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Preface & Executive Summary
We at Torreya are engaged in providing strategic advice to companies in the life sciences industry. Torreya has a three person team covering Chinese pharmaceutical companies that is in China at least six times a year. We also maintain a database of deals in the China market to analyze trends.

This report will provide you with:

• An overview of burgeoning market for in-licensing of pharmaceutical products into China
• A discussion of the types of products that Chinese companies are looking for, the trends in licensing activity, and typical deal terms
• Focus on the economics from China licensing and how they compare to other regional licensing options
• Advice on how to negotiate and structure a China licensing transaction

Please contact the Torreya China team if you have any questions or comments.

Jie Liu
Managing Director
jie.liu@torreya.com
Cell: 917.683.4003

Kylor Hua
Vice-President, M&A, NY
Kylor.hua@torreya.com
Cell: 917.208.1758

Vivian Xu
Associate, China, NY
Vivian.xu@torreya.com
Cell: 347.407.2044
Executive Summary

1. China licensing activity has skyrocketed.
   - Thus far in 2018, we have seen more than five deals a month announced, on average.
   - In contrast, five years ago (2014) there was roughly one deal a month announced.

2. The value of licensing activity in China has also risen.
   - The average upfront payment on a licensing deal in 2018 was $11.7 million (including pre-clinical deals). The average sum of milestones and upfronts in 2018 was $96.8 million.
   - In contrast, in the decade from 2008 to 2017 the average upfront payment was $7.9 million while the average deal value (milestones+upfronts) was $89.7 million.

3. Protection of intellectual property has improved substantially.
   - China has a modern intellectual property regime and provides full enforcement of patents on medicines today.
   - Interestingly, China offers 25 years of protection on newly filed drug patents versus 20 years in the United States and Europe.

Business Case for China Partnering

1. China offers an abundant source of non dilutive capital for Western pharma.
3. Substantial investment capital available with partnering.
4. Historical concerns involving IP theft and business practices increasingly irrelevant.
5. Rapidly growing market offering growth over time for Western drugs.
6. Source of fast, well executed clinical trial recruitment for drugs addressing prevalent diseases.
7. Very difficult to access China without a partner given market dynamics.
8. China partnering doesn't interfere with exits as China not a focus of big pharma.
9. Rapid times to deal completion possible versus other regional partnering.
Background on the Chinese Pharmaceutical Market
China Healthcare Spending Rising Dramatically

- Total consumption by Chinese consumers is poised to rise more than 150% in a single decade ending in 2020.
- Healthcare spending will rise even more, taking up 10% of the consumer budget by 2020.
- Most of this increased spending will take place along the coast, especially around Guangdong, Zhejiang, Jiangsu and Tianjin provinces.

Chinese Pharmaceutical Market Growth

Key Trends

- Chinese pharmaceutical market has grown six times larger in only 13 years
- China is the second largest pharma market in the world today
- Usage of Western medicines up massively
- High growth for cancer, cardiovascular and respiratory drugs given disease burden in Chinese population

China Will Lead Market Growth in the Pharma Sector Over the Next 50 Years

Torreya forecasts that the US pharmaceutical market will double while China market will quadruple over time. Japan, Germany and France markets will grow less than 200%.

Projected Global Pharma Expenditures For Six Largest Countries ($millions), 2017-2060

Growing Global Importance of Chinese Pharmaceutical Sector

Chinese companies have added $84 billion in shareholder value in just 18 months. This is despite major changes in the regulatory regime and increasing pressure on prices (especially via Essential Drug Lists).

Valuation of the Leading Chinese Private and Publicly-Traded Pharmaceutical Companies, Last 18 Months

Top 20 Chinese Pharma Companies by Value, August 30, 2017

<table>
<thead>
<tr>
<th>Company</th>
<th>Value Rank</th>
<th>Value Estimate ($ mil)</th>
<th>2016 Revenue ($mil)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yangtze River Pharma</td>
<td>1</td>
<td>$50,630</td>
<td>$8,300</td>
</tr>
<tr>
<td>Hengrui</td>
<td>2</td>
<td>$22,391</td>
<td>$1,606</td>
</tr>
<tr>
<td>CR Pharma Rx Segment</td>
<td>3</td>
<td>$19,087</td>
<td>$3,129</td>
</tr>
<tr>
<td>Qilu Pharma</td>
<td>4</td>
<td>$16,520</td>
<td>$1,666</td>
</tr>
<tr>
<td>Kangmei Pharma</td>
<td>5</td>
<td>$15,239</td>
<td>$3,159</td>
</tr>
<tr>
<td>Yunnan Baiyao</td>
<td>6</td>
<td>$13,505</td>
<td>$3,245</td>
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<tr>
<td>Fosun Pharma</td>
<td>7</td>
<td>$12,275</td>
<td>$2,125</td>
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<tr>
<td>Sinopharm - Rx Segment</td>
<td>8</td>
<td>$12,163</td>
<td>$1,994</td>
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<tr>
<td>CSPC Pharma</td>
<td>9</td>
<td>$9,252</td>
<td>$1,522</td>
</tr>
<tr>
<td>Huadong / China Grand</td>
<td>10</td>
<td>$6,863</td>
<td>$3,634</td>
</tr>
<tr>
<td>Tasly Pharma</td>
<td>11</td>
<td>$6,209</td>
<td>$2,017</td>
</tr>
<tr>
<td>Sino Biopharma</td>
<td>12</td>
<td>$6,097</td>
<td>$1,990</td>
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<tr>
<td>Neptunus Group</td>
<td>13</td>
<td>$5,831</td>
<td>$956</td>
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<tr>
<td>Chongqing Zhifei Bio</td>
<td>14</td>
<td>$5,765</td>
<td>$65</td>
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<tr>
<td>Kanghong Pharma</td>
<td>15</td>
<td>$5,038</td>
<td>$365</td>
</tr>
<tr>
<td>Salubris Pharmaceuticals</td>
<td>16</td>
<td>$5,010</td>
<td>$543</td>
</tr>
<tr>
<td>Kelun Pharma</td>
<td>17</td>
<td>$5,008</td>
<td>$1,241</td>
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<tr>
<td>Humanwell</td>
<td>18</td>
<td>$4,782</td>
<td>$1,784</td>
</tr>
<tr>
<td>Dongbao Pharma</td>
<td>19</td>
<td>$4,670</td>
<td>$286</td>
</tr>
<tr>
<td>GPC</td>
<td>20</td>
<td>$4,389</td>
<td>$2,939</td>
</tr>
</tbody>
</table>
Key Trends in the Chinese Healthcare Sector

There are a Number of Forces at Play that Favor In-Licensing Western Drugs:

- The population is aging and the health needs of the middle class is increasing
- Health care reform: the government vigorously increased investment in healthcare
- Policy support for biomedical innovation
- Per capita health expenditure increased
- Huge market, past 5 years CAGR ~20%
- Increased technological innovation capability
The Evolving Drug Approval Process in China
The China Drug Administration (CDA) oversees pharmaceuticals in China. CDA was formerly known as CFDA. New Drug Applications are managed by the Center for Drug Evaluation while enforcement of pharmaceutical regulations is managed by NIFDC and its provincial counterparts.
Separate Agency Will Oversee Drug Prices and Reimbursement

• Plans announced in 2017 also include the formation of a new Medical Reimbursement Agency (MRA).

• This agency will report to the State Council and will oversee medical insurance policy-making in China.

• Today, there are three basic health insurance approaches that cover urban employees, township residents, and rural residents, which are managed separately by the Ministry of Human Resources and Social Security (MHRSS), and the National Health and Family Planning Commission (NHFPC).

• These approaches will all be consolidated into MRA.

• MRA will also manage drug price regulation, and health service pricing and reimbursement policy-making.

• MRA will also management government procurement of drugs and medical devices.
Regulatory Filing Pathway is Driven by Where the Drug is Manufactured

<table>
<thead>
<tr>
<th>Manufacture Site</th>
<th>Filing Pathway</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outside China</td>
<td>Imported Drug Filing</td>
<td>• Licensor protects patents, know-how, trade secrets</td>
<td>• Typically takes longer than domestic filing</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Ability to manage global supply and control product quality</td>
<td>• Supply price not competitive, affects sales potential</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• May reduce US/EU COGs with the help of volume in China</td>
<td>• Concern over supply chain disruption</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Product viewed as high quality and may enjoy premium pricing</td>
<td></td>
</tr>
<tr>
<td>In China</td>
<td>Domestic Drug Filing</td>
<td>• May take less time to approval</td>
<td>• Concern over loss of technical know-how</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• May enjoy local government support, better tax treatment</td>
<td>• Tech transfer hurdle</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• May have competitive COGs</td>
<td></td>
</tr>
</tbody>
</table>

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Chinese Government Has Prioritized Biomedical Innovation

• To redirect the unsustainable investment into the real estate market, the Chinese government has chosen biomedical innovation as the next national priority with almost weekly new policies coming out of CDA, which have led to:
  • Accelerated regulatory review of innovative medicines
  • Significantly shortened development timeline by allowing local sponsors to use foreign data
  • Conditional approval based on foreign data for drugs that would address high unmet needs
  • Publication of an “orphan drug list” (120 diseases) as the first step to build out a new industry
  • A record level of capital chasing the next “BeiGene”, only exacerbated by the new access granted to pre-revenue biotechs to list on HK stock exchange
• Chinese government has been promoting “Healthy China 2030” policy
  • Goal is to take healthcare in China to levels seen in the US and Europe
  • Pharmaceutical companies receive incentives for rapid growth
• A further initiative called the Belt and Road initiative encourages Chinese companies to invest abroad and cooperate with foreign companies along an axis reaching from China westward to Africa, South Asia, MidEast and Eastern Europe
China Drug Administration offers VIP treatment for 48 Overseas Drugs

- While the initiative was first revealed in May 2018, the Center for Drug Evaluation (CDE) has officially published a list of 48 drugs approved in US, EU, JP that are urgently needed in China.

- As long as the sponsors can provide evidence that the drug works equally well across races, they can immediately apply for marketing approval and will be eligible for priority review.

- In a recent report, the CDE concluded that they took an average of 59 working days to process an NDA once it’s accepted for priority review – this is lightening speed by FDA / EMA standards.

<table>
<thead>
<tr>
<th>#</th>
<th>Product</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Alecensa</td>
<td>Chugai</td>
</tr>
<tr>
<td>2</td>
<td>Keytruda</td>
<td>Merck</td>
</tr>
<tr>
<td>3</td>
<td>Lynparza</td>
<td>AstraZeneca</td>
</tr>
<tr>
<td>4</td>
<td>Repatha</td>
<td>Amgen</td>
</tr>
<tr>
<td>5</td>
<td>Sylvant</td>
<td>Janssen</td>
</tr>
<tr>
<td>6</td>
<td>Vimizim</td>
<td>Bioclin</td>
</tr>
<tr>
<td>7</td>
<td>Uptravi</td>
<td>Actelion</td>
</tr>
<tr>
<td>8</td>
<td>Siliq</td>
<td>KHK</td>
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<td>9</td>
<td>Soliris</td>
<td>Alexion</td>
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<td>10</td>
<td>Ilaris</td>
<td>Novartis</td>
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<td>11</td>
<td>Prolia</td>
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<td>12</td>
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<td>Novartis</td>
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<td>Entyvio</td>
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<td>16</td>
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<td>18</td>
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<td>Eli Lilly</td>
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<td>Celgene</td>
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<td>21</td>
<td>Firazyr</td>
<td>Shire</td>
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<td>Ampyra</td>
<td>Acorda</td>
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<td>23</td>
<td>Erivedge</td>
<td>Genentech</td>
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<td>24</td>
<td>Otezla</td>
<td>Celgene</td>
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<table>
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<th>#</th>
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<th>Company</th>
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<tbody>
<tr>
<td>25</td>
<td>Arcalyst</td>
<td>Regeneron</td>
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<tr>
<td>26</td>
<td>Xenaizone</td>
<td>Prestwick</td>
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<tr>
<td>27</td>
<td>Kalbitor</td>
<td>Dyax</td>
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<tr>
<td>28</td>
<td>Vpiv</td>
<td>Shire</td>
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<td>29</td>
<td>Vyndaqel</td>
<td>Pfizer</td>
</tr>
<tr>
<td>30</td>
<td>Elelyso</td>
<td>Pfizer</td>
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<td>Kynanro</td>
<td>Genzyme</td>
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<td>Unituxin</td>
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<td>34</td>
<td>Odomzo</td>
<td>Novartis</td>
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<td>35</td>
<td>Lartruvo</td>
<td>Eli Lilly</td>
</tr>
<tr>
<td>36</td>
<td>Spinarra</td>
<td>Biogen</td>
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<tr>
<td>37</td>
<td>Austedo</td>
<td>Teva</td>
</tr>
<tr>
<td>38</td>
<td>Isquette</td>
<td>EUSA Pharma</td>
</tr>
<tr>
<td>39</td>
<td>Oxervate/Sentinel</td>
<td>Dompé</td>
</tr>
<tr>
<td>40</td>
<td>Tremfya</td>
<td>Janssen</td>
</tr>
<tr>
<td>41</td>
<td>Mepsevii</td>
<td>Ultragenyx</td>
</tr>
<tr>
<td>42</td>
<td>Shingrix Zoster Vaccine</td>
<td>GSK</td>
</tr>
<tr>
<td>43</td>
<td>Luxturna</td>
<td>Spark Therapeutics</td>
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<tr>
<td>44</td>
<td>Brinavess</td>
<td>Cardiome</td>
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<tr>
<td>45</td>
<td>Zontivity</td>
<td>Merck</td>
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<td>46</td>
<td>Harvone</td>
<td>Gilead</td>
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<td>Vosevi</td>
<td>Gilead</td>
</tr>
<tr>
<td>48</td>
<td>Strobil</td>
<td>Gilead</td>
</tr>
</tbody>
</table>

Source: CDE website.
Unlike the US FDA, which has issued clear guidance and regulation for clinical application after extensive input from experts in relevant fields, in China, no formal regulation has been issued.

