2.3 BIOTECH COMPANIES

1. This chapter provides guidance for Biotech Companies [1] seeking a listing on the Exchange pursuant to MB Chapter 18A ("**applicant**") or listed under MB Chapter 18A. This chapter covers: (i) the factors that the Exchange will take into account when considering whether an applicant is eligible and suitable for listing under MB Chapter 18A; (ii) the disclosures to be included in a listing document of a Biotech[1] applicant; (iii) subscription and allocation of shares under the IPO; and (iv) post-listing matters. The examples and factors taken into account in assessing a Biotech Company's suitability for listing in this chapter are by no means exhaustive and they should not be construed as being definitive as the Exchange considers the specific facts and circumstances of each case. See also the "Listing of Biotech Companies" on the Exchange's website for further information.

Conditions for Listing

2. An applicant that does not satisfy any of the financial eligibility requirements under MB Rule 8.05 may apply for listing under MB Chapter 18A[2] if it:

   (i) Can demonstrate that it is both eligible and suitable for listing as a Biotech Company;

   (ii) Has an initial market capitalisation at the time of listing of at least HK$1.5 billion;

   (iii) Has been in operation in its current line of business for at least two financial years prior to listing under substantially the same management[3]; and

   (iv) Has sufficient working capital to cover at least 125% of the group's costs for at least 12 months from the date of publication of its listing document (after taking into account the proceeds of the applicant's initial listing).

Eligibility and Suitability for Listing

3. An applicant can demonstrate that it is both eligible and suitable for listing under MB Chapter 18A if it is a Biotech Company that has:

   (i) Developed at least one Core Product[1] beyond the concept stage;

   (ii) Been primarily engaged in R&D for the purpose of developing the Core Product and has continued such R&D during the 12 months prior to listing;

[1] As defined in MB Rule 18A.01.

[2] For the avoidance of doubt, a biotech company which is able to meet the financial eligibility requirements under MB Rule 8.05 cannot apply to list under MB Chapter 18A.

[3] A Biotech Company applying for listing under MB Chapter 18A with an accountants' report covering two financial years must apply for a certificate of exemption from the relevant disclosure requirements under the Third Schedule of C(WUMP)O.

(iii) As its primary reason for listing to raise funds for R&D to bring its Core Product to commercialisation;

(iv) Ownership of patents relating to the Core Product, including registered patent(s), patent application(s) and other IP rights; and

(v) At least one sophisticated investor that has made a meaningful third party investment into the Company at least six months before the date of the proposed listing (which must remain at IPO).

4. The Exchange will also review, among other things, any change in ownership of the applicant during the 12 months prior to the date of the listing application in assessing the suitability of the applicant for listing.

Requirement (i) – Developed at least one Core Product beyond the concept stage

5. The Exchange would consider a Regulated Product[4] to have been developed beyond the concept stage if it has met the milestones specified below for the relevant Biotech Product[4], including (i) pharmaceuticals (small molecule drugs)[5], (ii) biologics[5] and (iii) medical devices (including diagnostics), as categorised by the Competent Authority[4]. For a Core Product that is a drug, the applicant must also demonstrate that it has a pipeline of potential Biotech Products.

	"Clinical Trial"[6] milestone	**"Regulatory"[7] milestone**
Drug (including pharmaceuticals and biologics)	(i) Completed Phase I clinical trial for a new drug or at least one clinical trial for a drug based on a previously approved product or a biosimilar. *Illustrations* (i) *Combined clinical trials (e.g. Phase I/II)*	(a) Competent Authority has no objection to commencement of Phase II (or later) clinical trials[8]. *Illustrations* (a) *Regulatory assurance from the Competent Authority*

4 As defined in MB Rule 18A.01.

5 In this chapter, pharmaceuticals (small molecule drug) and/or biologics are collectively being referred to and classified under the "Drug" category as they are subject to the same "Clinical Trial" and "Regulatory" milestones requirements.

6 Any reference to a "clinical trial" refers to a clinical trial on human subjects required by the Competent Authority. If the Core Product of an applicant has obtained approval from a Competent Authority to commence a later phase clinical trial on the basis of the results of earlier clinical trials conducted under a non-Competent Authority or another jurisdiction, which were reviewed and accepted by the Competent Authority, such earlier completed clinical trials would also be taken into account. The Exchange will assess this on a case-by-case basis. **Annex A.11** sets out a listing decision on the eligibility of a Core Product with clinical trial conducted under a non-Competent Authority.

