An Overview of the NCI SBIR Program

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Today's Presentation

Overview
Eligibility Requirements
Move to More Focused Solicitations
New SBIR Bridge Award
Submitting An Application

Overview

Why are SBIR and STTR Important?
NIH's primary resource for enabling commercialization of innovative high impact technologies, such as:

- Medical devices
- Therapeutics

- Provides incentive to academic investigators to translate technology (new company formation)
- One of the largest sources of early-stage life sciences financing

Reasons to Seek SBIR & STTR Funding

- Provides seed funding for innovative technology development projects
- Intellectual property rights are retained by the small business concern
- Not a loan – no repayment is required
- Doesn't impact stock or shares in any way (no dilution of capital)
- Provides recognition, verification and visibility
- Can be a leveraging tool to attract other funding (VC, etc.)

SBIR & STTR: Three-Phase Program

PHASE I – R41, R43
Feasibility Study
$100K and 6-month (SBIR) *
or 12-month (STTR) Award

PHASE II – R42, R44
Full Research/R&D
$750K and 2-year Award (SBIR & STTR) *
Commercialization plan required

PHASE III
Commercialization Stage
Use of non-SBIR/STTR Funds
These funding levels are guidelines. You should request the budget appropriate to accomplish the goals of the project.

Program Descriptions

SBIR: Set-aside Program for Small Business Concerns to engage in Federal R&D with potential for commercialization – set aside 2.5%

STTR: Set-aside Program to facilitate Cooperative R&D between Small Business Concerns and U.S. Research Institutions with potential for commercialization – set aside 0.3%

A $100M Program at the NCI

Eligibility Requirements

SBIR Eligibility Requirements

Small Business Concern
Organized for-profit U.S. business:
500 or fewer employees, including affiliates
Must be:
At least 51% U.S.- owned by individuals and independently operated
or

- At least 51% owned and controlled by another (one) business concern that is at least 51% owned and controlled by one or more individuals
- Principal Investigator's primary employment must be with the Small Business Concern

STTR Eligibility Requirements

- Applicant is a Small Business Concern
- Formal Cooperative R&D Effort
    - Minimum 40% by small business
    - Minimum 30% by U.S. research institution
- U.S. Research Institution
    - College or University
    - Other non-profit research organization
    - Federal R&D center
- Intellectual Property Agreement
    - Allocation of IP rights and rights to carry out follow-on R&D and commercialization
- Principal Investigator's primary employment may be with either the Small Business Concern or the research institution

SBIR and STTR Programs

(Critical Differences)

SBIR:

- Permits research institution partners (e.g., universities)
- Small business concern may outsource ~33% of Phase I activities and 50% of Phase II activities

STTR:

- Requires research institution partners (e.g., universities)
- 40% of the work should be conducted by the small business concern (for profit) and 30% by a U.S. research institution (non-profit)

Award always made to small business

NCI SBIR Funding Opportunities

NIH Issues Multiple SBIR Solicitations

SBIR/STTR Omnibus Grant Solicitation
Release: January
Receipt Dates: April 5, August 5, and December 5

SBIR Contract Solicitation (NIH, CDC)
Release: August
Receipt Date: Early November

NIH Guide for Grants and Contracts
Release: Weekly
Receipt Dates: Various
For more information visit:
http://sbir.cancer.gov

NCI is Moving to More Focused Solicitations

- Goal is to improve success in commercialization by focusing on more directed research.
- Invest in the technology priorities of NCI that also have potential for commercialization
- Catalyze targeted technology development and draw private sector investment in areas such as drug development and assays that measure treatment response
- Significantly increase the use of SBIR contracts.

New NCI SBIR Contract Funding Opportunities – DUE NOVEMBER 3rd

- Biopsy Instruments and Devices that Preserve Molecular Profiles in Tumors
- Development of Molecular Pharmacodynamic Assays for Targeted Therapies
- System to Analyze and Support Biomarker R&D Strategies
- Development of Anticancer Agents
- Innovative Methods for Manufacturing Safe, Effective Cancer Therapeutics
- Innovative Strategies to Protect Radiosensitive Organs and structures During Radiation Therapy

- Quantitative Tissue Imaging For Clinical Diagnosis and Treatment
- Antibody Array for Cancer Detection and Diagnosis
- Novel and Improved Assays fir Detecting Epigenetic Modifications
- Nanotechnology Imaging and Sensing Platforms for Improved Diagnosis of Cancer

