

# 共同创造更多世界级的创新药物

Uniting Together to Create World-class Innovative Drugs

## ——创新药物创业百家汇

“One Hundred Innovative Enterprise Program”

项目计划书（简化版）  
Program Plan (Simplified Version)



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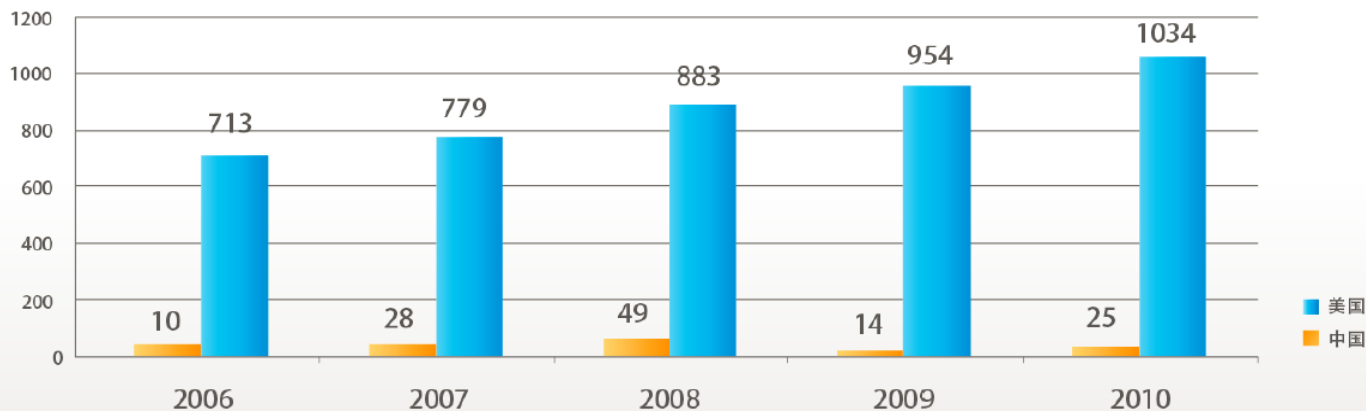
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## 汇报目录 Agenda

- 背景 Background
- 可行性 Feasibility
- 目标与策略 Objectives & Strategy
- 运营与投资 Operation & Investment
- 外部反馈 External Feedback

## 世界的创新源头在美国 Innovation Sources are Mostly in US

中美创新药物临床（批件）申请数目对比（2006-2010）  
Comparison of IND numbers between China and US (2006-2010)



现阶段中国创新药物研发的能力仍然非常薄弱  
The overall innovative drug R&D in china are still primitive

注：1、美国IND为备案制，无须批准，因此按照申报数目计算；2、中国仅统计真正1类新药，剔除伪1类新药（如国外已上市，新适应症，多次申报等）

Note: 1.IND application numbers in US ; 2.Only authentic new drug applications in China are listed; multiple applications and applications for drugs already marketed abroad or for new indications are excluded

数据来源：从FDA、SFDA和CDE网站上查询审评状态数据整理获得。Data sources: FDA, SFDA and CDE websites.

## 中国已经形成以企业为主体的生物医药创新研发格局 Enterprises Have Emerged as Leaders of Innovative Drug R&D in China

中国创新药物申报临床项目数量（2006-2011） The number of IND applications in China (2006-2011)

Rank	Sponsor	No.
1	江苏豪森 Hansoh	12
2	江苏恒瑞 Hengrui	9
3	先声药业 Sincere	7
4	正大天晴 ChiaTai TianQing	5
4	山东轩竹 XuanZhu	5
4	中科院上海药物所 SIMM	5
7	和记黄埔 Hutchison	4
7	中国医科院药物所 IMM-CAMS	4
7	沈阳华泰 Pharmtech	4
10	江苏原子医学研究所 JSINM	3

Rank	Sponsor	No.
11	新昌制药厂 Zhejiang Medicine	2
11	中国药科大学 China Pharm. U.	2
11	沈阳药科大学 Shenyang Pharm. U.	2
11	天津药物研究院 TIPR	2
11	浙江海正 Hisun	2
11	上海艾力斯 Eric Adams	2
11	卡南吉医药科技 Challenge-med	2
18	山东绿叶 Luye	1
18	南京长澳 ChangAo	1
18	南京海陵（扬子江） HaiLing	1

