三生制药
3SBIO INC.

2019年度业绩公告

2020年3月31日

珍爱生命／关注生存／创造生活
CHERISH LIFE CARE FOR LIFE CREATE LIFE

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2019年度业绩主要亮点

研发

302H（赛普汀）	完成技术审查、临床试验数据和生产现场核查
301S（益赛普预充针）	完成NDA申请
健尼哌（抗CD20抗体）	获得 GMP 证书，开始市场销售
609A（抗PD1抗体）	分别获FDA、NMPA临床试验批准
608（抗IL17抗体）	获得NMPA临床试验批准
Remitch (TRK-820)	获NMPA临床试验批准
SSS17（HIF-PH抑制剂）	获得NMPA临床试验批准

合作

SAMSUNG BIOEPIS · tlc · verseau · NUMAB Drug Innovators · GenSight BIOLOGICS · Sensorion · MPM Powering Breakthroughs in Life Sciences · Dana-Farber Cancer Institute

营销

- **新版医保**新增覆盖：适诺；益赛普新增成人重度斑块状银屑病适应症；益比奥/赛博尔新增非骨髓恶性肿瘤化疗引起的贫血适应症；优泌林NPH由乙类调整为甲类
- **医保谈判**：百泌达谈判成功，进入医保谈判目录
- 特比澳的销售突破20亿，排名从 2018 年的 49 位攀升至 2019 年第 15 位[1]
- 蔓迪销售取得强势增长，达到2.5亿，同比增长96.6%

财务

- 销售收入达到**5,318.1百万元**，同比增长**16.0%**
- 毛利达到**4,392.7百万元**，同比增长**18.5%**
- 研发费用增长**45.2%**，达到**526.6百万元**
- 母公司拥有人应占正常化纯利达到**1,392.3百万元**，同比增长**19.4%**
- 经营业务产生现金流量净额**1,887.4百万元**，同比增长**64.1%**
- 杠杆比率（不包括债券）由2018年的11.2%下降至**4.8%**

1 数据来源：IQVIA

医药改革全面铺开，继续鼓励创新

- 继续鼓励创新药的研发和销售
- 提升仿制品种质量，规范市场竞争

新药申报继续提速[1]

- 2019年 CDE 受理申请合计7,506件，同比增长13%。其中受理生物制品1078年，同比增长23%
- 新药上市申请177件，同比增长25%
- 新药上市申请平均批准时间427天，同比减少50%
- 国产新药的上市申请100%纳入了优先审评

医保目录更新

- 2019年8月，新版医保目录公布，新增品种148个，新增品种向肿瘤、慢性病、儿童用药等重点品种倾斜。“重点监控品种”全部被调出目录
- 2019年11月，新版医保准入谈判结束，97个药品谈判成功。根据医药魔方的统计，2018年国家批准上市的53种新药，有约20种进入了谈判目录。

《药品管理法》实施

- 2019年8月26日，新版《中华人民共和国药品管理法》获通过，于同年12月1日正式生效。
- 新的《药品管理法》将药品的加速审批上市、对创新药的鼓励、药品质量安全等以法律形式明确下来。
- 作为具体实施法规，NMPA也发布了《药品注册管理办法》的征求意见稿，明确了对创新药加速审评的细则

药品集中采购工作深化

- 从2018年开始开展的“4+7”城市药品集中采购工作，共25个中标品种，价格平均降幅为52%。最高降幅96%
- 2019年由国家医保局等部门联合推出的新一轮集中采购工作，将纳入更多的试点地区和更多的品种

1 数据来源：医药魔方统计

2019年研发进展

产品名称	靶点	进展
302H （伊尼妥单抗）	HER2	• 已完成技术审查、临床数据核查和生产检查
301S（益赛普预充针）	TNFα	• 生产申请被受理，CDE审评中
健尼哌	CD25	• 获得 GMP 证书，已开始市场销售
304R（健妥昔）	CD20	• 头对头（美罗华）对比的一期临床完成，三期临床核查
特比澳	MplR	• 儿童ITP三期临床进行中 • 血小板减少风险的肝功能障碍患者围手术期动员一期
SSS06	Long Acting EPO	• 多个一期完成，开始二期入组
RD001	PEG-EPO	• 一期完成，正在筹备二期入组
SSS07	TNFα	• 一期完成，正在筹备二期
602	EGFR	• 两项一期完成，正在筹备结直肠癌的后期临床
601A	VEGF	• AMD Ib 入组，DME I/Ib 期入组
SSS11	Uric acid	• 一期入组
608	IL-17A	• 一期入组
609A	PD1	• 获得NMPA 临床批件，筹备一期入组 • 获得 FDA临床批件，美国一期患者入组顺利
TRK-820 （Remitch）	κ-opioid	• 获得临床批件，筹备病人入组
SSS17	HIF-PHI	• 获得临床批件，筹备一期入组
VTX-0811	PSGL-1	• 获得授权

