CAPITAL MARKETS
HEALTHCARE IPOS

Is there a doctor in the house?

Baker McKenzie lawyers review the global biotech IPO landscape, considering how regulatory initiatives have aided growth

Last year was a strong year for initial public offerings (IPOs) in the biotechnology sector, with both the amount of capital raised and the volume of IPOs at the second-highest level in the last five years. As of November 2018* there had been 40 biotech IPOs, down slightly on the previous year's record of 44, but capital raised increased 10% to $4.2 billion, a figure only bettered in 2016 when $5.1 billion was raised.

Indeed, the last four years has been a bumper period for IPOs in the sector, with a 70% increase in biotech valuations over the period. Cross-border biotech IPOs have also been active, making up 20% of total issues and 43% of total capital raised. Chinese biotechs have been leading the way on cross-border listings with $1.8 billion raised, compared to $173 million in 2017. As for what has been driving this trend, according to Ben McLaughlin, global chair of Baker McKenzie's healthcare industry group:

"Strong investor appetite is fueling the number of listings and valuations, as the high risk versus high reward model makes the biotech sector an attractive area for both big pharma looking to accelerate R&D [research & development] and innovation, along with venture capital and private equity funds looking for the promise of rich exits down the line."

In addition, activity has also been boosted by the US Food and Drug Administration's efforts to speed up approvals, along with the Hong Kong Stock Exchange's (HKEx) new listing rules, which have made it easier for biotech companies to go public. "While Nasdaq remains the most popular choice for listings, it now faces competition for cross-border IPOs as the burgeoning growth of Chinese biotech means issuers will choose to take advantage of regulation changes in Hong Kong and list there instead," McLaughlin said.

On April 30 2018 the HKEx's new listing rule for pre-revenue biotech companies took effect, with the aim of attracting Chinese biotech listings away from the US and mainland China stock exchanges. As Ashok Lalwani, healthcare IPO partner at Baker McKenzie explains:

"The HKEx now allows biotech companies that aren't yet profitable or without revenue to list, provided their expected market capitalisation

1 MINUTE READ

Last year was strong for IPOs in the biotechnology sector, with the amount of capital raised increasing, despite a lower volume of IPOs.

Baker McKenzie's Ben McLaughlin, Ashok Lalwani and Adam Farlow discuss the factors driving these trends and consider what lies ahead for the sector, including the rationale for a healthcare company considering an IPO, the key business attributes of an IPO-ready healthcare company, the choice of listing venue, and the key issues such a company will need to consider before going public.

is more than HKD1.5 billion ($191 million). That compares to the three consecutive years of profit and revenue, which those listed on China's main exchanges – Shanghai and Shenzhen – must prove before listing. The new rules in Hong Kong mean the number of biotech companies coming to market in the early stages of R&D, and with no profit or turnover, is expected to grow."

Why consider an IPO?

Companies in the healthcare sector, particularly those in the areas of biotech and pharma, typically require a lot of expensive R&D. IPOs are a great way to get new, long-term funding for ongoing projects and developments.

For these types of companies, an M&A solution is not always easy, as it could still be financially too risky for other companies to take on the intellectual property (IP) and continue the development itself. A bank loan or other form of debt funding is usually not a good solution either, as companies need to have revenue generating assets or activities to pay back a loan.

Through an IPO, 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, including, in particular, sector specialists.

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 its general operating efficiency.

Key business attributes of an IPO-ready company

A healthcare company will usually want to do an IPO when it is at the stage of needing to take the next big step, such as rolling out new production or funding phase II clinical trials for a key compound. It will also be at a time when the amount of funding needed exceeds what can be privately sourced. A company that is considering going public will need to do a lot of preparation to determine whether it's IPO-ready or not. A key consideration will be whether it has a leading market position supported by clear and achievable strategic goals for revenue growth and profitability. It will need to develop a compelling equity story to explain clearly to potential investors what the business is and how it intends to grow.

As many stock exchanges allow pre-revenue companies to list, it will be important to show how the business is expected to develop and become profitable over time. To aid this, the company will need an attractive financial model, with an established quarterly forecast process and reliable financial reporting controls.

The company will also need to put in place an appropriately skilled, experienced and proven management team. For companies in the healthcare sector, developing a robust corporate governance framework is crucial and the company should ensure that it includes independent industry experts on its board, in addition to a reputable legal and accounting advisors with experience in the sector.

Choosing the location of your IPO

During the last few years, over 80% of listings by biopharma and healthtech companies were on their home market. However, the appeal of cross-border listings is growing. Any decision concerning the potential location of an IPO will be based on a number of considerations.

