



July 2005 SBIR Newsletter

7th Annual NIH SBIR/STTR Conference

Announcing a Free Two-Day Conference for Small Businesses Conducting Innovative Health-related Research

July 28-29, 2005

The Natcher Conference Center

National Institutes of Health

Bethesda, MD

Website and Registration - <http://grants.nih.gov/grants/funding/sbirconf2005/index.htm>

Highlights

Opportunities to meet one-on-one with NIH staff

Lots of networking time

This is your opportunity to get answers to *ALL* of your SBIR/STTR questions!!!

Poster session of SBIR/STTR Phase II awardees

SBIR Proposal review service for North Carolina firms

Send your draft proposal to SBTDC SBIR/STTR counselor [John Ujvari](#) for a review at least 14 days prior to your submission deadline. Proposals will be reviewed on an as-received basis.

This free service is available only to North Carolina firms.

Affinergy awarded SBIR grant to find growth factor mimetics

New proprietary compounds to be mined from Affinergy's proprietary libraries

Affinergy, Inc., a Duke University spinout with a proprietary site-specific biological delivery system, was recently awarded a \$256,000 Phase I SBIR grant (Small Business Innovation Research) from National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). This award is Affinergy's second SBIR grant in 2005 that funds research into proprietary materials for use in the treatment of a variety of diseases.

The funds will be used to accelerate activities to screen Affinergy's proprietary libraries of billions of peptides to find new molecules that mimic the positive clinical effects of growth factors currently on the market. The Phase I project will include laboratory studies to be conducted over the next year. Affinergy plans to file for a Phase II award, pending successful completion of Phase I.

"Affinergy is excited to accelerate our programs in the area of proprietary growth factors because the field holds such great promise downstream in the clinic," said Jonathan Gindes, vice president of finance & operations of Affinergy. "Affinergy's special competency with growth factors and the grant's truly novel approach helped us get this funded on the first submission."

From a business perspective, we are excited to move beyond licensing our coatings to Partners and towards building our own proprietary products. We look forward to rolling out a number of other Affinergy products as we continue to grow and build our company.”

“This Award is a special validation to our laboratory team’s focus on growth factors for the past twelve months,” said Paul Hamilton, Ph.D., director of research and development at Affinergy, who will serve as Principal Investigator for the Grant. “Growth factors have already proven to be a great success for patients in the spinal fusion market. We believe Affinergy is uniquely capable of expanding indications for existing growth factors and discovering new growth factors. We are grateful for the support of the National Institute of Arthritis and Musculoskeletal and Skin Diseases and look forward to accelerating this program.”

About Affinergy, Inc.

Affinergy develops site-specific biological and drug delivery systems using bio-friendly binders that selectively adhere to proteins, drugs, cells, and other biomaterial surfaces in order to kick-start biology toward an intended outcome. Affinergy is focused in the orthopedic and biologic drug delivery markets with a growing interest in cardiovascular applications. Affinergy’s technology was patented at Duke University and has been incubated at Becton Dickinson’s research center in Research Triangle Park. Affinergy was awarded 2005 Innovation of the Year by Frost & Sullivan in the category of Medical Device Coatings. For more information, visit <http://www.affinergy.com> or contact Peyton Anderson at 919-597-6227.

SBIR step 1: Finding an appropriate solicitation

by Julie Seward Nagel, PhD, Biotechnology Business Consultants, LLC

Research and development is critical to the success of technology-based companies. However, investment capital to fund R&D is not always available for small businesses. Federal grants and contracts can be a reliable source of non-dilutive capital to fund R&D for small businesses. The largest federal program to fund R&D toward commercialization is the SBIR/STTR program, which has 11 participating federal agencies awarding over \$2 billion annually.