7 The Exchange may consider accepting the clinical trials of a Biotech Product that are conducted by other non-Competent Authority on a case-by-case basis with reference to whether (i) such authority can be regarded or authorised as a comparable authority as to the Competent Authorities; (ii) the approval process of that authority in relation to the Biotech Product in question is comparable to the process and expertise of a Competent Authority in terms of assessing the robustness of a Biotech Product; and (iii) there are precedent cases and the basis of other Biotech Products seeking such comparable authority for guidance or reference.

8 Regulatory assurance obtained through a range of communications with the Competent Authority, including interviews, clinical trial design consultations/discussions, materials presented to and/or reviewed by the Competent Authority with respect to the Biotech Product.

	"Clinical Trial"[6] milestone	"Regulatory"[7] milestone
	An applicant is considered to have met the "Clinical Trial" milestone if it has completed one phase of combined clinical trials if the Competent Authority considers that such phase is standalone and equivalent to at least completion of Phase I. (ii) *In-licensed or acquired Core Product* The applicant must have independently completed at least one clinical trial since in-licensing or acquisition of the Core Product[9].	An applicant may satisfy the "Regulatory" milestone by disclosing in the listing document either regulatory assurance obtained from, or material communications with, the Competent Authority showing that there is no objection for the applicant to commence the next phase of clinical trials and there are no exceptions or carve-outs to such "no objection"[10].
Medical Device (including diagnostic devices)	(i) Completed at least one clinical trial for a Class II or above medical device (under the classification criteria of the relevant Competent Authority or Authorised Institution[11]). *Illustrations* (i) *Possible classification downgrade* An applicant that is aware or has become aware, prior to listing, of a possible and imminent downgrade of the risk classification of the medical device to below Class II as a result of proposed or promulgated regulatory changes will not satisfy such milestone.	(a) Competent Authority or Authorised Institution has no objection to commencement of next phase of clinical trials, or sales of the device. *Illustrations* (a) See above guidance – (a) "Regulatory assurance from the Competent Authority". (b) *Medical device regulated under NMPA's "Green Path"* An applicant with a medical device that has had its registration application conditionally accepted under the Green Path by the NMPA is considered to have satisfied such milestone if only procedural and/or administrative matters remain outstanding and no

9 If the applicant has not completed any clinical trials, the Exchange will evaluate why it has not done so and whether substantive R&D and other work/process equivalent to the completion of one clinical trial has been performed.

10 An applicant that has commenced a later phase of clinical trials before completing the previous phase of clinical trials will also need to demonstrate that the Competent Authority is satisfied that the relevant endpoints for the earlier phase of clinical trial have been reached, and the applicant will not be required to modify the design of the earlier phase of clinical trial.

11 An institution, body or committee duly authorised or recognised by, or registered with, a Competent Authority or the European Commission to conduct, assess and supervise clinical trials in the relevant clinical fields. The Exchange may, at its discretion, recognise another institution, body or committee as an Authorised Institution on a case-by-case basis.

	"Clinical Trial"[6] milestone	"Regulatory"[7] milestone
		impediments to registration of the device are expected.[12]

Other Biotech Products

6. A Biotech Product that does not fall under the "Drug (including pharmaceuticals and biologics)" or "Medical Device" categories based on the classification of the Competent Authority will be considered as "Other Biotech Products". This will be assessed on a case-by-case basis with reference to all relevant facts and circumstances, including whether (a) it has been developed beyond the concept stage by reference to the developmental milestones in the table set out in paragraph 5 above; and (b) there is an appropriate framework or objective indicators to enable investors to make an informed investment decision[13]. A determination to accept such a listing application would be a modification that may only be made with the consent of the SFC under MB Rule 2.04.

Requirement (ii) – Primarily engaged in R&D for the purpose of developing the Core Product and continued such R&D during the 12 months prior to listing

7. An applicant may substantiate that it has met this requirement using historical R&D expenses incurred for the Core Product (including the underlying platform/technology). For in-licensed or acquired Core Product, the applicant should have achieved R&D progress independently since the in-licensing or acquisition of the Core Product, which may be demonstrated if the Core Product has (a) progressed from one phase to the next phase of clinical trials[14]; or (b) obtained registration approval from the Competent Authority.