A healthcare company may find it helpful to list or raise capital in the same jurisdiction as the majority of its customers to improve visibility and brand recognition. A cross-border capital raising can also increase worldwide prominence.

Before choosing a listing venue it is important to consider valuation. Does a market have relevant analyst and investor expertise? Well-informed research analysts and investors can drive both a successful capital raising and a strong aftermarket. Some exchanges are more popular than others with innovative biopharma and healthtech companies-focused investors.

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. Investor appetite for the quality, stage of development and risks associated with a particular novel drug, therapy or other chemical or biological technology may differ across markets.

Biotech and many other healthcare companies operate in a highly regulated 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.

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 capitalisation. For example, a biotech 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 a track record of profitability, although the changes last year to the HKEx's listing rules specifically target pre-revenue biotech companies allowing them a new path to listing.

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.

Key issues to consider before listing

There are a number of key issues for biopharma and healthtech companies to consider before conducting an IPO; particularly healthtech companies, whose convergence of healthcare and technology could raise additional issues.

A company may want to consider restructuring prior to listing as in some

A healthcare company may find it helpful to list or raise capital in the same jurisdiction as the majority of its customers to improve visibility

jurisdictions investors may favour biopharma and healthtech companies that are narrowly focused on a key therapy or product. A company that wishes to take advantage of more flexible governance requirements or a different tax structure will also often explore a re-incorporation in conjunction with an initial listing.

A company will want to ensure that it has the necessary IP protection in place. Obtaining IP protection has historically been a challenge for healthtech companies. However in many jurisdictions, technology and computer software can now be protected by both copyright and patent law. It will be important for healthtech companies with novel technology to at least ensure an application for any technology invention is made publicly, before disclosing key information as part of any IPO.

A company may want to consider restructuring prior to listing

In some jurisdictions biopharma companies may be subject to additional levels of securities regulation

In recent years, there has been an increased focus on privacy and data protection. With each country having its own implementation and enforcement systems, it is important that biopharma and healthtech companies have appropriate policies, systems and processes in place for ensuring regulatory compliance as part of any listing.

Many products or therapies in the healthcare field must pass through clinical trials and a regulatory review process before being marketed or sold. It is critical for a biopharma and healthtech company to have the guidance of regulatory counsel to help explain in its prospectus disclosure what the relevant requirements are, where the company is with its application, testing or approval/registration process, the research methodology for the trials, and approximate timeline to bring to market.

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

Prior to listing, a company will need to go through a rigorous due diligence process, which will assist with the disclosure in the prospectus. The due diligence in this industry is typically more specialised than for most other companies, with a heavy focus on technology and IP rights and the freedom to operate within them.

Post-listing, there will be continuing disclosure obligations. Biopharma and healthtech companies can face challenges in meeting ongoing disclosure obligations to keep the market appropriately informed after listing. These ongoing reporting requirements may include disclosure of R&D, clinical trials, medical devices, regulatory approvals, IP rights and licensing.

By virtue of their asset and income mix, in some jurisdictions biopharma and healthtech companies may be subject to additional levels of securities regulation, such as providing more regular reports on cash flow and expenditures, as well as reporting on commitments to implement business objectives.

What next?

Investors suffered a bumpy ride in 2018, with stock markets globally experiencing renewed volatility. The healthcare sector was not immune to this and of the four biotech companies that debuted in Hong Kong in 2018 under the new listing rules, several saw significant falls from their offer price, which some commentators attributed to overvaluation. Overall, of the biotech IPOs recorded, approximately 50% were trading below their initial stock price one month after pricing.

Despite various geopolitical headwinds, healthcare companies are expected to be most active in the US and Asia. Commenting on the HKEx's new biotech company listing rules, Lalwani believes that, "The new rules mean…the number of biotech companies coming to the market in the early stages of R&D with no profit or turnover is expected to grow." There are certainly challenges ahead, and we expect new deal activity in the sector to reach its cyclical trough in 2020 as political uncertainty and regulations take their toll.

** Data correct as of November 30 2018, unless otherwise stated (Source: Refinitiv)*

Ben McLaughlin
Global chair of healthcare
Baker McKenzie, Sydney
E: ben.mclaughlin@bakermckenzie.com

Adam Farlow
Head of EMEA capital markets
Baker McKenzie, London
E: adam.farlow@bakermckenzie.com

Ashok Lalwani
Head of India practice
Baker McKenzie Wong & Leow, Singapore
E: ashok.lalwani@bakermckenzie.com