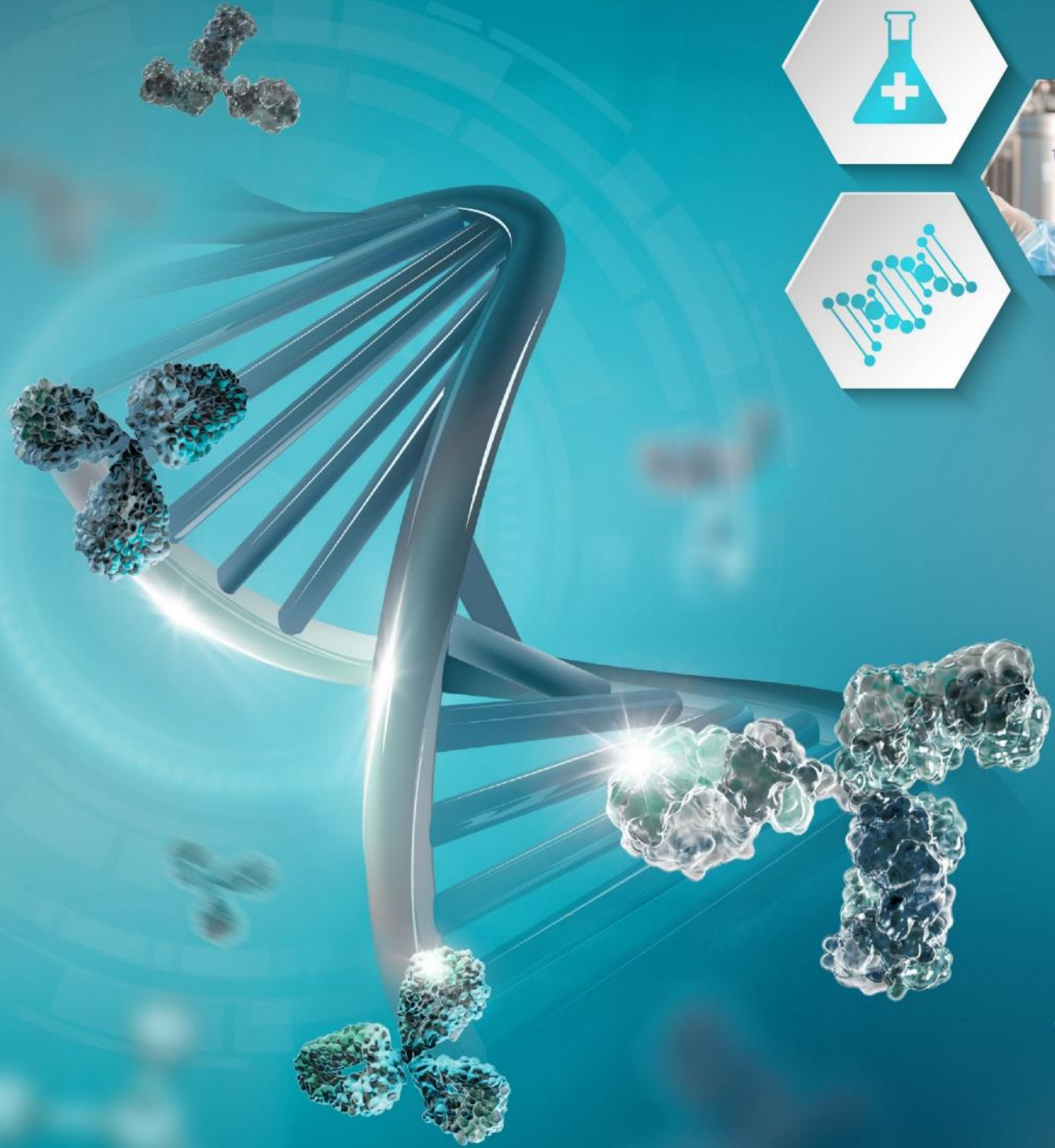




KELUN-BIOTECH
科伦博泰

2025 ANNUAL RESULTS PRESENTATION

2025年度业绩演示材料

MARCH 2026
2026年3月



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Readers are reminded to read and construe this presentation in conjunction with the announcement of the Company dated March 23, 2026 in relation to the annual results of the Company and its subsidiaries for the year ended December 31, 2025.

提醒读者在阅读本演示材料时，应与本公司于2026年3月23日刊发的截至2025年12月31日年度的本公司及其子公司年度业绩公告一并阅读。

THE COMPANY'S PIPELINE MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND/OR COMMERCIALIZED. THE COMPANY'S SHAREHOLDERS AND POTENTIAL INVESTORS ARE REMINDED TO EXERCISE CAUTION WHEN DEALING IN THE SECURITIES OF THE COMPANY.

公司的在研产品可能最终无法成功开发和/或商业化。本公司股东及潜在投资者在买卖本公司证券时应谨慎。

Today's Agenda

今日议程

01

Business Overview & Highlights 业务概览及亮点

02

Commercialization 商业化

03

Pipeline Review 产品管线介绍

04

Financial Performance 财务业绩

01 | Business Overview & Highlights

业务概览及亮点



Who We are 总览

A biopharmaceutical company committed to the R&D, manufacturing and commercialization of novel drugs in oncology, immunology, metabolism and other therapeutic areas

一家致力于肿瘤学、免疫学、代谢和其他治疗领域新药的研发、制造和商业化的生物制药公司



The largest shareholder
控股股东



KELUN-BIOTECH

科伦博泰

(6990.HK)



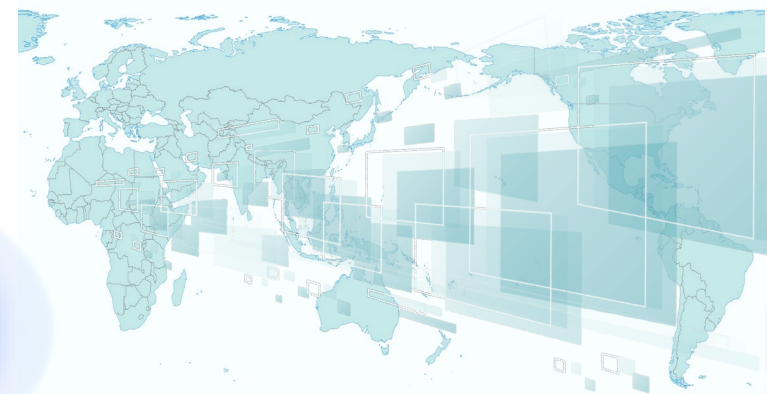
Biologics
Platform
大分子平台



DC Platform
“OptiDC™”
偶联药物平台
“OptiDC™”



Small Molecule
Platform
小分子平台



The second largest shareholder
and major collaborator
第二大股东及主要合作方



- **One of the first movers** in the development of antibody drug conjugates (ADCs), with over **a decade** of accumulated experience in ADC development
开发抗体偶联药物(ADC)的先行者之一，已积累十余年ADC研发经验
- The **first China-based company** that has established ADC collaboration with a top-ten biopharmaceutical MNC
首家与前十大生物制药跨国公司建立ADC合作的中国公司



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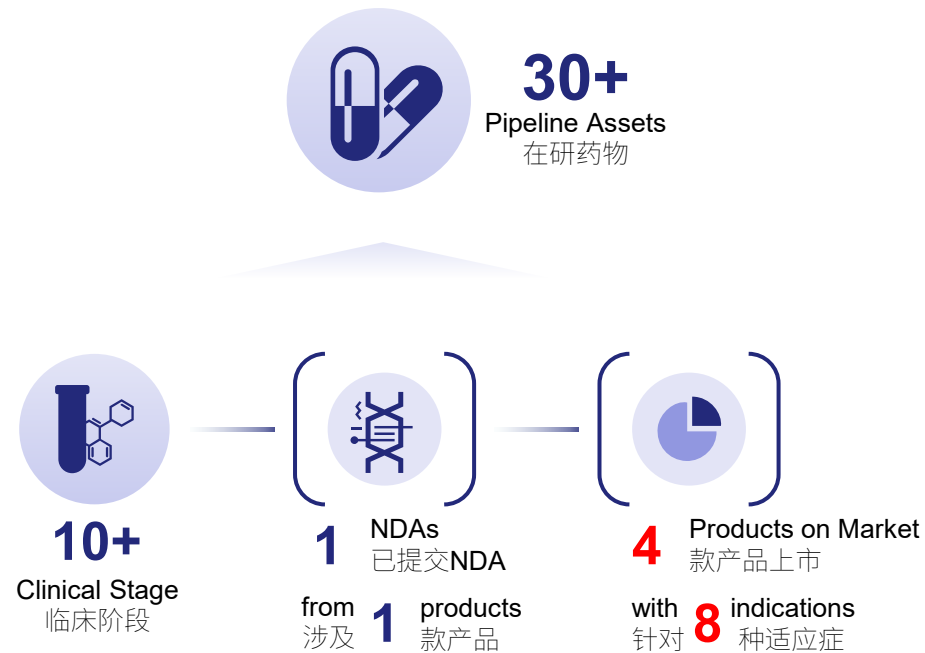
Kelun-Biotech at a Glance

科伦博泰公司概况



KELUN-BIOTECH
科伦博泰

An Integrated and Innovative Biopharmaceutical Company of Novel Drugs for the World
一家面向全球的综合创新生物医药公司



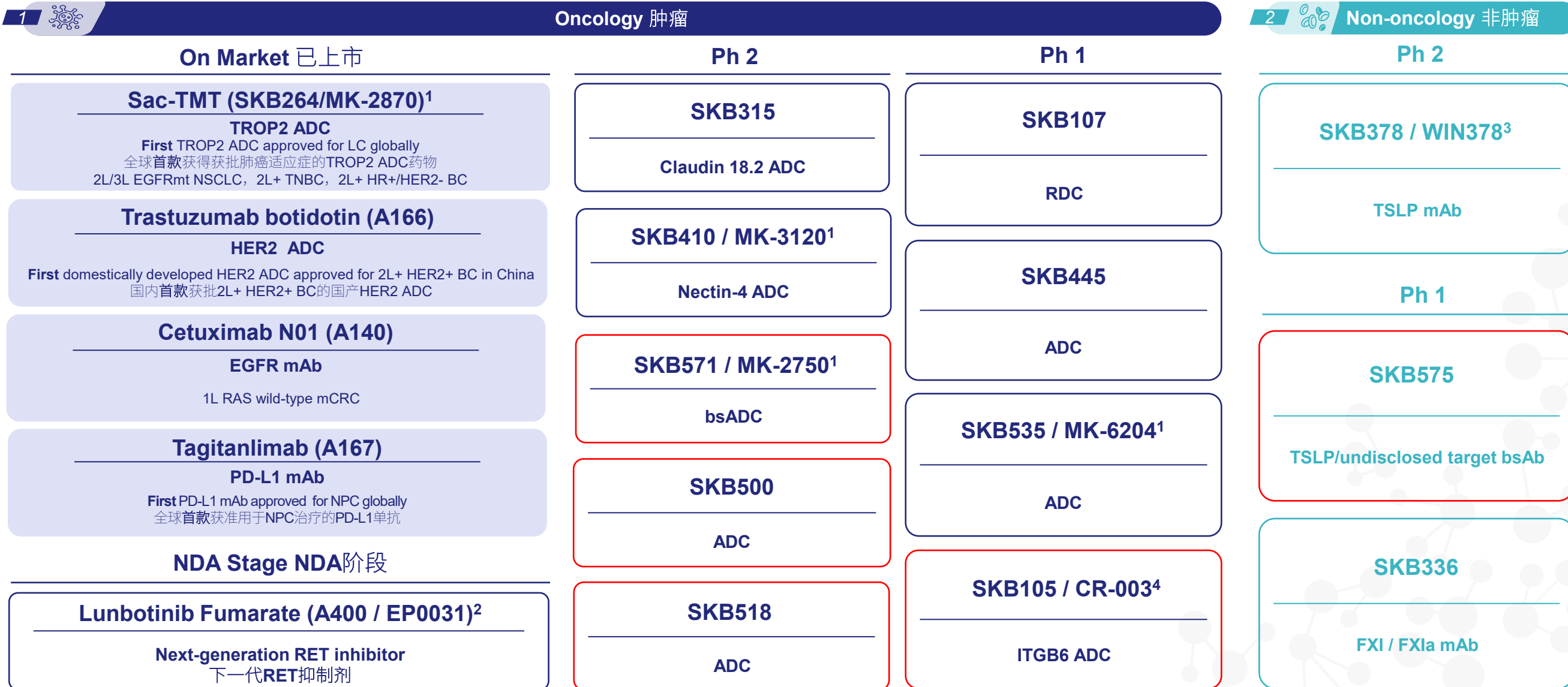
Note: ¹ As of December 31, 2025. 注: ¹ 截至2025年12月31日。



