LOEB & LOEB LLP

Life Sciences

MAY 2018

New Chapter for Hong Kong Capital Market – Biotech IPO

I. Background

After much anticipation, the Hong Kong Stock Exchange (the Exchange) recently issued a new set of rules, namely Chapter 18A of the Main Board Listing Rules (the "New Rules"), together with the guidance letter HKEX-GL92-18, for companies from the emerging and innovative sectors to make their debuts on the Exchange.

Under the New Rules, effective April 30, 2018, companies primarily engaged in the research and development and commercialization of biotech products, processes or technologies (the "Biotech Company(ies)") that do not meet any of the Main Board financial eligibility tests may apply for listing so long as they satisfy the following additional conditions:

(1) The applicant must demonstrate that it is both eligible and suitable for listing as a Biotech Company.

(2) The applicant must have, at the time of listing, an initial market capitalization of at least HK$1.5 billion.

(3) The applicant must have been in operation in its current line of business for at least two financial years prior to listing, under substantially the same management.

(4) The applicant must ensure that it has available working capital to cover at least 125 percent of the group's costs (which must consist of general, administrative, operating and R&D costs) for at least 12 months from the date of publication of its listing documents.

In determining condition (1), although the Exchange has provided a list of nonexhaustive and nonbinding factors that an application should possess, there are at least two issues on which potential applicants and their sponsors should remain alert.

II. Development Beyond Concept

The first issue is in the applicant's disclosure obligations. In order to fulfill the New Rules, the applicant will have to adopt a specific approach as opposed to the traditional approach of general disclosure. First, the type of disclosure will have to be specific to biotech business. For example, in determining whether the applicant has developed at least one core product beyond the concept stage, the Exchange has laid down a two-arm approach: (1) the applicant should at least have completed Phase 1 clinical trials;[1] or (2) for applicants that conduct clinical trials that do not strictly follow the traditional classification of Phase 1 and Phase 2 trials, the applicant should at least have demonstrated an acceptable safety profile with preliminary evidence of efficacy.[2] The problem here is with the disclosure under arm (1). While a no-objection letter, also known as an NOL, issued by a regulatory authority will be a direct evidence demonstrating that the commencement of Phase 2 clinical trials by the applicant has not been objected to, safety data and results of Phase 1 clinical trials should also be disclosed to the extent that the Exchange is satisfied that the core product has developed beyond the concept stage and possesses an

This publication may constitute "Attorney Advertising" under the New York Rules of Professional Conduct and under the law of other jurisdictions.

acceptable safety profile.[3] A balance will then have to be struck between data protection and data disclosure, as excessive disclosure may lead to contravention of data confidentiality. Second, the extent of disclosure will have to be monitored and reviewed. Although regulatory authorities will review data in regulatory submissions and inspectors will conduct on-site data reviews and routine inspections, it is impossible for them to go through each and every piece of data generated. To a certain extent, this relies on whether the applicant has kept and maintained a complete, consistent and accurate record of data, which is to be reviewed by its sponsor and lawyer. Third, a skilled third party should be engaged in verifying disclosed information. This activity may pose challenges to sponsors and their lawyers with little scientific and regulatory background, as it will be difficult for them to fulfill their obligations and responsibilities in verifying the accuracy of highly technical information contained in the prospectus.

III. IP Ownership

The second issue goes to intellectual property (IP) ownership. IP, especially patents, is one of the most important assets of a biotech business. Having a strong and diversified IP portfolio may not guarantee success, but a weak and questionable one can surely cause trouble to the listing of a biotech business. The Exchange expects that an applicant owns unquestionable IP rights in order to demonstrate its eligibility and suitability to list under the New Rules, and will consider the specific facts for each case and decide whether the applicant has satisfied the relevant standards.[4] The quality and quantity of IP held by the applicant are likely to be factors that the Exchange will consider. Hence, much emphasis will be placed on risk management and valuation as supported by an IP due diligence report on the assessment of substance and validity of the applicant's IP. Also, the applicant will have to prove that it has the freedom to operate its core products but has manageable infringement risks. The underlying technology of the applicant will impose an additional layer of complexity on the process of IP due diligence.

IV. Conclusion

While biotech companies are enthusiastic about the prospects of staging an IPO under the New Rules, care must be taken to ensure that the additional conditions have been fulfilled and reviewed by professionals with adequate scientific knowledge about the complex research and development process of biotech products, ranging from small molecule drugs and biologics to medical devices and technologies. For the time being, we have to wait and see how the Exchange will handle the listing applications under the New Rules.

If you have any questions, please don't hesitate to contact Lewis Ho, +852.3923.1136 or lho@loeb.com.

---

[1] Paragraph 75 of the Consultation Conclusions on a Listing Regime for Companies from Emerging and Innovative Sectors published on April 24, 2018 (the "Consultation Conclusions").

[2] Paragraph 96 of the Consultation Conclusion.

[3] Pursuant to 18A.04(2)(f) of the New Rules, the applicant is required to disclose all material safety data relating to its core product(s), including any serious adverse events.

[4] Paragraph 114 of the Consultation Conclusion.

This alert is a publication of Loeb & Loeb and is intended to provide information on recent legal developments. This alert does not create or continue an attorney client relationship nor should it be construed as legal advice or an opinion on specific situations.

© 2018 Loeb & Loeb LLP. All rights reserved.