

SBIR Newsletter

March 2007

Spring 2008 SBIR Seminars across North Carolina

Three 2- to 3-hour SBIR Seminars will be held across North Carolina this April. These workshops will provide an introduction to the SBIR/STTR programs, services that the SBTDC provides to those looking to submit proposals, as well as sources of additional program information. They will also present insights in how to prepare a winning proposal. Select workshops will offer a presentation from local SBIR awardees as well as service providers. Attendees will have the opportunity to meet with speakers as well as counselors from the SBTDC during and after the workshop. See agendas and register online at:

www.sbtcdc.org/events/sbir/workshops2008/

- **Charlotte** - April 15th, 8:00 – 11:00 AM
- **Winston-Salem** - April 17th, 6:00 - 7:30 PM
- **Research Triangle Park** - April 29th, 8:00 – 11:00 AM

NC Green Business Fund Grants

NC Green Business Fund Grants for Businesses (fewer than 100 employees) Engaged in Development or Commercialization of Certain Green Technologies

The NC Board of Science and Technology has issued a grant solicitation for the NC Green Business Fund for small to mid-sized businesses engaged in green-related businesses and processes. The proposal deadline is April 30th. To learn more, click on the link to the Green Business Fund webpage:

http://www.ncscienceandtechnology.com/NCGreenBusinessFund/Solicitation_FY0708GBF.htm

House SB Committee Releases Draft SBIR Bill at Hearing; SSTI Testifies

Source: SSTI Weekly Digest - Email: digest@ssti.org

A brief two-year reauthorization, bigger award sizes, VC eligibility clarification, and a \$10 million grant program for state/local outreach assistance are included in the draft SBIR reauthorization bill circulated by the House Committee on Small Business Chairwoman Nydia Velazquez during the third hearing on the topic, held March 13.

The SBIR program will sunset on Sept. 30, 2008, if reauthorization legislation is not passed by Congress and signed by the president before then.

Bigger Awards, Fewer Winners

The draft legislation doubles the award sizes for both Phase I and Phase II, authorizing awards of \$200,000 for Phase I and \$1.5 million for Phase II. In addition, the committee draft authorizes agencies to award “sequential Phase II awards” for testing and evaluation of promising technologies. The award sizes have not been increased since 1992, although some agencies have exceeded the current limits, as needed, for particular projects.

Since the bill does not increase the 2.5 percent set aside requirement for SBIR, the result will be fewer awards, thus increasing competition for small businesses and decreasing the number of innovations supported through the program.

Venture Capital eligibility

The most controversial element, as *Digest* readers following SBIR know, is whether or not small businesses owned by venture capital firms are eligible to compete for SBIR funding. Most of the testimony and questions during this third full Committee hearing focused on the issue. Steven Preston, administrator for the Small Business Administration (SBA), was subpoenaed to participate as the sole member of the first panel of the hearing to present the rationale for SBA’s current eligibility interpretation.

Preston expressed concern with the draft language, stating in his written testimony that “the committee print offers too broad a definitional change to the affiliation standards.” SBA is concerned about carryover of the redefinition of SBIR eligibility into all small business programs, potentially harming them inadvertently.

In addition, in his testimony, Preston illustrated the problem that arises with definitions of venture capital-owned companies “which includes patent and licensing organizations affiliated with institutions of higher education.” He expressed an interest in working with the committee to clarify the language.

The alternate view on the VC eligibility issue was the dominant topic of the testimonies of the first three witnesses during the second panel: Jim Greenwood, president of BIO; Mark Heesen, president of the National Venture Capital Association; and Mark Leahey, executive director of the Medical Device Manufacturers Association. The VC issue has been most prominently discussed in the industries associated with life science research and biomedical development.

All three witnesses appreciated the committee’s commitment to addressing the eligibility issue in the draft language. Heesen outlined how SBA’s definition was being applied in practice, taking some exception to Preston’s explanation. He also referenced the recent SBIR assessment by

the National Academy of Sciences, as he described the formerly complementary relationship of SBIR and VC, stating “the NAS report found that there are useful synergies between venture capital investment and SBIR funding in terms of selecting the most promising companies.”

Greenwood and Leahey explained the specific impact of SBA’s current definition on the biotech and medical device communities, respectively. Both witnesses cited the steep three-year decline in SBIR grant proposals to NIH as evidence of how SBA’s definition is negatively affecting biomedical research at its earliest stages. NIH applications declined 11.9 percent in 2005, by 14.6 percent in 2006, and by 21 percent in 2007; SBA’s Final rule on eligibility became effective Jan. 3, 2005. The current definition is slowing U.S. health-related innovation rather than increasing it, they contend.

Reauthorization of FAST

Authorized for the first time in the current expiring SBIR legislation and funded for only three years, the Federal and State Technology Partnership (FAST) is included in the committee draft bill at the same authorization level of \$10 million. The SBA-managed program would provide grants of up to \$250,000 per year to state and multistate initiatives dedicated to broadening SBIR’s reach geographically and/or increasing SBIR participation among women and minority small tech firms. Grants, limited to one per state, would have to be matched on a one-to-one basis by nonfederal sources and would be for performance periods of up to three years to allow greater continuity for states in planning, staffing and delivering services to client companies.