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Pipeline Overview

产品管线概览



Note: ¹ Licensing collaboration with MSD; ² Licensing collaboration with Ellipses Pharma; ³ Licensing collaboration with Windward Bio; ⁴ Collaboration with Crescent Biopharma. 注: ¹ 同默沙东的许可合作; ² 同Ellipses的许可合作; ³ 同Windward Bio的许可合作; ⁴ 同Crescent Biopharma的合作。

Cross-border Collaboration and Strategic Partners

跨境合作及战略伙伴



- Lunbotinib Fumarate (A400/EP0031) (Global rights out-licensed excluding Greater China, North Korea, South Korea, Singapore, Malaysia and Thailand 授出大中华区、朝鲜、韩国、新加坡、马来西亚和泰国以外的权利)
 - Global Ph 2 EP0031-101 trial for NSCLC 用于NSCLC的全球2期EP0031-101试验



- SKB378/WIN378 (Global rights out-licensed except for Greater China and parts of Southeast and West Asia 授出除大中华区及部分东南亚和西亚国家以外的权利)
 - Global Ph 2 POLARIS trial for asthma 用于哮喘的全球2期 POLARIS 试验



- SKB105/CR-003 (ex-Greater China rights out-licensed 授出大中华区以外的权利)
- SKB118/CR-001 (Greater China rights in-licensed 引进大中华区权利)
 - Global ASCEND Ph 1/2 trial for advanced solid tumor: first patient dosed 用于晚期实体瘤的全球ASCEND 1/2期试验：完成首例患者给药

Sac-TMT (SKB264/MK-2870) and Other ADC Assets



Sac-TMT (SKB264/MK-2870)¹

- MSD is evaluating sac-TMT as a monotherapy or with pembrolizumab (KEYTRUDA®)³ or other agents for several types of cancer across **17 global Phase 3 clinical studies**. 默沙东已布局**17项**以sac-TMT作为单药疗法或联合帕博利珠单抗(KEYTRUDA®)³或其他药物用于多种类型癌症的**全球3期临床试验**。
- Following are the tumor types where sac-TMT is currently being studied as part of the Phase 3 MSD-led program 以下为目前正在进行的sac-TMT研究（作为由默沙东主导的3期临床试验项目的一部分）的肿瘤类型：

Other ADC Assets 其他ADC资产²

- We are also collaborating with MSD on certain ADC assets to continuously explore favorable ADC pipeline portfolios:
我们亦正与默沙东就特定ADC资产展开合作，不断探索最优产品组合：



Note: ¹ The Company licensed the exclusive rights to MSD to develop, use, manufacture and commercialize sac-TMT in all territories outside of Greater China (Includes Mainland China, Hong Kong, Macau, and Taiwan); ² Granted MSD exclusive global licenses to research, develop, manufacture and commercialize multiple ADC assets and exclusive options to obtain additional licenses to certain other ADC assets. We retain the right to research, develop, manufacture and commercialize certain licensed and option ADCs for mainland China, Hong Kong and Macau; ³ KEYTRUDA® (Pembrolizumab) is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

注: ¹ 我们已向默沙东授予在大中华区（包括中国内地、香港、澳门、台湾）以外开发、使用、制造及商业化sac-TMT的独家许可; ² 我们已授予默沙东全球独家许可，以研究、开发、制造和商业化多项ADC资产，并向其授予独家选择权，以获得对若干ADC资产的额外许可。我们尚保留若干已许可及授予选择权的ADC在中国内地、香港及澳门研究、开发、制造和商业化的权利; ³ 可瑞达®(帕博利珠单抗) 是美国新泽西州罗威市默克公司的附属公司Merck Sharp & Dohme LLC 的注册商标。



2025 and 2026 YTD Achievements

2025年及2026年至今取得的成就



Pipeline Development 管线进展

On market 已上市

- **Sac-TMT (SKB264/MK-2870)**
 - 2L/3L EGFRmt NSCLC, 2L+ HR+/HER2- BC on Market 已上市
 - Multiple pivotal trials initiated 启动多项关键临床试验:
 - ◆ In China: 1L HR+/HER2- BC 于中国: 1L HR+/HER2- BC
 - ◆ Globally: 7 evaluated for CC, OC, EC, UC, TNBC and HR-low positive/HER2-negative BC 全球: 已布局7项(用于治疗CC、OC、EC、UC、TNBC及HR低阳性/HER2阴性BC)
 - Granted 2 BTDs for 1L NSCLC w/o actionable genomic alterations & 1L PD-L1+ NSCLC from NMPA 获得国家药监局授予两项突破性疗法认定, 用于1L治疗驱动基因阴性NSCLC及一线治疗PD-L1阳性NSCLC
- **Trastuzumab Botidotin (A166)**: 2L+ HER2+ BC on market 已上市
- **Tagitanlimab (A167)**: 1L NPC on market 已上市
- **Cetuximab N01 (A140)**: 1L RASwt mCRC¹ on market 已上市

NDA Stage NDA阶段

- **Lunbotinib Fumarate (A400)**: NDA accepted in 1L+ RET+ NSCLC 用于治疗1L+ RET+ NSCLC的NDA已受理

Ph 2

- **SKB571/SKB518/SKB500**: Ph 2 trials in China initiated 已启动在中国的2期试验
- **SKB378**: Global Ph 2 POLARIS trial for asthma initiated 已启动用于治疗哮喘的全球2期POLARIS试验

Ph 1

- **SKB107**: Ph 1 studies in China initiated 已启动在中国的1期试验
- **SKB535/SKB445/SKB105**: Ph 1 studies in China initiated 已启动在中国的1期试验
- **SKB575**: IND for atopic dermatitis approved 用于治疗特应性皮炎的IND申请已获批
- **SKB118**: first patient dosed of the global ASCEND Ph 1/2 trial for advanced solid tumors 用于治疗晚期实体瘤的全球1/2期ASCEND试验已完成首例患者给药



Commercialization 商业化

- **Sac-TMT (佳泰莱®)**, **tagitanlimab (科泰莱®)** and **Cetuximab N01 (达泰莱®)**: for the first time successfully included in the **NRDL** 首次成功纳入国家医保药品目录
- **30** provinces, and **300+** cities covered 覆盖30省级, 300+城市
- Established a team of **600+** in marketing, sales, medical affairs, strategic planning, commercial excellence departments, and marketing compliance and KA functions
组建**600+**人团队, 覆盖市场、销售、医学事务、策略规划与卓越运营以及营销合规及KA职能



Manufacturing and Quality management 生产及质量管理

- **Trastuzumab Botidotin (舒泰莱®)**: **First** ADC drug in China approved under a cross-provincial segmented production model 获批成为国内首个采用跨省分段生产模式的ADC药物



Financing 融资 / Capital Market 资本市场

- Completed H-share follow-on (~**USD 250mm**) 完成 H股配售 (~**2.5亿美元**)
- Currently included as a constituent of the MSCI Global Standard Indexes, FTSE Global Equity Index Series and HANG SENG family of indexes 目前已纳入MSCI全球标准指数、富时全球股票指数以及恒生指数系列成分股



Business Development 商务拓展

- **SKB378** global rights out-licensed except for Greater China and parts of Southeast and West Asia
授出**SKB378**除大中华区及部分东南亚和西亚国家以外的权利
- **SKB105** ex-Greater China out-licensed / **SKB118** Greater China in-licensed
授出**SKB105**除大中华区以外权利 / 引进**SKB118**大中华区权利

Note: ¹ Used in combination with FOLFOX or FOLFIRI regimens. 注: ¹ 与FOLFOX或FOLFIRI疗法联合使用。

*: KEYTRUDA® (Pembrolizumab) is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA. *: 可瑞达® (帕博利珠单抗) 是美国新泽西州罗威市默克公司的附属公司Merck Sharp & Dohme LLC 的注册商标。



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Academic Publications in 2025 and 2026 YTD

2025年及2026年至今学术发表

Pivotal Studies 关键研究

OptiTROP-Lung04 (LBA5, Presidential Symposium 重磅主席论坛口头报告)
2L EGFRmt NSCLC



OptiTROP-Lung03 (2026 ELCC: LBA4, Mini Oral session 小型口头报告; 2025 ASCO: #8057, Oral session 口头报告)
3L EGFRmt NSCLC



OptiTROP-Breast02 (LBA23, Proffered Paper 优选口头报告)
2L+ HR+/HER2- BC



OptiTROP-Breast01
2L+ TNBC

naturemedicine

KL166-III-06 (LBA24, Proffered Paper 优选口头报告)
2L+ HER2+ BC



KL167-III-08 (#6004, Oral session 口头报告环节)
1L NPC



Ph 1 / 2 Studies 1 / 2期研究

OptiTROP-Breast05
1L TNBC



OptiTROP-Lung01
1L EGFRwt NSCLC+A167



OptiTROP-Lung03
2L+ uncommon EGFRmt NSCLC



OptiTROP-Lung03 & KL264-I/II-01
w/wo EGFRmt NSCLC

naturemedicine

OptiTROP-Lung03
KRASmt NSCLC



SKB264-II-04
1L PD-L1+ NSCLC



SKB264-II-06
mCRPC



KL264-I/II-01
CC/EC+pembrolizumab*



KL264-I/II-01
Late-line UC



SKB315
GC/GEJC



KL400-I/II-01
RETmt MTC



SKB264-II-06
1L UC+pembrolizumab*



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Our OptiDC™ R&D Strategies

OptiDC™研发策略

Multi-pronged Strategy

多管齐下的策略

Continuous improvement and upgrade based on evolving understanding and Balanced focus on platform and pipeline development

基于理解的不断提升和对平台及管线开发的同等重视而持续改进和升级

1



Oncology 肿瘤

Develop ADCs & novel DCs to Achieve and Go Beyond Chemotherapy Replacement 开发ADC及新型DC以实现对化疗方法的替代和超越

1.1

Replace Chemotherapy 替代化疗



Novel Targets 创新靶点

Discover More
Oncology Targets
发现更多肿瘤靶点

- FIC oncology targets
FIC肿瘤靶点
- Biparatopic antibodies
双表位抗体
- Bispecific antibodies
双特异性抗体
- ...

