

Hong Kong Stock Exchange Issues New Guidance for Biotech Listings

The new guidance offers improved clarity on disclosure in the prospectus and suitability for listing of biotech companies.

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Since the implementation of the new listing regime for biotech companies under Chapter 18A of the Main Board Listing Rules (the Listing Rules) on April 30, 2018, The Stock Exchange of Hong Kong Limited (the Exchange) has offered more diversified choices for investors. Drawing from the Exchange's experience in the last two years and market feedback, the Exchange has recently released important and new guidance in relation to listing of biotech companies under Chapter 18A of the Listing Rules, which offer improved clarity on the relevant issues, including disclosure requirements and suitability for listing.

Background

As a whole, the new regime under Chapter 18A of the Listing Rules has been well received by investors, attracting their strong demand at time of IPO of biotech companies and with many biotech companies posting strong stock price performance post listing, including Alphamab and Venus Medtech, both of which Latham & Watkins recently advised on. To date, 18 pre-revenue biotech companies have been listed on the Exchange, including biotech companies that develop, manufacture and commercialize (i) therapeutics for treatment of immunological diseases; (ii) oncology biologics; (iii) vaccines; (iv) drugs and biosimilar drugs for cancers and autoimmune diseases; and (v) heart valve medical devices.

Based on its experience dealing with the listing applications of biotech companies and after taking into account market demands and comments from the Listing Committee, the Securities and Futures Commission, market practitioners and members from the biotech advisory panel, the Exchange has recently released:

- Enhanced disclosure requirements for biotech companies, set out in a new guidance letter GL107-20
- Further guidance on in-licensed or acquired products, biotech companies that develop medical devices, subscription of shares by existing shareholders, and the clawback mechanism, set out in the updated GL92-18 and GL85-16
- Guidance on disclosure regarding principal investigators, set out in the updated FAQ on the Listing Regime for Companies from Emerging and Innovative Sectors

Key Takeaways of the New Guidance:

- Under the new guidance, the Exchange focuses on the following disclosure requirements:
 - (i) Communication with regulatory authorities
 - (ii) Valuation of each round of pre-IPO investment with explanation of any material fluctuation from the immediate previous financing round
 - (iii) Details of the competitive landscape of product development and research
 - (iv) Burn rate – *i.e.*, the period of time that a biotech company can maintain its viability with existing cash balance (with and without the IPO proceeds)
- The summary section of the prospectus should be concise, precise and meaningful to enable non-sophisticated retail investors to understand scientific descriptions and the presentation of key clinical and pre-clinical data
- Flexibility for use of the listing proceeds for biotech companies that develop medical devices
- Further clarification on the categorization of “Other Biotech Product”
- Relaxation on conditions for existing shareholders participation in the IPO of a biotech company
- The Exchange’s discretion to grant clawback waivers on a case-by-case basis

1. Enhanced Disclosure Requirements

Chapter 18A of the Listing Rules sets out the disclosure requirements for the listing of pre-revenue biotech companies but such requirements are not sufficiently clear in various aspects. The new and updated guidance includes the following enhanced disclosure requirements applicable to biotech companies:

- **Summary section:** As many retail investors are attracted by biotech companies but these potential investors may not possess relevant biotech and medical science knowledge, simple or plain language should be used whenever possible when drafting the summary section of the prospectus to enable it to be accessible to the retail investors. The summary section must include, amongst other things, key disclosure of development timetable of core products and a risk factor that investors may lose all of their investments
- **Competitive landscape:** Biotech companies must disclose the competitive landscape in detail, including information on competitors’ current pipeline products, name and price of such products, and the expiration dates of potentially competing products’ key patents, if available
- **Addressable market:** Biotech companies must disclose material information on the relevant addressable market of their core products and pipeline products rather than the overall market. The disclosure must also include a comparison between biotech companies’ products and direct competing products in major areas such as technologies, indications, targeting market etc.