In recent years, several related associations and conferences have been established.


Despite of the policy uncertainty, the number of Chinese clinical trials for CAR-T therapy have skyrocketed in recent years and the diversity of targets addressed is impressive.
Key Recent Regulatory Changes to Accelerate Drug Approvals in China

1. Streamlining of the Clinical Trial Approval (CTA) process

2. Shortened Timeline for Imported Drug License

3. Expedited Orphan Drug Review Process

4. Improved Rules on Data Exclusivity

5. Expansion of the Marketing Authorization Holder (MAH) Program
Key Change #1: Streamline Clinical Trial Applications (CTA) Approval Process

• Previously, a CTA must had to be obtained before a clinical trial could start and the approval process has been lengthy (6-18 months).

• Proposed changes:
  • Negative notification system: CFDA has 60 business days to conduct its review for new drug clinical trial applications, and then the application will be deemed approved if no objection or question is raised.
  • The same notification requirements also apply to the amendment to clinical trial applications.
  • Separately the review timeline for NDA will be reduced from 150 working days to 120 working days.
Key Change #2: Shortened Registration Process for Imported Drug License

• Proposed changes to clinical trials and the registration of imported innovative drugs which have not previously been approved in any overseas country through an Imported Drug License (IDL).

• An overseas applicant can apply to conduct an international multicenter clinical trial (IMCT) in China for a new drug where no clinical trial has been conducted and no market approval has been obtained elsewhere in the world.
  • Currently, an imported drug must have already been approved for marketing, or at least have entered into the Phase II or III trial in an overseas country before an application to conduct an IMCT can be filed in China.

• An overseas applicant can proceed directly to the IDL registration filing for a new drug after finishing an IMCT in China.
  • Currently, the applicant will have to apply for an additional waiver of a Phase III trial with the CFDA before the IDL filing.

• The above changes, if implemented, may effectively shorten the registration period for an imported new drug by at least two years.

• In addition, clinical trial data generated overseas, or bioequivalence testing data from the EU, US or Japan, will be considered acceptable for IDL registration in China if the data complies with the CFDA’s requirements.
Key Change #3: Expedited Orphan Drug Review Process

- Currently there is no official definition or an orphan diseases in China and no special expedited orphan drug approval process is available
- In terms of clinical trial, the PRC Drug Registration Measures only mention the possibility of applying to the CFDA for a clinical trial waiver or for a reduction in the number of test subjects
- Such applications will be considered on a case-by-case basis

**Proposed changes:**
- The National Health and Family Planning Commission will issue a catalogue of rare diseases
- A rare disease patient registration system will be established
- The approval process for orphan drugs will be streamlined (application to the CFDA to reduce the number of test subjects and expedited approval will be available)
  - Orphan drugs that have been approved overseas, the CFDA will have the discretion to consider granting conditional approval for marketing and the applicant can supplement trial data after approval.
- Seven year data exclusivity for newly approved orphan drugs
Key Change #4: 
Improved Rules on Data Exclusivity

- Currently six-year data exclusivity period for drugs that contain new chemical entities
- **Proposed changes:**
  - Orphan diseases: 7 years
  - Biologic drugs: 12 years
  - Pediatric indication: 10 years
- Data exclusivity period will also be available to a new drug filed in China within one year after approval in the EU, US or Japan
- For drugs filed in China after the one-year period, data exclusivity protection will be available but the protection period will be reduced by the period of time delayed
Key Change #5: Improvement of the Marketing Authorization Holder (MAH) Program

- Previously applicants who seek approval for commercializing drugs that are manufactured in China must own a manufacturing facility that is capable of producing the drugs in accordance with GMPs.
- Under the new system, MAHs are responsible for the development and approval of drugs but manufacturing can be done by companies themselves or a CMO.
- Historically foreign drug developers chose their drug approvals as “imported drugs” with manufacturing done outside of China.
- MAH system allows foreign drug makers the options of seeking approval as domestic drugs rather than imported drugs by entrusting a qualified CMO in China.
Health In China
Life Expectancy in China

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<tr>
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<th>Expected</th>
<th>Observed</th>
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<tr>
<td></td>
<td>1990</td>
<td>2016</td>
</tr>
<tr>
<td>Females</td>
<td>70.4</td>
<td>69.2</td>
</tr>
<tr>
<td></td>
<td>77.3</td>
<td>79.9</td>
</tr>
<tr>
<td>Males</td>
<td>65.5</td>
<td>65.0</td>
</tr>
<tr>
<td></td>
<td>71.1</td>
<td>73.4</td>
</tr>
</tbody>
</table>

Leading Causes of Death in China

<table>
<thead>
<tr>
<th>2005 Ranking</th>
<th>2016 Ranking</th>
<th>% Change 2005-2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cerebrovascular disease</td>
<td>1</td>
<td>-1.5%</td>
</tr>
<tr>
<td>Ischemic heart disease</td>
<td>2</td>
<td>40.1%</td>
</tr>
<tr>
<td>COPD</td>
<td>3</td>
<td>-21.2%</td>
</tr>
<tr>
<td>Lung cancer</td>
<td>4</td>
<td>24.4%</td>
</tr>
<tr>
<td>Liver cancer</td>
<td>5</td>
<td>57.8%</td>
</tr>
<tr>
<td>Road injuries</td>
<td>6</td>
<td>13.6%</td>
</tr>
<tr>
<td>Stomach cancer</td>
<td>7</td>
<td>-9.0%</td>
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<tr>
<td>Alzheimer disease</td>
<td>8</td>
<td>-15.7%</td>
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<tr>
<td>Esophageal cancer</td>
<td>9</td>
<td>45.4%</td>
</tr>
<tr>
<td>Lower respiratory infect</td>
<td>10</td>
<td>-11.5%</td>
</tr>
<tr>
<td>Hypertensive heart disease</td>
<td>12</td>
<td>-16.7%</td>
</tr>
</tbody>
</table>

Leading Causes of Premature Death in China


Top 10 causes of years of life lost (YLLs) in 2016 and percent change, 2005-2016, all ages, number

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Top Causes of Disability in China


Top 10 causes of years lived with disability (YLDs) in 2016 and percent change, 2005-2016, all ages, number

Top Risk Factors Driving Death and Disability Combined in China

Top 10 risks contributing to DALYs in 2016 and percent change, 2005-2016, all ages, number

Importance of Top 10 Causes of Death and Disability in China Versus Other Countries

<table>
<thead>
<tr>
<th></th>
<th>Cardiovascular disease</th>
<th>Ischemic heart disease</th>
<th>COPD</th>
<th>Road injuries</th>
<th>Low back &amp; neck pain</th>
<th>Lower respiratory diseases</th>
<th>Lung cancer</th>
<th>Skin diseases</th>
<th>Liver cancer</th>
<th>Congenital defects</th>
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<td>339.1</td>
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</table>

China has higher rates of death and disability from stroke, lung cancer and liver cancer than other countries (on average). This likely reflects high rates of smoking and diet.
Therapeutic Areas of Most Interest for China Licensing Deals

- **Cardiology**
  - 230m Chinese have CVD due to unhealthy lifestyle (smoking, drinking, stress, etc.)*
  - Stroke is the #1 cause of death in China

- **Diabetes and Kidney Disease**
  - Currently 110 million diabetics, three times the US number, with many more undiagnosed*
  - High interest in kidney disease products for persons with end stage renal disease caused by diabetes

- **Cancer**
  - In 2015, China reported 4.3 million new cancer cases, accounting for 20 percent of the worldwide total*
  - Lung cancer especially problematic due to high rates of smoking

- **Central Nervous System**
  - Mental health conditions widespread
  - Undertreated
  - High interest in pain products as well

- **Respiratory**
  - COPD is the 3rd leading cause of death in China due to high pollution and 50% of men smoking

- **Orthopedics**
  - Aging population. China’s population over 65 will reach 170 million by 2020*

- **Liver disease and Virology**
  - Liver disease endemic in China. Hepatitis B is widespread

*Source: Top Market Series by International Trade Administration, US Department of Commerce.*
Intellectual Property Protection in China
Historical Perceptions Have Not Been Good

• “China has long been known as a manufacturing powerhouse – home to numerous legitimate Chinese and multinational production facilities. The problem over the past few decades has been that once Chinese producers learned how to manufacture foreign products, there were very few legal roadblocks to prevent them from reproducing those same products under different names and then pocketing the sales profits.”

• “Back in 2004, CBS’ 60 Minutes reported that ‘15-20% of all goods in China are counterfeit’ and there’s no evidence that the counterfeiting has slowed down in recent years. This has led to China’s reputation as one of the top global producers of cheap, IP-infringing knock-offs.”

• “In the US, for example, nearly 80% of all counterfeit goods seized in 2009 originated in mainland China. If Hong Kong and Taiwan are included in the count, that number jumps up to 90%. In 2011, reports showed that 8% of the country’s GDP consisted of unauthorized sales of counterfeit goods.”

Many executives of Western pharmaceutical companies are concerned about respect for intellectual property in China.

The Facts Today About IP in China

• China’s debut on the international arena of the intellectual property (IP) protection dates back to 1980, when it joined the World Intellectual Property Organization (WIPO), and demonstrated its intention to meet international standards of IP protection.

• Since then, China has acceded one after the other to the major international conventions and agreements for the protection of IPR, the Paris Convention of Industrial Property (Paris Convention) in 1984, the Patent Cooperation Treaty (PCT) in 1993, the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (Budapest Treaty) in 1995, the International Convention for the Protection of New Varieties of Plants (UPOV Convention) in 1999.

• After joining the WTO, the State Council in 2001 promulgated the Implementing Regulations of the Patent Law of the People’s Republic of China (Implementing Regulations). The State Intellectual Property Office of the People’s Republic of China (SIPO) also published a Patent Examination Guidelines (Guidelines) to further explain the Patent Law and the Implementing Regulations.

• Chinese patent law allows for the protection of patents on new chemical entity structures, biologics and processes associated thereof.

• However, Chinese patent law does not permit the patenting of diagnostic methods, human cloning, use of human embryos and natural substances.

• The China patent office processes over one million patent applications a year.

• China offers aggressive opportunities for civil, criminal and judicial enforcement of patents.
Enforcement of Patents in China

• Three ways to enforce a patent:
  “A patent holder has three venues for enforcing its patent rights in China: the patent office (SIPO), civil courts and the General Administration of Customs (GAC).”

• Infringement claims tried separately from validity:
  “Chinese courts try infringement and validity separately. It is common for the defendant to file a request for invalidation to the PRB in response to an infringement action. It depends on the court whether the infringement proceedings are then stayed until the validity of the patent has been determined (by the PRB or a court on appeal). But typically, the infringement proceedings for a utility model or design patent right will be stayed.”

Measures to Strengthen IP Underway

• “China’s top policy-making body proposed to explore a new patent linkage system. For example, under China’s old framework, drug approval process lacks association with patent protection. As such, only a simple non-infringement statement is required for the granting of drug approval, which makes it hard to hold the applicant liable for the authenticity or accuracy of that statement. The patent linkage system appears to mirror the U.S. system in certain aspects. Specifically, a drug applicant is required to disclose relevant patent information when filing an application for drug registration and notify the patentee with 20 days if the applicant is willing to challenge the original patent holder’s rights.”

• “A five-year maximum patent extension was also proposed so that new drugs can be introduced into China at the same time as in other countries. Further, draft rules that arguably extend regulatory data exclusivity periods based on the types of drugs—10 to 12 years for new therapeutic biologics, and six years each for new small molecule drugs, orphan drugs, and pediatric drugs—have also been proposed.”
“BEIJING – May 16, 2018 -- China will lengthen patent protection on pharmaceuticals to up to 25 years from 20 starting this month, in a move that appears aimed at deflecting U.S. criticism over intellectual property violations.

Beijing has also scrapped import tariffs ranging up to 6% on 28 categories of drugs, including those used to treat cancer.

The sudden extension is without a doubt a response to the trade frictions between China and the U.S.," said a patent lawyer in Beijing. The longer term could help bridge their gap on trade practices by offering more protection to foreign drugmakers, which in turn could encourage greater U.S. exports to China.”
China In-Licensing Activity and Deal Statistics
2018 is a Record Year for China In-Licensing Deals

Key factors behind the jump in licensing activity in 2018:
1. Encouragement of licensing over M&A following the 19th Party Congress.
2. Strong stock market valuations of companies that are licensing in many Western drugs.