注：仅统计真正1类新药 Only authentic Class 1 new drugs are included

数据来源：从SFDA和CDE网站上查询审评状态数据整理获得 Data sources: SFDA and CDE websites

## 中国的创新药物研发优势 China's Advantages in Innovative Drug R&D

### 研发直接成本优势 Direct R&D cost advantage



### 人力资源成本优势 Human resources cost advantage

- 远远低于欧美制药企业人力成本（应届PhD：中国RMB 10-15万 / 美国USD 10-15万）  
Much lower than that of Western pharms (Fresh PhD: China:RMB100K-150K / US: USD100K-150K)

### 临床患者病例来源优势 Vast patient population available for clinical studies

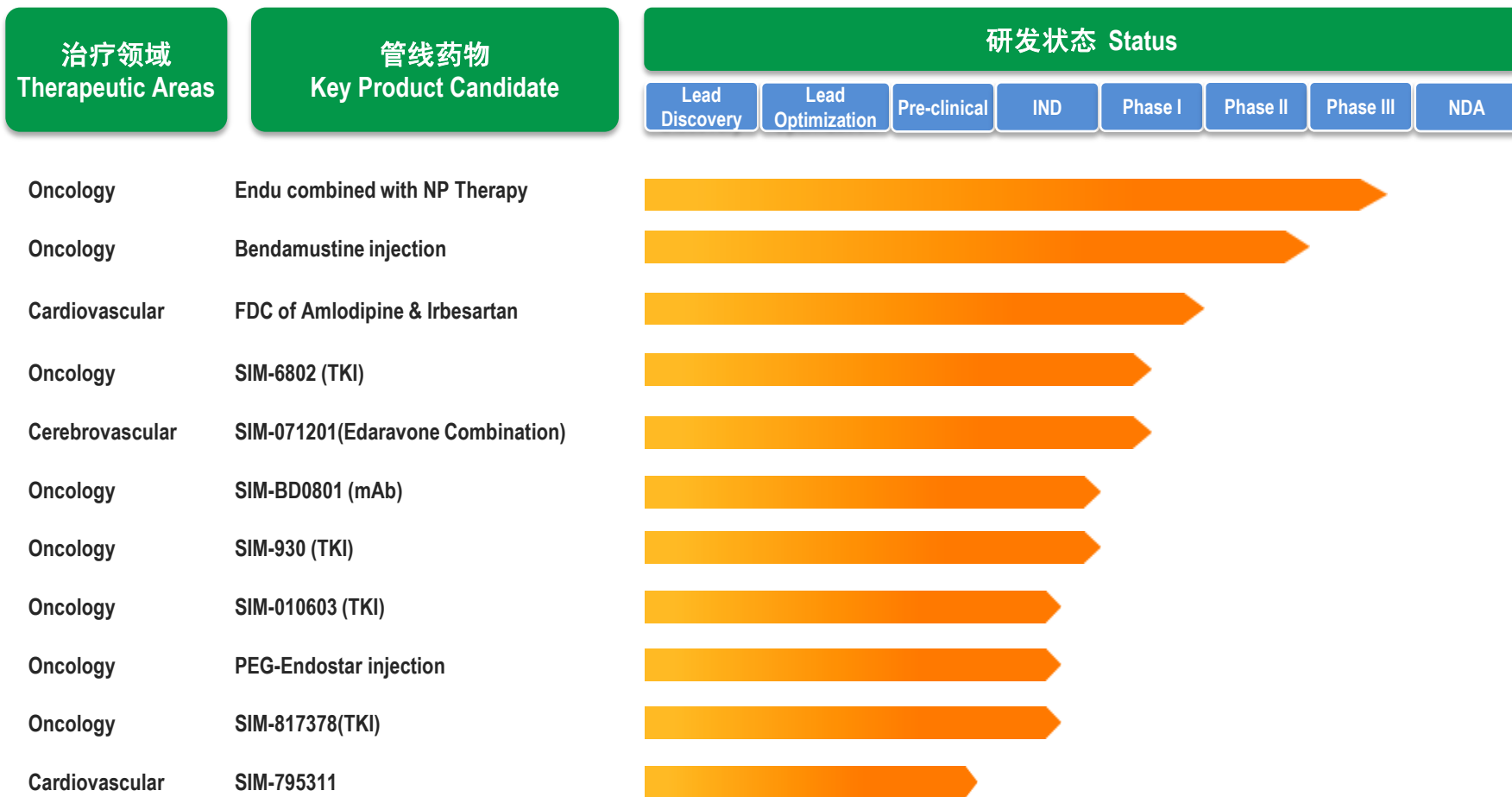
- 中国人口基数大，主要病种发病率增加 Large population base and increasing major disease incidence
- 中国大众保健意识提升，医疗市场容量增加 Enhanced public health awareness as well as increasing market capacity

