

**Baker  
McKenzie.**

# **GUIDE TO IPOs**

**FOR BIOPHARMA AND HEALTHTECH COMPANIES**



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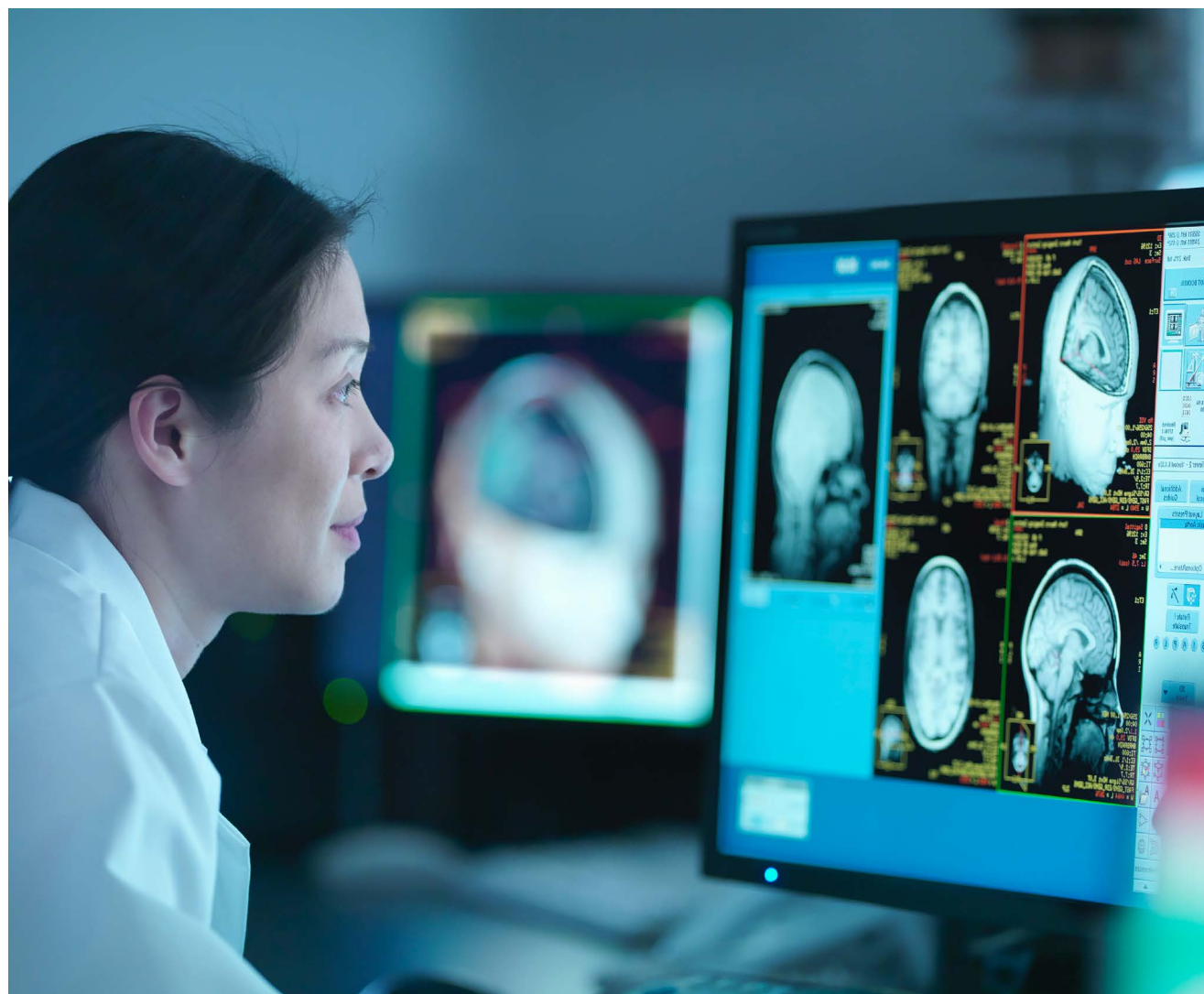
# Introduction

Biopharma and healthtech companies undertaking capital raisings can approach the world's capital markets in various ways. Through an initial public offering, listing either in its home jurisdiction or cross-border, a biopharma and healthtech company can access major global finance hubs and capital from a deep pool of investors around the world. In addition, 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 for the business to conform with the 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.**



