Introduction

Since 2018, biopharma companies become high-profile in the capital markets:

2018 is the bumper year of IPO for global pharmaceutical and biotech Industry with the value and volume both reaching a 10-year high according to the U.S., China and Hong Kong stock market data, and the momentum has not decreased since the beginning of 2019.

The HKEX introduced new rules in early 2018 to allow pre-revenue biotech companies to go public in Hong Kong. This move, together with other new measures, has become the most significant reform in the HKEX in 20 years. Not come singly but in pairs, Science and technology innovation board (STI) was established at the end of 2018, and piloted the registration-based IPO system on the Shanghai Stock Exchange. STI encouraging companies in six industries, including biotech through the differentiated arrangements in terms of profitability and shareholding structure. The restructured listing rule of STI will provide more financing opportunities to pre-revenue biotech companies.

A series of biotech companies engaged in the R&D of brand-name drugs have been able to listed on the biotech section of HKEX which has become the first sector on the main board of the HKEX to be tailed by industry attributes.

Since 2018, along with the announcement of a series of huge M&A transactions by Takeda to acquire Shire and Bristol-Myers Squibb to acquire Celgene, the list of M&A transaction in the pharmaceutical and biotech Industry has been continuously renewed. M&A activities in the pharmaceutical and biotech Industry have entered an active period with a series of biotech companies making major breakthroughs in the fields of oncology, rare diseases, gene therapy, etc.

In this context, we review the performance of the capital markets in the pharmaceutical and biotech Industry over the past period of time and look ahead to industry drivers. In the future, investment and financing activities in the pharmaceutical and biotech Industry will remain active in the securities market, and the Hong Kong market is expected to rise to the next level with the help of the new listing rule. The M&A market will also active through the increasing demand for branded drugs in pharmaceutical companies. We observed three trends:

- The first-in-class drugs continue to receive attention from the capital market, whose can effectively reduce R&D risks and maintain global market exclusivity will be favored
- Specialty drugs, orphan drugs, biologics and oncology in novel drugs will continue to be the tendency.
- Diversified cooperation between large multinational biopharma companies and emerging biopharma companies (EBP) will lead to new excellent enterprises in the capital market.
1. Pharmaceutical and biotech companies' IPOs continue to grow

2018 is the bumper year of IPO for global pharmaceutical and biotech industry regardless of the value or volume of transactions. According to the U.S., China and Hong Kong stock market data, total fundraising of IPOs in the global pharmaceutical and biotech Industry reached $11.5 billion in 2018, where 74 companies were listed through IPOs, reaching a 10-year high.

In the past decade, the overall IPO of US global pharmaceutical and biotech Industry has shown an upward trend in spite of volatility. As the global financial center, the US stands a prominent position in the scale and volume of fundraising in this field.

The Hong Kong market is one of the most attractive markets for global investors in Asia, and serves as an important link between China and global capital market. In the past decade, Hong Kong stock market has played an key role in the IPO of pharmaceutical and biotech Industry globally. 2018 IPO performance of pharmaceutical and biotech companies in Hong Kong stock market far exceeded 2017 in both volume and value, with 8 companies completed IPOs. In early 2018, the HKEX introduced new rules, allowing pre-revenue biotech companies to go public in Hong Kong. Five companies were successfully listed in Hong Kong through the new regulation in 2018.
The IPO performance for pharmaceutical and biotech-related industry in the A-share market has been volatile over the past decade. In 2017, biopharma IPO ushered in an outbreak, with total of 33 companies gone public. Whereas in 2018, only 3 biopharma companies went public with the impact of tightening IPO regulations. China’s pharmaceutical and biotech industry has made great progress. However the technology attributes of such industry in the A-share have yet to be fully reflected. It is expected that this trend will be completely broken when the STI is born where the launch of the STI will promote the discovery of industry value and usher in a booming IPO market.

### IPO Financing Scale of U.S. Stock, A-Share and HK Stock (US$Mn)

<table>
<thead>
<tr>
<th>Year</th>
<th>U.S. Stock</th>
<th>A-Share</th>
<th>HK Stock</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>956</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>5,807</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>2,566</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>1,492</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2013</td>
<td>4,627</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td>6,977</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2015</td>
<td>6,213</td>
<td></td>
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</tr>
<tr>
<td>2016</td>
<td>5,337</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2017</td>
<td>6,172</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2018</td>
<td>11,514</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: Capital IQ

### U.S. Stock, A-Share and HK Stock IPO Volume

<table>
<thead>
<tr>
<th>Year</th>
<th>U.S. Stock</th>
<th>A-Share</th>
<th>HK Stock</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>29</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>22</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>14</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2013</td>
<td>32</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td>73</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2015</td>
<td>56</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2016</td>
<td>40</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2017</td>
<td>71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2018</td>
<td>74</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: Capital IQ

Note: The IPO data of the U.S. stock market does not include the companies with the US as second listing that went for IPO in NYSE/Nasdaq; U.S. stock include NYSE and Nasdaq; A-share stock includes the Shanghai Stock Exchange and the Shenzhen Stock Exchange; Hong Kong stock includes the HKEX. Capital IQ with selected industry classification as S&P pharmaceuticals, biotech

2. **Total market value of the pharmaceutical and biotech sectors continues to raise**

As of the end of February 2019, the market value of the US pharmaceutical and biotech sector covers 9.9% of the overall US stock market, while the figures for A-share and Hong Kong stock were 6.7% and 7.9%, respectively. The scale of the US pharmaceutical and biotech sector is way beyond that of A-share and the Hong Kong stock markets.

