Corporate Finance

# HKEX introduced changes to guidance materials for biotech companies

## Introduction

The Stock Exchange of Hong Kong Limited (the "**Stock Exchange**") recently introduced several changes to the guidance materials for biotech companies that seek to list under Chapter 18A of the Rules Governing the Listing of Securities on the Stock Exchange (the "**Listing Rules**"). The new guidance materials intend to clarify the requirements for listing and disclosures in prospectus of biotech companies. The said changes were published in one new and two updated guidance letters (collectively, the "**Guidance Letters**"), as well as one set of updated frequently-asked questions ("**FAQ**").

## New Guidance Letter on disclosure in listing documents

Prospectus Disclosure Requirements

The new Guidance Letter HKEX-GL107-20 ("**GL107-20**") provided a comprehensive guidance on enhanced disclosure where biotech companies should consider and include in their listing documents. GL107-20 sets out the recommended disclosure requirements in relation to their biotech products and the communications with relevant authorities (the "**Relevant Competent Authority**") which are responsible for evaluating and approving their core biotech products (the "**Core Products**").

## Updated Guidance Letter on suitability for listing

Guidance on Suitability for Listing of Biotech Companies

The Stock Exchange updated Guidance Letter HKEX-GL92-18 ("**GL92-18**") to provide guidance on suitability for listing of biotech companies. A biotech company that does not meet the financial eligibility tests under Rule 8.05 of the Listing Rules may be allowed to list under Chapter 18A of the Listing Rules if it can demonstrate, among other things:

1. it has developed at least one Core Product beyond the concept stage;
2. it has been primarily engaged in the research and development ("**R&D**") for the purposes of developing its Core Product(s);
3. it has engaged in R&D of its Core Product(s) for a minimum of 12 months prior to listing;
4. it has as its primary reason for listing and raising funds for R&D to bring its Core Product(s) to commercialisation; and
5. it must have registered patent(s), patent application(s) and/or intellectual property in relation to its Core Products.

Major changes in GL92-18 have been summarised as follows:

Core Product beyond the concept stage

In relation to (1) above, the Stock Exchange would consider a Core Product to have been developed beyond the concept stage if it has met the developmental milestones specified for the relevant type of product. For example, for an in-licensed or acquired Core Product, the biotech company is expected to complete at least one clinical trial regulated by the Relevant Competent Authority on human subjects since the in-licensing or acquisition.

R&D of Core Products

The Stock Exchange sets out a list of non-exhaustive examples of how a biotech company could satisfy (3) above. For instance, for a Core Product which is in-licensed or acquired from third parties, it should demonstrate R&D progress since the in-licensing or acquisition, for instance, such product (1) progressed from preclinical stage to clinical stage, (2) progressed from one clinical phase to the next phase of clinical trial, or (3) obtained regulatory approval from the Relevant Competent Authority to market the Core Product. For a Core Product which has been commercialised in a given market for specified indication(s) and where the biotech company intends to apply a portion of the listing proceeds to, for example, (1) expand the indications of the commercialised biotech product, or (2) launch it in another market, the Stock Exchange would expect the company to spend further R&D on the Core Product in relation to the clinical trials required by the Relevant Competent Authority to either bring the Core Product for (1) a new indication; or (2) commercialisation in a new regulated market.

Use of Proceeds

In relation to (4) above, for biotech companies that develop medical devices with a short development cycle, after taking into account of their business plan and development stage of their products, they may allocate a portion of listing proceeds to set up production facilities for the manufacturing of Core Product(s) to bring it to commercialisation, and establish teams to commercialise its Core Product(s).

Patent or Trademarks

In relation to (5) above, the biotech company shall disclose in its prospectus details of any patent(s) granted and applied for in relation to the Core Product(s), unless the Stock Exchange is satisfied that such disclosure would require the disclosure of highly sensitive commercial information.

“Other Biotech Products” category

GL92-18 also sets out the factors which the Stock Exchange will consider for a biotech product to fall under “Other Biotech Products” category, which were previously set out in FQA No. 035-2018 issued by the Stock Exchange.

Clawback mechanism

The Stock Exchange considered that biotech companies potentially carry additional risks to retail investors. Therefore, if a biotech company wishes to modify the minimum public subscription requirement under Practice Note 18 to the Listing Rules in its proposed listing, the Stock Exchange will then consider whether to modify such requirement on a case-by-case basis if compelling reasons are furnished.

## Guidance Letter HKEX-GL85-16

Subscription of shares by existing shareholders

The Stock Exchange clarified that the "Existing Shareholders Conditions" in Guidance Letter HKEX-GL85-16 ("**GL85-16**") do not apply to biotech companies, and provided guidance on circumstances under which an existing shareholder of a biotech company could subscribe for additional shares in the company's proposed listing (which were previously set out in FAQ No. 038-2018 issued by the Stock Exchange). For instance, an existing shareholder holding less than 10% equity interests in a biotech company may subscribe for shares as cornerstone investor or placee subject to his confirmation that (in the case of subscription as a placee) no preferential treatment was given to him, and an existing shareholder holding 10% or more equity interests may subscribe for shares in the IPO as cornerstone investor, provided that the public float requirements under Rules 8.08 and 18A.07 of the Listing Rules have been complied with.

## FAQ

In addition to GL107-20, GL92-18 and GL85-16, the Stock Exchange amended the FAQ on Listing Regime for Companies from Emerging and Innovative Sectors, and in particular, clarified what material information shall be disclosed in the prospectus regarding a principal investigator ("**PI**") who is in charge of a biotech company's clinical trial, namely, if such PI has additional roles in a biotech company, such as acting as a member of scientific advisory panel, and receives compensation for such roles, particulars disclosures shall be included in the prospectus.

For enquiries, please feel free to contact us at:

E: cc@onc.hk
W: www.onc.hk
T: (852) 2810 1212
F: (852) 2804 6311

19th Floor, Three Exchange Square, 8 Connaught Place, Central, Hong Kong