### 政府支持 Government Support

- 生物医药已经成为中国的战略性新兴产业；Biomedical industry has become a strategically important emerging industry for government support;
- “重大专项”和各类“人才计划”的实施使政策支持落到实处。The industry is getting supports from implementation of government programs such as “Major Projects” and various “Talent Programs”.

## 先声药业研发管线

## Simcere's R&D Pipeline



## 先声药业2011年上市1.1类创新药“艾得辛”

Simcere's Category 1.1 New Drug 'Iremod' Launched in 2011

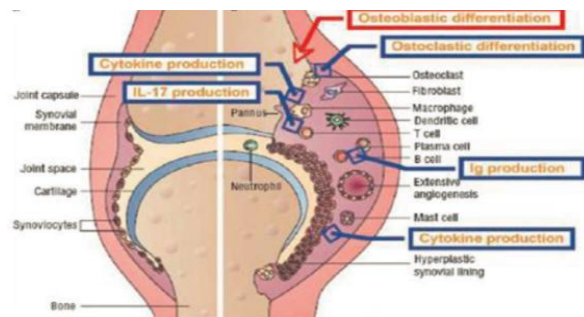


### 研发历程 R&D History

- 2002年, 启动研发 R&D initiated in 2002
- 2011年8月15日, 获新药证书 NDA approval in Aug.15, 2011
- 2012年1月正式上市销售 Launched in January 2012

### 适应症 Indications

- 活动性类风湿关节炎的症状治疗 For treatment of active rheumatoid arthritis symptoms
- 全球第一个上市的艾拉莫德制剂 **The first** launched Iguratimod drug product in the world





## 创新药物研发关键因素 Key Elements for Innovative Drug R&D

### ■ 优秀人才(第一要素)

Outstanding talent (The most critical element)

### ■ 持续投入的研究资金投入

Continuous R&D Investment

### ■ 完整研发产业链及实验设施

R&D facilities for entire pharmaceutical R&D value chain

### ■ 能整合各项资源的服务平台

Service platforms enabling integration of various resources

### ■ 重视知识产权保护

IP protection



## 现有园区模式的发展瓶颈 Bottlenecks in Existing Domestic Models

- 国内生物医药园区主要政策为给土地（如实验室、办公室）、税收政策等，对前述关键因素支持不完整，未形成系统、高效的创新研发产业链；

Domestic biomedical parks/incubators mainly provide free space (such as lab, office), tax benefit, etc. The key elements described earlier are not fully available, and systematic and efficient R&D value chain is not provided;

截至2011年底，全国各地园区创新型小公司尚未有上市或申报真正1类新药临床批件

As of the end of 2011, no small innovative R&D enterprise from a domestic biomedical park has achieved IPO, or filed a true category 1 IND

- 创新型企业均存在小而全的发展瓶颈，人员项目单一、专业不全面；

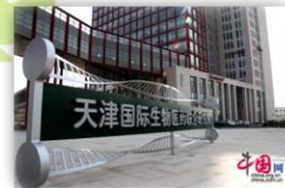
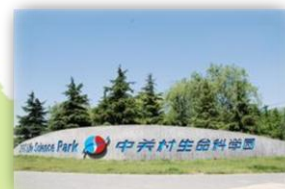
All innovative R&D enterprises face growth bottlenecks of being small and yet maintaining full functions: staff being unable to cover all essential scientific disciplines;

- 创新型企业大都缺乏对SFDA政策的应对及创新药物申报的经验；

Majority of innovative R&D enterprises lack knowledge and experience in dealing with SFDA regulations and in regulatory filings for innovative new drugs;

- 创新型企业除了资金需求外，更需要基于完整研发产业链的增值性服务平台。

Besides funding needs, innovative R&D enterprises have more needs for value-enhancing integrated R&D service platforms.