重要研发合作活动

verseau

NUMAB Drug Innovators

tlc

SAMSUNG BIOEPIS

GenSight BIOLOGICS

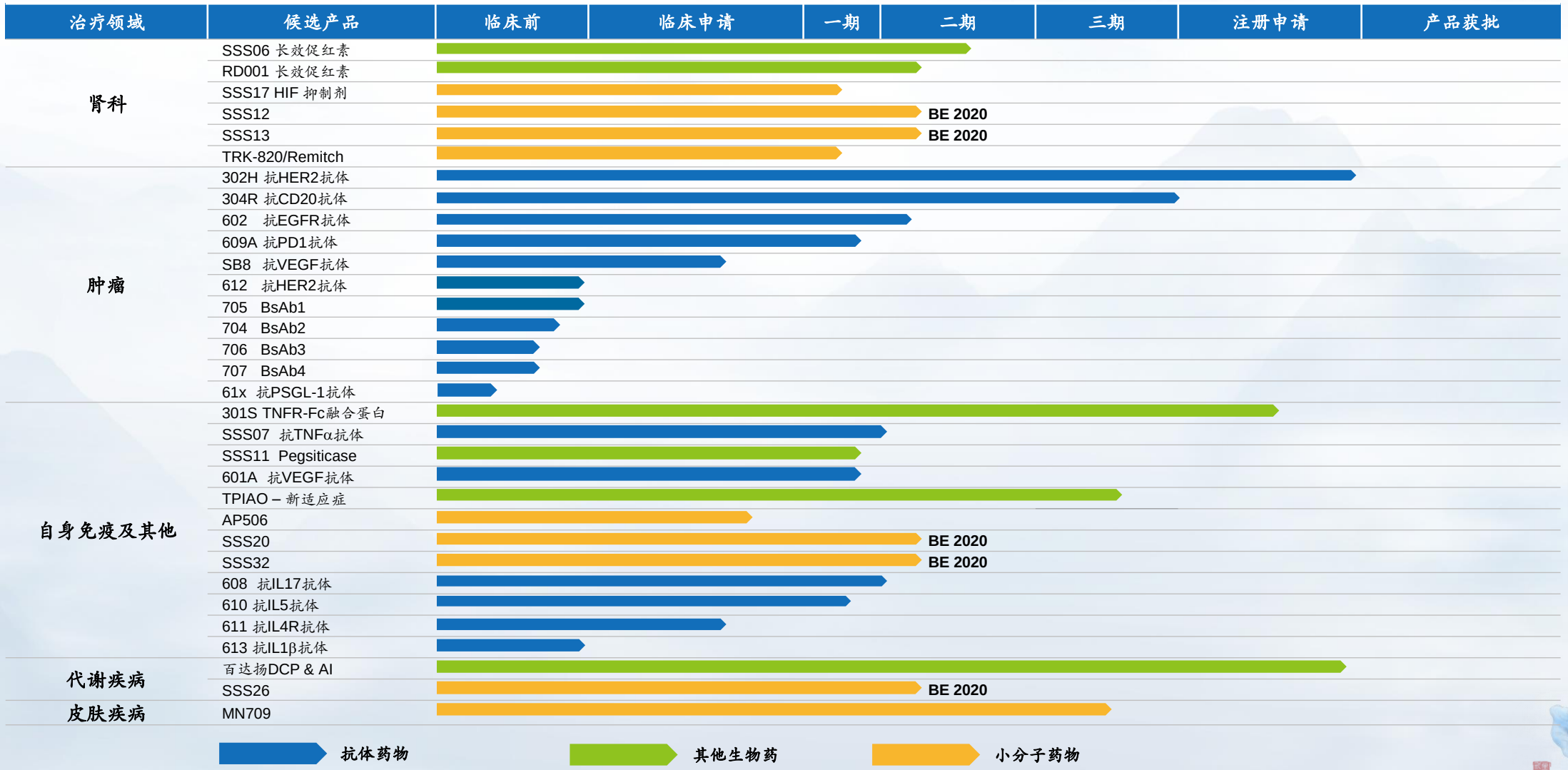
Sensorion

MPM Powering Breakthroughs in Life Sciences

Dana-Farber Cancer Institute

阵容强大的创新在研产品线

32 种在研产品，其中 22 种国家新药



肾科和自身免疫病及其他疾病治疗的生物药产品管线

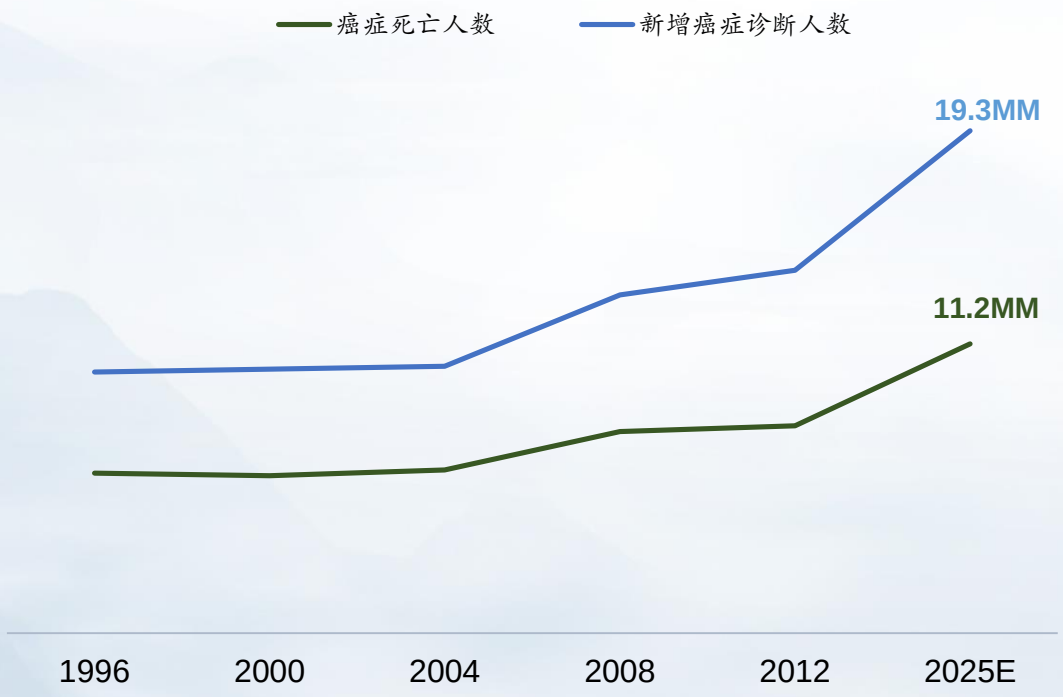
产品	靶点	适应证	临床前	临床申请	一期	二期	三期	上市申请	新药注册
301S	TNFα	类风湿性关节炎，强直性脊柱炎，银屑病							
SSS07	TNFα	类风湿性关节炎，强直性脊柱炎，溃疡性结肠炎							
608	IL17A	银屑病，银屑病关节炎，强直性脊柱炎							
610	IL5	哮喘，慢性阻塞性肺病							
611	IL4R	特应性皮炎，哮喘							
613	IL1β	多种自身免疫性疾病							
SBxx	XX	骨科疾病							
601A	VEGF	眼科疾病（AMD/DME等）							
SSS11	Uric Acid	高尿酸血症，顽固性痛风							
SSS06	EopR	肾性贫血							
RD01	EopR	肾性贫血							