In the past decade, the market cap of pharmaceutical and biotech companies in the US, A-Share and Hong Kong stock markets has experienced a rapid growth, among them the growth rate of A-Share and Hong Kong stocks exceeds the US stocks.
Total market cap of pharmaceutical and biotech companies in the A-share market (US$Bn)

Source: Capital IQ, Wind
Note: A-Share include the Shanghai Stock Exchange and the Shenzhen Stock Exchange.

Total market cap of pharmaceutical and biotech companies in the U.S. stock market (US$Bn)

Source: Capital IQ, Wind
Note: US stocks include NYSE and Nasdaq.

Total market cap of pharmaceutical and biotech companies in the HK stock market (US$Bn)

Source: Capital IQ, Wind
Note: Hong Kong stocks include the HKEX.
### 3. New listing rules in HKEX encourage the listing of pre-revenue biotech companies

On April 30, 2018, the new listing rules of the HKEX took effect. Two new chapters were added to the Main Board Listing Rule to allow pre-revenue biotech companies to go public in Hong Kong.

This new policy will not only provide biotech companies with a more attractive financing platform, but also provide investors behind biotech companies with an earlier exit channel in Hong Kong’s capital market.

#### Additional Listing Rules and Measures to Protect Shareholders

**Initial market capitalization**
- At least HK$1.5 billion

**Track Record**
- Have operated in its current line of business for at least two financial years prior to listing.
- Have operated under substantially the same management during the Track Record Period.

**Working Capital**
- Have sufficient working capital (after taking into account the IPO proceeds) to cover at least 125% of its capital requirements for the next 12 months after IPO.

**Cornerstone Investments**
- Any shares allocated to a cornerstone investor and any shares subscribed by existing shareholders of Applicant at the time of listing shall not be considered as held by the public.

**Risk Management**
- Fundamental change to principal business requires HKEx’s prior consent.
- Biotech Companies not satisfying the continuing obligation to maintain sufficient operations or assets are given up to 12 months to re-comply with the rule.
- A listed Biotech Companies must have a stock marker “B” at the end of its name.

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**Suitability to List**

- **Core Product regulated by a Competent Authority**
  - Competent authorities include the US Food and Drug Administration, the China Food and Drug Administration, and the European Medicines Agency.
  - HKEx may recognize another national or supranational authority as a competent authority in individual cases.

- **At least one core product beyond the concept stage**
  - Core product has completed at least one clinical trial conducted on human subjects.
  - Relevant competent authority has no objection for it to commence Phase II (or later) clinical trials to demonstrate bio-equivalency.

- **Sophisticated Investor and Meaningful Investment**
  - Applicant has received meaningful third-party investment from at least one sophisticated investor at least six months before listing.

Source: HKEx website
BeiGene develops and commercializes molecularly-targeted and immuno-oncology drugs for the treatment of cancer; 
Currently there are 6 internally-developed pipeline, including BTK inhibitor Zanubrutinib and PD-1 antibody Tislelizumab both with huge market potential and primacy for R&D; 
IPO Information: 
– Listing Date: 2018-08-08 
– Market Capitalization at Listing Date: HKD15.7 billion 
– Issue Price: HKD14.00 
– Total Fund Raised: HKD 2.98 billion

Ascletis is a biotech company established in March 2013, addressing unmet medical needs in three therapeutic areas: viral, cancer and fatty liver diseases. 
Currently focusing on R&D and commercializing the entire value chain of HCV, HIV, HBV brand-name drugs. 
IPO Information: 
– Listing Date: 2018-08-01 
– Market Capitalization at Listing Date: HKD15.7 billion 
– Issue Price: HKD14.00 
– Total Fund Raised: HKD 2.98 billion
**Hua Medicine (Shanghai) Ltd.**
(2552.HK)

- Hua Medicine, established in 2009, advanced its principle drugs comprising of Dorzagliatin for the treatment of Type 2 Diabetes, undertaking Phase III monotherapy trial, and mGLUR5 for the treatment of PD-LID;
- IPO Information:
  - Listing Date: 2018-09-14
  - Market Cap at Listing Date: HKD8.71 billion
  - Issue Price: HKD8.28
  - Total Fund Raised: HKD781 million

**Innovent Biologics, Inc.**
(1801.HK)

- Established in 2011, Innovent has built up a pipeline of 17 monoclonal antibodies in the fields of oncology, ophthalmology, autoimmune and cardiovascular diseases;
- IPO Information:
  - Listing Date: 2018-10-31
  - Market Cap at Listing Date: HKD18.54 billion
  - Issue Price: HKD 13.98
  - Total Fund Raised: HKD 3.16 billion

Source: Wind
Junshi BioPharm is an innovation-driven biopharma company which is dedicated to discover and develop first-in-class or best-in-class drugs through original innovation.

