Opportunities for US Life Sciences Companies in China

- Entry Vehicles and Key Operational Issues

April 12, 2013

Christina Zhang
Partner
Cooley LLP
Email: czhang@cooley.com
Tel: 86(21)488 0688
Agenda

China Life Science Overview

China Entry Strategies and Vehicles

IP Protection, Product Approvals and Other Key Operational Issues
China Life Science
Overview
Basic Facts

- Total population: 1,354,040,000
- Per capita income: Urban Households US$ 4340
  Rural Households US$ 1275
- GDP growth: 7.8%

Data Source: National Bureau of Statistics of China
2012 Data
China Life Sciences Industry Drivers

- Healthcare reform and increasing government expenditure
  - Over $250 billion in five years (2011-2015)

- R&D investments in innovative drugs
  - Over $7 billion in VC, M&A, IPO and corporate investments in 2012

- Increasing consumer purchasing power
  - Pharmaceutical market CAGR 22% for the last five years

- In 2012, China was the 3rd largest pharma market in the world.

Chinese Pharmaceutical Market Size
Source: IMS

2010, China was the 5th largest pharma market WW
2015, China will become the 2nd largest pharma market WW
2020, China will stay as the 2nd largest pharma market WW
Demographics

- Urbanization: **300 million** new city dwellers in the next 15 years
- Rapidly aging population: citizens over 60 years of age growing from 13% today to 31% by 2050
- Chronic diseases: increasing 20-30% each year

Returnees from overseas (a/k/a sea turtles)

- **433,000** in the last five years; **150,000** in life sciences alone
- Innovation, western style of management and global business practice

Sources: Ministry of Housing and Urban-Rural Development; National Bureau of Statistics of China; ChinaBio LLC
China’s Aspiration of Biopharmaceutical Innovation

- 10 innovative drugs with Chinese patents
- 20 branded generics with international competitiveness
- **US$309 billion** for the Science and Technology Development Program
- **US$10 billion+** for the National Biotechnology Development Program
- **US$15 billion+** for 162 drug development programs (75% provincial and municipal level)

(12th Five-Year Plan)

To upgrade China’s biopharmaceutical industry from “Big” to “Strong” through R&D innovations and system innovations.

How to do it?

How to measure it?

The 12th Five-Year Plan Objective
2012 China Life Science Trends

- In the world of China life science, VC investment, M&A transactions, partnering activity, especially cross-border deals – all of these metrics were up substantially in 2012.

<table>
<thead>
<tr>
<th>Area</th>
<th>Trend</th>
</tr>
</thead>
<tbody>
<tr>
<td>VC investment</td>
<td>↑↑</td>
</tr>
<tr>
<td>IPO</td>
<td>↓</td>
</tr>
<tr>
<td>M&amp;A</td>
<td>↑</td>
</tr>
<tr>
<td>Partnering</td>
<td>↑↑</td>
</tr>
</tbody>
</table>

Source: ChinaBio LLC
2012 is a Record Year for Life Sciences VC Investment in China

- Total investment jumped 65% to $946 M in 2012
- Average deal size set a new record at $49 M
- 2010 and 2012 were the high water mark for both investment size and volume in China vs. 2007 in the West
- 64% of the invested capital to drug companies and 30% to diagnostics firms

**Average Investment**

<table>
<thead>
<tr>
<th>Year</th>
<th>Average Investment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>$11 M</td>
</tr>
<tr>
<td>2010</td>
<td>$21 M</td>
</tr>
<tr>
<td>2011</td>
<td>$25 M</td>
</tr>
<tr>
<td>2012</td>
<td>$49 M</td>
</tr>
</tbody>
</table>

**Yearly Investment Amounts**

<table>
<thead>
<tr>
<th>Year</th>
<th>Investment Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>$409 M</td>
</tr>
<tr>
<td>2008</td>
<td>$327 M</td>
</tr>
<tr>
<td>2009</td>
<td>$318 M</td>
</tr>
<tr>
<td>2010</td>
<td>$1,013 M</td>
</tr>
<tr>
<td>2011</td>
<td>$572 M</td>
</tr>
<tr>
<td>2012</td>
<td>$946 M</td>
</tr>
</tbody>
</table>

*Source: ChinaBio LLC*
2012 is a Record Year for Life Sciences Partnering Deals in China

- Total amount doubled to $558 M and deal size almost doubled to $25 M
- Co-development and licensing deals have replaced marketing and distribution agreements over the last five years
- Cross-border deals in the partnership sector: 87% of the total
- Western pharmas are increasingly bringing their drugs and technologies to China seeking co-development partners
- Chinese pharmas are increasingly seeking regulatory approvals and partners in the West

Source: ChinaBio LLC
Why Should China Life Sciences Companies Be Interested in the West?