癌症治疗领域的生物药管线

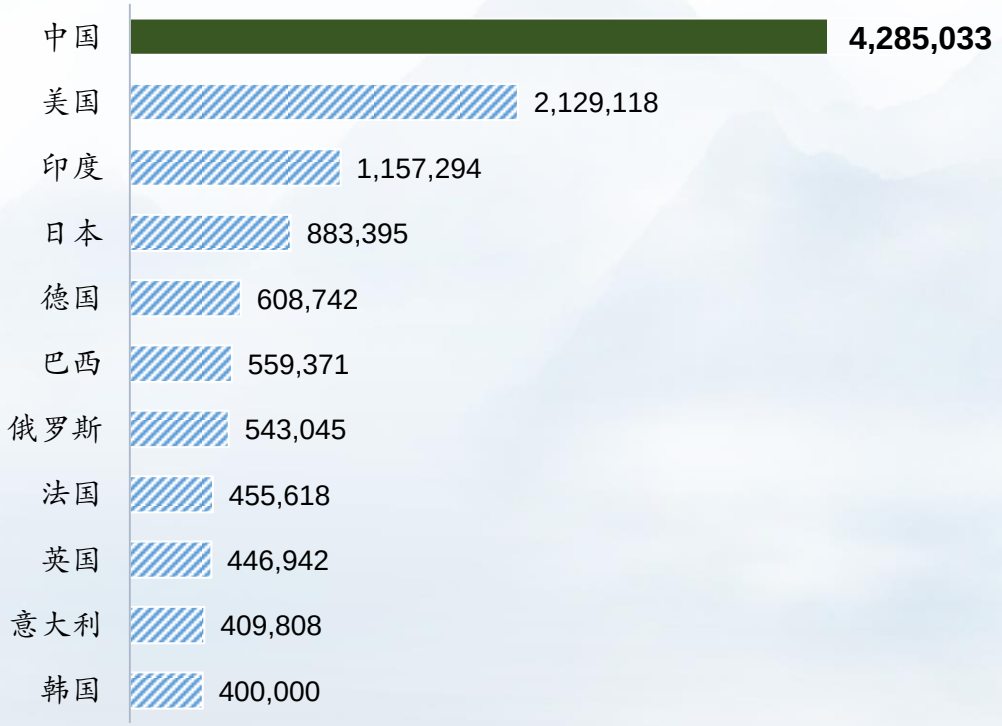
产品	靶点	适应证	临床前	临床申请	一期	二期	三期	上市申请	新药注册
302H	HER2	乳腺癌							
304R	CD20	非霍奇金淋巴瘤							
602	EGFR	结直肠癌							
609A	PD1	非小细胞肺癌，胃癌，肝癌							
SB8 (615)	VEGF	多种肿瘤							
612	HER2	乳腺癌，胃癌							
705	BsAb1	多种肿瘤							
704	BsAb2	多种肿瘤							
706	BsAb3	多种肿瘤							
707	BsAb4	多种肿瘤							
61x	PSGL-1	多种肿瘤							

