NEW GUIDANCE FOR BIOTECH COMPANIES
HKEX-GL92-18
AGENDA

1. Listing Rules/Guidance Materials of Biotech Chapter
2. Rationale behind updated and new Guidance Materials
3. Key updates in GL92-18
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Listing Rules/Guidance Materials of Biotech Chapter

- Chapter 18A
  - conditions for listing
  - contents of listing documents
  - continuing obligations

- Guidance Letter (GL92-18)
  - supplements suitability for listing

- Guidance Letter (GL107-20)
  - supplements disclosure in listing documents
AGENDA

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Rationale behind updated and new Guidance Materials

• Address the evolving complexity of the biotech industry

• Common issues encountered by Biotech Companies since the introduction of Chapter 18A

• Revised GL92-18 and introduced GL107-20
  - provide more clarity on requirements for listing and the required disclosure

  - facilitate Biotech Companies and market practitioners in the listing process and preparation of listing documents
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In-licensed or acquired core Product

- Biotech Company must demonstrate R&D progress such as:
  - progressed from pre-clinical stage to clinical stage
  - progressed from one to next clinical phase
  - obtained regulatory approval
Update #2 – R&D of commercialised Core Product (paragraph 3.2(c)(ii))

• Commercialised Core Product
  - Biotech Company applies a portion of listing proceeds to:
    - expand new indications
    - launch in new regulated market
Update #3 – Primary reason for listing (paragraph 3.2(d))

• For medical devices issuers with short development cycle:
  - depending on the business plan and development stage of pipeline products, may allocate a portion of the listing proceeds to:
    - set up manufacturing production facilities
    - establish sales, marketing and medical teams
Update #4 – Core Product beyond concept stage (paragraph 3.3(a) and (b))

• For a pharmaceutical or a biologic, Biotech Company:
  - must complete at least one regulated clinical trial in human subjects;
  or
  - explains why no clinical trial has been completed and whether substantive R&D work and processes equivalent to the completion of one clinical trial have been performed
Update #5 – Other Biotech Products (paragraph 3.4)

• Biotech Product is categorised under GL92-18 as it is categorised by the Competent Authority

• No re-classification of a Biotech Product as “Other Biotech Product” because it is unable to fulfil the requirements under paragraph 3.3

• Where there is no regulatory regime, a Biotech Product can be classified as “Other Biotech Product” after considering non-exhaustive factors such as:
  - number, selection process and diversity of test sampling population
  - time frame and impediments to commercialisation
  - impact factor of journals if pre-clinical and clinical results have been published
  - comparable framework and/or objective indicators under guidelines published by Competent Authorities
Update #6 – Subscription by existing shareholder (paragraph 5.2)

- Existing Shareholder Conditions in GL85-16 do not apply to Biotech Company

- Biotech Companies’ existing shareholders are allowed to participate in IPO. For example, an existing shareholder holding:
  - <10% of a Biotech Company’s shares may subscribe for shares as a cornerstone investor or as a placee
  - ≥10% of a Biotech Company’s shares may subscribe for shares as a cornerstone investor
  - an existing shareholder may exercise its contractual anti-dilution right and subscribe for shares

- Until Rule changes, need to apply for a waiver under Rule 9.09
Update #7 – Clawback mechanism (paragraph 8.1)

• Compelling reasons must be provided for modifications or waiver to the minimum public subscription requirement under Practice Note 18 of the Rules

• The Exchange will consider all applications on a case-by-case basis
DISCLOSURE GUIDANCE FOR BIOTECH COMPANIES
HKEX-GL107-20

Dr. Wei Zhang
Listing Division
AGENDA

1. Purpose of GL107-20
2. Major guidance under GL107-20
AGENDA

1. Purpose of GL107-20

2. Major guidance under GL107-20
GL107-20 – Recommended disclosure requirements

• GL86-16 “Guide on Producing Simplified Listing Documents Relating to Equity Securities for New Applications” still applies

• GL107-20 supplements GL86-16 and is intended to assist Biotech Companies in drafting their listing documents

• Listing document that does not follow GL107-20 may be considered not substantially complete
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1. Purpose of GL107-20

2. Major guidance under GL107-20
Summary section

• Plain language, full terms of key abbreviations when they first appear

• Cross-reference to Business section for highly technical content or detailed mechanism of action and full set of clinical results

• Provide fair and balanced timetable of Core Products’ development and avoid presenting favourable possibilities as certain or as more probable

• Risk factor that potential investors may lose all their investments
Competitive landscape

• Core Products and other key pipeline products to be commercialised in targeted markets
  – competitors’ current pipeline products targeting the same indication and their development stages
  – name, price and reimbursement coverage of available products
  – expiration dates of competing products’ key patents, etc.

• Material information on the addressable market of Core Products and other key pipeline products rather than the overall market

• Comparison between Biotech Companies’ products and direct competing products in major areas such as technologies, indications, targeting market, etc.
Communication with Competent Authorities

• Competent Authorities include:
  – National Medical Products Administration (NMPA)
  – US Food and Drug Administration (FDA)
  – European Medicines Agency (EMA)
  – other national or supranational authorities on a case-by-case basis

• Rule 18A.04(2)(c) vs. NMPA’s umbrella approval
  – Rule 18A.04(2)(c) requires disclosure of a summary of material communication with relevant Competent Authorities on Core Products
  – for NMPA’s umbrella approval: disclose whether NMPA has raised material concerns or objections towards clinical trials or a negative statement
  – for FDA and EMA: disclose all meaningful communication
Commercialised Core Product

• Disclosure for a commercialised Core Product in a given market for specified indication and intends to apply a portion of the listing proceeds to expand (a) the indications; or (b) launch it in another market:
  – a breakdown of the funds to support R&D, e.g. resources required to support further studies
  – importance in advancing the Core Product
Core Product and advanced pipeline candidates as orphan medicine and/or innovative therapy

• Drug pathway classification
  – any special regulatory pathway

• Regulatory strategy
  – any special commercialisation plan and/or market strategy to enter a primary market and other markets

• Collaboration with third party
  – experience of the third party and material terms of the collaboration
**Pipeline products**

- Specify the origins
  - internally developed or in-licensed?
  - jurisdiction rights (global? PRC? etc.)

- Highlight pipeline products
  - strategically and commercially critical to Biotech Company and Biotech Company will prioritise its development
  - a significant portion of proceeds will be applied

- Balanced disclosure
  - both favourable and unfavourable pre-clinical/clinical data

- Early pipeline products without any meaningful data should **not** be included

- Sponsors are responsible for accuracy of disclosure of pipeline products
Valuation and Sophisticated Investors

• Valuation
  – disclose valuation of each round of pre-IPO investments
  – explain any material fluctuations in each round of pre-IPO financing with reference to:
    – key development of the products
    – business milestones
    – competitive advantage over the peers

• Sophisticated Investors
  – disclose material information (e.g. fund’s background and track record)
Net liabilities and burn rate

• Net liabilities (in Summary and Risk Factor sections)
  – turning into a net assets position as a result of full conversion of convertible financial instruments upon listing

• Burn rate (in Summary and other relevant sections)
  – a reasonable period of time that a Biotech Company can maintain its viability
  – expected time for next round of financing
Contractual arrangements

• Listing Decision LD43-3 on contractual arrangements applies to Biotech Companies

• Contractual arrangements should only be adopted to meet foreign ownership restrictions
Thank You