By Comparison: Outbound China Pharma M&A Down in 2018

Key factors behind the decline in M&A activity in 2018:

1. Capital controls associated with currency access
2. CIFIUS restrictions on U.S. market access by Chinese companies
3. Encouragement of licensing over M&A following the 19th Party Congress


TORREYA | Creating Value Through China Partnering - OCT 2018
## Illustrative Licensing Transactions on Late-stage Products

in $mm

<table>
<thead>
<tr>
<th>Date</th>
<th>Licensor</th>
<th>Licensee</th>
<th>Asset(s)</th>
<th>Indication(s)</th>
<th>Stage in US</th>
<th>Upfront</th>
<th>Milestone</th>
<th>Total</th>
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<tbody>
<tr>
<td>Dec-17</td>
<td>Hangzhou Zhongmei</td>
<td>vTv</td>
<td>GLP-1R Agonist</td>
<td>type 2 diabetes</td>
<td>Ph2</td>
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<td>$75</td>
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<td>Zai Lab</td>
<td>Five Prime</td>
<td>FPA144</td>
<td>gastric cancer</td>
<td>Ph3</td>
<td>5</td>
<td>39</td>
<td>44</td>
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<tr>
<td>Dec-17</td>
<td>Fosun</td>
<td>Ardelyx</td>
<td>Tenapanor</td>
<td>IBS-C &amp; hyperphosphatemia</td>
<td>Ph3</td>
<td>12</td>
<td>113</td>
<td>125</td>
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<tr>
<td>Dec-17</td>
<td>Everest Medicines</td>
<td>Arena Pharma</td>
<td>Ralinepag / Etrasimod</td>
<td>PAH / ulcerative colitis</td>
<td>Ph3 / Ph2</td>
<td>12</td>
<td>212</td>
<td>224</td>
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<td>Oncolytics</td>
<td>Reolysin</td>
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<td>86</td>
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<td>Bremelanotide</td>
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<td>Ph3</td>
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<td>100</td>
<td>105</td>
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<td>Chiesi</td>
<td>Envarsus XR</td>
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<td>Byetta Bydureon</td>
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<td>50</td>
<td>100</td>
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<td>HIBP and VABP</td>
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<td>AGS-003</td>
<td>cancer</td>
<td>Ph3</td>
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<td>Vascepa®</td>
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<td>Brinavess™</td>
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<td>3</td>
<td>4</td>
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<td>Dec-14</td>
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<td>Medicines Co.</td>
<td>Angiomax &amp; Clevipres</td>
<td>cardiovascular treatments</td>
<td>Commercial</td>
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<td>125</td>
<td>148</td>
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<td>Oct-12</td>
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<td>Ironwood</td>
<td>Linaclotide</td>
<td>IBS-C</td>
<td>Commercial</td>
<td>23</td>
<td>125</td>
<td>148</td>
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</table>

1st Quartile: $5 $40 $45

Median: $9 $75 $84

Mean: $13 $83 $95

3rd Quartile: $50 $212 $262
## Illustrative Licensing Transactions on Early-stage Products

in $mm

<table>
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<th>Date</th>
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<th>Indication(s)</th>
<th>Stage</th>
<th>Total</th>
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<td>Harbour BioMed</td>
<td>HL161; HL036</td>
<td>Autoimmune; Dry Eye</td>
<td>Preclinical; Ph1</td>
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<td>Ionis Pharma</td>
<td>Suzhou Ribo</td>
<td>RNA-targeted therapeutics</td>
<td>Metabolic disease &amp; Cancer</td>
<td>Preclinical</td>
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<td>07/28/16</td>
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<td>Shandong Luoxin</td>
<td>YH25448</td>
<td>NSCLC</td>
<td>Preclinical</td>
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<td>Innovent Biologics</td>
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<td>Link Health</td>
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<td>3SBio</td>
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<td>siRNA Therapeutics</td>
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<td>Preclinical</td>
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</table>

1st Quartile: $19  
Median: $65  
Mean: $61  
3rd Quartile: $93
Deal Economics Have Improved in 2018

Of the 279 deals in our database, upfronts were disclosed 74 times and total deal economics (upfronts + milestones) were disclosed 90 times. The tables and charts provide summary statistics on upfronts and total payments across deals and time in USD millions. It is very clear that upfronts have gone up in 2018 and that total deal economics have also crept up over time.

<table>
<thead>
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<th>All Cases</th>
<th>Upfront</th>
<th>Total</th>
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<tr>
<td>Low</td>
<td>$1.0</td>
<td>$0.2</td>
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<tr>
<td>Q1</td>
<td>$2.6</td>
<td>$10.0</td>
</tr>
<tr>
<td>Mean</td>
<td>$8.6</td>
<td>$73.0</td>
</tr>
<tr>
<td>Median</td>
<td>$5.0</td>
<td>$50.5</td>
</tr>
<tr>
<td>Q3</td>
<td>$12.0</td>
<td>$103.3</td>
</tr>
<tr>
<td>High</td>
<td>$40.0</td>
<td>$450.0</td>
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<th>2004-2017</th>
<th>Upfront</th>
<th>Total</th>
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<tr>
<td>Mean</td>
<td>$7.2</td>
<td>$63.8</td>
</tr>
<tr>
<td>Median</td>
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<td>$42.0</td>
</tr>
<tr>
<td>Q3</td>
<td>$8.0</td>
<td>$100.3</td>
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<tr>
<td>High</td>
<td>$40.0</td>
<td>$450.0</td>
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<tr>
<td>Count</td>
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</table>

<table>
<thead>
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<th>2018 Only</th>
<th>Upfront</th>
<th>Total</th>
</tr>
</thead>
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<tr>
<td>Low</td>
<td>$1.0</td>
<td>$5.5</td>
</tr>
<tr>
<td>Q1</td>
<td>$3.4</td>
<td>$35.1</td>
</tr>
<tr>
<td>Mean</td>
<td>$10.9</td>
<td>$95.6</td>
</tr>
<tr>
<td>Median</td>
<td>$5.8</td>
<td>$69.0</td>
</tr>
<tr>
<td>Q3</td>
<td>$15.0</td>
<td>$118.5</td>
</tr>
<tr>
<td>High</td>
<td>$40.0</td>
<td>$424.0</td>
</tr>
<tr>
<td>Count</td>
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<td>57</td>
</tr>
</tbody>
</table>

**UPFRONT PAYMENT ONLY ($MM)**

- **Q1:** 2004-2017: $1.6, 2018: $3.4
- **Mean:** 2004-2017: $7.2, 2018: $9.9
- **Median:** 2004-2017: $4.3, 2018: $5.8
- **Q3:** 2004-2017: $8.0, 2018: $15.0

**UPFRONT + MILESTONES ($MM)**

- **Q1:** 2004-2017: $6, 2018: $35.1
- **Mean:** 2004-2017: $64, 2018: $96
- **Median:** 2004-2017: $42, 2018: $69
- **Q3:** 2004-2017: $100, 2018: $119

Upfront Payments Over Time

Upfront payments have crept up over time due to increasing market size and competition for deals.

Average Upfront Payment ($mm) 2004-2018

### Therapeutic Area Breakdown and Deal Statistics

<table>
<thead>
<tr>
<th>Therapeutic Area</th>
<th>Deal count</th>
<th>Percent of Deals</th>
<th>Upfront Payment Average ($mm)</th>
<th>Total Deal Average ($mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer</td>
<td>100</td>
<td>36.4%</td>
<td>$11.3</td>
<td>$98.9</td>
</tr>
<tr>
<td>Cardiometabolic</td>
<td>31</td>
<td>11.3%</td>
<td>$10.2</td>
<td>$88.7</td>
</tr>
<tr>
<td>CNS</td>
<td>17</td>
<td>6.2%</td>
<td>$3.0</td>
<td>$18.0</td>
</tr>
<tr>
<td>Anti-Infectives</td>
<td>15</td>
<td>5.5%</td>
<td>$5.6</td>
<td>$66.3</td>
</tr>
<tr>
<td>Virology</td>
<td>14</td>
<td>5.1%</td>
<td>$1.0</td>
<td>$101.0</td>
</tr>
<tr>
<td>Hospital</td>
<td>14</td>
<td>5.1%</td>
<td>$5.9</td>
<td>$20.9</td>
</tr>
<tr>
<td>Pain</td>
<td>12</td>
<td>4.4%</td>
<td>$2.8</td>
<td>$22.8</td>
</tr>
<tr>
<td>Women’s Health</td>
<td>10</td>
<td>3.6%</td>
<td>$5.0</td>
<td>$105.0</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>9</td>
<td>3.3%</td>
<td>$12.1</td>
<td>$141.3</td>
</tr>
<tr>
<td>Inflammation</td>
<td>8</td>
<td>2.9%</td>
<td>NA</td>
<td>$81.0</td>
</tr>
<tr>
<td>Dermatology</td>
<td>8</td>
<td>2.9%</td>
<td>$4.3</td>
<td>$6.0</td>
</tr>
<tr>
<td>Stroke</td>
<td>7</td>
<td>2.5%</td>
<td>$4.0</td>
<td>$23.8</td>
</tr>
<tr>
<td>Renal</td>
<td>7</td>
<td>2.5%</td>
<td>$2.0</td>
<td>$23.7</td>
</tr>
<tr>
<td>Respiratory</td>
<td>4</td>
<td>1.5%</td>
<td>NA</td>
<td>$114.0</td>
</tr>
<tr>
<td>Rheumatology</td>
<td>3</td>
<td>1.1%</td>
<td>$2.0</td>
<td>$77.5</td>
</tr>
<tr>
<td>Bone &amp; Ortho</td>
<td>3</td>
<td>1.1%</td>
<td>$4.0</td>
<td>$4.0</td>
</tr>
<tr>
<td>Men’s health</td>
<td>3</td>
<td>1.1%</td>
<td>NA</td>
<td>$0.2</td>
</tr>
<tr>
<td>Hematology</td>
<td>2</td>
<td>0.7%</td>
<td>$3.0</td>
<td>NA</td>
</tr>
<tr>
<td>Liver Disease</td>
<td>2</td>
<td>0.7%</td>
<td>NA</td>
<td>$15.2</td>
</tr>
<tr>
<td>Ophthalmology</td>
<td>2</td>
<td>0.7%</td>
<td>NA</td>
<td>$10.0</td>
</tr>
<tr>
<td>Vaccines</td>
<td>2</td>
<td>0.7%</td>
<td>$2.5</td>
<td>$2.5</td>
</tr>
<tr>
<td>Pediatrics</td>
<td>1</td>
<td>0.4%</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Rare Disease</td>
<td>1</td>
<td>0.4%</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Total</td>
<td>275</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The table at left shows the breakdown of China in-licensing deals by therapeutic area. The disease burden and payment system is different in China than in the West.

By far the greatest area of licensing activity has been cancer (36.4%) followed by cardiometabolic (11.3%).

Other popular areas for deals include anti-infectives, hospital, pain, GI, dermatology, inflammation, CNS, stroke and virology.

The TA with the highest average upfront has been cancer followed by GI. The highest total deal averages have been associated with GI and cancer medicines.

Phase of Development Breakdown and Deal Statistics

The table at left shows the breakdown of China in-licensing deals by phase of development.

By far the greatest area of licensing activity has been for approved products or products (33% of deals).

But there is robust activity at all points of development. Notably, 20% of deals were done at the preclinical level. Chinese pharmaceutical companies have robust R&D capabilities and are willing to collaborate with their Western counterparts on interesting science.

<table>
<thead>
<tr>
<th>Therapeutic Area</th>
<th>China Deal Count</th>
<th>Percent of Deals</th>
<th>Upfront Payment Average ($mm)</th>
<th>Total Deal Average ($mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved</td>
<td>94</td>
<td>33%</td>
<td>$8.7</td>
<td>$45.8</td>
</tr>
<tr>
<td>Pre-approval</td>
<td>10</td>
<td>4%</td>
<td>$11.3</td>
<td>$174.1</td>
</tr>
<tr>
<td>Phase 3</td>
<td>31</td>
<td>11%</td>
<td>$12.0</td>
<td>$83.6</td>
</tr>
<tr>
<td>Phase 2</td>
<td>56</td>
<td>20%</td>
<td>$7.6</td>
<td>$90.8</td>
</tr>
<tr>
<td>Phase 1</td>
<td>34</td>
<td>12%</td>
<td>$5.6</td>
<td>$74.7</td>
</tr>
<tr>
<td>Preclinical</td>
<td>56</td>
<td>20%</td>
<td>$3.0</td>
<td>$49.1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>281</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Comparison to Japan In-Licensing Deals

The tables at left shows the breakdown of China in-licensing deals by phase of development versus Japan in-licensing deals.

The average upfront on a Japan deal is three times higher than that for a China deal. The total deal packages for Japan are even higher.