全球及中国日益增长的癌症病人数量

日益增长的癌症发病和死亡人数



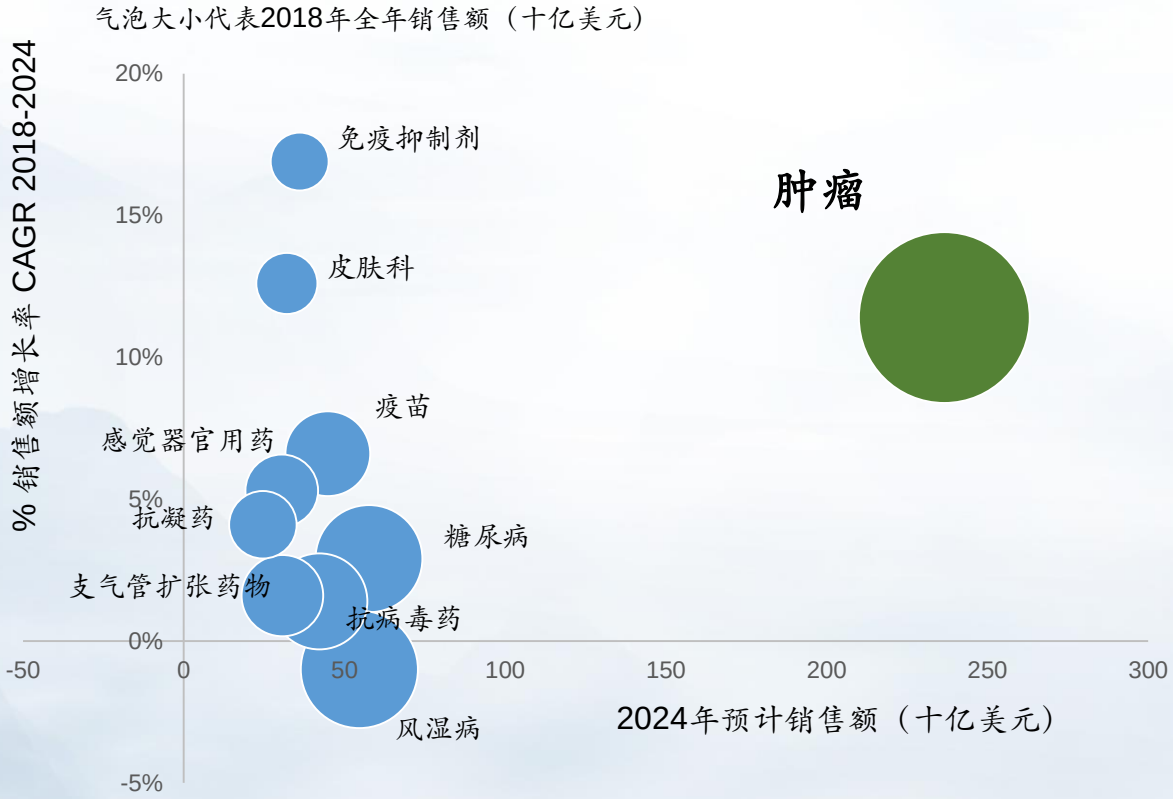
2018年各国新增癌症病人数预测



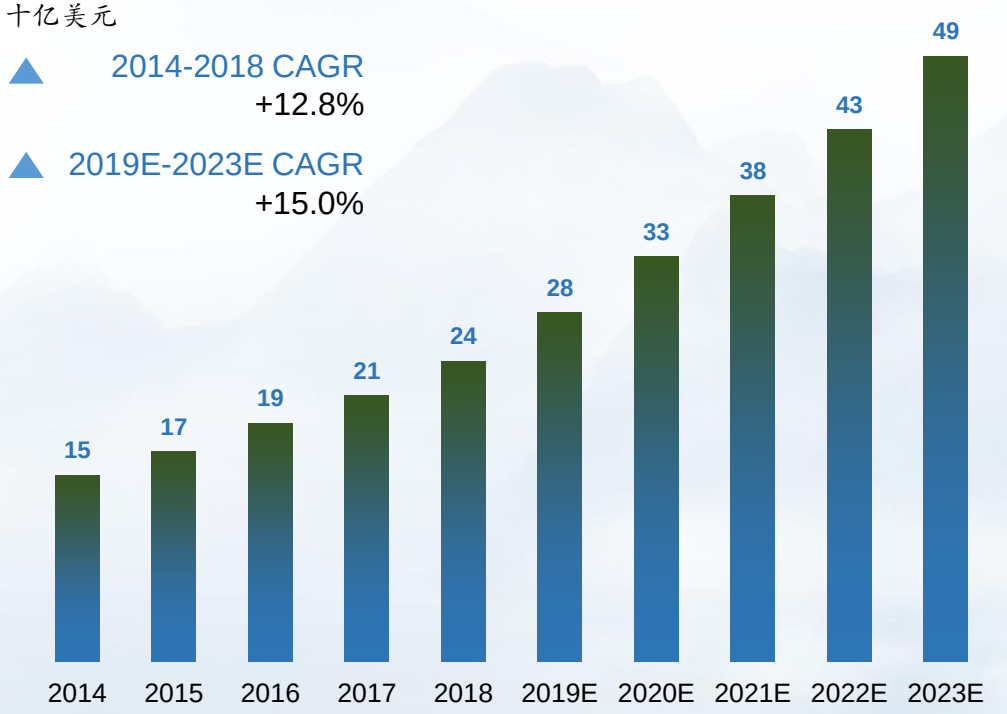
*数据来源：WHO, GLOBOCAN

全球及中国日益增长的癌症治疗药物市场

全球肿瘤市场销售额的日益增长



2014-2023年中国肿瘤市场



*数据来源： EvaluatePharma, Frost & Sullivan

全球及中国排名前十位的肿瘤药物

2019年全球前十位肿瘤用药排名

通用名	2019年销售额 (十亿美元)
Pembrolizumab	11.3
Lenalidomide	9.4
Nivolumab	8.6
Ibrutinib	8.1
Bevacizumab	7.2
Rituximab	6.6
Trastuzumab	6.2
Denosumab	5.0
Palbociclib	5.0
Enzalutamide	4.3

2019年国内前十位肿瘤用药排名

通用名	2019年样本医院销售额 (十亿元人民币)
紫杉醇	3.1
曲妥珠单抗	1.9
培美曲塞	1.6
贝伐珠单抗	1.6
利妥昔单抗	1.4
多西他赛	1.3
替吉奥	1.3
奥沙利铂	1.2
卡培他滨	1.0
奥希替尼	1.0

*数据来源：GlobalData, PDB

成熟靶点的广泛覆盖及下一代治疗手段的超前布局

4大研发中心，超过380名经验丰富的科学家团队


沈阳研发中心－生物药/化学药


上海研发中心 － 生物药


深圳研发中心 － 生物药


杭州研发中心 － 化学药

已覆盖肿瘤重要成熟靶点

- HER2
- CD20
- EGFR
- PD1
- VEGF
- PSGL-1

下一代肿瘤免疫治疗手段的超前布局

- 巨噬细胞靶向免疫疗法
- 编程CAR-T细胞疗法
- 多特异性抗体
- 双特异性抗体

综合性国际战略合作伙伴关系

成熟产品和技术平台

- AstraZeneca：GLP-1系列产品在中国的独家商业推广许可
- Lilly：胰岛素系列产品分销和推广的独家许可
- tlc：NanoX™ 技术的脂质体产品在中国大陆的商业推广
- TORAY：在中国开发和商业推广Remitch的独家权利
- SAMSUNG BIOEPIS：多项生物类似药的临床开发和商业推广合作

创新产品和技术平台

- REFUGE biotech：编程CAR-T细胞治疗方法的合作研究和商业推广
- verseau：巨噬细胞检查点调节剂的开发和商业推广
- GenSight BIOLOGICS：两项眼科相关疾病产品的潜在许可或开发的优先选择权
- NUMAB Drug Innovators：肿瘤领域的双特异和多特异抗体产品开发和商业推广
- MPM Powering Breakthroughs in Life Sciences / Dana-Farber Cancer Institute：投资于早期癌症药物研究和开发
- Sensorion：四种内耳疾病相关在研产品的潜在许可优先购买权

2020-2022年研发产品线展望

上市批准 (2020-2021)	• 302H (H1 2020) • 301S (H1 2021)
注册临床试验的启动 (2020-2021)	• SB8 • TRK-820 • 特比澳[1] • MN709 • 304R [2] • 601A [3]
II - III 期临床 (2020-2022)	• SSS06 • 608 • RD01 • 609A • 602 • 601A [4]
I-II期 临床 (2020-2022)	• 610 • 613 • 611 • 705 • 612 • SBxx