Junshi has a leading edge in the emerging field of immuno-oncology and for the treatment of autoimmune and metabolic diseases. Junshi is the first Chinese company filing IND application and NDA application to the NMPA for anti-PD-1 monoclonal antibody.

IPO Information:
- Listing Date: 2018-12-24
- Market Cap at Listing Date: HKD18.06 billion
- Issue Price: HKD19.38
- Total Fund Raised: HKD2.94 billion

Source: Wind
Cstone Pharmaceuticals (2616.HK)

- CStone Pharmaceuticals is a biopharma company focused on developing and commercializing innovative immuno-oncology and molecularly targeted drugs, the company has built a rich oncology pipeline of 14 drug candidates;
- The company adopted VIC model (VC+IP+CRO), dedicating in drug discovery, pharmacology, discovery of gene and animal research and development. The rapid R&D process of novel drug due to daily implementation of preclinical research through R&D outsourcing cooperation with CROs such as WuXi AppTec.
- IPO Information:
  - Listing Date: 2019.02.26
  - Market Cap at Listing Date: HKD12.7 billion
  - Issue Price: HKD12.00
  - Total Fund Raised: HKD 2.1 billion

Cstone Pharmaceuticals Stock Market Performance (Currency: HKD)

![Stock Market Performance Chart]

Source: Wind
4. The establishment of the STI will benefit biotech companies

- Science and technology innovation board (STI) was established at the end of 2018, and piloted the registration-based IPO system on the Shanghai Stock Exchange. Through the differentiated arrangements in terms of profitability and shareholding structure, STI has greatly enhanced the inclusiveness and adaptability of innovative enterprises.

- The restructured listing rule of STI will not only provide more financing opportunities to support high-tech innovative enterprises' development, but also become an important listing platform for biotech companies following the Nasdaq and HKEX biotech sector. Moreover, it provides an alternative exit channel for PE/VC.

Applicable industry

STI focuses on the following six types of high-tech industries and strategic emerging industries to promote the deep integration of the Internet, big data, cloud computing, artificial intelligence and manufacturing. Leading high-end consumption, promoting quality transform, efficiency transform, and power transform:

- New generation of IT
- New material
- High-end equipment manufacturing
- Biotech
- Energy conservation and environment protection
- New energy

5 differentiated listing standard

- In terms of market and financial conditions, STI introduced market cap indicators, combined with financial indicators such as revenue, cash flow, net profit and R&D investment, and set 5 differentiated listing standard (meet 1 out of 5), the existence of unrecovered losses is not a veto premise.

- For pre-revenue biotech companies, they must meet the main conditions of a market cap no less than RMB4 billion and at least one core pipeline to be approved for Phase II clinical trials.

<table>
<thead>
<tr>
<th>Standard</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The estimated market cap ≥ RMB1 billion AND The aggregate net profit in prior two fiscal years ≥ RMB50 million, and each of the prior two fiscal years &gt; RMB0 OR The net profit in the previous fiscal year &gt; RMB0 and the operating income ≥ RMB100 million</td>
</tr>
<tr>
<td>2</td>
<td>The estimated market cap ≥ RMB1.5 billion AND The operating income in the previous fiscal year ≥ RMB 200 million AND The proportion of aggregate R&amp;D investment in prior three fiscal years accounts for no less than 15% of the aggregate revenue in prior three fiscal years</td>
</tr>
<tr>
<td>3</td>
<td>The estimated market cap ≥ RMB2 billion AND The operating income in the previous fiscal year ≥ RMB 300 million AND The aggregate net cash flow from operating activities in prior three fiscal years ≥ RMB100 million</td>
</tr>
<tr>
<td>4</td>
<td>The estimated market cap ≥ RMB3 billion AND The operating income in previous fiscal year ≥ RMB300 million</td>
</tr>
<tr>
<td>5</td>
<td>The estimated market cap ≥ RMB4 billion. The main business or products need to be approved by the relevant state departments with a large market space and an initial results. Biopharma companies must have at least one core pipeline to be approved for Phase II clinical trials. Other companies accord with STI positioning need to have obvious technical advantages and meet the corresponding conditions</td>
</tr>
</tbody>
</table>
5. Branded drug Biotech Companies have attracted attention
Recently, biotech companies such as Loxo Oncology, which are engaged in R&D of brand-name drugs with significant progress in R&D and commercialization, have attracted attention from the capital market.

• Founded in 2013, Loxo Oncology is a biotech company innovating the development of highly selective drugs for patients with genetically defined cancers. In December 2017, it initiated submission of a New Drug Application for LOXO-101 to FDA who received application and granted priority review. LOXO-101 was officially approved in November 2018. The stock price fluctuated upwards as the market expected to rise after it passed the phase II clinical trial. On January 7, 2019, Eli Lilly announced that it would buy Loxo in full cash at a price of USD235 per share, with a total transaction value of USD8 billion.

