# bioentrepreneur

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## **Finance/Funding**



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#### How the US government can fund your company

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# Biotech firms can take advantage of many different US federal government programs set up to fund innovative research.

Securing federal grants may seem like an intimidating prospect, but if your company holds a technology that is relevant and useful to the government, then with guidance from skilled grant writers, it can win hundreds of thousands of dollars to advance its commercial interests. This article presents a road map for the various avenues of federal funding. Past grant winners also provide tips on writing stellar applications.

#### The road most traveled

Startup biotech companies most commonly acquire federal funds from the Small Business Innovation Research Program (SBIR) and the Small Business Technology Transfer Program (STTR) that are coordinated by the US Small Business Administration's (Washington, DC, USA) Office of Technology (see <u>Table 1</u>). Both programs fund technologies conceived by US entrepreneurs with fewer than 500 employees. The major difference between the two programs is that STTR only supports collaborations between companies and public research bodies. Both programs are a good fit for bioentrepreneurs because US biotech firms have 131 staff members on average, according to the Biotechnology Industry Organization (Washington, DC, USA).

The SBIR and STTP programs are fueled by contributions from various federal agencies such as the US Department of Defense (DoD; Washington, DC, USA), which has the biggest budget for small businesses (\$800 million), and the US National Institutes of Health (NIH; Bethesda, MD, USA), which has the second highest budget (\$450 million). The Defense Advanced Research Programs Agency (Arlington, VA, USA) also provides grants (see Box 1). Each participating agency earmarks 2.5% of its annual budget for the programs. The funds are also unlikely to dry up—this year the US Congress reauthorized the SBIR program until 2008 and the STTR program until 2009.

Ten federal agencies participate in the SBIR program, which, in 2002, handed out about 5,000 awards totaling \$1.5 billion. A subset of SBIRparticipating agencies—five in total—support the STTR program, whose 2002 total budget was \$65 million. Each agency runs its respective SBIR and STTR programs a little differently, but agencies generally can solicit grant proposals in specific research areas up to three times a year. In 2003, for instance, the NIH's National Cancer Institute is looking for entrepreneurs to develop antibody arrays for cancer treatments, whereas the National Center for HIV, Sexually Transmitted Diseases and Tuberculosis Prevention (Atlanta, GA, USA) aims to develop new laboratory tests that detect drug resistance. Entrepreneurs respond directly to such agency announcements, or they can secure independent contracts for original research ideas that are in line with an agency's agenda. In general, the DoD and the NIH support the bulk of SBIR and STTP funding for biotechnology.

Past SBIR grant winners say that the entire funding process, from filing a grant to actually getting money, stretches from about ten months to a year (see <u>Box 2</u>). The application is arduous, but the program is generally regarded as organized, efficient and timely. The review process for both SBIR and STTR grant proposals varies with the innovation being proposed; however, each agency follows identical review criteria when assessing applications. The <u>NIH's criteria</u> are considered good guidelines to follow.

Agencies' reviewers evaluate thousands of grant proposals each year, so it's important to catch their attention instantly (see Box 3). One crucial strategy is to get straight to the point. Grant proposals that fare the best are succinctly written while also proposing a technology that is innovative, financially viable and aligned with the government's research plan. Reviewers reject proposals that aim to accomplish too much-the key is to have a sharp-focused objective. It is also important to assemble a multidisciplinary team. For instance, an SBIR/STTP grant proposal to the NIH has a worse chance if the company does not have a health-related professional involved. Furthermore, say program officials, many applicants forget to receive regulatory clearances if their innovation requires human subjects for testing. Administrative mistakes like missing deadlines, or filing at the wrong office, are also extremely common.



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Businesses struggling to put proposals together can seek help from experienced grant writers at state-sponsored small business development centers. Federal officials also recommend communicating with relevant program managers to lessen confusion of any kind. About three months after submitting an application, applicants receive feedback from reviewers by way of a score between 100 and 500 (100 is a perfect score and almost a guaranteed indication that the company will get the grant). Companies with poor scores can improve their applications and apply again; program officials say they appreciate such perseverance.

Businesses can apply for phase I or phase II funding in both SBIR/STTR programs. Phase I SBIR grant winners receive up to \$100,000, and over eight months explore the viability of their concepts and submit a report, or 'feasibility study'. Past phase I winners can win phase II awards of up to \$750,000 for 'proof of principle' studies or developing a prototype of the proposed product. About 36% of all phase I SBIR awardees have also received phase II grants. Phase III, or the commercialization phase, is the ultimate objective of all SBIR/STTP initiatives, but neither program funds at that level of development. Phase III companies go on to seek capital in the private sector or apply for non-SBIR government 'follow-on contracts' to develop technologies further.