新的 IND 申请 / I 期临床 (2020-2022)	• 10-15 个新的抗体和双特异性抗体的 IND申报 (中美双报)
仿制药一致性评价 (2020-2021)	自身免疫和炎症疾病 • SSS20 • SSS32 • AP506 • TK805 肾科 • SSS12 • SSS34 • SSS13 • SSS38
上市申请提交 (2021-2022)	• 特比澳[1] (2021) • TRK-820 (2021) • MN709 (2021) • SSS12 (2021) • SSS13 (2021) • SSS20 (2021) • SSS32 (2021) • TK805 (2021) • SB8 (2022) • SSS34 (2022) • SSS38 (2022) • AP506 (2022) • 601A (2023) • 304R (2023)

*注
1：儿科免疫性血小板减少的适应症
2：肿瘤 (NHL) 及自身免疫疾病适应症
3：老年视网膜黄斑病变 (AMD)
4：糖尿病导致视网膜黄斑水肿 (DME)

遵循国际质量标准的战略性规模化的综合生产能力

- 10个剂型产线全部通过新版GMP认证
- 质量人员占基地生产人员总数的20%以上
- 总经理拥有超过10年的药品研发生产和质量控制经验

- 通过乌克兰、巴西、墨西哥等国家的生产认证
- 质量人员占基地生产人员总数的20%以上
- 质量总监拥有超过20年的药品生产与质量控制经验，曾在跨国企业担任领导职位，参与了国家医药指南和规范的编纂工作

- 服务Mylan和赛诺菲等世界知名企业
- 质量人员占基地生产人员总数的近40%
- 意大利生产线通过欧盟GMP认证

- 原有和新建产线于2013年和2016年全部通过GMP认证
- 质量人员占基地生产人员总数的20%以上
- 质量总监拥有超过十年的药品研发、生产和质量控制经验

- 通过哥伦比亚、巴西、墨西哥、乌克兰等国家的生产认证
- 通过欧盟QP审计
- 质量人员占基地生产人员总数的20%以上
- 质量总监拥有超过三十年的药品研发、生产和质量控制经验。

完整的细胞表达系统和充足的生产能力

	表达系统			现有生产能力
	原核细胞	真核细胞	化学药	
 沈阳生产基地	★	★		注射剂年产能5,000万支，按照欧盟标准建造和生产
 上海生产基地		★		超38,000升的抗体药物商业化生产基地，在国内大分子制药公司中产能排名第一位
 深圳生产基地		★	★	注射剂年产能4,000万支
 杭州生产基地			★	年产能片剂5亿片，硬胶囊剂2,500万粒，注射剂6,200万支，软膏、乳膏剂1,000万支，酊剂、喷雾剂560万瓶
 意大利生产基地	小容量注射剂（包括水针和冻干粉针）的制剂CMO, 通过欧盟标准认证的厂房，为 Mylan, UCB等企业提供CMO服务			

核心产品收入稳定增长

	2015	2016	2017	2018	2019	市占率 (%)[1]
特比澳	605	765	975	1,670	**2,323**	73.2
益赛普[2]	842	925	1,013	1,111	**1,144**	60.9
益比奥/赛博尔	727	773	855	897	**749**	41.6
蔓迪	24	65	94	127	**250**	66.3

*注：
1 特比澳，益赛普，EPO 产品来自于IQVIA 2019MAT，蔓迪来自于 CPA
2 益赛普于2016年4月1日起并表

在2019年国家医保目录中新增产品及适应症覆盖

丙酸氟替卡松乳膏（适诺）	新增医保品种，用于治疗多种皮肤疾病
重组人II型肿瘤坏死因子受体-抗体融合蛋白（益赛普）	新增“成人重度斑块状银屑病”适应症的覆盖
重组人促红素（益比奥/赛博尔）	新增“非骨髓恶性肿瘤化疗引起的贫血”适应症的覆盖
精蛋白锌重组人胰岛素（优泌林 NPH）	由医保乙类调整为医保甲类
艾塞那肽（百泌达）	谈判成功，进入医保谈判目录

强大的营销能力和遍及全国的营销网络

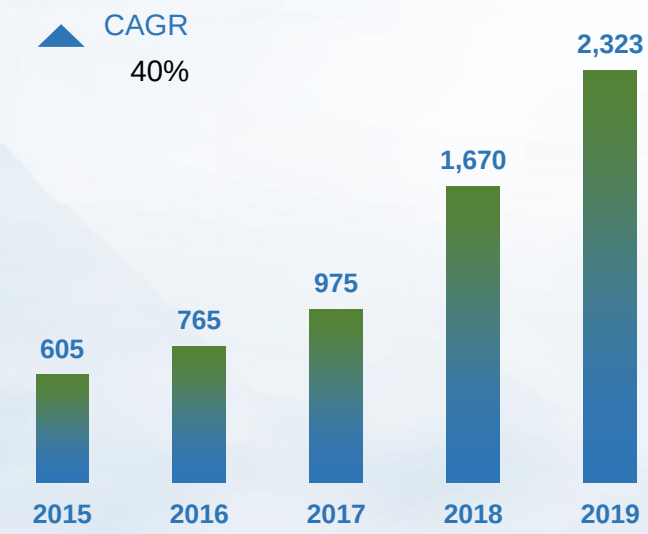
- 经过近 **30** 年市场验证的卓越营销团队
- 覆盖国内**所有的**省、自治区、直辖市
- **3,372** 名营销人员， **660** 名分销商以及 **2,079** 第三方推广商组成的庞大销售及分销网络
- 覆盖超过 **2,000** 家三级医院
- 覆盖超过 **14,000** 家二级医院或较低层级医院及医疗机构

