Portfolio Media. Inc. | 860 Broadway, 6th Floor | New York, NY 10003 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

New Opportunities For VC-Backed Life Sciences Cos.

Law360, New York (June 05, 2013, 1:04 PM ET) -- The insatiable funding requirements of early-stage life sciences companies demand an unending and time-consuming quest for capital. Inevitably, the path leads to the door of venture capital firms, which have been a traditional source of financing for drug discovery, drug development, diagnostics and other capital-intensive life sciences businesses. However, the bar to raising venture capital, as well as the cost of that capital, continues to rise.

As a result, companies are devoting ever-increasing efforts to secure alternative nondilutive sources of funding from governmental agencies, patient advocacy groups and other nonprofit organizations and strategic industry partners. This funding provides essential working capital more quickly and efficiently than raising equity, extends the runway to achieve meaningful scientific milestones (and higher valuations) in advance of an equity financing and cushions the dilutive effect of permanent funding once it is secured.

The federal Small Business Innovation Research (SBIR) grant program has been an important source of nondilutive financing for life sciences companies since the mid-1980s. Until recently, however, the regulatory framework for the SBIR program made it difficult for companies to take advantage of this key source of funding once they had obtained a first round of venture capital or other institutional financing.

New regulations, approved earlier this year, ease the dilemma many early-stage life sciences have faced between pursuing SBIR grants and institutional financing by setting some bright lines that give firms an unprecedented level of predictability, flexibility and opportunity.

Under the SBIR program, which is directed by the U.S. Small Business Administration, the 11 federal agencies with the largest extramural research and development (R&D) budgets — including, importantly, the National Institutes of Health (NIH) — offer competitive funding awards designed to encourage commercialization of innovative technologies.

The program is phased, awarding up to $150,000 for six months in phase I (covering basic feasibility research) and up to $1 million for two years in phase II (for continued research or R&D). In addition, phase III awards without dollar limits are available to companies to complete commercialization of SBIR-supported research but must be matched by funding from independent sources.

In 2012, participating agencies granted 4,796 SBIR awards totaling just over $1.8 billion, including 1,436 NIH awards totaling $591 million.

Revamping SBIR

In the past, firms seeking SBIR funding had to meet strict ownership and control benchmarks intended to benefit "small business concerns" owned by U.S. individuals. Among other matters, the government mandated majority ownership and control by individual U.S. citizens or permanent residents or, failing that, majority ownership and control by a business that is, in turn, owned and controlled by U.S. individuals. In addition, to fall within the definition of a qualifying small-business concern, a firm, together with its affiliates, could not have more than 500 employees.

The first of these requirements, that a company must be majority-owned and controlled by qualified U.S. individuals, has meant that for all practical purposes, life sciences companies may be eligible for SBIR awards for only a limited period of their development phase. Given the large capital requirements of these ventures, even a Series A investment by a venture capital firm may reduce individual ownership of a company below a majority, and this is certainly likely to occur once a follow-on round is closed.

Despite that a young drug discovery or diagnostics company would still be engaged in the type of research and development that the SBIR program is intended to encourage and support, this important source of funding becomes inaccessible very early in the financing life cycle of a promising life sciences venture.

The 500-employee limitation has proven to be an even more intractable hurdle for venture capital-backed companies largely because the definition of an "affiliate" under SBA rules has been applied with a very broad reach by the funding agencies. Often, a small company with only a handful of employees is aggregated with other portfolio companies of its affiliated lead venture capital investor that have hundreds of employees in total.

The SBA regulations provide, "Concerns and entities are affiliates of each other when one controls or has the power to control the other, or a third party or parties controls or has the power to control both. It does not matter whether control is exercised, so long as the power to control exists."

In determining whether power to control an entity exists, the agency considers a variety of factors, including whether an investor holds a significant percentage (including less than a majority) of voting stock, has the right to control the board of directors or holds significant corporate charter or contractual rights.

As applied by the SBA, where a venture capital firm is the largest holder of stock of an SBIR applicant (even with only 25 percent to 33 percent of the voting power), and absent a countervailing "identity of interest" among founders and angel investors, the venture capital firm will be deemed to hold the power to control the applicant.

As a result, the number of employees engaged by all other portfolio companies that the venture capital firm controls or has the power to control will be aggregated, with the likelihood that even a 10-employee SBIR applicant will exceed the 500-employee limitation by attribution.

It is no wonder that life sciences have been unable to take advantage of SBIR funding once they accept a first round of institutional financing. Many in the industry criticized the restrictions on venture capital as out of step with modern biotechnology finance, where experienced investor involvement is essential to the success of even the earliest-stage companies.

As the Biotechnology Industry Organization (BIO) said in 2012, “Restrictions on VC participation in the SBIR program have stifled innovation and investment — particularly in the case of biotechnology and other life sciences, where up front expenditures make the biggest difference.” Consequently, the biotechnology industry pushed hard for rule changes to boost innovation and the competitiveness of the SBIR program.

