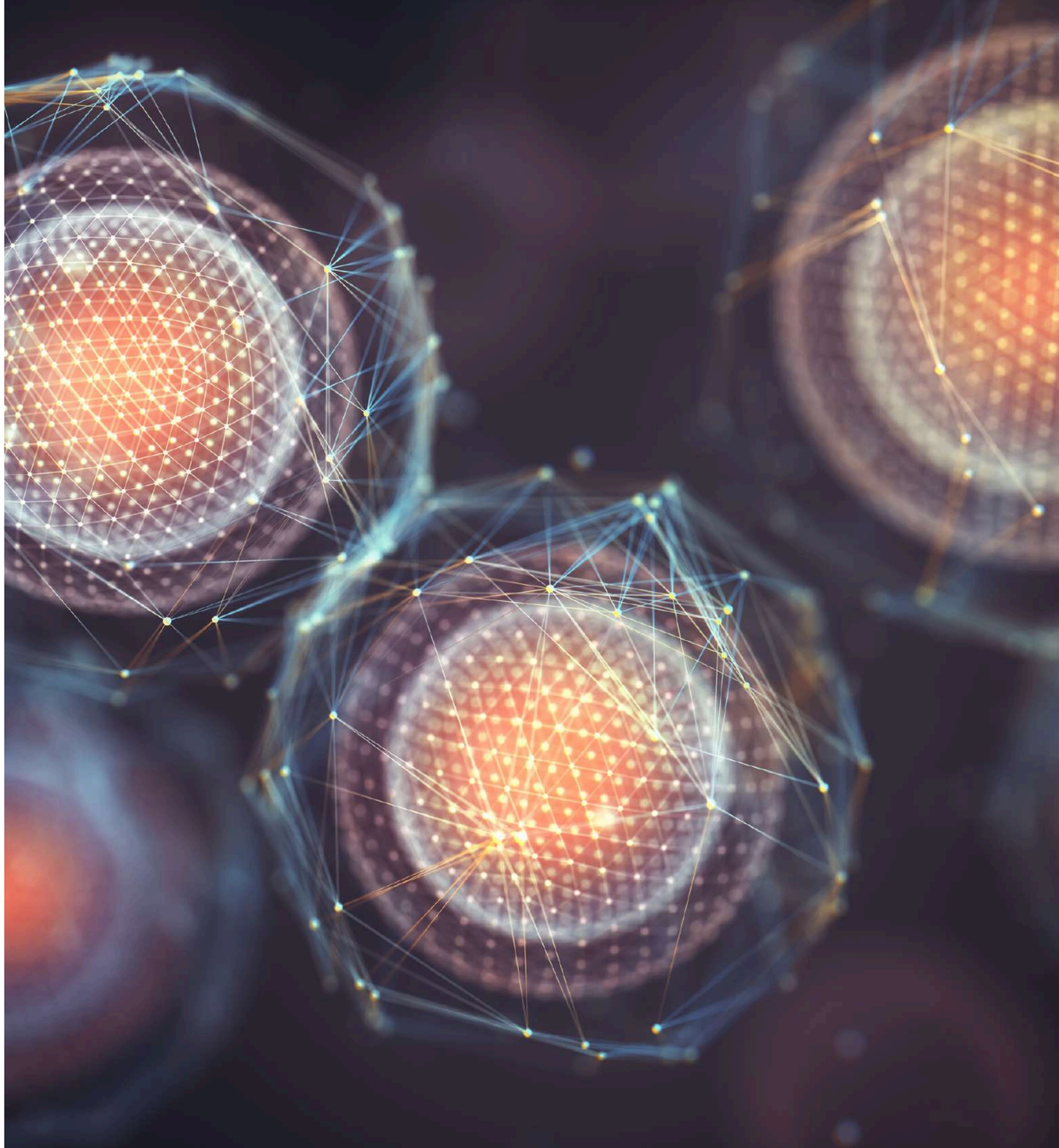
CHARLTONS
易周律师行

# LISTING
# BIOTECH COMPANIES IN HONG KONG

Webinar

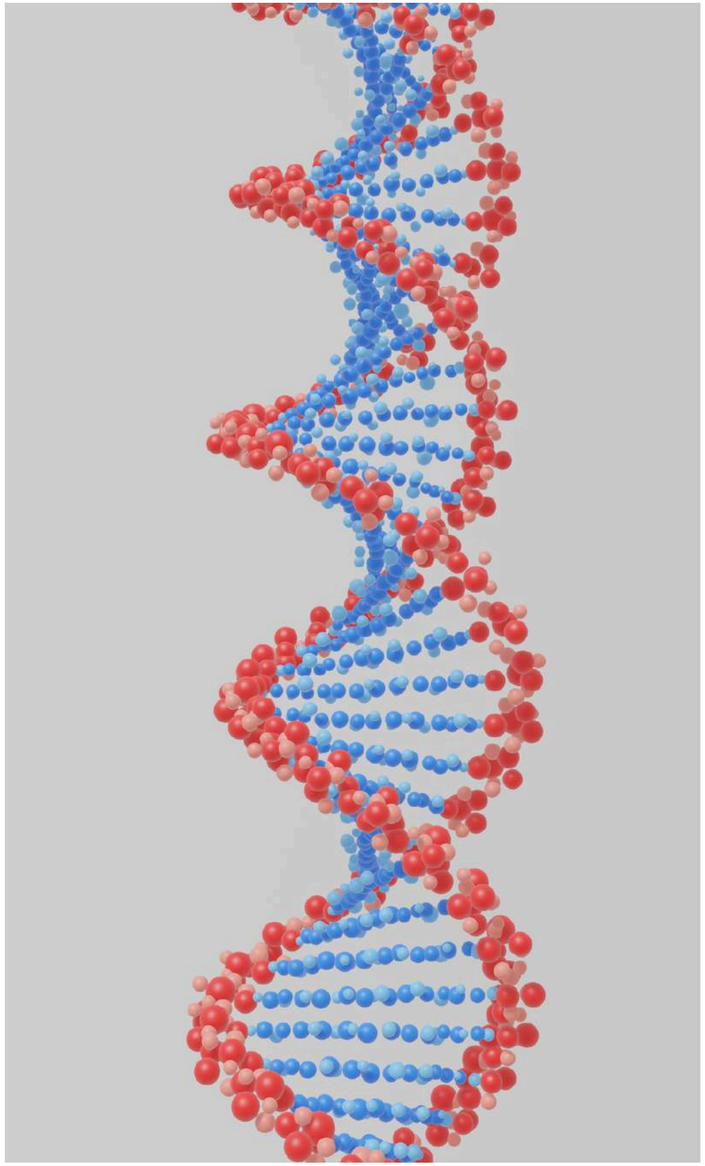


# INTRODUCTION

- Significant growth in Biotech due to global population growth & aging and technological innovation
- COVID-19 accelerated growth of drug companies developing mRNA technology & producers of vaccines & diagnostic products
- One of the “Strategic Emerging Industries” in China’s 14th Five Year Plan 2021 - 2025
- 2018: HKEX introduces listing regime for pre-revenue biotech to attract Chinese Biotech cos to list in HK instead of US NASDAQ

# INTRODUCTION (CONT.)

- HKEx is now one of the world's largest and Asia's largest fundraising hub for biotech companies
- 63 Chapter 18A listed companies as at 31 December 2023 and 2 listed in 2024 (as of June 2024)
- Several companies that listed under Chapter 18A have now satisfied Listing Rule 8.05 – upgraded to a general listing
- Nearly all Chapter 18A issuers are based in the PRC
- Chapter 18A issuers are eligible for inclusion in the Hang Seng Composite Index ("HSCI")
- Chapter 18A issuers included in HSCI or having corresponding A-shares listed in Shanghai or Shenzhen are eligible for Southbound trading under Stock Connect