Payload MoA 载荷作用机制

Expand Chemotherapy
Mechanisms
拓展化疗机制

- New TOPO inhibitors
新拓扑异构酶抑制剂
- New Tubulin inhibitors
新微管蛋白抑制剂
- DNA damage reagents
DNA损伤试剂
- ...

Conjugation 偶联

Site and load specific
conjugation
定点及定量偶联

- Site-specific conjugation
定点偶联
 - Lysine-specific 赖氨酸定点
 - Cysteine-specific 半胱氨酸定点
 - Enzymatic 酶促定点
 - Glycan-specific 糖基定点
- Dual payload conjugation
双向载荷偶联
 - DAR2/4/6/8
- ...

1.2

Go Beyond Chemotherapy 超越化疗



Develop Other Payload
MoAs & Adapted Compound
Structures
开发其他作用机制 &
适配的分子结构

- Radioisotopes 放射性同位素
- Immuno-modulators 免疫调节剂
- Targeted Protein degraders
靶向蛋白降解剂
- Other small molecules 其他小分子
- ...

2



Non-oncology 非肿瘤

Develop ADCs and novel DCs with Non-cytotoxic Payloads to Target Non-oncology Diseases

开发用于治疗非肿瘤疾病、具有非细胞毒性载荷的ADC和新型DC

- Develop ADCs and novel DCs configured with novel, non-cytotoxic payload strategies
开发配置新型非细胞毒性载荷策略的ADC和新型DC



Showcase with Novel DCs
新型DC展示

SKB107, SKB103, SKB565, SKB114, SKB005, etc.

Our ADC+IO Strategies

ADC+IO策略

Combo Therapy 联用疗法

1

ADC + PD-(L)1

- **SKB264 + pembrolizumab* in 1L PD-L1+ NSCLC: Ph 3 study readout 3期试验读出**
 - 1st Ph 3 trial of ADC + ICI globally to achieve its PFS primary endpoint in 1L NSCLC with positive OS trend observed. 全球首个ADC+ ICI在1L治疗NSCLC达到PFS主要终点的3期试验并观察到OS获益趋势
- **Other ongoing studies 其他进行中试验**
 - SKB264 + pembrolizumab Ph 3 studies
 - 🇺🇸 SKB264-III-14: 1L PD-L1- NSCLC
 - 🌐 9 Global trials in LC/BC/EC, etc. ¹
 - Ph 2: SKB315/SKB500 + A167

2

ADC + PD-1/VEGF

- **SKB118 was in-licensed from Crescent Biopharma in 2025, and its IND application was accepted by NMPA early this year.**
2025年自Crescent Biopharma授权引进SKB118, 临床试验申请已获受理
- Target to develop combination therapy of SKB118 with our proprietary ADC portfolio
目标开发SKB118与我们众多专有ADC系列资产的联用

Integration 一体化开发

- **Develop drug candidates with synergetic MoAs within one ADC compound**
在单一ADC化合物中开发具有协同作用机制的药物
- **SKB103:**
 - Bispecific targets with precise targeting and killing of tumor cells & activation of tumor immunity 精准靶向并杀伤肿瘤细胞&激活肿瘤免疫力的双靶点
 - IND application submitted 已提交IND申请
- **SKB565:**
 - Dual payloads with both toxin and immuno-stimulatory 毒素与免疫激动剂双载荷
 - IND application submitted 已提交IND申请
- **Other candidates 其他候选药物**

Note: ¹ These trials are led by MSD. 注: ¹ 该等临床试验由MSD主导。

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Firmwide Strategies and Future Prospects 公司层面整体策略与未来展望

Become a world-class biopharmaceutical company in oncology, immunology and other therapeutic areas

成为在肿瘤学、免疫学和其他治疗领域世界一流水平的生物制药公司



Advancing 推进

Our differentiated pipelines targeting indications with significant medical needs
针对有大量医疗需求的适应症的差异化产品管线



Innovating 创新

Optimized payload-linker strategies / novel DC designs and structures / expanded application to non-oncology
优化的有效载荷连接子策略 / 新型DC设计和结构 / 扩展到非肿瘤领域应用



Enhancing 夯实

Our end-to-end drug development and commercialization capabilities
我们端对端药物开发和商业化能力



Expanding 扩大

Our global footprint through strategic partnerships and improving our capabilities for the development, registration and commercialization of our products in ex-China market
通过战略合作扩大我们全球布局并提升我们在中国以外市场的产品开发、注册以及商业化能力



Optimizing 优化

Our operation system to become a leading global biopharmaceutical company
我们的运营体系，打造成为领先的全球生物制药公司



KELUN-BIOTECH
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02 | Commercialization 商业化



First batch of Commercial Products in China

第一批中国商业化产品



Sac-TMT (SKB264/MK-2870)

2L+ TNBC (Nov. 2024), 3L EGFRmt NSCLC (Mar. 2025), 2L EGFRmt NSCLC (Oct. 2025) and 2L+ HR+/HER2- BC (Feb. 2026) approved for marketing
2L+ TNBC (2024年11月), 3L EGFRmt NSCLC (2025年3月), 2L EGFRmt NSCLC (2025年10月)以及2L+ HR+/HER2- BC (2026年2月)已批准上市



Trastuzumab Botidotin (A166)

2L+ HER2+ BC approved for marketing (Oct. 2025)
2L+ HER2+ BC(2025年10月)已批准上市



Cetuximab N01 (A140)

1L RASwt mCRC approved for marketing (Feb. 2025)
1L RASwt mCRC (2025年2月)已批准上市



Tagitanlimab (A167)

3L+ NPC (Dec. 2024) and 1L NPC (Jan. 2025) approved for marketing
3L+ NPC (2024年12月)及1L NPC (2025年1月)已批准上市

Lunbotinib Fumarate (A400) (RET Inhibitor)
to launch in China market in 2027 1H¹
2027上半年在中国市场推出¹



Decades-long experience, industry connections and extensive network
数十年的经验、行业资源及广泛的网络

 These products for certain indications have been included in the 2025 National Reimbursement DrugList(2025年国家基本医保报销目录)
这些产品的若干适应症已纳入2025国家基本医保报销目录

Note: ¹ Based on the expected approval timeline of each late-stage project in our pipeline, subject to regulatory communications and marketing approval.
注: ¹ 基于我们管线内的每个后期项目的预期批核时间表, 并须经监管部门沟通并获得上市批准。

Marketing

市场营销



District & Hospital Coverage 区域及医院覆盖情况



Provinces, Cities Covered 覆盖省份、城市

- Covers **30** provinces, and **300+** cities 覆盖**30**省级, **300+**城市



Hospitals Covered 覆盖医院

- Number of hospitals covered: **1,200+** 覆盖医院数: **1,200+**



Experts Endorsement 专家认可

- Reached **tens of thousands** of healthcare professionals through various types of marketing campaigns to convey product and medical professional information
通过各类型市场推广活动覆盖**数万人次**医护人员, 传达产品及医学专业信息
- Obtained **authoritative endorsement** for our products from experts in clinical guidelines
获得专家对于我们的产品在临床指南中的**权威认可**
 - Guidelines of CSCO: Breast Cancer 2025 CSCO BC诊疗指南(2025年版)**
 - Guidelines of CSCO: Non-Small Cell Lung Cancer 2025 CSCO NSCLC诊疗指南(2025年版)**
 - Guidelines of CSCO: Nasopharyngeal Carcinoma 2025 CSCO鼻咽癌诊疗指南(2025年版)**
 - CBCS&CSOBO Guidelines for BC Diagnosis and Treatment (2026 Concise ed.) CBCS&CSOBO乳腺癌诊治指南与规范(2026年精要本)**
 - Guidelines for Diagnosis and Treatment of Advanced BC in China (2024 ed.)中国晚期乳腺癌规范诊疗指南(2024版)**
 - Chinese Medical Association Clinical Practice Guidelines for LC (2025 ed.) 中华医学会肺癌临床诊疗指南(2025版)**



Team Support 团队支持

Marketing 营销中心

- Established a fully-fledged marketing team of **over 600** people, with a departmental structure that includes marketing, sales, medical affairs, strategic planning and commercial excellence as well as marketing compliance functions, dedicated to preparing and implementing the marketing and commercialization of our strategic products

已组建了一支人数**超过600人**的成熟运作的营销团队, 部门组织架构包括市场、销售、医学事务、策略规划与卓越运营等多个部门以及营销合规职能, 致力于筹备并实行我们战略产品的营销和商业化

- Currently, among the commercialized products and therapeutic areas, the business team is divided into BC, LC, and other tumors based on indications, and the synergy of the indications of commercialized products are conducive to the implementation of marketing and promotional activities.

目前在已上市的产品和治疗领域中, 业务团队根据适应症情况划分为乳腺癌、肺癌以及其它瘤种领域, 已上市产品的适应症协同有利于营销推广活动开展。

- The commercialization team will continue to expand to capture more market opportunities in the future as more product and indications are launched and are included in the medical insurance

未来随着更多产品和适应症陆续上线以及纳入医保, 商业化团队未来会进行进一步的扩大, 以覆盖更多的市场机会

Distribution and Market Access

商务与市场准入

Market Access 市场准入



National Reimbursement Drug List Inclusion 入选医保目录

Sac-TMT (佳泰莱®) / Tagitanlimab (科泰莱®) / Cetuximab N01 (达泰莱®)
for the first time successfully included in the National Reimbursement Drug List which has
officially taken effect since January 1, 2026
首次成功入选国家基本医保目录，并于2026年1月1日正式实施



Listing Strategy 挂网策略

In 2025, sac- TMT (佳泰莱®), tagitanlimab (科泰莱®) and Cetuximab N01 (达泰莱®) have been
included in **31 provincial networks**, and trastuzumab botidotin (舒泰莱®) has been included in **5
provincial networks**.

2025年，佳泰莱®、科泰莱®和达泰莱®已完成**31个**省挂网，舒泰莱®已完成**5个**省挂网。



Inclusive Insurance 惠民保

To further reduce the burden of patients and implement the concept of **inclusive healthcare**, we
have been proactively facilitating the enrollment of sac-TMT(佳泰莱®) in provincial and prefecture
city level **Inclusive Insurance (惠民保)**, and has been **enrolled in more than 14 provinces and
30 cities**.

为了进一步减轻用药患者的经济负担，积极践行**普惠医疗**理念，我们积极推动sac-TMT（佳泰莱®）
参与省级及地市级“惠民保”计划的投保工作，目前已覆盖超过**14个**省份和**30多个**城市。

Distribution 渠道



Channel Layout 渠道布局

In 2025, our products were promoted through our self-built marketing teams. We've
stabilized relationship with multiple leading business groups, including **60+ first-tier
distributors and 400+ DTP pharmacies**.

