

WINNING STRATEGIES:

How to Create, Grow, and Sustain a Successful Life Sciences Company













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WINNING STRATEGIES: How to Create, Grow, and Sustain a Successful Life Sciences Company



Cross-Border R&D in China – Understanding the Regulatory Challenges





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Panelists



Moderator:

Paul A. Stewart, Silicon Valley Office Managing Partner,
Foley & Lardner LLP

Speakers:

David Rosen, Partner, *Foley & Lardner LLP*

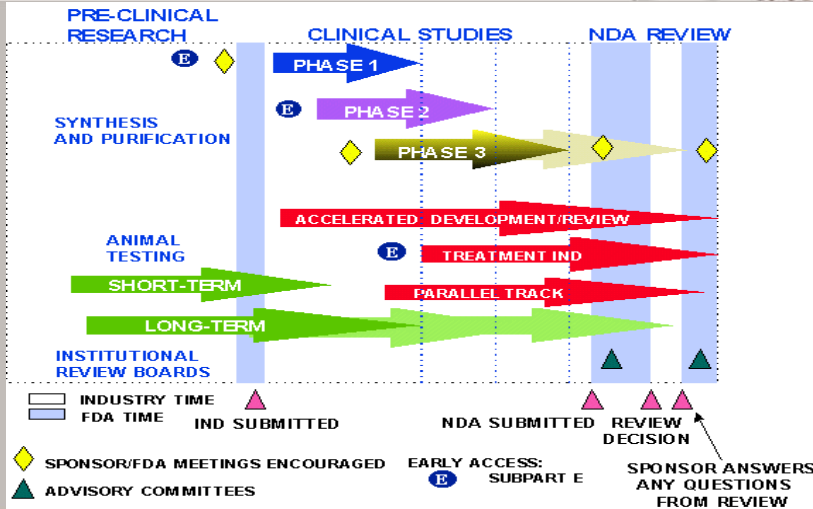
Sofie Qiao, Ph.D., President, CEO and Co-Founder, *LINQ Pharmaceuticals*

Jimmy Z. Zhang, Ph.D., M.B.A., Vice President, *Synergenics, LLC*

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The New Drug Development Process



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China Healthcare Market Update

Jimmy Z. Zhang, PhD, MBA



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CHINA OUTLOOK



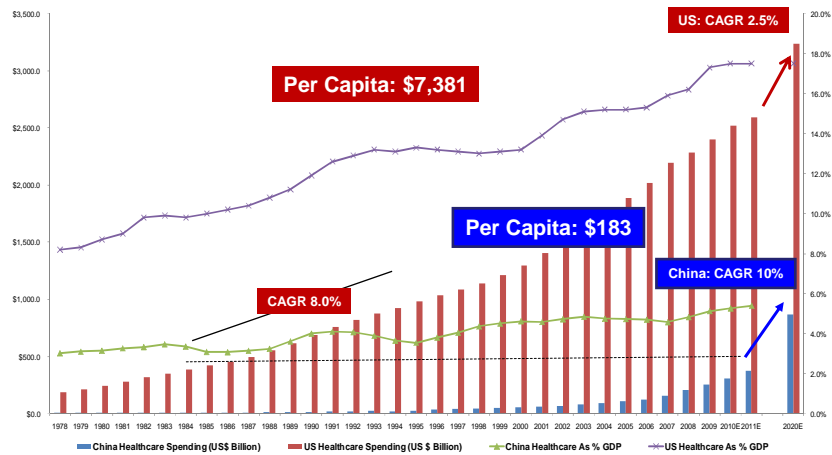
- 7th largest pharmaceutical market in 2005, 5th largest in 2008 (\$25B), 3rd largest by 2013 (\$73B), and largest by 2050
- 3rd largest single-country medical device market
 - \$2.3B IVD in 2010
- Largest market by population
 - Total population 1.34B (mainland, 2010), ↑ 5.84% over 2000
 - Dramatically shifting demographics:
 - ≥ 60 yr: 13.26% (↑2.93%)
 - ≤ 14 yr: 16.60% (↓6.29%)

