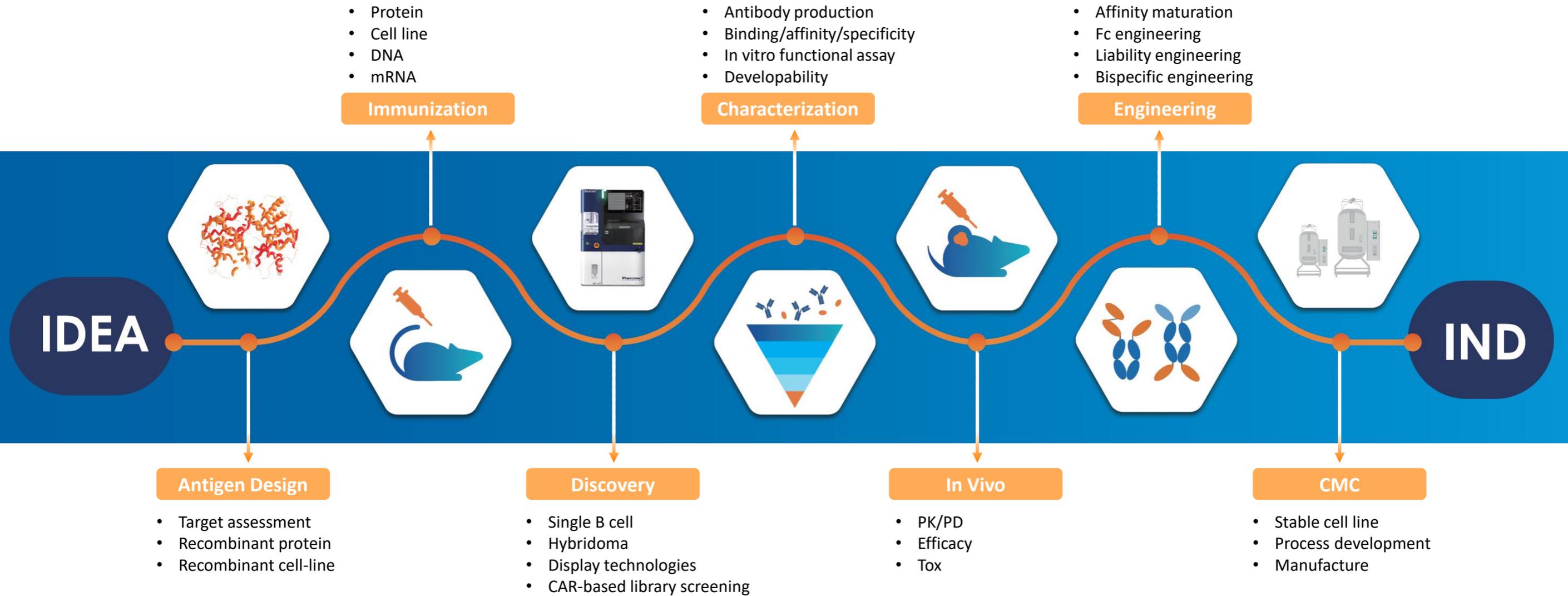
**mRNA-encoded TAAxCD3 engager can elicit excellent therapeutic potential with higher response rate, anti-tumor activity and longer treatment duration**