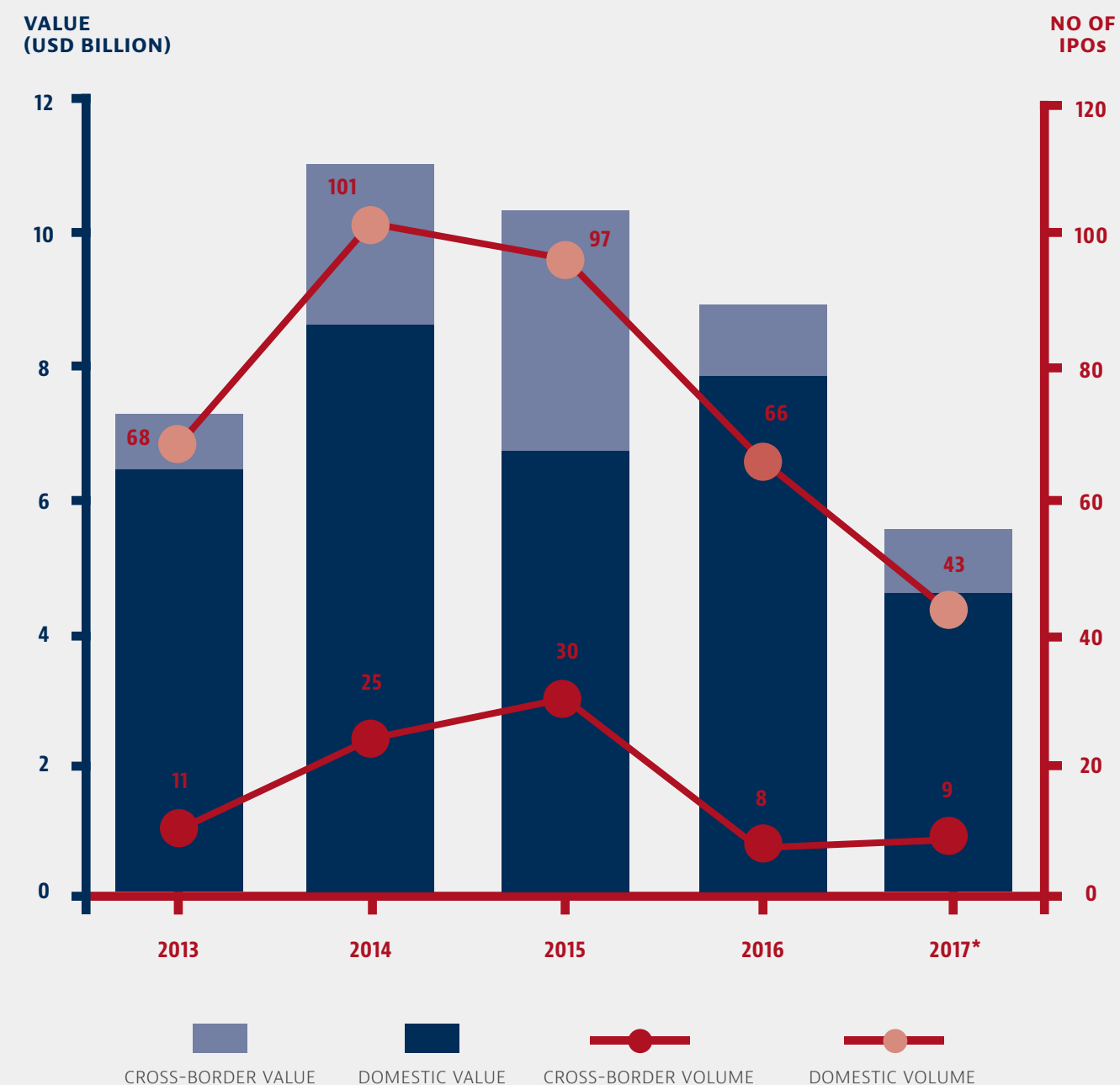


This guide will provide you with:

- 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.
- Key considerations to bear in mind when choosing your listing venue.
- Key issues and listing requirements that should be considered when preparing for an IPO.

If, during or after, your review of this guide, 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**.

