



# 2023半年度业绩公告路演

2023年8月24日



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## 01 业绩亮点

业务概况

新药研发

问答环节

财务回顾

董事长兼首席执行官  
娄竞 博士

# 2023上半年业绩摘要

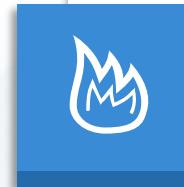


主要业绩指标 (百万元)	2023H1	2022H1	同比
营业收入	3783.8	3094.5	22.3%
毛利	3201.6	2565.2	24.8%
归属上市公司股东 净利润	980.6	966.9	1.4%
正常化归母净利润	1191.5	992.2	20.1%
每股净利润 (RMB)	0.40	0.39	2.6%



## 生物制药

收入同比增长**20%**至**29.1**亿元，**4**大核心品种，  
覆盖肾科、自免、血液、肿瘤等疾病领域



## 毛发健康

收入同比增长**36%**至**5.1**亿元，618电商销售再  
摘**榜首**<sup>1</sup>



## CDMO

收入同比增长**72%**至**9491**万元，**4**大基地同步  
增长



## 新药研发

- 益赛普水针，丽美治<sup>®</sup>获批上市；
- 608 (IL-17A人源化单克隆抗体注射液) 银屑病  
适应症III期临床入组完成；
- 613 (IL-1 $\beta$ 人源化单克隆抗体注射液) 急性痛风  
性关节炎II期临床试验达到主要终点

1. 获得天猫618 OTC品牌排行榜第一名；京东平台618医药单品第一名

# 持续精进ESG治理



红遍中国



益肾论道  
—基石引领经典—



- 勇担社会责任，积极投身公益
- 支持“强直性脊柱炎健康乡村工程”，累计帮助、救治强直、肿瘤、透析等患者数万人
- ESG治理获MSCI AA评级,超过全球88%的生物科技公司
- 入选标普全球《可持续发展年鉴（中国版）2023》



业绩亮点

董事长兼首席执行官  
娄竞博士

## 02 业务概况

新药研发

问答环节

财务回顾





# 生物制药

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# 特比澳—全球唯一商业化重组人血小板生成素



特比澳2023年上半年销售收入

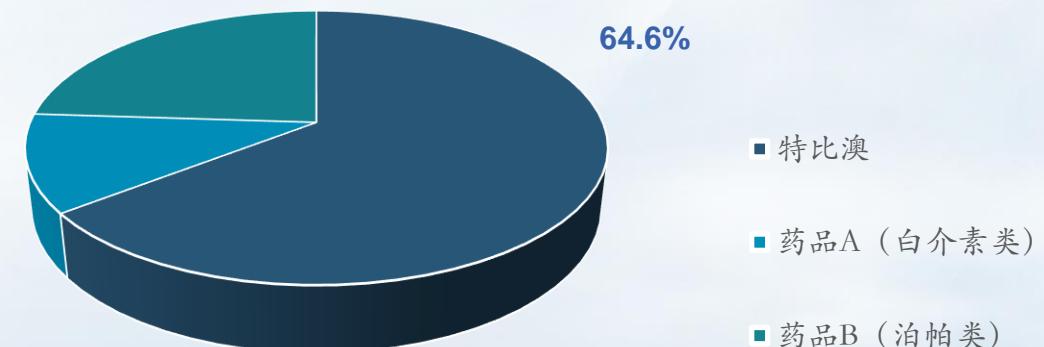
百万元



1

市占率首位

以销售额计市占率**65%<sup>1</sup>**，继续居于升血小板药物市场首位



1.数据来源：IQVIA 2023年1-6月，市场总量包含重组人血小板生成素，白介素-11, 泊帕类及罗普司亭

# 特比澳—临床研究推进适应症扩展



与内源性TPO结构一致  
作用于血小板生成的全过程

唯一  
拥有全程激活胞内通路能力

唯一  
对于巨核细胞有全程作用能力

唯一  
对于巨核细胞有全程保护能力



## 肿瘤领域

- 2022 获CSCO指南肿瘤治疗所致血小板减少症 (CTIT) 用药 A级推荐

## 其他领域

- 试验探索骨髓保护等领域应用

## 血液领域

- 儿童ITP: 已提交上市申请, NDA审评中

## 肝病领域

- CLDT: III期临床入组中, 预计2024年申报上市

# 促红素-益比奥 & 赛博尔双品牌



## 促红素2023年上半年销售收入

百万元



1

## 市占率首位

两品种市占率**43%<sup>1</sup>**, 稳居EPO产品市占率第一

- 益比奥®质量标准达到**欧洲药典**标准，获得临床充分认可
- 非集采省份呈现全面**正增长**，市场份额**明显增长<sup>2</sup>**
- 诊疗指南增加应用推荐<sup>3</sup>，肿瘤领域渗透率**双位数提升**

10%

肿瘤贫血  
治疗渗透率



1. 市占率数据来源：IQVIA  
2. 市场份额数据来源：CPA  
3. 《肿瘤相关性贫血实践指南2022》增加36000IU EPO对于MDS（骨髓异常增生综合征）的I级推荐；卫健委《2021年质控工作改进目标的函（国卫医质量便函[2021]51号）》

# 益赛普-多维探索，积极应对变革



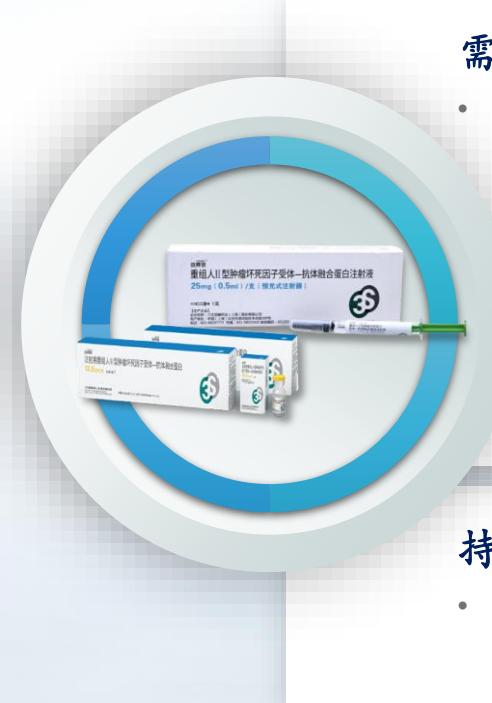
## 益赛普2023上半年销售收入

百万元



### 需求重回增长

- 慢病治疗需求重回正常



### 拓展新剂型

- 预充剂型已获批准，5月上市销售

### 持续基层下沉

- 积极推动基药目录准入工作、乡村振兴项目，提高基层诊疗水平，巩固先入优势

# 赛普汀-为患者提供更多选择



## 赛普汀2023年上半年销售收入

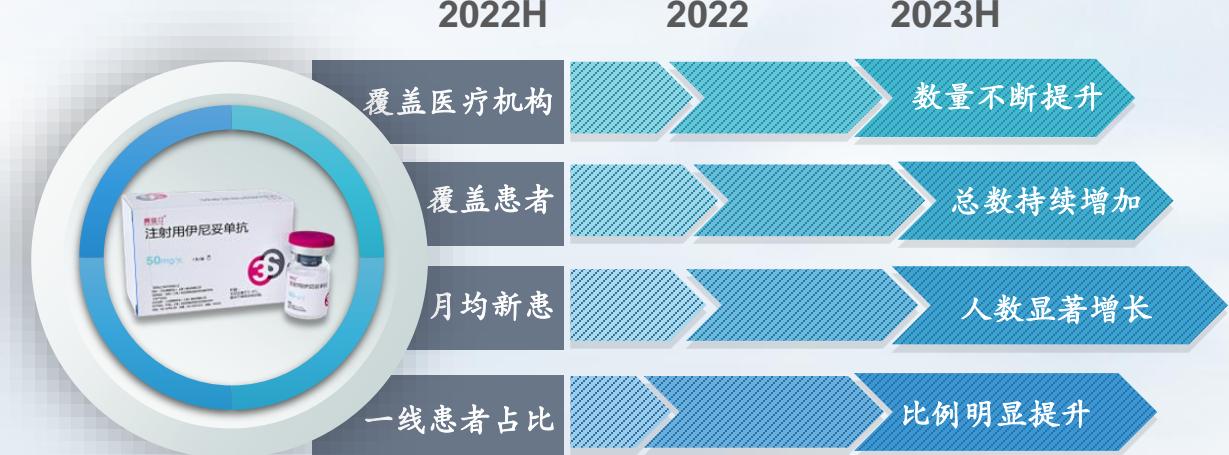
百万元



## HER2阳性晚期乳腺癌H治疗用药 I级推荐

I级推荐: (1) THP (IA) ; (2) TXH (2A)