Each of the 11 participating agencies issues solicitations on varying calendars and topics. Finding an appropriate solicitation that is a match for a company’s technology development goals can be a challenge. Here are four suggested rules to meet the challenge:

Rule #1 - Know the General & the Specific

Each Federal Agency that participates in the SBIR/STTR program publishes a general solicitation. Every entrepreneur looking for federal funding should first know and understand the general solicitations. Each agency is different; different deadlines, different rules, etc. Know the details of the agency that funds your specific technology.

Most agencies *only* accept proposals in response to specific published topics of interest to the specific agency. To be competitive, what you propose must fit a specific topic identified in the solicitation. The Department of Health and Human Services (NIH, CDC, FDA) are different; they publish an annual general solicitation and a list of topics of interest. They accept investigator initiated ideas. Further, NIH also publishes special solicitations to fund specific topics of interest. In making a decision to respond to a general or special solicitation, carefully consider the fit between the company’s technology and the goals of the program, and the amount of

money available. If you are considering applying under a NIH special solicitation, always contact the program director listed in the solicitation.

Rule #2 Tools for Accessing Solicitations

There are many differences between SBIR/STTR programs across participating agencies. Each agency varies on the timing of solicitations and the topics they seek to fund. There are several electronic sources which allow users to quickly and easily identify open solicitations from government agencies.

The single best portal for all things SBIR is <http://www.sbirworld.com> maintained by the National Science Foundation. SBIRworld.com has an open solicitation search engine that searches all open SBIR and STTR solicitations across agencies by key word. Most agencies also maintain listservs that alert one to the opening of solicitations.

Rule #3 Don't Assume

What a particular agency is looking fund in the SBIR/STTR program is not always intuitive. For example, historically there has been funding for proteomics, prostate cancer, and hydrogen fuel cells at the Department of Defense SBIR program. NIH funds worker safety and environmental research as well as drug development. Do your homework on what various agencies have funded in the past by viewing closed solicitations at <http://www.sbirworld.com>.

Rule #4 Stay Informed

It is critical to stay abreast of all the information that is out there regarding SBIR/STTR contracts and grants. One mechanism to do so is the use of electronic listservs and e-newsletters. Check agency websites and for information about subscribing to listservs and newsletters. Agencies can make changes to solicitations after their initial release; check for these at <http://www.sbirworld.com>.

There is a wealth of opportunity for funding research and development endeavors for small companies at the federal level. Awareness of these opportunities is the first step in developing a strategic plan on how to effectively use SBIR/STTR grants and contracts to further the goals of your company.

BioLink awarded SBIR grant to aid patients needing TPN

BioLink Life Sciences, Inc. of Cary, NC announced funding of a Phase 1 Small Business Innovation Research (SBIR) grant award by the National Institutes of Health (NIH). The NIH grant will support BioLink's initial development of a novel iron supplement for TPN (total parenteral nutrition) formulations. "Receipt of an NIH award puts us in the top 10 percent of small companies developing novel health care products," noted Dr. Deanna Nelson, BioLink's President. "This SBIR grant validates our unique approach to improving the care and quality of life of all Americans."

Today, about 40,000 people in the United States rely on TPN for sustenance and survival. TPN users include those with cancer, gastrointestinal diseases, major body burns, extensive wounds, and AIDS. The majority of these patients are anemic because they cannot take oral iron supplements and none of the currently marketed TPN formulations contain iron, primarily due to the toxicity of most intravenous iron supplements.

In their SBIR proposal, BioLink described a novel iron supplement for TPN formulations using ferric pyrophosphate (FePPi), the most stable and least toxic of iron salts. FePPi promotes iron transfer to cellular systems within the body, without releasing toxic free iron and causing oxidative stress. Under BioLink's current proposal, the effects of FePPi on the physicochemical stability of the TPN formulation will be evaluated. This is a key step towards development of a commercial product for safe, intravenous iron delivery for the prevention and/or treatment of iron deficiency in TPN patients.

This is the second SBIR grant awarded to BioLink in 2005. Earlier this year, BioLink announced the award of a SBIR Grant from the USDA for the development of novel PRO-Dyes®. These on-carcinogenic dyes will be used in a state-of-the-art system that can detect contamination in meat packing plants.