## IPOs in the Biopharma and Healthtech Industry

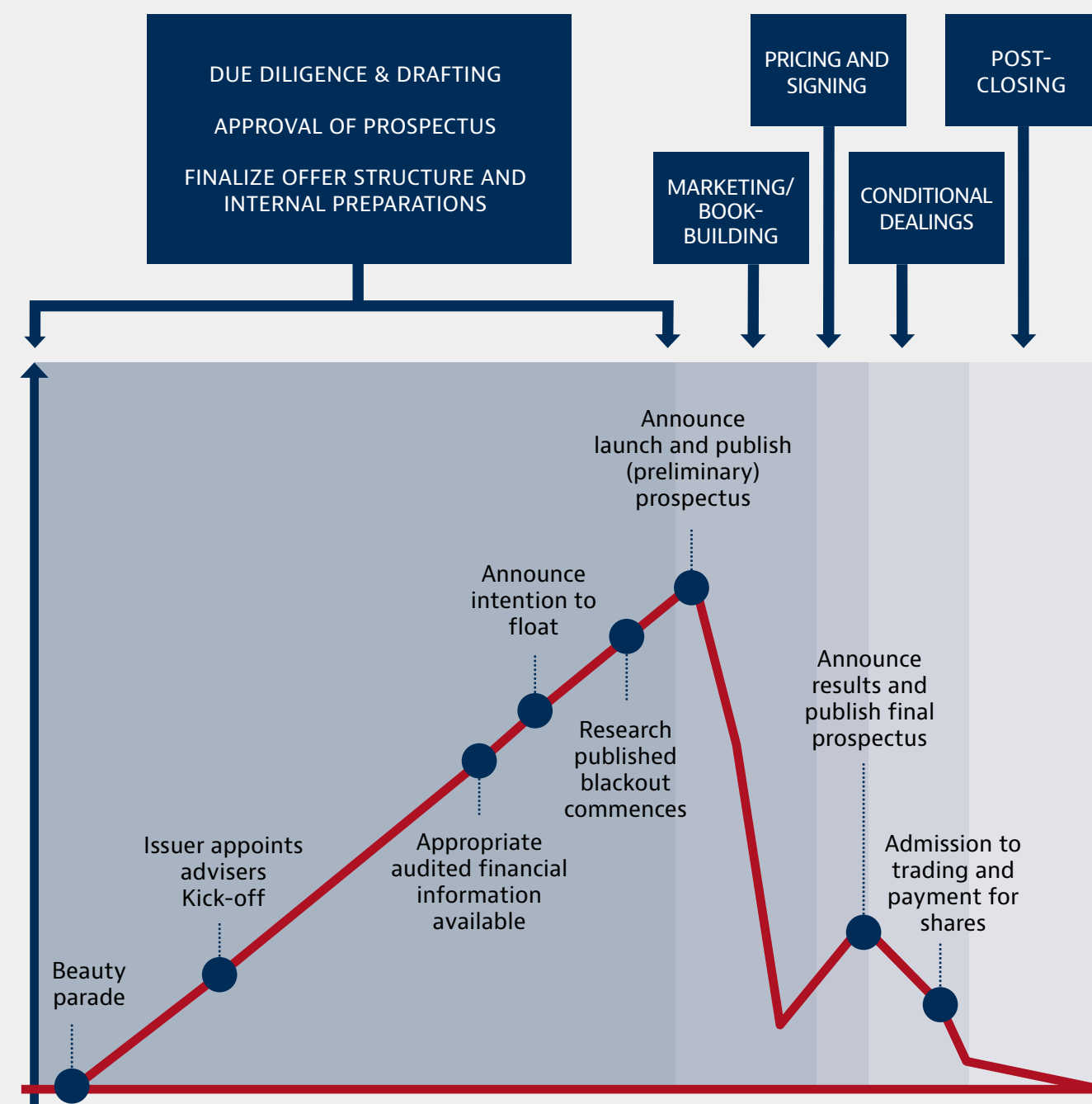


\*2017 data as of 10 October 2017

# Key Stages and Indicative Timeline



While no two IPOs are ever identical, you can see above a general overview of the tasks that must be undertaken and to the right, 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.

