Davis Polk

Listing Pre-Revenue Biotech Companies in Hong Kong

What You Need to Know

Since April 2018, the Hong Kong Stock Exchange has had a regime for listing biotech companies that have yet to record any revenue, which is an important first step towards opening up the Hong Kong market to companies at the pre-revenue stage that are of good quality but are not yet able to comply with the traditional profit record or large capitalisation and revenue record listing criteria. In the two years following the launch of this regime, 16 pre-revenue biotech companies were listed, raising a total of HK$39.7 billion.

What company may qualify?

- Has minimum expected market cap of HK$1.5b
- Meets enhanced working capital requirement (125% of requirement for 12 months following date of prospectus)
- Has two years' record of operations in the current business under substantially the same management
- Is able to demonstrate that it is both eligible and suitable as:
  - Having at least one core product beyond the concept stage (measured against development milestones specified by the Stock Exchange in the relevant Guidance Letter)
  - Being primarily engaged in research and development ("R&D") for the core product(s) for at least 12 months
  - Having, as primary reason(s) for listing, the raising of funds for R&D for the core product(s), or (for companies that develop medical devices with a short development cycle) setting up production facilities to bring such product(s) to commercialisation
  - Having a portfolio of registered patents, patent applications and/or intellectual property in relation to the core products
  - If engaged in R&D of pharmaceutical (small molecule drugs) products or biologic products, having a pipeline of those potential products

Guidance Letter HKEX-GL92-18 provides a number of tests for determining whether a product has developed beyond the concept stage. These vary according to the type of product – whether it is a pharmaceutical / small molecule drug, a biologic / biosimilar product or a medical (including diagnostic) device. Products that do not fall within these categories will be examined on a case-by-case basis.

An applicant is required to be primarily engaged in R&D for the core product(s) for at least 12 months. For companies that have in-licensed or acquired a core product, the Stock Exchange expects the applicant to demonstrate some R&D progress since the in-licensing or acquisition. 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 the substantial R&D work done by the applicant must be equivalent to the completion of one clinical trial.

Must there be external validation of the business?

- The applicant must have previously received meaningful third-party investment from at least one sophisticated investor (including financial institutions) at least six months before listing
- The investor must remain in place at the time of listing

Guidance Letter HKEX-GL92-18 provides guidance on the concept of meaningful third-party investment from a sophisticated investor. Whether an investment is meaningful will be determined by reference to the nature of the investment, the amount invested, the size of the stake taken up and the timing of the investment.

The sophistication of an investor will be examined by reference to factors such as net assets or assets under management, relevant investment experience, and the investor's knowledge and expertise in the relevant field.

Example:

The Stock Exchange may consider as sophisticated investors: (a) a dedicated healthcare or biotech fund or an established fund with a department that specialises or focuses on investment in the biopharmaceutical sector; (b) a major pharmaceutical / healthcare company; (c) a venture capital fund of a major pharmaceutical / healthcare company; and (d) an investor, investment fund or financial institutional with minimum assets under management of HK$1b.

Example:

The Stock Exchange may consider as meaningful investment:

Market cap of listing applicant	Percentage invested in total issued share capital
HK$1.5b – 3b	≥5%
HK$3b – 8b	≥3%
>HK$8b	≥1%

Are these the only requirements?

- Even if a company complies with all the express requirements of the rules and guidelines, there is no guarantee that its listing application will be approved. The Stock Exchange has reserved a significant amount of discretion in screening listing applicants. The factors set out above are neither exhaustive nor binding, and the Stock Exchange may take into account other relevant circumstances in assessing the listing suitability of the company.

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What must the company put in the prospectus?

- The company will be required to make enhanced disclosures in its prospectus, covering a number of specific items including but not limited to:
  - The company's strategic objectives
  - Details of each core product including regulatory approvals required or obtained, communications with regulators, stage of research, safety data, market opportunities, patents, rights with respect to in-licensing arrangements, etc.
  - Details of the company's R&D experience
  - Details of relevant experience of the directors and senior management
  - Salient terms of service agreements with key management and technical staff, and measures in place to retain such persons in the company's employment
  - Details of legal claims and proceedings with impact on the R&D of a core product
  - Specific risks, general risks and dependencies
  - Estimate of various operating cost items
  - Competitive landscape of core products in target markets and addressable (as opposed to overall) market size of core products
  - All meaningful communications with the National Medical Products Administration in China or other competent authorities
  - Material terms and conditions of collaboration (including IP right ownership)
  - Product origins (whether in-licensed or internally developed)
  - Valuation of each round of pre-IPO investments and explanation of fluctuations
  - "Burn rate" (i.e. the period of time a biotech company can maintain its viability using existing balance without IPO proceeds)

Enhanced disclosure requirements will apply to the prospectuses of pre-revenue biotech listing applicants.

Can existing shareholders and cornerstone investors take part in the IPO?

- Provided that no preferential treatment has been given, existing shareholders with less than 10% equity interest in the applicant can participate in the IPO as either an anchor investor or a cornerstone investor. However, an existing shareholder who holds 10% or more can participate only as cornerstone investors, subject to obtaining the customary waiver from the Stock Exchange

- But note the public float requirements for pre-revenue biotech companies:
  - Besides complying with the normal public float requirement (25% except for certain large capitalisation companies), a portion of the total number of the applicant's issued shares with a market cap of at least HK$375m must be held by the public at the time of listing
  - Any shares subscribed by cornerstone investors or existing shareholders at the time of listing will not count as being held by the public for this purpose

Where, in a biotech listing, the retail tranche is significantly oversubscribed, hence triggering the full clawback mechanism (to enable Hong Kong retail investors to be given 50% of the entire global offering), there is currently some uncertainty as to whether a clawback waiver will be granted along the same lines as other types of listings (i.e. based on an offer size of around HK$5b). It now appears that the Stock Exchange 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 Stock Exchange is technically reserving discretion but prepared to grant a clawback waiver for biotech listing applicants.

At least a market cap of

HK$375m

must be in public hands at listing

What continuing obligations apply?

- A number of post-listing periodic disclosures in the interim and annual reports regarding R&D activities will be required
- Companies that do not have sufficient operations to justify a listing may be suspended or delisted, subject to the Stock Exchange's discretion to grant a 12-month grace period for recompliance
- There will be restrictions on fundamental changes to the business post-listing (including through acquisitions, disposals or other transactions)
- Biotech companies listed under the new regime will have a marker "B" for the stock name
- The post-listing requirements may be waived upon application, if the listed biotech company is able to comply with the Listing Rule 8.05 financial eligibility requirement (i.e. it is no longer a pre-revenue company that can only be listed under the new regime, but can meet the general listing eligibility requirements)

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