The difference is a reflection, of course, of the economic value of products in each territory. With a GDP/Capita almost five times higher, the ability to achieve higher pricing for products in Japan more than outweighs the larger size of the Chinese population.

We do expect to see the gap in deal economics between the territories narrow in the years ahead.

### China Territory In-Licensing Deal Statistics

<table>
<thead>
<tr>
<th>Phase</th>
<th>China Deal Count</th>
<th>Percent of Deals</th>
<th>Upfront Payment Average ($mm)</th>
<th>Total Deal Average ($mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved</td>
<td>94</td>
<td>33%</td>
<td>$8.7</td>
<td>$45.8</td>
</tr>
<tr>
<td>Pre-approval</td>
<td>10</td>
<td>4%</td>
<td>$11.3</td>
<td>$174.1</td>
</tr>
<tr>
<td>Phase 3</td>
<td>31</td>
<td>11%</td>
<td>$12.0</td>
<td>$83.6</td>
</tr>
<tr>
<td>Phase 2</td>
<td>56</td>
<td>20%</td>
<td>$7.6</td>
<td>$90.8</td>
</tr>
<tr>
<td>Phase 1</td>
<td>34</td>
<td>12%</td>
<td>$5.6</td>
<td>$74.7</td>
</tr>
<tr>
<td>Preclinical</td>
<td>56</td>
<td>20%</td>
<td>$3.0</td>
<td>$49.1</td>
</tr>
<tr>
<td>Average</td>
<td>281</td>
<td></td>
<td>$8.6</td>
<td>$72.9</td>
</tr>
</tbody>
</table>

### Japan Territory In-Licensing Deal Statistics

<table>
<thead>
<tr>
<th>Phase</th>
<th>Japan Deal Count</th>
<th>Percent of Deals</th>
<th>Upfront Payment Average ($mm)</th>
<th>Total Deal Average ($mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved</td>
<td>40</td>
<td>18.4%</td>
<td>$73.2</td>
<td>$174.4</td>
</tr>
<tr>
<td>Pre-approval</td>
<td>4</td>
<td>1.8%</td>
<td>$39.0</td>
<td>$431.7</td>
</tr>
<tr>
<td>Phase 3</td>
<td>32</td>
<td>14.7%</td>
<td>$26.5</td>
<td>$229.4</td>
</tr>
<tr>
<td>Phase 2</td>
<td>32</td>
<td>14.7%</td>
<td>$33.7</td>
<td>$225.8</td>
</tr>
<tr>
<td>Phase 1</td>
<td>18</td>
<td>8.3%</td>
<td>$13.0</td>
<td>$154.7</td>
</tr>
<tr>
<td>Preclinical</td>
<td>91</td>
<td>41.9%</td>
<td>$17.4</td>
<td>$316.8</td>
</tr>
<tr>
<td>Average</td>
<td>217</td>
<td></td>
<td>$33.0</td>
<td>$323.0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Japan vs. China</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.8X</td>
<td>4.4X</td>
</tr>
</tbody>
</table>

Most Important Licensees in China
Key Players Looking for China Rights to Pharmaceuticals

Top 25 Companies by Number of Deals Done

<table>
<thead>
<tr>
<th>Rank</th>
<th>Company</th>
<th>Deal count</th>
<th>Upfront Payment Average ($mm)</th>
<th>Total Deal Average ($mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>SciClone</td>
<td>21</td>
<td>$3.0</td>
<td>$17.3</td>
</tr>
<tr>
<td>2</td>
<td>Lee’s Pharmaceuticals</td>
<td>13</td>
<td>$1.0</td>
<td>$42.5</td>
</tr>
<tr>
<td>3</td>
<td>Fosun Pharma</td>
<td>12</td>
<td>$10.4</td>
<td>$55.0</td>
</tr>
<tr>
<td>3</td>
<td>China Medical System</td>
<td>12</td>
<td>$2.0</td>
<td>$72.5</td>
</tr>
<tr>
<td>5</td>
<td>3SBio</td>
<td>11</td>
<td>$2.3</td>
<td>$3.5</td>
</tr>
<tr>
<td>6</td>
<td>Zai Lab</td>
<td>9</td>
<td>$9.6</td>
<td>$66.5</td>
</tr>
<tr>
<td>7</td>
<td>Simcere Pharma</td>
<td>7</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>8</td>
<td>Sinopharm</td>
<td>6</td>
<td>$1.0</td>
<td>$1.0</td>
</tr>
<tr>
<td>9</td>
<td>Ascletis</td>
<td>5</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>9</td>
<td>Tasly</td>
<td>5</td>
<td>$21.0</td>
<td>$63.0</td>
</tr>
<tr>
<td>9</td>
<td>Canbridge</td>
<td>5</td>
<td>$15.5</td>
<td>$117.0</td>
</tr>
<tr>
<td>9</td>
<td>Hisun</td>
<td>5</td>
<td>$13.5</td>
<td>$63.3</td>
</tr>
<tr>
<td>13</td>
<td>Eddingpharm</td>
<td>5</td>
<td>$6.0</td>
<td>$86.5</td>
</tr>
<tr>
<td>13</td>
<td>Sihuan Pharma</td>
<td>5</td>
<td>$6.0</td>
<td>$6.8</td>
</tr>
<tr>
<td>15</td>
<td>Hengrui</td>
<td>4</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>15</td>
<td>Luoxin Pharma</td>
<td>4</td>
<td>$12.0</td>
<td>$94.0</td>
</tr>
<tr>
<td>15</td>
<td>Everest Medicines</td>
<td>4</td>
<td>$9.5</td>
<td>$127.2</td>
</tr>
<tr>
<td>18</td>
<td>China Pioneer Pharma</td>
<td>3</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>18</td>
<td>Yabao</td>
<td>3</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>18</td>
<td>I-Mab</td>
<td>3</td>
<td>$20.0</td>
<td>$120.0</td>
</tr>
<tr>
<td>18</td>
<td>CSPC</td>
<td>3</td>
<td>$9.8</td>
<td>$45.0</td>
</tr>
<tr>
<td>18</td>
<td>Sinovant</td>
<td>3</td>
<td>$4.0</td>
<td>$50.3</td>
</tr>
<tr>
<td>18</td>
<td>Gloria Pharma</td>
<td>3</td>
<td>$3.5</td>
<td>NA</td>
</tr>
<tr>
<td>18</td>
<td>Nhwa</td>
<td>3</td>
<td>$2.5</td>
<td>$5.5</td>
</tr>
<tr>
<td>18</td>
<td>Chiva Pharma</td>
<td>3</td>
<td>$2.0</td>
<td>$68.7</td>
</tr>
</tbody>
</table>

The table at left shows the breakdown of China in-licensing deals by licensee.

By far the most active players have been SciClone, Lee’s Pharmaceuticals, Fosun Pharma, China Medical and 3SBio. These five companies have been at it for over a decade and have good expertise in business development.

Other active players include Zai Lab, Simcere, Sinopharm, Ascletis, Tasly, Canbridge, Hisun, Eddingpharm and Sihuan Pharma.
Top 25 Companies by Average Upfront Payment Made ($mm)

<table>
<thead>
<tr>
<th>Rank</th>
<th>Company</th>
<th>Licensing Deals Completed</th>
<th>Upfront Payment Average ($mm)</th>
<th>Total Deal Average ($mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Cstone</td>
<td>2</td>
<td>$26.0</td>
<td>$405.0</td>
</tr>
<tr>
<td>2</td>
<td>AstraZeneca China</td>
<td>1</td>
<td>$23.0</td>
<td>$148.0</td>
</tr>
<tr>
<td>3</td>
<td>Tasly</td>
<td>5</td>
<td>$21.0</td>
<td>$63.0</td>
</tr>
<tr>
<td>4</td>
<td>Sanofi</td>
<td>1</td>
<td>$21.0</td>
<td>NA</td>
</tr>
<tr>
<td>5</td>
<td>I-Mab</td>
<td>3</td>
<td>$20.0</td>
<td>$120.0</td>
</tr>
<tr>
<td>6</td>
<td>Apollo Bio</td>
<td>2</td>
<td>$19.5</td>
<td>$85.0</td>
</tr>
<tr>
<td>7</td>
<td>Cambridge</td>
<td>5</td>
<td>$15.5</td>
<td>$117.0</td>
</tr>
<tr>
<td>8</td>
<td>Daiichi Sankyo</td>
<td>1</td>
<td>$15.0</td>
<td>$32.5</td>
</tr>
<tr>
<td>9</td>
<td>Hisun</td>
<td>5</td>
<td>$13.5</td>
<td>$63.3</td>
</tr>
<tr>
<td>10</td>
<td>Luoxin Pharma</td>
<td>4</td>
<td>$12.0</td>
<td>$94.0</td>
</tr>
<tr>
<td>11</td>
<td>Antengene</td>
<td>1</td>
<td>$12.0</td>
<td>$162.0</td>
</tr>
<tr>
<td>12</td>
<td>Fosun Pharma</td>
<td>12</td>
<td>$10.4</td>
<td>$55.0</td>
</tr>
<tr>
<td>13</td>
<td>BeiGene</td>
<td>2</td>
<td>$10.0</td>
<td>$133.0</td>
</tr>
<tr>
<td>14</td>
<td>Lummy</td>
<td>1</td>
<td>$10.0</td>
<td>$40.0</td>
</tr>
<tr>
<td>15</td>
<td>CSPC</td>
<td>3</td>
<td>$9.8</td>
<td>$45.0</td>
</tr>
<tr>
<td>16</td>
<td>Zai Lab</td>
<td>9</td>
<td>$9.6</td>
<td>$66.5</td>
</tr>
<tr>
<td>17</td>
<td>Everest Medicines</td>
<td>4</td>
<td>$9.5</td>
<td>$127.2</td>
</tr>
<tr>
<td>18</td>
<td>Huadong Medicine</td>
<td>2</td>
<td>$8.0</td>
<td>$83.0</td>
</tr>
<tr>
<td>19</td>
<td>YOFOTO (China) Health</td>
<td>1</td>
<td>$6.5</td>
<td>$10.0</td>
</tr>
<tr>
<td>20</td>
<td>Eddingpharm</td>
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<td>$6.0</td>
<td>$86.5</td>
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<td>21</td>
<td>Sihuan Pharma</td>
<td>5</td>
<td>$6.0</td>
<td>$6.8</td>
</tr>
<tr>
<td>22</td>
<td>Chiesi</td>
<td>1</td>
<td>$6.0</td>
<td>$6.0</td>
</tr>
<tr>
<td>23</td>
<td>Adlai Nortye Biopharma</td>
<td>2</td>
<td>$5.0</td>
<td>$86.0</td>
</tr>
<tr>
<td>24</td>
<td>Shanghai Sinobioway</td>
<td>2</td>
<td>$5.0</td>
<td>NA</td>
</tr>
<tr>
<td>25</td>
<td>Nuokang Medicine</td>
<td>2</td>
<td>$5.0</td>
<td>$5.0</td>
</tr>
</tbody>
</table>

The table at left shows the breakdown of China in-licensing deals by licensee. Here companies are ranked by the average upfront payment made. To some degree this may reflect the underlying assets that are licensed in rather than the company’s inherent willingness to spend money. Upfront payments also neglect other important indicia of value such as royalties, minimum quantity commitments and milestones. Many companies do not report upfronds thus this table necessarily provides an incomplete picture.

The leaders in spending on upfronds (on average) are Cstone, AstraZeneca, Tasly, Sanofi and I-Mab.

The biggest spenders in aggregate upfront dollars paid are Fosun and Tasly.
Top 20 Licensees Interested in Pharma China Rights

3SBio
HQ: Shenyang, China
Market Cap: $3.7 billion
Revenue: $607 million
EBITDA: $204 million
Rank by Deals Done: #5

**DESCRIPTION:** 3SBio is all about biologics. They are a leading marketer of EPO, a TPO agonist, a TNFa modulator for rheumatoid arthritis, and other related products. Their key TAs are oncology, autoimmune, dermatology, and nephrology.

**DEALS:** Actively looking to license in complementary products or biologics that they can manufacture and sell in China. Acquired Biopure, a protein manufacturer in Canada in 2017. Has done 11 in-licenses from Western & Japan companies. Invested in a $25 million round for Refuge Biotechnologies of Canada in April 2018.

**www.3sbio.com**

ApolloBio
HQ: Beijing, China
Private company
Rank by Average Upfront Payment: #6

**DESCRIPTION:** ApolloBio is a recently formed vehicle looking to license in late-stage oncology new drugs and cell & gene therapeutic technologies into Greater China. This company has been advised by the Chinese financial firm HollyHigh.

**DEALS:** Actively looking to license in products in oncology and gene therapy. In April 2018, Apollo licensed Toca511 & Toca FC, a Phase 3 gene therapy product for recurrent glioma from Tocagen for $16mm upfront, $111mm in milestones and royalties. In May 2018, Apollo licensed VGX-3100, a DNA vaccine for cervical dysplasia from Inovio Pharma for $23mm upfront, milestones and royalties.