Requirement (iii) – Primary reason for listing is to raise funds for R&D to bring the Core Product to commercialisation

8. The applicant must substantiate the need to raise funds, having regard to, among other things, historical R&D expenses and/or any post-approval R&D or other activities required by the Competent Authority. The listing document should include a breakdown of the IPO proceeds allocated to each indication of the Core Product and other products, with details of the applicant's future development plans (with expected timeline) for such products. A portion of listing proceeds may be allocated to:

For Core Product that is a medical device	(i)	Commercialisation of a Core Product that is a medical device, such as building new or expanding existing manufacturing facilities, establishing sales, marketing and medical teams, and providing relevant education and/or training to healthcare professionals. The applicant should justify such allocation of IPO proceeds with reference to the expected demand

[12] "Green Path" is a regulatory pathway under which the NMPA grants priority review and accelerated approval to selected medical device candidates. An applicant may demonstrate that there is no impediments to registration of the device under "Green Path" if it can prove that no registration application of the same product type/classification admitted to the "Green Path" has been rejected by the NMPA after submission. This will be assessed on a case-by-case basis.

[13] In the absence of any regulatory framework setting out external milestones or an objective framework to assess the development progress, market and clinical relevance of a product, the Exchange will consider, among other things, (i) the number, selection process and diversity of the test sampling population, and data from pre-clinical studies and clinical trials; (ii) timeframe and impediments to commercialisation; (iii) whether the pre-clinical and clinical results have been published in medical/scientific journals with a high impact factor; and/or (iv) guidance published by Competent Authorities on aspects of a comparable framework and/or objective indicators of "Other Biotech Products".

[14] The applicant must have conducted all R&D for the entire phase of the clinical trial, or where applicable, R&D work from pre-clinical to clinical stage which is required by the Competent Authority.

		for its Core Product and product candidates, and the utilisation rate of existing manufacturing facilities.
For Core Product with further development	(i)	Further development of a Core Product (whether or not it has been commercialised), such as (a) expanding its indications (provided that it will be regulated as the same product) and/or launching it in another regulated market; and (b) conducting further clinical trials or clinical evaluation required by the Competent Authority and/or the relevant authority of other regulated market(s).
For out-licensed or jointly developed Core Product	(i)	Further development of an out-licensed or a jointly developed Core Product, provided that the applicant can demonstrate that it has effective control over the R&D, manufacturing and commercialisation of the Core Product in the intended/targeted indications and jurisdictions where it has retained such rights.

Requirement (iv) – Registered patent(s), patent application(s) and/or IP in relation to its Core Product

9. The applicant must demonstrate that it has ownership of IP rights relating to the Core Product, and disclose in its listing document details of any patents granted and applied for in relation to the Core Product[15]. For in/out-licensed or jointly developed Core Product, the applicant must demonstrate that it owns and will own all IP independently developed by the applicant.

Requirement (v) – At least one sophisticated investor has made a meaningful investment at least six months before the date of the proposed listing and such investor will remain at IPO

10. This requirement is intended to demonstrate that a reasonable degree of market acceptance exists for the applicant's R&D and Biotech Product[16].

Sophisticated investor	(i)	Assessed on a case-by-case basis with reference to the investor's net assets/assets under management, and relevant investment experience, knowledge and expertise in the Biotech field. The following investors are generally considered as a sophisticated investor: (a) A fund dedicated to healthcare or Biotech, or that has a division/department that specialises/focuses on investments in the biopharmaceutical sector; (b) A major pharmaceutical/healthcare company, or a venture capital fund of a major pharmaceutical/healthcare company; and (c) An investor, investment fund or financial institution with minimum assets under management of HK$1 billion.

[15] An applicant may not be required to do so if it can demonstrate to the Exchange that such disclosure involves highly sensitive commercial information. In such case, the applicant must disclose in the listing document the reasons for not disclosing details of its patents.

[16] An applicant that is a spin-off from a parent company may not be required to comply with this requirement if it can demonstrate to the Exchange's satisfaction that there is such market acceptance (e.g. in the form of collaboration with other established R&D companies).

