Hong Kong Stock Exchange Issues Additional Guidance on Pre-Revenue Biotech Listings

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Introduction

April 2020 marks the second anniversary of the new pre-revenue biotech listing regime under Chapter 18A of the Listing Rules that has helped a total of 16 companies to list on the HKEx so far. The HKEx has recently made some significant improvements to the rules to provide further clarification and flexibility to the market. This note summarizes key changes to the Chapter 18A related guidance letters issued by the HKEx and shares our reading of what these changes mean for upcoming listing applicants.

What's new?

- The HKEx has issued an entirely new guidance letter focused on prospectus disclosure of biotech companies (GL107-20).
- Major updates to the existing guidance letter on Suitability for Listing of Biotech Companies (GL92-18), partly to incorporate certain existing interpretations under frequently asked questions (FAQs) and also to add new clarifications relating to in-licensed products, use of proceeds and clawback waiver.
- Additional clarification under the guidance letter on placing to connected clients, and existing shareholders or their close associates (GL85-16) for existing shareholders of biotech companies to participate in the HKIPO.

The details

- New Disclosure Requirements – in addition to the points in the main text of Chapter 18A, the HKEx has created an entirely new guidance letter (GL107-20) setting out further disclosure requirements. Overall, the guidance letter reflects and memorializes HKEx comments during its vetting of recent Chapter 18A listing applications. The disclosure requirements include the following which is a non-exhaustive list:
  - Streamlined summary section with balanced timetable of core product development and risk factor disclosure
  - Competitive landscape of core products in targeted markets, with details on competitors' pipeline products, name, price and reimbursement coverage, as well as expiration dates of competing products' key patents, as applicable and available
  - Addressable market size of core products and other key pipeline products rather than overall market size
  - All meaningful communications with the National Medical Products Administration in China or other competent authorities or a negative statement if there is no such communication with the relevant competent authority
  - Where a core product has been commercialized in one specific market and the listing applicant proposes to use the IPO proceeds to expand such core products to other

indications or markets, additional disclosure on breakdown of funds to support R&D and their importance in advancing such core products

- Regulatory strategy, including timeline of next regulatory milestone and qualification in a particular regulatory pathway
- Material terms and conditions of collaboration, including intellectual property right ownership

  DPW commentary: this will also typically include key commercial terms such as details of milestone and royalty payments. Biotech companies are minded to manage the process of obtaining disclosure consent from their collaborating partners
- Clear disclosure on product origins (i.e. whether it is in-licensed or internally developed)
- Highlight pipeline product that is strategically or commercially critical, and where applicable, a biotech company's intention to apply a significant portion of IPO proceeds to such product even if it is a non-core product
- Valuation of each round of pre-IPO investments and explanation of material valuation fluctuations
- New "burn rate" disclosure on the period of time a biotech company can maintain its viability using existing cash balance without IPO proceeds, and when the biotech company expects to raise its next round of financing based on its burn rate

  DPW commentary: there is no prescriptive minimum burn rate period and biotech companies only need 125% working capital for the next 12 months from prospectus date with IPO proceeds. However, faster burn rate may lead to greater regulatory scrutiny and more prominent risk disclosure. As burn rate disclosure is forward-looking in nature, such disclosure shall be accompanied by key assumptions underlying the burn rate calculation to avoid misleading investors

- Clear guidance for marketed Core Products
  - Where a product is already beyond concept stage and commercialized in a given market, it is still possible to classify such product as a Core Product for the purpose of a HKEx listing, but there needs to be R&D expenses and work done in further clinical trials to expand indications of the product or launch in a new regulated market
- Clearer guidance for in-licensed Core Products

  DPW commentary: historically, the requirement for an in-licensed core product is simply R&D for 12 months before listing and demonstration of R&D progress since in-licensing. It has been unclear as to what constitutes "R&D progress" and the revised guidance letter provides greater visibility in a non-exhaustive fashion:
  - R&D progress means "phase-crossing" progress, i.e., from pre-clinical stage to clinical stage, from one clinical phase to the next, or obtaining marketing approval from a competent authority
  - At least one human clinical trial needs to be completed since in-licensing or a biotech company needs to demonstrate that the substantive (non-administrative) R&D work done by itself is equivalent to the completion of one clinical trial