**www.apollobio.com**

BeiGene
HQ: Cayman Islands
Market Cap: $7.5 billion
Revenue: $340 million
EBITDA: -$238 million
Rank by Average Upfront Payment: #13


**DEALS:** Actively looking to license in late-stage or commercial products for China in oncology with a focus on assets that would complement their PD-1 or BTK. Also looking to license in global rights for promising oncology products that are early stage. In July 2017 BeiGene cross-licensed its PD-1 inhibitor ex-China to Celgene while licensing in commercial products for China.

**www.beigene.com**

Canbridge
HQ: Beijing, China
Private company
Rank by Average Upfront Payment: #7

**DESCRIPTION:** Canbridge is all about bridging global first-in-class specialty therapies and unmet medical needs in China. It has four assets in clinical development and is actively looking for more licensing opportunities. TA focus areas thus far have been oncology and rare disease.

**DEALS:** In Feb 2018 Canbridge licensed China rights to Neratinib from Puma Bio for $30mm upfront, $70mm in milestones and royalties. In June 2015 Canbridge licensed China rights to Asunercept for GBM and MDS from Apogenix. In March 2016 Canbridge licensed rights in China to AV-2013 for GIST from AVEO.

**http://www.canbridgepharma.com/**
Top 20 Licensees Interested in Pharma China Rights (cont.)

**CMS**

HQ: Shenzhen, China  
Market Cap: $2.9 billion  
Revenue: $768 million  
EBITDA: $311 million  
Rank by Deals Done: #3

**DESCRIPTION:** China Medical System is a major marketer and distributor of pharmaceutical products in China. It markets many drugs including Plendil for hypertension, Deanxit for depression and Ursofalk for gallstones.

**DEALS:** Because of its broad sales and marketing network, CMS is open as to therapeutic area for products but excels in GI, CNS, Cardiometabolic and anti-infectives. Has signed over a dozen licenses, asset purchases and distribution deals with companies that include AstraZeneca, Lundbeck, Novartis and VAXIMM.

http://en.cms.net.cn

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**CSPC**

HQ: Shijiazhuang, China  
Market Cap: $12.4 billion  
Revenue: $3.5 billion  
EBITDA: $800 million  
Rank by Deals Done: #3

**DESCRIPTION:** CSPC is a major conglomerate that is interested in pharma R&D and markets innovative drugs and TCM. CSPC is also the world’s largest manufacturer of Vitamin C and a major manufacturer of caffeine.

**DEALS:** CSPC has an office in Princeton, NJ and is actively searching to license in innovative pipeline products for China. Also looking to acquire generics and well known dietary supplement brands. In Sep 2018 licensed China rights to duvelisib from Verastem for $15mm upfront, $30mm in milestones and royalties. In June 2017 entered into a research collaboration with UT Health in spinal cord injury.

www.cspc.com.hk

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**CStone Pharma**

HQ: Beijing, China  
Private company  
Rank by Average Upfront Payment: #1

**DESCRIPTION:** CStone Pharma was formed in 2016 to bring innovative products to China and has raised $410mm thus far. Focused on oncology drugs and is in late stage development of a PD-L1 inhibitor for the China market.

**DEALS:** Actively looking to license in post-POC oncology products for China. Will consider clinical collaborations for earlier stage products. Licensed Ivosidenib (AML) from Agios in June 2018 for $12mm upfront, $412mm in milestones and royalties. Also, in June 2018, licensed Avapritinib for GIST from Blueprint Medicines for $40mm upfront, $346mm in milestones and royalties.

www.cstonepharma.com

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**Everest Medicines**

HQ: Beijing, China  
Private company  
Rank by Average Upfront Payment: #17

**DESCRIPTION:** Everest Medicines is focused on licensing products address critical unmet medical needs for patients in Greater China and have a high probability of market approval. Formed in late 2017 by C-Bridge Capital.

**DEALS:** In Sep 2018, Everest licensed Cefepime from VenatoRx for cUTI and HABP/CABP. In June 2018, Everest licensed FGF401 for HCC from Novartis. In Feb 2018, Everest licensed Eravacycline from Tetraphase for infection for $7mm upfront and $36.5mm in milestones. In Dec 2017 Everest licensed Ralinepag and Etrasimod for PAH and UC from Arena for $12mm upfront and other payments.

www.everestmedicines.com
Top 20 Licensees Interested in Pharma China Rights (cont.)

**Fosun Pharma**
- HQ: Shanghai, China
- Market Cap: $10.1 billion
- Revenue: $3.2 billion
- EBITDA: $493 million
- Rank by Deals Done: #3

*DESCRIPTION:* Fosun Pharma is a leader in the Chinese pharmaceutical market with an interest in innovative medicines and generics. Fosun Pharma is also involved in healthcare services and medical devices with operations in China and elsewhere.

*DEALS:* Fosun is a prolific licensee. Fosun will also consider investment and has been active in M&A (e.g., bought Gland Pharma in 2017). Key deals have been a JV with Kite for CAR-t in China ($40mm upfront), a license for Tenapanor from Ardelyx ($12mm upfront) and a license of Avatrombopag from Dova ($5mm upfront).

[www.fosunpharma.com](http://www.fosunpharma.com)

**Jiangsu Hengrui Medicine Co ("Hengrui")**
- HQ: Lianyungang, China
- Market Cap: $31 billion
- Revenue: $2.2 billion
- EBITDA: $615 million
- Rank by Deals Done: #15

*DESCRIPTION:* Jiangsu Hengrui Medicine Co ("Hengrui") is China’s leader in oncology medicines. Hengrui also markets products in immunology, cardiovascular and endocrine medicine. Pronounced: “Heng-Ray”.

*DEALS:* Hengrui is more quiet on deals than one might expect given its high market cap. The company is focused mainly on internal R&D. In 2016, Hengrui licensed the rights to Telemylesin from Oncolys. In 2015, Hengrui licensed the rights to VARUBI for CINV from Tesaro. And, in 2013, Hengrui entered into a preclinical collaboration with X-Body for AMD (ophthalmology).


**Hisun**
- HQ: Taizhou, China
- Market Cap: $1.7 billion
- Revenue: $1.5 billion
- EBITDA: $169 million
- Rank by Upfronts: #9

*DESCRIPTION:* Hisun is a major global player in API which also markets pharmaceuticals across China. For NCEs, Hisun has 6 Key TAs of focus: oncology, CV, metabolic (liver and diabetes), immunology, ophthalmology and anti-infectives. Also interested in novel generics and nutritionals for the China market.

*DEALS:* Licensed Thermodox® from Celsion (cancer drug) in 2013 for $30mm upfront. Licensed Pritumumab for cancer from Nascent Biotech in 2016. Licensed CBLB612, a stem cell therapeutic from Cleveland Biolabs in 2009.

[www.hisunpharm.com](http://www.hisunpharm.com)

**Huadong Medicine**
- HQ: Hangzhou, China
- Market Cap: $8 billion
- Revenue: $4.2 billion
- EBITDA: $411 million
- Rank by Upfronts: #18

*DESCRIPTION:* Huadong Medicine sells modern medicines, TCM, API and biologics in China. Huadong is a subsidiary of China Grand Enterprises, a $200 billion holding company with significant interests in the life sciences. Huadong is the largest marketer of immunosuppressant drugs in China and is interested licensing in drugs for a range of therapeutic areas to marketed by its 5000 reps.

*DEALS:* In Apr 2018, Huadong/China Grand announced the acquisition of Sinclair Pharma for £166m to supplement its aesthetic medicine platform. In Dec 2017 Huadong licensed China rights to TTP273, a GLP-1 agonist for $8mm upfront.

Top 20 Licensees Interested in Pharma China Rights (cont.)

I-Mab Biopharma
HQ: Shanghai, China
Private company
Rank by Average Upfront Payment: #5

DESCRIPTION: I-Mab Biopharma has raised $500mm to build a Chinese powerhouse in biologics. Has strength in both CMC and all aspects of biologics R&D.
DEALS: I-Mab likes to in-license Phase 2 stage assets to build first in class immunology and oncology pipeline for China. Has done four deals so far and looking to do more. Licensed HyLeukin from Genexine in 2017. Licensed Mor-202 from Morphosys for multiple myeloma in 2017 for $20mm upfront, $80mm in milestones and royalties. Licensed Olamkicept, an IL-6 modulator, from Ferring in 2016.

http://www.i-mabbiopharma.com

Lee’s Pharm
HQ: Hong Kong
Market Cap: $431 million
Revenue: $140 million
EBITDA: $42 million
Rank by Deals Done: #2

DESCRIPTION: Lee’s Pharm markets drugs across China in the following areas: cardiovascular, oncology, gynecology, urology, dermatology, and ophthalmology.
DEALS: Lee’s Pharm is a prolific licensing partner in China for Western companies and, by our count, has done 13 deals since 2013. Rarely reports deal economics. Key licensing deals have included rights to TAB014 for AML in 2018; Aerosurf for ARDS from Windtree in 2017 ($1mm upfront and $37mm in milestones); Duoxal for otitis media from SALVAT in 2016; Resolvine ER from Kato for diabetic retinopathy in 2016 and Tecfarfarin from Armatheon, an anti-coagulant, in 2015.

www.cspc.com.hk

Luoxin
HQ: Beijing, China
Private company
Revenue: $1.4 billion
Rank by Average Upfront Payment: #10

DESCRIPTION: Luoxin (pronounced “Loo-O-shin”) is a leading Chinese pharmaceutical company with full capabilities in R&D, manufacture and commercialization of innovative and generic medicines. With 3500 sales reps, Luoxin reaches 25,000+ hospitals in China plus 100,000+ clinics and 100,000+ pharmacies. Key areas of interest are GI, metabolism, respiratory and cancer.
DEALS: Actively looking to license in generics and innovative drugs. Can invest through its $150mm fund. Licensed TRULANCE for constipation from Synergy in 2018 for $12mm upfront, $56mm in milestones and royalties.

www.luoxin.cn

SciClone Pharmaceuticals
HQ: Shanghai, China
Private company
Rank by Average Deals Done: #1

DESCRIPTION: SciClone is a long established marketer of pharmaceuticals in China. SciClone was acquired by a consortium of investors in 2017 led by GL Capital. SciClone’s main focus is on therapies for liver disease, cancer and cardiovascular disease. SciClone has been the single most active China licensee.
DEALS: In 2016 SciClone licensed three drugs including PT-112 from Phosplatin for cancer; ABLT0812 from Ability Pharma for lung cancer and Dusquetide for oral mucositis from Soligenix. In 2015 SciClone licensed VIBATIV®, an antibiotic for China from Theravance.
Top 20 Licensees Interested in Pharma China Rights (cont.)

**Sihuan Pharma**
- **HQ:** Beijing, China
- **Market Cap:** $1.9 billion
- **Revenue:** $373 million
- **EBITDA:** $247 million
- **Rank by Deals Done:** #13
- **DESCRIPTION:** Sihuan Pharma markets cardio-cerebral vascular system, central nervous system, metabolism, anti-infective, oncology, and diabetes drugs. Sihuan has China’s largest franchise of drugs for stroke (cerebro-vascular disease). Sihuan markets through 3000+ distributors in China and does not field its own reps.
- **DEALS:** Looking for late stage products for CV, dermatology and oncology. Sihuan signed a license in 2017 to market Princess VOLUME for dermatology from Croma Pharma. Sihuan has a 9 person business development team with four people in the U.S.

**Sinovant Sciences**
- **HQ:** Tianjin, China
- **Market Cap:** $4.5 billion
- **Revenue:** $2.5 billion
- **EBITDA:** $376 million
- **Rank by Average Upfront Payment:** #3
- **DESCRIPTION:** Tasly is a large Chinese pharmaceutical company with historical strength in Traditional Chinese Medicines.
- **DEALS:** Tasly is actively looking to in-licensing Western medicines for the China market and has interest in treatments for chronic diseases such as diabetes, kidney disease, liver disease and oncology. In June 2018, Tasly entered into a license and collaboration deal with Mesoblast for cell therapy products for heart disease. Consideration was $40mm upfront, $25mm in milestones and royalties. Has also licensed drugs from EA Pharma, Lilly, Proteotech and Genexine.

