



沛嘉医疗创新与国际化展望

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中国市场给创新医疗器械企业提供了前所未有的发展机遇

✓ 市场大

- 老龄化，患者数量增长迅速
- 医疗机构数量增加
- 国家政策支持

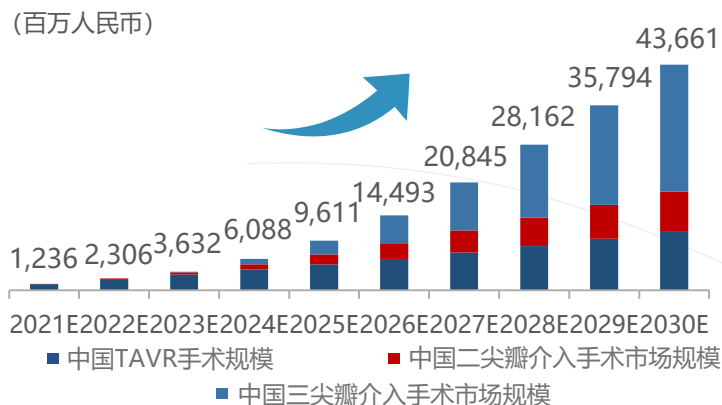
✓ 前所未有的机遇

- 资本市场的支持
- 创新产品层出不穷
- 知识结构升级和海外人才回归带来医疗行业人才和工程师红利
- 国际合作机会广泛



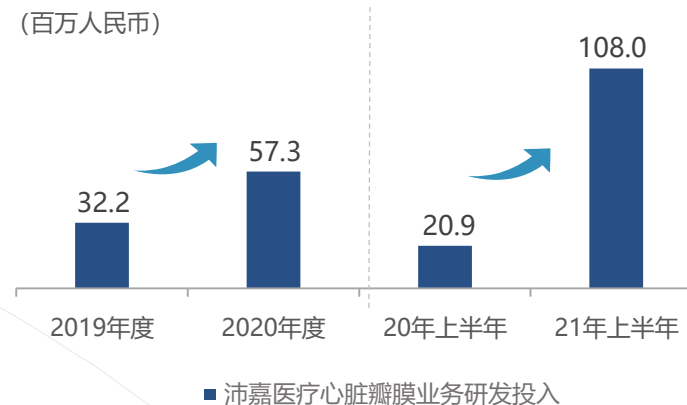
心脏瓣膜病是中国创新医疗器械领域的黄金赛道

- 心脏疾病是仅次于恶性肿瘤的**第二大死亡类型**¹
- 主动脉瓣、二尖瓣、三尖瓣病患市场巨大，有望在未来十年成长为**数百亿级**的市场²



研发投入成为创新医疗器械企业占据制高点的关键

- 头部药企研发投入五年间从十亿人民币到十亿美金。创新带来了中国药企的腾飞，医疗器械公司也将不断加码研发
- 沛嘉医疗致力于推动心脏瓣膜领域国产替代和自有技术的创新和升级，积极布局海外知识产权，探索全球化发展路径



资料来源:

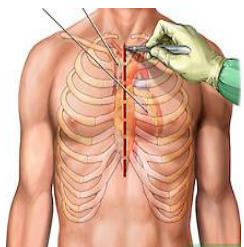
1. 国家卫计委, 世界卫生组织, 中国卫生健康年鉴2020, 弗若斯特沙利文分析

