CHARLTONS
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LISTING PRE-REVENUE BIOTECH COMPANIES IN HONG KONG

Webinar

INTRODUCTION

- April 2018 new listing regime for companies from high-growth emerging and innovative sectors
  - New Chapter 18A (Biotech Companies) of the Main Board Listing Rules
- Chapter 18A provides for the listing of biotech companies that cannot satisfy the Listing Rule 8.05 financial eligibility tests
- Previously, early stage biotech companies could not list on the HKEx as did not satisfy Listing Rule 8.05
  - Pre-revenue Chinese biotech companies typically listed on the NASDAQ instead
- HKEx is now the world's second largest and Asia's largest fundraising hub for biotech companies
- Healthcare sector as a percentage of HKEx IPO funds raised:
  - 2018-May 2022: third largest sector, 19% of all funds raised (c.f. 7% in 2014-2017)

INTRODUCTION (CONT.)

- 50 Chapter 18A IPOs, raising an aggregate HK$115 billion (as at June 2022)
- Several HKEx-listed biotech companies with dual listings (Nasdaq or Shanghai Star Market)
- Several Chapter 18A issuers have conducted post-IPO capital raising
- Several companies that listed under Chapter 18A have now satisfied Listing Rule 8.05 – upgrade to a general listing
- Nearly all Chapter 18A issuers are based in the PRC
- Strong investor demand for Chapter 18A IPOs (e.g. New Horizon Health Limited – second highest oversubscription of a HKEx IPO ever)
- Chapter 18A issuers are eligible for inclusion in the Hang Seng Composite Index ("HSCI")
- Chapter 18A issuers included in HSCI or have corresponding A-shares listed in Shanghai or Shenzhen are eligible for Southbound trading under Stock Connect
- There is no pre-revenue biotech listing regime for GEM

REQUIREMENTS FOR LISTING

Introduction

- Chapter 18A: listing of biotech companies that cannot satisfy the Listing Rule 8.05 financial eligibility tests
- If satisfy Listing Rule 8.05 – cannot list under Chapter 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 (supplemented by HKEx Guidance Letters GL92-18, GL85-16 and GL107-20)
- Biotech advisory panel

REQUIREMENTS FOR LISTING (CONT.)