## 可行性——资源整合增值服务 Feasibility—Resource Integration & Value-Enhancing Service

**创新药物创业百家汇：**是由先声药业集团依托自身拥有完整的创新药物研发产业链、国内研发成功经验、系统的创新项目评价能力及丰富的国际合作研发及管理经验，主导投资建设的最适合海外生物医药领域专家学者（华裔为主）回国创业的、独立性、开放性的**科技创新创业城市综合体**。

“One Hundred Innovative Enterprise Program” is an independent and open **innovation and entrepreneurship science park**, built upon Sincere's key strengths: entire R&D value chain for innovative drug R&D; successful domestic R&D experiences; capability of systematic evaluation of innovative drug R&D programs, and international R&D collaboration and management experiences. The program is most suitable for biomedical returnee entrepreneurs.

### 着力解决： Main Issues to Solve:

创新型小企业： Small Innovative R&D Enterprises:

- 缺乏科技创新和创业的资金 Lack of funding for innovation and entrepreneurship
- 无力建立完整的研发产业链及技术平台 Inability to build quality technology platforms and entire R&D value chain
- 无力整合研发创业的必备资源 Inability to integrate essential R&D resources

### 重点构建： Our Focuses:

完整的研发产业链增值性服务与项目评估体系

Value-enhancing service for integrated pharmaceutical R&D value chain and project evaluation system

## 先声国际合作研发能力 Sincere's International Collaborative R&D Capabilities

- 先声药业已建成国内制药企业功能最齐全、人才结构最完整的研发机构之一，拥有完整的创新药物研发产业链（包括实验室）；

Sincere has built an R&D organization that is among the most comprehensive ones in China, and has integrated R&D value chain for innovative drug R&D (including labs);

- 拥有系统的创新药物项目评估、项目管理及国际合作经验：并先后与AdvenChen，Epitomics，OSI，GSK，BMS以及Merck成功建立了多种模式的合作关系，取得了一系列的合作研发成果。

Systematic project evaluation, project management and international collaboration experiences for innovative drug R&D; Established international collaborations with AdvenChen, Epitomics, OSI, GSK, BMS and Merck with various collaboration models, and have achieved a series of milestones.



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## 国际成功模式——GSK与英国政府SBC项目

### Successful International Model—GSK & British Government's SBC Project

#### “Stevenage Bioscience Catalyst” (SBC)

- SBC提出——“开放式创新”概念，为学术界、制药和生物技术三者的合作创造世界一流的环境；针对新创生物技术公司的需求，提供有协作氛围的场地和设施；

SBC proposes an ‘Open Innovation’ concept: providing world class environment for collaboration among academia, pharmaceutical & biomedical companies, and providing space and facilities designed for collaboration to meet the needs of biomedical companies.

- SBC由英国政府机构、葛兰素史克（GSK）、风险投资基金共同组建的面向小型生物技术公司的投资和服务平台

SBC is a joint venture among the UK government, GlaxoSmithKline (GSK) and VC funds, and is created as investment and service platforms catering small biotech companies.



## 目标与策略 Objectives & Strategy

- 通过5年努力，吸引或组建80-100家创新生物医药科技公司，形成创新创业集群并具备规模优势，以成为南京市“321”计划生物医药领域的最重要组成部分；

Attracting or forming 80-100 innovative biomedical R&D companies in 5 years, forming a cluster of innovation and enterprises with the advantages of scale, and becoming the most important component of the Nanjing “321 Plan” in the area of biomedical science and technology;

- 引进不少于1000位具有硕士学位以上的专业人才，具有海外留学研究背景的高端人才不少于100位；国家“千人计划”、江苏省“双创人才”、南京市“紫金人才”等高层次领军人才不少于50人；

Recruiting >1000 scientists with master degree or above, >100 high level scientists with overseas study and research experience, >50 leading talents including recipients of governments' highest level talent recruitment programs such as the National “Thousand Talents” Program;

- 项目运行后，每5年有20-30个具有自主知识产权的创新药物进入临床研究，在国内创新药物申报临床占比10-20%；通过10年努力，获得新药证书创新药物5-10个，在欧美上市创新药物2-3个。

After program initiation, ensuring 20-30 IND approvals in every five-year period, accounting for 10-20% of all IND applications in China; Accomplishing 5-10 NDA approvals by SFDA, and 2-3 NDA approvals in US/Europe in 10 years.