- Access innovative pipeline and large global markets
- Acquire leading technologies and R&D capabilities
- Exploit strong currency and access to capital
- Value arbitrage between China vs. U.S./European capital markets
2012 is a Record Year for Life Sciences M&A in China

- Average deal size set a new record at $116 M
- 54% of deals are pharmaceutical deals
- What are buyers looking for in China?
  - Local knowledge and capabilities
  - Product portfolio/pipeline
  - Commercial infrastructure

Sources: Lazard Frères & Co. LLC, ChinaBio LLC
IPO was the only category that did not follow the dominant 2012 pattern

The lower results derived more from general market conditions than from any problems specific to pharma

Shanghai Fosun Pharma garnered $512 million in its Hong Kong IPO

Source: ChinaBio LLC
Life Science Funds Active in China

Cooley has worked with many prominent life science funds active in China, including:

- Decheng Capital, Frontline BioVentures, IDG Capital Partners, Kaiwu Capital, Matrix Partners
- Qiming Venture Partners, Vivo Ventures, GGV Capital, Sequoia Capital, Kleiner Perkins, etc

Source: ChinaBio LLC
Entry Strategies and Vehicles
Different Entry Options

- Selection of vehicle is driven by Foreign Investment Catalogue and other considerations
  - Encouraged projects
  - Restricted projects
  - Prohibited projects

No legal presence
- Licensing
- Distribution
- Consulting

Legal presence
- Representative office
- Wholly foreign-owned enterprise (WFOE)
- Equity joint venture (EJV) or cooperative joint venture (CJV)
- Foreign-invested companies limited by shares
- Domestic company (VIE)
Different Entry Options (cont’d)

Representative Office

- Quick and easy to set up
- Difficult to close down
- Hiring must be through a third party agency

Limited scope of activities:
- Liaison or market research for head office;
- No profit-making activities.
Different Entry Options (cont’d)

Wholly Foreign-owned Enterprise (WFOE)

Cash, tangible assets as well as IP can be contributed as capital; caveats:
- IP license cannot be contributed as capital;
- IP cannot account for more than 20% of total capital
- Cash contribution no less than 30%

Total investment and registered capital requirement

Capital contribution schedule

Business scope

Approvals by MOC, SAIC, NDRC and other agencies
- determined by business scope and total investment

Typically, not an option for “restricted” industry.

MOC = Ministry of Commerce
SAIC = State Administration of Industry and Commerce
NDRC = National Development and Reform Commission
Different Entry Options (cont’d)

Equity Joint Venture (EJV)

Material amendments of JV contract are subject to approval by authorities

Equity transfer is subject to approval by authorities

Similar approval process and registered capital requirement as WFOE

Four items subject to unanimous board consent:
- Amendment of JV’s Articles of Association;
- Termination or dissolution of the JV;
- Increase or decrease of the registered capital of the JV; and
- Merger or split-up of the JV.
Domestic Company (VIE)

- Setup by PRC investors
- Often deployed in restricted industries
- Only registration with SAIC is required
Typical Deal Structures

- Offshore Wholly-owned plus Onshore WFOE

Diagram:
- Offshore
- Onshore
- Future Investors
- ABC USA
- Cayman Holding Co
- HK Holding Co
- China WFOE

If dollars invested:
- Cash contribution
- 100%

If RMB invested:
- Cash contribution
- 100%
Typical Deal Structures (cont’d)

- Offshore Wholly-owned plus Onshore JV

Diagram:

- ABC USA
- Cayman Holding Co
- HK Holding Co
- Future Investors
- China JV
- Investor X PRC Entity

Flow:
- If dollars invested:
  - 100% from ABC USA to Cayman Holding Co
  - Future Investors
- If RMB invested:
  - Y% from Future Investors to China JV
  - X% from Investor X PRC Entity to China JV
- Cash contributions are indicated in the diagram.
Typical Deal Structures (cont’d)

- **Offshore JV plus Onshore JV**

  - **ABC USA**
  - **Investor X**
  - **Cayman Holding Co**
  - **HK Holding Co**
  - **China JV**
  - **Investor X PRC Entity**

  - If dollars invested: License in exchange for equity
  - If RMB invested: Y% cash contribution
  - Onshore
  - Offshore

  - 100% cash contribution
  - Future financing
Typical Deal Structures (cont’d)