**Zai Lab**
- **HQ:** Shanghai, China
- **Market Cap:** $912 mm
- **Revenue:** $0 million
- **EBITDA:** -$66 million
- **Rank by Average Upfront Payment:** #16
- **DESCRIPTION:** Zai Lab is focused on developing drugs for the China market in the fields of cancer, immunology and infection control. The company has a strong pipeline, access to a venture fund and an excellent management team. Zai Lab also has global rights to a number of products in development and will make offers for global rights on high quality early stage programs.
- **DEALS:** Zai Lab licensed the rights to Novocure’s TTF technology in Sep 2018 for $15mm upfront and other payments. In 2016 Zai licensed the rights to Nirapirib for China from TESARO for $15mm upfront, $40mm in milestones and royalties.
Getting a China Licensing Deal Done
Key Phases of a China Licensing Project

There are Seven Key Phases to Licensing a Drug to a Chinese Partner

1. Research on Positioning and China Opportunity
2. Partnership Materials and Outreach
3. Deal Structuring and Economics
4. Transaction Negotiation
5. Transaction Diligence
6. Identify Prospective Partners
7. Transaction Closing

This diagram outlines the process of licensing a drug to a China partner. In the pages that follow, we focus principally on key considerations in the process that are somewhat unique to the China setting.
Preparing for Licensing: The Most Important Step

- Preparing to license a product to China is the most important step. This is because the China market is very different from those of the U.S. and Europe.
- Background research on epidemiology of the underlying disease, currently available treatments, pricing of drugs in the market is important.
- Efforts to understand the market size are important and one should not count on partners to explain the market.
- Other important steps for preparation include work on the regulatory pathway, timelines and clinical trial designs (if a product is in clinical development).
- It is essential to figure out the market exclusivity and patent situation for a drug ahead of time. Is there patent protection in place at all? If so, how long do those patents extend?
- Manufacturing location is important. In general, local manufacturing will involve much lower COGS than offshore manufacture. However, many licensors are reluctant to tech transfer manufacturing processes to local partners.
- A key issue that we have seen at Torreya repeatedly is that the foreign cost of goods is too close (or even above) the local price point. In practice, this means that there is no real market for a product because there is not a profit margin.
- In general profit margins in China need to be as high as they are in the West or even higher given the structure of drug distribution system. The good news is that pricing practices favor highly innovative Western products.
The same process that is used for pharma licensing works well for the China context.

Torreya strongly believes that a great set of non-confidential and confidential materials is one of the most important steps to a good outcome in partnering.

- This will flow from market research and work on positioning in the market.
- Significant upfront preparation takes time and can slow down a process but, in our experience, is well worth it.
- We like to say at Torreya: “Start slow, finish fast.” “Start fast. Finish slow – if at all”.

At Torreya we often will support materials preparation with thorough market research studies on the China opportunity. Key potential steps include:

- Engagement with CDA on regulatory before beginning partnering processes. CDA is very accessible and their feedback can be invaluable. It is particularly important to note that CDA feedback can enhance value obtained from the partnering process.

- Engagement with CROs beforehand. China has a rich set of CROs who provide much more than advice on clinical plans and timelines. We have found that CROs can bring potential customers to hospitals that will treat patients and allow a company to learn about the Chinese patient journey and situation well ahead of time.

- Engagement with physicians and key opinion leaders beforehand. Chinese KOLs are also highly accessible and generally thrilled to hear from Western companies interested in accessing their expertise.
Identification of Prospective Partners

• A key element of any outlicensing project is the identification of counterparties to contact and associated outreach.

• This is a little more challenging than usual for China partnering because many Chinese pharmaceutical companies are unfamiliar to Western companies.

• Hopefully this presentation will be helpful in giving you a starting list of companies to research for partnership activity.

• Research on past deals can be helpful in figuring out who has been interested in related assets before. Also, IQVIA data on related products can be useful in figuring the players in a therapeutic area, their share and how they price products.

• At Torreya, we generally plan a full-scale engagement process understanding that multiple decision-makers and relationships may be involved.

• We have found again and again in the China case that one cannot predict ahead of time who will actually be prepared to close a partnering deal. Many idiosyncratic factors come into play. As a result, we counsel licensors to be prepared to "kiss many frogs in search of the prince". It is important to conduct a comprehensive outreach effort.
Engaging With Prospective Partners

• We have found that engagement with partners is straightforward for companies that have business development representatives in the United States and Europe.

• Engaging with counterparts in China is somewhat more challenging. This is because many Chinese executives do not use email much if at all. Further, practices that work for Western companies where one can guess someone’s email simply (e.g., firstname.lastname@company.com) do not work in China. This is because many Chinese company executive use personal email addresses rather than corporate addresses.

• By far the best tool to use in China is WeChat. Over 900mm Chinese people in China use this app. One can rapidly reach a senior decision-maker at a Chinese company via WeChat.

• However, one cannot know someone’s WeChat name without meeting with them in person so this tool is not good for making initial contact.

• Obviously, a helpful approach is to go through a trusted intermediary to make introductions to companies. This could be an investor, a law firm, a consultant or a financial advisor such as Torreya.

• Language is mixed. Chinese companies can be grouped into three buckets: (1) those who engage heavily with the West and have overseas infrastructure, (2) those who sometimes engage with the West and have a few executives who speak English and (3) those who rarely engage with the West and rarely speak English. We have found that engagement in partnering without a Mandarin speaker is quite challenging unless one engages only with the first type of company.
It is tempting to go through persons meeting at conferences to carry out a China partnering campaign. While we at Torreya have found that business development conferences can be useful, many of the relevant partners for a campaign don’t show up or send persons that are too junior to really have a discussion. At Torreya we advise those looking for China partnering deal to carry out in-person roadshows to see Chinese companies on their turf. This can involve a fair bit of travel within China. In our experience more than one trip will be needed to have time to see everyone that is relevant and to engage.

One of the benefits of in-person engagement is that many Chinese companies are looking to learn and so the deal is about more than the particular product – it is about a relationship that will allow each company to share its thinking, outlook and know-how over an extended period of time. The potential for this tacit “partnership” can be best communication through in-person dialogue.

An obvious further benefit is that you get a chance to see the executives, clinicians and researchers of your prospective partner and their facilities. Many Westerners are surprised by how large and impressive the facilities are at Chinese companies.
Keys to Effective Engagement: Socialization

• Chinese culture involves frequent mixing of social events with business dealings.

• Bonding via business entertainment is a “high context” activity and allows business partners to really get to know each other and talk about their lives, their homes, their past and their families.

• You should expect to have many dinners with a prospective partner.

• Legend has it that the Chinese are heavy drinkers and prolific eaters.
  • Our experience at Torreya is that while dinners with endless dishes coming off of a Lazy Susan are common, drinking is generally kept under control.
  • One should be prepared for differences in food types and cultural practices.

• We have had our fair share of unusual foods and drinks including deer tendon, plum wines, chicken feet, river fish, duck web, etc.
  • Most of it tastes really good. Smile and enjoy it.
  • Most Chinese executives prefer beer over wine.

• Gifts and favors are to be expected. Bringing gifts for a partner is good practice.
  • Your gift should typify the culture or place that you come from (e.g., a Beatles CD if you are British or a CheeseHead hat if you are from Milwaukee).
  • Expensive or lavish gifts such as a Hermes purse are not appropriate.
Keys to Effective Engagement: Meeting Decision-Makers

• Most Chinese companies are significantly more hierarchical in decision-making structure than Western companies – or even Japanese companies.

• For many companies there is a single decision-maker – the Chairman.

• Obviously, building a relationship with the Chairman of a potential partner is very important.
  • At Torreya, we have generally found that if a company wants to do business with you, it will not be difficult to get a meeting with the Chairman.
  • We have also found that this is where having a Mandarin speaker available is important.
  • It is rare to find a Chairman of a Chinese pharmaceutical company that is fluent in English.
  • In some cases, when dealing with conglomerates or SOEs (state owned enterprises) it is not clear who the decision-makers are at all. Be sure to ask and figure this out as best as you can.

• You might be surprised to learn that if you invite the Chairman of the company you are talking with to visit your site in the U.S. or Europe that he or she will often readily accept.
  • You then need to be prepared to reciprocate the same hospitality you saw in China.
  • Taking the counterparty out to a typical meal in the place you are from is a good practice (e.g., shrimp & grits in North Carolina; a pub in Britain; great seafood in Boston; steak in New York City).
Negotiation Approaches and Experience

• What you have heard is largely true: negotiation in China is different than in the West, or even Japan.
• Japan is known for indirect, sometimes “Kabuki” negotiation where signals are sent subtly and the unsaid in discussions can be very important.
• The Chinese can be more direct but will also conduct extended multi-person negotiations over time.
• Many Westerners view the Chinese negotiation style as unprincipled. We at Torreya encourage Western companies to simply understand that negotiation styles can be different.
• Bear in mind the following:
  • Chinese companies will often ask you what you want in a deal. The right response is to generally outline one or two structures that would work for you and to point to comparable transaction economics. It is better to allow the counterparty to make the first offer. It is also helpful to be reassuring. Many companies are worried that they simply can’t get a deal or can’t afford it.
  • It is not infrequent that a Chinese counterparty will change terms on a deal late in discussions. While this behavior is viewed as antithetical in Western culture, haggling is an essential part of Chinese culture. And, it is understood in China that haggling does not end until a contract is signed.
  • We have seen situations repeatedly where a Chinese counterparty will drop their price substantially in the final hours of discussions. The right response in this type of situation is generally to walk and give the other side a chance to come back.
  • Given this reality it is important to maintain competitive tension as negotiations unfold. It is critical not to give any party exclusivity until they are prepared to sign a binding contract.
Some Advice for Negotiation

• Take time to build a good relationship well before negotiations begin
• Read between the lines
• Don’t take your counterpart literally; gather “clues”
• Your counterparty will pay attention to what you do more than what you say
• Pay close attention to context and non-verbal comments
• Ask for further clarification as issues come up – get as much explained as possible
• Draw out the other side’s full ideas with questions
• Try to get the decision-maker in the room
• Ask the other side to be more direct when you aren’t sure what is being said
• Face is very important in China. This means the other side should not be humiliated
• Be careful of challenging the other side too much – they may lose face
• Explain that you do not fully understand when difference arise

Some good articles on negotiating in China

• “Negotiating In China: 10 Rules for Success.” by Jack Perkowski, Forbes, Mar 2011
• “Negotiations, Chinese Style.” by Betsy Neidel, China Business Review, Nov 2010
A Western company should base their partner selection not only on deal economics but also the capabilities of the Chinese partner that can deliver the development plan, ensuring success of your product under agreed timeline and receipt of future payments.

Key issues in selecting a partner:
- Ability to pay in dollars within a short time period, for example, 15 days upon closing
- Be wary of partners that need to convert RMB to US dollars to close a transactions
- Language skills of various functional areas that you will interact with post deal
- Visiting 3 – 5 potential partners for reverse diligence is crucial in making the final selection

Hiring a law firm that has China office will make contract negotiation easier due to issues unique for China:
- Withholding tax
- Net sales definition in the new Two-Invoice distribution system
- Be clear about payment and taxes you are responsible for
- Choose the right jurisdiction and law for disputes (note Chinese courts do not enforce US judgements)

Register license agreements with the relevant Chinese authorities
- Make sure Chinese partners register with the appropriate agency and provide proof before the license becomes effective
- Trademark licenses are exception and are required by regulation to be handled by the licensor
Some Pitfalls to Avoid

• Failure to maintain competitive tension can lead to bad outcomes.
• Failure to understand comparable deals and economics. Asking for too much can backfire.
• Selection of a licensee based solely on the size of an upfront while neglecting the partner’s ability to get the drug approved and appropriately commercialized in China.
• For early stage drugs (before Phase 3), it is common for Chinese companies to ask to be part of the global multi center studies. Be cautious in agreeing to this request due to protocol approval timelines or requests for protocol change.
• Understand that many Chinese companies do not have experience in doing licensing deals and diligence:
  • Important to be patient and helpful with the Chinese counterparty
  • Do not be surprised to hear frustration expressed if and when expectations are not met
• Overreliance on datarooms. China is behind the “Great Internet Wall”. The internet access to Western data rooms is very slow in China and we have found that requiring a Chinese counterparty to download copious documents to understand an opportunity can be problematic.
• Overreliance on email communications. Better to use WeChat and mobile phones.
Historically, the time to completion of a China outlicensing project at Torreya (from start to finish) has averaged six months. The time breakdown of activities is roughly as follows:

<table>
<thead>
<tr>
<th>Process Phase</th>
<th>Activity</th>
<th>Time Involved</th>
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<tbody>
<tr>
<td>Preparation Phase</td>
<td>Market research and discussions with KOLs</td>
<td>6-8 weeks</td>
</tr>
<tr>
<td></td>
<td>Preparation of materials</td>
<td></td>
</tr>
<tr>
<td>Marketing Phase</td>
<td>Effective job of maximizing the number of parties contacted</td>
<td>8-10 weeks</td>
</tr>
<tr>
<td></td>
<td>Get through CDA’s and a strong group of parties for creating negotiation leverage down the road</td>
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<tr>
<td></td>
<td>One or two trips to China for confidential management presentations and social engagement with counterparties</td>
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<tr>
<td></td>
<td>Provide a sensible level of interaction with management and relevant advisers (preliminary diligence)</td>
<td></td>
</tr>
<tr>
<td>Structuring, Diligence and Closing Phase</td>
<td>Confirmatory diligence activities</td>
<td>8 weeks</td>
</tr>
<tr>
<td></td>
<td>Perhaps a meeting on-site at your offices and a dinner with one to three lead parties</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Negotiate, analyze and structure transaction</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Close transaction with assistance of legal counsel</td>
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</tbody>
</table>

Certain types of projects can go more quickly and others more slowly. In general, the more advanced an asset is in development the faster a process can proceed. R&D projects take substantial education and engagement. In contrast, commercial asset sales can get done in as little as three months.
Structuring a China Deal
Common Deal Structures

A research collaboration involves joint development of drugs with one party sharing technology and know-how while the other pays for the work and may undertake part of the research.