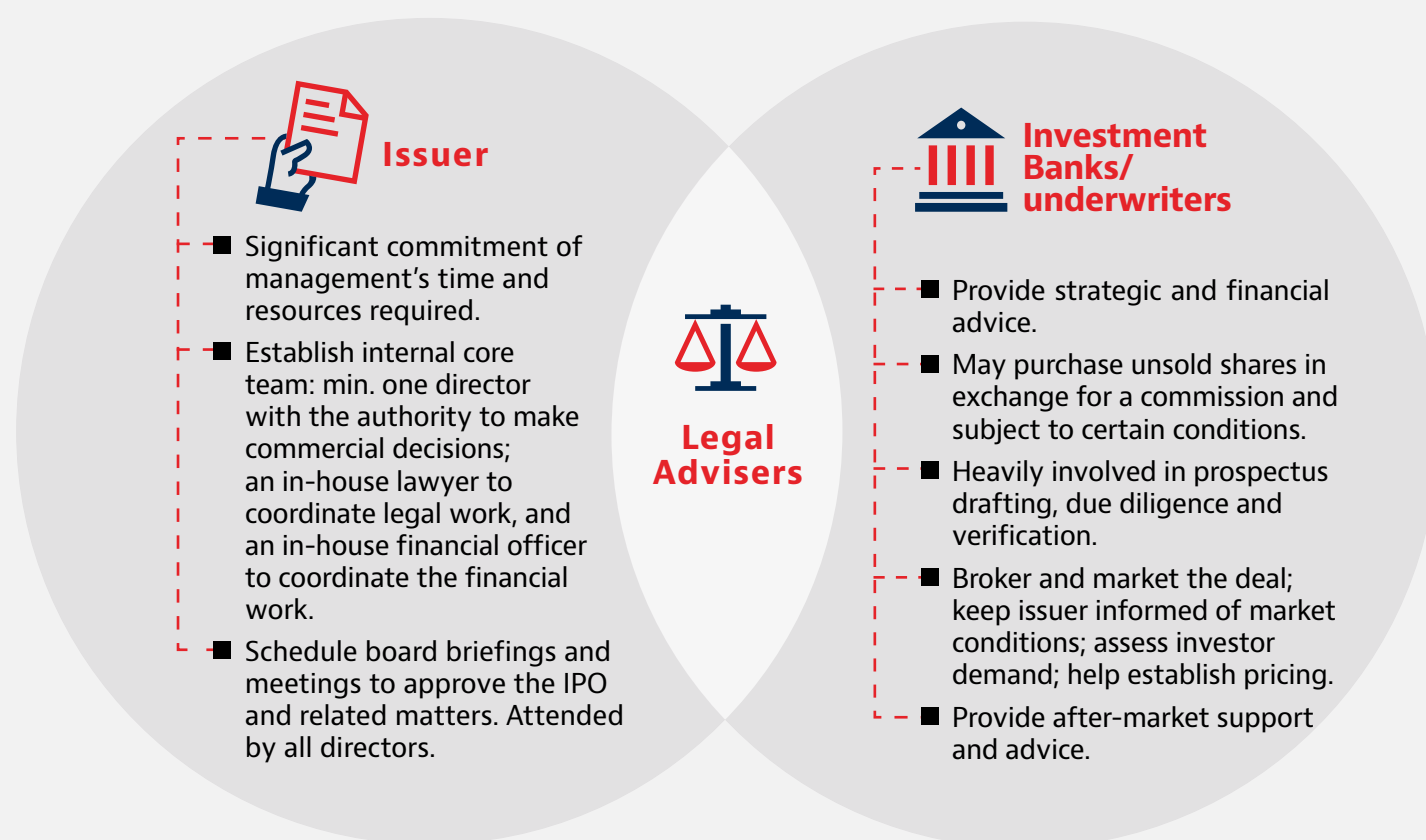


\* Mountain represents estimated level of assistance by advisors

# 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 or a key employee, 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 a great strength and depth of experience in conducting legal due diligence, preparing prospectuses, issuing carefully considered legal opinions and negotiating key documentations, such as underwriting agreements. Due to our presence in 47 countries 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 regulator.

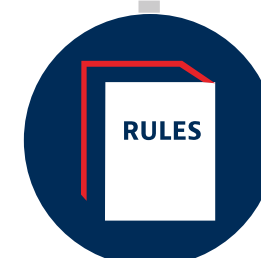
### Accounting firm

- 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

The regulators act as the main legal authorities that regulate the IPO process and requirements, and will, depending on jurisdiction, typically comprise at least one financial regulator, stock exchange or both.