The STTR review process is almost identical to that of SBIR and there are only a few differences between the two programs. In STTR, businesses must be affiliated with a research institute, university or nonprofit organization. The business must complete at least 40% of the research and the partner institute must carry out at least 30%. The principal investigator (PI) can also be a staff member at either the business or its partnering institute. In the SBIR program, a company must employ the PI.

In addition to the links in <u>Table 1</u>, <u>several websites</u> include links to SBIR information pages of every participating federal agency.

#### On the wild side

The Advanced Technology Program (ATP) at the National Institute for Standards and Technology (NIST; Gaithersburg, MD, USA) is another avenue of federal assistance that fosters risky but strikingly original research with clear commercialization potential (see Table 1). For example, the ATP gambled on the fields of proteomics, bioinformatics and DNA diagnostics before almost any other US government funding program. In 2002 the ATP had a budget of \$200 million with \$61 million going to new awardees. The ATP will fund a single company's research for up to three years, with a maximum award of \$2 million, and as far as the prototype phase. ATP also funds company consortiums, providing unlimited funds for up to five years. Direct costs such as equipment are also covered, but companies must pay indirect expenditures such as attorneys' bills and electricity. Businesses of all sizes can apply to the program, but if history serves well, then small businesses need not fear-64% of all ATP award winners have been businesses with fewer than 500 employees, and of those the majority had rosters of less than 20.

The ATP is a very competitive program. In 2002 it received 1,076 grant applications, of which only 12% won funding. According to ATP program

managers, grant reviewers look for proposals that articulately, yet concisely, describe the core innovation. The reviewers also expect detailed commercialization plans and scientific methodologies that outline each stage of research. If an idea is risky, then entrepreneurs should also include the inherent risk and feasibility of their idea in the application.

The most important part of the application is the description of the innovation itself, which should demonstrate both economic and social potential. Possible grant-winning ideas might include a new method of tissue engineering or a cure for spinal cord injuries. Like the SBIR/STTP programs, ATP grant reviewers also respond to applicants with an 'oral debrief' that includes remarks and suggestions pertaining to a proposal. Program managers say it is a good idea to incorporate any suggestions and reapply if you are turned down.

#### Beyond federal agencies

When traditional funding channels dry up for research that advances US military and civilian interests, companies can also approach the US legislature. The Congressional Special Interest Research Programs (CSIRP) sponsor biomedical research that is requested by the US Congress rather than a federal agency. The DoD office <u>US Army Medical Research and Material Command</u> (USAMRMC) administers CSIRP and is responsible for releasing funds to award winners.

The programs are not included in the US president's budget, but Congress adds funds to the DoD budget so CSIRP funding levels vary every year. In 2002, at least \$50 million was directly earmarked for the program. Grant seekers from academia, industry or grassroots organizations approach congressional offices with research proposals. Congressmen then forward their chosen selections to DoD officers who allocate funding amounts. Grantees can receive up to about \$2 million per topic. The USAMRMC has managed over 100 projects since 1990, together totaling \$3 billion.

The CSIRP is divided into three broad areas of biomedical research:

- <u>Research directed at specific disease.</u> The office of <u>Congressionally</u> <u>Directed Medical Research Programs</u> sponsors multidisciplinary research to prevent certain diseases in military women and dependents. Grassroots advocacy groups pushed for research particularly in the diseases of breast cancer, prostate cancer, ovarian cancer and neurofibromatosis.
- Advanced Technology Programs. Administered by the <u>Telemedicine</u> and <u>Advanced Technology Research Center</u> (and separate from NIST's ATP programs), these programs fund research on disaster relief and emergency medical services for benefit to military personnel in remote areas. The program also supports applications of defense and aerospace technology to advanced healthcare delivery.
- Programs Related to the War-Zone Mission. Overseen by the Directorate of Research and Development, the program supports biomedical research that enhances the quality of care for military personnel. Research areas include osteoporosis, HIV and intravenous membrane oxygenators, or devices that oxygenate patients with acute lung damage.

Government negotiations are often shrouded in secrecy. Networking skills are a boon to those seeking funding of this sort (see Box 4). To get to the right congressional representatives or defense officials, companies can also hire consultants with contacts and expertise in DoD and Congressional funding programs or funding programs at other federal agencies. Commonly referred to as the 'beltway bandits' such companies comprise a large cottage industry (see Table 2).

