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Biotech start-ups filing for HKEX IPOs

Insights on risk, countermeasures for survival and growth

The Conclusions to the New Board Concept Paper published by the Hong Kong Stock Exchange ("the Exchange") on 15 December 2017 and the subsequent *Consultation Paper on a Listing Regime for Companies from Emerging and Innovative Sectors* published on 23 February 2018 propose amendments to the existing rules to allow the listing of:

- Biotech companies that do not meet any of the financial eligibility tests of the Main Board
- High-growth and innovative companies with weighted voting right (WVR) structures
- Qualifying Issuers seeking a secondary listing on the Exchange.

On 24 April 2018, the Exchange announced the new rules and added three new chapters in the Main Board Listing Rules to facilitate the listing of companies from emerging and innovative sectors as mentioned above. These new rules, which took effect on 30 April 2018, allow emerging and innovative companies seeking to list under the new regime to submit formal applications from that date.

Following this reform, on 8 May 2018, Ascletis Pharma, a Hangzhou-based biotech company which is close to commercialising a new hepatitis C drug, became the first biotech company without profit or revenue to file for an IPO on the Exchange.

Although listing opportunities are now open to high-risk, high-reward biotech companies, the following concerns have also inevitably started to surface:

- Without a proven track record of profit or revenue, and since R&D can have unpredictable outcomes, some biotech firms may not succeed and could cause shareholders to lose part or all their investment.
- Biotech stocks generally trade based on drug data, including clinical trial failures, competition or regulatory obstacles. This poses great challenges to management, as they are not able to ensure positive outcomes of clinical trials and control what regulatory requirements will be announced by the regulator or what their competitors are doing.

- Inherent risk factors and typical features of biotech companies include the following:
  - Clinical development involves a lengthy and expensive process with uncertain outcomes, and results of earlier studies and trials may not be indicative of future clinical trial results.
  - Undesirable side effects could halt clinical development, and consequently delay regulatory approval and commercialisation.
  - Failure to develop promising pipelines, as well as long product development timelines could jeopardise market opportunities or lead to missed opportunities.
  - Third parties – such as clinical research organisations (CRO), contract manufacturing organisations (CMO), site management organisations (SMO), licensing and collaborative partners, and sales and marketing agencies – may fail to fulfil their contractual, performance and delivery obligations.
  - These companies are vulnerable to data or information security breaches, including cyber threats, and malicious attacks to acquire valuable, sensitive and confidential data such as clinical trial data, personal patient data, patent information, trade secrets, and technical know-how.
  - Companies are subject to healthcare laws and regulations in different jurisdictions, including those related to anti-kickback, anti-bribery and corruption, false claims, transparency, health information privacy and security, and others. Therefore, any misconduct or other improper activities by employees and third parties can result in penalties, reputational damage, and legal or financial consequences for the company. Some examples of related laws and regulations include the *Law of the People's Republic of China against Unfair Competition*, *Cybersecurity Law of the People's Republic of China, Draft Law for Personal Data Protection,* and *Administrative Measures for Scientific and Technical Data*.
  - Obtaining drug regulatory approvals from the FDA, SDA (formerly known as the CFDA), EMA or other equivalent authority can be time-consuming, and significant resources are needed to ensure ongoing regulatory compliance and continued regulatory review.
  - Failure to protect intellectual property (IP) rights – particularly regarding patents, trade secrets, technical know-how, and confidential and proprietary information – can jeopardise competitive position. There is also the risk of legal proceedings related to potential infringement of other companies' IP rights.

It is crucial that biotech firms seeking to list on the Exchange deploy an operating model that optimises their chances of survival and sustainable growth, ultimately protecting and safeguarding the interests of public investors.

In view of the risk factors highlighted above, we believe that companies should focus on adopting the following as part of their IPO preparation. These should also serve as the relevant due diligence focus from the sponsor's perspective:

R&D, clinical testing and commercialisation

The end-to-end R&D, clinical trials and commercialisation process is highly complex, and involves sophisticated scientific and technical capabilities. It is therefore critical to implement and maintain comprehensive clinical governance that covers anything from feasibility research, preclinical studies, clinical trials and manufacturing, to the supply or distribution of drugs or medical devices.

