



Hong Kong

August 2019

## HKEX REPORT ON THE CES HK BIOTECHNOLOGY INDEX

The Stock Exchange of Hong Kong (**HKEx**)<sup>1</sup> published a Research Report: Investment Benchmark for Asia's Biotechnology Sector: CES HK Biotechnology Index<sup>2</sup> in May 2019 highlighting HKEx's role in financing China's growing biotechnology sector and the instrumental role to be played by the CES HK Biotechnology Index (**CES HK Biotech**)<sup>3</sup> launched in November 2018 to track Hong Kong-listed Chinese biotechnology companies.

### The Biotech Medical Industry at a Glance

HKEx's Biotech Research Report<sup>4</sup> attributes the biotech industry's considerable growth in recent years to various factors including global economic development, increased demand due to population growth and aging populations, and technological advances. EvaluatePharma's 2017 World Preview<sup>5</sup> estimated that biotech products would make up 52% of the 100 best-performing pharmaceutical products by 2022, with the biomedical industry's share of the broader pharmaceutical market rising from 17% in 2008 to 30% in 2022. This trend is also reflected in the Asian market. Between 2011 and 2016, for example, Mainland China's pharmaceutical market grew at a Compound Annual Growth Rate (**CAGR**) of

15%.<sup>6</sup> China included encouraging a healthy population as a national strategy in 2016 and the cost of China's healthcare service is expected to reach RMB 16 trillion by 2030.<sup>7</sup>

Biomedical companies in their growth stage are primarily financed through venture capital and equity financing as opposed to debt financing. Compared to traditional sectors, biomedical companies require significant and long-term investment which is expensive and high risk, particularly in the case of drug development where the chance of a drug candidate in Phase I clinical trials receiving final approval from the US Food and Drug Administration (**FDA**), is just 10%.<sup>8</sup> Biomedical companies need funding of US\$250 million on average, require eight to ten years from concept to product launch, and average annual losses of US\$30 million.<sup>9</sup> The report also notes increased concentration in the biomedical sector due to the intensely competitive nature of drug research and development. For example, in 2017 alone, there were over 400 mergers and acquisitions in the global biomedical sector involving over US\$180 billion, most of which involved large companies acquiring small and medium-sized enterprises to obtain emerging technologies.<sup>10</sup>

1 [https://www.hkex.com.hk/?sc\\_lang=en](https://www.hkex.com.hk/?sc_lang=en)

2 [https://www.hkex.com.hk/-/media/HKEX-Market/News/Research-Reports/HKEx-Research-Papers/2019/CCEO\\_Biotech\\_201905\\_e.pdf?la=en](https://www.hkex.com.hk/-/media/HKEX-Market/News/Research-Reports/HKEx-Research-Papers/2019/CCEO_Biotech_201905_e.pdf?la=en)

3 <https://www.cesc.com/en/Index/Hong-Kong-Overseas/Ces-Hk-Biotech.html>

4 [https://www.hkex.com.hk/-/media/HKEX-Market/News/Research-Reports/HKEx-Research-Papers/2019/CCEO\\_Biotech\\_201905\\_e.pdf?la=en](https://www.hkex.com.hk/-/media/HKEX-Market/News/Research-Reports/HKEx-Research-Papers/2019/CCEO_Biotech_201905_e.pdf?la=en)

5 <https://info.evaluategroup.com/rs/607-YGS-364/images/WP17.pdf>

6 McKinsey, "CPA-McKinsey China Hospital Pharmaceuticals Report: An In-depth Perspective". August 2017.

7 State Council's "Outline of the Healthy China 2030 Plan". October 2016.

8 BIO, "Clinical Development Success Rates 2006-2015". May 2016.

9 R&D-based Pharmaceutical Association Committee under the China Association of Enterprises with Foreign Investment, et. al. ("Facilitating the design and implementation of the clinical research framework, deepening the formation of the medical innovation ecosystem"), December 2017.

10 HKEx. "Investment Benchmark for Asia's Biotechnology Sector: CES HK Biotechnology Index". May 2019.

## Capital Market Reforms and New Listing Rules for Biomedical Companies

A number of international securities markets have implemented market reforms in recent years to attract the listing of biomedical companies.