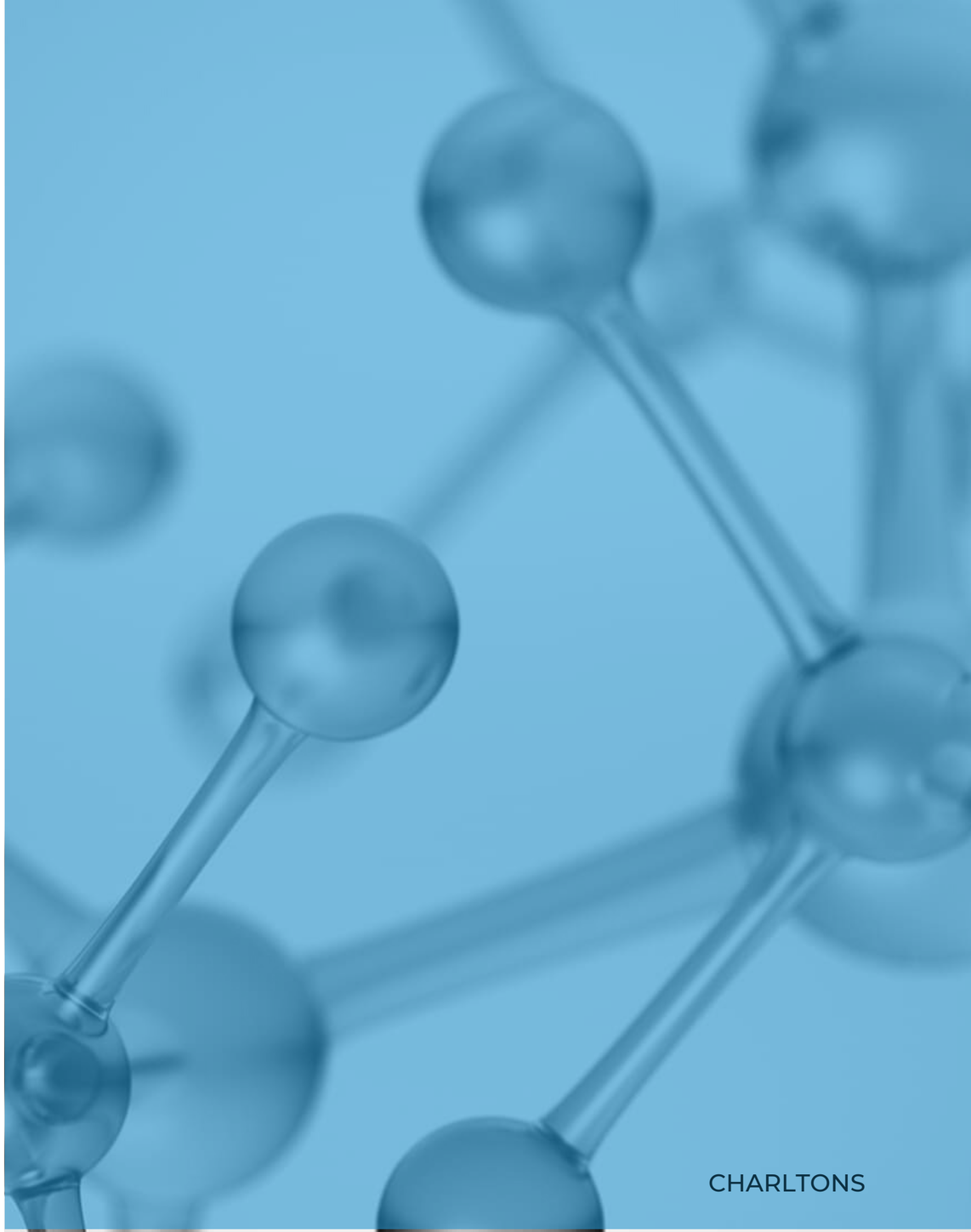
Suitability requirement

- "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
- Suitability criteria in HKEx Guidance Letter GL92-18 "Suitability for Listing of Biotech Companies"

REQUIREMENTS FOR LISTING (CONT.)

Suitability requirement: Core Product developed beyond the concept stage

- Requirement to have developed at least one Core Product 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 and approved by a Competent Authority based on data derived 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.)

Suitability requirement: Core Product developed beyond the concept stage (cont.)

Pharmaceutical (small molecule drugs) • Products based on previously approved products: successful completion of at least 1 clinical trial conducted on human subjects, and no objection by CA for commencement of Phase II (or later) clinical trials • New products: completion of Phase I clinical trials (i.e. trials on human subjects categorised as Phase I by the FDA or equivalent), and no objection by CA for commencement of Phase II (or later) clinical trials • In-licensed or acquired products: generally, completion of at least 1 clinical trial on human subjects since in-licensing or acquisition	*Medical devices (including diagnostics)* • Categorisation of product as Class II medical device or above • Completion of 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
Biologics • New products: completion of Phase I clinical trials, and no objection by CA for commencement of Phase II (or later) clinical trials • Biosimilar products: completion of at least 1 clinical trial on human subjects, and no objection by CA for commencement of Phase II (or later) clinical trials to demonstrate bio-equivalency • In-licensed or acquired products: completion of at least 1 clinical trial on human subjects since in-licensing or acquisition	*Other Biotech products* • Considered on a case-by-case basis • HKEx will consider same factors as for pharmaceutical, biologics and medical devices, and whether there is an appropriate framework or objective indicators for investors to make an informed investment decision • HKEx categorisation according to CA categorisation • If no regulatory regime specifying external milestones/objective framework for assessing the development progress, market and clinical relevance – HKEx will consider various factors, e.g. number, selection process and diversity of test sampling population

REQUIREMENTS FOR LISTING (CONT.)

Suitability requirement: Core Product developed beyond the concept stage (cont.)

HKEx Listing Decision LD135-2022 (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 both the EMA and the CFDA/NMPA to commence the global pivotal Phase 2/3 clinical trial satisfies the relevant Core Product eligibility requirements under GL92-18 and Chapter 18A?

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

REQUIREMENTS FOR LISTING (CONT.)

Suitability requirement: Primary engagement in R&D for developing Core Product(s)

- Requirement to be primarily engaged in R&D for the development of its Core Product(s)
- Requirement to have been engaged in the R&D of its Core Product(s) for at least 12 months before listing
- If in-licensed or acquired Core Product: R&D progress since in-licensing or acquisition
- If Core Product has been commercialised for specified indication(s) and intend to apply listing proceeds to expand the indications or launch it in another market: additional R&D relating to the clinical trials required by the Competent Authority for the new indication or commercialisation in the new regulated market

Suitability requirement: Primary reason for listing

- Requirement that the applicant's primary reason for listing is to raise finance for R&D to bring its Core Product(s) to commercialisation

- Specific HKEx guidance if develop medical devices with short development cycles

REQUIREMENTS FOR LISTING (CONT.)