2025年，我们的产品通过自建的营销团队进行产品推广。我们已与多家头部商业集团及零售
连锁建立稳定合作关系，其中包含**60+家**一级经销商及**400+家DTP药房**



Training 培训

The company provided nationwide training to **nearly 10,000 pharmacists** in 2025, which
has significantly enhanced the professionalism of terminal services and improved the ability
to provide patients with medication guidance.

公司于2025年累计培训**药剂师近10,000人次**，显著提升了终端服务的专业水平，并增强了为
患者提供用药指导的能力。



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科伦博泰



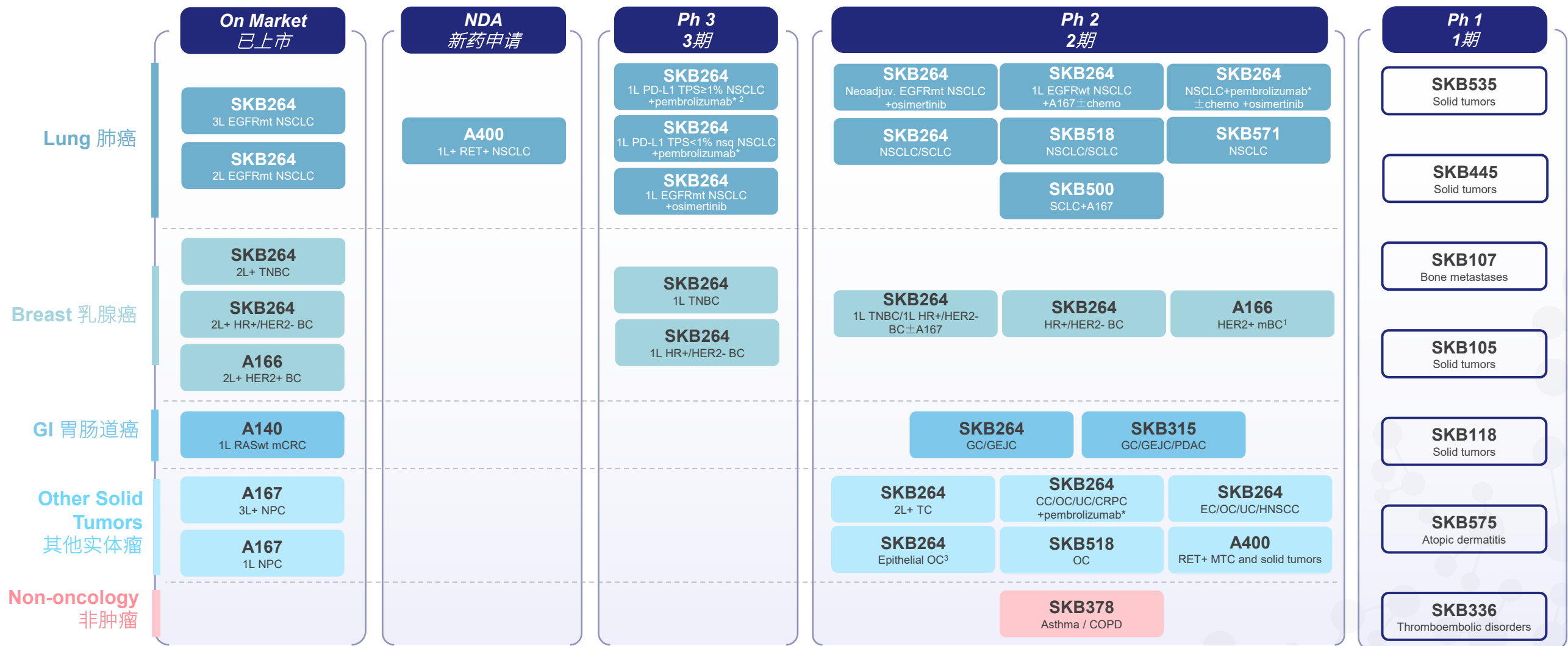
KELUN-BIOTECH
科伦博泰

03 | Pipeline Review 产品管线介绍



Our Clinical Studies

我们的临床试验布局



Note : ¹ Previously treated with ADC with a topoisomerase inhibitor payload; ² Primary endpoint met and communicating with the authority regarding the submission of a sNDA; ³ Including fallopian tube cancer or primary peritoneal cancer

注: ¹ 既往接受过有效载荷为拓扑异构酶抑制剂ADC治疗; ² 已达到主要终点并正与监管机构就提交sNDA进行沟通; ³ 包括输卵管癌或原发性腹膜癌。

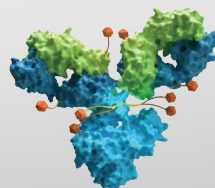
*: KEYTRUDA® (Pembrolizumab) is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA. *: 可瑞达® (帕博利珠单抗) 是美国新泽西州罗威市默克公司的附属公司Merck Sharp & Dohme LLC 的注册商标。



KELUN-BIOTECH
科伦博泰

Sac-TMT (SKB264/MK-2870)

Development Plan 临床开发计划



Antibody 抗体	TROP2 mAb (Sacituzumab) - High antigen affinity and targeting effect TROP2单抗(Sacituzumab) - 高抗原亲和力及靶向效应
Linker 连接子	Unique bifunctional linker - maximizes payload delivery to tumor cells 独有的双重机制连接子- 最大化有效载荷传递至肿瘤细胞
Payload 有效载荷	Novel TOPO1 inhibitor (belotecan derivative) with moderate cytotoxicity 中等毒性新型TOPO1抑制剂 (贝洛替康衍生物)
Conjugate 偶联	Cysteine conjugation半胱氨酸偶联
DAR	7.4

Sponsored by Kelun-Biotech科伦博泰申办



Status 状态	Indication 适应症
Approval 已获批	2L+ TNBC ¹ 2L EGFRmt NSCLC 3L EGFRmt NSCLC 2L+ HR+/HER2- BC
Phase 3 3期	1L HR+/HER2- BC 1L TNBC ² 1L EGFRmt NSCLC+osimertinib 1L PD-L1 TPS<1% nsq NSCLC+pembrolizumab* 1L PD-L1 TPS≥1% NSCLC+pembrolizumab* ³
Phase 2 2期	Neoadjuv. EGFRmt NSCLC+Osimertinib

Sponsored by MSD MSD申办



17 Global Phase 3 Clinical Studies 17 项全球3期临床研究

- 4 studies in BC, including:
 - 3 in triple negative breast cancer
 - 1 in HR+/HER2- BC
- 5 studies in LC, including:
 - 3 in wild-type NSCLC
 - 2 in EGFRm NSCLC
- 1 study in GI cancer, including:
 - Advanced/metastatic gastroesophageal adenocarcinoma
- 6 studies in gynecological cancers, including:
 - 2 in endometrial cancer
 - 2 in cervical cancer
 - 2 in ovarian cancer
- 1 study in GU cancer, including:
 - Metastatic UC

Multiple Tumors 多种实体瘤
Global collaboration with MSD
与默沙东全球范围内合作



We are also collaborating with MSD on several global Phase 2 basket studies for sac-TMT as monotherapy or in combination with other agents for multiple solid tumors and those studies are ongoing.
我们亦与默沙东合作开展多项sac-TMT作为单药治疗或联合其他药物治疗多种实体瘤的全球2期篮子研究，且该等研究正在进行中。

Note: ¹ Used in adult patients with unresectable locally advanced or metastatic TNBC who have received at least two prior systemic therapies (at least one of them for advanced or metastatic setting); ² including participants whose tumor are PD-L1 negative, or PD-L1 positive and have relapsed after prior anti-PD-(L)1 inhibitor in early stage disease; ³ Primary endpoint met and communicating with the authority regarding the submission of a sNDA.

注: ¹ 用于既往至少接受过2种系统治疗(其中至少1种治疗针对晚期或转移性阶段)的不可切除的局部晚期或转移性TNBC成人患者; ² 包括PD-L1阴性或PD-L1阳性且既往早期阶段接受过抗PD-(L)1抑制剂治疗后复发的受试者; ³ 已达到主要终点并正与监管机构就提交sNDA进行沟通。

KEYTRUDA® (Pembrolizumab) is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA. *.可瑞达®(帕博利珠单抗)是美国新泽西州罗威市默克公司的附属公司Merck Sharp & Dohme LLC的注册商标。

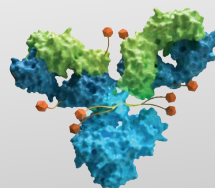


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Sac-TMT (SKB264/MK-2870)

Data Readout with China-based Pivotal Studies

中国关键临床研究的数据读出



Antibody 抗体

TROP2 mAb (Sacituzumab) - High antigen affinity and targeting effect
TROP2单抗(Sacituzumab) - 高抗原亲和力及靶向效应

Linker 连接子

Unique bifunctional linker - maximizes payload delivery to tumor cells
独有的双重机制连接子 - 最大化有效载荷传递至肿瘤细胞

Payload 有效载荷

Novel TOPO1 inhibitor (belotecan derivative) with moderate cytotoxicity
中等毒性新型TOPO1抑制剂 (贝洛替康衍生物)

Conjugate 偶联

Cysteine conjugation 半胱氨酸偶联

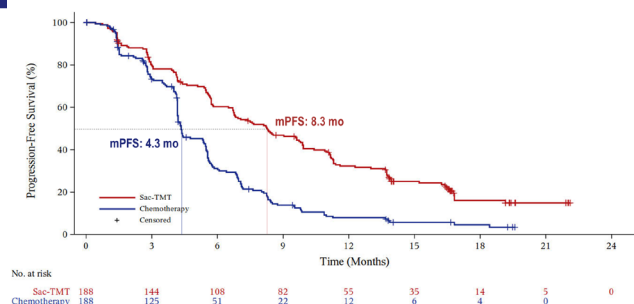
DAR

7.4

2L EGFRmt NSCLC

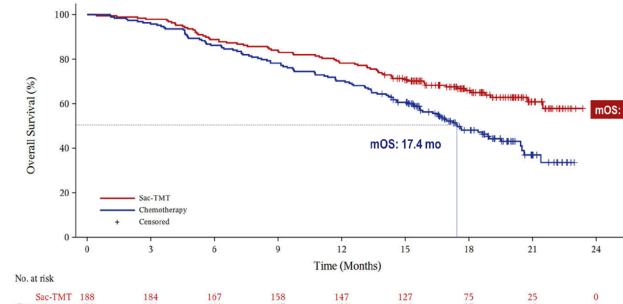
Sac-TMT vs platinum-based chemo in patients who progressed on EGFR-TKIs

PFS HR: 0.49 (95% CI: 0.39 - 0.62)



Data cutoff: July 06, 2025 数据截止时间: 2025年7月6日

OS HR: 0.60 (95% CI: 0.44 - 0.82)

