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HKEX's Updated Guidance Materials for Biotech Companies

On 29 April 2020, the Stock Exchange of Hong Kong Limited (the "Exchange") published new and updated guidance materials for pre-revenue biotech companies, providing prospective issuers and the market with more clarity on the requirements for listing and the related disclosures.

Highlights

- Enhanced disclosures to help retail investors better understand the biotech company[1], its core products[2] and the risks associated with their investment
- Additional guidance for the flexible use of IPO proceeds for biotech companies at a later stage of development
- Additional guidance on special cases identified by the Exchange over the past two years

Background

Two years ago, the Exchange introduced a new listing regime, which included a new chapter enabling the listing of pre-revenue biotech companies on the Exchange's Main Board ("Chapter 18A"). Since then, a total of 18 pre-revenue biotech companies have listed in Hong Kong, raising a total of HKD 44.3 billion, accounting for 7.4 percent of IPO funds raised in Hong Kong during that period. The new listing regime has improved the vibrancy and diversity of the Hong Kong capital markets and has helped cultivate a local ecosystem for biotech investments, making Hong Kong the world's second-largest biotech fundraising hub.

During this time, the Exchange has seen heightened interest from global institutions and the retail market for these pre-revenue biotech companies, which led to the development and publication of these new and updated guidance materials.

Appendix I summarises the new disclosure recommendations in Guidance Letter 107-20, while **Appendix II** summarises the updates to existing guidance materials. The key additions and amendments are discussed below.

Enhanced disclosures for retail investors

Pre-revenue biotech companies' listings initially targeted institutional investors with the knowledge and experience needed to understand their core product. However, as time went on, these companies gained in popularity, attracting a significant number of retail investors to apply for their IPO shares as well. In August 2018, the first Chapter 18A listing in August 2018 had only about 9,000 investors applying for its shares; whereas the latest Chapter 18A listing on 22 May 2020 had well over 190,000 investors applying, with the majority being retail investors.

In order to help retail investors better understand the biotech company, its core products and the risks associated with their investment, the Exchange has added the following recommendations:

- streamline the summary section with simple/plain language, a balanced timetable of core product development and additional risk factor disclosures;
- provide a comparison between the core products and pipeline products to current available competitors in the market;

[1] A company primarily engaged in the research and development, application and commercialisation of biotech products.
[2] A biotech product that is required by applicable laws, rules or regulations to be evaluated and approved by a competent authority based on data derived from clinical trials on human subjects before it could be marketed and sold in the market regulated by that competent authority which forms the basis of a biotech company's listing application under Chapter 18A.

- address market size of core products and other pipeline products, rather than the overall market size;
- include clear disclosures on core products' origins, such as whether it is in-licensed or internally developed;
- disclose valuations on each round of pre-IPO investments and explain any material fluctuations, with reference to key product development and business milestones; and
- add a new "burn rate" disclosure, which show the amount of time biotech company can maintain its viability with existing cash balances, and when they expect to raise their next round of financing.

Greater flexibility for use of IPO proceeds

IPO proceeds raised through Chapter 18A should primarily be used for funding research and development of soon-to-be commercialised Core Products. With the increased diversity of biotech companies seeking to list in Hong Kong, it has become necessary to account for the funding needs of biotech companies at later stages of development with products ready to be commercialized.

In order to allow for greater flexibility in a biotech company's use of IPO proceeds, the Exchange has updated the following guidance:

- for an already commercialised core product, a significant portion of the listing proceeds may be used to expand the core product's market or usage, as long as it is spent on further research and development in connection with clinical trials by a competent authority[3]. Additional disclosures will be required, detailing the breakdown of resources needed and the importance of the IPO proceeds in advancing the core product;
- for a medical devices company, a portion of the listing proceeds may be re-allocated (depending on the facts and circumstances) to setting up production facilities for the manufacture of its core products or for establishing sales, marketing and medical teams for commercialisation.

Additional guidance on special cases

The biopharmaceutical industry focuses on novel drug discovery and clinical research aimed at treating diseases and medical conditions. Given the scientific nature and novelty of the technologies involved, some companies found it challenging to determine if their products met the requirements of Chapter 18A. To address this issue, the Exchange updated its guidance and provided clarifications as follows:

- for a biotech company with in-licensed or acquired core products, the biotech company must demonstrate the progression of their core product's research and development (through "phase-crossing", such as from pre-clinical stage to clinical stage, one clinical stage to the next, or obtaining marketing approval from a competent authority), for at least 12 months prior to listing. There should also be at least one clinical trial on human subjects regulated by a relevant competent authority or an explanation as to why no such clinical trial was completed;
- for core products that do not fall within the three main categories (pharmaceutical, biologics or medical devices), its categorisation should follow the competent authority's categorisation, and additional considerations will be made when assessing the core products' development progress;
- for core products classified and regulated as orphan medicines and/or innovative therapies, further disclosures should be made as to the basis of this classification, the commercialisation plan, as well as the calibre and experience of participating research institutions.