2. 市场规模数据来自弗若斯特沙利文行业研究报告

至善尽心 敬畏生命

已有治疗方式

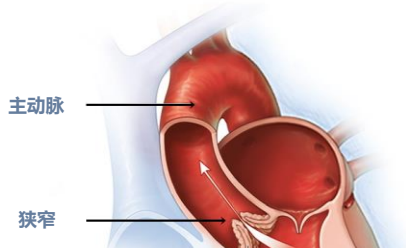
未来研究方向



笼球式机械瓣主动脉瓣置换以及二尖瓣置换获得成功，标志着心脏瓣膜外科手术基本成熟

外科手术

1960



Alain Cribier博士完成了首例经导管主动脉瓣置换术

介入主动脉瓣置换

2002第一台手术
2011年FDA批准



MitraClip技术应用于二尖瓣反流的临床治疗中

介入二尖瓣修复

2003年第一台手术
2013年FDA批准

介入非植入方案

更耐久的瓣膜材料

二尖瓣置换（经导管）

三尖瓣修复/置换

主动脉瓣反流

- 无植入物方案优于植入方案

- 实现瓣膜的长效性
- 生物干瓣、高分子瓣等

- 较修复治疗可能更长久有效
- 技术上的珠穆朗玛峰

- 从“被遗忘的瓣膜”到近期全球研发热点与独特的挑战

- 纯反流病人尚未有特别成熟的介入治疗方案

未来可期



- 在二尖瓣、三尖瓣、反流瓣、非植入技术和创新瓣膜处理技术方面均有布局

提高人体植入后的耐久性 是瓣膜材料创新的重要方向

- 提高生物瓣膜的耐久性是改善患者生活质量和推广瓣膜介入手术的关键。随着人均寿命的延长和退行性心脏瓣膜病发病率不断提高，寻找更合适的瓣膜材料一直是心脏瓣膜领域的研究热点
- 非戊二醛处理的生物瓣有望大幅提高瓣膜寿命，而高分子瓣膜则可能摆脱生物源材料的多项缺点