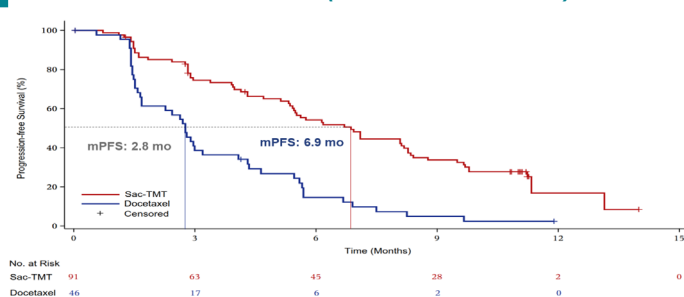


Source来源: ESMO 2025

3L EGFRmt NSCLC

Sac-TMT vs docetaxel in patients who progressed on EGFR-TKIs and platinum-based chemo

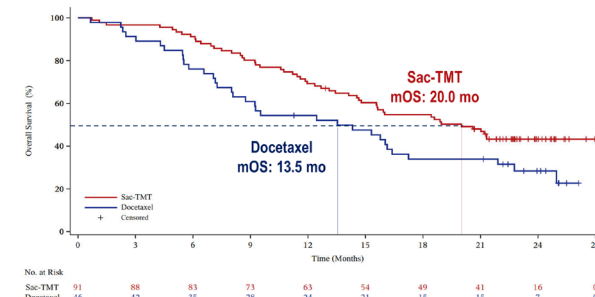
PFS HR: 0.30 (95% CI: 0.20 - 0.46)



Data cutoff: Dec 31, 2024
数据截止时间: 2024年12月31日

Source来源: ASCO 2025

OS HR: 0.63 (95% CI: 0.40 - 0.98)



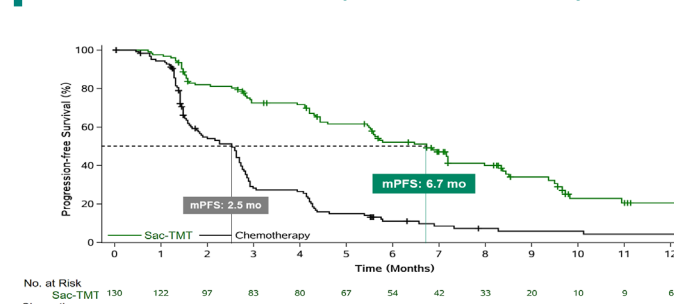
Data cutoff: Dec 11, 2025
数据截止时间: 2025年12月11日

Source来源: ELCC 2026

2L+ TNBC

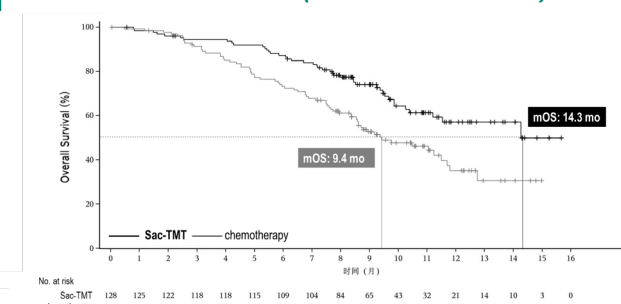
Sac-TMT vs ICC in patients with previously treated LR/M TNBC

PFS HR: 0.32 (95% CI: 0.24 - 0.44)



Data cutoff: Nov 30, 2023 数据截止时间: 2023年11月30日

OS HR: 0.53 (95% CI: 0.36 - 0.78)

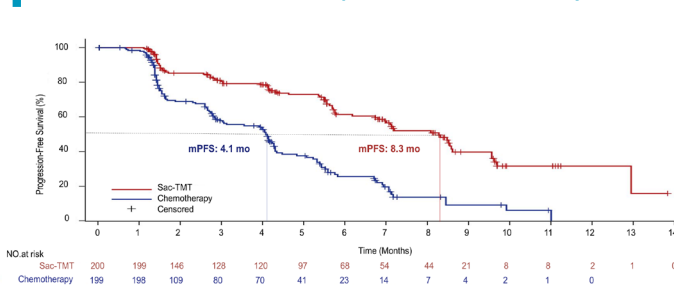


Source来源: ASCO 2024 & Label

2L+ HR+/HER2- BC

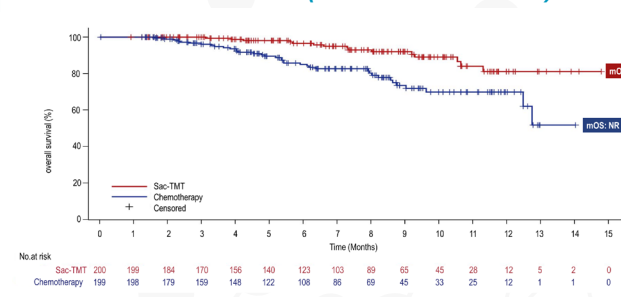
Sac-TMT vs ICC in patients with previously treated LA/M HR+/HER2- BC

PFS HR: 0.35 (95% CI: 0.26 - 0.48)



Data cutoff: Jan 22, 2025 数据截止时间: 2025年1月22日

OS HR: 0.33 (95% CI: 0.18 - 0.61)

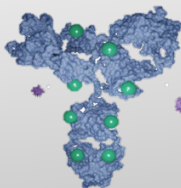


Source来源: ESMO 2025

Sac-TMT demonstrated a manageable safety profile, with no unexpected safety signals identified
Sac-TMT展示出可管理的安全性, 未发现非预期的安全性信号

Trastuzumab Botidotin (A166)

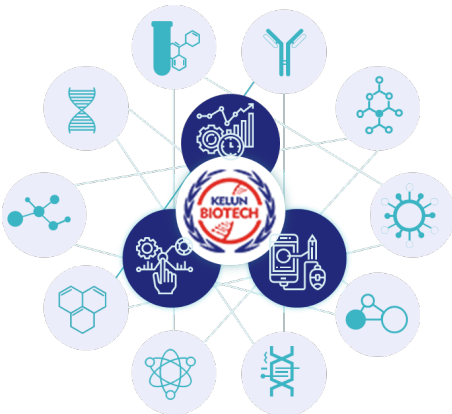
The First Domestically Developed HER2 ADC Approved for 2L+ HER2+ BC 国内首款获批 2L+ HER2+ BC的国产HER2 ADC



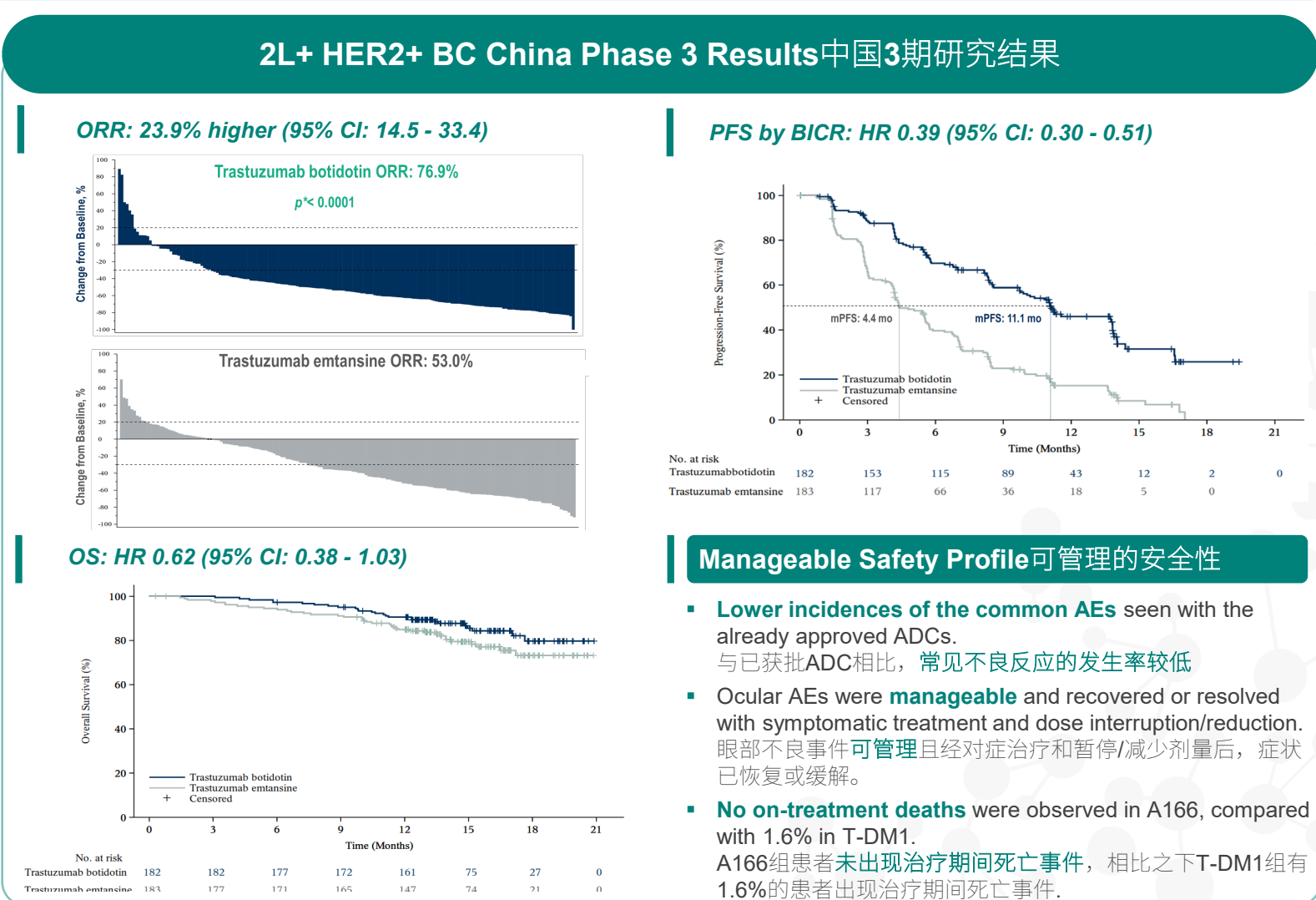
Antibody 抗体	The same amino acid sequence as Herceptin (trastuzumab) 与赫赛汀（曲妥珠单抗）的氨基酸序列相同
Linker 连接子	Val-Cit linker – an enzyme (Cathepsin B) cleavable linker Val-Cit连接子 – 酶（组织蛋白酶B）可裂解连接子
Payload 有效载荷	Duostatin-5, MMAF derivative - Novel and highly cytotoxic tubulin inhibitor Duostatin-5, MMAF衍生物 – 新型高细胞毒性微管蛋白抑制剂
Conjugate 偶联	Site-specific conjugation technology for a homogeneous DAR 均匀DAR定点偶联技术
DAR	2

Key Developments主要研究

Status 状态	Indication 适应症
Approved 已获批	2L+ HER2+ BC
Phase 2 2期	HER2+ BC previously received a topoisomerase inhibitor payload ADC 既往接受过有效载荷为拓扑异构酶抑制剂ADC治疗的HER2+ BC