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

- **Other technical experts, such as intellectual property valuers.**
- **Communications consultant to assist the company in public relations surrounding the IPO.**
- **Depository/registry responsible for managing the shareholder register.**
- **Independent financial advisors, 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:

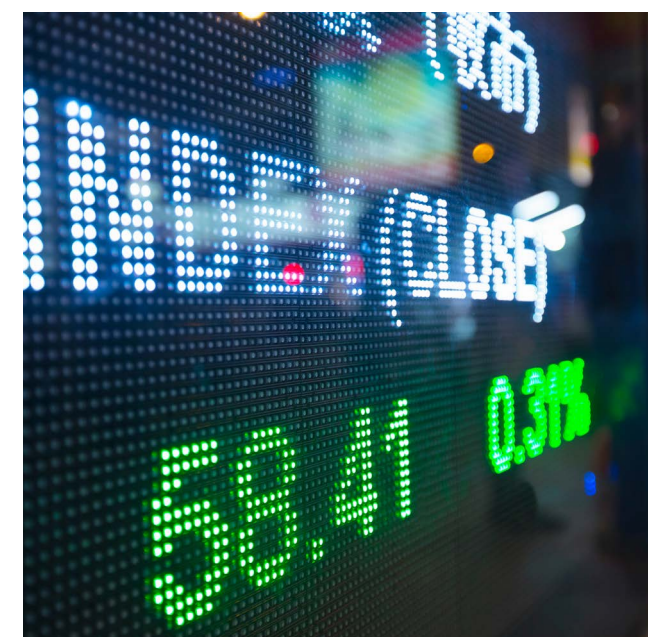
- 1 Prioritize your goals for the listing. These can include, for example, access to a broader investor base, greater visibility among biopharma and healthtech industry peers or another goal.
- 2 Consider the likelihood that a particular exchange can meet those goals.
- 3 Seek an exchange where investors and other market participants are familiar with other companies in the biopharma and healthtech industry and understand the value of your science.
- 4 Analyze the trading price and volume of comparable biopharma and healthtech 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 biopharma and healthtech 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 80% of listings by biopharma and healthtech companies were on their home market between 2014 and 2017.\* 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 biopharma and healthtech companies increasingly consider factors that might motivate them to go public outside their home market, many of which we cover in detail below.

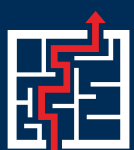
In any event, when considering an IPO, it is crucial to establish what the main goals of the IPO are. This will guide the company in assessing which stock exchange and listing option will best help it to meet



these goals. Detailed summaries of the principal attributes and listing requirements of 47 listing venues around the world can be found in Baker McKenzie's **Cross-Border Listings Handbook**.

\*Data sourced from Thomson Reuters, as of 4 December 2017.

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



### STRATEGIC GOALS

**Increased Brand Visibility** - A biopharma and healthtech company may find it helpful to list or raise capital in the same jurisdiction as its major markets or customers are located, to establish visibility and brand recognition. A cross-border capital raising company can also increase worldwide prominence.

**Participation in Indices** - Provides investors with clear and independent benchmarking of stocks, sectors and the market as a whole. Creates the basis for portfolio trading by active and passive investors.

**Liquidity availability** - 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.



### 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 innovative biopharma and healthtech 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** - Biopharma and healthtech companies concentrating on particular products or therapies may be more prevalent on certain exchanges or in certain jurisdictions, which may assist investors and analysts to provide more accurate valuations. The concentration of university-related laboratories and biopharma and healthtech incubator companies should also be considered in choosing among jurisdictions and listing venues.

### COSTS

**Initial flotation and ongoing compliance costs**

**Currency: FX considerations**

**Legal/market risks**



### REGULATORY ENVIRONMENT

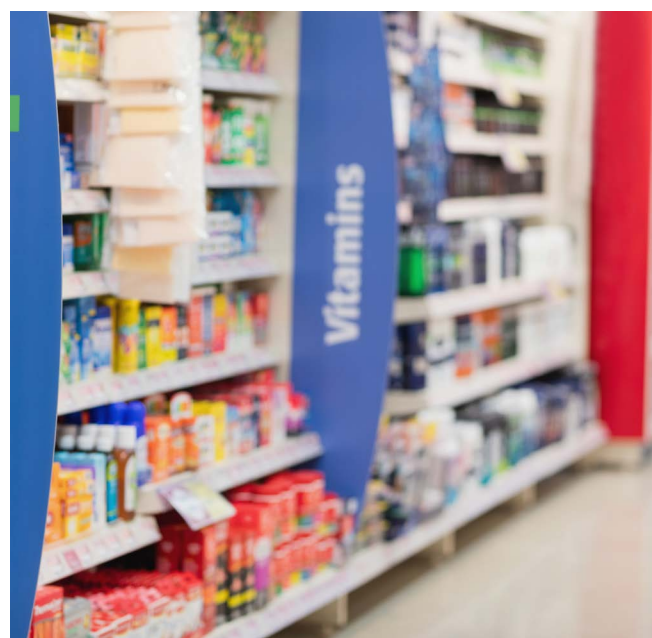
**Initial listing requirements** - Selecting the most suitable jurisdiction requires careful assessment of a company's ability to meet the relevant listing requirements, whether relating to financial track record or assets, minimum number of shareholders, public float, minimum share price or capitalization. For example, a biotechnology company in the R&D phase for a novel product 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 testing and regulatory approval process for a product or therapy 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 biopharma and healthtech companies in that country.