In response to these concerns, the SBIR/Small Business Technology Transfer Reauthorization Act of 2011, which extended the SBIR program through Sept. 30, 2017, provided legislative authorization for agencies to apply a broadened definition of a “small-business concern” under the SBIR program. In January 2013, the SBA adopted final rules to implement this legislation.

The regulations open the SBIR program to companies that are majority-owned by multiple “venture capital operating companies, hedge funds, private equity firms or any combination of these,” allowing early-stage life sciences companies to solicit investors without being forced to choose between SBIR and institutional financing. Important changes have also been made to ameliorate the effect of the affiliation rules and the 500-employee limitation.

Changes Bring New Opportunities

Under the new framework, life sciences companies seeking both venture capital and SBIR funding must still ensure either that no single venture capital investor owns more than 50 percent of the company.

However, an SBIR applicant now may either be more than 50-percent-owned by multiple venture capital operating companies, hedge funds, private equity firms or any combination of these, as well as more than 50-percent-owned and controlled by individuals as under the old rule. Joint venture combinations of these are also allowed. The investment firms must have a place of business and be organized in the U.S.

Importantly, the employee attribution rules have been loosened but not entirely eliminated. First, a venture capital or other investment firm will not be treated as an affiliate of an SBIR applicant, unless the level of stock ownership (or power to control stock ownership) is at least 40 percent of the voting equity of the applicant, “based on the totality of the circumstances.”

Further, even if a venture capital company or other institutional investor is deemed to be an affiliate of the SBIR applicant, employees of other portfolio companies of that investor will be attributed to the SBIR applicant only if the institutional investor owns a majority of the voting equity or holds a majority of the seats of the board of directors of the portfolio company.

The 40-percent floor and definition of a "controlled portfolio company" are especially helpful in creating a predictable framework for SBIR applicants. In setting bright lines, the new affiliation and attribution standards give firms an unprecedented level of predictability where, previously, SBA-affiliation standards took into account general and often vague principles of control and left the SBA free to consider the totality of the circumstances to find affiliation, even though no single factor alone was determinative.

Despite the bright lines, however, the new rules do not provide relief for strategic corporate partners, so SBIR applicants that have strategic investors in addition to venture capital firms will still need to proceed with caution to avoid the affiliation rules.

The new framework is being implemented initially as a pilot program: The rules provide that up to 25 percent of SBIR funds from the National Institutes of Health, National Science Foundation and U.S. Department of Energy (and 15 percent from all other agencies) may be awarded to investor-owned businesses. Each agency participating in SBIR — those with external R&D budgets of over $100 million — is required to allocate 2.5 percent of its R&D budget to SBIR awards.

Unfortunately, the ramp-up in implementation of the SBIR venture capital rules may not occur until 2014 due to federal government funding cycles and the need to create the appropriate agency infrastructure to support the rules.

For example, the NIH issued its solicitation for calendar 2013 SBIR funding proposals prior to the SBA finalizing the new rules in January and as a result, did not include the venture capital rule-making in that solicitation. The NIH has announced that it must update its electronic systems, forms and application instructions before SBIR applicants will be able to take advantage of the venture capital rules but that it anticipates publishing an updated solicitation announcement mid-year in 2013. Other agencies that provide SBIR funding to the life sciences industry, including the U.S. Department of Defense, may be even further delayed.

One shortcoming of the legislation that authorized the new venture capital rules is that it applies only to eligibility under the SBIR program. One other federal program that provides substantial benefit to life sciences companies is the waiver of application fees under the Prescription Drug User Fee Act (PDUFA) that is available for the first human-drug application that a small business, as defined by the SBA, submits to the U.S. Food and Drug Administration.

For 2013, the filing fee for a new drug application (NDA) that includes the submission of clinical data is $1,958,800 and for an NDA not requiring clinical data, is $979,400. Thus, the availability of a fee waiver from the FDA is equivalent to meaningful nondilutive governmental funding.

In the absence of a regulatory initiative from the SBA to apply the same eligibility standards to PDUFA fee waivers as to SBIR awards, drug development companies that are funded by venture capital firms will continue to face the same affiliation and employee aggregation hurdles that previously applied under the SBIR program.

Despite these limitations, the new rules will enable small life sciences firms to obtain significant levels of institutional equity funding without risking SBIR eligibility and will provide many venture capital-backed companies with an additional tool to finance the early stages of the daunting transition from preclinical development to commercialization of life-saving drugs.

--By William B. Asher and David A. Wittenberg, Choate Hall & Stewart LLP

William Asher is co-chairman of the business and technology and life sciences groups at Choate Hall & Stewart in Boston. David Wittenberg is a member of the firm's business and technology group.

The opinions expressed are those of the author and do not necessarily reflect the views of the firm, its clients, or Portfolio Media Inc., or any of its or their respective affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.