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Obstacles to IPOs faced by life sciences companies

By Alan Wovsaniker

11-10-2018 Comments (0)

Initial public offerings (IPOs) are often seen as attractive by business owners in the life sciences or biotech field, writes Alan Wovsaniker, a partner with Lowenstein Sandler, in an Expert View column on the topic.

The need for capital in a life sciences business tend to be great, as the cost to develop new drugs, therapies or medical devices is extremely expensive and it takes many years to receive regulatory approval to market and sell such drugs, therapies or medical devices.

A successful IPO not only brings immediate cash to the table, but once a company's shares are publicly traded after an IPO, subsequent equity capital raises are quicker and easier, facilitating multiple rounds of financing over a period of years as a company's drugs, therapies or medical devices are developed. If all goes well, those subsequent financings can all be common stock financings, hopefully at higher prices with less and less dilution so that the complexities and cost of capital raising can come down.

Additionally, an IPO is a way of providing liquidity for the current shareholders of the company. Assuming the IPO results in a Nasdaq or NYSE listing, early pre-IPO investors will be able to begin to have a market to sell their shares, typically 180 days after the IPO, as underwriters will want to lock up pre-IPO shareholders for a period after the IPO to avoid immediate selling pressure on the newly-public company's stock.

Notwithstanding these attractions, there are numerous obstacles to achieving a successful IPO which owners of life sciences companies should be aware of before embarking on the IPO process. IPOs are one of those areas in which extensive advance planning can be highly desirable. The following list is far from exhaustive.

(1) It takes money to make money

Effecting an IPO is a lengthy and expensive process. An IPO requires that a registration statement be prepared with all material business, management and financial information about a company. The prospectus in the registration statement, which is the document used to market the offering, can easily run to 100 printed pages plus financial statements.

An underwriter willing to work with the company must be selected and the underwriter and its counsel have to be satisfied with the registration statement and such counsel's due diligence process before the registration statement is filed, as the underwriter can have liability for material misstatements or omissions along with the company if the underwriter has not exercised proper due diligence.

The process of preparing a registration statement for an IPO before its initial filing with the Securities and Exchange Commission (SEC) can take at least two months. Once filed with the SEC, at least another month will go by until the SEC provides comments on the registration statement. Then there is likely to be approximately a month or so of editing the registration statement as the company responds to a number of rounds of comments from the SEC.

Towards the tail-end of this period, there will be a 'roadshow' of approximately two weeks when the company and the underwriters go out to the market to describe their story. The SEC will finally declare the registration statement effective at the end of this process so that sales can be made.

As just this brief summary indicates, the process is time consuming (five to six months once you get started) and expensive with professional fees, including attorneys and accountants, and printing costs likely to be well over $1 million.

Unfortunately, windows of market opportunity to complete a successful IPO can come and go, and at the end of the roadshow, there may or may not be a market for the company's stock, or a market may be there, but at a price that the company does not view as favorable based on its view of the company's prospects. That is where having money can be critical. Many life sciences companies embark on the IPO process because they need financing, and by the end of the six months they are broke and desperate, with no ability to negotiate terms with investors or underwriters or to say no and wait for a better deal and a better valuation.

Accordingly, the ability to go into the IPO process with money or current investors in the company willing to support the company in the IPO can be the difference between a successful IPO and a failed IPO. It is often not possible, but it is highly desirable for a life sciences company to spend time before it begins the IPO process, to explore all possible private sources of capital, whether it is from venture capital firms, high net worth individuals, bank loans, government or private disease foundation grants or partnering with larger pharmaceutical companies.

Terms of pre-IPO financing can seem onerous. However, if the IPO window is not open or robust when you get there, you do not want to be stuck.

(2) All money is not equal

In addition to wanting to have as sizeable a war chest as practical before you embark on an IPO process, it is also desirable to have the right kind of investors. It is common for underwriters to expect that existing key shareholders will also invest in the IPO. It sends a great message to Wall Street if they are willing to do so. If the insiders are investing in the IPO, so the thinking goes, then it must be a good deal and others will follow suit.

Well known institutional investors who invest prior to the IPO can also be critical in other ways. If a company does run short of capital, there is nothing better than a shareholder base which is able and willing to provide interim or bridge financing to keep the company going, especially if the IPO gets delayed. The investor base may have other contacts in the field who will look to follow them in investing in the company. Further, having seasoned professional investors in the company before the IPO can lend stability and credibility to the process.

A seasoned investor will have seen many of the twists and turns that an IPO process can take. They 'know the game' and are not likely to pressure management or the board if the process takes longer or costs more than anticipated. Ideally, some of those seasoned investors are sitting on the board and can help direct the process.

(3) Create 'markers'

Many life sciences companies that go public are pre-revenue and do not expect to have revenue for many years until their technology can clear Phase II and Phase III clinical trials, obtain FDA regulatory approvals and successfully become commercialized. Without revenues as a quarterly marker for investors, it is difficult for the market to measure progress.

Thus, it is important for a life sciences company to create a game plan or 'story' up front that investors can follow and use to mark the company's progress.

A life sciences company should ask itself, what are the data inflection points? What will it be able to tell investors going forward about the progress of a Phase II or Phase III clinical trial? How can it continually differentiate itself from the competition who may also be attempting to address the same market that the company's technology is attempting to address? What are the realistic timelines for completing clinical trials and bringing the product to market and how will investors understand where the company is on that continuum?

If a life sciences company sets reasonable expectations and then delivers, it is more likely to maintain a stable market price, especially where quarterly financial results do not tell much of
a story.

Conclusion

Of course, there are many other elements necessary to a successful IPO process:

(a) A company needs knowledgeable accountants, who are able to audit its financial statements in a timely manner for inclusion in the prospectus and who know SEC 'hot button' financial issues and how best to respond to accounting comments from the SEC. It is of course best if there has been a history of doing audits to make sure all internal controls and systems are adequate for timely and accurate SEC reporting.

(b) A company needs an experienced legal team who has been through the process before, and is willing to dedicate attorneys with experience to spend the time to understand the company, efficiently draft the disclosures required in the registration statement, how to respond to SEC comments and work on the deal.

(c) Experienced counsel and accountants can also make sure that underwriters and financial sources reviewing the company find a well-organized company (which reduces investor concerns). Board minutes for all significant corporate actions must be in place, proper documentation for all issuance of equity should be available, employee stock options must have been properly priced and the certificate of incorporation, by-laws and corporate governance policies must be appropriate for a public company. Developing an electronic data room with all material corporate agreements can be done in advance and will facilitate the process. All of these matters can and should be commenced and completed well before the underwriting process begins, which is another reason why advance planning is important.

(d) It is of course highly desirable to have a strong management team in place, including not just the chief executive officer, but also a chief financial officer who has credibility with Wall Street and a strong board of directors. The NYSE and Nasdaq require that a majority of directors be independent, that there be an auditing, compensation and nominating committee consisting of independent directors and that audit committee members have the requisite financial expertise.

An IPO is never easy. But with the right team in place and some luck and good timing, an IPO can solve the financing problems inherent in the life sciences product development process.

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