Conclusion

Since the launch of the new listing regime two years ago, a wide range of biotech companies have chosen to list in Hong Kong, which has in turn drawn a significant number of institutional and retail investors to Hong Kong's biotech sector. We have been encouraged by the healthy interest shown in this biotech ecosystem, and believe in the continued growth of the sector for years to come.

These new and updated guidance materials are a natural development towards refining the listing procedures, achieving a balance between increased flexibility for biotech companies and upholding investor protection. We believe the Exchange's continued review and revisions to Chapter 18A and its guidance will be essential in promoting the sustained growth of diversity in Hong Kong's biotech ecosystem while boosting its appeal for investors.

[3] A national or supranational organisation recognised by the Exchange for the approval of biotech products, such as the US Food and Drug Administration, China's National Medical Products Administration, and the European Medicines Agency.

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Appendix I – Overview of New Disclosure Recommendations in GL107-20 (April 2020)

Disclosure Recommendations	
The following disclosures for Chapter 18A listings are recommended, where applicable:	
1.	**Summary section** • use simple/plain language when possible, without compromising scientific accuracy • provide full terms and explain them using plain language when a key abbreviation first appears • use meaningful headings and sub-headings to highlight the content • cross-reference to the business section for highly technical content or detailed descriptions • disclose development timetable of core products in a fair and balanced manner, avoiding boosterism • disclose a risk factor as to how the failure of R&D may have a material adverse impact on the biotech company and could lead to potential investors losing their investments
2.	**Competitive landscape and addressable market** • disclose competitive landscape of core products and other key pipeline products in the targeted market of commercialisation, including: a) current available competitors to the core product, including its price and insurance reimbursement coverage; b) current pipeline products the core product would potentially compete with; c) expiring dates of intellectual property rights of competitors to the core product • disclose material information on the relevant addressable market of the core product and other key pipeline products, rather than the general, overall market • provide a comparison between the core product to its competitors in major areas such as technology, indication, target market, etc
3.	**Communication with competent authorities** • disclose all meaningful data with competent authorities (such as the US Food and Drug Administration, China's National Medical Products Administration, and the European Medicines Agency), including whether material concerns or objections were raised towards the completed or ongoing clinical trials or a negative statement if there is no communication between the biotech company and the relevant competent authority
4.	**Commercialised core products** • if a portion of the listing proceeds will be used to expand an already commercialised core product's specified indication or market, disclose: a) a breakdown of the funds to support further R&D (such as resources required for further studies); b) the importance of the funds in advancing the core product
5.	**Core products and advanced pipeline candidates classified and regulated as orphan medicines and/or innovative therapies** • disclose the basis for drug candidates to qualify in a particular regulatory pathway, the exemptions granted by the relevant competent authorities and the advantages for drug products admitted, reviewed and potentially approved under such designation • disclose the drug product's commercialisation plan and/or market strategy, including a timeline of the next regulatory milestone leading up to the filing of new drug applications, and key differences between the primary and other markets • define the calibre and experience of participating research institutions, including who will own the intellectual property rights, patent and sub-licensing rights
6.	**Pipeline products** • specify the origins (i.e. in-licensing or internally-developed) and jurisdiction rights pertaining to the biotech products • highlight pipeline products that are strategically or commercially critical to the biotech company • ensure a balanced disclosure of material information on relevant studies, irrespective of whether the results are favourable or not • disclose development progress (including how long it has been under development and future plans) for each pipeline product and summarise such information in the pipeline table • exclude disclosure for products at a very early preclinical stage with no meaningful preclinical research data or if the data is deemed scientifically sensitive
7.	**Valuation** • disclose valuation of each round of pre-IPO investments and explain material fluctuations in valuations with reference to key development of the products, business milestones and competitive advantages
8.	**Sophisticated investors** • disclose material information on sophisticated investors (such as fund's background and track record)

Appendix I – Overview of New Disclosure Recommendations in GL107-20 (April 2020) (continued)