    DPW commentary: this on the one hand clarifies that a biotech company must complete one clinical trial regulated by a competent authority after in-licensing, and on the other hand gives flexibility for the biotech company to demonstrate R&D work equivalent to the completion of one clinical trial, i.e., progress in an ongoing Phase II or Phase III trial may be equivalent to the completion of a Phase I trial

- Greater flexibility for use of proceeds
  - Primary reason for listing now includes commercialization and setting up production facilities, instead of clinical R&D only

    DPW commentary: this appears to be limited only to medical device companies. For biotech companies that have either small molecule or biologics core products, the primary reason for listing remains to be raising funds for R&D of its core products
- Clarification on other Biotech Products
  - The HKEx will categorize a biotech product as it is categorized by its competent authority. If a biotech product is regulated as a pharmaceutical, biologics or medical device, a biotech company cannot reclassify such product as "Other Biotech Product" under the HKEx biotech regime because it is unable to fulfill the requirements applicable to a pharmaceutical, biologics or medical device under Chapter 18A and GL92-18
- Participation by existing shareholders

  DPW commentary: participation by existing shareholders in biotech listings has been a useful feature in the past transactions, although there has been confusion about what kind of investors can be anchor or cornerstone investors and whether certain investors with board seats or holding more than 10% equity interest can still apply. These have all been formally clarified:
  - Subject to no preferential treatment confirmations from the biotech company and the sponsors, existing shareholders with less than 10% equity interest can choose to become either an anchor investor or a cornerstone investor; however, those holding more than 10% would need to be a cornerstone investor, subject to obtaining an additional customary waiver from the HKEx
  - Certain conditions under the existing guidance letter on confirmation of no board seat and not being a connected person no longer apply
  - It is our reading that the sponsors would still need to formally apply to the HKEx for existing shareholders to participate in the IPO
- Clawback

  DPW commentary: in recent biotech IPOs (such as Venus Medtech, InnoCare and Akeso), it has become common for the retail tranche to be significantly oversubscribed, hence triggering the full clawback mechanism to enable Hong Kong retail investors to be given 50% of the entire global offering. The HKEx has customarily granted clawback waivers to reduce the level of retail participation where the offering size is sizeable, normally around HK$5 billion. Most biotech listings so far are below that threshold, hence not able to qualify for such waiver

  It now appears that the HKEx may accept clawback modification for biotech listings on a case-by-case basis with compelling reasons. Given the guidance letter has omitted the key criterion of an offering size, it is likely that the HKEx is technically reserving discretion but prepared to grant a clawback waiver for biotech listing applicants

HKEx biotech regime at a glance

- Who can apply – pre-revenue biotech companies (small molecule, biologics, devices and others)
- Who cannot apply – those that have enough profit, revenue, cash flow that can meet the traditional Chapter 8 eligibility tests
- Key numbers:

- For self-developed drug candidates, at least **one core product** beyond concept stage
- For in-licensed drug candidates, completion of at least **one human trial** or equivalent by the listing applicant, even if the drug candidates are developed beyond concept stage in other regulated market(s) by its licensing partner(s)
- At least 12 months of R&D for core product(s) before IPO
- Market Capitalization of at least **HK$1.5 billion**
- Working capital covers at least **125%** of costs for a period of **12 months** from date of prospectus, including IPO proceeds
- **Highest percentage** of IPO proceeds need to be dedicated to R&D and commercialization of core product
- Meaningful investment from "sophisticated investor" at least **six months** before date of IPO
- Existing shareholders may participate in the IPO but those holding more than **10%** must be a cornerstone investor
- In addition to the usual **25% public float** requirement, biotech companies must have at least **HK$375 million** of market capitalization in public hands, excluding shares held by cornerstone investors and shares subscribed by existing shareholders

If you have any questions regarding the matters covered in this publication, please contact any of the lawyers listed below or your usual Davis Polk contact.

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