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McKenzie.**

Guide to IPOs for Biotech and Pharma Companies

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Introduction

Biotech and pharma companies undertaking capital raisings can approach the world's capital markets in various ways. Through an initial public offering (IPO), listing either in its home jurisdiction or cross-border, biotech and pharma companies can access major global finance hubs and capital from a deep pool of investors around the world.

A company may have a choice to list either via a traditional IPO or, alternatively, via a business combination with a special purpose acquisition company (SPAC), which is already listed. This is also known as a de-SPAC transaction. A detailed comparison of some of the features and requirements applicable to de-SPACs in a number of jurisdictions across the regions is available in [Baker McKenzie's Global SPACs Guide](#).

The biotech and pharma industry has an increasing choice of stock exchanges as companies consider factors such as the ability to meet listing criteria, the regulatory environment for biotech and pharma companies, location of industry peers, their preferred shareholding structure, revenue-generating stage, access to an investor base, and ongoing requirements and costs.

An IPO can help a company raise its profile with customers, suppliers and the media, as well as providing it with an opportunity to improve internal systems and controls, and increase the general operating efficiency of the business as it prepares to comply with the relevant regulatory scheme for public companies.

Key business attributes of an IPO-ready company:

- Leading market position, supported by clear and achievable strategic goals for revenue growth and profitability.
- Attractive financial model, with an established quarterly forecast process and reliable financial reporting controls.
- Appropriately skilled, experienced and proven management team.
- Robust corporate governance framework.

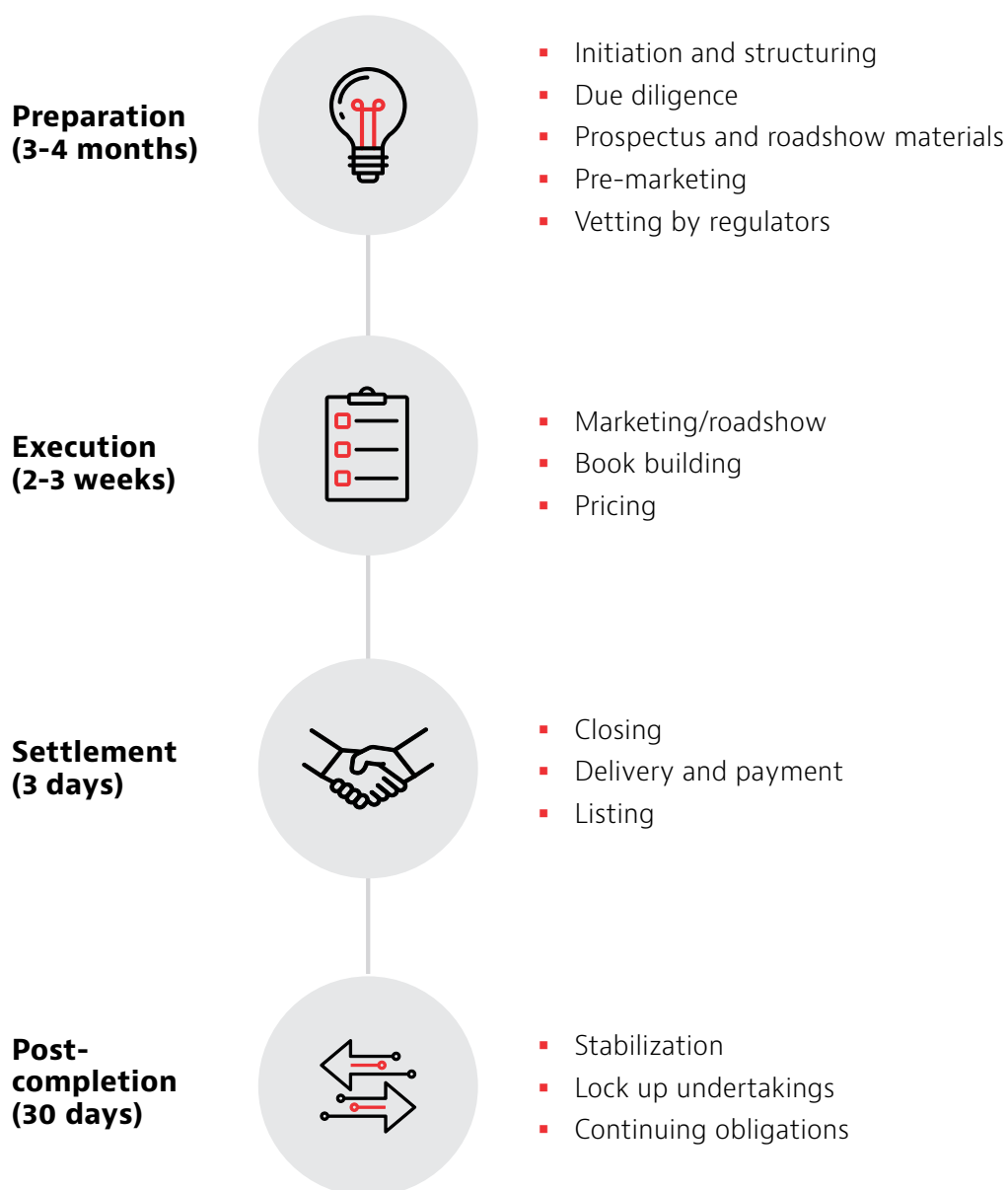
This guide will provide you with:

- An overview of the key stages of the process and an indicative timeline.
- A who's who as regards the IPO deal team.
- Practical tips to help you achieve a successful IPO.
- Important considerations to bear in mind when choosing a listing venue.
- Key issues for biotech and pharma companies to consider when preparing for an IPO.

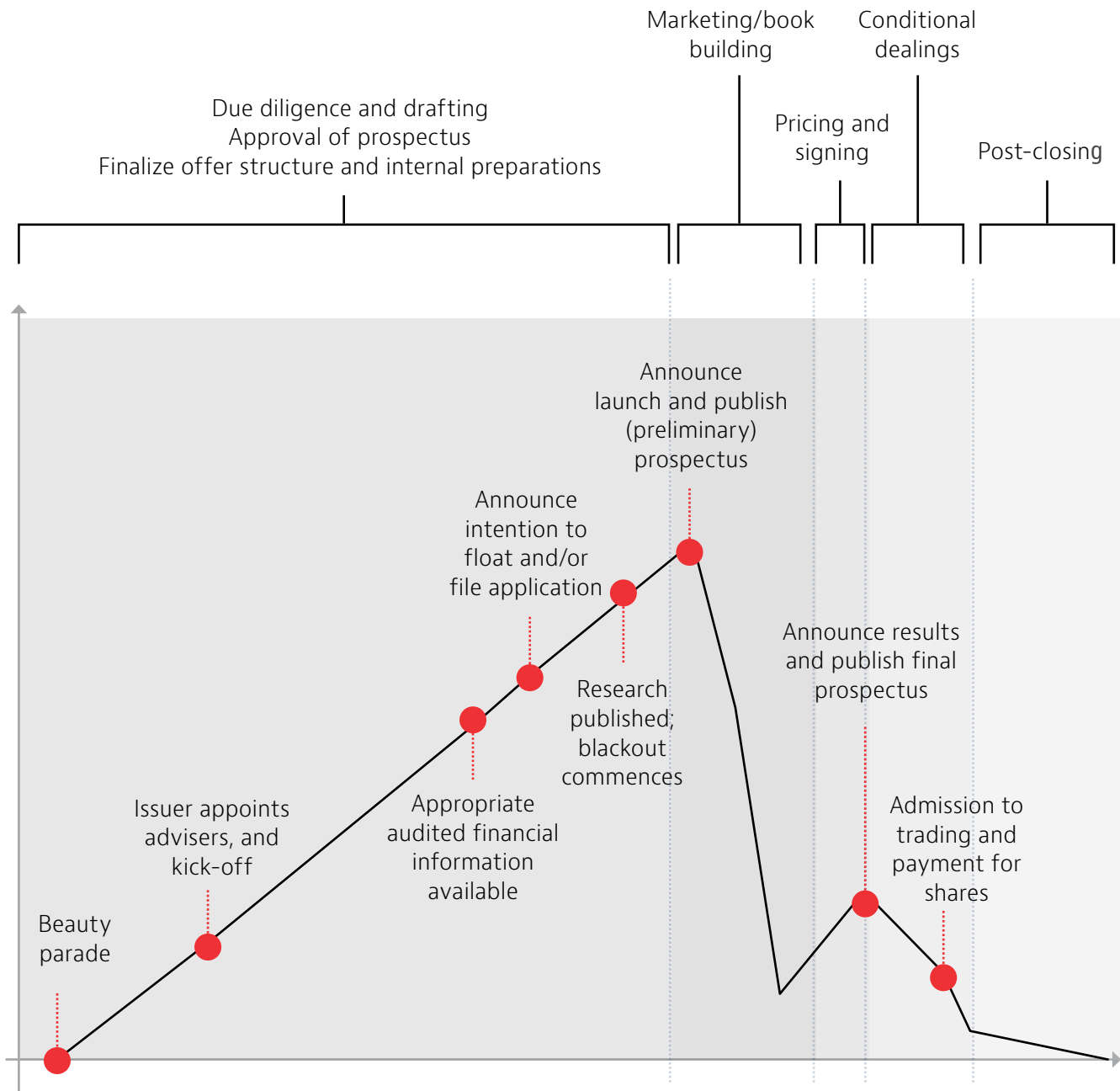
If you have any questions, whether to clarify points or to initiate or progress a discussion on a future IPO for your company, please do not hesitate to get in touch with your [Baker McKenzie contacts](#).