#### Conclusions

There are federal funds aplenty and bioentrepreneurs have ample access to them. To win grants, companies should stick to key strategies like proposing technologies that are federally relevant, writing focused proposals and communicating extensively with agency officials. And don't get discouraged if your first applications get rejected, because the rewards are definitely worth your perseverance. Winning a grant is like learning to ride a bicycle—once you learn how, you never forget.

#### **Related material**

<u>SBIR World</u>, <u>Small Business Administration</u>, Zyn Systems,

# Table 1: Different types of grants for startups

Type of funding	Grant size and time	Agency	Focus of research
	Phase I: \$100,000 for six months	US Department of Health and Human Services	Biomedical research pertaining to each agency of the NIH
		•National Institutes of Health (NIH;	
		Rockville, MD, USA)	
		US Department of Defense	Defense research supporting ground
		•Army (Washington, DC, USA)	troops
		•Office of the Under Secretary for Defense (Washington, DC, USA)	Biodefense, sensors, nanotechnology
		•Special Operations Command (Washington, DC, USA)	Biodefense, sensors, nanotechnology
		•Defense Advanced Research Projects Agency(Washington, DC, USA)	Biodefense, sensors, nanotechnology
		Navy (Washington, DC, USA)	Maritime defense research
		•Air Force	Aviation defense research
		•Special Operations Command	Defense research
		National Aeronautics and Space Agency (NASA; Washington, DC, USA)	Aerospace technology, space science, earth science, biological and physical research, space flight
		US Department of Commerce	
SBIR grant/contracts		National Oceanic and Atmospheric	Ocean science, marine science,
	Phase II: \$750,000 for two years	Administration (Silver Spring, MD, USA)	ocean observation systems, cartography
		<ul> <li>National Institute of Standards and Technology(Gaithersburg, MD, USA)</li> </ul>	Advanced biological and chemical sensing technologies, new analytical methods, healthcare, medical physics
		<u>US Department of</u> Agriculture (Washington, DC, USA)	Scientific problems or opportunities in agriculture with potential for public benefit
		<u>US Department of</u> Education (Washington, DC, USA)	Special education and rehabilitation services, vocational and adult education
		<u>US Department of</u> Energy (Germantown, MD, USA)	Computational research, energy efficiency, nuclear energy, fossil energy, biological energy
		US Environmental Protection Agency	Solutions to broad array of environmental problems in US
		National Center for Environmental	
		Research (Washington, DC, USA)	
		US National Science Foundation (Washington, DC, USA)	Biological, chemical, physical sciences
STTR grants	Phase I: \$100,000 for one year	us pepartment of Transportation	Sensors and software Advanced biological and chemical sensing technologies, new analytical methods, healthcare, medical physics
		US National Institutes of Health (NIH; Rockville, MD, USA)	
	Phase II: \$500,000 for two years	US Department of Defense, Office of the Under Secretary for	Biodefense, sensors, nanotechnology
		National Aeronautics and Space Agency (NASA; Washington, DC, USA)	Aerospace technology, space science, earth science, biological and physical research, space flight
		US Department of Energy (Germantown, MD, USA)	Computational research, energy efficiency, nuclear energy, fossil energy, biological energy
		<u>US National Science</u> Foundation (Washington, DC, USA)	Biological, chemical, physical sciences
ATP grants	Single company: \$2 million for two years	US National Institute of Standards and Technology (Gaithersburg, MD, USA)	Advanced biological and chemical sensing technologies, new analytical methods, healthcare, medical physics
			Consortium: Unlimited funding for up to five years

#### Box 1: Cracking DARPA's code

The Defense Advanced Research Programs Agency (DARPA; Arlington, VA, USA) last year gave about \$137 million for high risk, high pay-off projects. Like every federal agency, DARPA publishes specific proposal solicitations in specific research areas like biological defense systems, but also welcomes independent solicitations. DARPA funds about one in three new projects and the best time to seek DARPA support is in the spring. DARPA reviewers look for sound technical ideas with a defined post-research business plan. Proposed projects have a better chance if a DARPA program manager has expertise within the proposed subject area. Awarded contracts are of varying lengths and amounts though contractors typically receive \$200,000 per year. The selection process moves forward as following:

- <u>A program manager solicits proposal abstracts and reviews independently submitted proposals.</u> DARPA program managers discourage 'blind proposals,' or submitting proposals without prior discussions with DARPA program managers. Blind proposals rarely reach the right reviewer.
- After reviewing an abstract, program managers notify applicants on their chances of receiving funding. Potential contract winners are asked to file full submissions. If the project's objective is not clearly presented within the first three pages of the proposal, there is a good chance reviewers will miss the idea due to the huge numbers of applications they must evaluate.
- Internal scientific panels review the proposals for relevance to DARPA's goals. Officials assess a combination of factors including the scientific validity of the technology, its relevance to DARPA and its importance to the agency's overall mission.
- <u>Contract negotiation follows for selected proposals.</u> DARPA program managers recommend that proposals include both a technical plan and a transition plan for commercialization of the developed technologies.