**Corporate Governance** - It is important for a biopharma and healthtech 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 biopharma and healthtech companies



Biopharma and healthtech 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 healthtech 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 biopharma and healthtech company's operating group is an important issue to consider at the onset. In some jurisdictions, investors may favor biopharma and healthtech companies that are narrowly focused on a key therapy

or product over those that offer a wide range of products. For example, a number of established biopharma and healthtech 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.

For corporate governance, tax or marketing reasons, a biopharma and healthtech 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

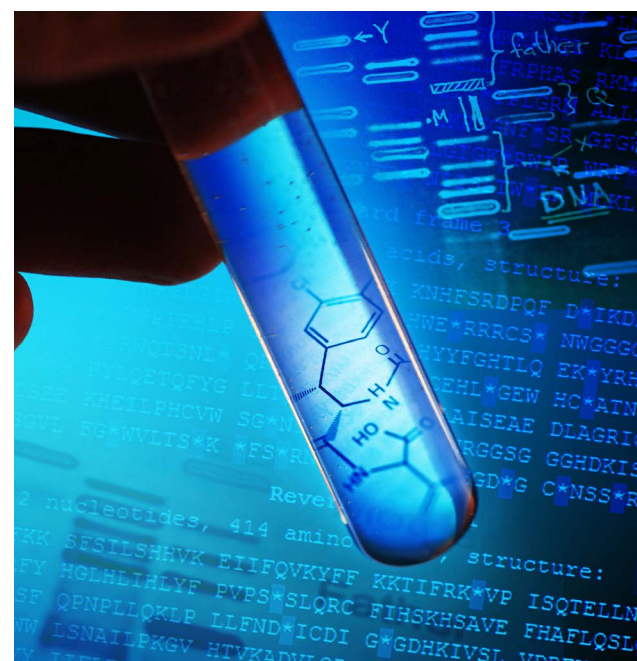
The pathway for a biopharma company obtaining intellectual property protection in the form of a patent for a new drug or therapy is well trodden, but obtaining intellectual property protection has historically been a challenging business issue for healthtech companies. However, in many jurisdictions, technology software and computer programs can now be protected by both copyright and patent law - provided that the invention has not been disclosed, except where subject to appropriate confidentiality restrictions. Accordingly, it will be important for healthtech 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.





## Privacy and data protection

Data is extremely important to many biopharma and healthtech 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 to their business model, biopharma and healthtech companies must ensure regulatory compliance with privacy and data protection laws. With each country having its own implementation and enforcement systems, it is important that biopharma and healthtech companies have appropriate policies, systems and process in place for ensuring regulatory compliance as part of any listing.