New NCI SBIR Contract Funding Opportunities – DUE NOVEMBER 3rd

- Multifunctional Therapeutics Based on Nanotechnology
- High Level Programming Language to Expedite Development of User Interfaces
- Mobile Computing for Consumer-centered Cancer Prevention and Control
- Health Information Technology to Facilitate Patient-centered Communication in Cancer-related Care
- Development of shRNA Library Screening Technology for Cancer-Related Targets
- Novel Antibody Epitope Mapping Technologies
- Development of Novel Protein Expression Technologies for Glycosylated Cancer Related Proteins
- Peptide Aptamers: New Tools to Capture and Study Protein Interactions in Lieu of Immunological Reagents

More Information on NCI SBIR & STTR Website
http://sbir.cancer.gov

New SBIR Bridge Award

Phase II SBIR and Commercialization Success

Today, many awardees complete the SBIR Phase II award without advancing the technology far enough to attract private investment

Significant resources are required for getting through the FDA approval process
This funding gap is known as the "Valley of Death"

SBIR Phase II Bridge Award

Follow-On Award to the SBIR Phase II Award
Goal is to help early-stage companies cross the "Valley of Death" by:

- Helping to facilitate partnerships with third party investors/strategic partners
- Incentivizing partnerships earlier in the development process by sharing in the investment risk

The Bridge Award is modeled after NSF's "Phase IIB Option" and has the same key feature:

- SBIR company is expected to raise third-party funds. Competitive preference & funding priority will be given to applicants who do so.

Phase II Bridge Pilot at NCI

- Third-party funds are expected to equal or exceed NCI funds being requested
- Third-party funds may include:
- Cash, liquid assets, convertible debt
- Sources of third-party funds may include:
- Another company, venture capital firm, individual "angel" investor, foundation, university, state or local government, or any combination

Third-party investors are expected to bring:

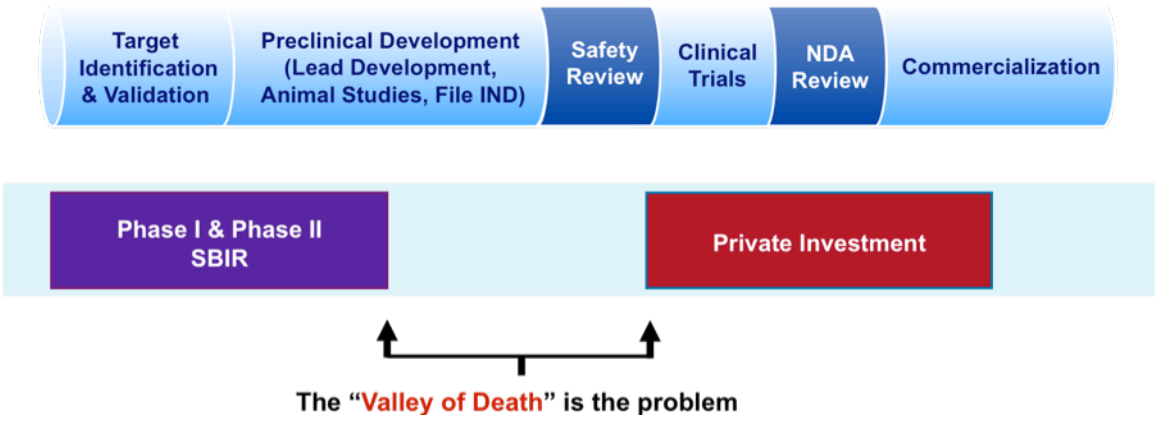
- Rigorous commercialization due diligence
- Commercialization guidance during the award
- Additional financing beyond the initial third-party investment

Phase II Bridge Pilot at NCI
RFA-CA-08-021

- Pilot will focus on **cancer therapies and cancer imaging**
- Budgets up to **$1 million per year for up to 3 years from NCI**
- Development efforts must be predicated on a previous SBIR Phase II grant and may include:
  - Pre-clinical R&D needed for regulatory filings (e.g. IND or IDE)
  - Clinical trials
- Application Dates: **September 19, 2008** and February 27, 2009
- **NCI intends to commit up to $10M in FY 2009 to Bridge Awards**

