

Hong Kong Offers New Capital Markets Opportunity for Life Sciences and Healthcare Companies

by Simon Chan, Esq. and Evan Ng

Historically, the US, and, in particular, the NASDAQ market, has been the predominant place for IPOs of life sciences and healthcare companies. However, 2018 may be the year in which things start to change. Hong Kong is now opening up its IPO market to a new category of “pre-revenue companies in emerging and innovative sectors”. Last December, the Hong Kong Stock Exchange (the “**HKSE**”) began an overhaul to its listing rules that would give such companies the option to raise capital in the Hong Kong market. Hong Kong will become an attractive market in which to list, particularly for those life sciences and healthcare companies that wish to obtain greater access to Asia-based investors and the vast consumer market in China. While the HKSE did not include any definitions for companies from emerging and innovative sectors, or so-called “new economy companies”, the HKSE is nevertheless clearly targeting life sciences and healthcare companies, and comprehensively includes the key segments of (1) drugs; (2) medical devices; (3) diagnostics and healthcare services; and (4) digital health. Further, the HKSE has been actively promoting this initiative globally. We expect companies in China, Hong Kong and in the U.S. to explore listing opportunities. Even though the risk profile of such companies is higher than has historically been acceptable in the Hong Kong market, the HKSE views that the fact that such companies are generally subject to strict regulatory oversight and are required to reach certain specified objective milestones during its development process as mitigating factors.

The HKSE expects to have new rules ready by mid-2018 after a final public consultation launched last month, which will be open until March 23, 2018. In the interim, many companies are already preparing themselves to be among the first wave of such companies to take advantage of the new IPO rules. This article highlights some of the key factors you should take into account in evaluating a potential IPO in Hong Kong.

Hong Kong’s New Listing Regime

A new chapter 18A in HKSE’s listing regulations will be created for pre-revenue/pre-profit biotech companies (the “**New Chapter**”), under which qualifying applicants would **not** be

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required to have any revenue track record. In contrast, a regular applicant for listing on the main board of the HKSE must, if not generating a profit, have at least HK\$500 million (approximately US\$64 million) in revenue for the most recent audited financial year, in addition to meeting certain market capitalization and cashflow requirements.

Under the New Chapter, applicants would need a minimum expected market capitalization at the time of listing of at least HK\$1.5 billion (approximately US\$192.8 million), with at least one core product under development that has proceeded beyond the concept stage, which, from HKSE considers to be a product that has met the development milestones specified for the relevant type of product (for example, for a new pharmaceutical (small molecule drugs) product or a new biologic product, an applicant must demonstrate that it has completed Phase I clinical trials and the relevant competent authority (i.e., FDA (US), CFDA (China), EMA (Europe)) or any other national or supranational authority which the HKSE recognizes as a competent authority on a case by case basis) has not objected to its commencing Phase II (or later) clinical trials) . These applicants must meet the enhanced working capital requirements (125% of its current requirements over the next 12 months following listing), have been operating their current line of business for at least two years, and have previously received meaningful investment (being more than just a token investment) from at least one sophisticated investor (including financial institutions) at least six months before the date of the proposed listing (and which must remain at IPO).

Given the higher-risk nature of pre-revenue/pre-profit biotech companies, the HKSE has concerns about the creation of Shell companies if such companies end up failing. To avoid such a scenario, the HKSE proposes to restrict companies that list under the New Chapter from undertaking any transaction that would result in a fundamental change to its principal business without the prior consent of the HKSE. If such a listed company fails to meet any continuing obligation to maintain sufficient operations or assets, it would be given a period of up to 12 months to regain compliance with the requirement, failing which the HKSE would cancel its listing.¹

By eliminating the revenue track record requirement in the New Chapter, the HKSE hopes to attract pre-profit/pre-revenue life sciences and healthcare companies that are currently not eligible to list in Hong Kong in order to diversify its issuer base and enhance its competitiveness as a listing venue for the long run.

The Pieces Are Falling into Place

We believe the current environment is ripe for new life sciences and healthcare IPOs on the HKSE based on a number of factors:

- Companies across the globe desire access to the growing healthcare market in Asia and, in particular, China², and Hong Kong has historically been a logical jumping off point for these companies due to its strong infrastructure business and proximity to China.
- Asian institutional investors seeking access to deal flow view the Hong Kong market favorably. Hong Kong has been a leading global IPO portal with strong institutional investor support. According to the annual market statistics published by the HKSE,

Hong Kong ranked the second in the world in 2014 in terms of the amount of funds raised. The city became the world leader for two consecutive years in 2015 and 2016, with total funds raised of US\$31.8 billion and US\$24.8 billion, respectively. In 2017, it ranked third following the NYSE and the Shanghai Stock Exchange.