## 以战略合作联盟方式积极推进项目实施

Promoting Project Implementation in the Form of Strategic Alliance

### 主办单位 Hosts



IDG 资本  
IDG Capital Partners

(酝酿中 / In planning stage)



### 协办单位 Collaborators

- 国家“千人计划”联谊会（酝酿中）“Thousand Talents Program” Association (In planning stage)
- 美国美中医药开发协会（SAPA）
- 美国华人生物医药科技协会（CBA）
- 美国WSGR律师事务所（酝酿中）US law firm (In planning stage)
- 先声默沙东医药 Sincere-MSD JV



### 依托单位：先声药业集团 Base: Sincere Pharm. Group

- 是集研发，生产、营销为一体的现代新型药业集团；A pharmaceutical company with integrated R&D, manufacturing, and sales/marketing;
- 连续数年创新研发投入均超过销售收入的7%，2007-2011年研发总投入达到8亿元；Consecutively investing >7% of total revenue in R&D, with a total R&D investment for 2007-2011 reaching 0.8 billion RMB;
- 第一个在纽交所上市的中国化学生物药公司，具备良好的融资和抗风险能力。The first Chinese pharmaceutical company listed in NYSE, with strong financing and risk-resistant ability.



## 构建与研发产业链相配套的系统化的增值服务体系 Building Systematic Value-Enhancing Service System Matching the Entire R&D Value Chain

### 八大专业性增值服务 Eight Value-Enhancing Services

- 提供创新药物研发所需的开放实验室及公共服务技术平台； Providing open labs and common service technology platforms necessary for innovative new drug R&D;
- 提供相关的中试条件和临床试验药品GMP生产服务； Providing related scaling up facilities and GMP manufacturing services for clinical trial materials;
- 直接提供或协调多种渠道的风险投资基金服务； Directly providing funding or coordinating various venture capital funding services;
- 协调国内外相应的研发配套资源（如安全性评价、临床研究等）； Coordinating domestic and international R&D resources (such as safety evaluation, clinical research, etc.);
- 与地方政府一同协助在中国SFDA进行新药临床报批及注册，并建立药监部门绿色通道； Working together with local governments, assisting in IND and NDA filings with SFDA, and establishing green channel for new drug application and evaluation with local and state FDA;
- 提供全面系统的项目评估、专利评估、技术转让及市场化拓展服务； Providing comprehensive project evaluation, IP assessment, technology transfer, business development and market exploration;
- 研创成果产业链完善及商业化服务； Providing services for industrialization and commercialization of the R&D product;
- 协助申报国家及省市各类创新创业启动资金、人才计划（包括“千人计划”等）； Assisting in application for various national and Jiangsu start-up funds and talent recruiting programs (including the national “Thousand Talents” Program).



## 资源共享、风险共担、利益向创业者倾斜的运行机制

### Novel Mechanism for Innovation: Sharing Resources and Risk, with Benefits Leaning towards Entrepreneurs

- **资源共享：** 建立以创新药物产业集群为特色的城市主题功能区，特显科技创新创业企业的集聚优势和效应，协助创业企业获得更多政府政策支持、社会资源支持、资金人才支持等，共享先声药业完整的创新药物研发产业链；

**Resource Sharing:** Build main functional areas featuring an innovative R&D industrial cluster, emphasizing the advantages of scale for the cluster, and help start-ups to obtain more support in government policy, community resources, capital and human resources, and sharing Simcere's integrated R&D value chain for innovative drug R&D;

- **风险共担：** 构建完整的创新药物研发共性技术平台及服务体系，提供国际一流水平的公共支持及产业链增值服务，充分调动创业者的积极性，让创业者真正成为“老板”（即使在风投方占控股地位时，始终不参与对公司的日常经营活动，确保运作及IP独立性）；

**Risk Sharing:** Build comprehensive innovative R&D common platforms and supporting systems; provide world-class public support and value-enhancing R&D value chain services; fully increase entrepreneurs' enthusiasm and motivation by allowing them to remain as the real 'boss' (the investor not to participate in company's daily operations even when the investor has become the majority owner, in order to ensure start-ups' operation and IP independency);

- **利益向创业者倾斜：** 主要投资方通过持有公司70%左右的股份注入启动资金；在创业企业取得阶段性成果后，采取“利益向创业者倾斜”的机制，以奖励股权方式增加创业者持股比例，最终让创业者成为大股东(甚至成为控股方)。

**With Benefits Leaning Towards Entrepreneurs:** Major investor injects start-up capital and holds up to ~70% of the shares of company. We will adhere to a policy of 'With benefits leaning towards entrepreneurs': with equity give-back as an incentive to the entrepreneurs to increase their ownership, and in the end making them the majority owner (or even the holding party).