# HCAb High-efficiency CAR-T Functional Screening Platform Boosts the Innovation of Cell Therapies





# Nona's Technology Platform is Open to the Entire Industry



## Partnerships: Innovative Platform Endorsed by Global Leading Players

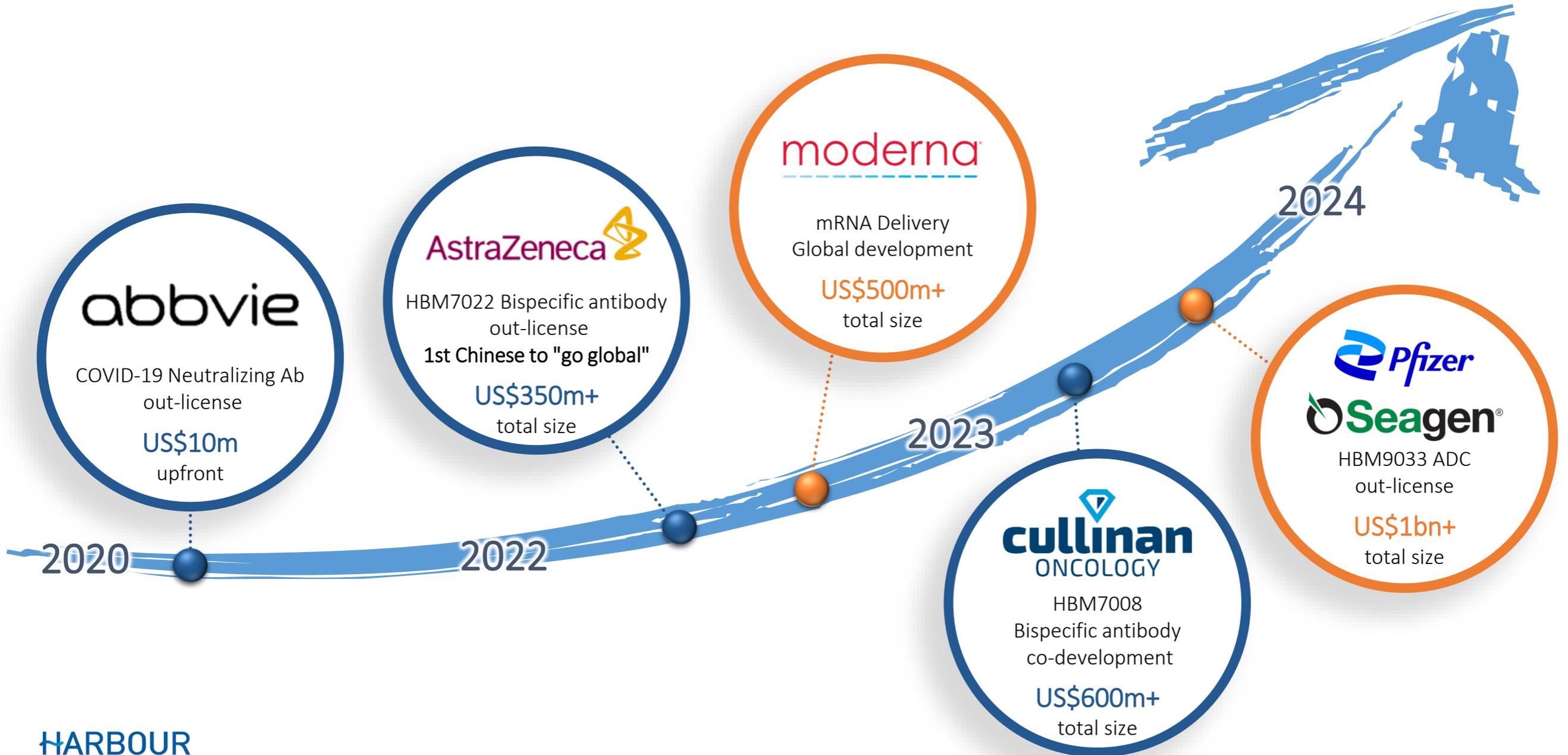
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### Mr. Youchen Chen