REQUIREMENTS
FOR LISTING (CONT.)

Suitability requirement: Patents

- Requirement to have registered patent(s), patent application(s) and/or intellectual property (“IP”) in relation to Core Product(s)

REQUIREMENTS
FOR LISTING (CONT.)

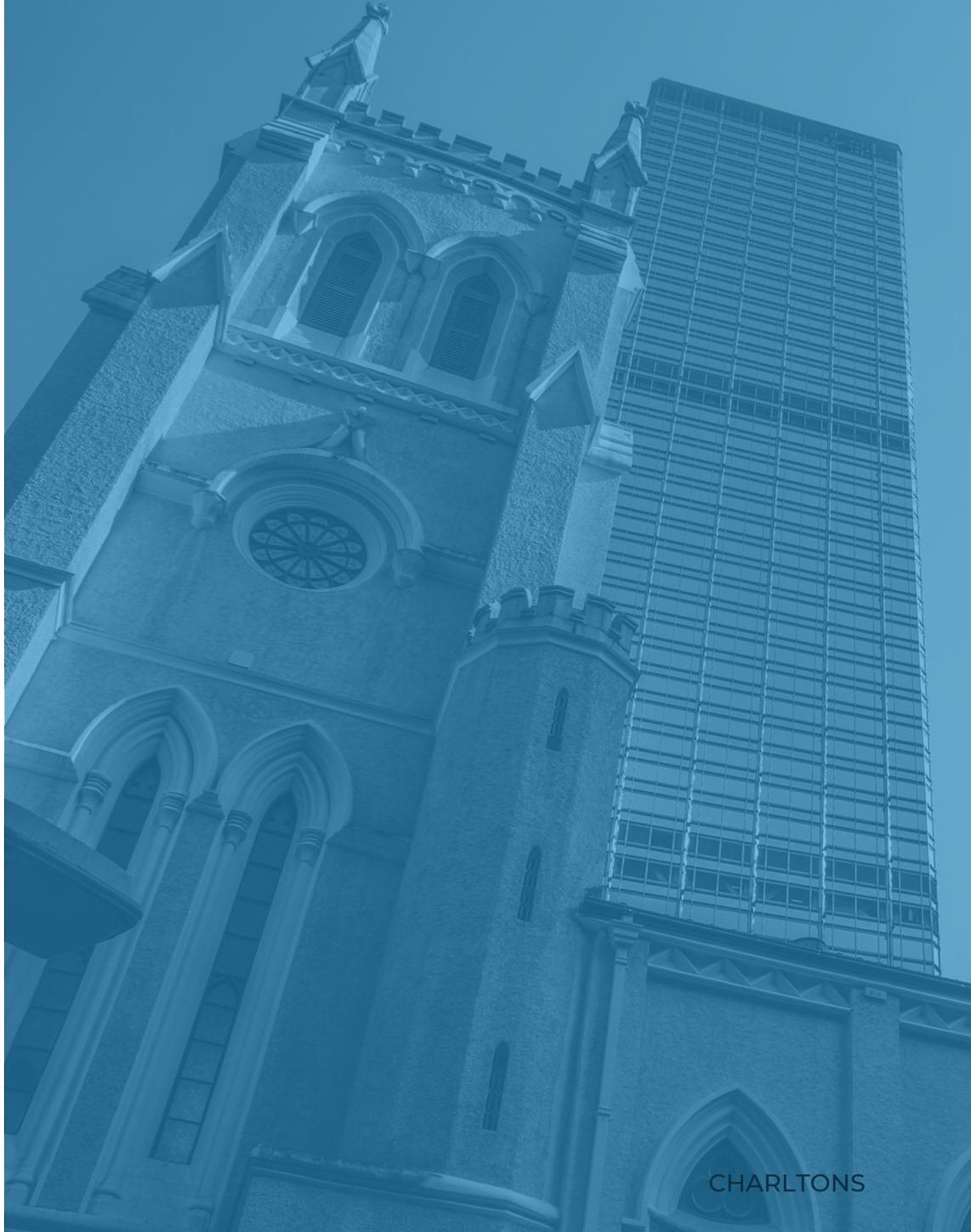
Suitability requirement: Product pipeline

- If engaged in R&D of pharmaceutical (small molecule drugs) products or biologic products: requirement to have a pipeline of those potential products

REQUIREMENTS FOR LISTING (CONT.)