具有重大增长潜力的市场领先产品

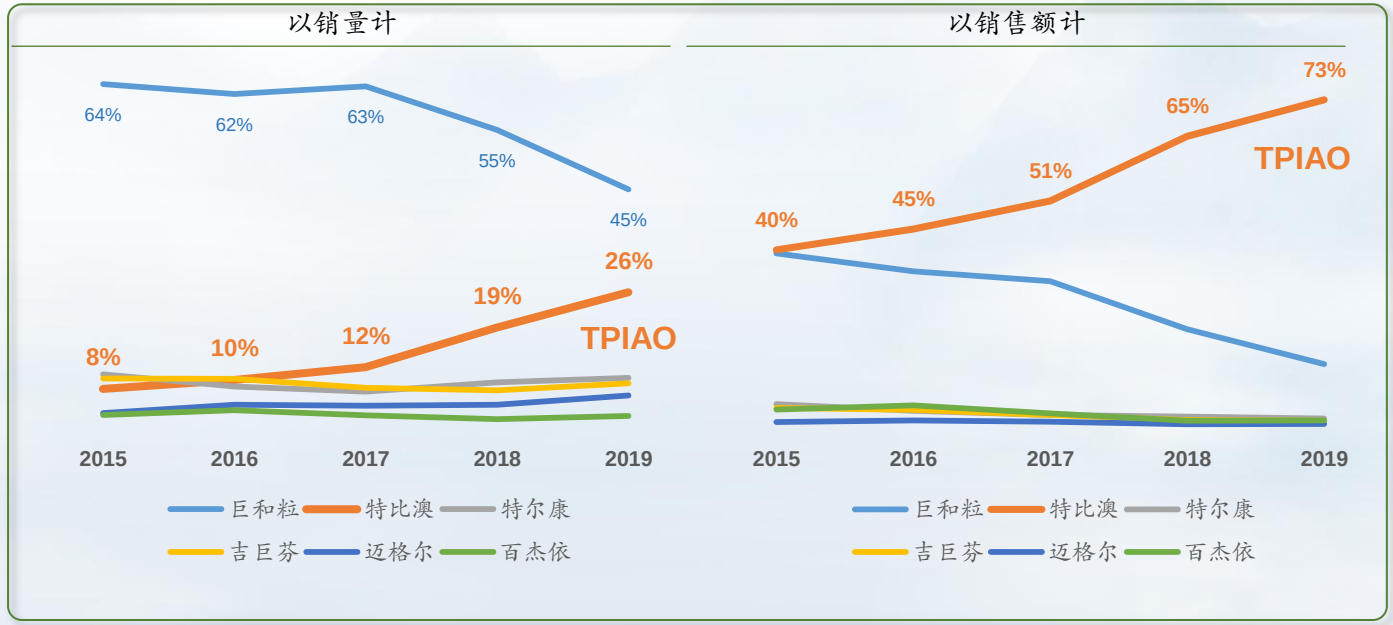
特比澳

- 自发研发的首个上市和全球唯一商业化的rhTPO产品
- 市场渗透率依然较低，未来增长潜力巨大
- 通过儿科及肝病适应症的拓展提高覆盖
- 布局小分子产品，提高在适应症领域内的协同性

销售额年均40%的强势增长



低市场渗透率，未来前景可期



*数据来源： IQVIA

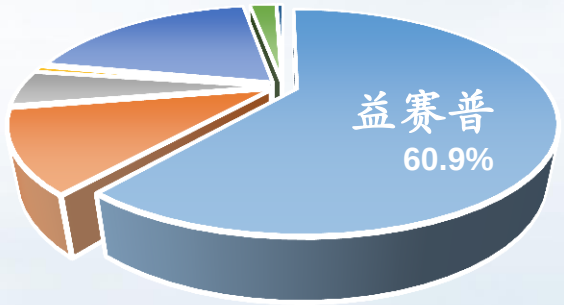
具有重大增长潜力的市场领先产品（续）

益赛普

- 中国市场**首个上市**的肿瘤坏死因子α抑制剂
- 在2019年国家医保目录中新增**成人重度斑块状银屑病适应症**的覆盖
- 5%-9%的渗透率
- 已向国家药监局申请益赛普**预充式注射剂**的生产批件并获得受理
- 申请如获批准，该产品应为国内药企肿瘤坏死因子α抑制剂产品中**唯一**的预充式剂型
- 已获得印度、泰国、菲律宾、墨西哥等**15个国家**的批准

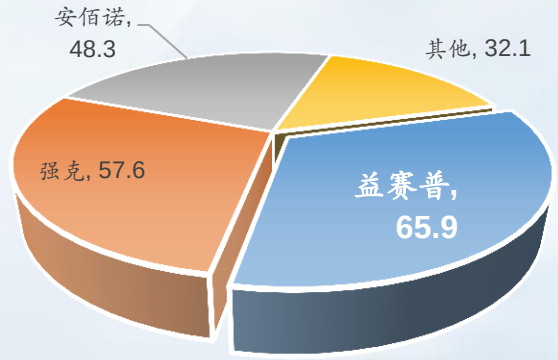
自上市以来一直处于同类产品领导地位

2019年抗肿瘤坏死因子领域销售额占有率[1]