Key Stages and Indicative Timeline

While no two IPOs are ever identical, set out below is a general overview of the tasks that must be undertaken and their place in the IPO timetable.



Due to the bespoke elements of every business, we would advise consulting your [Baker McKenzie contacts](#) to discuss how these tasks and the timing indicated might need to be tailored for your company.

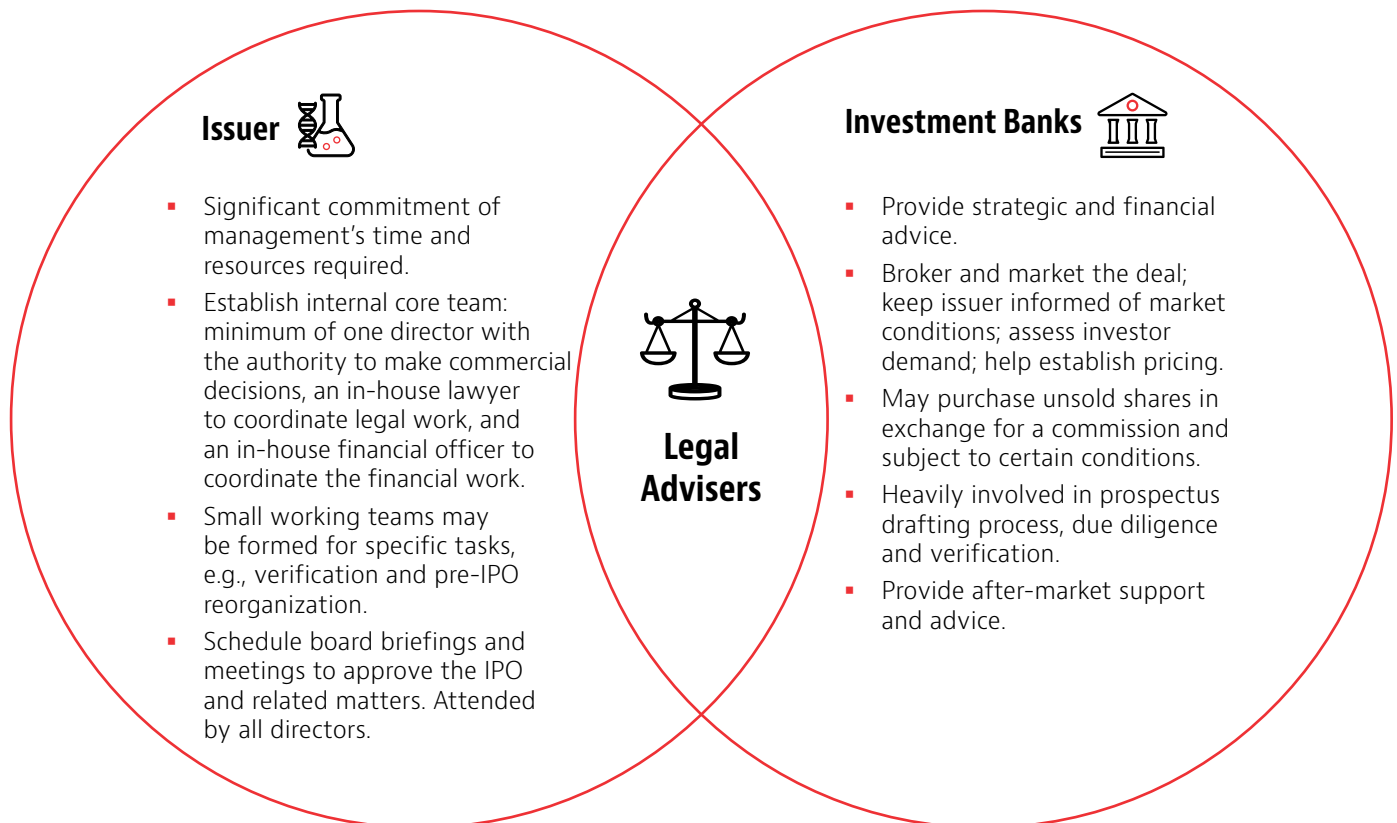


Note: Mountain represents estimated level of assistance by advisers

The IPO Team

The IPO process involves many working parties. Establishing the right team of professionals that can navigate the complex interplay of all parties involved is critical for a successful IPO.