--抗HER2单抗 (H), 包括我国已上市的曲妥珠单抗、生物类似药、伊尼妥单抗



# 毛发健康



# 蔓迪-安全有效的外用生发药物龙头



## 蔓迪2023年上半年销售收入

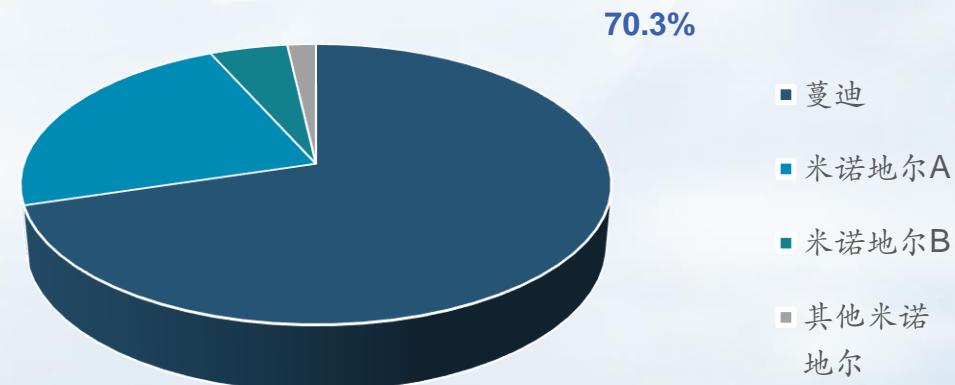
百万元



1

## 市占率首位

蔓迪在医疗机构市占率**70%**，稳居米诺地尔市场第一<sup>1</sup>



1. 市占率数据来源：CPA

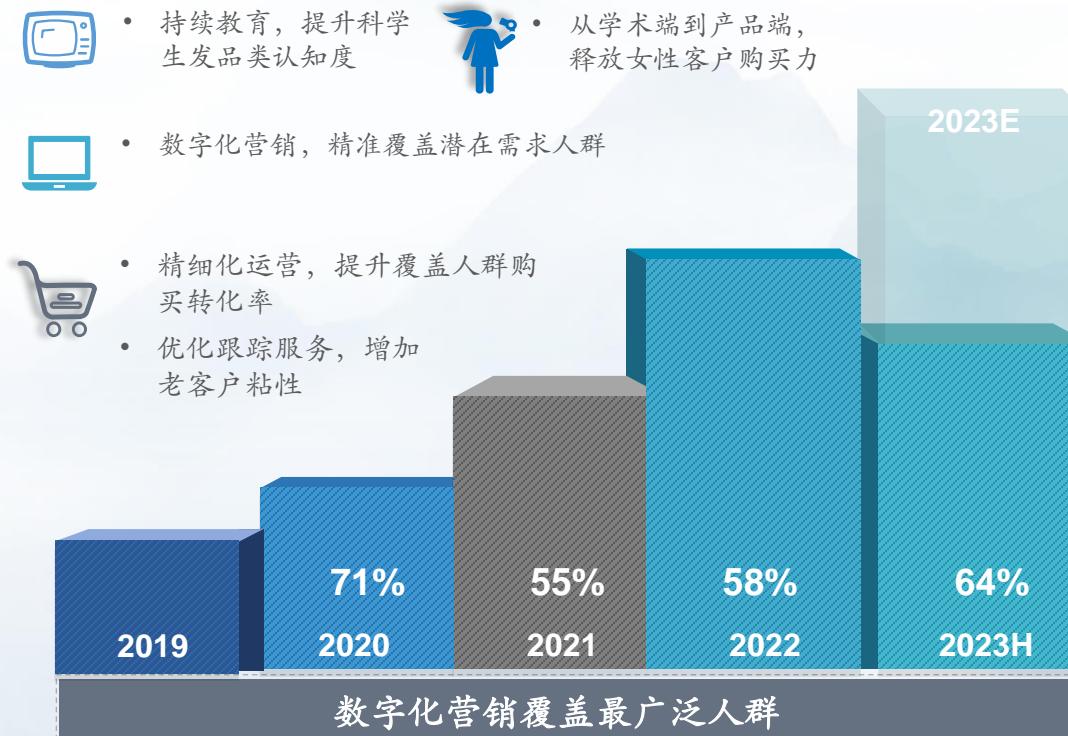
# 释放消费属性，数字化营销引领品牌成长

## 科学有效的生发选择正在赢得更多认可

- 米诺地尔作为科学、有效、安全、便捷的生发手段，市场规模持续提升
- 蔓迪（5%浓度米诺地尔）获中国女性雄激素脱发（FAGA）指南最高等级推荐



数据来源：EvaluatePharma, Insights数据库



# 打造产品矩阵，扩展品牌价值



## 曼迪品种矩阵不断丰富

01

**曼迪**

60/90mL 男士单月装/疗程装

02

**曼迪 小白瓶**

30mL女性单月装，方便定量

03

**曼迪 Pro**

10mL小容量，配置多种刷头，满足出差，旅游场景便携需求

04

**曼迪 洗发水**

向毛发相关的生活场景渗透

05

**曼迪 小密梳**

兼具激光按摩和上液功能，上药、养护一体化头部健康智能工具

06

**曼迪 精灵瓶**

针对发际线，发缝的精细化升级

**曼迪 泡沫剂**

即将上市，填补头皮敏感人群用药需求



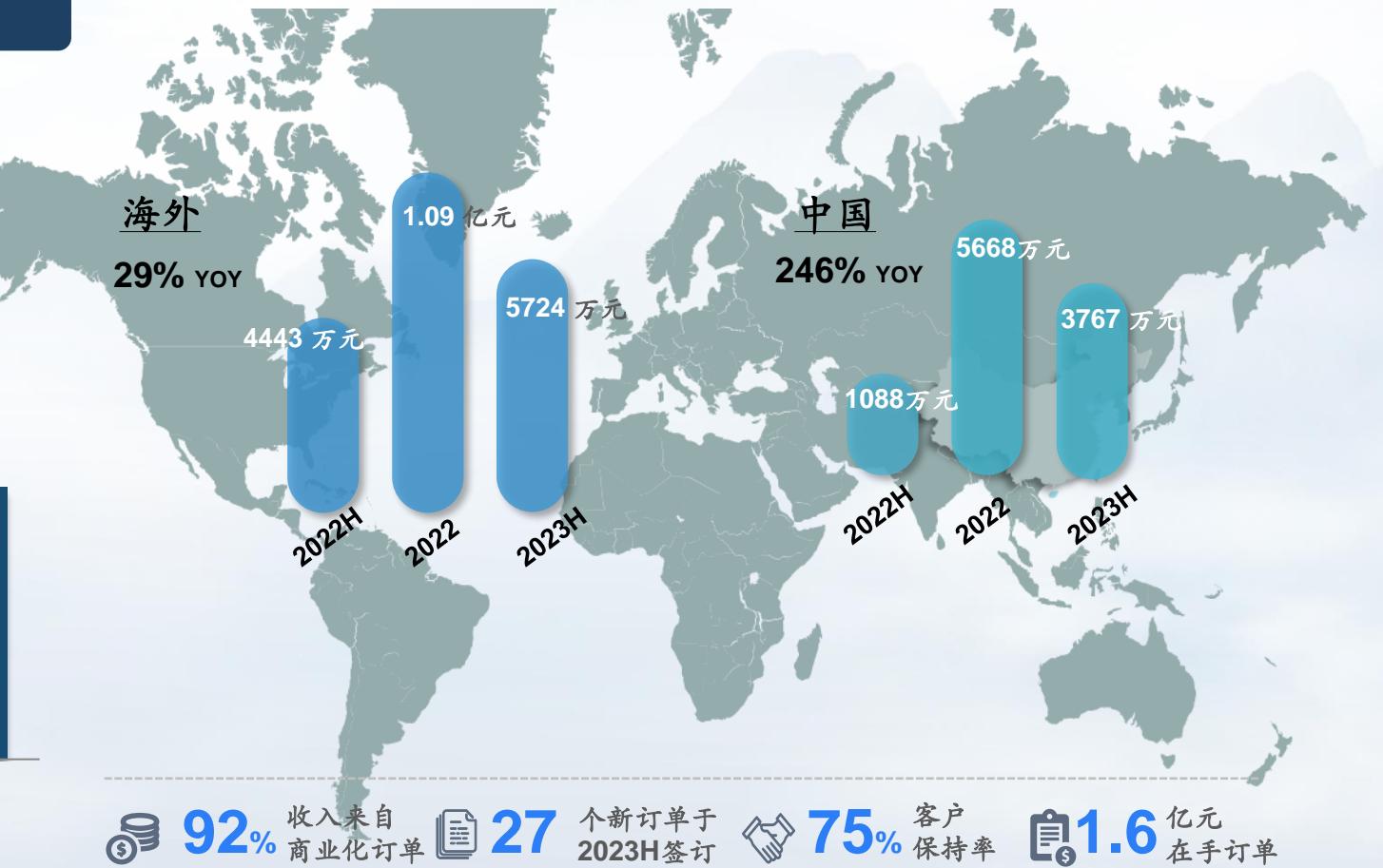
# CDMO业务



# 国内CDMO服务先行者



## CDMO业务2023上半年收入





# 差异化优势支持客户产品开发

- 4大基地，提供全面的生物制药研发、生产能力覆盖

生物药      制剂      基因与细胞治疗  
培养基      亲和层析填料

- 丰富的全流程制药经验与完善的设施，解决生物制药行业“**不可能三角**”



7

个国家/地区 GMP  
认证



**德生生物**

一期7.6万升即将投入使用；  
二期培养基、填料产线在建



**Sirton**

欧盟标准多剂型CMO服务

**晟国医药**  
一次性+不锈钢灵活布局  