对整个品类的增长贡献最大

2019年抗肿瘤坏死因子领域
销售额同比增长量[1]（单位：百万元）



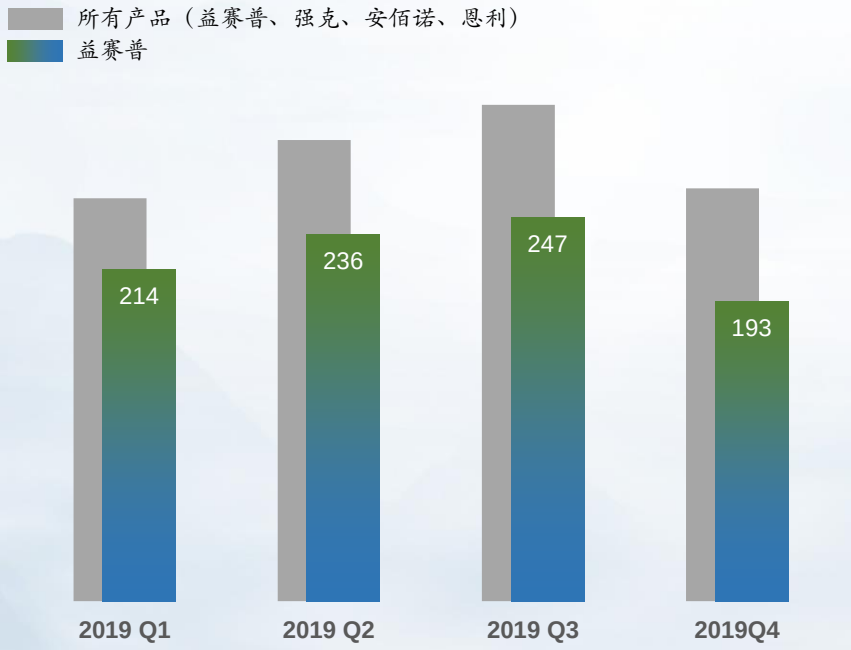
*数据来源：IQVIA

具有重大增长潜力的市场领先产品（续）

益赛普

价格承压，但增长潜力依然巨大

2019年融合蛋白类 TNFα 产品与益赛普销售金额 [1]



依那西普类产品与阿达木单抗类产品的比较

	依那西普类产品	阿达木单抗类产品
结核感染率 [2]	0.57/百人年 （44/7690 病人年）	1.62/百人年 （86/5317 病人年） P<0.0001
慢性严重肝脏损害导致住院率 [2]	0.39 /百人年	0.75 /百人年 p<0.0035
抗药抗体发生率[3]	0 %（200 病例）	31.2% （199 病例）
给药频率	每周2次 x 25mg	每两周一次 x 40mg
剂型	注射用粉针	预充式针剂
美国上市时间	1998年 （恩利）	2002年（修美乐）
中国上市时间	2005年 （益赛普）	2010年（修美乐）

1. *数据来源：IQVIA*
2. *Chiu YM., et al., A real world risk analysis of biological treatment (adalimumab and etanercept) in a country with a high prevalence of tuberculosis and chronic liver disease: a nationwide population-based study. Scand J Rheumatol., 46: 236-240. 2017.*
3. *2. Moots RJ, et al., The impact of anti-drug antibodies on drug concentration and clinical outcomes in rheumatoid arthritis patients treated with adalimumab, etanercept, or infliximab: Results from a multinational, read-world clinical practice, non-interventional study. PLoS One, 12 (4): e0175207， DOI：10.1371.*

具有重大增长潜力的市场领先产品（续）

益比奥和赛博尔

- 仍是国内唯一一家获得三种适应症的促红素品牌
- 自2002年起一直处于国内 rhEPO市场支配性领导地位

2019年出现负增长原因

- 2018年招标中多个省份价格下降在10%以上
- 更换规格

2020年以后

1. 2019年中标价格稳定，影响因素解除
2. 继续推进双品牌协同战略，保持价格稳定
3. 医保新增“非骨髓恶性肿瘤化疗引起的贫血”适应症的覆盖
4. 国内血液透析的渗透率仍低于其他国家，未来渗透率的提高将带来rhEPO使用的增长
5. 外科围手术期的红细胞动员以及肿瘤化疗引起的贫血适应症仍处于增长初期