Suitability requirement: Prior meaningful third party investment

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



REQUIREMENTS FOR LISTING (CONT.)

Suitability requirement: Prior meaningful third party investment (cont.)

- Factors considered in assessing whether investor is sophisticated: net assets, AUM, relevant investment experience, and knowledge and expertise the relevant field
- Sophisticated investors:
  - 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 at least HK$1 billion

REQUIREMENTS FOR LISTING (CONT.)

Suitability requirement: Prior meaningful third party investment (cont.)

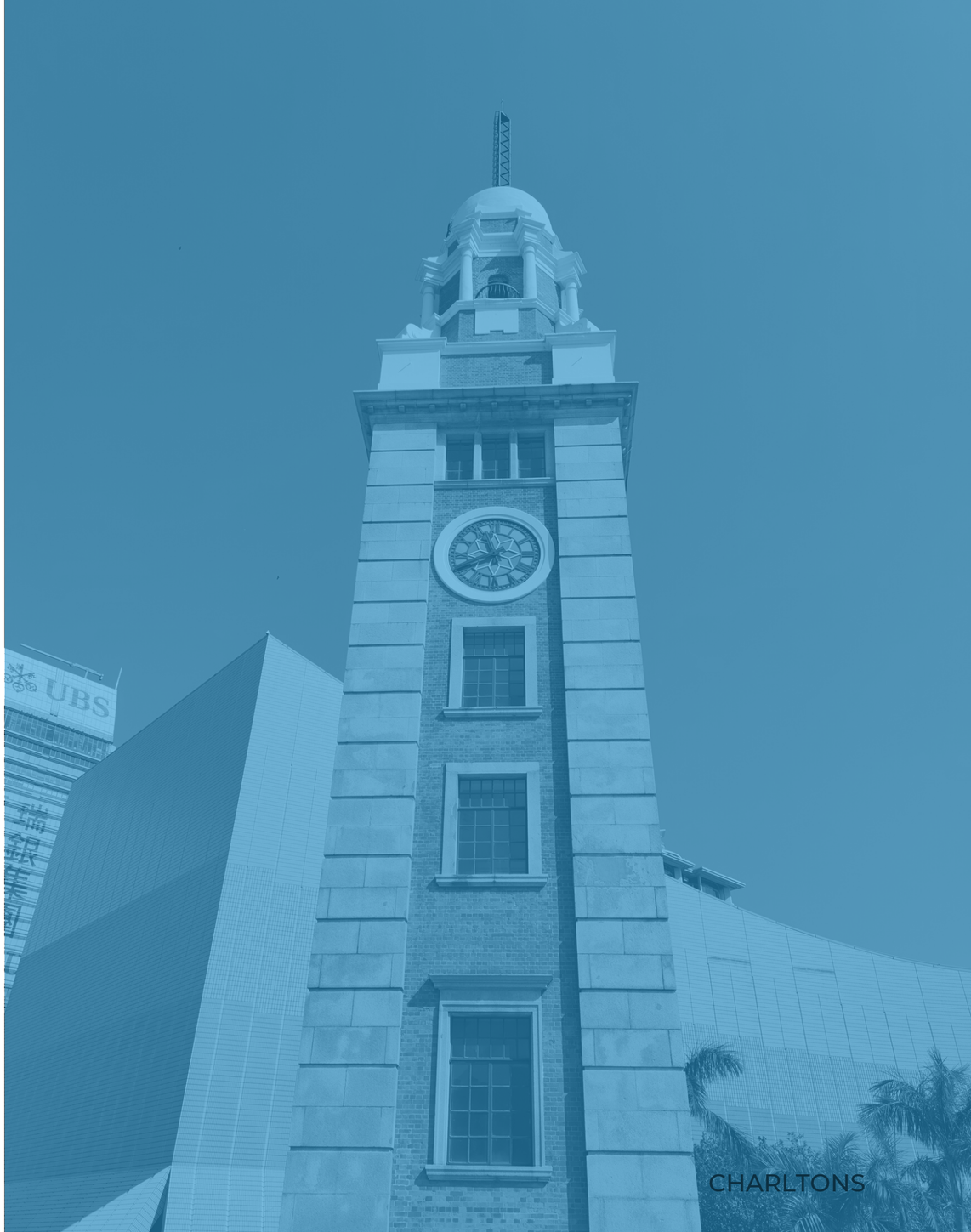
- Factors considered in assessing whether investment is meaningful: nature, amount, stake and timing of investment

Applicant's market capitalisation *(HK$)*	Investment amount to be 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



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

REQUIREMENTS FOR LISTING (CONT.)