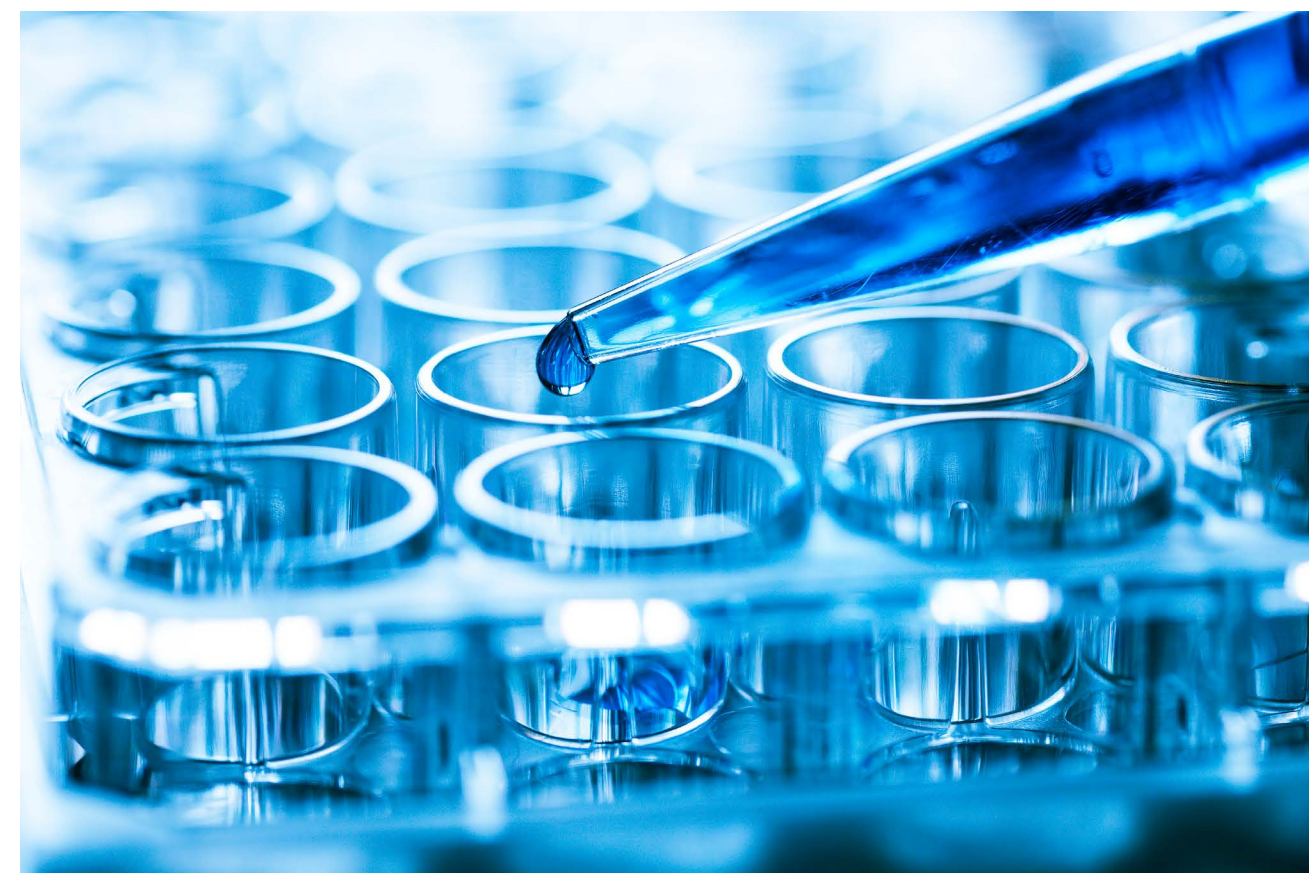
## Describing the business

Biopharma and healthtech companies, particularly those focused on novel therapies, technologies or approaches, should be mindful of a number of specific prospectus disclosure issues that commonly arise.

One of the most challenging aspects for a biopharma and healthtech 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 healthtech 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.

The key prospectus challenge is to write explanations that are accurate and fulsome, while satisfying investors' and regulators' desires for cogent, easily understood information.



## Clinical trials and regulatory review

In addition, many products or therapies in the biopharma and healthtech 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.