Reauthorization and improvement of FAST and explaining the important role state and local TBED efforts play in nurturing SBIR participation and innovation were the central points of the written testimony submitted to the hearing by the fourth panelist, Mark Skinner, SSTI’s vice president.

“SBIR over the past 25 years has evolved into a state-federal-industry partnership in ways that I do not believe are fully realized by the federal agencies and perhaps even Congress,” Skinner wrote. The testimony explains state and local technology-based programs – now present in nearly every state – have become the *de facto* marketing and outreach arm of the federal program, filter potential applicants for SBIR appropriateness, and move SBIR technologies closer to commercialization by providing linkages to angel and venture capital groups, production partners and, in some cases, direct financial assistance toward Phase III.

The fifth and final witness on the second panel of the hearing was Dr. Charles Matthews, professor of entrepreneurship and strategic management at the University of Cincinnati. Dr. Matthews emphasized the importance of the federal SBIR program in creating a leveraged economic impact on regional economies, providing specific examples of the integral relationship that exists between the public-private TBED initiatives of southwest Ohio, SBIR funding, and the region’s small technology firms.

In addition to SSTI's support for FAST reauthorization, Greenwood stated in his oral testimony that BIO supported FAST. Preston, when asked directly by Committee Chairwoman Velazquez whether or not the SBA supported FAST reauthorization, gave a qualified endorsement, adding that he wanted to talk with his staff more about the particulars of the program as included in the reauthorization draft.

Same Time Next Year?

Committee markup for the draft bill had not been scheduled at the time of the hearing, but the process is anticipated to pick up speed, now that a draft has been prepared. After clearing the House Committee on Small Business, SBIR reauthorization moves to the House Committee on Science, which shares SBIR oversight.

The current draft only extends the SBIR program for two years – the shortest extension in the program's 25 year history. As a result, the next reauthorization process would need to begin next spring to avoid the current pressures to renew the program prior to its pending sunset in six short months.

The written testimonies of all six witnesses for the hearing are available at <http://www.house.gov/smbiz/hearings/hearing-03-13-08-sbir/hearing-03-13-08-sbir.htm>.

The draft SBIR reauthorization legislation is available at http://www.ssti.org/Publications/Draft_SBIR_Legislation.pdf.

10th Annual NIH Conference

Registration is now open for the NIH National SBIR Conference to be held in Atlanta on July 22 & 23, 2008 at the Omni Hotel and CNN Center.

- Learn how to tap into NIH's R&D funding resources for small businesses interested in biomedical and behavioral research.
- Talk face-to-face with NIH program staff.
- Network with researchers, entrepreneurs and biotech business owners.

To Register Now Visit: <http://grants.nih.gov/grants/funding/SBIRConf2008/index.htm>.

Affinergy Awarded 5 New SBIR Grants, Including a \$2.0 Million Phase 2 Program

RESEARCH TRIANGLE PARK, N.C., March 10, 2008 - Affinergy, Inc., a Duke University spinout with a proprietary site-specific biological delivery system, announced that it has been awarded multiple SBIR grants. One of the awards is a Phase 2 SBIR program for \$2,053,845. The Phase 2 grant is funded through the NIH by the National Institute of General Medical Sciences. The focus of the program is to advance development and optimization of Affinergy peptide linkers to accelerate a patient's natural healing processes. The other 4 grant awards are for Phase 1 programs that, in aggregate, exceed \$1m.

"Affinergy is very excited to move forward with these important programs," said Jonathan Gindes, Affinergy's CFO & SVP of Business Development. "This further validates our technology as reviewed by scientific peers and acknowledges the progress that was demonstrated by our staff during the previous 18 months. Affinergy and our shareholders are grateful for the ability to continue product development for these programs. We also look forward to completing the 4 new Phase 1 grants and applying for Phase 2 support for each of those programs."

"We are anxious to initiate the Phase 2 activities and accelerate the pathway to commercialization," said Shrikumar Nair, Ph.D., Affinergy's Section Head for Discovery Chemistry who is Principal Investigator for the Phase 2 program. "We have achieved great momentum with this program and are excited by the potential to improve the clinical performance of a number of different products. This program could provide a significant clinical benefit for a large number of patients."

About Affinergy, Inc.

Affinergy develops site-specific biological systems using biofriendly linkers that selectively adhere to proteins, drugs, cells, and biomaterial surfaces in order to kickstart biology toward an intended outcome. Affinergy is focused on developing coatings and medical devices for the orthopedic and cardiovascular markets. Affinergy's technology was patented at Duke University and was awarded 2005 Innovation of the Year by Frost & Sullivan in the category of Medical Device Coatings. For more information, visit www.affinergy.com.

For more information, contact Peyton Anderson, Chief Executive Officer of Affinergy, Inc., at 919-433-2229 or panderson@affinergy.com.

Spring 2008 SBIR National Conference: May 27-30 in Orlando

The 2008 SBIR/STTR National Spring Conference in Orlando will bring together not only federal program administrators from all of the 11 SBIR participating agencies, but also venture capital and angel investors, secondary market and traditional lenders, university and federal laboratory representatives and other experts who provide assistance with the scale-up of early-stage ventures. You will also hear presentation by SBIR Award winners who have successfully commercialized their research.

More Information: <http://www.sbirflorida.org/>