• R&D driven biotech companies without marketed product may remain unprofitable for a long time, yet investors are still willing to give them a high valuation in reward for their sales expectations after pipelines got approved. The leading R&D level of such companies in certain segments makes them often the preferred M&A targets for large pharma companies.

• Phase II/III of clinical trails are the key time nodes affecting valuation from perspective of the stock price performance of U.S emerging biotech companies. Along with partial clinical data of brand-name drugs (safety/effectiveness) been disclosed, investors are optimistic about the future marketization and licensing possibilities of new drugs, thereby driving up the valuation.

Loxo Stock Price after Reinstatement 2014-2019 (Currency: USD)

Source: Capital IQ, Annual report
6. The launching of brand-name drugs boosts performance up

There has been no lack of Loxo-like cases in history, such as Amgen, which was listed on U.S. stock exchange in 1984. The company’s performance did not change much before Neulasta went public in 2002, yet its market value fluctuated upwards from 1998 to 2002 with the positive expectations of Neulasta through phase III clinical trials.

Neulasta’s performance after marketed is in line with investors’ expectations, the stock price is stable for a long time. With the rapid release of new drug sales, the company’s EPS boosted, and the P/E multiple went downward.

Amgen’s core products, Peugestin (Neulasta) and Denosumab (Prolia/Xgeva), were approved by the US FDA in January 2002 and June 2010, respectively. From actual sales performance, both drugs are rapidly increasing and stabilizing at a high sales level every year. In 2017, Peugestin and Denosumab brought considerable revenue of USD4.53 billion and USD3.55 billion respectively.
In 1953, Thalidomide, produced by Chemie Gruenenthal, Germany, was officially launched as a sleep aid and was widely used in pregnant women to stop vomiting during pregnancy. In the early 1960s, reports a large number of infant malformations caused by this drug made the drug banned in many countries and withdrew from the pharmaceutical market.

Celgene acquired Thalomid (Thalidomide) in 1992. With the development of research on leprosy, rheumatism and various types of malignant tumors, the drug has backed to market. The drug was approved by the US FDA in 1998 for the treatment of erythema nodosum leprosum (ENL). In May 2006, the drug was approved by the FDA for a new indications, multiple myeloma (MM). Thalomid has long occupied more than 90% of Celgene’s total sales revenue after marketing, with a peak sales of $500 million. To prevent fetal exposure to fetus from this teratogenic drug, the company has developed a comprehensive program to control prescriptions, dispensing and drug use, the System for Thalidomide Education and Prescribing Safety (S.T.E.P.S) which was submitted to the FDA as part of the NDA. The company’s patents based on S.T.E.P.S largely rule out the competition of generic drugs, so that a drug whose patent has expired still brings huge profit to the company.

In 2005, the Revlimid (Lenalidomide), a new derivative of Thalidomide was successfully approved by FDA. The drug was rapidly occupying the US market with better efficacy and fewer side effects, becoming the company’s new main source of income.

Although offsetting some of Thalomid’s sales share, the combined sales revenue of these two drugs is still beyond impressive, and the business model of acquiring drugs and improving it has made Celgene a big win. With the company’s performance explosive growth. The company’s total market cap is also rising in fluctuation, high recognition with a peak of more than $100 billion, reflecting the of the capital market for the company.
In the securities market, investors are willing to give high valuations to brand-name drug companies which brought excellent returns to investors. Behind this is the brand-name drug (especially the first-in-class drug) which has made a huge profit to the company by virtue of less competition and less price pressure during the exclusive period. This is unreachable for generic drugs or Me-too/Me-better drugs.

7. Capital markets has raised attention to brand-name drug companies

In early 2013, AbbVie Inc., originally the brand-name drug division of Abbott Laboratories, successfully went public through a spin-off. After the spin-off, new Abbott retained its nutrients, medical diagnostics and generic drugs businesses, while AbbVie took away almost all of its patented drugs, including Humira, Niaspan, Creon and Tricor.

After spin-off, AbbVie focused on brand-name drug R&D, its R&D investment has been raised to the level of leading pharmaceutical companies within a short period of time. The company has also patched up R&D inefficiency through cooperation. The two new companies formed after the spin-off of Abbott's brand-name drug business better matched investors with different investment preferences.

Humira achieved the global sales #1 for six consecutive years after surpassing Plavix in 2012, continuously bringing high profits to the company. Viekira, a hepatitis C cocktail developed jointly by Albert and Enanta, was successfully open to sell in 2014, and investors’ confidence in the company has increased significantly.

At the end of 2014, AbbVie’s capital market performance had a strong run, with a PE ratio of 53x. In the third year after established, AbbVie’s market value has exceeded Abbott’s total market value before the spin-off with a CAGR of 16% in the past seven years. Shareholders’ earnings are significant. Market performance had a strong run, with a PE ratio of 53x. In the third year after established, AbbVie’s market value has exceeded Abbott’s total market value before the spin-off with a CAGR of 16% in the past seven years. Shareholders’ earnings are significant.