金属瓣膜时代

生物瓣膜时代

高分子瓣膜时代



1952
第一例机械瓣膜植入用于治疗主动脉瓣反流患者

机械瓣

- 由耐用材料制成，如碳，钛，特氟龙，聚酯和涤纶
- 需稀释药物来预防血液凝固



1972s
Hancock猪心包瓣膜是第一个市售的生物心脏瓣膜

猪心包瓣膜

- 与机械瓣相比，生物相容性增强，抗凝药物使用减少
- 采用戊二醛交联技术



1980s ~ 1990s
牛心包瓣膜最早出现于1976年，直到后来才被广泛应用

牛心包瓣膜

传统牛心包处理技术

- 采用戊二醛交联技术
- 相对于猪心包更厚¹更耐用²
- 更少发生并发症²
- 在血液动力学方面有更好的表现²
- 但醛基易导致瓣膜钙化，缩短瓣膜寿命

“非醛交联”技术

- 使用即用型干燥TAVR瓣作为材料
- 将开发减少或完全消除戊二醛使用的新技术，可有效抵抗瓣膜钙化

高分子瓣膜在手术瓣膜的临床已经开展，预期介入瓣膜也会跟进

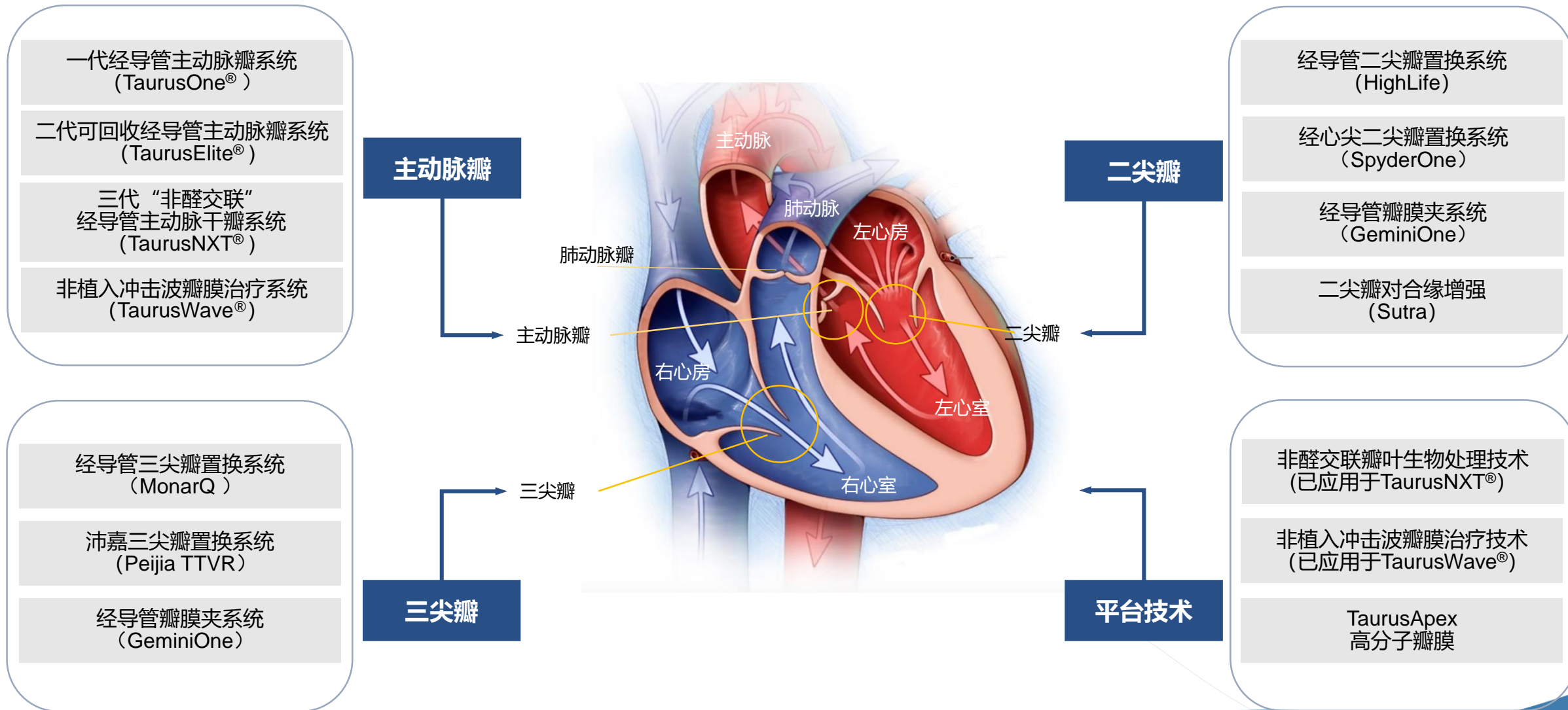
下一代人工瓣膜

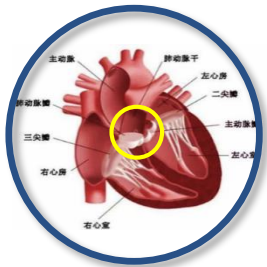




- 高分子瓣膜或可提高物理韧性，且具有更优的抗钙化能力，能大幅提高耐久性
- 如能进一步减少人造瓣叶厚度，有望进一步缩小器械的尺寸

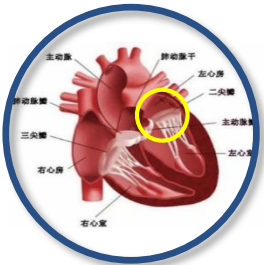


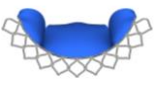

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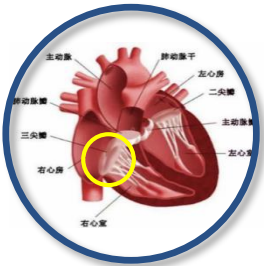





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- Yap, K. H., Murphy, R., Devbhandari, M., & Venkateswaran, R. (2012). Aortic valve replacement: is porcine or bovine valve better?. Interactive cardiovascular and thoracic surgery, 16(3), 361-373.

