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Funding Gap For Life Science Cos. Is Still A Problem

Law360, New York (September 05, 2013, 12:16 PM ET) -- During the first half of 2013, midstage life sciences companies have seen more initial public offerings than any year since 2004. However, for startup life sciences companies, the capital markets are decidedly less optimistic. Before these young companies can take advantage of a hot IPO market, they must raise substantial sums of money for research and development, intellectual property protection and clinical trials.

In fact, the typical drug or device company completing a successful IPO in the first half of 2013 raised approximately $100 million through private investments before its public offering. In the current regulatory environment, this is a discouragingly difficult task for startups but particularly challenging for those scientists and entrepreneurs without personal connections to well-healed investors who can contribute early-stage capital.

Congress passed the bipartisan Jumpstart Our Business Startups Act in April 2012 with the intention of facilitating access to early-stage capital by loosening general solicitation restrictions and permitting crowdfunding. While these changes are improvements, they are not likely to bridge the funding gap for startup biotech ventures.

The principal problem is that the JOBS Act does not address the reality of how companies typically attempt to raise early-round capital, namely through well-connected individuals who have a network of relationships with others who want to invest in promising new ventures. The current regulatory scheme discourages the use of intermediary “finders” to establish investor contacts for these companies.

The U.S. Securities and Exchange Commission should consider revising broker-dealer regulations to facilitate the use of finders and help startup life sciences companies bridge the ever-increasing funding gap.

VC Financing

While venture capital firms have traditionally provided substantial cash for emerging life sciences companies, the number of first-time deals for life sciences companies fell in 2012 to the lowest level since 1995. Moreover, out of the total pool of venture capital cash invested, fundraising allocated specifically to life sciences companies dropped from 19 percent in 2009 to 12.5 percent in 2012.

Although the first half of 2013 showed some improvement in the way of first-time funding for life sciences companies, it is still too early to tell whether this trend will continue. This disturbing trend has been attributed to venture capital’s hesitation to invest in risk-prone biotech startups, which must negotiate both an extended time to market and regulatory uncertainty surrounding the approval of new drugs or devices.

Thus, in order to reach a level of maturity, which may attract the attention of VCs, most startup drug and device companies must first seek funding elsewhere.

SBIR Grants

Many life sciences companies attempt to raise funds from nondilutive sources, such as government grants, nonprofit loans or investments and strategic partnerships with other industry members. One potential source of nondilutive financing is the soon-to-be revamped Small Business Innovation Research (SBIR) grant program.

SBIR phase 1 and phase 2 awards (up to $1.15 million for the first two and a half years) help life sciences companies complete basic feasibility research and development. Although SBIR grants currently only lend themselves to companies who have not received any venture-backed financing, new regulations set to take effect in 2014 (or later) will loosen these restrictions.

Certainly, this alternative source of funding for early-stage life sciences companies is an appealing one. But even with an SBIR grant in its pocket, the average startup life sciences company will require much more capital in its early stages before it can attract substantial funds from institutional investors.

Angel Investors and Crowdfunding

With venture-backed money increasingly hard to come by, and nondilutive funding insufficient even when it can be obtained, life sciences companies must rely upon the bread and butter of early-stage fundraising: friends, family and angel investors. In the first half of 2012, the average angel round financing for a life sciences company raised $1.77 million.

Recognizing the importance of angel funding, the JOBS Act amends Rule 506 to provide a new exemption that allows the use of general solicitation in connection with fundraising. As a result, early-stage companies will soon be allowed to communicate more broadly to reach potential investors with whom they do not have a prior relationship — either directly or through an investment banker or other registered intermediary.

The new general solicitation rules set to take effect later this month require cumbersome verification procedures that place the burden on an issuer to determine accredited investor status. Prominent angel groups have indicated that these new rules will likely deter angel investments because investors must provide personal financial information to others in order to verify their status as accredited investors.

More problematic are revisions to Form D for use with Regulation D offerings, which, as proposed, will require a company to decide before it embarks on fundraising whether to retain the flexibility to use general solicitation. If a company opts to use general solicitation, it will be subject to the more onerous accredited investor verification requirements.

On the other hand, a company that initially chooses to forego the ability to use general solicitation and avail itself of the existing self-verification representations widely used today may forfeit an offering's qualification for exemption if the company opts to use general solicitation to raise additional funds later in the fundraising process.