Abbott’s Total Market Cap Before and After the Spin-off 2009-2019 (US$Bn)

Note: The market value benchmark date is the first trading day of each year.
Source: Capital IQ
M&A Transaction

1. M&A Transactions Active in the Pharmaceutical and biotech Industry
The overall global M&A transactions in pharmaceutical and biotech industry have increased in the past decade despite of volatility:

- It is expected that the scale of **M&A in 2019 will further increase** represented by the acquisition of Loxo Oncology by Eli Lilly with a deal value of 8 billion US dollars, **the scale of biopharma companies’ M&A increased significantly which mainly due to the structural and strategic adjustment needs of pharmaceutical companies, and the influence of media and public opinion. Increase of product lines, completion of industrial chain layout, and further consolidating market position remain the key motivations for M&A.**
- In January 2019, Bristol-Myers Squibb announced the acquisition of Celgene, a biotech company for USD 74 billion. The deal value was second only to the Pfizer/Warner-Lambert M&A transaction in 1999, making it the second largest transaction in the biopharmaceutical industry. In February of the same year, Roche announced to acquire Spark Therapeutics, the leader in gene therapy, for USD4.3 billion. The frequent M&A activities this year have made the M&A volume of the industry in the first two months of 2019 reach 57% of the whole year of 2018.
Value and Volume of M&A Deals in the Global Pharmaceutical and biotech Industry (US$Bn)

Source: MergerMarket, Deloitte Research

2. Large Pharmaceutical Companies Acquiring Biotech Companies have became a Key Driver in the M&A Market

Top 10 Transactions in the Global Pharmaceutical and biotech Industry since 2014

<table>
<thead>
<tr>
<th>Announcement Date</th>
<th>Bidder</th>
<th>Target</th>
<th>Deal Value (USD Million)</th>
<th>Type of Acquisition</th>
<th>Target Sub-Sectors</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 2019</td>
<td>Bristol-Myers Squibb</td>
<td>Celgene Corporation</td>
<td>89,489</td>
<td>100%</td>
<td>biotech, pharmaceuticals – drug development and commercialization</td>
</tr>
<tr>
<td>May 2018</td>
<td>Takeda Pharmaceutical</td>
<td>Shire Plc</td>
<td>78,198</td>
<td>100%</td>
<td>biotech, pharmaceutical</td>
</tr>
<tr>
<td>November 2014</td>
<td>Actavis plc</td>
<td>Allergan, Inc.</td>
<td>63,199</td>
<td>100%</td>
<td>Pharmaceutical – branded drugs and medical device research and development</td>
</tr>
<tr>
<td>July 2015</td>
<td>Teva Pharmaceutical Industries Ltd</td>
<td>Allergan plc (Generic Drug Business)</td>
<td>39,633</td>
<td>100%</td>
<td>Pharmaceutical – generic drugs</td>
</tr>
<tr>
<td>January 2016</td>
<td>Shire Plc</td>
<td>Baxalta Inc.</td>
<td>35,219</td>
<td>100%</td>
<td>Pharmaceutical – drug development and commercialization</td>
</tr>
<tr>
<td>January 2017</td>
<td>Johnson &amp; Johnson</td>
<td>Actelion Pharmaceuticals Ltd</td>
<td>29,592</td>
<td>100%</td>
<td>biotech, pharmaceuticals – drug development and commercialization</td>
</tr>
<tr>
<td>February 2014</td>
<td>Allergan plc</td>
<td>Forest Laboratories Inc</td>
<td>23,126</td>
<td>100%</td>
<td>Pharmaceutical – drug development</td>
</tr>
<tr>
<td>February 2019</td>
<td>Danaher</td>
<td>GE Healthcare Life Sciences (Biopharmaceutical Business)</td>
<td>21,400</td>
<td>100%</td>
<td>biotech – drug R&amp;D related instruments, consumables and software</td>
</tr>
<tr>
<td>March 2015</td>
<td>AbbVie Inc.</td>
<td>Pharmacynics Inc</td>
<td>19,045</td>
<td>100%</td>
<td>biotech, pharmaceuticals – branded drug development</td>
</tr>
<tr>
<td>February 2015</td>
<td>Pfizer</td>
<td>Hospira Inc</td>
<td>16,323</td>
<td>100%</td>
<td>Pharmaceutical – biosimilar</td>
</tr>
</tbody>
</table>

Source: Mergermarket, Deloitte Research
In the past five years, most of the top ten global Pharmaceutical and biotech M&A in transaction scale concentrated in the field of branded drug R&D excepting the Israeli generic drug giant Teva's acquisition of Allergan's generics business and the Pfizer's acquisition of biosimilar company Hospira. Key drivers of such M&A transactions include acquiring new products to diversify product lines, expanding business coverage, deepening business globalization, and entering new business areas.