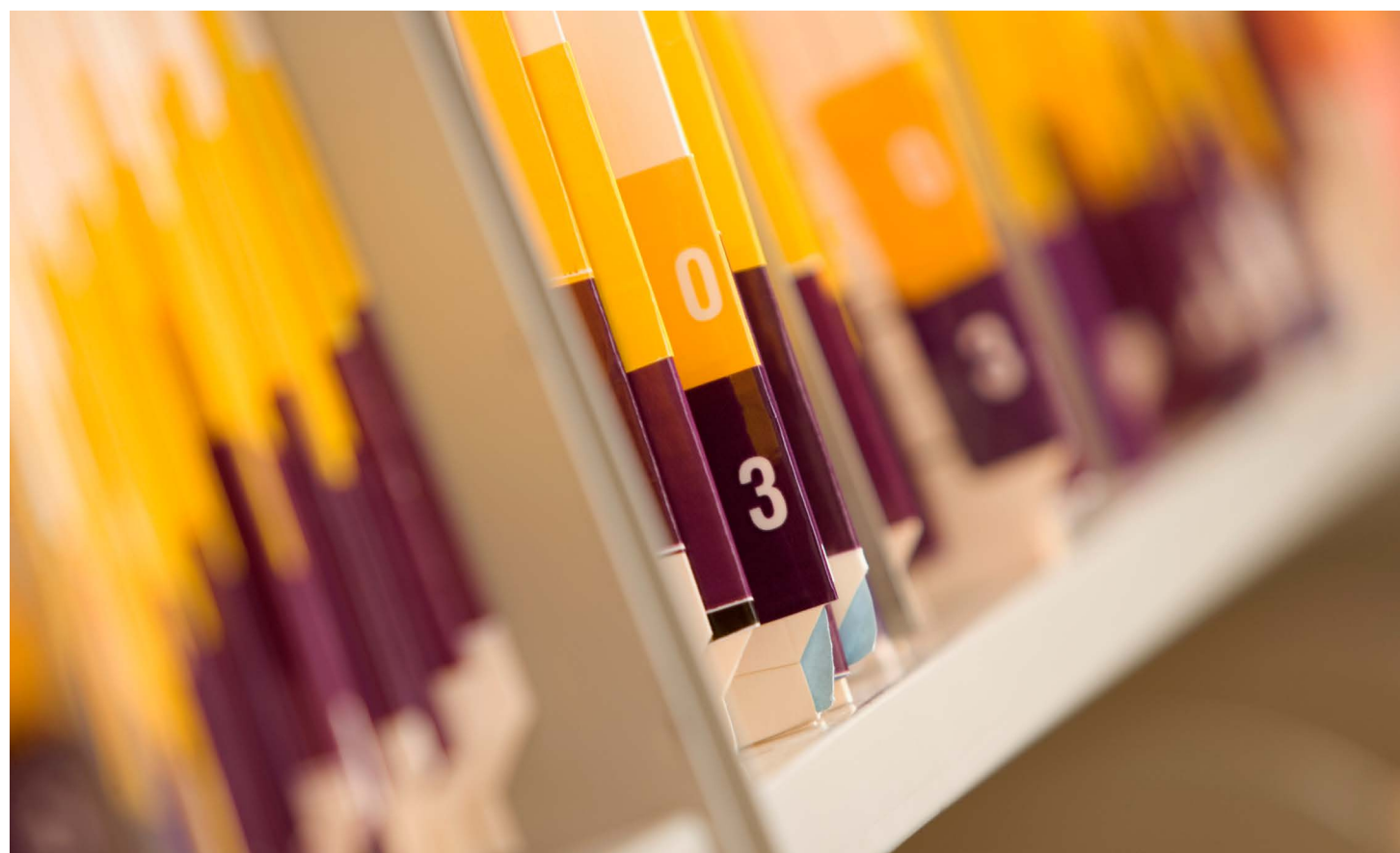
It is therefore critical for a biopharma and healthtech company to have the guidance of regulatory counsel to help the company explain in its prospectus disclosure what the relevant requirements are, where the company is in terms of the application, testing or approval/registration process, research 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, biopharma and healthtech companies should be mindful that they may be required, either by the regulatory authority or simply to meet market expectation, to provide enhanced prospectus disclosure. Additional disclosure may therefore be required in respect of some or all of the following:

- **Information on strategic objectives.**
- **Operating licenses.**
- **Details of any operations in laboratory research and development.**
- **Manufacturing and inventory control policies.**
- **Collective expertise, experience of key technical staff and the extent to which the business is dependent on key individuals.**
- **Employees engaged in quality control.**
- **Collaborative development and research agreements.**
- **Reimbursements by public healthcare systems or private insurers.**
- **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.**
- **Any assets necessary for production that it does not own.**
- **Compliance with all applicable laws (particularly privacy and data protection laws).**
- **Claims, litigation or material adverse findings in**



### investigations in respect of product liability, personal injury and/or wrongful death resulting from usage of pharmaceutical products.

In addition, some regulatory authorities may ask for an asset valuation or other expert's report to be included in the prospectus.

## Due diligence

The due diligence investigation for biopharma and healthtech companies is typically more specialized than for most other

companies, with a heavy focus on technology and intellectual property rights, and the freedom to operate within them.

An enterprise that relies on a new science, products or technology 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. It is 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.

In addition to this intellectual property emphasis, due diligence investigations for biopharma and healthtech companies often focus on other areas particularly relevant to the industry, such as:

- **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 biopharma and healthtech company's major customer, either directly or indirectly.

## Disclosure obligations after listing

A biopharma and healthtech company developing a new science, product or technology can face challenges in meeting ongoing disclosure obligations to keep the market appropriately informed after listing. In some jurisdictions, a reporting code or similar guidance

may exist to help listed biopharma and healthtech 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 biopharma and healthtech companies having been fined by securities regulators for not promptly or properly disclosing the results of clinical trials.

## Assets and income mix

In some jurisdictions, by virtue of their asset and income mix, biopharma and healthtech 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.

# Baker McKenzie contacts

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

### Global Chair, Capital Markets



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