VP, Corporate Development and Investor Relations



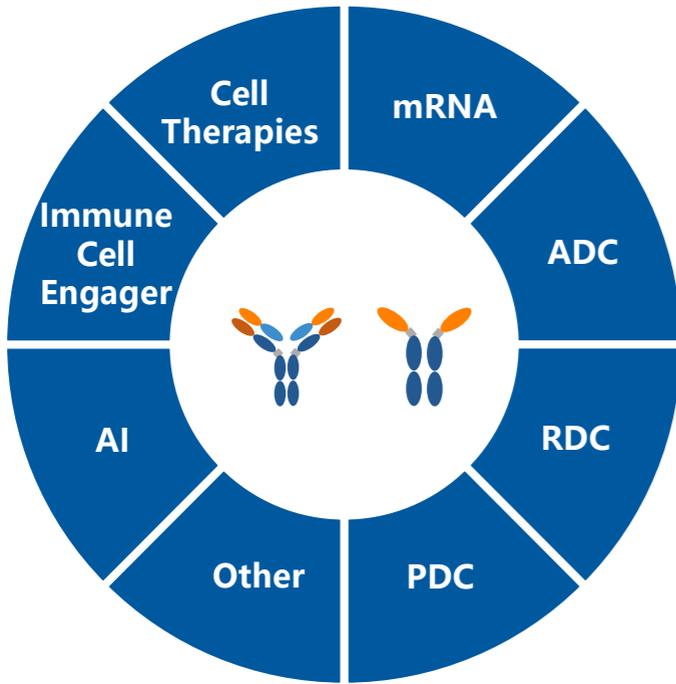
# Continuous Endorsement from Global Leading Pharma as A Strong Validation of Our Technology Platform



# Multimodal and Multidisciplinary Collaborations Extended to Various Top International / Domestic Partners

Collaboration Areas

Types of partners have been increasingly diversified



## Financial Highlights: Sizable Net Profits Achieved for the First Time

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**Ms. Lisa Tong**

Head of Finance



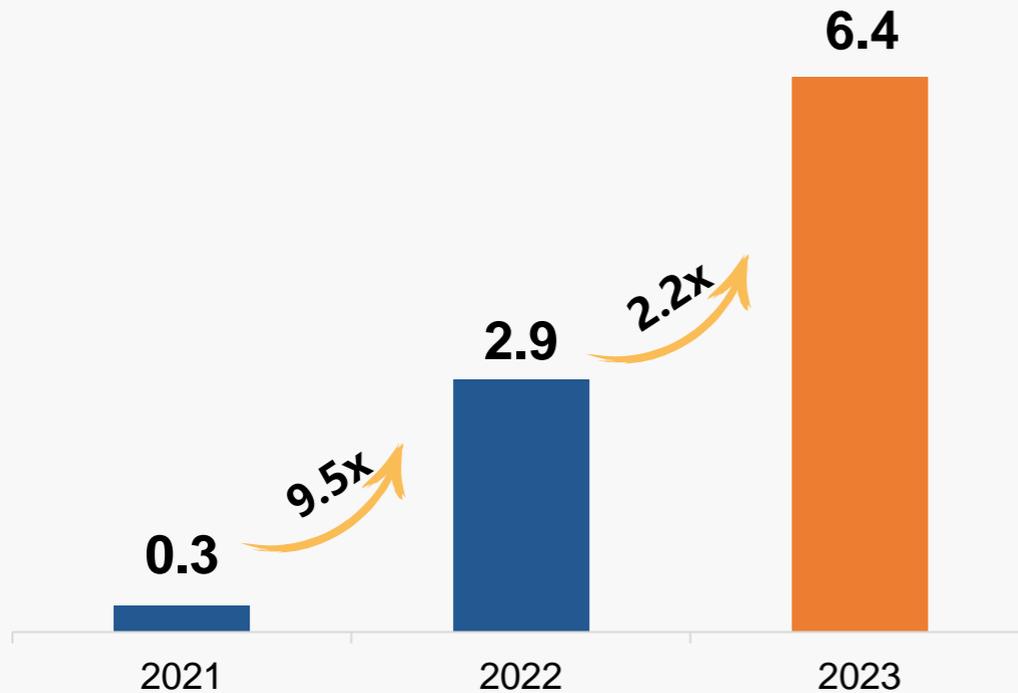


# Sizable and Quality Net Profits Achieved for the First Time

## Continued Strong Revenue Growth Achieved in FY23

- Revenue achieved **Exponential Growth** from **2021 to 2023**
- Increase in 2023 is mainly attributable to licensing business