Meaningful investment	(i) Assessed on a case-by-case basis with reference to the nature, amount, size and timing of the investment. As an indicative benchmark, the following amounts will generally be considered as a "meaningful investment":

Market capitalisation of applicant (HK$)	1.5 to 3 billion	> 3 to 8 billion	> 8 billion
Investment amount (% of issued share capital of applicant at time of listing)	not less than 5%	not less than 3%	not less than 1%

Guidance on Disclosure

General principles

11. Given the business nature of a Biotech Company, there is uncertainty over whether it will be able to successfully commercialise its product candidates in the future. With significant retail participation, it is especially important that a Biotech Company considers the following, in addition to the general and overriding principles and disclosure guidance applicable to all applicants set out in **Chapter 3**, when drafting the listing document:

Present fair, balanced and accurate information to potential investors	(i) Clear and precise disclosures on, among other things, the applicant's business models and products should be provided without compromising the scientific accuracy. (ii) Specify in the "Definitions" section that the meaning of the Core Product is as ascribed to it in MB Chapter 18A and is the product for the purpose of satisfying the eligibility requirements under MB Chapter 18A and this chapter. (iii) Specify the full term of any abbreviation when it first appears in the "Summary" section, and explain it using plain language in the "Summary" section, with cross-references to the "Business" section for highly technical content or detailed description of science, such as the mechanism of action (MOA) and clinical data of a product. *Examples in plain language drafting in the "Summary" section* ✓ *The Core Product is a small molecule drug for the treatment of breast cancer.* ✓ *The Core Product is a blood-based diagnostic kit for cancer screening and detection.* × *The Core Product is a recombinant anti-PD-L1 humanised BsAb, being developed for the treatment of mCRC.* × *The Core Product is a proprietary, non-invasive, multiple target RNA test kit and the first and only molecular cancer screening and detection test in the world.*

	(iv) Disclosures that were considered misleading should be avoided, including where the applicant described itself as: (a) a "leader" of a particular market (e.g. oncology) even though it targets a very small subset of such market, or is one of the many treatments targeting the same indication; and (b) having "robust execution capabilities", "a proven track record" or "strong manufacturing facilities" even though none of its product candidates have been commercialised.
Avoid marketing/ emotional language and generic disclosures	(i) Disclosures should be specific and substantiated. Avoid the following descriptions for (a) the applicant's products: "novel", "top-notch", "leading", "blockbuster potentials", "state-of-the-art technologies", "first-in-class" and "unmet needs"; (b) clinical trials: "late-stage" and "near late-stage"; and (c) the background of pre-IPO investors: "completed a number of landmark investments" and "invested in high-quality middle-market companies". (ii) Statements that the applicant's products are likely to be more competitive, better or superior[17] should be scientifically specific (e.g. in terms of effectiveness and/or ease of administration of the product). (iii) Overly emotional language or aggrandised marketing statements should be avoided, e.g. "the goal is to give life a second chance".
Use diagrams, flowcharts and tables where appropriate	(i) Diagrams and/or flowcharts should be used to explain complex and technical matters, such as MOA of the Core Product and key products. (ii) Tables should be used to present extensive information (e.g. clinical data of the applicant's products, information of competing or peer products, material development milestones, pre-IPO investments, and IP rights).
Avoid excessive reliance on the industry consultant	(i) Directors should provide their views on scientific and technical aspects of the applicant's products and product candidates, and avoid excessive reliance on its advisers or consultants, e.g. the industry consultant.

Section-specific disclosures

"Summary" section

12. A Biotech Company should include the following information preferably in the following order:

Disclaimer	(i) A disclaimer that (a) the applicant is a biotechnology company seeking to list on the Main Board of the Exchange under MB Chapter 18A on the basis that it is unable to meet the requirements under MB Rule 8.05; (b) the Core Product(s) is/are the product(s) for the purpose of satisfying the eligibility requirements under MB Chapter 18A and this chapter, and (where applicable) is/are in the early stages of clinical development; and (c) the applicant may continue to incur substantial costs and expenses in relation to R&D activities for the Core

[17] For example, a product that is "first-in-class" may not necessarily be better or superior as it may simply mean that it has a new MOA, but not with proven and better safety or efficacy profile than its peer products with the same indication.