提供专业的生物药研发及生产  
服务



**广东三生**

质粒、mRNA、病毒载体、  
细胞治疗等CGT服务



30年

生物药研发  
生产经验

30年

无事故  
安全生产

40+

药品国内外  
上市经验

>10万升

有效产能  
稳定运营

A circular background image showing a close-up of laboratory glassware, including a blue screw cap and clear vials, set against a white background.

业绩亮点

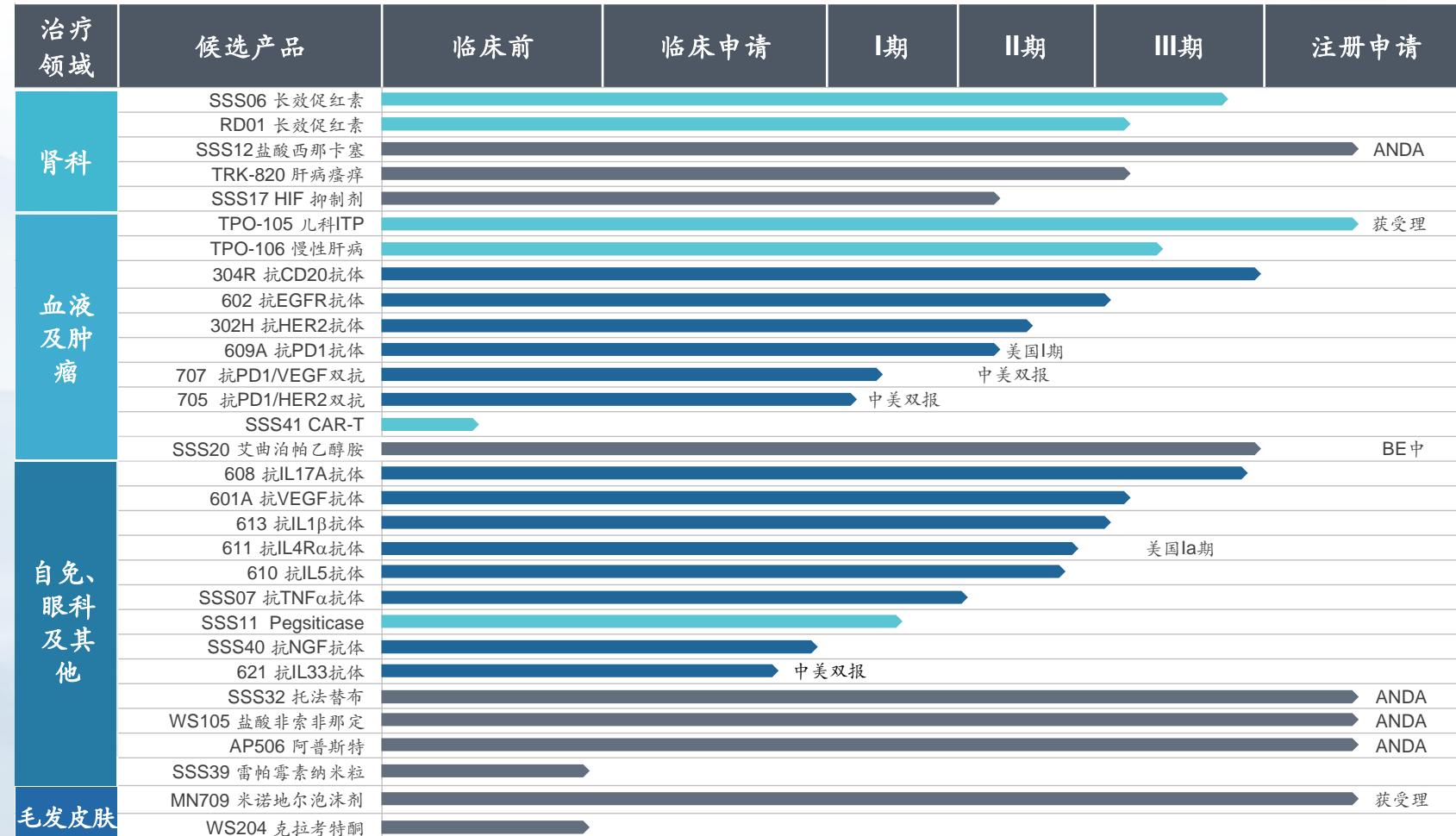
### 03 新药研发

业务概况

问答环节

财务回顾

# 研发管线



3个  
临床前产品

5个  
IND&临床I期

7个  
临床II期

10个  
临床III期&NDA

5个  
BE/ANDA产品

- 小分子药物
- 抗体药物
- 其他生物药



5

个研发品种

- 围绕透析及并发症

Remitch 盐酸纳呋拉啡口崩片

CKD瘙痒 (慢性肝病引起的瘙痒-III期临床)

获批上市

盐酸西那卡塞

甲状腺功能亢进

ANDA

SSS06 NuPIAO (rESA)

长效EPO

Phase III

RD 01 PEG-EPO

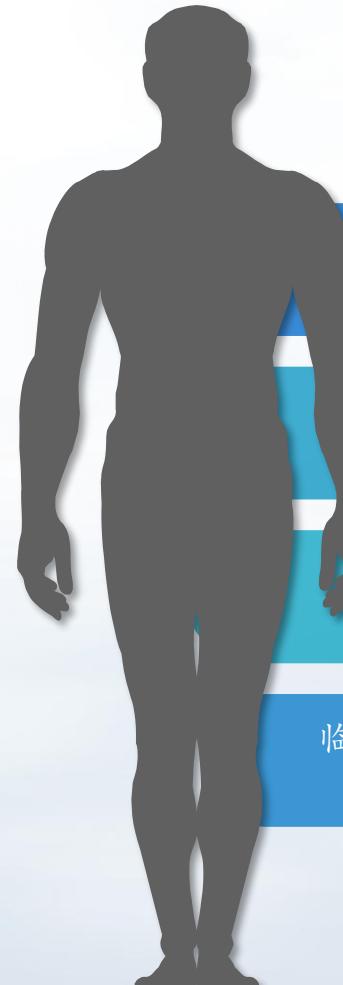
长效EPO

Phase III

SSS17 HIF 抑制剂

CKD贫血

Phase II



丽美治® 盐酸纳呋拉啡口崩片

国内中重度透析瘙痒首个、唯一上市对症药物，  
解决传统阿片类药物呼吸抑制、便秘和成瘾性

治疗1年有效率80%以上，VAS评分持续降低<sup>1</sup>

获日本、欧洲、中国等多国权威  
指南推荐<sup>2</sup>

临床向国内的患者群体更加  
庞大的肝病瘙痒延伸

中国透析瘙痒患者



有效且安全的治疗选择

1: Kozono H, et al. Int J Nephrol Renovasc Dis. 2018 Jan 15;11:9-24; Kumagai H, et al. Am J Nephrol. 2012;36(2):175-83.