BioLink is a North Carolina biotech company that is developing innovative products to enhance the safety of foods, drugs and diagnostics. In addition to the above activities, BioLink focuses on the development of "repaired" drugs having better safety profiles. Registered "blockbuster" drugs that have significant bioavailability problems, such as poor uptake or rapid degradation in the body, may be modified to improve delivery or bioavailability. By retaining the therapeutic activity of the parent drug, and minimizing its side effects through modification to a "repaired" drug, the time and cost of development and FDA approval may be significantly reduced. BioLink has filed several patents relating to its technologies, and has begun to work with pharmaceutical partners towards commercialization, marketing and distribution its products.

To learn more about BioLink, call (919) 678-9478, e-mail them at info@biolinkonline.com, or visit the company's website at www.biolinkonline.com.

SBIR proposal writing basics: Prove feasibility in the middle of Phase I

Gail & Jim Greenwood, Greenwood Consulting Group, Inc.

So when are you supposed to prove the feasibility of your innovation in an SBIR or STTR project? The easy answer is that the proof of technical feasibility should be achieved in the Phase I project, since that is the main purpose of Phase I. The Phase I proposal should include a definition of the technical risk that must be overcome, a measure of success in doing so, and a justification of why that measure is appropriate. For further discussion on feasibility definition/quantification/justification, see our "Phase I as a Feasibility Study" article we wrote for the SBIR Alerting Service in 1999 on our website (<http://g-jgreenwood.home.att.net>) or in the Alerting Service archives.

A more useful answer to the "when do you prove feasibility" question is to consider proving it before the end of the Phase I project. There are several reasons why feasibility might be proven part way through Phase I, rather than at the very end of the project.

First, some agencies only accept Phase II proposals from companies that are invited to submit them. Most notable among these is the Dept of Defense (DOD), which is by far the largest SBIR/STTR agency. The invitation process begins part way through the Phase I effort, and includes consideration of how feasible your answer is to solving DOD's problem. Therefore, not concluding feasibility until the end of the Phase I project may hurt your chances of getting a Phase II invitation.

Second, many DOD components have “Fast Track” programs in which Phase I winners can by pass the invitation process and have a very high chance of a Phase II award if they can bring outside funds (e.g., from industry, or a DOD acquisition program) to their Phase II project. The process of applying for Fast Track starts part way through the Phase I project, so it can be important to have proven feasibility so you can prepare your Fast Track application. Further, proof of feasibility may be critical to your ability to attract the necessary third party funding.

Third, the sooner you know that your innovation is feasible, the quicker you can complete strategic partnerships, secure outside funding sources, and identify subcontractors for the Phase II project. It takes time to create these important relationships, and it may be hard to secure them until you have proven feasibility—both are reasons why it can be advantageous to prove feasibility earlier in Phase I rather than later.

Finally, if your innovation proves to be infeasible, you would rather know this as early as possible in the Phase I project. This might give you, for example, an opportunity to redirect the remainder of the Phase I effort—but that’s a topic for a future proposal writing tip.

Several important footnotes to this discussion:

- a. We are not implying that you necessarily have a four or five month Phase I SBIR project (vs the normal six month term). There likely will still be plenty of tasks to be performed after you conclude feasibility, such as completing the research and data collection and preparing the final report.
- b. However, some agencies would like to see Phase I projects finished in less than six months. Both the Special Operations Command (SOCOM) in the DOD and the Homeland Security Advanced Research Projects Agency (HSARPA) have problems they’d like solved “yesterday” so proposing an abbreviated Phase I project schedule may be very appealing to them.
- c. Several DOD components (namely Army, Navy and Missile Defense Organization) have Phase I options in their SBIR programs. These options can provide additional funding to Phase I winners. However, these DOD components do not exercise a Phase I option until they have selected the firm for a Phase II award. Therefore, proof of feasibility cannot be postponed until the option period, but must be done during the base SBIR project.
- d. While your goal may be to prove feasibility in less than six months, Phase I projects involve high risk research and therefore may not go according to plan. Some projects even require “no cost extensions” beyond the usual term.
- e. Never sacrifice the quality of a Phase I project just to try to conclude feasibility in an abbreviated period. Shoddy work or incomplete data likely will not convince agency representatives and proposal reviewers that you have proven feasibility, and may leave a negative impression about the quality of your work.