Other eligibility requirements: Working capital requirements

- 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 into account the IPO proceeds
    - Costs should consist substantially of general, administrative and operating costs, and 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:
  - Listing Rule 8.08(1): general public float requirement
  - Listing Rule 18A.07: additional Chapter 18A-specific public float requirement – a portion of applicant's issued shares with a minimum HK$375 million market capitalisation must be held by the public at the time of listing
- Any shares allocated to a Cornerstone Investor and any shares subscribed by existing shareholders at the time of listing will not be regarded as publicly held for the purpose of Listing Rule 18A.07
  - This is not a requirement in determining the applicant's public float for Listing Rule 8.08(1)
- "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 and Cornerstone Investors

- "Existing Shareholder Conditions" under HKEx Guidance Letter GL85-16 do not apply to Chapter 18A companies
- Existing shareholders are allowed to participate in a Chapter 18A IPO provided that the company complies with Listing Rules 8.08(1) and 18A.07
- Existing shareholder holding less than 10% of the applicant's shares can subscribe in the IPO as either a placee or a Cornerstone Investor. Applicant and sponsor confirmation:
  - Placee – no preference was given to the shareholder in making the allocation
  - 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
- HKEx will usually grant a waiver from Listing Rule 9.09 (prohibition on core connected persons from dealing in the shares for which listing is sought) to a Chapter 18A company

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

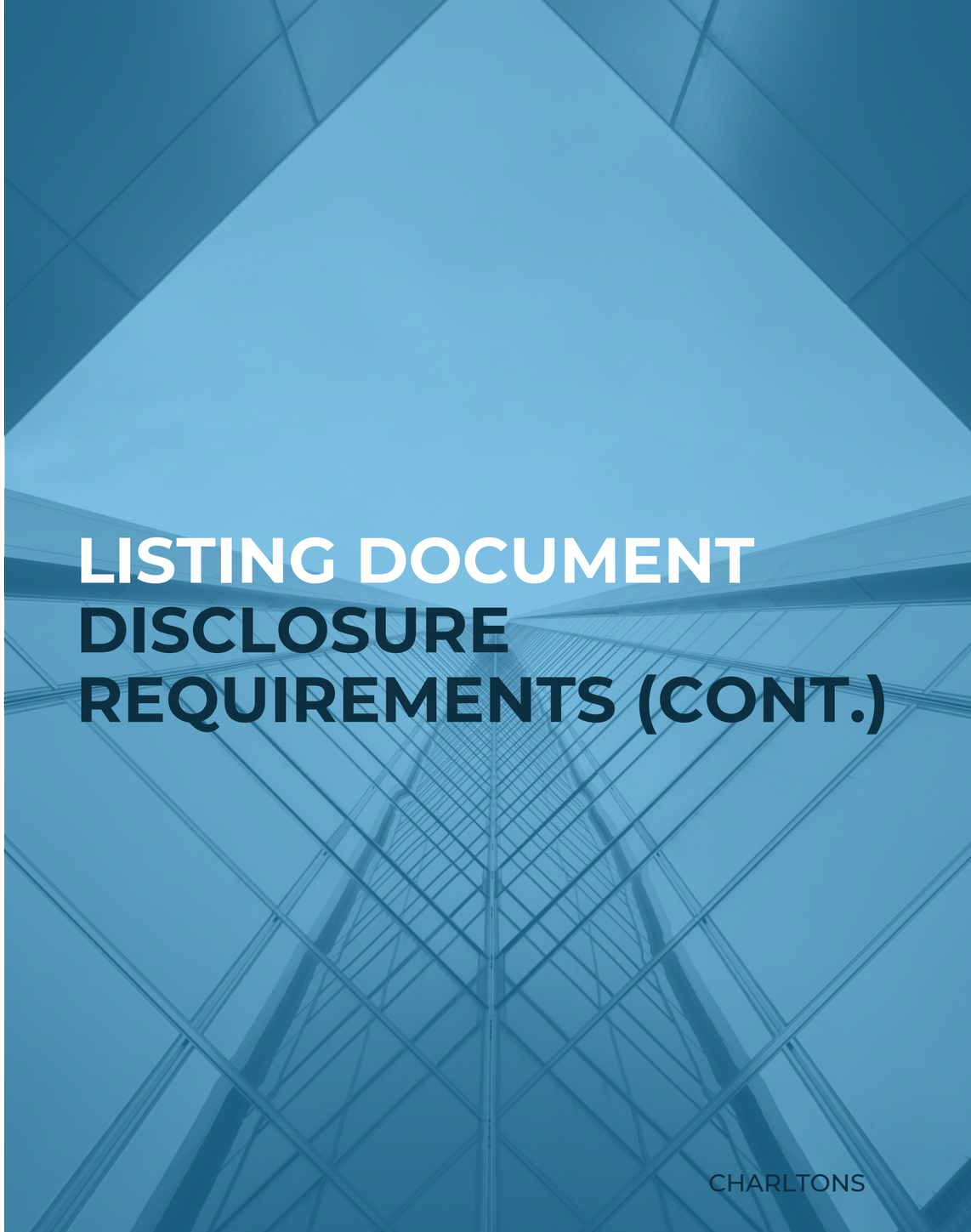
- Chapter 18A accountants’ report covers two financial years (not the standard three financial years)