		Product(s), and the Core Product(s) may not be successfully developed or marketed.
Introduction	(i)	Introductory paragraph with at least the following information: (a) the year in which the applicant was established and its areas of medical focus; (b) number of Core Products and product candidates in the applicant's pipeline; and (c) brief description of the Core Products, including the intended indication(s) and targeted stage of disease. *Examples* ✓ *We are a biopharmaceutical company engaged in the R&D, manufacturing and commercialisation of drugs for treating cancer since our incorporation in 2018. We have self-developed one Core Product (with the treatment of breast cancer as its leading indication) and in-licensed two products from third parties (namely Collaborator A and Collaborator B). We are also developing ten clinical stage drug candidates in the pipeline.* × *We are a fully integrated, innovative biopharmaceutical company committed to the R&D, manufacturing and commercialisation of novel drugs to address significant unmet medical needs in China and globally. Empowered by our fully fledged innovation capabilities and a powerful and productive cross-functional management system, we are dedicated to the development of differentiated treatments to improve the existing standard of care. Notably, we are a pioneer and leading developer of immune drugs worldwide, with over a decade of accumulated experience in immune drugs development. Our collaboration with Collaborator A to develop up to ten pre-clinical drugs is the largest biopharmaceutical licensing deal in terms of deal value to date secured by a China-based company according to our Industry Consultant.*
	(ii)	An applicant that is a spin-off from a listed parent company should disclose such fact.
Pipeline chart	(i)	Pipeline chart that is disclosed upfront and categorised by product (rather than intended indications), including, for each product, (a) whether it is internally-developed, acquired or in-licensed; and (b) dates of key regulatory milestones achieved or to be achieved in each jurisdiction that the product is being developed. Avoid presenting favourable possibilities as certain or as more probable than is likely to be the case.
	(ii)	For drugs, type of therapy (i.e. monotherapy or combination therapy) and intended applications (e.g. third-line treatment for a given cancer), and for medical devices, its risk classification.

Concise overview of the applicant and its Biotech Products	(i) A description of each Core Product and key product, including (a) regulatory approvals required and/or obtained in each jurisdiction that the product is being developed, and the status of clinical trials (with start/end dates); (b) addressable market and competitive landscape (see guidance in paragraph 14 below); (c) competitive advantages and/or limitations of the applicant's product (e.g. higher efficacy or ease of administration); and (d) if applicable, plans to out-license the product. (ii) R&D capabilities (e.g. composition of R&D team, total R&D expenses for all products and for the Core Product, respectively and, if any, outsourced R&D), IP owned by the applicant (e.g. granted/pending patents), manufacturing capabilities (which should correspond to its products development stage and not be overstated), and commercialisation strategy (see guidance in paragraph 16 below). (iii) Summary of key risks of the applicant and its products (as disclosed in the "Risk Factors" section). (iv) Valuation of the applicant (including total amount and number of rounds of financing from pre-IPO investors, and the identity of the sophisticated investor and its shareholding in the applicant). (v) Cash burn rate (see guidance in paragraph 17 below) and key financial indicators relevant to the applicant's stage of development. (vi) Recent developments.

"Risk Factors" section

13. A Biotech Company should include the following risks specific to its products, the markets in which the applicant plans to commercialise its products, operations and industry, and arranged the risk factors in the following order:

Risks relating to the applicant's products and the markets in which it plans to commercialise its products	(i) Higher risks faced by an applicant with pipeline products in pre-clinical development stage. (ii) Difficulties in recruiting suitable patients for clinical trials for rare disease indications. (iii) Details of major adverse events, including their actual and potential impact on the applicant (e.g. legal proceedings related to IP of the applicant's products, negative publicity on the applicant's products, clinical holds[18] on similar products, and unfavourable guidelines, recommendations or study results). (iv) High levels of competition in the market of the applicant's product.

[18] A clinical hold is an order issued by a Competent Authority to the trial sponsor to delay a proposed clinical trial or to suspend an ongoing trial.

Risks relating to the applicant's operations and industry	(i) Failure to successfully develop or obtain regulatory approval for the applicant's pipeline products. (ii) Infringement and/or expiry of IP rights, including challenges by third parties over in-licensed IP which may affect the applicant's use of such IP, or material restrictions on the applicant's right to develop and commercialise in/out-licensed products (including termination events). (iii) Product liability in respect of jointly developed products or products supplied by third parties. (iv) Acceptability of clinical trial results across different jurisdictions. (v) Inclusion of the applicant's products in a reimbursement scheme may significantly drive down its prices.