未来将继续保持快速稳定的增长态势

具有重大增长潜力的市场领先产品（续）

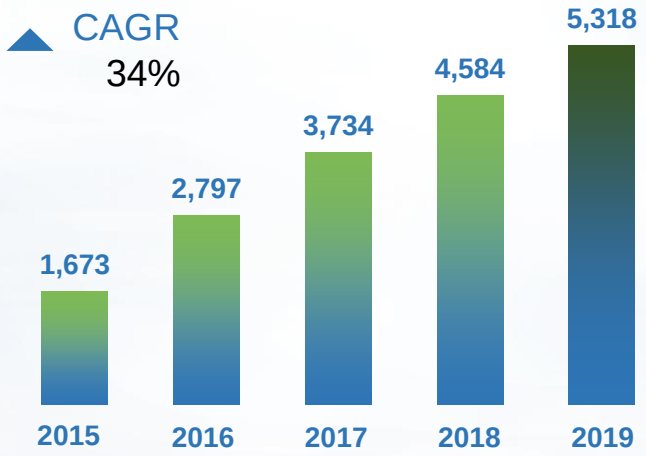
蔓迪（米诺地尔酊）

- 用于脱发治疗
- 唯一一种受到《中国雄激素性秃发诊疗指南》推荐的外用药物
- 近三年销售额强势增长，预期三年后销售额可达10亿元

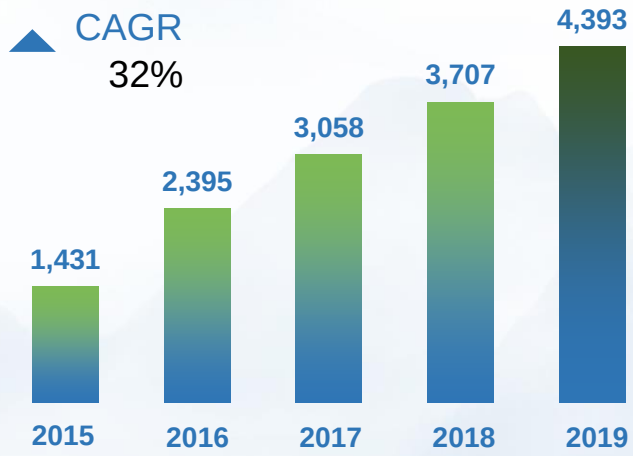
经营业绩的持续强劲增长

单位：百万元人民币

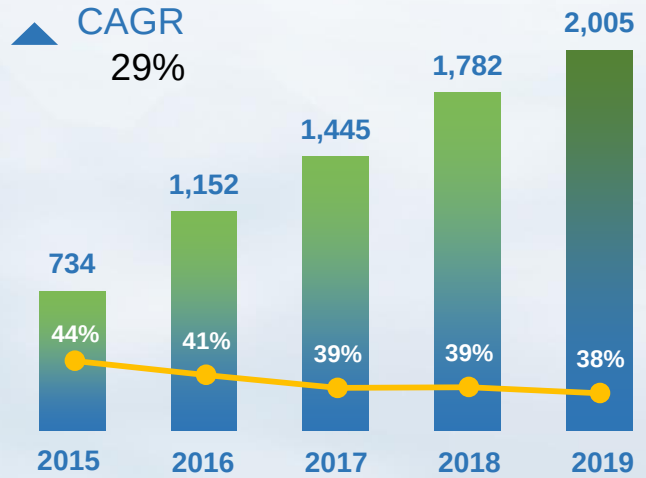
收入



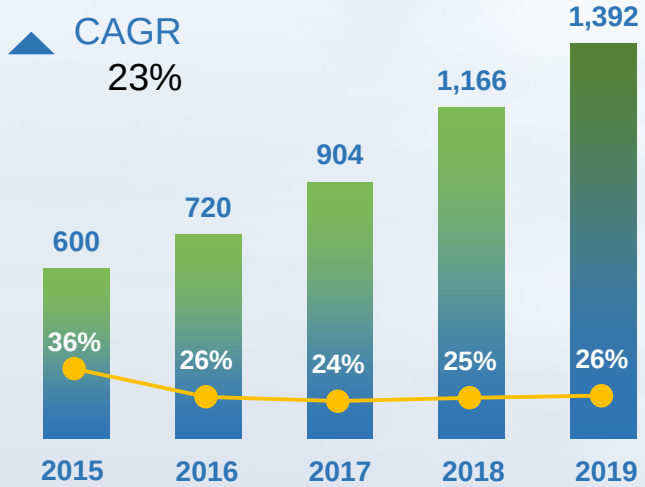
毛利



正常化 EBITDA



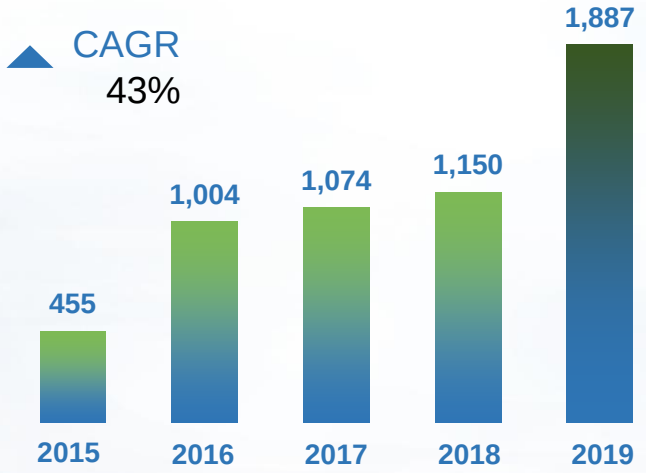
母公司拥有人应占正常化净利润



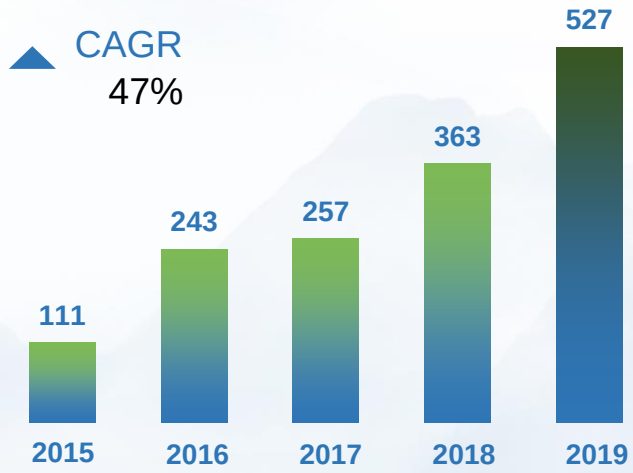
卓越的运营管理能力

单位：百万元人民币

经营业务产生现金流量净额



研发费用

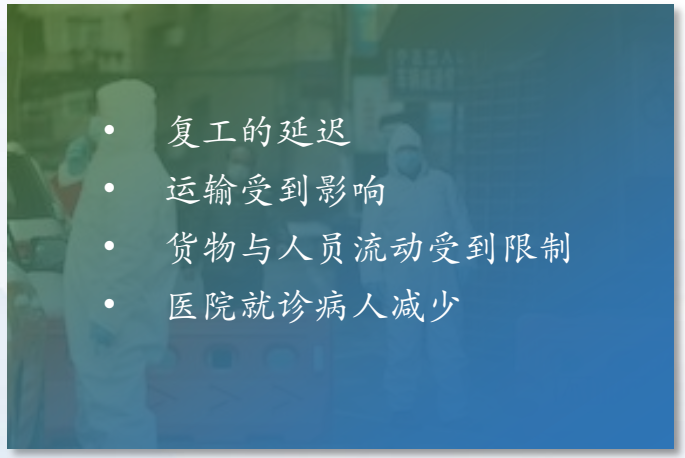


销售费用

财务费用

新型冠状病毒肺炎的影响

疫情影响



- 复工的延迟
- 运输受到影响
- 货物与人员流动受到限制
- 医院就诊病人减少

对公司的风险挑战

- 对生产和研发基本无影响
- 对某些产品的销售产生影响，且恢复需要时间

公司应对

- 密切跟踪和审慎分析疫情带来的风险
- 缩减开支，聚焦重点，保持稳健充足的现金流

展望

运营	✤ 各项经营指标及各主要产品收入继续保持稳定增长
新产品	✤ 新产品上市 (赛普汀、益赛普预充式水针等)
研发	✤ 加大研发投入，继续加快推进临床试验及新品种的临床申请
对外合作	✤ 继续开展BD合作和品种引进
生产	✤ 继续扩大生产能力

公司战略

目标愿景	立足中国的全球领先生物制药企业
定位	创新的生物制药和核心产品组合
聚焦领域	肿瘤、自身免疫、肾科、代谢、皮肤科
四大平台	研发平台、生产制造平台、营销平台、投资合作平台

THANKS

珍 爱 生 命 · 关 注 生 存 · 创 造 生 活

CHERISH LIFE CARE FOR LIFE CREATE LIFE