#### Box 2: Voices of experience

The Stratatech Corporation (Madison, Wisconsin) is a biotechnology company that won a phase 1 ATP grant this year. The company is working on a technology that would enable the storage of living human cells and organs at room temperatures. Stratatech also won SBIR funding this year. Principal investigator Paul Conrad, who is also the engineering manager at Stratatech, speaks of his experiences with both ATP and SBIR.

SBIR proposal ideas differ a lot from ATP proposal ideas, says Conrad. "With SBIR grants it's better to propose ideas that are more essential to the success of the company. But with the ATP you can go out on a limb," he says.

The SBIR grant application process is very organized and tightly follows its evaluation deadlines, says Conrad. But getting an ATP award is another ball game altogether. The application process is extremely difficult and often plagued by delays. For instance, Stratatech submitted an ATP technical proposal last August, expecting to receive preliminary comments within 6 weeks. But it was November before the company heard from any reviewers. The company quickly followed up with a business proposal and were soon invited to make an oral presentation in December. Getting an oral interview at the ATP is a very good sign, says Conrad, so when Stratatech executives came back from Washington, they assumed they had bagged the grant. But six months passed before the company finally saw the money. "We're a small company and are very hand-to-mouth with funding. The delays [with ATP] had a serious destabilizing impact on our fundraising efforts and slowed us down in the venture capital markets," says Conrad.

Another biotechnology company, Chromatin (Chicago, IL, USA), has won ATP awards several times; this year, they won one for work on multi-gene, mini-chromosomes that assist the delivery of genes into plants. Mich Hein, Chromatin president and chief executive officer gives the following advice to companies seeking money from either program:

- Find as much alignment as possible between the company's goals and the objectives of the government agency. Communicate extensively with the agency right from the start.
- The body of the grant should indicate that a company knows exactly what it will do and why—the more
  difficult it is to understand the gist of a proposal, the less likely a grant will be accepted. Grant writers
  should avoid superfluous information.
- · Make sure the proposed budget matches up with activities.
- If there is an area where you occupy one key niche but there are other players that can bring value to the
  proposal, contact them and incorporate their expertise into the project. Demonstrating the ability or desire
  to collaborate strengthens the chance of getting funding.

#### Box 4: The buddy network

A small biotechnology company, HandyLab (Ann Arbor, MI, USA), is waiting to formalize a sub-contract this year with the Department of Defense. HandyLab creates portable 30-minute nucleic acid- and protein-based diagnostic systems for infectious and hereditary diseases.

Despite having the funding mechanism in place, Sundaresh Brahmasandra, HandyLab's vice president of product development, feels that getting a contract with the DoD is a vague process that hinges on cultivating contacts within the agency. Because of connections between one of HandyLab's board members and Veridian (Arlington, VA, USA), a defense contracting company, HandyLab was invited last year to submit proposals to the DoD, recalls Brahmasandra. HandyLab's technology has applications in bio-warfare so the company responded to the request.

Recently, HandyLab heard it is likely to be awarded a subcontract with a defense contracting research laboratory at the University of Buffalo, New York. For companies looking for DoD contracts, Brahmasandra recommends building a good network. And many defense specialists echo that advice including Col. Jerry Warner, president of the defense contracting company Defense Life Sciences. To get DoD contracts "it makes sense to team up with somebody who is prominent in [defense] circles," says Brahmasandra. "It's a little bit of a buddy network."

#### Table 2: Firms that help companies obtain federal funds

Company	Expertise
Steven Wolfe Associates (Washington, DC, USA)	Expertise in lobbying congressional representatives, and funding processes within the Department of Defense
Defense Life Sciences (McLean, VA, USA)	Expertise in securing grants from the Department of Defense
<u>DawnBreaker (Roc</u> <u>hester, NY, USA)</u>	Assists companies to acquire SBIR/STTR and ATP funding from the Environmental Protection Agency, the National Science Foundation, the National Cancer Institute, the Department of Energy and the Department of Defense.
<u>Biotechnology</u> <u>Business</u> <u>Consultants (Ann</u> <u>Arbor, MI, USA)</u>	Assist small companies through the government granting process.
<u>Veridian (Arlington</u> , VA, USA)	Helps companies secure contracts from the Department of Defense

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