"Industry Overview" section

14. A Biotech Company should include the following information:

Addressable market	(i) Drivers and barriers to entry in the industry and markets targeted by the applicant. (ii) For each of the intended indications of the Core Products and key products[19]: (a) Standard treatment protocol for the disease, including details of clinical guideline recommendations and the safety and efficacy of each treatment option. (b) In each of the applicant's targeted markets, the size and growth rate of the addressable market, and the prevalence, incidence rate and patient diagnostic rate of the disease. (c) Target patient population for each intended application (e.g. third-line treatment for a given cancer), including recurrence rate of the disease. (iii) Key underlying quantitative and qualitative assumptions and bases used to derive the estimated addressable market size, the reasonableness of which should be reviewed by the sponsors.
Competitive landscape	(i) Products and product candidates that compete or may potentially compete with each of the Core Products and key products in the targeted therapeutic areas, including: (a) Name and approval date/development status, expiration dates of key IP rights, route of administration, type of technology used,

[19] For example, an applicant with a Core Product that is a third-line treatment for a disease should disclose the overall market for the disease, and then the market for third-line treatment for the disease to reflect the limited pool of patients that the product targets.

	intended/targeted indications and intended applications (e.g. third-line treatment for a given cancer), and safety and efficacy. (b) If commercialised, annual treatment cost, market share (including similar products launched in other jurisdictions and other factors that affect pricing in the target market), and whether it is included in any reimbursement scheme (if so, details such as the percentage of reimbursement).

"History and Development" section

15. A Biotech Company should include the following information:

Achievement of key milestones	(i) Dates of key development milestones relating to the Core Product (e.g. commencement/completion of clinical trials and registrational approval).
Sophisticated investors	(i) Background of the investor (including, where applicable, its ultimate beneficial owner). (ii) Assets under management or net assets, track record in the relevant biotech or healthcare industries, and investment expertise of the general partners or ultimate beneficial owner (where applicable).
Valuation	(i) Explain the reasons for any material changes in valuation between each round of financing by reference to key developments of products, achievement of business/product milestones and material regulatory/policy changes that are relevant to the applicant.

"Business" section

16. A Biotech Company should include the following information:

Business model	(i) Whether the applicant's products/product candidates are internally-developed, acquired, in/out-licensed, or a combination of these.
Details of each Core Product and key product	(i) Description of the product, including its MOA[20] and whether the product was internally developed, in-licensed or acquired. (ii) Timeline of regulatory milestones leading up to the commercialisation of the product (e.g. dates of IND filing, commencement/completion of clinical trials and registration filing and details of additional R&D to be conducted[21]), and, if applicable, key differences between the primary and other targeted markets.

[20] For a drug product, modality (including whether it is a "me too" or "me-better" drug) and type of therapy (i.e. monotherapy or combination therapy). For an orphan drug or innovative drug, basis for qualification of drug candidate under a particular regulatory pathway and exemptions granted by the relevant Competent Authority.

[21] The applicant should also disclose whether or not such R&D is required by the Competent Authority.

	(iii) Relevant and up-to-date preclinical/clinical data and explanations for any delay, suspension or premature conclusion of clinical trials (such as due to adverse events), including: (a) Clinical trial design, such as (1) whether the trials are randomised, controlled or double-blinded, (2) whether it is the current standard of care or recommended modality according to national and international guidelines, and (3) the risk of being requested by the Competent Authority to modify the design of such clinical trial and the potential impact on the registration timeline. (b) The sponsor and the results of the clinical trial, such as (1) primary and secondary endpoints, (2) planned and actual number of patients enrolled, (3) inclusion and exclusion criteria, and (4) qualitative and quantitative description on the occurrence, nature and severity of adverse events (AE), serious adverse events (SAE), and treatment emergent adverse events (TEAE). If none, a negative statement in this regard. (iv) Addressable market and the competitive landscape of the intended/targeted indications of the product (see guidance in paragraph 14 above). (v) R&D expenses attributable to the Core Product, which are broken down by development stage (together with an explanation of any material fluctuations during the track record period), and expressed as a percentage of the applicant's total operating expenses (i.e. R&D costs, selling and marketing expenses and administrative expenses).
Technology platforms	(i) Brief description of the technology platform used to discover and develop product candidates and, if any, the key IP rights owned by the applicant in respect of such platform[22].
Material terms of in/out-licensing arrangements	(i) Counterparty (e.g. background, operational scale and independence). (ii) Scope of licence (e.g. indications and geographical restrictions). (iii) Development stage of product at time of in/out-licensing[23], and R&D activities that have been and will be conducted by the applicant after the in/out-licensing (including actual and anticipated R&D expenses and how it will be funded). (iv) Key rights and obligations of the applicant and the licensor (e.g. milestone/royalty payments and their triggering events[24], termination events, dispute resolution mechanism and ownership of IP rights[25]).