Sources: IMS, National Bureau of Statistics, industry publications

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Total Healthcare Expenditures in China Is Low, But Growing Fast



Sources: Chinese Department of statistics & MOH, BEA database, Piper Jaffray estimates

China Healthcare Reform (2009-11) – RMB 850B



Objectives:

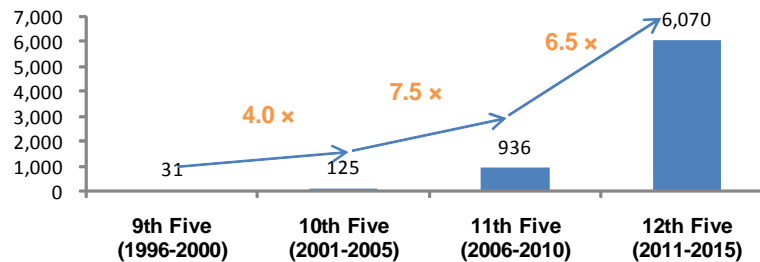
- To expand basic medical insurance programs including:
 - to insure 90% of its population by 2011
 - to increase government insurance subsidy RMB120/person from RMB20-40/person
- To improve healthcare service infrastructure in grassroots medical facilities (RMB100 billion)
- To establish essential drug list (EDL) and its distribution system
- To promote public medical service equity and establish a nationwide standard "health record" for the entire population
- To reform public hospitals (2011 nation-wide implementation): separation of pharmacies from hospitals

China 12th 5-Year Plan

12th 5-year plan goal

- Improve R&D capability and encourage development of innovative drugs
- Enhance international footprint
- Strengthen medicine quality assurance system and technology
- Support transformation of leading local pharmaceutical companies

Central government funding for biomedical
USD in millions



Sources: McKinsey & Company, CHIC 2011 presentation

China Is Reforming Intellectual Property Laws



- Third Patent Law Amendment: One Step Closer To International Standard (effect on October 1, 2009)
 - adoption of an “absolute novelty bar”
 - definition of “invention made in China”
- From “Copied In China”...
 - new chemical entities (NCEs) not protected until 1993
- ...To “Engineered In China”...
 - “doing the same things cheaper and better,”
- ...To “Invented In China”
- Major Differences between China and US Patent Laws
 - First to file
 - No one year grace period on publication
 - No patents on methods of treatment
 - No CAFC (Court of Appeals for the Federal Circuit)
 - No case law

Sources: Piper Jaffray; SIPO



LINQ Pharmaceuticals

Sofie Qiao, Ph.D.

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LINQ Pharmaceuticals



- Mission – to deliver best-in-class small molecule therapeutics cost-effectively and great shareholder returns time-efficiently
- Strategy – trans-Pacific approach
 - Optimally accessing resources/capabilities in Asia and the US
 - Focused on best-in-class programs
- Team – experienced co-founders
 - Sofie Qiao, Ph.D.
 - Kewen Jin, M.D.

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LEAD Recap



- Vision - Turn drug discovery NPV positive
- Mission – Generate best-in-class and differentiated drug candidates
- Strategy – Headquartered in Bay Area with a small office in Shanghai, utilizing Chinese CRO capabilities to conduct small molecule discovery against validated targets for which the scientific team have unique insight
- Execution – Team with a business plan decided on 2 initial targets (i.e. no licensing) to conduct patent-busting chemistry-driven discovery
- Result – Raised Series A of \$17 million, generated 2 preIND candidates (cancer and antibiotics) in 2 years, and acquired by BioMarin in less than 3 years for up to \$97 million

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LINQ – LEAD 2.0



- Improve Capital Efficiency
 - Smaller team and entirely virtual
- Expand Asia Exposure
 - Fundraising in China as well as US
 - PreIND deal-making possibly in Asia
- Refine Target Selection
 - Focus on therapeutic areas with huge global potential
 - Select targets which are recently validated
- Create more value
 - preIND stage deal followed by M&A

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