- Interest in life sciences and healthcare companies is rising due to recent regulatory reforms by the China Food and Drug Administration (CFDA). The regulatory burdens for foreign companies desiring to enter the Chinese market have been substantially eased and we expect the sector to heat up. For example, one of the CFDA's reforms is the "Decision to Adjust Relevant Items Concerning Imported Drug Registration"³ which is intended to facilitate the review and approval process for imported drugs, particularly for innovative imported drugs. The CFDA has also issued a series of draft amendments to the relevant laws and regulations in relation to the marketing authorization holder regime, use of foreign clinical trial data for registration of drugs or medical devices and the implementation of a U.S.-styled "Orange Book"⁴.

Hong Kong is Ready To Go

Pre-revenue life sciences and healthcare companies could not previously list in Hong Kong and were limited to listings in the US or Europe. Several Chinese firms had launched some of the biggest life sciences and healthcare IPOs in the US in the past two years. BeiGene Ltd. raised approximately US\$182 million on NASDAQ in February 2016⁵. In September 2017, Zai Lab Ltd. raised about US\$150 million on NASDAQ⁶.

The HKSE's move to allow pre-revenue life sciences and healthcare companies to list is timely. The Chinese life sciences and healthcare industry is booming with both companies and investors filling out the emerging venture ecosystem. With a growing pipeline of companies knocking at its doorstep, and a growing healthcare industry in China, Hong Kong is positioning itself as an ideal IPO option given its geographical proximity to the key Chinese market.

Since the HKSE announcement last December, many life sciences and healthcare companies have made inquiries directly through the HKSE, or have engaged investment banks and professional consultants to begin the process of raising capital in Hong Kong, accordingly to a local news report. The market is excited about the possibilities that may open up for fundraising in the Asia-Pacific region after implementation of the New Chapter. In the meantime, we eagerly await the results of the HKSE process.

If you have any questions regarding the matters covered in this publication, please contact any of the lawyers listed in this article or your regular Dorsey & Whitney contact.

¹ The "Consultation Conclusions – A Listing Regime for Companies from Emerging and Innovative Sectors" and the "FAQs on Proposed New Listing Regime for Emerging and Innovative Companies" published by the HKSE on 23 February 2018.

² China is the second largest pharmaceutical market in the world, and is forecasted to grow from \$108 billion in 2015 to \$167 billion by 2020, representing an annual growth rate of 9.1%, according to the "2016 Top Markets Report – Pharmaceuticals" published by the International Trade Administration of the US Department of Commerce. The total healthcare expenditure in China reached RMB4.6 trillion (or US\$667.2 billion) in 2016,

nearly quadrupling the RMB 984.3 billion spent in 2006 (or US\$141.7 billion), according to China Statistical Yearbook 2017 published by the National Bureau of Statistics of the People's Republic of China. However, healthcare expenditure accounted for only 6.2% of the country's GDP in 2016, which was far lower than the proportion spent in many high-income countries (2014: US 17.1%; Canada 10.4%; France 11.5%; Germany 11.3%; Australia 9.4%) and its neighbors (2014: Japan 10.2%; Korea 7.4%), according to the World Bank Open Data.

³ Chinese version of the said decision was published on October 10, 2017 on <http://www.sda.gov.cn/WS01/CL0050/178363.html>.

⁴ Chinese version of the "Draft Amendments to the Drug Administration Law" was published on October 23, 2017 on <http://www.sda.gov.cn/WS01/CL0050/178902.html>; Chinese version of the "Draft Amendments to the Provisions for Drug Registration" was published on October 23, 2017 on <http://www.sda.gov.cn/WS01/CL0050/178900.html>; Chinese version of the "Draft Amendments to the Regulations for the Supervision and Administration of Medical Devices" was published on October 31, 2017 on <http://www.sda.gov.cn/WS01/CL0050/216088.html>; and Chinese version of the "Notice Concerning Publication of China Marketed Drug Catalogue" was published on December 28, 2017 on <http://www.sda.gov.cn/WS01/CL0050/220786.html>.

⁵ News article titled "BeiGene announces closing of its initial public offering" published on globenewswire.com of NASDAQ on February 8, 2016.

⁶ News article titled "Zai Lab Limited announces pricing of U.S. initial public offering of ADSs" published on globenewswire.com of NASDAQ on September 20, 2017.