Core Deal Team



Unless restricted from selling by virtue of also being part of the management of the company, a key employee, a controlling shareholder or a pre-IPO investor, an IPO also gives the company's existing shareholders an opportunity to sell and thereby realize some or all of their investment in the company.

Marrying the two sides of the core deal team are the legal advisers

We, at Baker McKenzie, are well versed in assuming the crucial coordinating role that lawyers take in any IPO transaction. We have great strength and depth of experience in conducting legal due diligence, preparing prospectuses, issuing carefully considered legal opinions and negotiating key documentation, such as underwriting agreements. Due to our presence in 45 locations worldwide,

we are also able to boast a hugely beneficial, established profile and working relationship with more regulators and stock exchanges than any other global law firm.

Since the issuer will still have to run its business during the IPO process, this level of support can be crucial to significantly reducing the burden on management.

Other Parties

Two other key parties in any IPO are the accountants and the regulators.

Accounting firm

- Audit and report on the issuer's historical financials and pro forma financial results.
- Conduct financial and tax due diligence.
- Advise on internal controls, provide comfort letters related to the audits performed on historical statements and on the adequacy of working capital.



Regulators

- Act as the main legal authorities that regulate the IPO process and requirements.
- Typically involves at least one financial regulator, stock exchange or both.



Further additional parties that may be involved in the IPO deal team include:

- Technical experts, such as intellectual property valuers, industry experts, internal control experts and property valuers.
- Communications consultant to assist the company in public relations surrounding the IPO.
- Depository/registry responsible for managing the shareholder register.
- Receiving banks that deal with any proceeds received from retail investors.
- Independent financial advisers who can provide advice on business plan, financial modelling, investment case and business valuation.

Eight Practical Tips for a Successful Listing

Regardless of the jurisdictions and listing venues considered for a capital raising, a company should always aim to start to prepare for an IPO at least **12 to 24 months in advance**. It can then increase its chances of success by following these practical tips:

- 1** Prioritize your goals for the listing. These can include, for example, access to a broader investor base, greater visibility among biotech and pharma industry peers or another goal.
- 2** Consider the likelihood that a particular exchange can meet those goals.
- 3** Seek an exchange where investors and other market participants are familiar with companies in the biotech and pharma industry and understand the value of industry products and services.
- 4** Analyze the trading price and volume of comparable biotech and pharma stocks on the exchanges being considered.
- 5** Understand the liability risks of listing on a particular exchange.
- 6** Choose financial, legal and accounting advisers that have biotech and pharma industry knowledge and on-the-ground experience with local and international aspects of listing on a particular exchange.
- 7** Critique any timetable provided by an adviser, exchange or other third party to confirm that it is realistic.
- 8** Quantify all initial and ongoing costs associated with a particular exchange. These can include, for example, initial listing fees, annual fees, ongoing disclosure costs and other compliance-related costs.

Stock Exchanges

Over the past few years the majority of listings by biotech and pharma companies were on their home market.

In many cases, this could be attributed to the close ties that those issuers had established with their home countries, culturally, economically, and in terms of their fundamental infrastructure. However, the appeal of cross-border listings is growing as biotech and pharma companies increasingly consider factors that might motivate them to go public outside their home market, many of which we consider below.

In any event, when considering an IPO, it is crucial to establish what the main goals of the IPO are. This will guide the company to assess which stock exchange and listing option will best help it to meet these goals. Detailed summaries of the principal attributes and listing requirements of more than 40 listing venues around the world can be found in Baker McKenzie's [Cross-Border Listings Guide](#).



Core Considerations

We recommend that any decision concerning the potential location of your IPO be based upon these core considerations.