- Open to current and recently expired NIH SBIR Phase II projects

Example: How the Bridge Award Would Apply in the Area of Drug Development



Example: How the Bridge Award Would Apply in the Area of Drug Development

SBIR Bridge Award addresses the problem by bridging the "Valley of Death"

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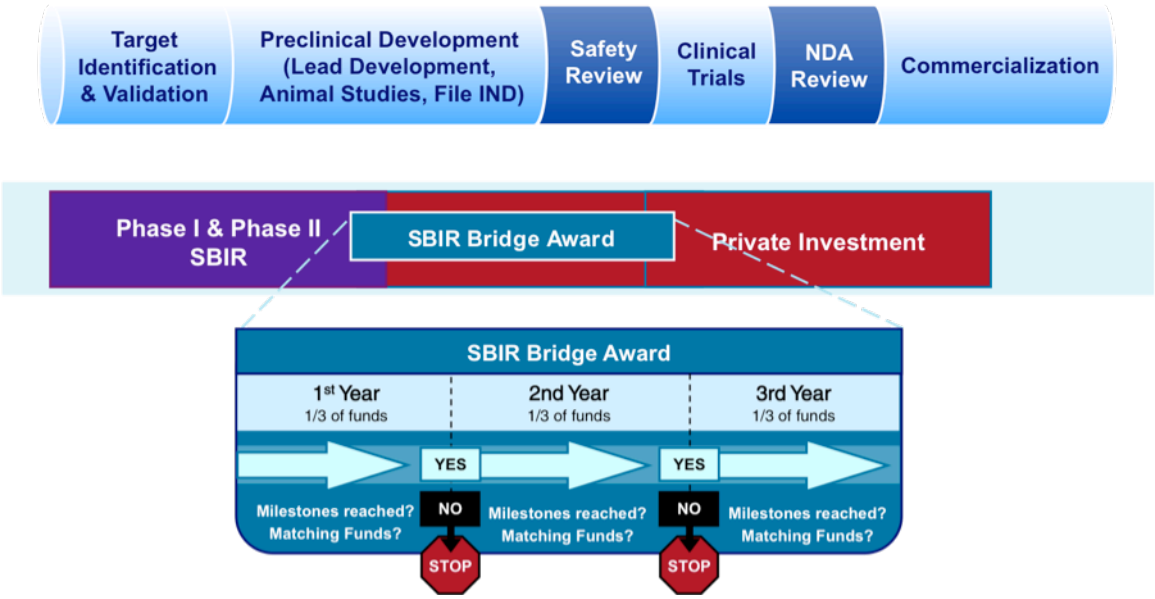

SBIR Bridge Award allows NIH to share investment risk by incentivizing investors or strategic partners to evaluate projects and commit funds much earlier

Establishing a new SBIR Development Center

Development Center Goals

- Assemble the scientific and business expertise needed to optimally manage the SBIR program
- Integrate all SBIR initiatives with NCI's program priorities
- Foster collaborations with other Institutes at NIH which share common technology needs
- Offer services on a reimbursable basis
- *Increase the return on investment for the SBIR program*

Key Activities and Metrics

Center Activities:

- Market the program to attract the best companies
- Relationship building with stakeholders
- Active management of projects and better oversight
- Facilitate success through mentorship
- Create investor networks focused on commercializing cancer technologies
- Examine correlations between activities and outcomes; fine tune the program

Near-term Metrics (1 – 3 years):

- Improvement Over Previous Rounds
- Number and quality of proposals received
- Achievement of technical and commercial milestones
- Number of Phase I awardees who successfully compete for a Phase II award

Long-term Metrics (3 – 5 years):

- Innovation Metrics

- Invention disclosures, patents, publications
- Commercialization Metrics
- Number of products impacting the cancer community, cumulative sales, license agreements
- FDA approvals for marketing
- Company sold or merged, acquisition of outside capital

Submitting an Application

Keys to a Strong Application

- Significant, innovative, and focused science
- Significant product and/or commercial potential
- A product-focused application is more likely to have support of business reviewers
- A project with sound financial projections is more likely to attract a partner
- Translational research/clinical applications projects should involve the appropriate collaborators
- Oncologists
- Pathologists
- Statisticians

Know NIH Review Criteria

- **Significance**: Does the study address an important problem and have commercial potential?
- **Approach**: Are design and methods well-developed and appropriate? Are problem areas addressed?
- **Innovation**: Are there novel concepts or approaches? Are the aims original and innovative?