2: 《欧洲慢性瘙痒指南》，《中国老年皮肤瘙痒症诊断与治疗专家共识》，《中国慢性瘙痒管理指南》，《日本皮肤瘙痒诊断治疗指南》



# 重点研发管线-血液/肿瘤

**TPO-105**

儿童ITP

NDA 审评中

**TPO-106**

慢性肝病血小板减少

Phase III

**602(抗EGFR抗体)**

结直肠癌

已完成 Phase II

**赛普汀**

Her-2阳性乳腺癌 新辅助

Phase II

**707 (VEGF/PD-1双抗)**

实体瘤

Phase I

特比澳：每年1.3万新发儿童ITP患者<sup>1</sup>以及35万+CLDT患者<sup>2</sup>，临床充分验证安全性及有效性

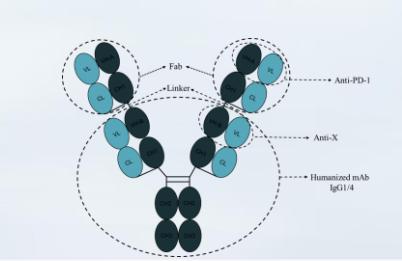
赛普汀：探索在Her-2阳性乳腺癌新辅助治疗中的应用，拓展乳腺癌患者覆盖面

**2023 ASCO** 大会发表伊尼妥单抗

- 1) 联合吡咯替尼治疗HER2突变型NSCLC，
- 2) 联合帕妥珠单抗、紫杉醇和卡铂用于乳腺癌新辅助，
- 3) 联合卡瑞利珠与优替德隆治疗转移性乳腺癌等三篇研究报告

探索新适应症

The screenshots show abstracts from the 2023 ASCO Annual Meeting. The first abstract discusses neoadjuvant inetumab combined with pertuzumab, paclitaxel, and carboplatin (TCbiP) for locally advanced HER2-positive breast cancer. The second abstract discusses anti-HER2 antibody inetumab plus camrelizumab and olaratumab for pretreated HER2-positive metastatic breast cancer. The third abstract discusses the safety and efficacy of inetumab in combination with pyrotinib in HER2 mutant patients with small cell lung cancer (NSCLC). All abstracts are labeled as phase II trials.



**CLF<sup>2</sup> (common light chain Linear-Fabs-IgG) 双抗平台**

开发新分子

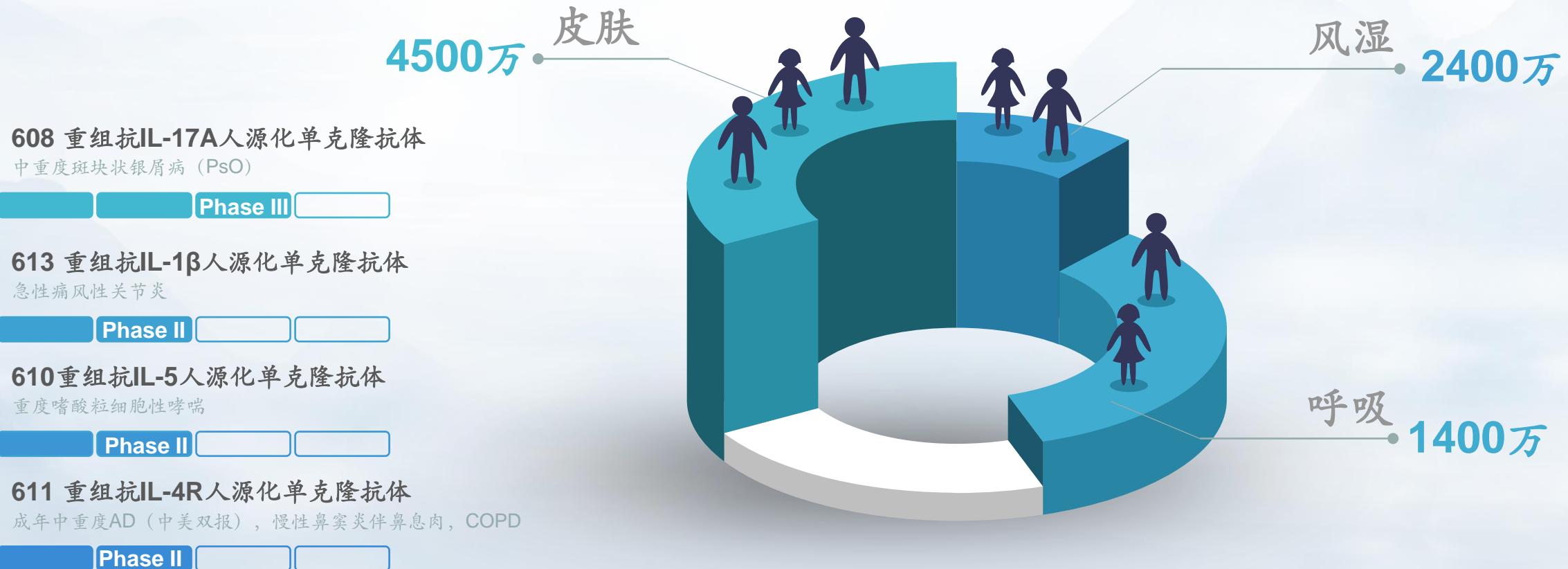
**707 (VEGF/PD-1双抗) :**

- 依托集团CLF<sup>2</sup>专利平台开发的靶向VEGF/PD-1双抗
- 全球进展第二，已于国内开展晚期或转移性实体瘤患者的Ia期临床研究，美国IND已获批

1. 数据来源：儿童原发性免疫性血小板减少症诊疗规范

2. 数据来源：李冰,陈国凤.慢性肝病患者血小板减少原因及治疗研究进展[J].人民军医,2014,57(9):1024-1025,1030. 数据测算方法：肝硬化患者中血小板减少至低于5万，需进行侵入性操作的人群

## 聚焦中国自免的广阔市场



# 重点研发管线-皮肤毛发



1st

FDA 40年来批准的首个新机制痤疮治疗用药

- Winlevi®是Cosmo 开发的全球首款上市的针对12岁以及以上的寻常痤疮患者的外用雄激素受体抑制剂，于2021年11月获得FDA批准上市<sup>1</sup>

67  
万

美国处方量最大的痤疮用药

- Winlevi®已经成为美国市场处方量最大的痤疮药物，截至2023年7月，有超过1.5万名的医生开具了该款药品的处方，处方量超67万张<sup>2</sup>