Data Readout 数据读出



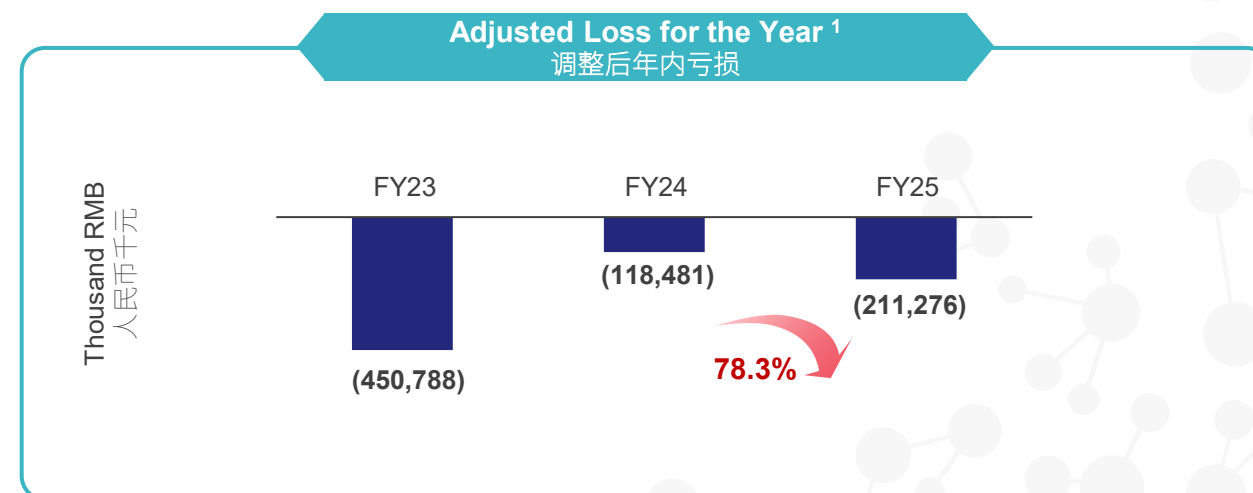
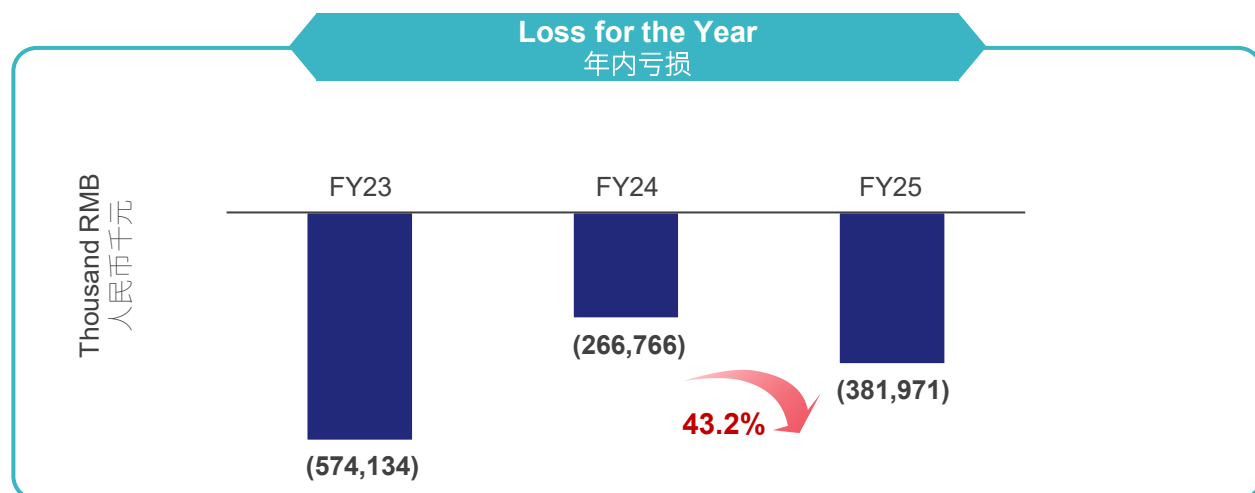
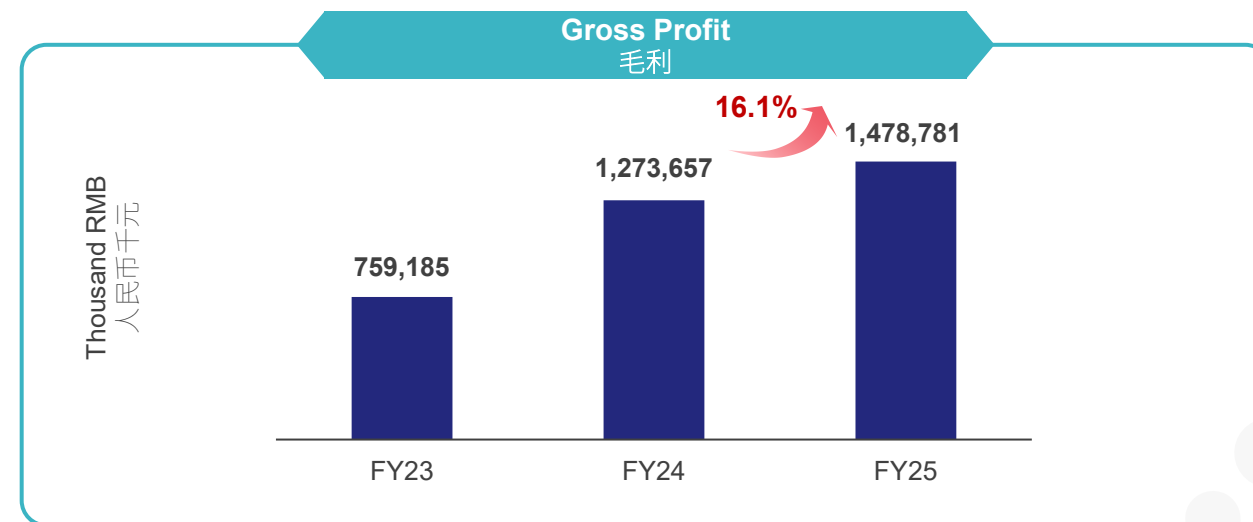
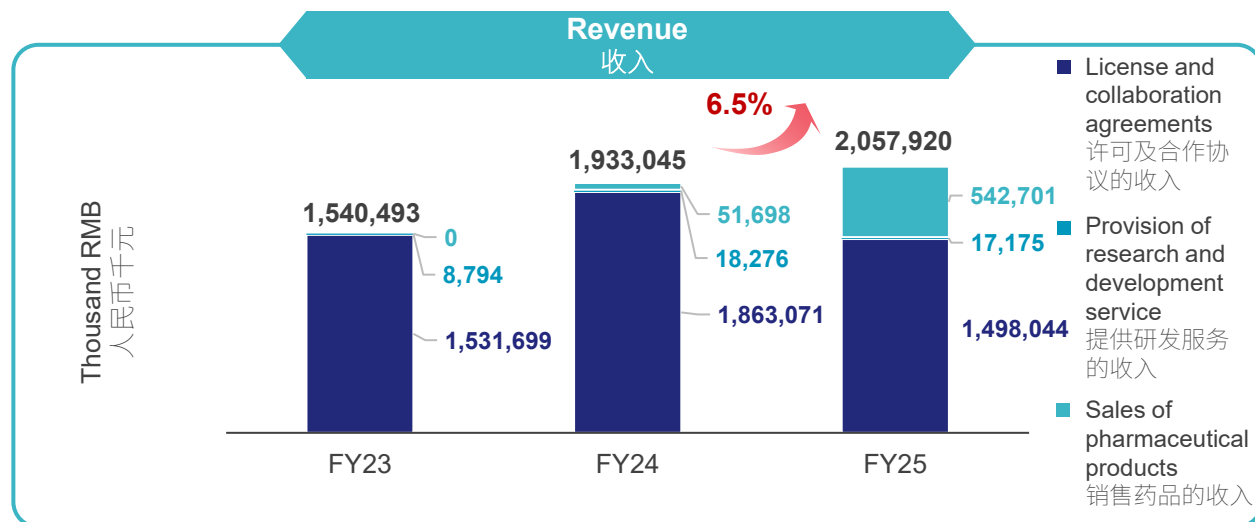
Data cutoff: April 26, 2025 数据截止时间: 2025年4月26日

04 | Financial Performance 财务业绩



Revenue and Margins

收入及利润

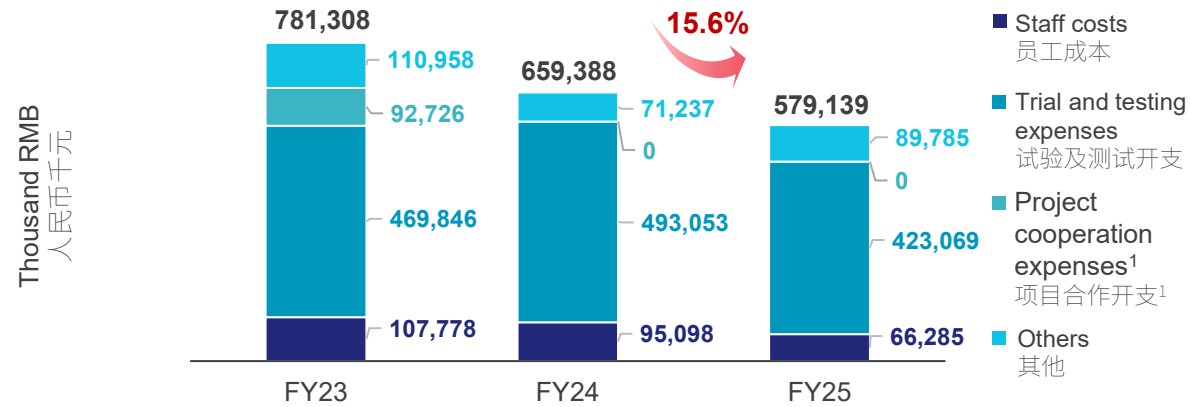


Source: Earnings announcement 资料来源: 业绩公告

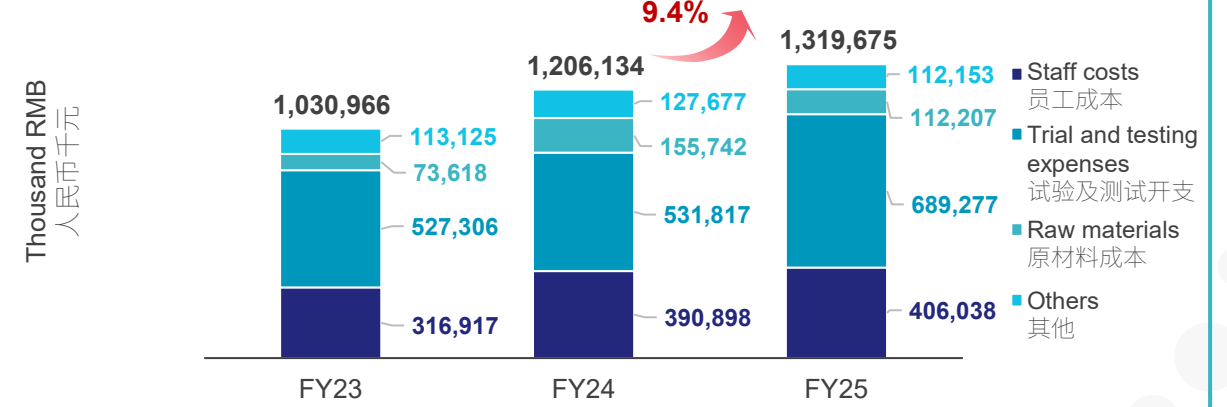
Note: ¹ Calculated by deducting equity-settled shared-based payment from loss for the year. 注: ¹ 计算方法为年内亏损扣除以股权结算的股份支付。