## 运营与投资 Operation & Investment

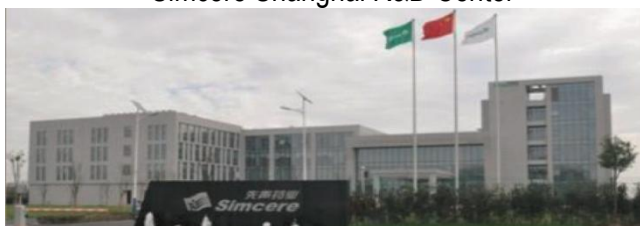
**创新药物创业百家汇：**采取“边建设、边运作”的方式运营。先声药物研究院已建成25000平方米且在国内医药企业中具有设备先进、功能齐全、布局合理的自主研发系统；在本项目运行初期用于过渡——可以支撑先期启动的10个创新创业团队的科研设施及相关配套。

**“One Hundred Innovative Enterprise Program”:** This program is being initiated, and will be continuously executed during construction. Simcere has already built one of the most comprehensive R&D organizations in China. The existing facilities, when used during early transition phase of the program, can support 10 early-enrolled innovative enterprises.

### 先声药业研究院（南京） Sincere R&D Laboratories (Nanjing)



先声上海张江研发中心  
Sincere Shanghai R&D Center



先声烟台重组蛋白研发中心  
Sincere Yantai Recombinant Protein R&D Center



## 完善的创新成果产业化基地

### Comprehensive Base for Industrialization of Innovative Products

**创新药物创业百家汇：**充分利用先声东元制药公司已有的GMP生产车间和技术平台，为各创新创业公司提供相关的中试研究和临床试验药品的GMP生产等。

**“One Hundred Innovative Enterprise Program”：** Making full use of existing Simcere Dongyuan GMP plants and technology platforms, providing innovative start-ups with related scaling up facilities and GMP manufacturing services for clinical trial materials.



## 投资规模 Scale of Investment

### 资金投入：Financial Investment

- 总投资额：约人民币30-40亿元； Total investment: ~ 3-4 billion RMB;
- 规划面积：约40-50万平方米； Total area: ~400-500K square meters;
- 资金来源：由先声药业和PE、VC共同筹措； Sources of funding: jointly raised by Simcere, PE & VC;
- 建设周期：5年，计划分3期建设完成。 Duration of construction: 3 stages, in 5 years.

### 土地投入：Land Investment

- 南京市浦口区新浦路，先声药业集团全资子公司先声东元制药有限公司厂区（471亩）； A land of 78 acre, currently occupied by Simcere Dongyuan Pharmaceutical Manufacturing Company (a Simcere's fully owned subsidiary), Xinpu Rd., Pukou, Nanjing;
- 分期建设：现有厂区及车间将保证百家汇项目中试放大需求。 Staged construction: current plants to meet the needs for pilot manufacturing of the enterprises.

## 外部反馈——国家“千人计划”联谊会的支持

### External Feedback—Support from “Thousand Talents Program” Association

#### 5位生物医药与生命科学专业委员会骨干成员参会讨论人才引进项目

文/本刊编辑部

2011年10月16日，饶毅、许嘉森、王鹏、张丹、谢良志5位“千人计划”专家联谊会生物医药与生命科学专业委员会骨干成员齐聚北京，召开研讨会，讨论“千人计划”专家联谊会如何参与南京先声药业集团提出的“新型人才引进—创新创业计划”。

此次研讨会主题明确。来自先声药业的“千人计划”专家王鹏博士从立项背景、项目内容、项目目标、优势及创新

点、项目计划、进度及运营、项目投资和美国华人专业人员对此项目的初步反馈等七个方面系统地介绍了“创新药物创业百家汇”这个项目。听完介绍后，与会的专家肯定了该项目：如果成功，或将对我国人才引进和创新药物研发都有着重要作用。