- Offshore JV plus Onshore WFOE

Diagram:

- ABC USA
- Investor X
- Cayman Holding Co
  - License in exchange for equity
  - If dollars invested
  - 100%
- HK Holding Co
  - Future financing
  - Cash contribution
- China WFOE
  - Cash contribution
  - If RMB invested
  - 100%
- China JV
Typical Deal Structures (cont’d)

- Offshore JV plus Onshore VIE

ABC USA → Cayman Holding Co

PRC Individuals → Cayman Holding Co

Cayman Holding Co → HK Holding Co

Future Investors → HK Holding Co

If dollars invested:

- 100% Cash contribution

If RMB invested:

- 100% Cash

HK Holding Co → China WFOE

China WFOE → Domestic Company

Service and licensing Agreement

Control Agreements

PRC Individuals → Domestic Company

Domestic Company → 100%
IP Protection, Product Approvals and Other Key Operational Issues
Recent Developments

- **Regulatory developments:**
  - higher penalties for counterfeiters:
    - a fine of up to 3 times the illegal gains, or up to RMB 100,000
    - a fine of up to 5 times the illegal gains, or up to RMB 250,000

- **Enforcement:**
  - 14,000 counterfeit drug cases in 2012 (source: Chinapeace)

- **Litigation:**
  - 2510 patent dispute cases heard in 2012 (source: SIPO)
  - 5670 foreign-related IP cases in the past 5 years (source: The Supreme People’s Court)
  - Shanghai - foreign companies winning rate in IP cases was 86.2% in 2011 (source: Xinhua Net)
Recent Hot Topic: Mandated Reward & Compensation for Employee Inventors

- Default reward/compensation scheme in the absence of agreement or policy

**Reward**
- Invention patent – no less than 3000 RMB per patent
- Utility model or design patent – no less than 1000 RMB per patent

**Compensation**
- Invention patent or utility model patent - no less than 2% of annual profits from exploitation
- Design patent - no less than 0.2% of annual profits from exploitation
- Or - make a lump sum payment based on the above rates
- no less than 10% of the licensing fees in the case of patent licensing
Practical Suggestions

- Act early to protect your trademarks and domain names: **Squatting is Prevalent**

- Protecting against theft by employees:
  1. Confidentiality and non-compete
  2. Segregation of confidential information
  3. Active monitoring of downloading

- Implement IP policy to encourage innovation and avoid application of the default scheme
## Two Approval Tracks

<table>
<thead>
<tr>
<th>Imported Drug Registration</th>
<th>New Drug Registration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Offshore registration holder</td>
<td>Onshore registration holder</td>
</tr>
<tr>
<td>Manufactured overseas</td>
<td>Manufactured in China</td>
</tr>
<tr>
<td>Local agent needs to be appointed</td>
<td>Contract manufacturing is possible but entrusting party must also have <strong>manufacturing license</strong></td>
</tr>
<tr>
<td>No international multicenter trials may be conducted in China unless the drug has</td>
<td></td>
</tr>
<tr>
<td>- entered Phase II or Phase III trials outside of China</td>
<td></td>
</tr>
<tr>
<td>- approved outside of China if it is preventive vaccines</td>
<td></td>
</tr>
</tbody>
</table>

### Drug Administration Law is being amended

- To accelerate the approval of innovative drugs
- To make it easier to do contract manufacturing
- To delegate some authorities to provincial FDAs
Foreign Exchange Controls

- State Administration of Foreign Exchange ("SAFE")
- Foreign exchange for payment of goods, services, dividends and royalties: not difficult to get
- Capital account (loans, investment etc): approvals required
- Free convertibility will not happen soon
Employment

General observations

- Chinese labor law is pro-employees
- There is no employment at will; legal basis is required for termination
- “Special categories” are protected from termination

Specific requirements

- Every employee must be covered by labor contract
- Labor contracts have either fixed terms or open terms
- Severance pay is required except for special circumstances
Foreign Exchange, Employment, FCPA and Other Issues (cont’d)

Foreign Corrupt Practices Act ("FCPA")

- Criminal statute applicable to US persons doing business abroad
- Prohibits bribery of “foreign government officials or employees”
- Most of the hospitals are state-owned in China and doctors are considered to be “government employees” under FCPA
- FCPA prohibits direct or indirect bribery
- Violation could carry significant fines and jail terms
Questions
Thank You from the Cooley China Team

Christina Zhang  Brad Peck  Patrick Loofbourrow

James Lu  Benjamin Qiu

Dali Qian  Oak Ma  Monica Xu