- **Investigator**: Is the investigator appropriately trained and capable of managing the project?
- **Environment**: Does the scientific environment contribute to the probability of success? Is the environment unique?
- **Commercialization**: Is the company's business strategy one that has a high potential for success?

Key #1
Start Application Process Early!

- Start developing your application as early as possible. You need time to develop a strong proposal.
- Seek help of experienced applicants early in process
- Assemble a strong scientific team
- If you have a weakness or gap in expertise, fill it early

Key #2
Consider Your Company's Strengths and Weaknesses

- Consider your company's strengths
- Try to exploit those strengths to address a specific NIH Program initiative
- Consider your weaknesses too
- It is rare that a small company will have all the necessary expertise for a strong application

- If you have no track record of commercialization, consider getting a partner who does
- Partner with other companies or academics to fill gaps
- Contact NIH Program Director in advance to discuss your proposal and receive feedback
- Review similar currently funded projects in the NIH CRISP database (http://crisp.cit.nih.gov/)

Key #3
Always Consider the Reviewers

Who is going to review your application?

- 10 or more on the Review Panel who will score your application
- However, primary review by 2-4 persons with appropriate expertise assembled by SRA
- Combination of academic and business professionals

Key #3
Always Consider the Reviewers

What are they looking for?

- Readable and understandable application
- Do not assume they will know everything you know
- You understand your application best so convey it to them
- Clear and concise language, "lay summary"
- Clear plan for Phase I, II and commercialization

Feasible methods

- Appropriate objective tests of success for each Specific Aim
- Promising preliminary data are very influential
- Solid letters of support for commercialization

Key #3
Always Consider the Reviewers

Read your material critically as if you were the Reviewer

- What are the weaknesses?
- Point out potential difficulties, do not hide them
- Suggest ways to address them or provide rationale
- Recruit an independent reader

Provide alternative methods if a particular approach is not successful
Help the Reviewer write his analysis

Key #3
Always Consider the Reviewers

- Be realistic about your goals
- Provide a feasible timetable for key objectives
- Be realistic about your budget
- Ask Program Director for early guidance

Application Checklist

- Have you honestly assessed the commercial viability of your technology?
- Do you have a talented professional to be a PI?
- Is the PI supported by the right team? Does he or she have the time?
- Do you have the resources to write the grant application or contract proposal?
- Do you have the resources and capabilities to execute?
- Do you have the business resources needed for a successful launch?

Success Stories

Success Stories
Naviscan (San Diego, Calif.)

- PEM Flex™ PET Scanner has unprecedented 2 mm imaging capability enabling detection of the earliest stages of breast cancer (in situ) and tumors less than 2 millimeters in size with very high accuracy and sensitivity (93%). This cannot be achieved by any other modality, including MRI and is important for early detection.

Highlights

- SBIR funding received from 1994-2005
- FDA-Cleared in July 2003
- Venture-backed capital received in 2005
- 40 Employees

Success Stories
Xenogen and Spectros

- Dr. Benaron has founded five optical imaging systems companies since 1986. Three companies that received NCI SBIR funding succeeded; two that did not, failed. Xenogen's In Vivo Imaging System and Spectros T-Stat ischemia detection device have both achieved success.

Highlights

- Xenogen sold for $80 million to Caliper Life Sciences in 2006; remains a leader in drug discovery/research optical molecular imaging systems
- Spectros T-Stat first device approved by U.S. FDA for ischemia detection.

Success Stories
NovaRx (San Diego, Calif.)

- Patented vaccine technology that blocks the effects of TGF-β so that the vaccine is more potent in amplifying the immune system's ability to destroy cancerous cells. As compared to current approved therapies, Lucanix™(lung cancer vaccine) shows dramatic increase in median survival time (581 days vs. 240 days) and 2-year survival rates (47% vs. < 20%). It has received fast-track status from the FDA to accelerate the speed to which this promising vaccine reaches patients.

Highlights

- SBIR funding received from 2002 through 2010
- 2 Phase III clinical trials (lung cancer and glioma)
- Venture capital raised matches SBIR funding
- Additional vaccines for other tumor sites are being explored and show great promise.

http://sbir.cancer.gov

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