[22] Such disclosures should not be more prominent than those relating to the Core Product and key non-Core Products.
[23] Include any adverse information on the scientific validity or safety of the product.
[24] If product is in-licensed, whether any licensing payments will be paid out of IPO proceeds.
[25] The applicant should set out the parties' respective rights to own foreground or self-developed IP (e.g. clinical trial results, improvements).

Collaborative development and research agreements	(i) Collaborative partner (e.g. background, operational scale and independence[26]), collaboration period and schedule. (ii) Key rights and obligations of the parties (e.g. sub-licensing rights, milestones, profit and cost sharing arrangements and ownership of IP rights, termination events and dispute resolution mechanism). (iii) Joint steering committee (e.g. composition of committee, and its roles and responsibilities). (iv) Arrangements for combination therapies (e.g. responsibility for purchases/supplies of drugs, liabilities of each party under the arrangement (particularly, who will bear any product liability arising from a combination drug supplied by third party), ownership of the development and commercialisation rights of the jointly-developed product, and possible side effects of combined treatment).
Commercialisation	(i) Commercialisation strategy, which should be tailored to the development stage of the applicant's products, including: (a) Strategies implemented or to be implemented to achieve market acceptance and adoption (e.g. how to on board doctors and/or become recognised under clinical guidelines). (b) Manufacturing capabilities (e.g. building/expanding manufacturing capacities and obtaining ISO certifications). (c) Expected pricing and affordability of product (e.g. inclusion in any insurance reimbursement schemes or centralised/volume-based procurement and pricing schemes will likely reduce the pricing of the product, and how this would impact the revenue and profitability of the product going forward). (d) Profitability of product (i.e. whether the Company is expected to capture a considerable return from sales of the product). (e) Distributorship model (see **Chapter 4.5** for further guidance), and compliance with local law (e.g. the Two-Invoice System Rules in the PRC). (f) Potential cannibalisation of products with overlapping indications or similar therapeutic areas. (g) For commercialised products, the revenue model and a breakdown of revenue by product/service during the track record period and information on the products sold and background of the customers.

[26] For research institutions or CROs engaged by the applicant, additional information including their calibre and experience, and ownership of sub-licensing rights, as well as the applicant's selection criteria and oversight over them. For a principal investigator ("**PI**") who is in charge of or supervising an applicant's clinical trial and concurrently has additional role(s) in such applicant, additional information and basis including (i) the PI's specific functions and additional role(s) in the applicant, and the terms of compensation, if any; and (ii) whether such compensation to the PI may impair the integrity of the applicant's clinical trial.

R&D capabilities	(i) Existing operations in R&D, and the collective expertise and experience of key management and technical staff, including their identities, qualifications, areas of specialisation and relevant work experience. (ii) Whether all key R&D personnel involved in the development of the Core Product remained employed by the applicant during the track record period and as at the LPD, and if not, the impact of their departure. (iii) If the Core Product is in-licensed, whether (a) the applicant relies on any R&D conducted (or continues to be conducted) by the licensor; and (b) any personnel from the licensor is employed by the applicant.
IP rights	(i) Patents granted and applied for in relation to the Core Product and key products, including the identity of the inventor and owner and the aspects of such products protected by the patents (e.g. whether key technology or product packing). (ii) Whether a freedom-to-operate (FTO) analysis has been conducted (including details of any soon-to-expire patents, and actual breaches of IP rights and its impact on the applicant's operations), and a positive statement by the Directors on whether it has infringed any IP rights of third parties.
ESG	(i) Social risks associated with inappropriate use of products (e.g. non-prescribed use of labelled drugs) and the effects of product pricing on access to healthcare, and internal control policies to mitigate such risks. (ii) Measures to protect patient data and comply with privacy laws and regulations, and to monitor how contracted parties (e.g. CROs, CDMOs) handle, use, store, treat and dispose of hazardous material and waste. (iii) See **Chapter 4.3** for guidance on CG and ESG matters.