随后，与会专家就“千人计划”专家联谊会如何以适当的方式参与“创新药物创业百家汇”项目这个问题提出了



5位专家在轻松愉悦的气氛中热聊

操作层面上的实际建议。最后，研讨会得出结论，待王鹏与江苏省或南京市相关政府部门沟通并达成共识后，以政府产业园的名义向联谊会提出书面申请，联谊会再向中组部汇报批准后实施。■

信息来源：《千人》2011年12月刊 Source: “Thousand Talents”, Dec., 2011

## 美国生物医药界积极响应

### Active Responses from US Biopharmaceutical Communities

迄今在海外华人生物医药专业人员中做过9场推介，都取得了一致高度的反响和认可：A total of 9 seminars on 'Hundred Innovative Enterprises Program' have been given, receiving active responses and recognitions at all meetings:

- **2011年10月1日在“SAPA总部及全美各地分会领导团队年度工作会议”（美国纽约州，60多名参会者）**  
Oct. 1, 2011: “Annual Conference of SAPA Headquarters and Local Chapters Leadership Teams” (New York, >60 attendees)
- **2011年10月8日，美国波士顿CABA主办的“创业与投资”会议（100多名参会者）**  
Oct. 8, 2011: “Entrepreneurship and Investment” (sponsored by CABA, Boston, MA; >100 attendees)
- **2011年10月26日，第四届中国留学人员南京国际交流与合作大会（100多参会者）**  
Oct. 26, 2011: “The 4th Nanjing International Exchange & Collaboration Symposium for Overseas Students & Scholars” (>100 attendees)
- **2011年11月5日，波士顿，SAPA-NE“生物药研发”会议（100多参会者）**  
Nov. 5, 2011: “Biologics Drug R&D Symposium”(sponsored by SAPA-NE; >100 attendees)
- **2011年11月10日，马里兰，CBA先声专场（100多参会者）**  
Nov. 10, 2011: “CBA -- Sincere Session”(Maryland; >100 attendees)
- **2011年11月12日，圣地亚哥，SABPA年会（200多参会者）**  
Nov. 12, 2011: “SABPA Annual Conference”(San Diego, CA; >200 attendees)
- **2011年11月19日，旧金山，CABS先声专场（100多参会者）**  
Nov. 19, 2011: “CABS -- Sincere Session”(San Francisco, CA; >100 attendees)
- **2011年12月10日，费城，SAPA-GP职业发展会议（200多参会者）**  
Dec. 10, 2011: “SABPA-GP Symposium on Career Development”(Philadelphia, PA; >200 attendees)
- **2012年1月29日，新泽西，SAPA职业发展会议（200多参会者）**  
Jan. 29, 2012 “SAPA Symposium on Career Development”(New Jersey, >200 attendees)
- **2012年5月23日，北卡州研究三角园，南京市委杨书记“321计划”推介会（200多参会者）**  
May 23, 2012: “Nanjing 321 Plan Introductory Seminar” (RTP, North Carolina, >200 attendees)

## 美国生物医药界积极响应

### Active Responses from US Biopharmaceutical Communities

- 2011年10月30日，SAPA总会长黄保国博士（赛诺菲）率SAPA代表团访问先声药业，并就该项目签署合作协议；Oct.30, 2011  
SAPA delegation led by Dr. Baoguo Huang (Sanofi; SAPA Chairman) visited Simcere, and signed collaboration agreement for “One Hundred Innovative Enterprises Program”.



- 美国WSGR律师事务所表示高度认同和赞赏，并已开始为此项目开展工作；WSGR(US law firm) expressed a high degree of recognition and appreciation for the program, and has initiated work for the program.
- 与美国其他有关专业人员的交流：Communications with other US professionals:
  - 2011年11月14日，圣地亚哥，与近十家美国著名生物医药风投基金会谈；Nov.14, 2011: Meeting with more than 10 biomedical VC funds in San Diego, CA;
  - 2011年11月18日，考察位于旧金山的加州政府生物医药孵化中心，并与中心主任会谈。Nov.18, 2011: Visiting Center of CA Government Biomedical Incubators in San Francisco, CA, and meeting with the director of the center.