- Certificate of exemption from the applicable requirements under the Third Schedule to the C(WUMP)O

LISTING DOCUMENT DISCLOSURE REQUIREMENTS

Enhanced disclosure required under Listing Rule 18A.04

- Company's strategic objectives
- Details of each Core Product
- Statement that there has been no material unexpected or adverse change since the date of any relevant regulatory approval
- Details of the company's R&D experience
- Details of the directors' and senior management's relevant experience
- Measures in place to retain (and arrangements in case of the departure of), and the salient terms of service agreements with, key management/technical staff
- Disclosure of any legal claims/proceedings that may influence the company's R&D for any Core Product
- Disclosure of general and specific risks
- An estimate of cash operating costs and other specified costs (e.g. R&D costs)
- If obtained an expert technical assessment, inclusion of the assessment
- Prominent warning that the Core Product(s) may not ultimately be successfully developed and marketed



LISTING DOCUMENT
DISCLOSURE REQUIREMENTS (CONT.)

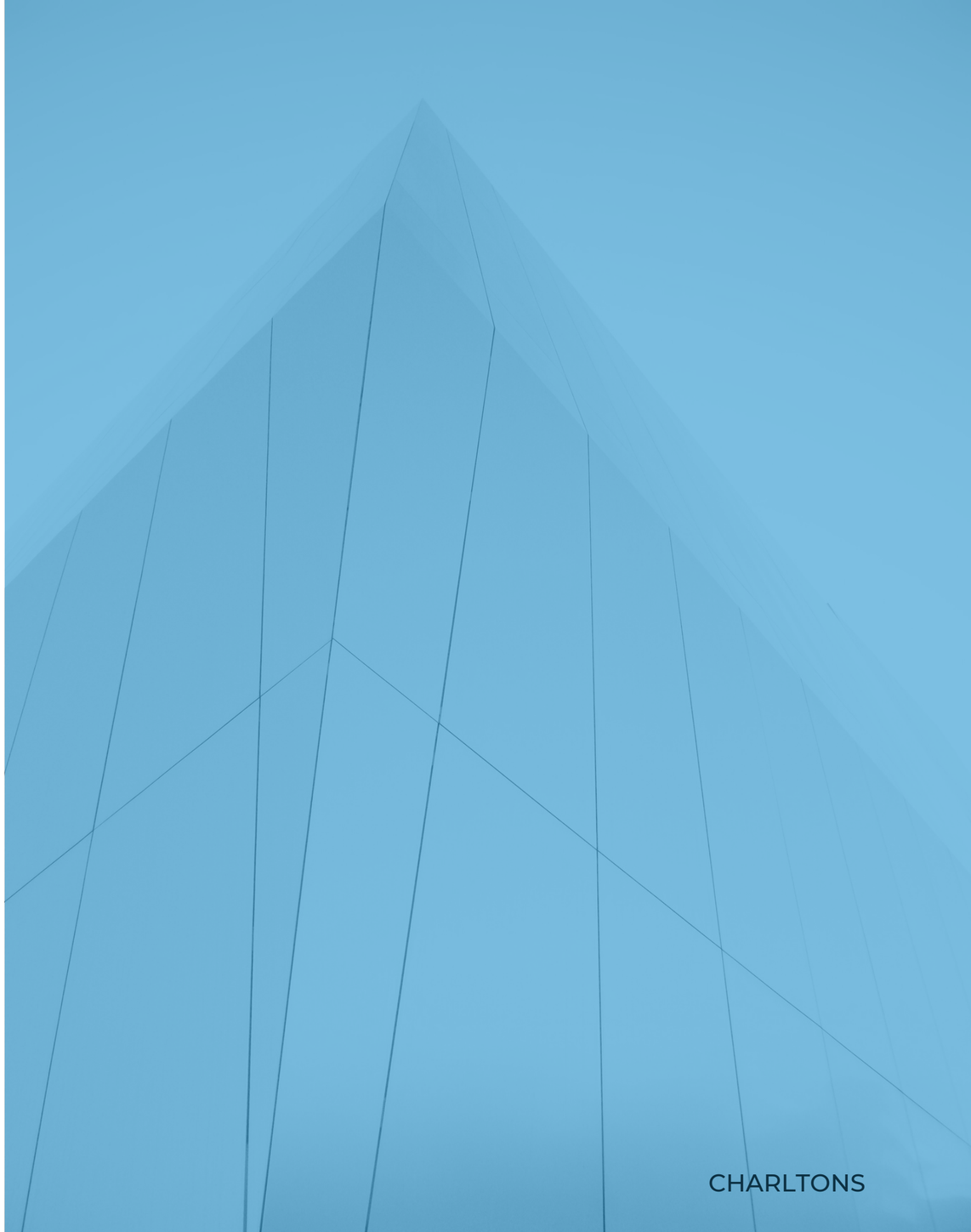
HKEx Guidance Letter GL107-20 “Disclosure in listing documents for Biotech Companies”