# REQUIREMENTS FOR LISTING

## Introduction

- **Chapter 18A: listing of biotech companies that cannot satisfy the Listing Rule 8.05 financial eligibility tests**
- Cos satisfying LR 8.05 – cannot list under Ch. 18A
- Chapter 18A applicants must satisfy:
- Chapter 8 eligibility criteria (apart from Listing Rules 8.05 to 8.05C)
  - Additional eligibility criteria in Chapter 18A & Chapter 2.3 of the Guide for New Listing Applicants)
- Biotech advisory panel: can be consulted by HKEX, Listing Committee and SFC on as needed basis

# REQUIREMENTS FOR LISTING (CONT.)

## Suitability requirement

- "Biotech Company": company primarily engaged in the research and development ("R&D"), application and commercialisation of Biotech products, processes or technologies ("Biotech Products")

- "Biotech": the application of science and technology to produce commercial products with a medical or other biological application

- Eligibility & Suitability for Listing criteria in Ch. 2.3 (Biotech Companies) of HKEx's **Guide for New Listing Applicants**

# REQUIREMENTS FOR LISTING (CONT.)

## At least one Core Product developed beyond the concept stage

- "Core Product": Biotech Product that forms the basis of the listing application which is required by applicable laws/rules/regulations to be evaluated & approved by a Competent Authority based on data from clinical trials on human subjects before being marketed and sold in the market regulated by that Competent Authority

- Chapter 18A Competent Authorities:
  - US Food and Drug Administration ("FDA")
  - China Food and Drug Administration ("CFDA")
  - European Medicines Agency ("EMA")

- HKEx discretion to recognise other authorities as Competent Authorities

# REQUIREMENTS FOR LISTING (CONT.)

## At Least One Core Product developed beyond the concept stage (cont.)

***Drugs (inc. pharmaceuticals (small molecule & biologics)***

1. Products based on previously approved product:

(a) Completed at least 1 clinical trial conducted on human subjects (the "Clinical Trial Milestone") +
(b) CA has no objection for commencement of Phase II (or later) clinical trials (the "Regulatory Milestone")

2. New products:

**(a) C**ompleted Phase I clinical trial (i.e. on human subjects); + (b) CA has no objection for commencement of Phase II (or later) clinical trials

3. In-licensed or acquired products: Completed at least 1 clinical trial on humans since in-licensing or acquisition & no objection from CA to further clinical trials

***Medical devices (including diagnostics)***

- Categorisation of product as Class II medical device or above
- Completed at least 1 clinical trial on human subjects
- Endorsement (or no objection) by CA or AI to proceeding to further clinical trials OR no objection to commencing sales of the device

# REQUIREMENTS FOR LISTING (CONT.)

## Other Biotech Products

- Biotech products that are not in “Drug” and “Medical Device” categories = “Other Biotech Products” & are assessed on case-by-case basis by reference to: (a) their development beyond the concept stage and (b) whether there is an appropriate framework or objective indicators to allow investors to make an informed investment decision.

- Acceptance of a listing application requires SFC consent under LR 2.04

HKEx Listing Decision (May 2022)

- Whether Product X (one of Company A’s Core Products) which completed Phase 1 clinical trials under Australia’s Therapeutic Goods Administration (“TGA”) and subsequently obtained approval from the EMA & CFDA/NMPA to commence global pivotal Phase 2/3 clinical trial satisfied relevant Core Product eligibility requirements under the Guide for New Listing Applicants and Chapter 18A?

- Based on the specific facts and circumstances of the case, HKEx determined that Product X satisfied the Core Product eligibility requirements

# REQUIREMENTS
# FOR LISTING (CONT.)

**Primary engagement in R&D for developing Core Product(s)**

**Applicant must:**

- be primarily engaged in R&D for the development of its Core Product(s)
- have been engaged in the R&D of its Core Product(s) for ≥ 12 months before listing
- If in-licensed or acquired Core Product: R&D progress since in-licensing or acquisition

## Primary reason for listing

- Applicant must demonstrate a need for fund raising having regard to:
  - its historical R&D expenses; and/or
  - post-approval R&D or other activities required by Competent Authority

- Listing document must disclose:
  - IPO proceeds allocated to Core Product(s) & other products
  - applicant's development plans & expected timeline for each product