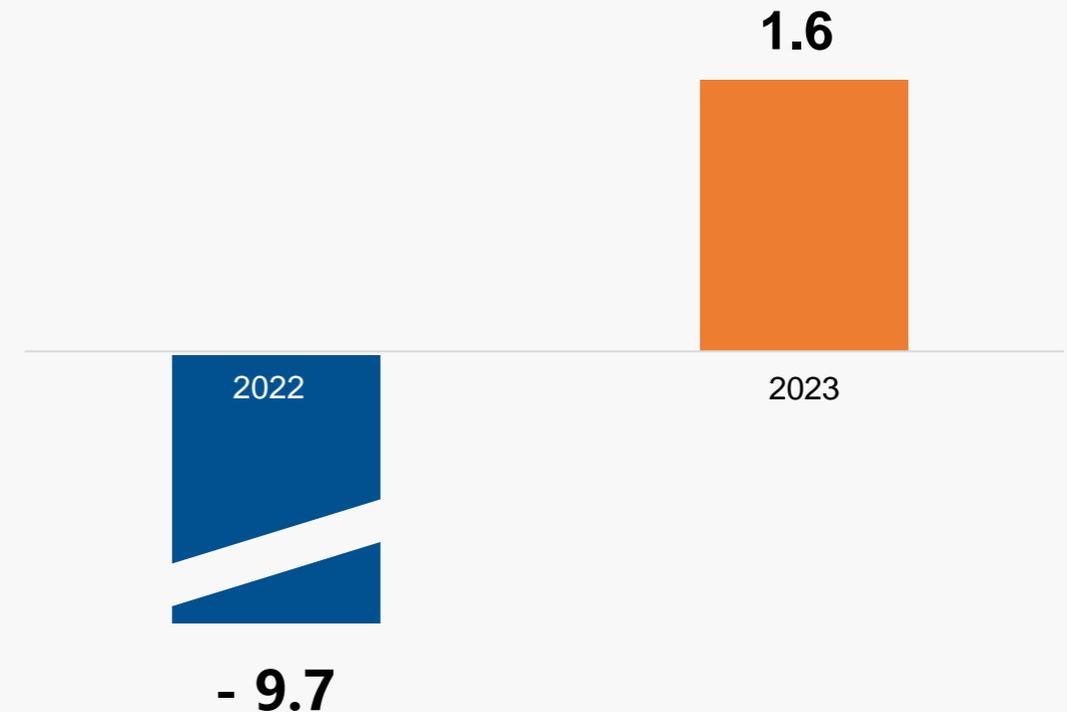
(Unit: RMB Billion )



## Sizable and Quality Net Profits Realized for FY23

- We achieved **Net Profits** on annual basis for the **FIRST** Time in corporate history, 4 years after IPO