## WS204 克拉考特酮乳膏剂

12岁以上寻常痤疮

Bridging Trial



## MN709 米诺地尔泡沫剂

雄性激素性秃发



NDA

## WS105 非索非那定片

季节性过敏性鼻炎，慢性特发性荨麻疹



ANDA

以上中国人有  
不同程度的痤疮问题

95%

1亿

年龄介于10至25岁的  
年轻群体有寻常痤疮

3-7%



的比例出现痤疮瘢痕，对患  
者的生理和心理造成损害



# 重点管线品种上市展望



# 608 (抗IL-17A 单抗)

## PsO II期临床数据显示确切疗效

- 12周数据显示，608各剂量组疗效并明显优于安慰剂组及已上市品种

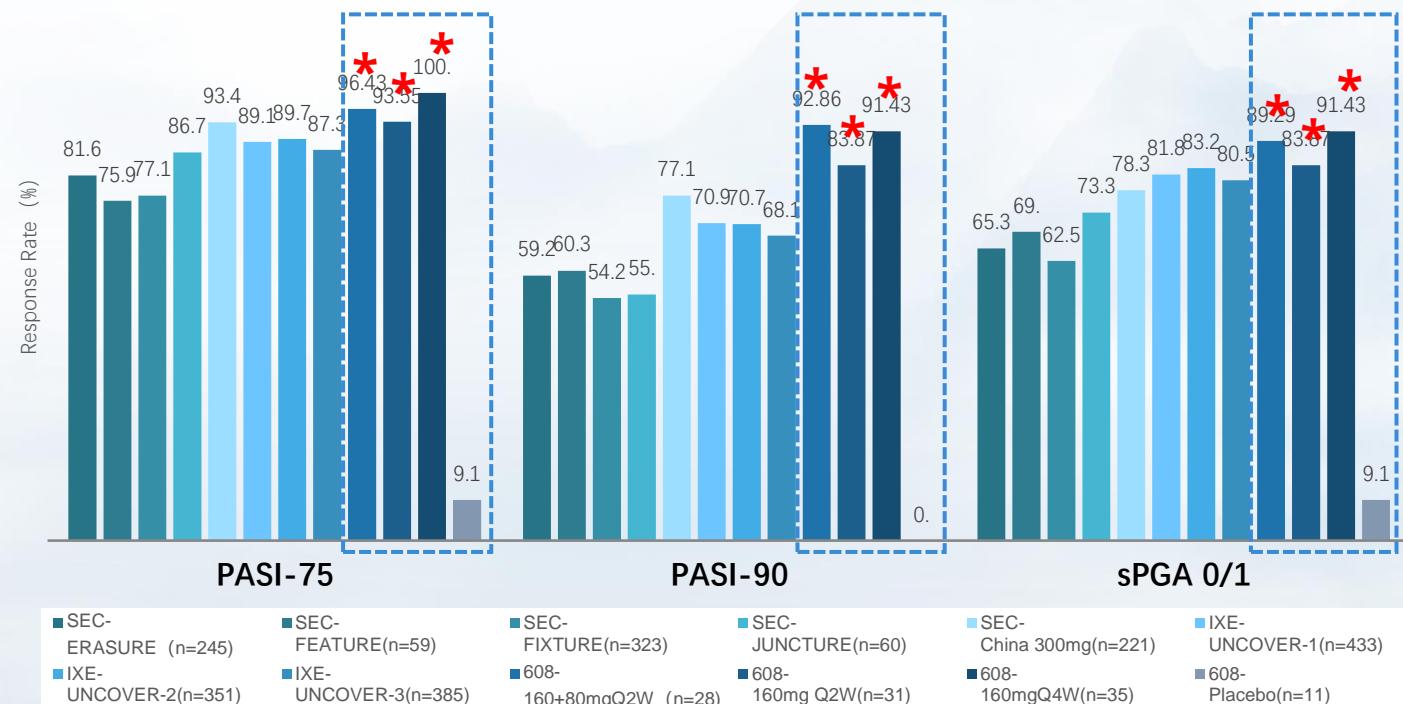
	608A组 (n=28)	608B组 (n=31)	608C组 (n=35)	安慰剂 (n=11)	司库奇尤 单抗 300mg (W0-W4 QW) + Q4W
PASI 75	96.4%	93.5%	<b>100.0%</b>	9.1%	80.6%
PASI 90	92.9%	83.9%	<b>91.4%</b>	0.0%	57.2%
PASI 100	46.4%	48.4%	<b>57.1%</b>	0.0%	33.6%
sPGA 0/1	89.3%	83.9%	<b>91.4%</b>	9.1%	67.9%
PASI 75 +sPGA 0/1	89.3%	83.9%	<b>91.4%</b>	9.1%	/
PASI 90 +sPGA 0/1	89.3%	80.6%	<b>91.4%</b>	0	/

- 研发进展位列国内第三位

2024

预计NDA

608、司库奇尤单抗、依奇珠单抗银屑病患者12周主要终点数据



注：T=试验药物，P=安慰剂组

1. 608 A组代表：160mg LD/loading dose)+80mg Q2W, 608 B组代表：160mg Q2W; 608 C组代表：160mg Q4W

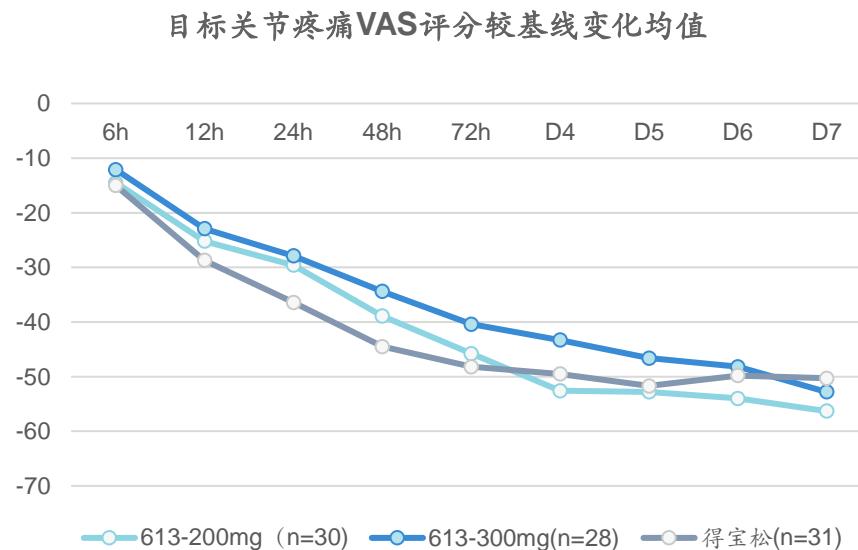
2. PASI75, PASI90,PASI100分别定义为PASI较基线改善≥75%，≥90%和≥100%

3. sPGA 0/1定义为sPGA为0分或1分，且较基线降低≥2分；sPGA 0定义为银屑病皮损完全消退

# 613 (抗IL1 $\beta$ 单抗)

## 急性痛风性关节炎II期临床达到主要终点

- 给药后**6小时**即开始起效
- 随给药时间推移，613在改善疼痛方面优于对照组

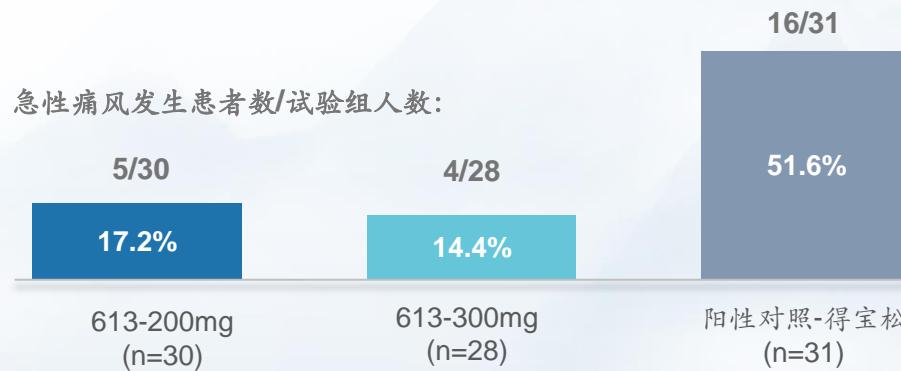


- 研发进展位列同靶点国内**第二位**

2025  
预计NDA

给药后12周新的痛风急性发作发生率显著低于对照

急性痛风发生患者数/试验组人数：



企业名称	适应症	产品代码
长春金赛	急性痛风性关节炎III期招募中 幼年特发性关节炎I/II期招募完成 晚期恶性实体瘤I期招募中	金纳单抗
三生国健	急性痛风性关节炎II期已达到主要临床终点 周期性发热综合征、全身型幼年特发性关节炎I期已完成	SSGJ-613
交晨生物	预防结直肠癌患者的化疗性腹泻II期 痛风性关节炎II期； 预防化疗毒副作用和治疗复发转移结直肠癌II期 用于预防化疗毒副作用I期	UA007