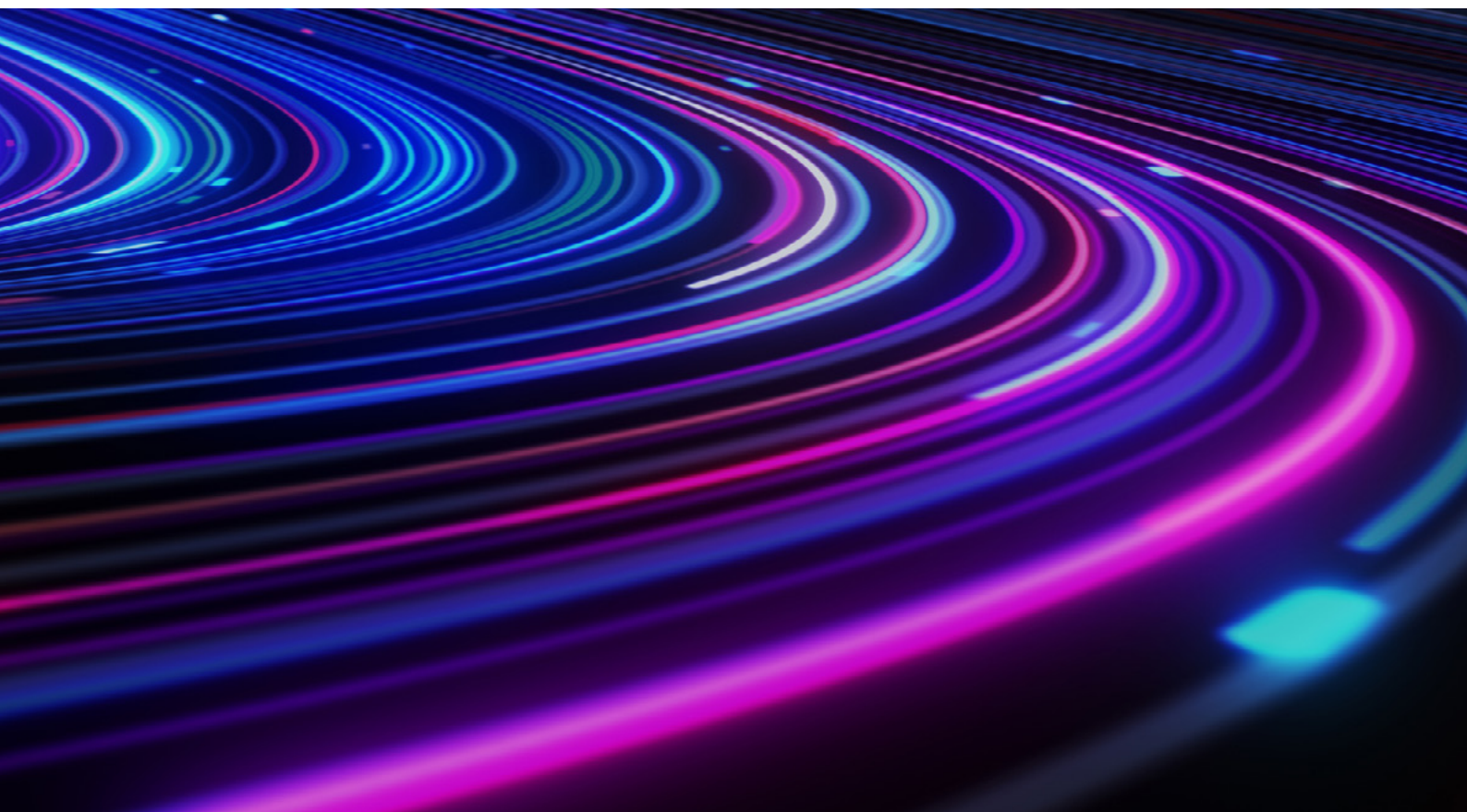
Strategic goals

Increased brand visibility - A biotech or pharma company may find it helpful to list or raise capital in the same jurisdiction in which its major markets or customers are located, in order to increase visibility and brand recognition. A cross-border capital raising can also increase worldwide prominence.

Participation in indices - An index provides investors with clear and independent benchmarking of stocks, sectors and the market as a whole. This also creates the basis for portfolio trading by active and passive investors.

Liquidity - Some exchanges are better placed to deal with large capital raisings, some offer a more efficient means to raise smaller amounts of capital, while some offer more flexible requirements for already-listed companies to raise additional capital.

Share class structure - A company may want to retain a certain share class structure. Each jurisdiction has its own requirements for different class structures and there may be a listing regime tailored for biotech and pharma companies in certain jurisdictions.





Factors affecting valuation

Analyst and investor expertise -

Well-informed research analysts and investors can help drive a successful capital raising and a strong aftermarket. Some exchanges also have market participants with an acute understanding of comparable biotech and pharma companies.

Investor appetite - Investors' appetite for the quality, stage of development and risks associated with a particular novel drug, therapy, or other chemical or biological technology may differ in each market.