In the recent cases that we have advised on, the Exchange questioned whether the scope of addressable markets considered by an issuer, including sub-markets within China, or the global market, was appropriate

- **Communication with competent regulatory authorities:** Some competent regulatory authorities may adopt a one-time umbrella approval, under which, disclosure should be made as to whether any material concerns or objections have been raised regarding any of the biotech company’s completed or ongoing clinical or pre-clinical trials. A negative statement must be made that there has been no such communication

In the recent cases that we have advised on, the Exchange has requested the companies to elaborate

on their material communication with or any feedback from relevant regulators

- *Commercialized core products*: Biotech companies must disclose the breakdown of funds to support research and development (R&D) if the biotech company intends to use part of the listing proceeds to expand the indications of its core product that has been commercialized in a given market for a specified indication or launch it in another market
- *Core products and advanced pipeline candidates classified and regulated as orphan medicines and/or innovative therapies*: Biotech companies must disclose (i) the basis for drug candidates to qualify in a particular regulatory pathway, the exemptions granted by the relevant competent authorities; (ii) the commercialization plan to enter a market including a timeline of regulatory milestones; and (iii) the material terms and conditions of collaboration and the owner of the relevant IP rights and sub-licensing rights
- *Pipeline products*: Biotech companies must disclose whether pipeline products are in-licensed or internally-developed and provide material information on pre-clinical studies or clinical trials for each pipeline product, including with respect to any unfavorable results or side effects observed. If there are inherent uncertainties on such pipeline products, biotech companies must disclose any associated risk factors

Balanced presentation is a key focus in US biotech offerings, for instance an issuer cannot disclose favorable efficacy data without disclosing all relevant side effects. In our precedent Hong Kong biotech IPOs, we have also seen the Exchange focus on the procedures regarding engagement of leading academics and related professionals and details of training guidelines

- *Valuation*: Biotech companies must disclose the valuation of each round of pre-IPO financing with an explanation of material fluctuations in valuation from the immediate round of pre-IPO financing
- For US listing, the SEC is focused on “cheap-stock” and whether prior rounds of financing were issued at a lower price than they should have been, which may result in an accounting charge to the issuer. This is particularly where there have been material fluctuations in the price of prior rounds
- *Sophisticated investors*: Biotech companies must disclose material information such as sophisticated investor’s background and track record in the relevant industries
 - *Burn rate*: Biotech companies must disclose the period of time that it can maintain its viability with its existing cash balance with and without the IPO proceeds and when it expects to raise its next round of financing based on its burn rate

Burn rate is not an accounting term. We understand that this term is defined in a number of different ways, including as (i) the cash operating costs per month relating to R&D activities, and which would exclude depreciation and amortization related expenses, (ii) the adjusted average monthly net cash used in operating and investing activities and (iii) the average monthly cash used in operations plus expenditures for property, plant and equipment

- *Principal investigators*: If the principal investigator in charge of or supervising, a biotech company’s clinical trial has additional roles in the company, the prospectus should disclose those additional functions, the terms of compensation (if any) and whether such compensation may impair the integrity of the clinical trial

In the listing projects we have recently advised on, the Exchange has been focusing on whether such investigators are able to maintain independence, and also focused on contributing authorship by issuer’s employees on representative publications on product safety and efficacy

2. How to assess suitability criteria for in-licensed or acquired products?

The updated GL92-18 explains certain issues regarding how the Exchange will assess the suitability of listing of biotech companies that have in-licensed or acquired products (rather than having developed them

internally). In making this assessment, the Exchange has indicated that it will look for listing applicants to do the following:

- To demonstrate that the biotech company has engaged in R&D for a minimum of 12 months prior to listing, such company should illustrate to the Exchange how such products have progressed during the period since in-licensing or acquisition from preclinical stage to clinical stage, from one clinical stage to the next phase of clinical trial, or to approval from the competent regulatory authority to market the product
- To demonstrate that such product has developed beyond concept stage, biotech company may show the Exchange that at least one clinical trial in human subjects has been completed since the in-licensing or acquisition. If the applicant has not completed at least one clinical trial, the Exchange will evaluate why no clinical trial has been completed and whether substantive R&D work and process(es) equivalent to completion of one clinical trial on human subjects have been performed by the biotech company, so as to determine whether the product has developed beyond concept stage based on the circumstances of each biotech company

3. Expanded the scope where medical device biotech companies can use the proceeds raised

In assessing whether or not the primary reason for listing of medical device biotech companies is to raise funds for R&D to bring core products to commercialization, the Exchange will take into account business plans and the development stage of pipeline products of biotech companies that develop medical devices, such that they may allocate a portion of listing proceeds to set up production facilities to bring core products to commercialization, establish sales, marketing teams, etc., to commercialize its core products.