- General drafting guidance
- Clear disclosure of business model (in-licensing model and/or self-developed model)
- Detailed guidance of disclosures relating to Core Products and key non-Core Products
- Disclosure of material IP rights, and directors’ statement as to whether the applicant has infringed any third parties’ IP rights
- Disclosure of material information on the addressable markets of Core Products and key non-Core Products
- Disclosure of the valuation of each round of pre-IPO investment, and reasons for any material fluctuations in valuation, and material information on sophisticated investors
- Disclosure of a reasonable time period, with basis, that it can remain viable with existing cash balance and the IPO proceeds, and when it expects to conduct its next round of financing based on burn rate

BIOTECH COMPANIES' CONTINUING OBLIGATIONS

Enhanced disclosure in financial reports

- Annual and 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 Chapter 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 RELATING TO 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 company'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 Listing Rule 13.24 (i.e. the obligation to maintain sufficient operations and assets to warrant its continued listing), HKEx may suspend dealings, cancel its 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

MCQs

Question 1

Which of the following is NOT a suitability requirement to list under Chapter 18A?

(A) The applicant must have developed at least one Core Product beyond the concept stage

(B) The applicant must have been engaged in the R&D of its Core Product(s) for at least one year prior to listing

(C) The applicant's primary reason for listing must be the raising of funds for R&D to bring its Core Product(s) to commercialisation

✓ (D) The applicant must have received meaningful third party investment from at least one sophisticated investor at least 12 months before the listing

Question 2

Which of the following authorities is NOT recognised as a Competent Authority in Chapter 18A?

- ✓ (A) The Hong Kong Drug Office
- (B) The China Food and Drug Administration
- (C) The US Food and Drug Administration
- (D) The European Medicines Agency

Question 3

Which of the following is NOT an eligibility requirement for listing under Chapter 18A?

(A) A minimum HK$1.5 billion market capitalisation at the time of listing

✓ (B) A track record of operating in the Biotech Company's current line of business for a minimum of two financial years prior to listing under substantially the same management and ownership

(C) Working capital available to cover at least 125% of the group's costs for at least one year from the listing document date

(D) A portion of the Biotech Company's issued shares with a market capitalisation of a minimum HK$375 million are held by the public at listing

Question 4

Which of the following is correct for a Chapter 18A IPO?