Number and value of peer listings -

Biotech and pharma companies concentrating on particular services, therapies or products may be more prevalent on certain exchanges or in certain jurisdictions, which may assist investors and enable analysts to provide more accurate valuations and provide a benchmark for an issuer's share price in the aftermarket. The concentration of peer companies should also be considered when choosing between jurisdictions and listing venues as it can help provide a benchmark for an issuer's share price in the aftermarket.

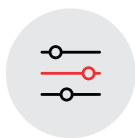


Costs

Initial flotation and ongoing compliance costs -

In addition to the variable listing costs of each stock exchange, the company

will need to assess the costs of ongoing compliance, such as financial reporting, which may vary significantly between jurisdictions.



Regulatory Environment

Initial listing requirements -

Selecting the most suitable jurisdiction requires careful assessment of a company's ability to meet the relevant listing requirements, whether relating to financial track record or assets, minimum number of shareholders, public float, minimum share price or capitalization.

For example, an early-stage company in the product development phase may be more likely to satisfy requirements on exchanges that offer asset test financial requirements, rather than requiring a track record of profitability. In addition, prospectus disclosures covering matters such as the regulatory approval process for a therapy, service or product could require significant time and costs to satisfy.

Regulatory environment -

Investors active on certain exchanges may be more comfortable with, and place higher valuations on, companies that operate in certain countries, depending on the level of industry regulation applicable to biotech and pharma companies in that country.

Corporate governance - It is important for a biotech or pharma company to determine early on whether it will be able to meet all the ongoing regulatory obligations for its chosen exchange, remembering that such requirements may be more stringent on certain exchanges or in certain jurisdictions than others.

Key Issues for Biotech and Pharma Companies

Biotech and pharma companies should be aware of the following key issues often encountered by industry peers undertaking the process of capital raising and listing on a stock exchange. In particular, listings of biotech companies, which reflect the convergence of healthcare and technology, raise additional issues that need to be addressed as part of any listing.

Restructuring prior to listing

The business and corporate structure of a biotech or pharma company's operating group is an important issue to consider at the onset.

In some jurisdictions, investors may favor biotech and pharma companies that are narrowly focused on a key therapy, service or product over those that offer a wide range. For example, a number of established biotech and pharma companies have spun-off key operating divisions in recent years as a means of attracting investors. Investor preferences such as these – which may shift over time – can factor into a company's structuring decisions early on in the listing process.

There may also be foreign ownership restrictions that impact on the pre-IPO restructuring plans and legal advice should be taken at an early stage.

Likewise, some jurisdictions may have more regulatory approval requirements than others in implementing a restructuring.

For corporate governance, tax or marketing reasons, a biotech or pharma enterprise may decide to re-incorporate out of its home jurisdiction to another location.

Companies that wish to take advantage of more flexible governance requirements or a different tax structure will often explore a re-incorporation in conjunction with an initial listing.

IP protection

The pathway for a pharma company obtaining intellectual property protection in the form of a patent for a new drug or therapy is well trodden, but obtaining intellectual property protection has historically been a challenging business for a biotech company.

However, in many jurisdictions, technology software and computer programs can be protected by both copyright law and patent law. In some cases, disclosure of an invention too soon may complicate patent protection.

Accordingly, it will be important for companies with novel technology to ensure that at least an application for

any technology invention is made before publicly disclosing key information as part of any IPO.

A biotech or pharma company should also ensure that it maintains its intellectual property portfolio and continues to monitor and address any infringement risks as an ongoing governance matter.

Privacy and data protection

Data is extremely important to many biotech and pharma companies, with there being an exponentially increasing number of ways in which such organizations can collect, store, use and potentially disclose personal or sensitive information.

Given the importance of such data and the fact that respective jurisdictions will have their own implementation and enforcement systems in place, pre-listing efforts must focus on identifying the locations where data is collected and/or held, and on ensuring that existing business processes are compliant with the relevant data protection and privacy laws. Consideration should also be given to identifying any barriers to compliance

with privacy or data protection regimes in new target markets.

Data protection and privacy regimes typically require the company to secure personal data from unauthorized loss or disclosure. As a result, IT security arrangements are another important element to be examined and tested, such that full and accurate disclosure can be provided as part of any listing.

Due diligence

The due diligence investigation for biotech and pharma companies is typically more specialized than for most other companies, with a heavy focus on technology and intellectual property rights, protections and controls.