Costs and Expenses 成本和费用

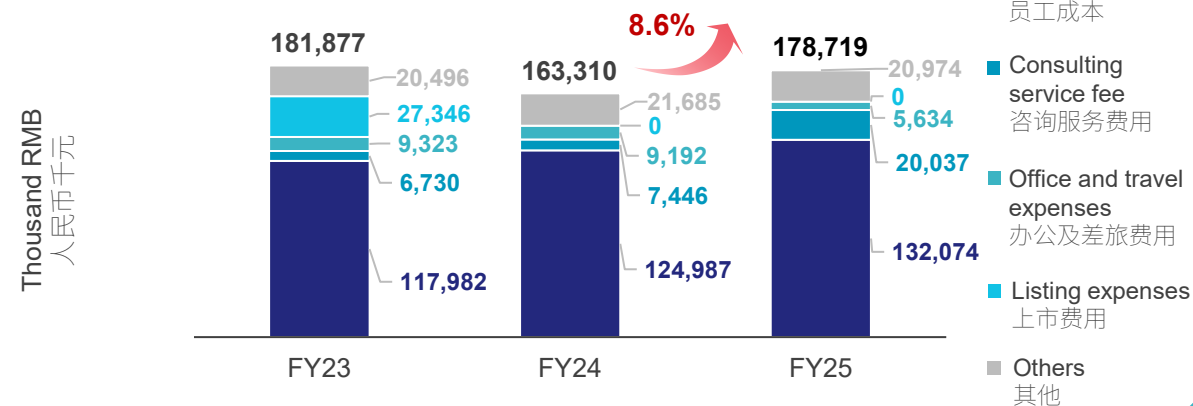
Cost of Sales 营业成本



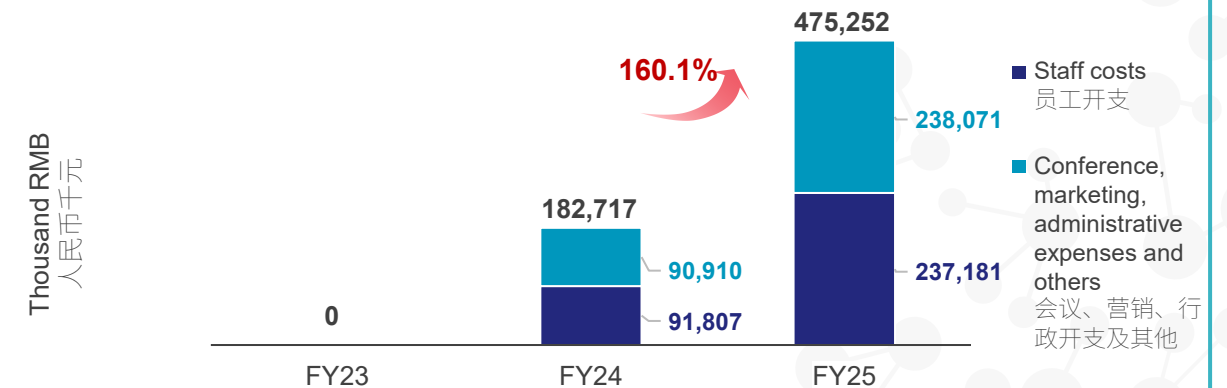
R&D Expenses 研发开支



Administrative Expenses 行政开支



Selling and Distribution Expenses 销售和分销开支

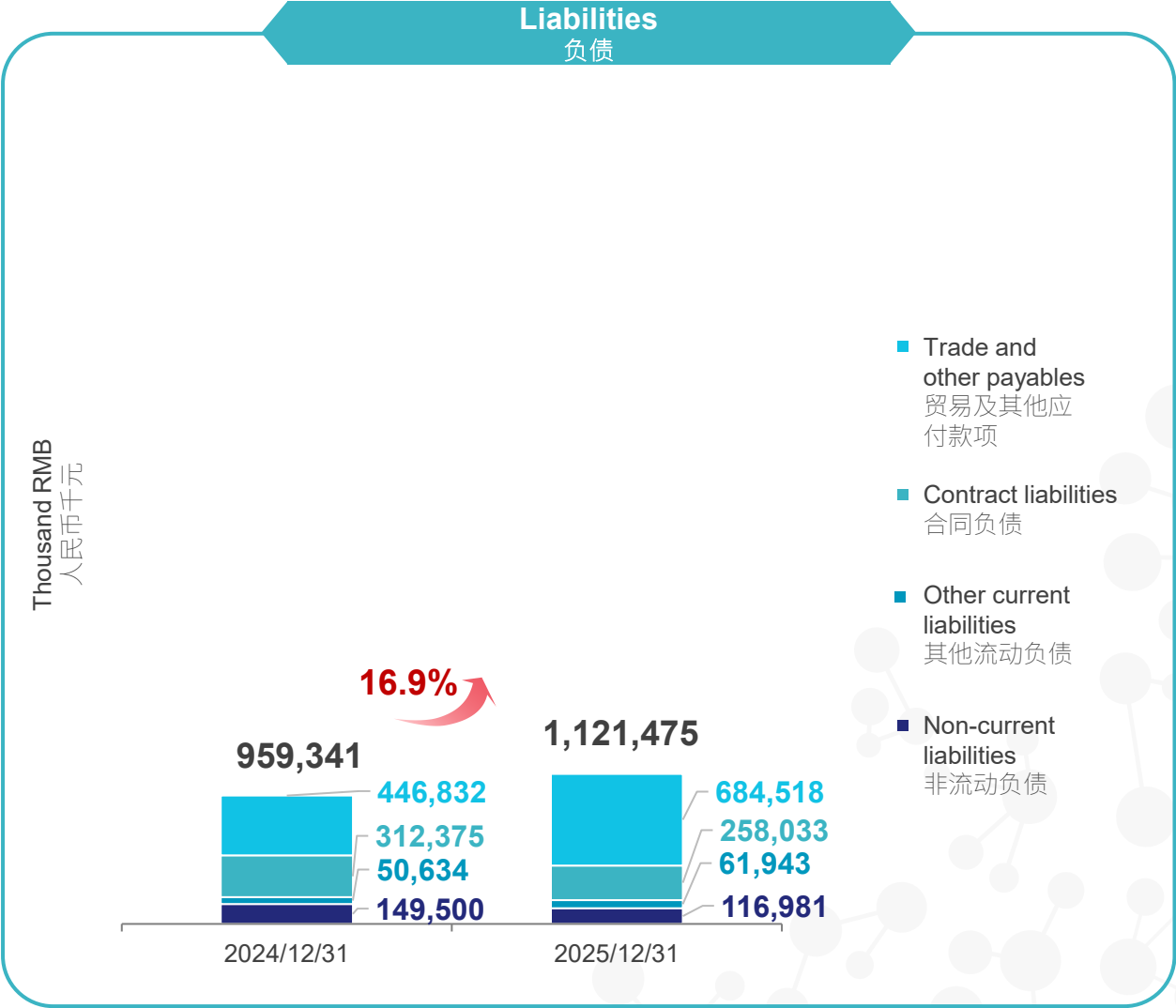
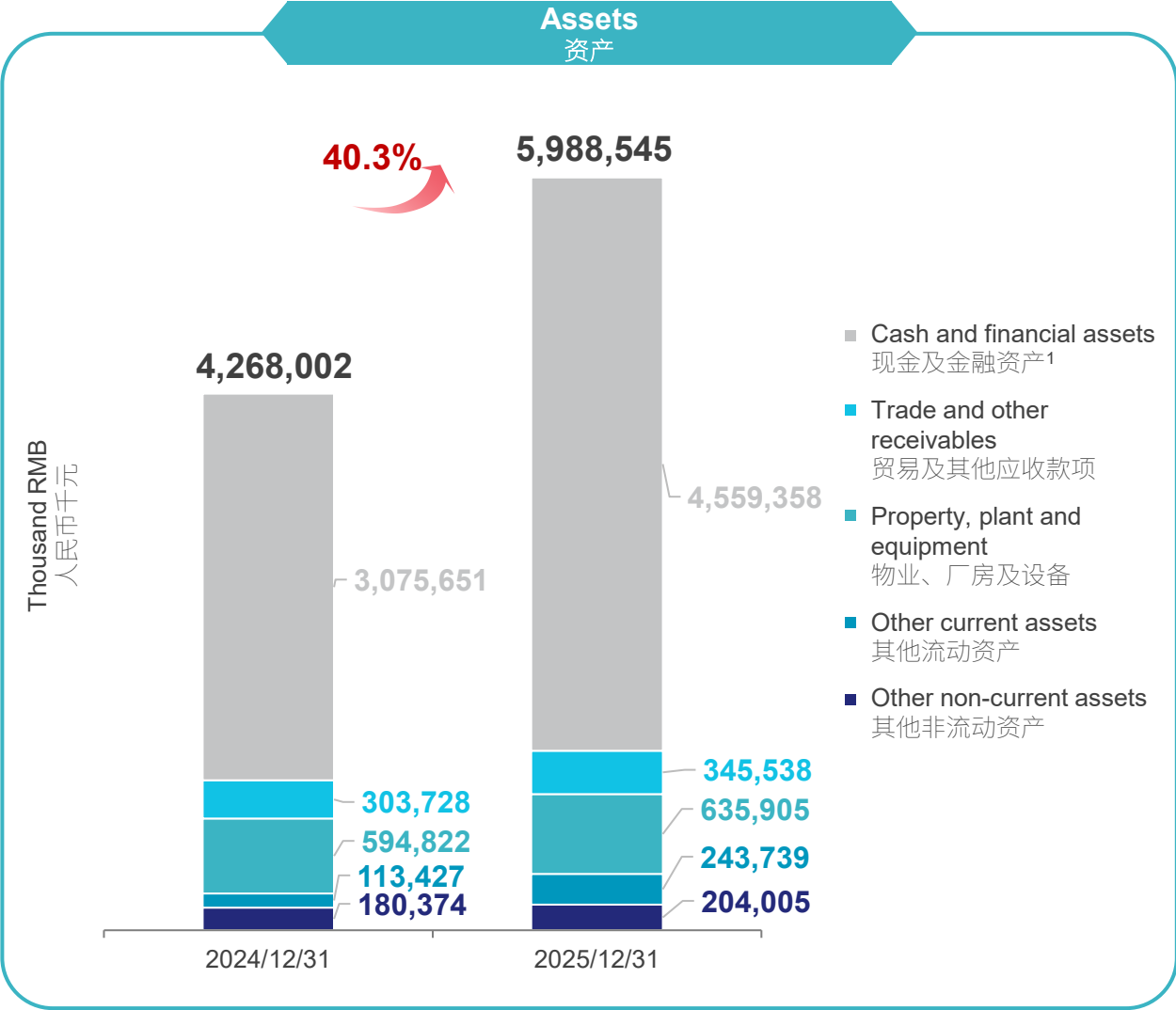