A distribution deal gives a Chinese company the right to distribute a drug that has been approved in China using an Import Drug License. The deal will usually last a fixed period of time and will involve shipment of drug to the Chinese partner at a known supply price.

A joint venture involves joint clinical development of a drug and, possibly, co-marketing the drug. Unlike a license, profits are usually split in a joint venture. One party will usually supply product and know-how while the other will buy in and provide market access.

A license deal gives a Chinese company the right to market a drug in the China market in exchange for payments (upfronts/milestones) and a royalty. This deal type is the most common by far.

Other less deal structures include asset sales where a Chinese company acquires a drug’s marketing authorization, brand and inventory for a fixed price; investment, where a Chinese firm acquires a partial stake in the licensor (sometimes investments are accompanied by paid up licenses – sometimes free licenses are provides) and product/license exchanges such as the BeiGene/Celgene deal where one party licenses pipeline while providing distribution rights to commercial products to the other.
The Importance of Manufacturing in Deal Structuring

Manufacturing and supply is another important component in licensing

- Most Chinese companies prefer tech transfer manufacturing to China
  - To enjoy benefits of tax breaks, land purchase and support in regulatory approval
  - To control supply
  - To be competitive in COGs

Regulatory filing pathway is driven by where drug is manufactured:

- IDL (Imported Drug Filing): drug made outside China
- Domestic Drug Filing: drug made in China by local manufacturer
- Depending how your choice of product supply, you will have different obligations and responsibilities
  - For IDL pathway, the Chinese drug administration requires site audit and compliance to Chinese regulations
Subsection

Example of Research Collaborations
Ionis Enters into Collaboration with Ribo to Advance RNA-Targeted Therapeutics in China

CARLSBAD, Calif., April 18, 2017 /PRNewswire/ -- Ionis Pharmaceuticals, Inc. (NASDAQ: IONS) today announced a collaboration and license agreement with Suzhou Ribo Life Science Co., Ltd. (Ribo) to develop and commercialize RNA-targeted therapeutics in China. Ionis granted Ribo a license for the right to commercialize in China two Ionis Generation 2+ antisense drugs in metabolic disease and cancer and an option to license a third pre-specified Generation 2+ antisense drug. In addition, Ribo will be responsible for conducting a multi-year research and drug discovery program to identify drugs that utilize Ionis’ ssRNAi technology. Ionis will receive an undisclosed up-front payment and equity in Ribo. Ionis retains the rights to develop and commercialize ssRNAi technology and all drugs under the collaboration outside of China.

Following the identification of a development candidate, Ribo may exercise its option to license each drug by paying Ionis a license fee. For each drug that Ribo licenses, Ribo will be responsible for all development and commercialization activities and costs in China. Ionis is eligible to receive development, regulatory and commercial milestone payments as each drug advances. In addition, Ionis is eligible to receive royalties on net sales of each drug.

Ribo will provide Ionis a royalty-free license to the data and intellectual property created under the collaboration.
Subsection

Examples of Joint Ventures
Joint Venture Example: Kite / Fosun Deal

Kite Pharma and Fosun Pharma Establish Joint Venture in China to Commercialize Autologous T-Cell Therapies to Treat Cancer

SANTA MONICA, Calif. & SHANGHAI--(BUSINESS WIRE)--Kite Pharma (Nasdaq:KITE) and Shanghai Fosun Pharmaceutical (Group) Co., Ltd. (Fosun Pharma) (600196.SH,02196.HK), today announced a joint venture, Fosun Pharma Kite Biotechnology Co., Ltd. (company name subject to the approval of relevant registration authorities), to develop, manufacture and commercialize axicabtagene ciloleucel in China with the option to include additional products, including two T cell receptor (TCR) product candidates from Kite. Axicabtagene ciloleucel (KTE-C19), Kite's lead product candidate, is an investigational chimeric antigen receptor (CAR) T-cell therapy under development for the treatment of B-cell lymphomas and leukemias. The joint venture will be registered in Shanghai and owned equally between Kite Pharma, a pioneer in the field of engineered T-cell therapy for cancer, and Fosun Pharma, a leading healthcare group in China.

Under the terms of the agreement, Fosun Pharma will provide the RMB equivalent of $20 million in funding to support clinical development and manufacturing activities and Kite will provide certain technical transfer services to the joint venture. Each party will share in any profits from the joint venture with Kite Pharma receiving 40 percent and Fosun Pharma receiving 60 percent. Kite will also receive an upfront fee of $40 million from the joint venture, funded by Fosun Pharma, regulatory and commercial milestones totaling $35 million and mid-single digit sales royalties for axicabtagene ciloleucel (KTE-C19).
Joint Venture Example: Juno / WuXi Deal

Juno Therapeutics and WuXi AppTec Announce New Company to Develop Novel Cell-Based Cancer Immunotherapies in China

SEATTLE and SHANGHAI, April 7, 2016 /PRNewswire/ -- Juno Therapeutics (NASDAQ: JUNO), a biopharmaceutical company focused on re-engaging the body’s immune system to revolutionize the treatment of cancer, and WuXi AppTec, a leading open-access R&D capability and technology platform company serving the pharmaceutical, biotechnology, and medical device industries, today announced that they have started a new company in China. JW Biotechnology (Shanghai) Co., Ltd’s mission is to build China’s leading cell therapy company by leveraging Juno’s world-class chimeric antigen receptor (CAR) and T cell receptor (TCR) technologies together with WuXi AppTec’s R&D and manufacturing platform and local expertise to develop novel cell-based immunotherapies for patients with hematologic and solid organ cancers.

Juno and WuXi AppTec have equal initial ownership in JW Biotechnology (Shanghai) Co., Ltd, which after meeting certain conditions will have access to licensing product candidates from Juno’s pipeline for development and commercialization in China. In exchange, Juno will receive an upfront payment in equity, milestone payments, and royalties on any net sales. Dr. Ge Li will serve as Chairman of the Board of JW Biotechnology (Shanghai) Co., Ltd, and the remainder of the Board of Directors will initially include Dr. James Li, Hans Bishop, Steve Harr, M.D., Juno’s Chief Financial Officer and Head of Corporate Development, and Edward Hu, WuXi AppTec’s Chief Financial Officer and Chief Investment Officer.
Subsection

Examples of Simple Licenses
CANbridge Acquires China Rights to Puma Cancer Candidate in $70 Million Deal. This Drug was recently approved in the U.S.

• Feb. 1, 2018 Puma Biotechnology Inc. (NASDAQ:PBYI) granted Canbridge Life Sciences Ltd. (Beijing, China) exclusive rights to develop and commercialize cancer drug Nerlynx neratinib in China, including Hong Kong and Macau, and Taiwan.

• Puma markets Nerlynx in the U.S. for the extended adjuvant treatment of patients with early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy.

• Puma will receive a $30 million upfront payment and is eligible for regulatory milestones of up to $40 million, plus sales-based milestones and double-digit royalties.

• Canbridge will be responsible for submitting regulatory applications in its territories, and the company expects to provide Nerlynx in parts of Greater China by mid-2019. Canbridge said it believes Nerlynx has "significant commercial potential" in Greater China in HER2-positive cancers, including gastric cancer.
Ardelyx Announces License Agreement with Shanghai Fosun Pharmaceutical Industrial Development Company Limited for Tenapanor in China

Ardelyx to Receive Up to $125 Million in Upfront Payment and Subsequent Milestones

FREMONT, Calif., Dec. 11, 2017 /PRNewswire/ -- Ardelyx, Inc. (NASDAQ: ARDX) today announced that the company has entered into a license agreement with Shanghai Fosun Pharmaceutical Industrial Development Company Limited (Fosun Pharma) providing Fosun Pharma with the exclusive rights to develop and commercialize Ardelyx's lead product, tenapanor, in China for the treatment of patients with irritable bowel syndrome with constipation (IBS-C) and for the treatment of hyperphosphatemia related to chronic kidney disease. The agreement also provides Fosun Pharma the rights to commercialize tenapanor for other indications for which it is approved in the United States. Tenapanor is an investigational oral, minimally systemic NHE3 inhibitor discovered and developed by Ardelyx.

Under the terms of the agreement, Ardelyx will receive an upfront payment of $12 million and is eligible to receive additional milestones of up to $113 million, as well as tiered royalty payments on net sales ranging from the mid-teens to 20 percent. Fosun Pharma will have the exclusive rights to market and sell tenapanor in China.
Arena Pharmaceuticals and Everest Medicines Enter into Development and Commercialization Partnership for Ralinepag and Etrasimod in China

Arena eligible to receive up to $224M, including upfront and milestone payments, in addition to royalties

SAN DIEGO, Dec. 5, 2017 /PRNewswire/ -- Arena Pharmaceuticals, Inc. (NASDAQ: ARNA), a biopharmaceutical company focused on developing novel, small molecule drugs across multiple therapeutic areas, and Everest Medicines Limited ("Everest"), a C-Bridge Capital-backed biopharmaceutical company focused on developing and commercializing innovative pharmaceutical products in China, announced today that they have entered into a development and commercialization partnership for ralinepag and etrasimod in mainland China, Taiwan, Hong Kong, Macau, and South Korea (the "Territories"). Arena is developing ralinepag, a Phase 3-ready next-generation, oral, selective prostacyclin receptor (IP) agonist for the treatment of pulmonary arterial hypertension (PAH), and etrasimod, a Phase 2 oral, next-generation, S1P receptor modulator, being evaluated for multiple autoimmune diseases, including ulcerative colitis, a form of inflammatory bowel disease.

Under the terms of the agreement, Arena has granted Everest exclusive rights to develop and commercialize ralinepag and etrasimod in the Territories. In return, Arena will receive an upfront payment of $12 million, is eligible to receive up to $212 million in development and commercial milestone payments and is entitled to receive up to low double-digit royalties on net annual sales of both ralinepag and etrasimod.
BeiGene and Mirati Therapeutics Announce Exclusive License Agreement for Sitravatinib in the Asia Pacific Region

BeiGene Acquires Asia Rights to Mirati Cancer Treatment in $133 Million Deal

CAMBRIDGE, Mass. and BEIJING, China and SAN DIEGO, Jan. 08, 2018 (GLOBE NEWSWIRE) -- BeiGene, Ltd. (NASDAQ:BGNE), a commercial-stage biopharmaceutical company focused on developing and commercializing innovative molecularly targeted and immuno-oncology drugs for the treatment of cancer, and Mirati Therapeutics (NASDAQ:MRTX), a clinical-stage targeted oncology company, today announced an exclusive license agreement for the development, manufacturing and commercialization of Mirati’s sitravatinib in Asia (excluding Japan), Australia, and New Zealand. Mirati will retain exclusive rights for the development, manufacturing and commercialization of sitravatinib for the rest of world.

Sitravatinib (MGCD-0516) is a spectrum-selective kinase inhibitor which potently inhibits receptor tyrosine kinases (RTKs) including RET, TAM family receptors (TYRO3, Axl, MER), and split family receptors (VEGFR2, KIT). Sitravatinib is being evaluated as a single agent in a Phase 1b expansion trial enrolling patients that harbor RET, CHR4Q12, and CBL genetic alterations in NSCLC and other tumors. Under the agreement Mirati will receive an upfront cash payment of $10 million from BeiGene. Additionally, Mirati is eligible to receive up to $123 million of additional payments based upon the achievement of certain development, regulatory and sales milestones as well as significant royalties on future sales of sitravatinib in the licensed territory.
HIGH POINT, N.C.--(BUSINESS WIRE)--vTv Therapeutics Inc. (Nasdaq:VTVT) today announced that vTv Therapeutics LLC has entered into a licensing agreement with Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. (“Huadong Pharmaceutical”), a wholly-owned subsidiary of Huadong Medicine Co., Ltd. (SZSE: 000963.SZ), for rights to develop and commercialize vTv Therapeutics’ GLP-1r agonist program in China and other Pacific Rim countries.

December 21, 2017

Under the agreement, vTv has granted Huadong Pharmaceutical an exclusive license to develop, manufacture and commercialize vTv Therapeutics’ GLP-1r agonist program in China, Hong Kong, Macau, Taiwan, Thailand, Vietnam, Indonesia, Malaysia, Philippines, Singapore, Myanmar, Cambodia, Laos, Brunei, South Korea and Australia. Under the terms of the agreement, vTv Therapeutics will run a Phase 2 Multi-Regional Clinical Trial (MRCT) including sites in the US and other regions in the Pacific Rim.

The licensing agreement includes rights to TTP273, an oral small molecule GLP-1R agonist, which met its primary endpoint and demonstrated a statistically significant reduction in HbA1c in a Phase 2 trial of type 2 diabetes. The compound was well-tolerated, with negligible incidences of nausea and vomiting across all arms of the study. Trends towards weight loss were also observed.

vTv will receive an $8 million upfront payment in connection with the signing of the agreement subject to satisfaction of customary conditions and is eligible for up to an additional $75 million in milestone payments related to development, regulatory and commercial milestones. In addition, vTv will be eligible to receive royalty payments on sales of commercialized products in the territories.
Subsection

Example of License Deal Combined with Investment
Zhejiang Huahai Pharma acquired Greater China rights to EU-101, a preclinical immuno-oncology candidate discovered by Eutilex of South Korea, in a $65 million agreement

Huahai made a $30 million equity investment into Eutilex, and it will pay up to $35 million in milestones on 10 immuno-oncology indications.