### United States

NASDAQ<sup>11</sup> is the primary market for listing global biomedical companies. It operates a flexible listing regime, which allows companies to list on different boards according to their financial performance based on their profits, assets and size. In February 2019, approximately 745 companies involved in the health sector were listed on NASDAQ, including 171 biomedical companies. These included a number of Chinese medical companies including BeiGene, Hutchison MediPharma and Zai Lab. In April 2012, the Jumpstart Our Business Startups Act<sup>12</sup> was implemented with the specific purpose of supporting equity financing and listing of emerging businesses and innovative SMEs, such as biotech companies.

### Europe

Similar reforms have also been implemented across European stock exchanges.

#### London

In 1995, the London Stock Exchange<sup>13</sup> introduced the Alternative Investment Market<sup>14</sup> to boost the UK's biotech industry. In 2014, the UK had the highest number and value of new venture capital investments in the biotech industry in Europe.

#### Frankfurt

The Frankfurt Stock Exchange launched a new market (its Neuer Markt) in 1997<sup>15</sup> to provide a funding platform for high-growth technology companies. After its initial success in the late 1990s and early 2000s, the Neuer Markt was closed in late 2002 following the bursting of the 'stock price bubble' of the Internet boom and declining investor confidence following a

number of corporate failures and financial scandals.<sup>16</sup> In 2003, the Frankfurt Stock Exchange restructured its stock market into two separate boards with differing disclosure standards, and, in 2005, it established a "junior board" for SMEs.<sup>17</sup> These reforms boosted Germany's biotech industry and Germany now manufactures 40% of the drugs manufactured in Europe.

### Asia

Asia's biotech industry is relatively young compared to those of the US and Europe. China's biomedical industry has flourished due to policy reforms, the efficient implementation of nationwide strategies (including the 13th Five-Year Plan<sup>18</sup> and the Healthy China 2030 Plan<sup>19</sup>), regulatory authority reforms (including those undertaken by the State Food and Drug Administration<sup>20</sup>) and medical insurance catalogue reforms, as well as standardised evaluation, priority review and accelerated approval of innovative drugs. In particular, the Mainland's 13th Five-Year Plan has a specific focus on technological innovation, rather than on generic drugs and autonomous innovation, which were the focus of the 11th and 12th Five-Year Plans, respectively. China's biomedical industry has clustered around the Yangtze River Delta, the Pearl River Delta and Bohai Bay. Shenzhen has also attracted innovative biomedical companies and its biomedical industry was valued at over RMB 200 billion in 2016.

## Hong Kong's Support for China's Biomedical Companies

In the biggest change to its Listing Rules<sup>21</sup> for 25 years, HKEx introduced new Listing Rules in April 2018 to allow pre-revenue biotech companies to list on HKEx's Main Board without meeting the qualifying financial tests of HKEx Listing Rule 8.05. The new regime for pre-revenue biotech companies was aimed primarily at China's new generation of biotech companies which have traditionally listed on New York's NASDAQ.

<sup>11</sup> <https://www.nasdaq.com>

<sup>12</sup> <https://www.sec.gov/spotlight/jobs-act.shtml>

<sup>13</sup> <https://www.londonstockexchange.com/home/homepage.htm>

<sup>14</sup> <https://www.londonstockexchange.com/exchange/prices-and-markets/stocks/aim/aim-Index.html>

<sup>15</sup> <https://www.boerse-frankfurt.de/home?lang=en>

<sup>16</sup> Hans-Peter Burghof and Adrian Hunger. "Access to Stock Markets for Small and Medium Sized Growth Firms: The Temporary Success and Ultimate Failure of Germany's *Neuer Markt*." October 2003.

<sup>17</sup> HKEx. "Listing Regime Reforms for Dual-Class Share Structure and Biotech Industry". November 2018.

<sup>18</sup> <http://en.ndrc.gov.cn/newsrelease/201612/P020161207645765233498.pdf>

<sup>19</sup> <https://www.who.int/healthpromotion/conferences/9gchp/healthy-china/en/>

<sup>20</sup> <http://www.sfdachina.com>

<sup>21</sup> [https://www.hkex.com.hk/Listing/Rules-and-Guidance/Listing-Rules?sc\\_lang=en](https://www.hkex.com.hk/Listing/Rules-and-Guidance/Listing-Rules?sc_lang=en)

The key requirements for a pre-revenue biotech company to list on HKEx are that it must:

1. be able to demonstrate that it is suitable for listing in accordance with HKEx Guidance Letter 92-18: Suitability for Listing of Biotech Companies;<sup>22</sup>
2. have an initial market capitalisation at listing of at least HK\$1.5 billion;
3. have been in operation in its current line of business for at least two financial years prior to listing under substantially the same management; and
4. have sufficient working capital to cover at least 125% of the group's costs (including: (a) general, administrative, operating and production costs, if applicable; and (b) research and development costs) for at least 12 months from the date of publication of its listing document.