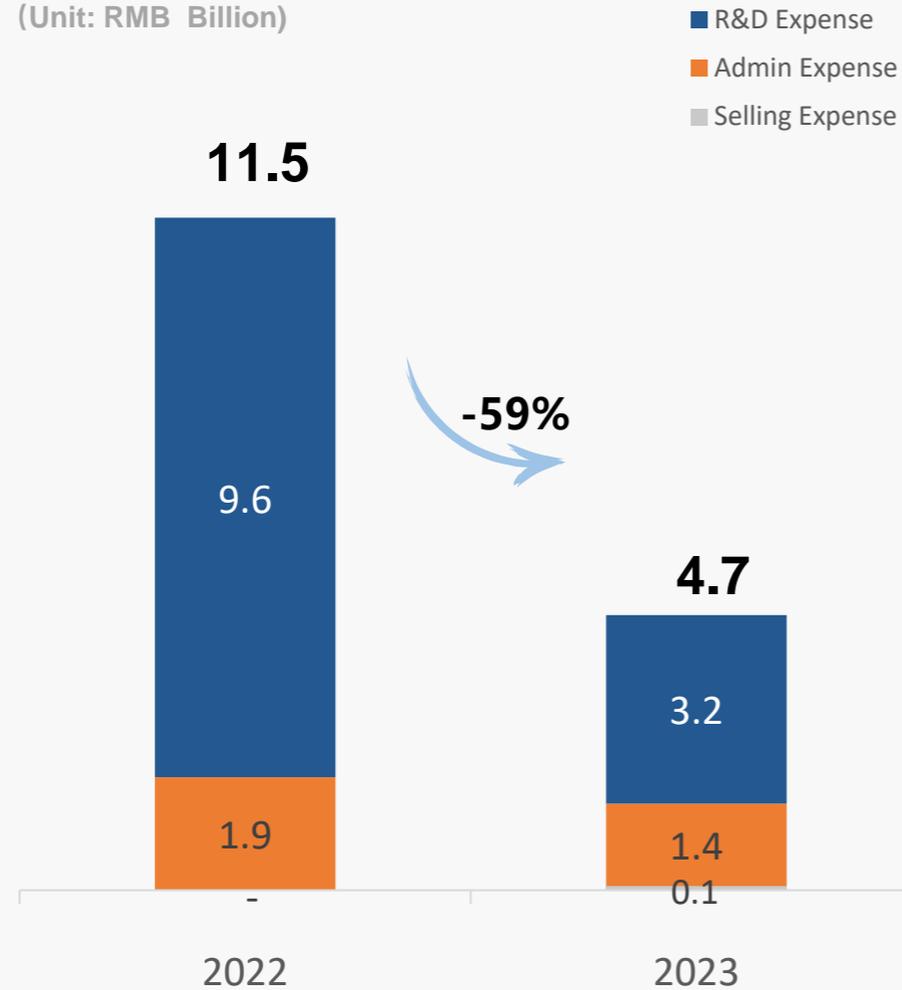
(Unit: RMB Billion )



# Robust Cash Reserve via Efficient Cost Control and Sizable Net Profits Realized in FY23

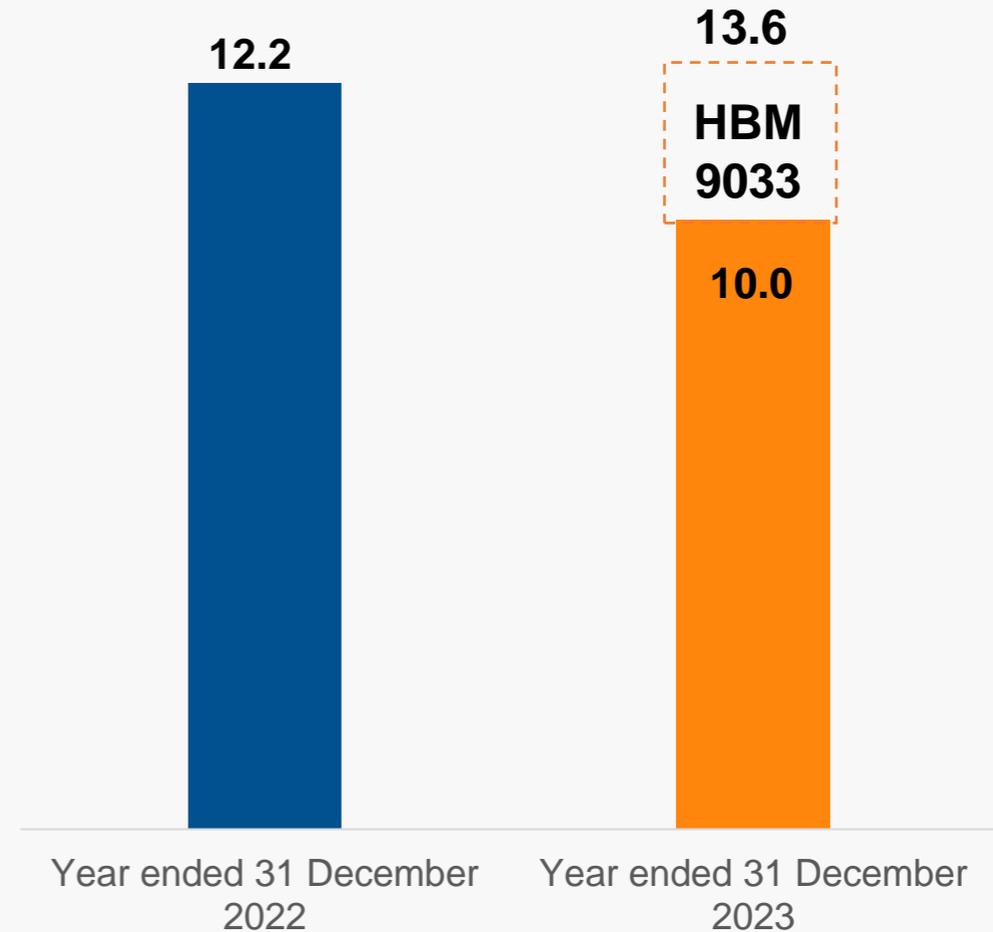
## Significant Cost Saving from Efficient Management