### 3. Large Pharmaceutical Companies Enhance Innovation through Frequent M&A

- As the growth of biosimilar drugs continues in recent years, pharmaceutical companies will inevitably face a decline in annual income of drugs after the exclusive period.
- Under the background of drug expenditure slowing down, large scale pharmaceutical companies have to find a transformation in their “price driven" performance growth model. Drug development has long cycle, high risks, and requires a large amount of long-term investment. Smaller biotech companies or emerging biopharmaceutical companies are recognized with the ability to offer innovative products or technologies. Under such ecological environment, frequent M&A of pharmaceutical companies has become a trend.

#### Bristol-Myers Squibb’s Acquisition of Celgene

On January 3, 2019, Bristol-Myers Squibb and Celgene jointly announced that the two parties have reached an acquisition agreement. Bristol-Myers Squibb will acquire Celgene for a total value of USD 74 billion (corresponding enterprise value of USD 89.5 billion), making it the largest M&A transaction in recent years. Bristol-Myers Squibb and Celgene are ranked third and fifth in the 2017 top ten companies by annual revenue in the field of tumor. With Bristol-Myers Squibb’s star product Opdivo and Celgene’s blockbuster Revlimid, the new Bristol-Myers Squibb is expected to take over the first place from Roche in the field of oncology. The Merger will also greatly strengthen Bristol-Myers Squibb’s business in immunity, inflammation and cardiovascular.

#### Lilly’s Acquisition of Loxo

On January 7, 2019, Lilly announced that it will acquire Loxo Oncology, a company that develops genome-defined precise cancer drugs, for a total value of USD 8 billion. This has become the first major deal since Lilly’s new CEO Dave Ricks took office, which shows Lilly’s ambitions in the field of cancer-targeted drugs.

#### Roche’s Acquisition of Spark Therapeutics

- On February 25, 2019, Roche Holding announced to acquire Spark Therapeutics, a leader in gene therapy, for USD 4.3 billion.
- Founded in 2013, Spark is a gene therapy company with a rich pipeline, covering hereditary eye diseases, hemophilia, lysosomal storage diseases, and neurodegenerative diseases:
  - Spark’s first gene therapy Luxturna, which treats children and adults with specific hereditary eye diseases, was approved in December 2017. Spark also works with Pfizer to develop Fidanacogene Elaparvovec for the treatment of hemophilia B, which has entered Phase III in clinical trials. SPK-8011 for the treatment of hemophilia A is also expected to enter Phase III in clinical trial this year.
- The acquisition of Spark Therapeutics can benefit Roche in making up for its shortcomings in the layout of gene therapy sector, and strengthening its hemophilia R&D department as a supplement to its heavyweight drug Hemlibra for the treatment of hemophilia A. Additionally, Roche faces a severe patent threat this year, which is also a key driver of its M&A: the patent of Rituxan, a key product for treatment of hematological cancer, has expired at the end of 2018 in the United States; the biosimilar drug Truxima, approved by EMA and FDA in July 2017 and November 2018, respectively, is expected to be officially launched in the first half of 2019; the other three heavyweights Avastin, Herceptin, and Tarceva will lose patent protection in 2019 in the United States, facing severe price cuts.
Outlook and Key drivers

**Investment, financing and M&A activities in pharmaceutical and biotech industry will remain active**

As more biotech companies are listed on the HKEX, the biotech sector of HKEX will become more mature as the investors who prefer to biotech companies are gathered, while it is also expected to be in line with the US stock market, and we expect to observe there:

- Stronger IPO financing activities
- More active secondary market transactions

In addition with the mature US stock market and the establishment of the A-share Science and Technology Innovation board. The global investment and financing activities in pharmaceutical and biotech industry will remain active.

In terms of M&A, large pharma companies have been required to update their pipeline in response to price cuts and the adverse effects of patent cliffs. In addition, large pharma companies are generally better at addressing market sales and regulatory requirements of late stage drugs than emerging biopharma companies (EBP). Therefore, the heat of M&A activity drive by the patent-protected innovative drugs, will not be reduced.
We have observed the following trends:

**1. The first-in-class drugs continue to receive attention from the capital market, whose can effectively reduce R&D risks and maintain market exclusivity will be favored.**

In the field of brand-name drugs, concepts such as First-in-class, Me-better and Me-too are often used. Strictly speaking, those concepts are not precisely defined, yet they can be used for helping people to understand some characteristics by labeling brand-name drugs in a vivid way:

- **Me-too/Me-better:** In the case of breakthrough novel drugs with patent protection in the market, Me-too drug developers are looking for similar molecular structures that are not protected by patents based on the mechanism of action of this novel drug in order to achieve similar or even better efficacy. If the molecular structure changed is significant and the compound has advantages in activity, metabolism, toxicity, etc., then this novel drug may be regarded as a Me-better drug.

- **First-in-class:** Unlike Me-too/Me-better, the First-in-class drug often has a major breakthrough in terms of mechanism of action, indications and molecular entities which can be analogized as New molecular entity (NME)/new chemical entity (NCE) described in FDCA's 505(b)(1) of FDA.

The First-in-class drugs will continue to draw attention from the capital market while it bring huge potential benefits to enterprises yet with less competition in the market, it also come under less pressure from the government, public opinion and supply/demand sides.