## 美国生物医药界积极响应

### Active Responses from US Biopharmaceutical Communities

- 截至2012年3月，已经与美方有意向创业团队签署合作意向书20多份，正在与其中十余个创业团队进行深入的合作探讨； More than 20 letters of intent for collaboration have been signed with US start-up teams, and more than 10 of them have proceeded to further collaboration discussion stage.
- 美国生物医药界特别关注： Special recognition from US biomedical communities:
  - 政府对生物医药产业的支持 Government support for biomedical industry
  - 先声已经拥有的完整创新药物研发产业链、研发能力和经验、国际合作成功经验和项目评价能力 Simcere's comprehensive innovative drug R&D value chain, R&D capability and experiences, and successful international R&D collaboration experiences and project evaluation capabilities
- 现阶段，中国的风险投资尚缺乏对生物医药的了解；先声的项目评价能力可大大加强政府、风投与生物医药创业型企业之间的合作。 China VC community still lacks understanding of biomedical industry; Simcere's project evaluation capabilities could strengthen collaborations among government, VC and innovative biomedical enterprises.



## 总结 Summary

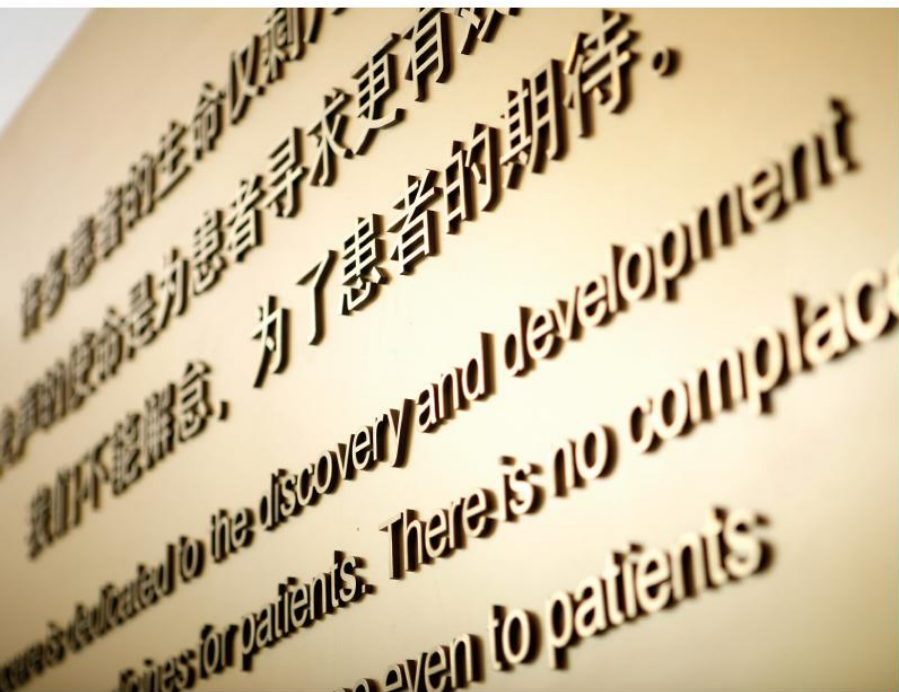
- 充分运用低成本的优势——为创业型生物医药公司搭建的公用开放平台  
Fully utilizing cost advantages—providing open platforms for innovation-oriented biomedical enterprises
- 注入了中国创新药物研发经验——拥有制药企业完整产业链的增值平台  
Providing domestic innovative drug R&D experiences—having value-enhancing platforms based on entire R&D value chain of a pharmaceutical company
- 解决创业型公司的资金需求——由制药公司、PE、VC共同筹措  
Meeting the funding needs of innovative enterprises—Sources of funding: Jointly raised by Simcere, PE & VC

适合海外生物医药领域专家回国发展的创业机会  
*Suitable for biomedical returnee entrepreneurs*

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资源共享、风险共担、利益向创业者倾斜的全新开放创新创业机制  
集政府政策、社会风投及制药企业完整产业链的增值平台  
适合海外生物医药领域专家回国创业的科技创新创业城市综合体

Innovative policy of 'Sharing resources and risk, with benefits leaning towards entrepreneurs'

Value-enhancing service system that includes government policy, venture capital and integrated pharmaceutical R&D value chain for innovative drug R&D

Science and technology innovation and entrepreneurship park most suitable for biomedical returnee entrepreneurs



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