Source: Earnings announcement 资料来源: 业绩公告

Note: ¹ Related to license and collaboration agreements 注: ¹ 与许可和合作协议相关

Assets and Liabilities

资产和负债



Source: Earnings announcement 资料来源: 业绩公告

Note: ¹ Comprises cash and cash equivalents, restricted deposits, financial assets measured at fair value through profit or loss, financial assets measured at amortized cost 注: ¹ 包括现金及现金等价物、受限制存款、按公允价值计量且其变动计入当期损益的金融资产以及按摊销成本计量的金融资产的金融资产



KELUN-BIOTECH
科伦博泰

A1 | Financial Statements 财务报表



Consolidated Statement of Comprehensive Income

综合损益表

RMB'000	Year ended December 31, 截至12月31日止年度	Year ended December 31, 截至12月31日止年度	Year ended December 31, 截至12月31日止年度
	2023	2024	2025
Revenue 收入	1,540,493	1,933,045	2,057,920
Cost of sales 营业成本	(781,308)	(659,388)	(579,139)
Gross profit 毛利	759,185	1,273,657	1,478,781
Other net income/(expense) 其他净收入	89,809	139,755	145,243
Selling and distribution expenses 销售和分销开支	(19,534)	(182,717)	(475,252)
Administrative expenses 行政开支	(181,877)	(163,310)	(178,719)
Research and development expenses 研发开支	(1,030,966)	(1,206,134)	(1,319,675)
Loss from operations 经营亏损	(383,383)	(138,749)	(349,622)
Finance costs 财务成本	(84,309)	(3,796)	(6,158)
Loss before taxation 税前亏损	(467,692)	(142,545)	(355,780)
Income tax 所得税	(106,442)	(124,221)	(26,191)
Loss for the year attributable to equity shareholders of the Company 公司权益股东应占年内亏损	(574,134)	(266,766)	(381,971)

Consolidated Balance Sheet

综合资产负债表

RMB'000	As at December 31, 于12月31日 2023	As at December 31, 于12月31日 2024	As at December 31, 于12月31日 2025
Non-current assets 非流动资产			
Property, plant and equipment 物业、厂房及设备	607,783	594,822	635,905
Right-of-use assets 使用权资产	84,950	163,283	122,591
Intangible assets 无形资产	1,336	2,579	1,100
Financial assets measured at fair value through other comprehensive income ("FVOCI")按公允价值计量且其变动计入其他全面收益的金融资产	/	/	70,080
Other non-current assets 其他非流动资产	8,199	14,512	10,234
Total Non-current assets 非流动资产总额	702,268	775,196	839,910
Current assets 流动资产			
Inventories 存货	63,032	110,506	240,944
Trade and other receivables 贸易及其他应收款项	214,761	303,728	345,538
Amounts due from related parties 应收关联方款项	1,352	2,921	2,795
Financial assets measured at fair value through profit or loss ("FVPL") 按公允价值计量且其变动计入当期损益的金融资产	633,705	1,448,319	935,310
Financial assets measured at amortized cost 按摊余成本计量的金融资产	325,870	283,979	292,574
Restricted deposits 受限制存款	39,993	6,850	87,677
Cash and cash equivalents 现金及现金等价物	1,528,774	1,336,503	3,243,797
Total Current assets 流动资产总额	2,807,487	3,492,806	5,148,635
Total assets 总资产	3,509,755	4,268,002	5,988,545

Consolidated Balance Sheet (Cont'd)

综合资产负债表（续）

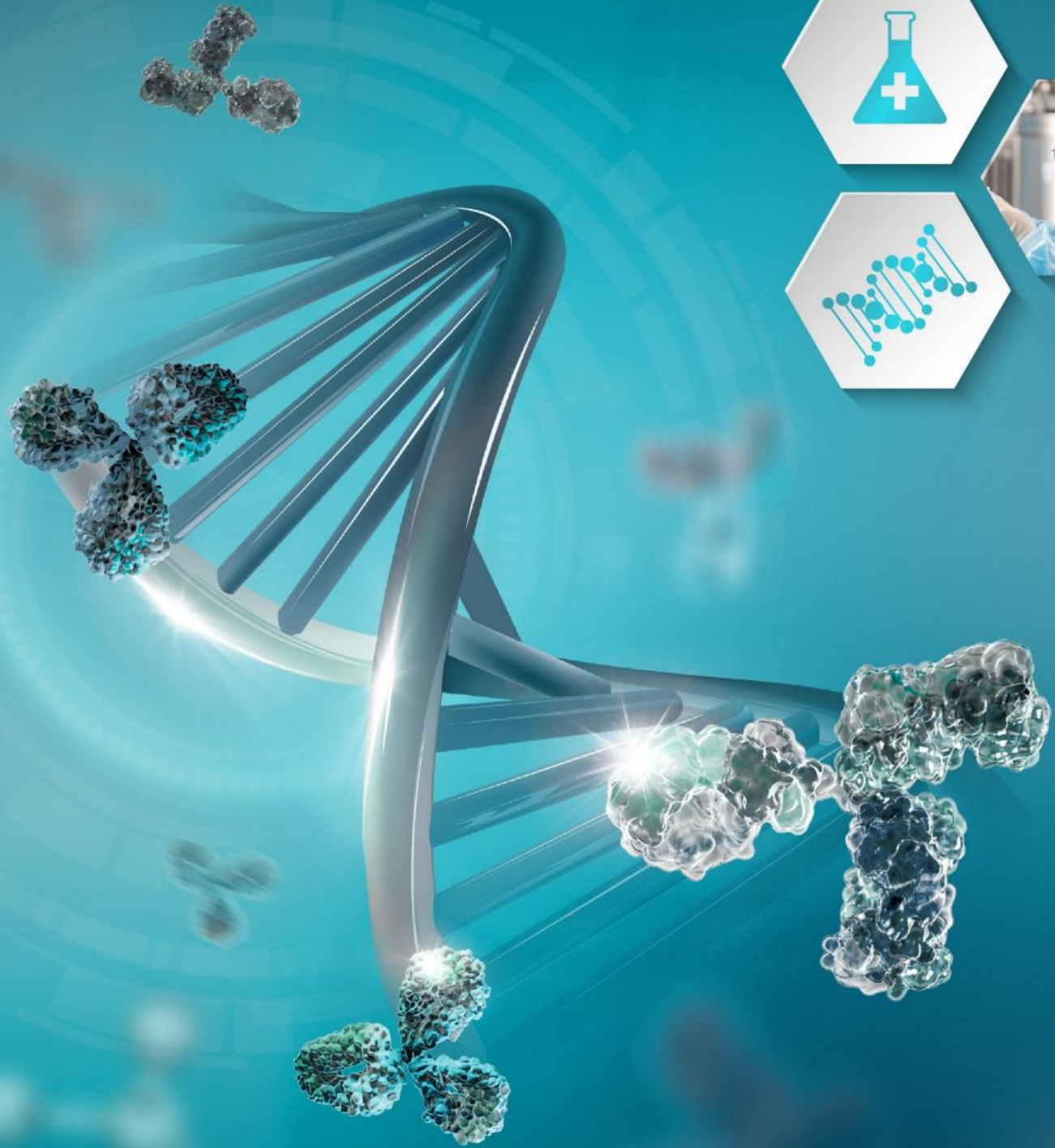
RMB'000	As at December 31, 于12月31日 2023	As at December 31, 于12月31日 2024	As at December 31, 于12月31日 2025
Current liabilities 流动负债			
Trade and other payables 贸易及其他应付款项	523,477	446,832	684,518
Amounts due to related parties 应付关联方款项	21,429	8,792	17,542
Contract liabilities 合约负债	510,692	312,375	258,033
Lease liabilities 租赁负债	54,406	41,842	44,401
Total Current liabilities 流动负债总额	1,110,004	809,841	1,004,494
Non-current liabilities 非流动负债			
Lease liabilities 租赁负债	5,513	84,905	44,043
Deferred income 递延收入	64,741	64,595	72,938
Total Non-current liabilities 非流动负债总额	70,254	149,500	116,981
Total liabilities 总负债	1,180,258	959,341	1,121,475
Capital and reserves 资本及储备			
Share capital 股本	219,196	227,268	233,186
Reserves 准备金	2,110,301	3,081,392	4,633,884
Total Equity 总权益	2,329,497	3,308,661	4,867,070



Consolidated Statements of Cash Flows

综合现金流量表

RMB'000	Year ended December 31, 截至12月31日止年度 2023	Year ended December 31, 截至12月31日止年度 2024	Year ended December 31, 截至12月31日止年度 2025
Operating activities 经营活动			
Net cash used/(generated) in operating activities 经营活动（所用）/产生的现金净额	59,559	(429,770)	(180,300)
Investing activities 投资活动			
Payment for the purchase of property, plant and equipment 购买物业、厂房及设备付款	(80,962)	(77,460)	(125,685)
Proceeds from disposal of property, plant and equipment 出售物业、厂房及设备所得款项	5	30	3
Payment for intangible assets 无形资产付款	(1,268)	(3,659)	(565)
Payment for investment in financial assets measured at fair value through profit or loss 投资按公允价值计量且其变动计入当期损益的金融资产的付款	(2,060,000)	(3,210,000)	(4,530,000)
Proceeds from redemption of financial assets measured at fair value through profit or loss 赎回按公允价值计量且其变动计入当期损益的金融资产的所得款项	1,436,828	2,416,933	5,067,140
Payment for investment in financial assets measured at amortized cost 投资以摊余成本计量的金融资产的付款	(320,000)	(103,102)	(2,883,857)
Proceeds from maturity of financial assets measured at amortized cost 以摊余成本计量的金融资产到期所得款项	-	155,253	2,883,978
Net cash generated/ (used) in investing activities 投资活动产生/（所用）的现金净额	(1,025,397)	(822,005)	411,014
Financing activities 融资活动			
Repayment of bank loans 偿还银行贷款	(100,000)	-	-
Repayment of other borrowings from Kelun Pharmaceutical 偿还来自科伦药业其他借款	(294,040)	-	-
Net proceeds from issuance of new shares 发行新股份所得净款项	158,681	1,094,108	1,777,434
Proceeds from issuance of shares with preferential rights 发行优先股所得款项	1,323,475	-	-
Issuance of ordinary shares by initial public offering and over-allotment, net of issuing costs IPO及超额配售的普通股发行（扣除发行成本）	1,370,939	-	-
Interests paid 已付利息	(563)	-	-
Capital element of lease rentals paid 已付租金的资本部分	(66,762)	(54,601)	(43,215)
Interest element of lease rentals paid 已付租金的利息部分	(9,449)	(2,288)	(6,158)
Net cash generated from financing activities 融资活动产生的现金净额	2,382,281	1,037,219	1,728,061
Net increase in cash and cash equivalents 现金及现金等价物净增加额	1,416,423	(214,556)	1,958,775
Cash and cash equivalents at beginning of year 于1月1日的现金及现金等价物	92,960	1,528,774	1,336,503
Effect of foreign exchange rate changes 汇率变动的影响	19,391	22,285	(51,481)
Cash and cash equivalents at December 31 于12月31日的现金及现金等价物	1,528,774	1,336,503	3,243,797



KELUN-BIOTECH
科伦博泰

THANK YOU
非常感谢！