# 611 (抗IL-4R 单抗)

## 特应性皮炎II期临床疗效明显优于对照

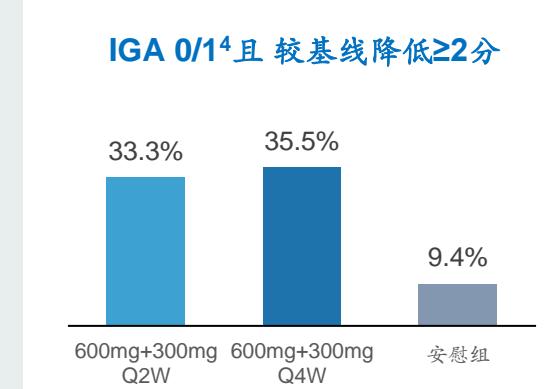
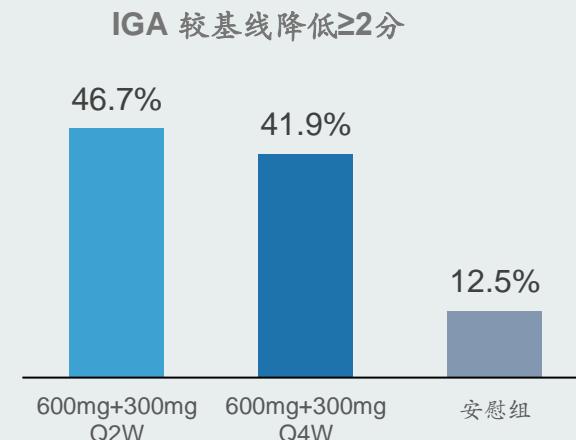
- 16周数据显示同等剂量下611在 EASI-75和缓解瘙痒方面表现高于已上市同靶点药物

剂量组	EASI 75 <sup>2</sup>	IGA 0 / 1	EASI 50	NRS ≥4 <sup>3</sup>
组A <sup>1</sup> N=30	60%	33.3%	73.3%	46.7%
组B N=31	48.4%	35.5%	77.4%	45.2%
安慰剂 N=32	15.6%	9.4%	18.8%	15.6%
达必妥 (Q2W)	48~51%	27~36%	65~69%	36~41%

- 国内研发进展位列国内第三位

2026

预计NDA



企业名称	适应症	产品代码
康诺亚	特应性皮炎III期 已达到主要临床终点 慢性鼻窦炎伴鼻息肉病III期，招募完成 哮喘II/III期 尚未招募	CM310
康乃德	中度至重度特应性皮炎 II期 已完成； 中重度合并2型炎症的持续性哮喘II期 招募完成	CBP-201
三生国健	特应性皮炎 II期 已达到主要临床终点， III期方案准备	SSGJ-611

1. 611组A代表：600mg LD/loading dose)+300mg Q2W，组B代表：600 mgLD+300mg Q4W;  
2. EASI75,,EASI50分别定义为EASI较基线改善≥75%和≥50%

3. 瘙痒数字模拟评分表NRS≥4分定义为瘙痒NRS的周平均值较基线降低≥4分  
4. IGA 0/1定义为IGA为0分(皮损完全清除)或1分 (皮损几乎完全清除)

# 610 (抗-IL5 单抗)

显著改善重度哮喘患者的肺功能

- 研发进展位列国内第一位

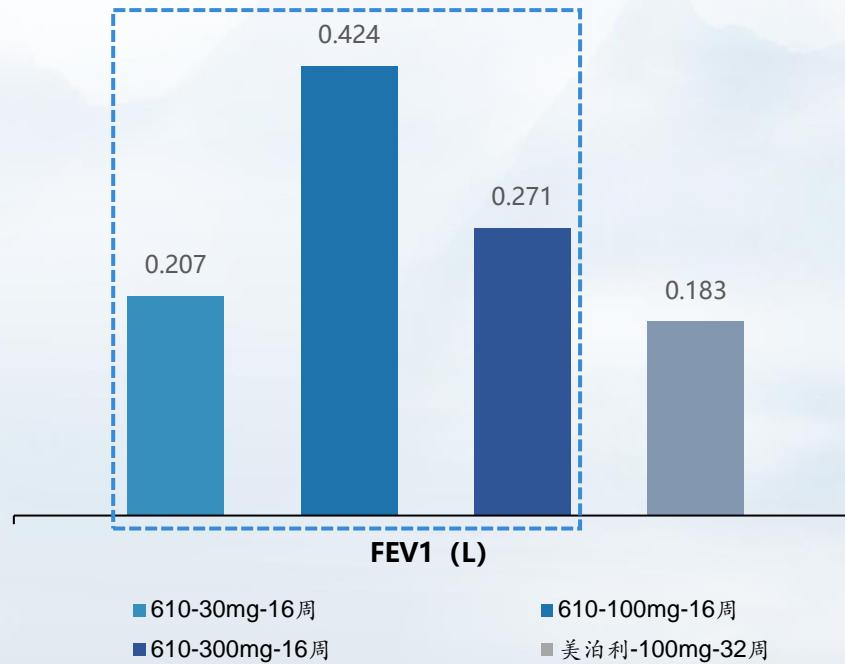
企业名称	产品代码	适应症
三生国健	SSGJ-610	嗜酸性粒细胞哮喘II期招募中
恒瑞医药	SHR-1703	嗜酸性粒细胞哮喘II期招募中；哮喘I期招募中；支气管哮喘I期已完成
百奥泰	美泊利珠单抗-BAT 2606	慢性鼻窦炎伴鼻息肉病I期招募完成

- 重度嗜酸性粒细胞哮喘患者的II期入组已完成

2027

预计NDA

Ib临床盲态下分析结果显示FEV1<sup>1</sup>改善



1. FEV1，即第1秒用力呼气量，是哮喘临床试验常用的替代终点，与临床终点哮喘恶化间有良好的相关性



# SSS06 (长效重组人促红细胞生成素)

## II期临床显示安全有效

- 二代 EPO, 半衰期延长, 给药间隔可延长至**两周**, 匹配化疗患者治疗周期
- II期数据显示两个剂量组均安全有效, 用药后血红蛋白 (Hb) 变化与现有EPO**一致**
- 临床III期全部受试者访视**已完成**

2024

预计NDA

rhEPO 和 SSS06 临床疗效数据对比:

	rhEPO (维持筛选剂量)	rESA QW (0.5ug/kg)	rESA QOW (1.0ug/kg)
平均基线血红蛋白(g/L)	110.70	110.1	<b>112.9</b>
评价期平均血红蛋白(g/L)	108.9	106.5	<b>107.7</b>
主要疗效终点			
评价期平均Hb相对基线变化(g/L)	-1.8	-3.7	<b>-5.1</b>
评价期平均Hb相较基线变化量修正均数(g/L)	-6.5	-8.3	<b>-8.2</b>
修正均数差值(95% CI)		1.8(-1.8, 5.4)	<b>1.6(-2.1, 5.4)</b>

# 601A (抗VEGF单抗)

## BRVO II期临床数据显示确切疗效

- 24周数据显示，601A主要和关键疗效均表现出较雷珠单抗更优的趋势

主要和关键疗效指标	601A试验组 (n=31)	雷珠单抗对照组 (n=29)
目标眼24周BCVA较基线变化 (个字母)		
均值(标准差)	<b>18.3 (12.87)</b>	16.2 (10.50)
目标眼24周CRT较基线变化 (um)		
均值(标准差)	<b>-310.6 (231.53)</b>	-301.5 (174.83)