# REQUIREMENTS FOR LISTING (CONT.)

# REQUIREMENTS
# FOR LISTING (CONT.)

## Patents

- Applicant must have registered patent(s), patent application(s) and/or intellectual property (“IP”) for Core Product(s)

- For in/out-licensed or jointly developed Core Products, applicant must own all IP independently developed by the applicant

# REQUIREMENTS
# FOR LISTING (CONT.)

## Product pipeline

- Applicants engaged in R&D of pharmaceuticals (small molecule drugs products or biologic products) must have a pipeline of those potential products

# REQUIREMENTS FOR LISTING (CONT.)

## Prior meaningful third party investment

- Applicant must have previously received meaningful third party investment (more than just a token investment) from at least one sophisticated investor at least 6 months before proposed listing
    - Investment must continue at listing date
- On a spin-off listing: HKEx may not require compliance with this criteria if there is a reasonable degree of acceptance for the applicant's R&D & Biotech Product

# REQUIREMENTS FOR LISTING (CONT.)

## Prior meaningful third party investment (cont.)

- Factors considered in assessing whether investor is sophisticated: net assets, AUM,, relevant investment experience, & knowledge & expertise in the relevant field
- Sophisticated investors include:
  - Dedicated healthcare/Biotech funds, or funds with division/department specifically
  - investing in biopharmaceutical sector

    Major pharmaceutical/healthcare companies and their venture capital funds
  - Investors/investment funds/financial institutions with AUM of ≥ HK$1 billion

# REQUIREMENTS
# FOR LISTING (CONT.)

## Prior meaningful third party investment (cont.)

- Factors considered in assessing whether investment is meaningful: nature, amount,, stake & timing of investment

| Applicant's market capitalisation *(HK$)* | Investment amount considered meaningful *(% of applicant's issued share capital on listing)* |
|---|---|
| 1.5-3 billion | ≥ 5% |
| 3-8 billion | ≥ 3% |
| >8 billion | ≥ 1% |

# REQUIREMENTS
# FOR LISTING (CONT.)

## Other eligibility requirements: Expected market capitalisation

- Minimum expected market capitalisation at listing: HK$1.5 billion (LR 18A.03(2))

# REQUIREMENTS
# FOR LISTING (CONT.)

## Other eligibility requirements: Track record

- Track record of operating in current line of business for a minimum of two financial years before listing under substantially the same management (LR 18A.03(3))

# REQUIREMENTS FOR LISTING (CONT.)

## Other eligibility requirements: Working capital requirements

- LR 18A.03(4): Working capital available to cover at least 125% of the group's costs for at least 12 months from the listing document date, after taking IPO proceeds into account
    - Costs should consist substantially of general, administrative & operating costs, & R&D costs
    - A substantive portion of IPO proceeds should be applied to these costs

# REQUIREMENTS FOR LISTING (CONT.)

Other eligibility requirements: Ownership continuity

- In assessing Chapter 18A listing suitability, HKEx considers any change in the applicant's ownership in the 12 months before the listing application date

# REQUIREMENTS FOR LISTING (CONT.)

## Other eligibility requirements: Public float

- Chapter 18A listing applicants must satisfy:
  - LR 8.08(1): general public float requirement
  - LR 18A.07: a portion of applicant's issued shares with market capitalisation of ≥HK$375 million must be held by the public at the time of listing
- Shares allocated to Cornerstone Investors / subscribed by existing shareholders at listing are not regarded as publicly held under LR 18A.07
- "Cornerstone Investors": investors in an IPO who are given a guaranteed allocation of shares irrespective of the final offer price

# REQUIREMENTS FOR THE IPO

## Subscription of IPO shares by existing shareholders & Cornerstone Investors

- "Existing Shareholder Conditions" do not apply to Ch. 18A companies
- Existing shareholders can participate in a Ch. 18A IPO provided applicant complies with LR 8.08(1) & 18A.07
- Existing shareholder holding ≤ 10% of applicant's shares can subscribe in IPO as a placee or Cornerstone Investor. Applicant and sponsor confirmations required that:
  - For a Placee – no preference was given to the shareholder in making the allocation
  - For a Cornerstone Investor – the only preferential treatment given to the shareholder was that of assured entitlement at IPO price, and the terms of the shareholder's acquisition are substantially the same as those of the other Cornerstone Investors
- Existing shareholder holding 10% or more of the applicant's shares can subscribe in the IPO as a Cornerstone Investor, but not as a placee