An enterprise that relies on new science, products or technologies in an ever-changing industry landscape will only be as valuable as its “pipeline” of products and technologies, which is driven by what rights the company has to use the science, product or technology.

If intellectual property rights in a product or technology cannot be properly secured, there is a risk that the company will be limited in its ability to exploit the business in the way it contemplates, and potentially its ability to prevent competitors from directly copying the product/service, or reproducing the concept in a slightly altered form. It is therefore critical for such an enterprise to be as certain as possible that it (i) actually has all of the rights it claims to have, (ii) has protected as much of its intellectual property as it possibly can with patents, trademarks, copyrights and confidentiality agreements, and (iii) has determined as best it can that its intended use of the intellectual property is not subject to third party infringement claims.

Furthermore, it can be essential to have those individuals who helped create the products or technologies - whether they are employees, consultants or others - assign any ownership rights they have in those products and technologies to the company.

As already touched on, given the importance of data to the core value of most biotech and pharma companies, due diligence efforts must also focus on identifying the locations where data is collected and/or held, and on ensuring that existing business processes are compliant with data protection and privacy laws.

These efforts should extend to identifying any barriers to compliance with privacy or data protection regimes in new target markets and to the adequacy of IT security

arrangements, given that data protection and privacy regimes typically require the company to secure personal data from unauthorized loss or disclosure.

In addition to these issues, due diligence investigations for biotech and pharma companies often focus on other areas particularly relevant to the industry, such as:

- Having an established research and development pipeline, and timelines for new product or service offerings.
- Applicable export control restrictions, and whether import/export licenses are already in place for core products and services.
- Reliance on third party products or licences.
- Licensing and distribution models for core products.
- Financial statement matters such as revenue recognition and impairment issues.
- Plans to retain and expand the company’s customer base.
- Status of clinical trials.
- Governmental permits.
- Certificates, licenses and product registrations.
- Privacy and data protection compliance.
- Reporting of medical side effects.
- Advertising restrictions.
- Directions, labelling and packaging requirements.
- Safety and credibility ratings.

Understanding the exposure to potential changes in laws, regulations and governmental policies can be critical. In addition to analyzing those changes in the context of both general compliance and revenues, a governmental entity itself may be a biotech or pharma company’s major customer, either directly or indirectly.

Key employees

Identifying key employees is important not only for obtaining assignments of intellectual property, as described above, but also for securing services that may be necessary for the ongoing success of the company.

Employees who drive innovation and product development are essential to securing the R&D pipeline, which can maintain the competitiveness of the company. Employees with knowledge of legacy systems can also be important, particularly if current systems and applications are built on a platform

written in an older coding language that may be unfamiliar to newer employees.

It is therefore important for issuers to devise appropriate incentive plans to retain talent, whether before or after listing.

Describing the business

Determining how best to explain the company's business model or a particular application, service or product can be challenging for an early-stage biotech or pharma company.

The key prospectus drafting challenge is to provide explanations that are accurate and complete, while satisfying the requirements of both investors and regulators for cogent, easily understood information.

One of the most challenging aspects for a biotech or pharma company to undertake in the prospectus is how best to explain a novel science, technology or product that it is seeking to exploit, including the indications for which the science, technology or product is being developed, and any difficulties in distributing and marketing it.

It can be equally challenging for a biotech company to clearly articulate the complexity of the technology that is underpinning its business case and the

effect of such technology on the delivery of healthcare solutions.

Biotech and pharma companies should also carefully consider the key risks associated with their business model, particularly those focused on novel therapies, technologies or approaches. A proper explanation of key business risks specific to the company, and how the company is managing and preparing for those risks, is an important aspect of prospectus disclosure.

Formulating a strong equity story is also important for marketing and book building purposes. The company will often need to work with the investment banks for this exercise.

Business risks of particular relevance to biotech and pharma companies include:

- Ownership and control of intellectual property assets.
- Reliance on a set of core products or services, or failure to develop and successfully launch new products or services.
- Liquidity for future operations and product development.
- Fast-paced changes in the competitive landscape.
- Exposure to cyber-risks that could lead to disclosure or theft of proprietary information or customer data.
- Compliance with the regulatory regimes applicable to the business in existing markets, and potential regulatory hurdles in target markets.
- Resourcing and reliance on key employees.

Clinical trials and regulatory review

Many products or therapies in the biotech and pharma field must pass through a regulatory review process or screening before the product or therapy can be marketed and sold.

Government-regulated clinical trials are important in many jurisdictions in respect of novel drugs and therapies. The registration of devices is often required for importation, exportation and sale even though the functionality of the device may not have a specific health or therapeutic application.