In the listing of Venus Medtech which we have advised on, the only medical devices biotech IPO to date, the Exchange agreed that Venus Medtech earmarked 30% of its proceeds for the commercialization of the core products, with 5% for the R&D of core products, 30% for the R&D and commercialization of non-core products, and 35% for other miscellaneous purposes.

4. Categorization of “Other Biotech Products”

The Exchange expressly pointed out that it will categorize a biotech product the same way as its competent regulatory authority does. If a biotech product is regulated as a pharmaceutical, biologic, or medical device, the biotech company cannot re-classify its products as an “Other Biotech Product” if it is unable to fulfil any of the requirements of the relevant category.

5. Subscription of shares by existing shareholders

The Exchange clarified in the updated GL92-18 that existing shareholders are allowed to participate in the IPO of a biotech company provided that the company satisfies the relevant public float requirements. The conditions set out in GL85-16 for existing shareholders to participate as cornerstone investors/placees do not apply to biotech companies (including the condition that such shareholders do not have the power to appoint directors or any other special rights). An existing shareholder holding less than 10% of shares in the biotech company may participate in the IPO as placee or cornerstone investor:

- In the case of placee, the applicant and its sponsor must confirm that no preference in allocation was given
- In the case of subscription as a cornerstone investor, the applicant and its sponsor must confirm that no preference was given to the existing shareholder other than the preferential treatment of assured entitlement at the IPO price and the terms must be substantially the same as for other cornerstone

investors

Core connected persons, including shareholders holding 10% or more of shares, must subscribe for shares in the IPO as a cornerstone investor and must seek for a waiver from the Exchange demonstrating that it is a genuine, independent and public investor.

Given the complexity and technicalities of the products which biotech companies are developing, sophisticated investors are best placed to understand their business, particularly those existing shareholders who have spent time to understand the underlying science and possess the relevant expertise in investing in biotech companies. Therefore, it is sensible to allow existing shareholders to participate in the IPO given the nature and the likely significant funding needs of biotech companies. This is very commonly seen in US IPOs. Separately, it is also beneficial for biotech companies to place more shares to institutional investors who are more informed and also may be more willing to hold their investments for a longer period of time to allow for the products to proceed to commercialization.

6. Clawback mechanism

As biotech companies potentially carry additional risks to investors, waiver from strict compliance with clawback mechanism under Practice Note 18 will be considered on a case-by-case basis and compelling reasons are required for such waiver applications.

In many recent biotech IPOs, we have seen significant retail interest, in many instances resulting in the public offer tranche being significantly oversubscribed by hundreds of times, resulting in the clawback mechanism being triggered and decreasing by 50% of the offer shares available for institutional investors. As mentioned above, it is beneficial for the long-term development of biotech companies if they have sophisticated institutional investors within its shareholder base who best understand the company's products and prospects, and who would also be most able to participate in future rounds of fund raising as the products reach their next stage of development. Therefore, whilst the typical biotech listing candidate will not satisfy the market capitalization requirement for the standard clawback waiver, it would make commercial sense to allow for a flexible clawback mechanism for biotech IPOs. The guidance letter has not set out the parameters for how the Exchange might exercise its discretion. However, it appears that the Exchange will be willing to consider alternative arrangements for future biotech IPOs.

7. Conclusion

Through the implementation of the new guidance, we see the Exchange laying out a practical disclosure road map for biotech companies that will assist them in providing the type and level of disclosure that the Exchange views as necessary to fully inform investors participating in the IPOs of rapidly growing biotech companies on the Exchange. The level of guidance provided by the Exchange is substantially more extensive than that provided by regulatory authorities in the more mature U.S. biotech IPO market. The overall focus of the new guidance on the description of the drug development process, its underlying science, the relevant regulatory framework in which it takes place, and the commercial markets that drugs in development may address, is expected to result in a more robust level of disclosure and a greater level of consistency between the substantive disclosures made by biotech companies seeking listing on the Exchange and their peers listing on the U.S. markets. In addition to providing a better level of protection to investors considering investing in biotech company IPOs on the Exchange, we also anticipate that the growing similarity between this disclosure and that which is typical in the U.S. market will increase the confidence of international investors in investing on biotech company IPOs on the Exchange, which vigorously drive the growth of this market.

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