- BRVO III期临床正在入组中

2024  
预计NDA

52周研究周期目标眼各访视节点BCVA较基线的变化值  
FAS



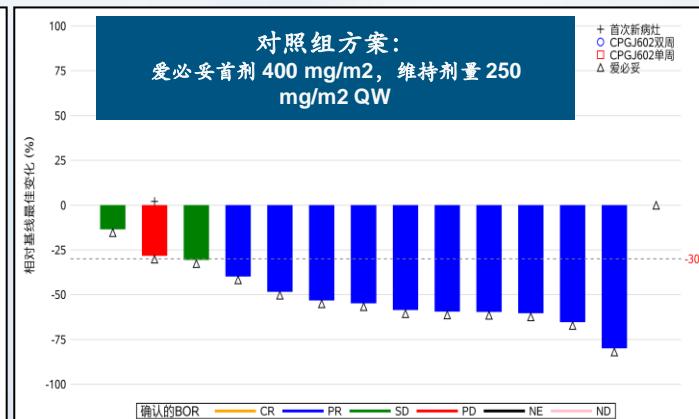
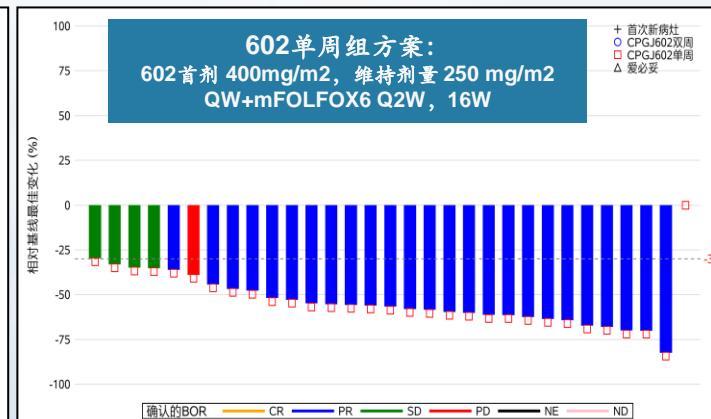
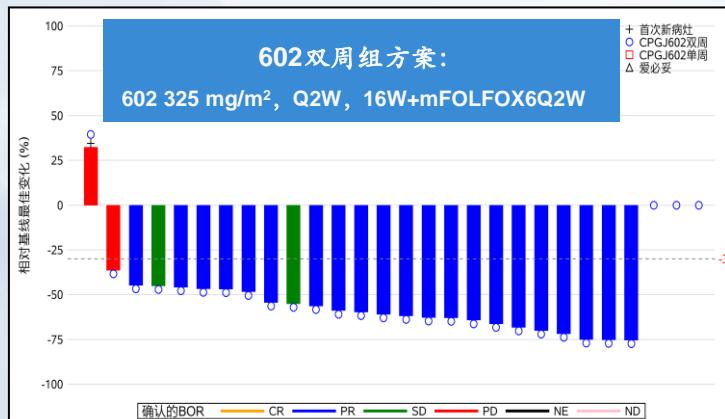
- BCVA:最佳矫正视力
- CRT:平均中心视网膜厚度

# 602 (抗EGFR单抗)

一线治疗mCRC II期临床数据显示疗效显著

		602双周组 N=28(%)	602单周组 N=31(%)	爱必妥组 N=14(%)
BIRC (独立影像 评估)	最佳总缓解率	<b>22 (78.6)</b>	<b>26 (83.9)</b>	10 (71.4)
	完全缓解(CR)	0	1 (3.2)	0
	部分缓解(PR)	<b>22 (78.6)</b>	<b>25 (80.6)</b>	10 (71.4)
	病变稳定(SD)	<b>4 (14.3)</b>	<b>4 (12.9)</b>	2 (14.3)