The First-in-class drugs are often the novel drug Global, and the huge benefits brought to enterprises are also reflected in the global market returns, and will also be watched by the global capital market.

The main risk of the First-in-class drugs comes from long research and development time, huge R&D investment and high R&D risk. Therefore, companies that can effectively shorten the R&D cycle, save R&D investment or reduce R&D risk by its technology or business model will be favored.

In addition, it will bring more lasting benefits to the enterprise if the First-in-class drugs can prolong its patent protection period after commercialization, or maintain its market exclusivity through Orphan drug designation.

**2. Specialty drugs, orphan drugs, biologics and oncology in novel drugs will continue to be the tendency.**

**3. Diversified cooperation between large multinational biopharma companies and EBP will lead to new excellent enterprises in the capital market.**

**4. Brand-name drugs ushered in the era of globalization, biotech companies tend to gain global development right and quickly conduct clinical research in multi-centers around the world to capture more markets after drugs are approved.**

The First-in-class drugs are conspicuous in the context of the gradual growth of global drug spending, the market is increasingly eager to the approval of brand-name drugs. With the pressure of losses of exclusivity.
The market growth expectation is mainly due to the approval of novel drugs with flat growth of global drug spending

Global pharmaceutical spending is predicted to outpace overall health care spending. Global prescription drug sales are expected to rise from US$900 billion in 2019 to US$1.2 trillion by 2024. From 2019 to 2024, CAGR for prescription drug is expected to be 6.7 percent, or two times the 2.4 percent over 2011–2018.\(^1\)

Drivers of growth are predicted to be novel therapies that address key, unmet needs and increased access to drugs.

The Chinese government has focused on managing drug pricing through the use of an Essential Drug List and a National Reimbursement Drug List (NRDL).

Losses of exclusivity (LOE) continues to put pressure on pharm companies

IQVIA expects that the expected impact of LOE for brand-name drugs in the developed markets is expected to peak in 2019, the impact of LOE in developed markets for small molecules will be larger in the next five years at $121 billion compared to $105 billion from 2014–2018, a 15% increase.\(^2\)

Notes: Developed markets include: U.S., Japan, Germany, France, Italy, U.K., Spain, Canada, S. Korea, Australia
Source: IQVIA, 2019
2. Specialty drugs, orphan drugs, biologics and oncology in novel drugs will continue to be the tendency

IQVIA expects that between 2014 and 2018, the average spending on new brand-name drugs was $43.4 billion. New products launching between 2019 and 2023 are expected to have a slightly higher overall level of spending, approximately $45.8 billion.

Along with the increasing number of launches, the type of products continues to shift to specialty, orphan, biologic and oncology products. Specialty is expected to represent nearly two-thirds of newly launched drugs over the next five years, and oncology approximately 30%. Orphan drugs could represent 45% of NME should the level of FDA orphan designations for in-progress research and breakthrough designations produce successful launches at current, historic rates.\(^3\)

The increasing use of biomarkers to segment and treat appropriate patients will characterize more launches.

Under this trend, biopharma focusing on the above novel drug research will continue to be hot topics in the capital market and M&A market.

### Developed Markets New Brand Spending and Share of Total Brand Spending Constant (US$Bn)

![Graph showing average annual global NME launches](image)

**Notes:** New Brands defined as those launched less than two years previously, measured separately in each country as launches of the same products are at different times. Source: IQVIA, 2019

### Average Number of Global NME Launches Annually per Period and Percentage of Launches by Type

![Graph showing percentage of launches by type](image)

**Notes:** Percentages do not sum as segments are not mutually exclusive. NME = new molecular entity. Source: IQVIA, 2019
3. Diversified cooperation between large multinational biopharma companies and EBP will lead to new excellent enterprises in the capital market. Global large biopharm companies have descended R&D returns

According to Deloitte LLP, the R&D returns of novel drugs by large biopharma companies have fallen to the lowest level in nine years, only 1.9%. For multinational biopharma companies with annual investment of over US$10 billion, high-intensity R&D investment may not correlated with higher returns. Investors pay more attention to the company’s current products, the potential growth of pipelines and future performances.4

The decline in R&D returns has led to a significant division of labor between large pharma companies and EBP, with more and more R&D work being done by biotech companies.

EBP companies are increasingly taking their products to market on their own.

According to the research of IQVIA, EBP are those with less than $500 million in revenue or with less than $200 million in R&D spending. Over the past decade, the percent of R&D activity being led by EBP companies has increased from 60% in 2009 to 72% through October 2018.

EBP companies are launching 68 NME over the past five years, up from 47 in 2009 to 2013.5

In this context, large biopharma companies will continue to form a variety of partnerships with EBP besides the current M&A trend.
Business Model 1: EBP could get a down payment and a potential milestone payment by developed in cooperation with large biopharma companies. These cash flows are critical for talent, R&D and operations before product launches.