Eutilex will also receive royalties on China sales. In an unusual provision, Huahai will gain from Eutilex’s out-licensing revenues of EU-101, and it will receive royalties on ex-China sales.

About Lead Antibody Therapy, EU-101

EU-101 is a preclinical-stage human monoclonal antibody agonist that binds to 4-1BB -- also called CD137 -- a protein receptor expressed in many immune cells, particularly CD8+ and CD4+ T cells. When binding to CD137, EU-101 activates T cells and prolongs their life, resulting in a more potent attack on cancer that is not limited to any specific cancer or to the number of applicable cancer indications.

EU-101 is being studied alone and in combination with immune checkpoint inhibitors, and has been shown to work with PD-1/PD-L1 inhibitors to produce an amplified immune response.
Example of Distribution Deals
Exclusive Agency and Distribution Agreement for Cystistat®

March 25, 2008 - China Medical System Holdings Ltd. (AIM: CMSH), the profitable Chinese pharmaceutical group which focuses on R&D, manufacturing, distributing and marketing of pharmaceutical products and medical equipment primarily in China, is pleased to announce that it has signed an exclusive agency and distribution agreement (the 'agreement') with Bioniche Teoranta ('Bioniche') to distribute Cystistat® in China (excluding Hong Kong).

Cystistat® is Bioniche’s proprietary sodium hyaluronate product and indicated for the temporary replacement of the glycosaminoglycan (GAG) layer in the bladder. The GAG layer of the bladder is known to be deficient in conditions known as cystitis, a syndrome of acute or chronic origin.

Under the agreement, CMS is committed to purchase a minimum quantity of Cystistat® from Bioniche in the next five years. CMS has the option to extend the agreement to eight years upon reaching certain purchase targets within the next five years and indefinitely upon maintaining the purchase targets in subsequent years.

Commenting on the agreement, Mr. Lam Kong, CEO of CMS, said: “We are very pleased with the addition of Cystistat® to our portfolio. This agreement is an example of our dedication to enhance our international reputation and become a leading pharmaceutical company in China. Combining the strength and success of our sales network together with the clinical efficacy of the product, we are confident that the sales of Cystistat® will reach a new height and contribute to CMS’s growing profitability.”
Relevance of CFIUS and Export Controls
The Biotechnology Industry and Ongoing U.S. – China Trade Tensions

• The U.S. has significantly ramped up pressure on China after the election of President Trump in 2016.

• In 2018 we have seen the U.S. impose tariffs on many Chinese goods followed by retaliation from China.

• In this context there are several issues impacting the transfer of pharmaceutical intellectual property and assets to Chinese companies.

• The first is CFIUS (the Committee on Foreign Investment in the United States). CFIUS has the authority to block acquisitions of U.S. companies by Chinese companies and, more recently, to review and block investments by Chinese companies into U.S. companies.

• The second is the U.S. Department of Commerce’s export control regime which is administered by the Bureau of Industry and Security. *

• In practice, with rare exceptions, the U.S. does not have regulations which would prevent U.S. companies from licensing the rights to drugs or most technologies to Chinese companies.

• However, it is important to be aware of the regulations so that one can avoid crossing lines that would create legal issues for a potential transaction.

*Source: Bureau of Industry and Security
Department of Commerce Export Controls

Source: Eric McClafferty and Brooke Ringel, Risky Business: Managing Export Control Compliance in the Biotechnology Industry,” Lab Manager, November 2012:

• “The U.S. government has national security interests in certain types of information and goods that may cross borders and exercises those interests through export controls.

• Export control regulations govern shipments of military items and a variety of less-sensitive dual-use chemicals and biological materials, including certain human, animal and plant pathogens; toxins; and genetically modified organisms. The regulations also cover export of equipment (for example, certain storage tanks, reactors, agitators, valves, and pumps).

• The U.S. Department of Commerce’s Bureau of Industry and Security (BIS) and the U.S. Department of State’s Directorate of Defense Trade Controls (DDTC) are the two agencies primarily responsible for control of most biotechnology goods and technology exports from the U.S. BIS administers the Export Administration Regulations (EAR). The EAR cover dual-use products, software, and technology that can be used for commercial and military (or terrorist) end uses.

• BIS regulates certain dual-use microorganisms, toxins, biological equipment, and related technology identified by the Australia Group, an international association that seeks to stem the development of biological and chemical weapons through export controls. BIS also controls the export of select agents. Licenses are required to export these products to many countries.”

Key Point: U.S. export controls are principally focused on preventing the proliferation of biological warfare agents and not on the sharing of rights to pharmaceutical products between countries. The exception would be if biological materials involving organisms or certain sensitive vaccine technology would be involved in a license agreement.
CFIUS Rules and Foreign M&A Deals

Source: Latham and Watkins, “Overview of CFIUS Process,” Link:

"CFIUS was created in 1988 by the Exon-Florio Amendment to the Defense Production Act of 1950. CFIUS’ authorizing statute was amended by the Foreign Investment and National Security Act of 2007 (FINSA). This statutory framework authorizes the President of the United States (through CFIUS) to review “any merger, acquisition, or takeover ... by or with any foreign person which could result in foreign control of any person engaged in interstate commerce in the United States.” CFIUS' role is to evaluate whether and to what extent such transactions could impact US national security. If a transaction could pose a risk to US national security, the President may suspend or prohibit the transaction, or impose conditions on it.

After formally accepting a filing, CFIUS has 30 calendar days to “review” the transaction and decide whether to clear it or commence an “investigation” (essentially, an extension or continuation of the initial review) instead. That investigation can last up to an additional 45 days, although the process can be terminated early, at any point during the 45-day investigation period. If CFIUS still has not resolved any potential national security concerns at the end of the 45-day investigation period, CFIUS is responsible for making a formal recommendation to the President as to whether to clear or block the transaction.”
CFIUS Effect on Life Sciences M&A and Licensing Deals

• CFIUS blocked several life sciences transactions in 2017.

• While not made public, the effect of this transaction blockage has been to almost completely halve Chinese company acquisitions of U.S. life sciences companies.

• **However, CFIUS rules today do not require review of licensing transactions. We believe that this partly explains the rapid rise in Chinese licensing deals in 2018.**

• An important development was publication of the FIRMMA guidelines in October 2018.

• These guidelines require that many Chinese investments in U.S. biotechnology companies will undergo a CFIUS review.

  • Practically speaking, we at Torreya believe that it would be inadvisable to include investment dollars in licensing deals going forward until more clarity emerges on how the FIRMMA rules will be implemented in practice.

  • The FIRMMA rules involve a number of exemptions for CFIUS review. If it is very clear that an investment associated with licensing deal will be exempted from review then one could go ahead and include the investment as part of a transaction.
Goodwin Proctor, Treasury Department Imposes Mandatory Filing Requirement on Parties to Certain Foreign Investments in U.S. Critical Technologies Companies, October 12, 2018 (link):

• “On Wednesday, October 10, 2018, the Department of the Treasury exercised its authority under the recently passed Foreign Investment Risk Review Modernization Act (FIRRMA) to implement a Pilot Program that expands the jurisdiction of the Committee on Foreign Investment in the United States (CFIUS) and imposes mandatory filing requirements on certain transactions in the U.S. technology sector.

• The Pilot Program requires parties to file a declaration with CFIUS at least 45 days in advance of certain foreign-person investments in U.S. businesses that are involved with critical technologies used in specified industry sectors. Parties failing to file a required declaration may be subject to a civil penalty up to the amount of the transaction value.

• The Pilot Program will impact many foreign investments across 27 U.S. industry sectors, including computer storage and semiconductor manufacturing, military hardware, research and development in biotechnology and nanotechnology, optical instrument and lens manufacturing, wireless communications, petrochemicals, energy storage and distribution, and others.

• The Pilot Program requires the filing of a declaration with CFIUS at least 45 days in advance of certain investments by a foreign person in an "unaffiliated" U.S. business that produces, designs, tests, manufactures, fabricates, or develops one or more "critical technologies" that the U.S. business either utilizes in connection with its activities in, or designs specifically for use in, a "Pilot Program Industry."

• "Emerging and foundational technologies" soon to be controlled pursuant to a separate, interagency process underway and expected to target technologies not currently subject to ITAR or EAR controls, possibly including technologies relating to artificial intelligence, robotics, cybersecurity, advanced materials, telecommunications, and biomedicine, among others."
Exemptions from CFIUS Declaration Filings

Goodwin Proctor, Treasury Department Imposes Mandatory Filing Requirement on Parties to Certain Foreign Investments in U.S. Critical Technologies Companies, October 12, 2018 (link):

"Investments meeting the criteria above are nevertheless not subject to the declaration filing requirement if the investment would afford the foreign person:

• No “control” of the U.S. business by the foreign person, under the pre-FIRRMA, low-threshold, multifactored criteria that CFIUS has traditionally applied to that determination;

• No access to material nonpublic technical information that is necessary to design, fabricate, develop, test, produce, or manufacture critical technologies, including processes, techniques, and methods;

• No membership or observer rights on the U.S. business’s board of directors or equivalent, or the right to nominate such a person; or

• No involvement, other than voting their non-“control” shares, in the substantive decision-making of the U.S. business regarding the use, development, acquisition, or release of “critical technology.”

Implications: An investment by a Chinese company that involves a small stake (less than 10%), no board involvement and lack of information rights to technology information would be exempt from CFIUS review.
Summary

• CFIUS regulates acquisitions of U.S. biopharmaceutical companies and has blocked several Chinese attempted M&A deals in recent years.

• As of October 2018 CFIUS also regulates investments by Chinese companies in U.S. biopharma companies that have an element of control.

• There are separate export control regulations which prohibit the export of materials or knowledge that would have applications in biological warfare.

• Thus far, there are no regulations in place that prevent licensing transactions by U.S. companies to Chinese companies.

• A key point is to avoid structure such transactions so that a Chinese company has control over the U.S. company. This could happen only if the Chinese company takes an equity position in the U.S. company.
Torreya China Team and Capabilities
Torreya has a three person team covering Chinese pharmaceutical companies. The team regularly calls on 30+ Chinese corporates and investors.

All members of the team carry out investment banking work in China and are fluent in Mandarin.

Key activities include inbound partnering; outbound M&A and domestic M&A advisory.

Members of the team are in China at least six times a year.

Torreya is currently running multiple partnering processes in China.

Jie Liu  
Managing Director, China
- Leads China coverage for Torreya
- Spends several months a year on China business development activities
- Was at J&J and Teva in BD
- MBA, Wharton
- Speaks Mandarin

Kylor Hua  
Vice President, M&A
- 20+ transactions at Torreya with total value over $2 billion
- Strong in M&A and licensing processes
- B.A. in Economics & Cog. Sci., University of Rochester
- Speaks Mandarin & Japanese

Vivian Xu  
Associate, China
- Joined Torreya in July 2016
- Formerly Analyst at Fosun Group, healthcare investment team
- M.P.A., Columbia University
- Speaks Mandarin

**Jie Liu:**  
Managing Director, China  
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- **Sandoz Sale**  
  Sale of generics portfolio to Fosun Pharma  
  $18 million  
  August 2017

- **Sandoz Sale**  
  Sale of ANDA portfolio to Casi Pharmaceuticals  
  January 2018

- **EAPharma License**  
  License of China Rights to AJT-240 to Tasly  
  June 2018
Torreya is Active in the China Market

专注于医药行业内的企业兼并与收购，企业融资，专利权交易等
我们的优势在于长期稳定的客户关系，丰富的行业从业经验以及对生命科学领域的专注

交易数量 No. 1
2015-2017年在世界范围内完成的医药行业并购/专利权交易数量最多

50笔以上交易
自2015年所以来完成生命科学领域的交易数量达50笔以上

超过$100亿
自2014年以来完成交易数额达$100亿美元以上；自2007年以来完成交易数量150多笔；按交易数量排名前10位的国际化投资银行
League Table, Advisory Roles in China Licensing and Asset Sale Transactions, 2015 to 2018

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<td>6</td>
<td>Geller Biopharm</td>
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<td>NA</td>
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</tbody>
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Due to its dedicated China licensing advisory team and market knowledge Torreya has rapidly become the leader in inbound asset level transaction advisory roles involving China pharmaceutical companies.
<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Email</th>
<th>Cell</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jie Liu</td>
<td>Managing Director, China</td>
<td><a href="mailto:Jie.liu@torreya.com">Jie.liu@torreya.com</a></td>
<td>917.683.4003</td>
</tr>
<tr>
<td>Kylor Hua</td>
<td>Vice President, M&amp;A, NY</td>
<td><a href="mailto:Kylor.hua@torreya.com">Kylor.hua@torreya.com</a></td>
<td>917.208.1758</td>
</tr>
<tr>
<td>Vivian Xu</td>
<td>Associate, China, NY</td>
<td><a href="mailto:Vivian.xu@torreya.com">Vivian.xu@torreya.com</a></td>
<td>347.407.2044</td>
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