# REQUIREMENTS
# FOR THE IPO (CONT.)

## Clawback mechanism

- Must present compelling reasons for a modification to the Practice Note 18 minimum public subscription requirement

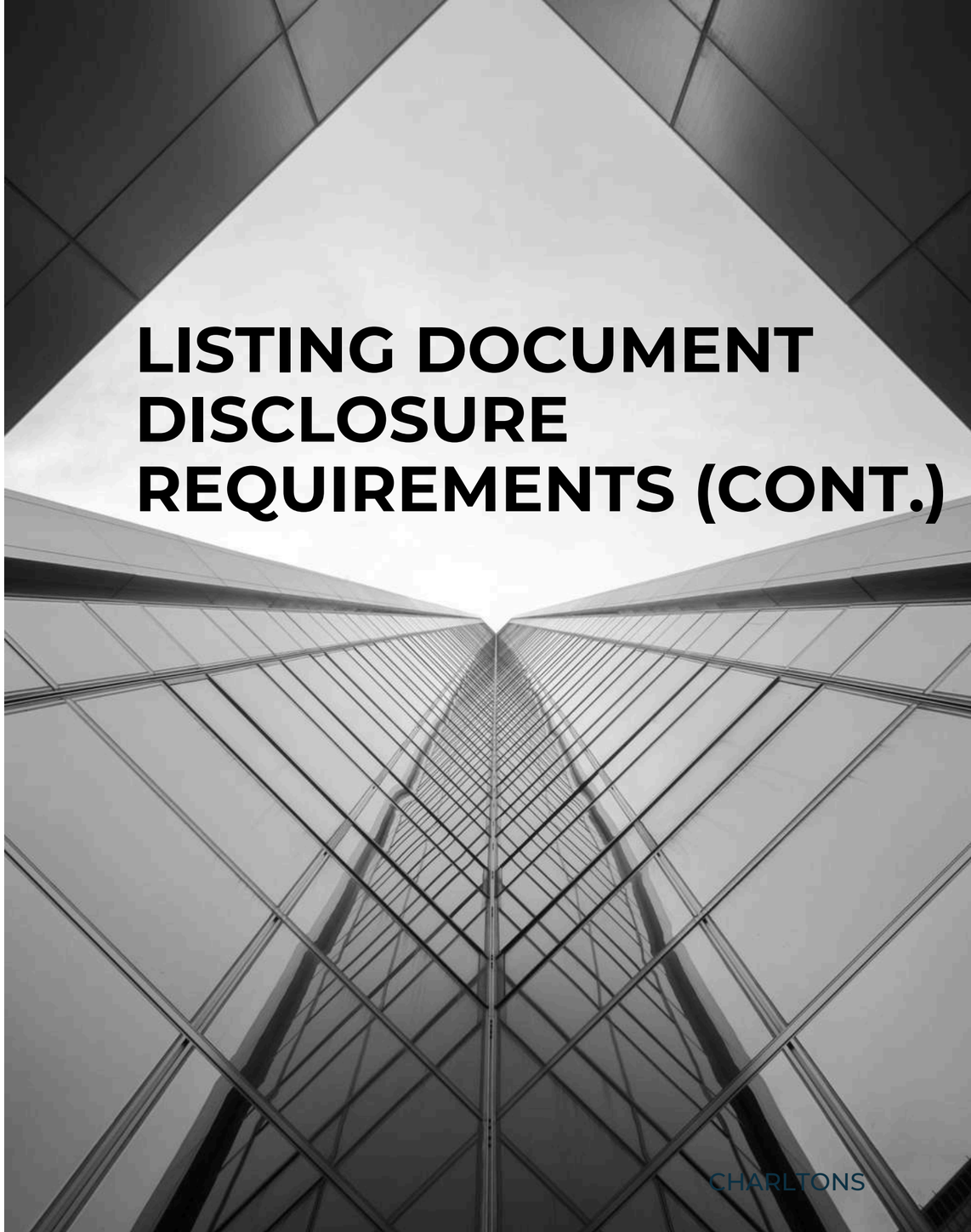
## Accountants’ reports

- Chapter 18A accountants’ report covering 2 financial years (instead of 3)
- Certificate of exemption from the applicable requirements of the Third Schedule to C(WUMP)O