In addition, biotech companies, CROs, CMOs and their appointed distributors must establish relevant systems and procedures to ensure they are complying with Good Clinical Practice (GCP), Good Manufacturing Practice (GMP) and Good Supply Practice (GSP):

- GCP includes regulations and guidelines enforced by the SDA and comparable foreign regulatory authorities for products in clinical development.
- GMP and GSP are guidelines and regulations which are issued from time to time pursuant to the Drug Administration Law of the People's Republic of China.
- Both GMP and GSP aim to minimise the risks of contamination, cross-contamination, and errors during the manufacturing process, and ensure that pharmaceutical distribution enterprises distribute pharmaceutical products that comply with the guidelines and regulations to safeguard quality.

Data management and information security

The clinical data fraud and loss of clinical trial data from completed or future clinical trials can result in failure or delays in regulatory approval efforts, and significantly increase costs to recover or reproduce data. Changes or modifications made to the data must be tracked, monitored, reviewed and authorised to prevent data being tampered with. Any inappropriate disclosure of confidential or proprietary information can incur liability, and product development and commercialisation can be delayed.

Biotech companies and/or CRO are expected to establish good data management systems; an overarching information security policy governing information classification; and a process to collect, record, process, analyse, store, protect, maintain, overwrite and dispose of critical clinical development and trial data, as well as personal patient data, patent information, trade secrets and technical know-how.

Reliance on third parties

If partners or third parties such as CROs, CMOs, sales & marketing agents and distributors fail to fulfil their obligations, or if they make any decisions to terminate these agreements, this can negatively impact biotech companies' ability to grow, obtain regulatory approval for products and commercialise products. Biotech companies need to establish a comprehensive third-party selection process; create co-sourcing and outsourcing policies and procedures that cover pre-qualification evaluation; assess their expertise and capabilities; and effectively manage third parties. This is to ensure that the performance of contractual duties and delivery of results meet prescribed standards.

Ongoing performance monitoring mechanisms should be in place, and appropriate key performance indicators (KPI) should be adopted to measure their performance effectively, e.g. timelines, milestones, and costs incurred during product development or clinical trials. Agreements entered into must be vetted by seasoned legal counsel to protect biotech companies' interests. This is especially true when desired clinical development timelines are not met by the CRO, or there are disputes over the leakage of any proprietary information related to drug applicants by collaborative partners.

Government regulations and compliance

The time required to obtain approval from the SDA and comparable foreign authorities is unpredictable, but typically takes many years following the commencement of clinical trials. It also depends on numerous factors, including the discretion of regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product's clinical development, and may vary in different jurisdictions.

Biotech companies need to establish and maintain a complete register or depository of prevailing laws and regulations that are applicable to them. They should also conduct proactive and retrospective checks to ensure that any regulatory changes are captured in the depository, and where relevant or applicable, the impact of the change is reviewed and addressed accordingly in a timely manner.

With reference to potential misconduct, or fraudulent or illegal activities, a preventive compliance programme should be put in place, including:

- The development and distribution of written standards of conduct, as well as written policies, procedures and protocols that showcase the company's commitment to compliance
- The designation of a compliance officer and/or other incumbent charged with developing, operating and monitoring the compliance programme
- The development and implementation of regular compliance training and education for all employees
- A programme that enables and protects whistle-blowers, and allows staff to voice concerns
- Auditing and continuous monitoring to identify problems, issues, internal control breakdowns, breaches or non-compliance
- The development of policies and procedures to investigate identified cases of non-compliance or misconduct.