Disclosure Recommendations	
The following disclosures for Chapter 18A listings are recommended, where applicable:	
9.	**Net liabilities*** • disclose in the summary and risk factors section if the company incurred net liabilities during the track record period as a result of significant fair value change of convertible financial instruments and that they will be fully converted upon listing, therefore turning into a net assets position
10.	**Burn rate** • disclose in the summary and other relevant sections: a) a reasonable period of time, with basis, that a biotech company can maintain its viability with existing cash balance with and without the IPO proceeds; b) when the biotech company expects to raise its next round of financing based on its burn rate
11.	**Contractual arrangements** • Biotech companies adopting contractual arrangements should refer to LD43-3 for further guidance

***Applicable to all listing applicants.

Appendix II – Overview of Updates to Existing Guidance Materials

Additional guidance
GL92-18 (Guidance on suitability for listing of Biotech Companies)
Additional guidance for biotech companies with in-licensed or acquired core products • to demonstrate engagement in R&D of its in-licensed or acquired core products for at least 12 months prior to listing, the biotech company must be able to demonstrate its R&D progress since the in-licensing/acquisition, which might include: a) progress from preclinical stage to clinical stage; b) progress from one clinical phase to the next phase of clinical trial; c) obtaining regulatory approval from the competent authority to market the core product • at least one clinical trial (on human subjects) regulated by the relevant competent authority should be completed since the in-licensing/acquisition. If not, the reason for the absence of a clinical trial will be evaluated, and whether substantive R&D work and processes equivalent to one clinical trial on human subjects have been performed by the biotech company. Any administrative process will not be considered as substantive R&D work
Additional guidance for biotech companies with commercialised products • in the case of a core product which has already been commercialised in a given market for specified indications, if the biotech company intends to apply a significant portion of the listing proceeds to expand the core product's indication or market, the funds should be used for further R&D expended on the core product in connection with clinical trials required by the competent authority for the expansion
Additional guidance for medical device companies • for biotech companies that develop medical devices which have a short development cycle, the Exchange may consider the biotech companies' business plan and pipeline development stage such that a portion of the listing proceeds could be allocated to setting up production facilities for the manufacture of its core products or establishing sales, marketing and medical teams for commercialisation
Additional guidance for 'other biotech products' • for biotech products that do not fall within the three main categories (pharmaceutical, biologics, or medical devices), a biotech company cannot re-classify such products as 'other biotech product' simply because it is unable to fulfil any of the requirements for the three main categories. The Exchange will follow the categorisation of the biotech product as categorised by the relevant competent authority • for biotech products that do not fall within the three main categories, there may be no regulatory regime setting out external milestones or an objective framework to assess the products' development progress, market and clinical relevance. In that case, the following will be considered: a) the number, selection process and diversity of the test sampling population, and availability of data from pre-clinical and clinical trials; b) time frame and impediments to commercialisation; c) whether the pre-clinical and clinical results have been published in medical/scientific journals, and the impact factor of the journals; d) relevant guidelines, views and aspects of a comparable framework or objective indicator of 'other biotech products' published by competent authorities
Additional guidance for subscription of shares by existing shareholders • an existing shareholder holding less than 10 percent of shares in the biotech company may subscribe to IPO shares as a cornerstone investor or a place, whereas those with more than 10 percent of shares may only participate as a cornerstone investor • an existing shareholder with contractual anti-dilution rights may exercise such rights and subscribe to shares in the IPO, which aligns with current guidance for special rights of pre-IPO investors in IPOs outside of Chapter 18A. • where allocations will be made to core connected persons, the biotech company must apply for a waiver for Rule 9.09 (dealing in securities to be listed by a core connected person)
Additional guidance on the clawback mechanism • where biotech companies wish to propose any modification to the minimum public subscription requirement under Practice Note 18 of the Listing Rules, they must provide compelling reasons for such modification to the Exchange, which will be considered on a case-by-case basis

Appendix II – Overview of Additions to Existing Guidance Materials (continued)

Additional Guidance
GL85-16 (Guidance on placing to connected clients, and existing shareholders or their close associates)
Clarification on existing shareholders conditions not applying to biotech companies • for the avoidance of doubt, the existing shareholder conditions in GL85-16 do not apply to biotech companies, due to the significant funding needs of biotech companies and the importance of shareholder funding • existing shareholders can participate in the IPO of a biotech company provided that the applicant complies with other Listing Rules in relation to shares held by the public • see additional guidance for subscription of shares by existing shareholders in GL92-18
GL86-16 (Guidance on producing simplified listing documents relating to equity securities for new applications)
Disclosure requirement on change in financial position due to convertible financial instruments • see disclosure recommendation for net liabilities in GL107-20 in Appendix I
FAQ on Listing Regime for Companies from Emerging and Innovative Sectors
• two FAQs were removed and incorporated into GL92-18 • see additional guidance for 'other biotech products' and subscription of shares by existing shareholders