Secrets to SBIR funding success: Liaising with your funding agency

If I'd Known Then What I Know Now...Schmooze or lose

“The government is a predictable source of cashflow,” quotes DeRosier. “That’s the second academic myth I learned.” She warns companies not to pre-spend their SBIR money until it is deposited in their bank account. “I received one award notice in June and was told the money would arrive in September, but I didn’t actually receive the deposit until February.” “The bureaucracy in the SBIR program seems to be worse than the R01 environment,” notes Dr. Steck. “There are more monthly reports, and the accounting matters are more time consuming.”

A great score on your SBIR proposal isn’t money in the bank. “Even if you get a great score from the reviewers, and even if the agency tells you that they want to make an award, you can expect to have to jump through a hoop of discussion and negotiations,” says Gail Greenwood. “First,” according to Greenwood, “anticipate that the agency will want to ask some questions about your cost proposal.”

Notes Dr. Shih, “It is helpful to meet face-to-face with SBIR program directors in the various agencies, who, for the most part, are very approachable and helpful.” Jim Greenwood agrees. “Don’t be a stealth Phase I recipient: communicate with the agency. The word is ‘schmooze,’ and if you aren’t doing it in the Phase 1 project, you are making a big mistake.”

Dr. Shih offers suggestions based on his Phase II application experience. “Talk with potential end-users in your target market and, if possible, obtain letters of support from them. Agencies are focusing more and more on how you plan to commercialize your product or technology in Phase II.”

To win Phase II “you have to prove yourself to the awarding agency,” notes Jim Greenwood. “Don’t be labeled an SBIR Phase I whiner. A whiner is a winner who contacts the agency repeatedly about management woes and routine problems. Why would an agency want to prolong such agony by giving a whiner a Phase II award?”

Keys to SBIR success: Don’t go it alone

“Have someone critique your proposal,” recommends Dr. Friedman. “A fresh set of eyes to review the proposal prior to submission is very useful.” Friedman has used the SBTDC’s SBIR resources since the early days of his SBIR efforts. “The help provided by the SBTDC was invaluable. But it was not only the hints, success stories, and reminders that we get every month from the SBTDC’s SBIR newsletter. John Ujvari actually sat down and read the proposal in detail, read the comments from last’s year’s reviewers, and made extensive suggestions on how to answer them,” notes Rudy Rodriguez, President of Advanced Animal Diagnostics.

“Read the proposal instructions carefully and obtain sample grant proposal from others to ensure appropriate formatting and contents,” recommends Dr. Shih. “Focus the Phase II study with measurable endpoints consistent with industry standards.”

“The SBTDC’s SBIR workshops have provided a unique opportunity to directly interact with SBIR personnel from federal agencies and to share experiences with other SBIR award winners,” said Phil Schaefer, SBIR award winner and Chief Scientist at Vortant Technologies of Weaverville in western North Carolina.

Happy SBIR Motoring

Numerous SBIR resources, including proposal preparation assistance, workshops, sample proposals and conferences are available for North Carolina’s SBIR applicants. For more information, visit <http://www.sbtadc.org/sbir>.

Dr. Shih offers this advice to growing a SBIR funded tech company: “Building an entrepreneurial business is like driving a car, and cash is your fuel. In this current funding climate where gas stations are far apart, the SBIR grant program remains a viable option for entrepreneurs to fill their tanks and extend their drive. Good luck, and happy motoring.”