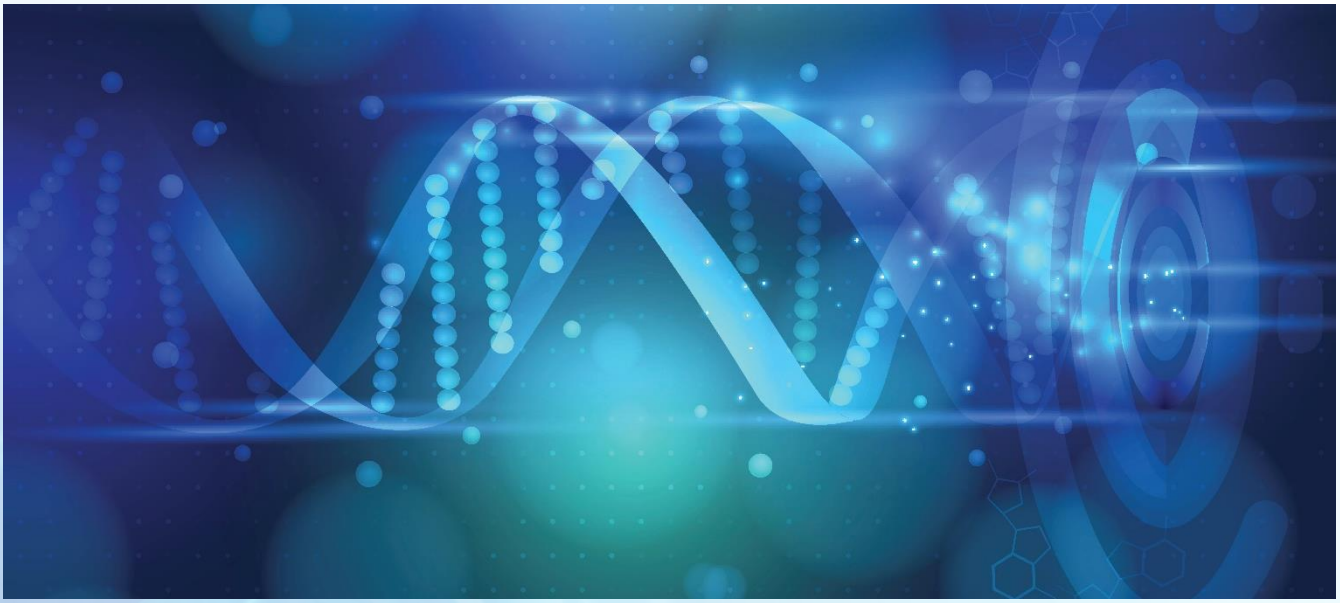
Intellectual property

To succeed, biotech businesses rely heavily on their ability to obtain and maintain patent protection for their products. There is no guarantee that the patent applications will be granted. Further, if the company's intellectual property rights are ever challenged, there is the possibility that they may lose their exclusive patent rights, and may be prevented from developing and/or commercialising their products. Biotech companies therefore need to have competent professionals to oversee, review and manage all patent filing and application, and proactively perform searches or due diligence to prevent any breaches of others' IP rights which could lead to significant legal and financial consequences. An in-house database or software program should be established to capture, update and maintain all potential patents (in progress of filing) and patents granted. Patent expiry and other patent statuses should also be monitored closely.

In accordance with China's *Measures for the Implementation of Data Protection for Pharmaceutical Tests (Interim) (Draft Guidance)*, eligible drug applicants must submit their application for clinical trial data protection to the SDA along with their application for a marketing licence, and specify the protection tenure and reasons for applying for such protection. Once this regulation is in effect, eligible biotech companies will have extra assurance that their proprietary data (IP) and competitive position are protected.

Key personnel

Biotech companies are highly dependent on experienced scientists, analysts, researchers, medical personnel, key managers and executives. If they are not successful in attracting and retaining highly qualified personnel, they may not be able to successfully implement the business strategy. Besides conventional employee incentive programmes, companies should also look into talent acquisition, development and retention programmes, and identifying high-potential candidates or successors as part of the succession planning. Additional or separate confidentiality, non-compete and conflict of interest agreements should be signed between biotech companies and key personnel, especially for high-risk groups such as R&D, clinical development and trial teams.



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