(A) An existing shareholder holding less than 10% of a Biotech Company's shares is allowed to subscribe for shares in its IPO as a placee and/or as a Cornerstone Investor

✓ (B) An existing shareholder holding 10% or more of a Biotech Company's shares is allowed to subscribe for shares in its IPO as a Cornerstone Investor, but not as a placee

(C) Any shares allocated to a Cornerstone Investor and any shares subscribed by existing shareholders at the time of listing may be regarded as publicly held for the purpose of Listing Rule 18A.07

(D) Any shares allocated to a Cornerstone Investor and any shares subscribed by existing shareholders at the time of listing will not be regarded as publicly held for the purpose of Listing Rule 8.08

Question 5

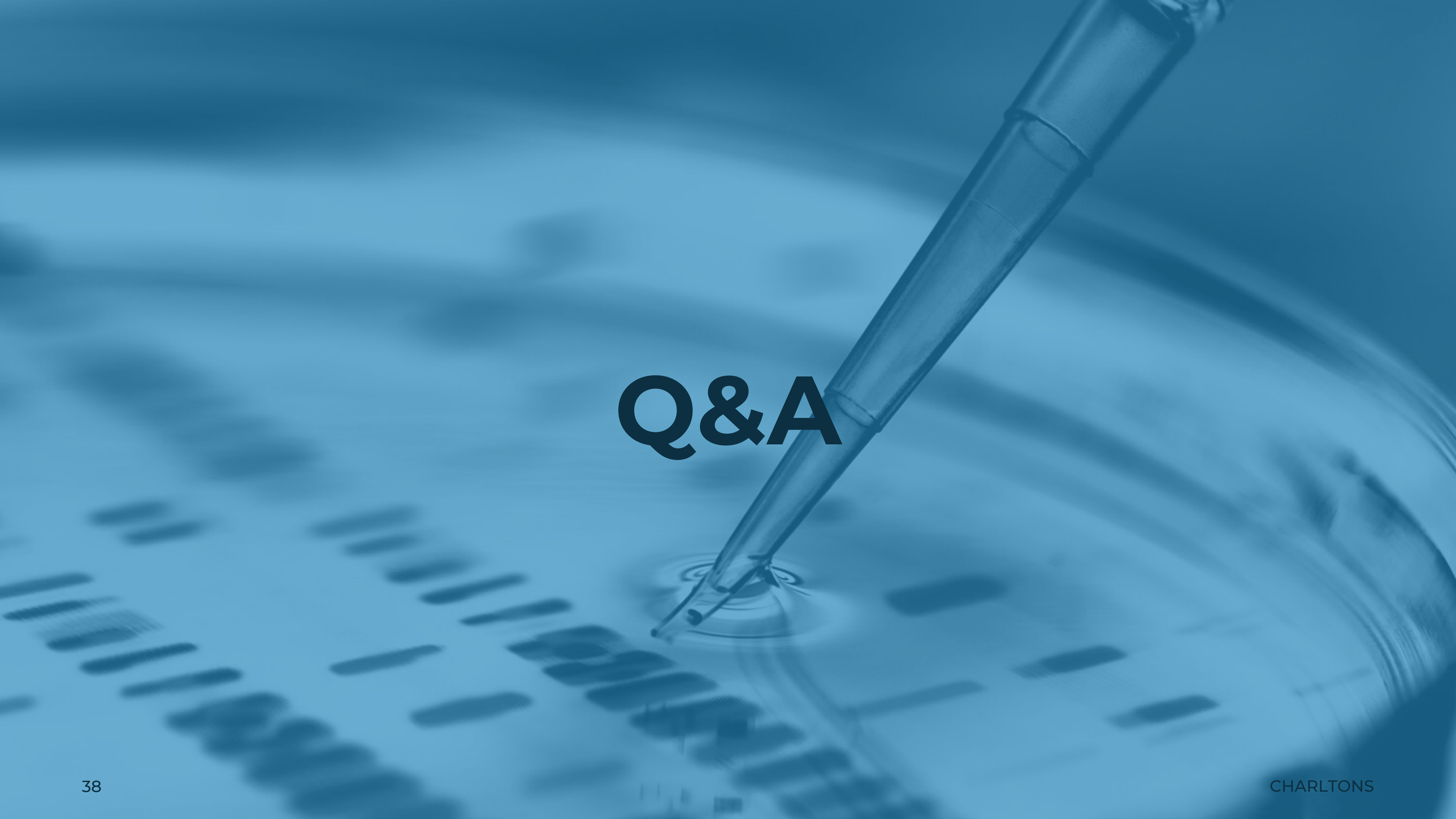
What happens when a company that listed under Chapter 18A is able to meet one of the three financial eligibility tests under Listing Rule 8.05?

(A) The company is no longer required to comply with the enhanced annual and interim report disclosure requirements of Chapter 18A

(B) The public float requirement that applies specifically to Chapter 18A companies (i.e. at least HK$375 million market capitalisation must held by the public) no longer applies

✓ (C) The company is no longer required to be identified through the stock marker “B”

(D) All of the above



Q&A

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