BIRC疗效评估：602单周组和双周组均显示出优于爱必妥的趋势



首席财务官  
何翔先生

业绩亮点

业务概况

问答环节

新药研发

## 04 财务回顾

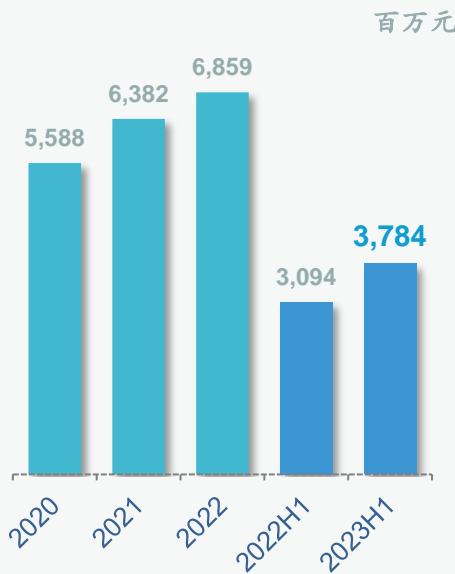


# 财务分析



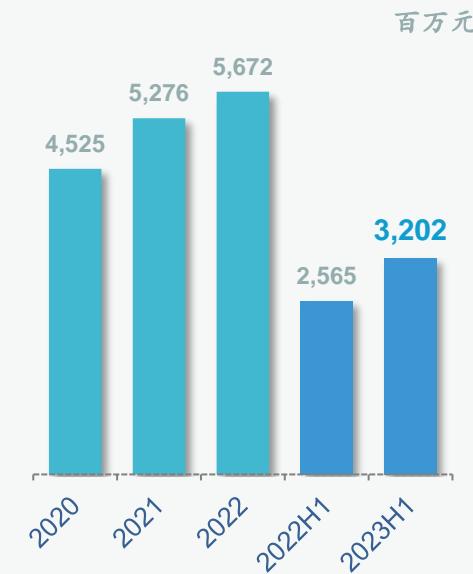
收入

**22.3%** YOY



毛利

**24.8%** YOY



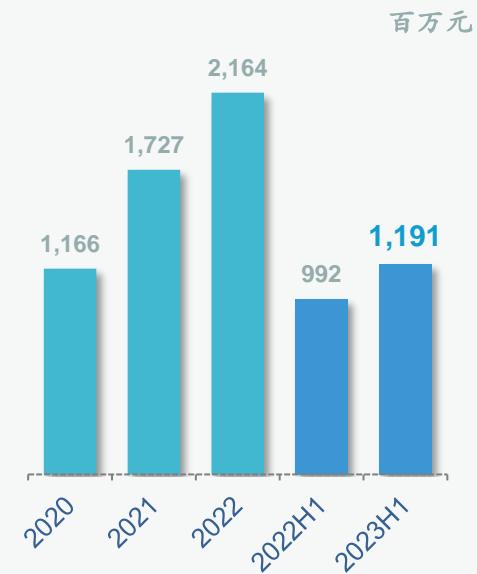
归属上市公司股东净利润

**1.4%** YOY



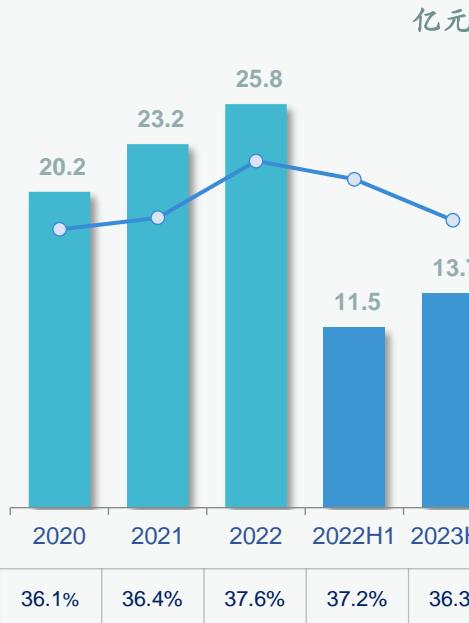
正常化归母净利润

**20.1%** YOY



# 费用率下降

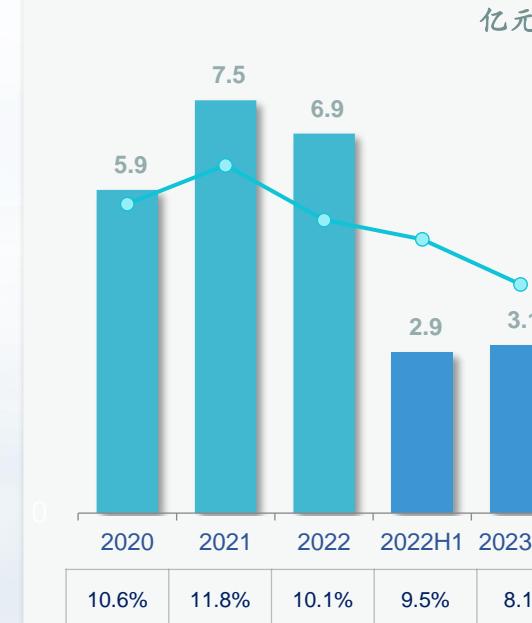
## 销售费用



销售费用率

36.1% 36.4% 37.6% 37.2% 36.3%

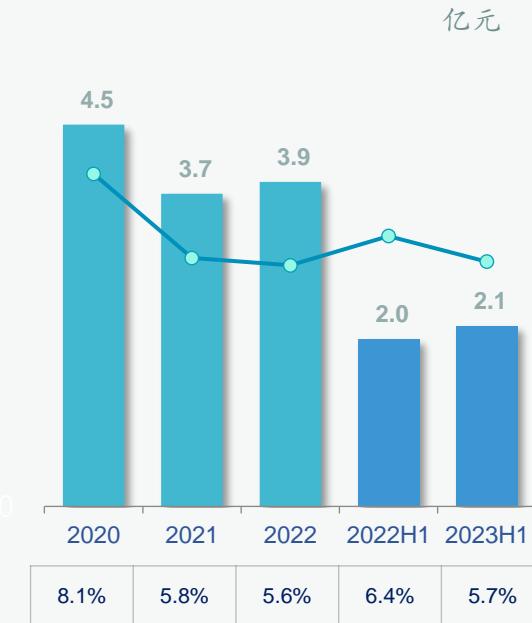
## 研发费用



研发费用率

10.6% 11.8% 10.1% 9.5% 8.1%

## 管理费用



管理费用率

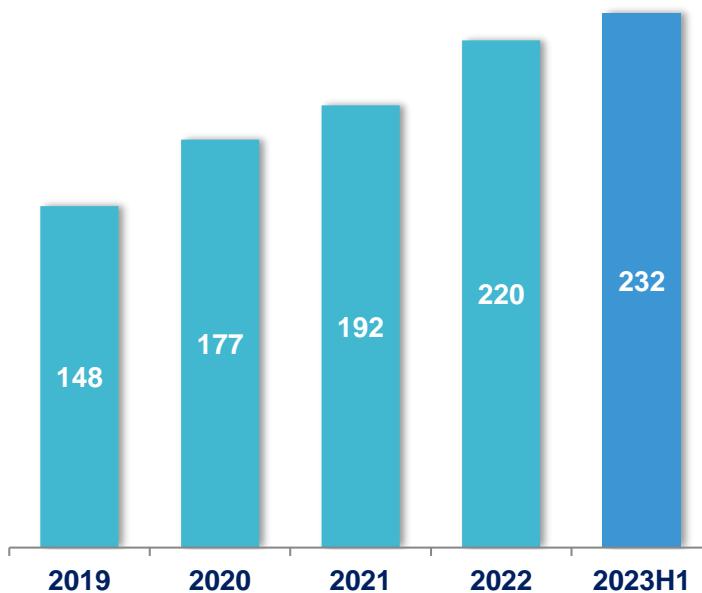
8.1% 5.8% 5.6% 6.4% 5.7%

# 资产结构保持稳定



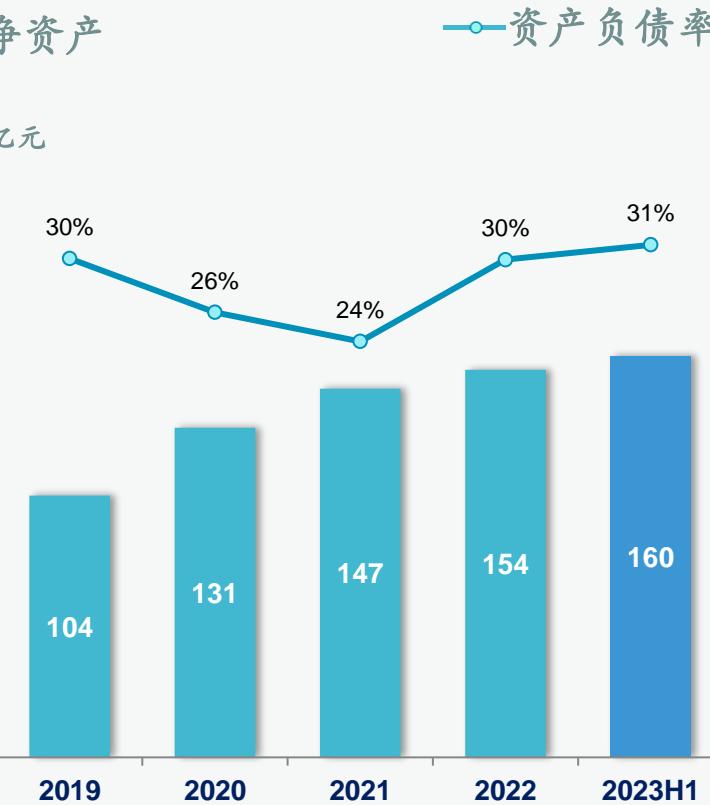
总资产

亿元



净资产

亿元



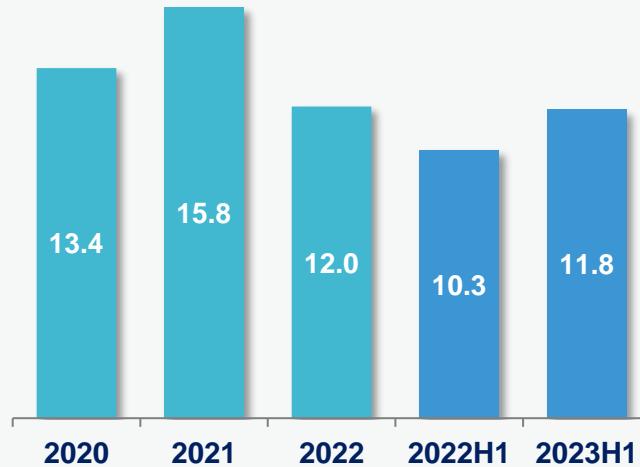
# 现金流情况优秀，现金资产储备充裕



经营性现金流净额

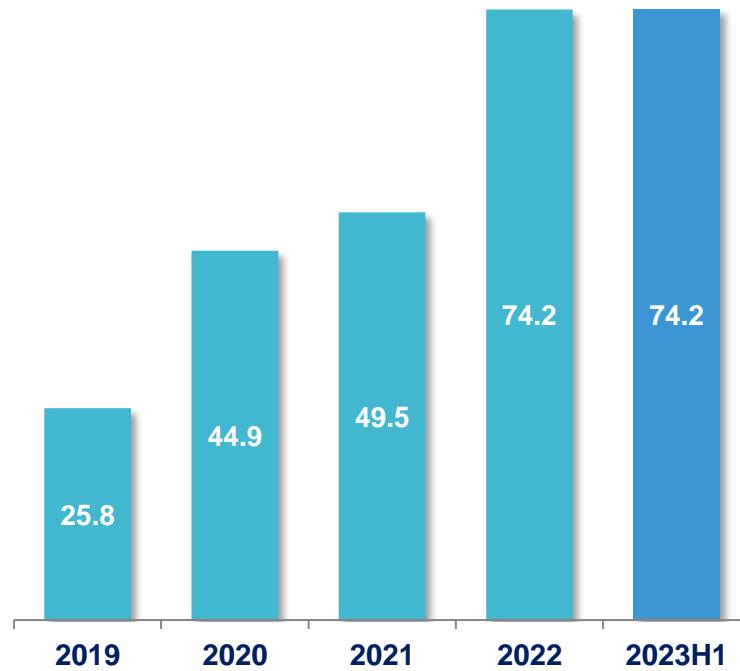
15.3% YOY

亿元



资金存量

亿元



# 收益具有显著吸引力



每股收益 (人民币)

**2.6% YOY**

元人民币



净资产收益率(ROE)



# 持续稳健增长，坚持股东回馈



归属股东净利润  
5年CAGR 10.7%

## 业绩稳健

持续向股东交付稳健增长的业绩

SUSTAINABLE

特比澳

## 独家品种

顺利续约，增长潜力可期

EXCLUSIVE

赛普汀

## 一线用药

临床认可提升，打开增长瓶颈，跻身抗体类肿瘤药销售额TOP20

PROFESSIONAL

蔓迪

## 第一品牌

渗透率提升，高增长持续，皮肤毛发领域不断拓展

UNIQUE

研发

## 新药上市

2023上半年3款新药陆续上市；预计未来每年均有1-2个重磅新药上市

PROMISING

### 分红派息



- 稳健的盈利水平支持可持续的派息政策
- 支付2022年股息**0.1HKD**每股，对应股息率**1.4%**

### CB 回购



- 累计赎回可转债全部发行金额**3.2亿**欧元
- 消除股本稀释风险



业绩亮点

管理层团队

业务概况

财务回顾

新药研发



# THANKS

**3SBio Inc. (1530.HK)**  
**Investor Relations**  
**ir@3sbio.com**

珍爱生命 · 关注生存 · 创造生活  
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