For further details of the Chapter 18A listing regime for pre-revenue biotech companies, please see Charltons' April 2018 newsletter New Rules for Listing Biotech Companies on the Hong Kong Stock Exchange.<sup>23</sup>

Hong Kong's Listing Rules also recognise the China Food and Drug Administration as a regulator qualified to evaluate biotech products equivalent to the US FDA and the European Medicines Agency.

The exit channel provided by the 2018 HKEx Listing Rule changes may also assist in attracting more venture capital to high-risk high-return biotech companies. Hong Kong investors are more familiar than their foreign counterparts with Mainland China's market and laws and regulations, putting them in a good position to assess the investment risks associated with Chinese biomedical companies. The ability of Mainland Chinese investors to buy HKEx-listed Chinese biotech stocks through Stock Connect<sup>24</sup> should also help to provide a pool of investors for financing the sector.

## Major Biotechnology Indices

Biotech indices and financial products have been introduced in various global biotech markets to further increase investors' accessibility to the biotech industry. These include the S&P Biotechnology Select Industry Index launched by Standard & Poor's in January 2006 which has 119 constituent stocks and a total market capitalisation of US\$7,078 million<sup>25</sup> and the Nasdaq Biotechnology Index which has 221 constituent stocks and is now a major sector index covering Nasdaq-listed companies specialised in biotech and gene pharmaceuticals.

## CES HK Biotechnology Index

With Asia's biotech industry in its infancy, there are few large pharmaceutical companies in Asia and no world class biotech R&D centres. Asian investors and analysts also lack the experience and expertise required to assess investment opportunities in the pharmaceutical sector.

The China Exchanges Services Company Limited, a joint venture between the stock exchanges of Shanghai, Shenzhen and Hong Kong, launched the CES HK Biotechnology Index<sup>26</sup> (**CES HK Biotech**) in November 2018 to track HKEx-listed biomedical companies – both those listed under the 2018 regime for pre-revenue biotech companies and those at a more advanced developmental stage.

## Financial Products based on Biotech Indices

### United States

The US has the world's largest market of biotechnology exchange-traded funds with 18 different biotech ETFs collectively managing approximately US\$19 billion of assets. Their underlying stocks are all listed in the US and they mainly track three major US biomedical indices – the Nasdaq Biotechnology Index, the S&P Biotechnology Select Industry Index and the New York Stock Exchange's biotechnology index. There are also six leveraged and inverse biotech ETFs.

### Europe

The European biotech market features two biotech ETFs which are listed in London and Frankfurt. The London-listed ETF,

<sup>22</sup> [https://en-rules.hkex.com.hk/sites/default/files/net\\_file\\_store/new\\_rulebooks/g/l/gl9218.pdf](https://en-rules.hkex.com.hk/sites/default/files/net_file_store/new_rulebooks/g/l/gl9218.pdf)

<sup>23</sup> <https://www.charltonslaw.com/new-rules-for-listing-biotech-companies-on-the-hong-kong-stock-exchange/>

<sup>24</sup> [https://www.hkex.com.hk/Mutual-Market/Stock-Connect?sc\\_lang=en](https://www.hkex.com.hk/Mutual-Market/Stock-Connect?sc_lang=en)

<sup>25</sup> S&P's website, as of 31 January 2019.

<sup>26</sup> <https://www.cesc.com/en/Index/Hong-Kong-Overseas/Ces-Hk-Biotech.html>

which is the larger of the two, has US\$490 million of assets under management and is the first European-listed ETF to track the US Nasdaq Biotechnology Index.

## Asia

Mainland China has six biotech index funds, four of which track Mainland A-share biotech indices and two of which track US biotech indices. China has no biotech ETFs and no biotech index futures or other related derivatives available for trading at present.

## Report Conclusion

HKEx's Biotech Research Report expects HKEx's 2018 listing regime for pre-revenue biotech companies to facilitate the emergence of large innovative biotech companies which will in turn foster the development of core industries in the region. It also sees the launch of the CES HK Biotechnology Index as instrumental in increasing the diversity of Hong Kong's capital market.

The report sees the future direction of Asian biotechnology as lying in the use of biotech in developing therapies for human illnesses, an area likely to be highly significant for China as it becomes stronger in the field of biomedical innovation.

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