**Innovent Biologics**
According to public information, Innovent Biologics has twice reached strategic cooperation with Eli Lilly to obtain a total $3.3 billion in down payment and potential milestones:
- The companies will collaborate on three bispecific monoclonal antibody that target the protein PD-1 in an effort to unblind the immune system to malignancies in the body. In exchange for Innovent’s help, Eli Lilly is promising more than $1 billion in payments over the next decade, tied to development, regulatory and sales milestones.
- Under the new deal, Eli Lilly is on hand to develop and commercialize each treatment outside of China, while Innovent retains the local right. Innovent Biologics will receive additional sales commissions and other payments if the above antibodies are successfully commercialized outside of China.
- In addition to its cooperation with Eli Lilly, Innovent Biologics has also collaborated with institutions such as Adimad to discover monoclonal antibodies.

Innovent Biologics has listed on HKEX in 2018.\(^6\)

Business Model 2: By acquiring the rights within Greater China / Asia-Pacific region of late clinical stage pipeline from large biopharma. EBP can complete the clinical trial in China in a relative short period of time and achieving good returns.

**Zai Lab**
The cooperation model between Zai Lab and the pharmaceutical company is to obtain R&D and commercial rights for the products in the Greater China region or the Asia-Pacific region through the payment of Royalty.

According to the public information, since 2014, Zai Lab has established its pipeline products through obtaining R&D and commercial rights from Sanofi, Bristol-Myers Squibb, Tesaro and etc. in the Greater China region.\(^7\)

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<th>Pipeline</th>
<th>Originator</th>
<th>Region</th>
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Source: Company website
Business Model 3: The R&D for brand-name drug often link with a lengthy period and a massive investment. Pharma company usually had invested tons of money/time during clinical trial phase II/III in exchange for valuable clinical data. By acquiring the rights of the drugs that have not achieved required results in clinical trial Phase III, EBP can use their exclusive technology platform to complete the development in a relative short period of time at a lower cost, and achieve a long-term prosperous profit.

**Denovo Biopharma**
Based on its **AI and big data** biomarker platform, Denovo precisely searches for effective biomarkers for the **global development of the first-in-class drug**. The business mode for Denovo is to acquire the **global rights** of the late stage clinical drugs. Denovo’s technology enables biotech and pharmaceutical companies to design new clinical trials in a targeted patient population to achieve significant efficacy and/or less adverse effects by identifying biomarkers correlated to patients’ responsiveness to drug candidates retrospectively.

According to public information, Denovo had acquired global rights of three first-in-class drug from Eli Lilly, Bristol-Myers Squibb and etc.

- **Enzastaurin**, one of the pipeline in Denovo, with all global rights (including development, production and commercialization) acquired from Lilly, who conducted many clinical studies with Enzastaurin including phase III clinical trials in diffuse large B cell lymphoma (DLBCL) and glioma (GBM).
- Another first-in-class drug, **Pomaglumetad, a novel schizophrenia drug** that has been completed in phase II trials by Lilly.
- Denovo has obtained all of its **global rights including all approved materials, clinical data, patents and trademarks.** It is expected that Phase III clinical trials will be launched in the near future.
- Denovo also obtained a **global right (including global R & D, production and marketing)** for Liafensine, the first-in-class drug for the treatment of resistant depression, from Bristol-Myers Squibb and AMRI.  

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<td>BMS, AMRI</td>
<td>Global</td>
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Source: Company website
Business Model 4: The professional team will conduct independent R&D of the first-in-class drugs from scratch based on their early R&D results whilst they took employment with large-scale well-known research institutions.

SyneuRx International (Taiwan) Corp.
The professional team of SyneuRx is composed of experienced professionals engaged in independent R&D of novel drugs for the treatment of diseases related to the central nervous system based on their early R&D results whilst they took employment in large well-known research institutions or academic centers.

According to the SyneuRx Prospectus, the intellectual property of its R&D pipeline was invented by the founders at the well-known research centers (Massachusetts General Hospital and UCLA), and many of the drugs under development have received orphan drug designation and breakthrough therapy designation by FDA, in which the Orphan Drug Exclusivity will last 7-7.5 years.

After the completion of Phase III clinical trial/NDA, SyneuRx will obtain high-value down payment, milestone payment and royalty after marketing through cooperation and out-licensing with multinational pharma companies.⑨

### Therapeutic area | Pipeline | Indication | FDA Designation
--- | --- | --- | ---
Psychiatry | SND11 | Adolescent Schizophrenia | Orphan drug |
 | SND12 | Refractory Schizophrenia | Orphan drug |
 | | | Breakthrough therapy |
 | SND13 | Adult Schizophrenia | Breakthrough therapy |
 | SND14 | Early Dementia | |
 | SND51 | Dementia & Psychosis Symptoms | |
 | SNG12 | Depression & Suicidality | |
 | SNA1 | SNA1 Refractory Depression | |

Source: Company website
Endnotes

2.  IQVIA Market Prognosis, Sep 2018.
3.  IQVIA Market Prognosis, Sep 2018.
5.  IQVIA Market Prognosis, Sep 2018.
6.  Prospectus of Innovent Biologics Inc.
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