(Unit: RMB Billion)



## Robust Cash Reserve

(Unit: RMB Billion)



## Outlook: Advance Technology Innovation and Focus on Unmet Medical Needs

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### **Dr. Jingsong Wang**

Founder, Chairman of the Board  
and Chief Executive Officer



# FY24 Catalysts and Milestones

## Harbour Therapeutics



- ### Clinical Stage Assets
- ✓ HBM 9161: BLA re-submission 
  - ✓ HBM 4003: initiation of pivotal study, indication expansion 
  - ✓ HBM 1020: initial safety data readout 
  - ✓ HBM 9378: complete readout of Ph I data 

- ### Collaboration Assets <sup>1</sup>
- ✓ HBM 7008: Ph I data readout
  - ✓ HBM 7022: Ph I/II data readout
  - ✓ HBM 9033: initiation of Ph I clinical study

- ### Preclinical Assets
- ✓ 1-2 projects to apply for IND

## Nona Biosciences



- ### Technology Platform
- ✓ Platform upgrade: HCAb+ / mRNA / CAR-T / AI ...
  - ✓ Bispecific / multi-specific antibody
  - ✓ Application expansion to PDC, RDC, etc.

- ### Technology Services
- ✓ Expand service network and territories
    - ✓ West Coast, Central US
    - ✓ EU
    - ✓ APAC ...

- ### Technology Licensing
- ✓ Deepen strategic collaboration with leading biotech/pharma and research institutions at technology and asset level
  - ✓ Milestone payments achieved

# ■ Outlook (FY24 and Beyond): ■ Advance Technology Innovation and Focus on Unmet Medical Needs

HARBOUR  
BIOMED

## Building “HCAb Plus” Ecosystem by Connecting Global Resources

- Multiple **best-in-class** pipelines
- Build antibody pipelines **focusing on tumor immunotherapy** while **diversifying into non-oncology**
- Advance several **first-in-class** innovative drugs to clinical stage
- Become a global leader in **BsAb** while maintaining leading position in mRNA, cell therapy, ADC, etc.
- **Commercialization** through collaborations with partners

Technology  
Validation

Innovation



## Empowering Global Biotech Ecosystem Through Innovation

- Harbour Mice® continue to disrupt monopoly from overseas innovation
- Explore new modalities including **PDC, RDC, AI**, etc.
- Build **“Nona Innovative Network”** to bridge technology platform with global healthcare resources
- Deepen platform-based strategic collaboration with top MNCs
- Create a multifaceted **ecosystem bridging top-tier industry and academic resources**



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# Q&A

Contact us at:

[IR@harbourbiomed.com](mailto:IR@harbourbiomed.com)