Equity crowdfunding is the next big thing for certain types of startups. When the SEC finalizes regulations to permit equity crowdfunding, a restriction will limit the amount of money that a company may raise to $1 million in any 12-month period. Although $1 million is no small sum of cash, for life sciences companies, the aggregate costs of product development, clinical trials and IP protection are much more significant even at an early stage.

Furthermore, a company with a "crowd" of individual investors will need to devote substantial time and expense to managing those relationships as the company develops and grows. It also remains to be seen whether institutional investors, such as venture capitalists, would be willing to invest in a company alongside less sophisticated crowd investors. Some established venture capitalists have said that their firms may require companies to buy out or unwind crowd investors before making any significant commitments.

While the JOBS Act changes are a positive step and the problems noted above may be addressed, the impact of permitting general solicitation and equity crowdfunding for life science ventures is not likely to be as significant as hoped. Life sciences companies need substantial sums of capital to make meaningful progress on development and clinical studies to reach the stage where institutional firms will invest.

And, as with venture capitalists, individual angel investors are often hesitant to commit even a relatively small amount before knowing that the startup will be successful in raising sufficient capital from other sources to reach its goals. Therefore, these companies need to round up a large number of individual investors with substantial funds to invest, and these investors are much more likely to be found through personal connections rather than by general solicitation techniques.

Unfortunately, federal and state securities laws regulating individuals who are compensated to identify these investors do not currently support the efforts of early-stage companies.

Navigating the Murky Broker-Dealer Regulations

The reality is that most early-stage companies need to identify a multitude of deep-pocketed, accredited investors — and they need help to do it. Often, they use the services of "finders" —individuals and firms with a Rolodex full of contacts who introduce companies to wealthy individuals for a fee based on the amount these individuals invest.

Generally, anyone who is compensated in this manner is required to register with the SEC as a broker-dealer, which requires the individual finder or one or more of the principals of a firm to pass rigorous examinations.

Unregistered finders can jeopardize a company's future. Federal and state securities laws provide a basis for an investor to rescind its investment if the company used an unlicensed finder even if there were no misrepresentations about the company's existing business or prospects and, in fact, even if the company makes progress as planned.

Furthermore, the company may be barred from future exempt offerings under Regulation D or find it even more difficult to take advantage of public offerings at a later stage because of increased legal and accounting disclosures triggered by the broker-dealer violation.

Despite what some finders claim in their sales pitches, the SEC's position on whether an individual or firm must register as a broker-dealer is far from clear. Emerging life sciences companies are rightly hesitant to engage unlicensed finders in their efforts to raise early stage capital.

In response to the problem, several states have proposed amendments to their blue sky laws, clarifying the distinction between a broker-dealer and a finder. Other states have proposed an alternative, easy-to-obtain license for finders.

Although these instances of state action are steps in the right direction, they do not resolve the lack of clarity in federal securities laws. Indeed, if Congress and the SEC truly wish to jumpstart emerging life science businesses, they should provide an avenue for finders to operate effectively and efficiently in

the marketplace without stringent licensing requirements. These finders could then connect startup companies with wealthy investors without risking the future of the very companies they were engaged to help.

This suggestion is not new — the SEC started down this path in 2006. The SEC's Advisory Committee on Smaller Public Companies solicited public comment on a proposal to spearhead a multiagency effort to create a streamlined and cost-efficient registration process for finders — a recommendation which the SEC Government-Business Forum on Small Business Capital Formation had urged the SEC to adopt for 17 out of the last 18 years. That proposal, unfortunately, never came to fruition.

Moving Forward

The SEC's next step should be to reassess the current state of the broker-dealer regulations to ensure they are consistent with the reality of how many startup companies typically raise early-stage capital in today's marketplace, namely through business connections and trusted relationships with deep-pocketed individuals.

With the removal of the general solicitation restrictions, companies can now publicly seek investments from accredited investors with whom they have no pre-existing relationship. By enabling the use of compensated finders, the SEC would further facilitate the fundraising process by opening existing channels of investment that will likely be more successful.

Even with a loosening of the restrictions on the use of unregistered finders, the existing federal and state anti-fraud rules would continue to play an important role in policing bad behavior. Therefore, the SEC should think long and hard about whether unregistered finders may better serve emerging companies' capital needs while simultaneously maintaining adequate levels of investor protection under securities laws.

With the recent JOBS Act legislation, we move closer to a time when it will no longer matter how a company identifies a willing investor, so long as that investor meets the accredited investor qualifications. For startup medical device and drug companies attempting to succeed in the face of drawn-out U.S. Food and Drug Administrationapproval processes and expensive clinical trials, the time to act is now.

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