"Financial Information" section

17. A Biotech Company should include the following information:

Revenue	(i) Any revenue generated during the track record period should be broken down by (a) Core Product, (b) other products, and (c) other services (e.g. CRO services) provided by the applicant.
Cash burn rate	(i) Cash burn rate (i.e. period of time the applicant can maintain its operations with its existing cash balance and IPO proceeds), which should be based on reasonable assumptions and representative of the applicant's future operations (e.g. changes in R&D and other expenses consistent with the stage of development of its products).

	(ii) When the applicant expects to raise the next round of financing after IPO taking into account the expected IPO proceeds and the cash burn rate.
Breakdown of R&D expenses attributable to the Core Product	(i) R&D expenses attributable to the Core Product and/or the underlying technology, which are broken down by development stage (together with an explanation of any fluctuations during the track record period), and expressed as a percentage of the applicant's total operating expenses (i.e. R&D costs, selling and marketing expenses and administrative expenses).

Subscription and allocation of shares under the IPO

18. A Biotech Company seeking to list under MB Chapter 18A is expected to have significant ongoing funding needs in order to develop its Core Product to commercialisation. As existing investors are likely to have subscribed for shares in the Biotech Company on the basis of their confidence in its prospects, they may wish to be able to continue to participate in future fundraisings (including the IPO) to prevent dilution to their shareholding.

Existing shareholder of a Biotech Company may participate in IPO	(i) An existing shareholder and/or its close associates may, provided that the applicant complies with MB Rules 8.08(1) and 18A.07[27], participate in the IPO of the Biotech Company. An existing shareholder must subscribe for shares in the IPO as a cornerstone investor if it holds 10% more of the shares in the applicant prior to IPO, but may subscribe either as a cornerstone investor or placee if it holds less than 10% of the shares in the applicant prior to IPO. The applicant and its sponsors must confirm that no preference in allocation was given to the existing shareholder; and in the case of subscription as cornerstone investor, that no preference was given other than the preferential treatment of assured entitlement at the IPO price and the terms are substantially the same as other cornerstone investors. (ii) An existing shareholder with a contractual anti-dilution right may exercise such right and subscribe for shares in the IPO in accordance with the existing requirements in **Chapter 4.15**.
Core connected person of the Biotech Company	(i) The applicant must apply for, and the Exchange will ordinarily grant, a related MB Rule 9.09 waiver, if allocations of shares of a Biotech Company will be made to a core connected person.
Clawback mechanism	(i) The Exchange will consider any proposed modification to the minimum public subscription requirement in an IPO under MB Practice Note 18 on a case-by-case basis. The applicant must provide compelling reasons for such modification, as a Biotech Company carries additional potential risks to retail investors.

[27] For the avoidance of doubt, the Existing Shareholders Conditions set out in paragraph 12 of **Chapter 4.15** do not apply to Biotech Companies.

Biotech Company with a WVR Structure

19. The Exchange presumes a MB Chapter 18A applicant fully meeting the requirements under MB Chapter 18A to have satisfied (i) the Innovative Company Requirements and shall qualify as an innovative company for the purpose of MB Chapter 8A; and (ii) the external validation requirement under **Chapter 2.2**. However, such applicant seeking to list with a WVR structure under MB Chapter 8A shall remain subject to all other applicable requirements under **Chapter 2.2** (including the lock-up requirement) and MB Chapter 8A.

Post-listing Matters

20. A Biotech listed issuer is not required to meet the profit test in MB Rule 8.05(1), the market capitalisation/revenue/cash flow test in MB Rule 8.05(2) or the market capitalisation/revenue test in MB Rule 8.05(3) at the time of listing, the application of the revenue ratio and the profit ratio to any proposed transaction that these issuers propose to undertake may not be appropriate.

21. The Exchange may exercise its discretion under MB Rule 14.20 to disregard the revenue ratio and profit ratio for a Biotech listed issuer and consider other relevant indicators of size, including industry specific tests suggested by the issuer, on a case-by-case basis. The listed issuer must provide appropriate alternative tests to the Exchange for consideration.