沛嘉医疗在心脏瓣膜病领域的产品管线布局



领域	产品名称	进度	产品特色	
<div data-bbox="104 301 369 565">  </div> <div data-bbox="63 743 206 1100" style="writing-mode: vertical-rl; background-color: #0056b3; color: white; padding: 10px; text-align: center;">主动脉瓣</div> <div data-bbox="295 579 677 736" style="background-color: #0056b3; color: white; padding: 10px; text-align: center; margin: 10px 0;">置换</div> <div data-bbox="295 1100 677 1258" style="background-color: #0056b3; color: white; padding: 10px; text-align: center; margin: 10px 0;">修复</div>	<div data-bbox="792 334 1245 486" style="background-color: #0056b3; color: white; padding: 10px; text-align: center;"> TaurusOne® 一代经导管主动脉瓣系统 </div>	<div data-bbox="1302 348 1403 465">  </div>	<div data-bbox="1467 334 1844 486" style="background-color: #ccc; padding: 10px; text-align: center;">上市 (2021.4)</div>	<div data-bbox="1880 287 2456 511" style="border: 1px solid #0056b3; border-radius: 15px; padding: 10px;"> <ul style="list-style-type: none"> • 牛心包、双层防漏裙边 • 顺应性佳、平衡的径向支撑、大网孔设计 </div>
	<div data-bbox="792 582 1245 735" style="background-color: #0056b3; color: white; padding: 10px; text-align: center;"> TaurusElite® 二代可回收经导管 主动脉瓣系统 </div>	<div data-bbox="1302 605 1416 733">  </div>	<div data-bbox="1467 582 1844 735" style="background-color: #ccc; padding: 10px; text-align: center;">上市 (2021.6)</div>	<div data-bbox="1880 529 2456 782" style="border: 1px solid #0056b3; border-radius: 15px; padding: 10px;"> <ul style="list-style-type: none"> • 回收能力强 • 血管过弓性能优秀 • 三款上市可回收产品中性能公认最佳 </div>
	<div data-bbox="792 829 1245 982" style="background-color: #0056b3; color: white; padding: 10px; text-align: center;"> TaurusNXT® 三代“非醛交联”经导管 主动脉瓣系统 </div>	<div data-bbox="1302 848 1403 976">  </div>	<div data-bbox="1467 829 1844 982" style="background-color: #ccc; padding: 10px; text-align: center;">临床实验 (21Q3)</div>	<div data-bbox="1880 805 2456 1029" style="border: 1px solid #0056b3; border-radius: 15px; padding: 10px;"> <ul style="list-style-type: none"> • 全球技术领先的非戊二醛交联瓣技术 • 上市TAVR公司中，三代产品进度领先 </div>
	<div data-bbox="792 1105 1245 1258" style="background-color: #0056b3; color: white; padding: 10px; text-align: center;"> TaurusWave® 非植入冲击波 瓣膜治疗系统 </div>	<div data-bbox="1276 1126 1421 1229">  </div>	<div data-bbox="1467 1105 1844 1258" style="background-color: #ccc; padding: 10px; text-align: center;">临床实验 (21Q4)</div>	<div data-bbox="1880 1048 2456 1286" style="border: 1px solid #0056b3; border-radius: 15px; padding: 10px;"> <ul style="list-style-type: none"> • 全球首个冲击波技术在瓣膜修复中的应用 • 非植入性、非创伤性的应对钙化性主动脉瓣的修复方案 </div>

领域	产品名称	进度	产品特色
 二尖瓣	置换 HighLife 经导管二尖瓣置换系统	 产品已于欧洲、澳大利亚、美国等地开展临床试验 21Q4/22中国临床	<ul style="list-style-type: none"> 全球进度领先的经房间隔二尖瓣置换产品 临床数据优异、高歌猛进 CoreValve的创始团队
	置换+修复 Sutra 二尖瓣对合缘增强	 型式试验/动物试验	<ul style="list-style-type: none"> 沛嘉自主研发的二尖瓣置换产品 复合锚定机制、经心尖
	修复 GeminiOne 经导管瓣膜夹系统	 动物试验	<ul style="list-style-type: none"> 修复+置换（后叶置换） 有望应对50%以上的二尖瓣反流的病患需求
		 型式试验/动物试验	<ul style="list-style-type: none"> 自主研发且独立的缘对缘专利设计 多角度分离设计、更大的夹合臂长、一体自动锁定、独立操纵抓捕片等技术特点，也可用于三尖瓣修复

领域	产品名称	进度	产品特色
 <p>三尖瓣</p>	<p>MonarQ 经导管三尖瓣置换系统</p> 	动物试验	<ul style="list-style-type: none"> 与美国医疗技术孵化器 inQB8 技术合作 CardiAQ 的创始团队 全球领先的经导管三尖瓣置换技术路线
	<p>TaurusWave® 非植入冲击波瓣膜治疗技术</p> 	临床实验 (21Q4)	<ul style="list-style-type: none"> 全球首个冲击波技术在瓣膜修复中的应用 非植入性、非创伤性 也可应对除主动脉瓣以外的其他瓣膜钙化性病变
 <p>平台技术</p>	<p>TaurusNXT® 非醛交联瓣叶生物处理技术</p> 	临床实验 (21Q3)	<ul style="list-style-type: none"> 全球技术领先的非戊二醛交联干瓣技术 作为平台技术，有望成为生物瓣膜材料的主流处理方式
	<p>TaurusApex 高分子瓣膜</p> 	动物试验	<ul style="list-style-type: none"> 创新的非生物瓣技术 体外试验数据理想。生物相容性强、几乎无细胞毒性 厚度薄、断裂力提高，能大幅提高耐久力

ME TOO出海

- 专利风险巨大
- 巨额投入，而同质化产品的利润空间难以弥补巨额投入
- 渠道品牌被国际巨头把握
- Made in China的认可度不高

现况:

- ① ME TOO出海高值耗材从未真正打开欧美规范市场
- ② 第三世界市场可能存在机会，但收益和投入相比吸引力不高

VS

创新/独家/技术领先产品出海

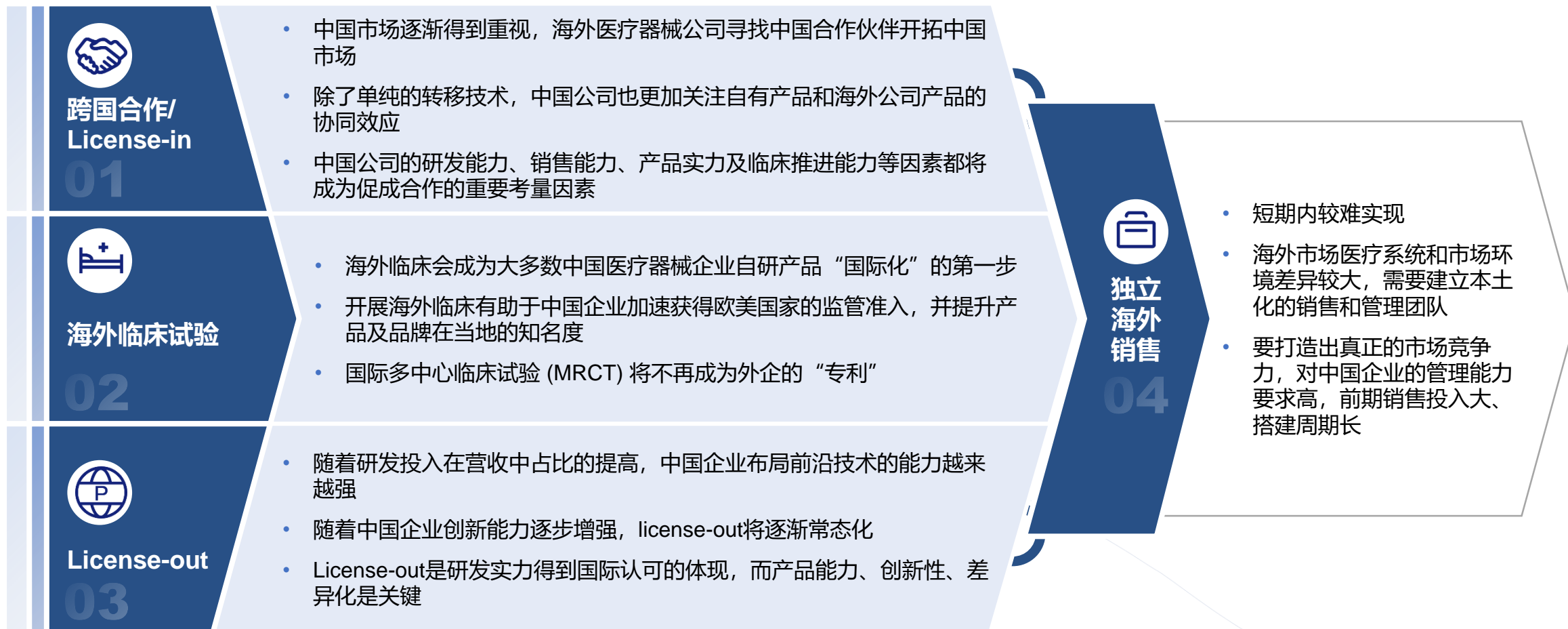
- 能和欧美同行一较高下的领先技术/产品，才是真正的市场竞争力
- 需要沉下心来专注研发和创新，不断扩大研发投入
- 临床需求远未被完全满足，介入瓣膜市场创新空间巨大

现况:

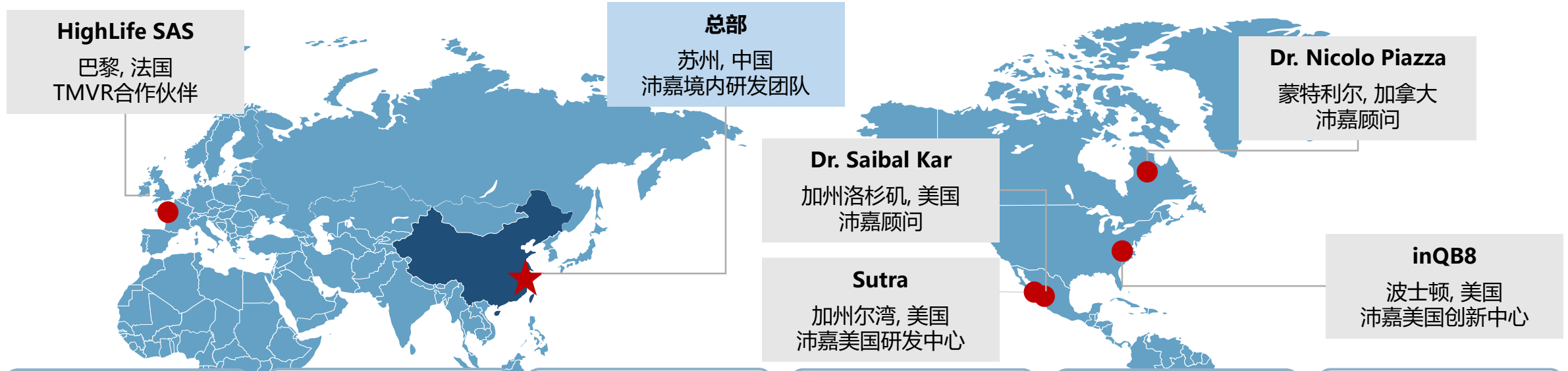
- ① 只有沿着中国药企国际化创新之路，积极布局全球领先前沿技术，在欧美市场获得认可，才能真正的“走出去”
- ② 但考虑到销售网络搭建的高成本以及国际巨头的强大品牌优势，短期内还难以在海外市场形成较强的竞争力，可采用先授权合作、后自营的方式逐步出海



国际化阶段



沛嘉医疗积极布局海外专利，建立全球化的研发平台



Dr. Nicolò Piazza
MD

- 加拿大McGill大学/德国心脏中心心脏介入科教授
- TVT, PCR London Valves, PCR, Asia/Chengdu Valves等多个国际医学会议担任Director



Dr. Saibal Kar
MD

- UCLA大卫格芬医学院教授
- HCA Healthcare结构心脏病介入和临床研究主任
- Centric Health Group年度风云人物
- 曾担任Medtronic, Boston Scientific 等多家跨国医疗器械公司顾问



Dr. Stephen Newman Oesterle
MD

- 恩颐投资创业合伙人
- 殷拓集团及淡马锡顾问
- 美敦力前高级副总裁
- 多家知名医疗器械公司的董事会成员和INED
- 曾担任哈佛医学院、斯坦福大学医学院和佐治城大学副教授



Mr. Georg Börtlein

- HighLife创始人
- CoreValve(TAVI)联合创始人, 公司以超过8亿美金的对价卖给美敦力
- Medtech领域的连续创业者



Dr. Arshad Quadri
MD

- inQB8 联合创始人
- 心外医生转型为发明家/企业家
- CardiAQ(TMVI)联合创始人, 公司以4亿美元的对价卖给爱德华
- Edwards前TMVR医疗事务副总裁
- 50项已授权和已发表的专利



Mr. Brent Ratz

- inQB8 联合创始人
- CardiAQ联合创始人
- InnovHeart总裁及CEO

沛嘉医疗研发管线着眼创新，诸多产品拥有国际化潜力

产品	技术来源	平台技术	全球专利能力	进度	不同深度的海外合作方式	对外授权 License-out
 TaurusNXT® 非醛交联瓣叶生物处理技术	自研	✓	✓	人体临床	海外经销合作	✓
 TaurusWave® 非植入冲击波瓣膜治疗技术	自研	✓	✓	人体临床	海外经销合作	✓
GeminiOne 经导管瓣膜夹系统	自研	✓	✓	动物试验 预计2022临床	研发、监管准入 到销售全面合作	✓
MonarQ 经导管三尖瓣置换系统	合作创新平台自研		✓	动物试验 预计2022临床	研发、监管准入 到销售全面合作	✓
Sutra 二尖瓣对合缘增强	合作研发平台自研		✓	动物试验 预计2022/23临床	研发、监管准入 到销售全面合作	✓
TaurusApex 高分子瓣膜	自研	✓	✓	动物试验	License-out	✓



全球同类产品人类临床首例，进度领先



感谢聆听!

沛嘉医疗有限公司

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