# LISTING DOCUMENT DISCLOSURE REQUIREMENTS

## Enhanced disclosure required by LR 18A.04

- Co.'s strategic objectives
- Details of each Core Product
- Statement of no material unexpected or adverse change since date of regulatory approval
- Relevant experience of directors' & senior management
- Co.'s R&D experience
- Measures to retain key management / technical staff, arrangements in case of their departure, & salient terms of their service agreements
- Estimate of cash operating costs & other specified costs (e.g. R&D & clinical trial costs)
- Statement of legal claims/ proceedings that could impact R&D for a Core Product
- Warning that Core Product(s) may not be successfully developed & marketed



# LISTING DOCUMENT DISCLOSURE REQUIREMENTS (CONT.)

# LISTING DOCUMENT
# DISCLOSURE REQUIREMENTS (CONT.)

## Ch. 2.3 Guide for New Listing Applicants

- Business model (in-licensing model and/or self-developed model)
- Material IP rights and directors' statement on infringement of third parties' IP rights.
- Material information on the addressable markets of Core Products and key non-Core Products
- Disclosure of valuation of each round of pre-IPO investment, reasons for any material fluctuations in valuation, & material information on sophisticated investors
- Disclosure of a reasonable time period for which it can remain viable with its existing cash balance & the IPO proceeds, & when it expects to conduct its next round of financing based on burn rate

# BIOTECH COMPANIES' CONTINUING OBLIGATIONS

## Enhanced disclosure in financial reports

- Annual & interim reports: details of R&D activities for the relevant period
  - Summary of expenditure on R&D activities
  - Details of the key stages and an indication of the likely timeframe for each Core Product under development to reach commercialisation
  - Prominent warning that a Core Product may not ultimately be successfully developed and marketed

## Calculation of percentage ratios for notifiable transactions

- Revenue ratio and profit ratio are two (of five) percentage ratios used when classifying notifiable transactions under Ch, 14 of the Listing Rules

- HKEx may exercise its discretion to disregard the revenue and profit ratios for Chapter 18A issuers, and consider other appropriate indicators of size

# BIOTECH COMPANIES' CONTINUING OBLIGATIONS (CONT.)

# BIOTECH COMPANIES' CONTINUING OBLIGATIONS (CONT.)

## Stock marker

- Chapter 18A listed companies have the stock marker "B" at the end of their stock name

# REQUIREMENTS ON CHANGES TO LISTED BIOTECH COMPANIES

## Material change of business

- HKEx consent required for any acquisition, disposal or other transaction/arrangement (or a series of such transactions/arrangements) that would result in a fundamental change to the Listco's principal business activities as described in its listing document

- HKEx will usually grant prior consent if satisfied that the company is engaging in legitimate business expansion or diversification as part of its business strategy

# REQUIREMENTS RELATING TO CHANGES TO LISTED BIOTECH COMPANIES (CONT.)

## De-listing of Biotech Companies

- If a Chapter 18A issuer fails to comply with LR 13.24 (i.e. obligation to maintain sufficient operations & assets to warrant continued listing), HKEx may suspend dealings, cancel listing or give the issuer up to 12 months to re-comply
    - This is shorter than the 18 months generally given to other listed issuers
    - Listing is cancelled if it fails to re-comply within 12 months

# REQUIREMENTS RELATING TO CHANGES TO LISTED BIOTECH COMPANIES (CONT.)

## Meeting the Listing Rule 8.05 financial eligibility tests

- Once a Chapter 18A listed company is able to satisfy Listing Rule 8.05, the following requirements cease to apply:
  - Stock marker “B” requirement
  - Prior HKEx consent required for transactions resulting in a fundamental change in the company’s business
  - Requirements relating to sufficiency of operations