It is therefore critical for a biotech or pharma company to have the guidance of regulatory counsel to help the company

explain in its prospectus disclosure what the relevant requirements are, where the company is in terms of the application, testing or approval/registration process, research methodology for the clinical trials and what an approximate timeline might be to bring the product to market.

The anticipated timing of the release of a particular drug, therapy or device is critical to determining the enterprise's value as of the date of its IPO.

Enhanced prospectus disclosures

In certain jurisdictions biotech and pharma companies should be mindful that they may be required to meet market expectation to provide enhanced prospectus disclosure.

Additional disclosure may be required in respect of some or all of the following:

- Information on strategic objectives.
- Operating licenses.
- Details of any laboratory research and development as well as the status and expected timeline for development and production.
- Collective expertise, experience of key technical staff and the extent to which the business is dependent on key individuals.
- Employees engaged in quality control.
- New technology substitution and systems failures.
- Product and technology commercialization delays.
- Current and expected market competitors.
- Any dependence on a limited number of customers or suppliers.
- Compliance with all applicable laws (particularly privacy and data protection laws).
- Claims, litigation or material adverse findings in investigations in respect of liability from usage of products and/or services.
- Manufacturing and inventory control policies.
- Collaborative development and research agreements.
- Reimbursements by public healthcare systems or private investors.
- Any assets necessary for production that it does not own.

Disclosure obligations after listing

Once listed, biotech and pharma companies can face challenges in meeting ongoing disclosure obligations to keep the market appropriately informed.

In some jurisdictions, a reporting code or similar guidance may exist to help listed biotech and pharma companies adopt certain industry-specific reporting practices. These can include disclosures covering matters such as research and development, clinical trials, medical devices, regulatory approvals, intellectual property rights, and licensing. Ongoing reporting on the status of clinical trials is a particularly challenging area often

encountered, with a number of biotech and pharma companies having been fined by securities regulators for not promptly or properly disclosing the results of clinical trials.

It is important for a biotech or pharma company to determine early on whether it will be able to meet all ongoing regulatory obligations for a chosen exchange.

Assets and income mix

The assets and income mix for certain biotech and pharma companies could affect the degree of regulatory and reporting compliance required.

In some jurisdictions, by virtue of their asset and income mix, biotech and pharma companies focused on research or in the development stage of operations may be subject to additional levels of securities regulation. In other jurisdictions, these companies may be subject to additional reporting requirements after listing. These additional reporting requirements may include providing more regular reports on cash flow and expenditures, as well as

reporting on commitments to implement business objectives.

Certain jurisdictions may require biotech and pharma companies to have detailed and specific plans to maintain substantive business operations and to update investors on their use of proceeds. This is to ensure the issuer's suitability for listing, as companies that are cash-heavy may be at risk of being regarded as a shell company.

Baker McKenzie Contacts

The most appropriate contacts within Baker McKenzie for inquiries about prospective listings are as follows:



Adam Farlow
Global Chair, Capital Markets
London
adam.farlow@bakermckenzie.com



Joakim Falkner
EMEA Chair, Capital Markets
Stockholm
joakim.falkner@bakermckenzie.com



Christina Lee
AP Chair, Capital Markets
Hong Kong
christina.lee@bakermckenzie.com



Mark Mandel
North America Chair,
Capital Markets
New York
mark.mandel@bakermckenzie.com



Fernando Castro
Latin America Chair,
Capital Markets
Santiago
fernando.castro@bakermckenzie.com

For transactions involving healthcare companies, we can also draw on the expertise and experience of our globally recognized healthcare and life sciences team:



Vanina Caniza
Global Chair,
Healthcare & Life Sciences
Buenos Aires
vanina.caniza@bakermckenzie.com



Elisabeth White
Healthcare & Life Sciences
Sydney
elisabeth.white@bakermckenzie.com



Jane Hobson
Healthcare & Life Sciences
London
jane.hobson@bakermckenzie.com



Randall Sunberg
Healthcare & Life Sciences
New York
Randall.Sunberg@bakermckenzie.com



Cecilia Pastor
Healthcare & Life Sciences
Madrid
cecilia.pastor@bakermckenzie.com



Henrique Frizzo*
Healthcare & Life Sciences
Sao Paulo
Henrique.Frizzo@trenchrossi.com



Roel Meers
Healthcare & Life Sciences
Brussels
roel.meers@bakermckenzie.com

* Trench Rossi Watanabe and Baker McKenzie have executed a strategic cooperation agreement for consulting on foreign law

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