Bringing Science to the Market: The NCI SBIR Program

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NCI SBIR Development Center

IMAT Principal Investigators Meeting
November 14th, 2011
Today’s Presentation

• Overview & Eligibility
• NCI SBIR Development Center
• NCI SBIR Initiatives
• SBIR and IMAT
• NIH SBIR/STTR Funding Opportunities
Congressional Goals

1. Stimulate technological innovation
2. Use small business to meet Federal R&D needs
3. Increase private-sector commercialization innovations derived from Federal R&D
4. Foster participation by minority and disadvantaged persons in technological innovation

Small Business Innovation Development Act of 1982
Small Business Technology Transfer Act Act of 1992
Set Aside

- **SBIR:** Set-aside program for small business concerns to engage in Federal R&D with the potential for commercialization
- **STTR:** Set-aside program to facilitate cooperative R&D between small business concerns and U.S. research institutions with potential for commercialization

~$110 million annually at the **NCI**
~$650 million annually at the NIH
• Provides seed funding for innovative technology development
• Provides recognition, verification and visibility
• Helps provide leverage in attracting additional funding or support (e.g., venture capital, strategic partner)

➢ Not a Loan
  ∴ No repayment is required
  ∴ Doesn’t impact stock or shares in any way (i.e. non-dilutive)

• Intellectual property rights retained by the small business
  • Bayh-Dole Act (1980)
PHASE I – R41, R43
• Feasibility Study
• $150K and 6-month (SBIR) *
• or 12-month (STTR) Award

PHASE II – R42, R44
• Full Research/R&D
• $1M and 2-year Award (SBIR & STTR) *
• Commercialization plan required

PHASE III
• Commercialization Stage
• Use of non-SBIR/STTR Funds

* Note: Actual funding levels may differ by topic.
SBIR Eligibility

- Applicant must be a Small Business Concern (SBC)
- Organized for-profit U.S. business
- 500 or fewer employees, including affiliates
- PD/PI’s primary employment (i.e., >50%) must be with SBC at the time of award and for duration of the project period
- 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
Applicant is a Small Business Concern

Formal Cooperative R&D Effort
- 40% by small business
- 30% by U.S. research institution

U.S. Research Institution: College or University; Non-profit research organization; Federally-Funded R&D Center (FFRDC)

Intellectual Property Agreement
- Allocation SBC of IP rights (to SBC) 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
The annual SBIR/STTR budget for each participating Institute or Center (IC) is proportional to the total annual budget appropriation for that IC.

<table>
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<tr>
<th>2010 Budget</th>
<th>SBIR</th>
<th>STTR</th>
<th>SBIR+STTR</th>
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<tbody>
<tr>
<td>NIH</td>
<td>$616M</td>
<td>$74M</td>
<td>$690M</td>
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<tr>
<td>NCI</td>
<td>$99M</td>
<td>$12M</td>
<td>$111M</td>
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Old SBIR Management Model at NCI

- Awards were managed by 40-50 people who managed a combination of NIH grant mechanisms
- The majority of these NCI program officers managed predominantly academic mechanisms and thus had an academic focus

New Development Center at NCI

- Team of 9 Program Managers/Directors, and one Center Director, entirely funded by NCI
- Exclusively focused on the management of NCI’s SBIR/STTR portfolio
- Directors have previous industry experience and professional networks to help mentor awardees in commercialization strategy and process
- Center is developing a range of new activities to help small businesses
- Center staff continues interactions with NCI program staff concerning cancer research
NCI SBIR Development Center

Michael Weingarten, MA (Director)
Previous
- NASA – Program Manager, NASA Technology Commercialization Program

Greg Evans, PhD (Team Leader)
Previous
- NHLBI/NIH – Program Director, Translational and Multicenter Clinical Research in Hemoglobinopathies
- NHGRI/NIH – Senior Staff Fellow

Jian Lou, PhD (Program Director)
Previous
- Johnson & Johnson – Research Scientist, Target Validation & Biomarker Development
- Lumicycle, Inc. – Director, Molecular Biology Systems Analysis

David Beylin, MS (Program Director)
Previous
- X/Seed Capital Management, LLC, Consultant
- Naviscan PET Systems, Inc., Vice President, Research

Deepa Narayanan, MS (Program Director)
Previous
- Naviscan PET Systems, Inc., Director, Clinical Data Management (Oncology Imaging & Clinical Trials)
- Fox Chase Cancer Center, Scientific Associate (Molecular Imaging Lab)

Ali Andalibi, PhD (Team Leader)
Previous
- NSF – SBIR Program Director, Medical Biotechnology
- House Ear Institute – Scientist & Director, New Technology and Project Development
- Trega Biosciences, Inc. – Research Scientist

Andrew J. Kurtz, PhD (Team Leader)
Previous
- NIH – AAAS Science & Technology Policy Fellow
- Cedra Corporation – Research Associate, Bio-Analytical Assay Development

Patricia Weber, DrPH (Program Director)
Previous
International Heart Institute of Montana – Manager, Tissue Engineering and Surgical Research
Ribi ImmunoChem Research, Inc. – Team Leader, Cardiovascular Pharmacology & Licensing
Trega Biosciences – Director, Microbiology & Immunology

Todd Haim, PhD (Program Manager)
Previous
- National Academy of Sciences – Christine Mirzayan Science and Technology Policy Fellow
- Pfizer Research Laboratories – Postdoc Fellow,
- Cardiac Pathogenesis & Metabolic Disorders

Julienne Willis (Program Specialist)
Mentoring and Facilitation

Goal

• To work closely with promising SBIR Phase II awardees in order for them to advance their technologies towards the clinic

Path

• Active management of projects and better oversight
• Mentor and guide companies throughout the award period
• Provide Phase II awardees access to regulatory consultants to accelerate the FDA approval process for drugs, biologics and devices
• When appropriate, act as a liaison to bring investors and NCI SBIR companies together
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 II Bridge Award

PHASE III
• Commercialization Stage
• Use of non-SBIR/STTR Funds

* Note: Actual funding levels may differ by topic.
Follow-on to SBIR Phase II

• Helps early-stage companies cross the “Valley of Death” by:
  • Facilitating partnerships with third-party investors & strategic partners
  • Incentivizing third-party investments earlier in the development process

➢ NCI is sharing in the investment risk with other investors

Incentive Structure

• Gives competitive preference and funding priority to applicants that can raise third-party funds (i.e., 1:1 match)
  • Affords NIH the opportunity to leverage millions in external resources
  • Provides valuable input from third-party investors in several ways:
    1. Rigorous commercialization due diligence prior to award
    2. Commercialization guidance during the award
    3. Additional financing beyond the Bridge Award project period
Technical Scope: Cancer Therapies, Imaging Technologies & Diagnostics

- Need for large amounts of capital for clinical validation and FDA approvals
- Opportunity to make a significant impact on many projects in the SBIR portfolio

Mechanism & Budgets

- Uses the SBIR Phase II (R44) competing renewal mechanism
- Provides up to $1 M per year for up to 3 years
- Available to current Phase II grant awards, and those that ended within last 2 years

Preferred Third-Party Matching Funds

- Cash, liquid assets, convertible debt

Sources of Funds

- Another company, venture capital firm, individual “angel” investor, foundation, university, state or local government, or any combination
San Diego, CA $3.0M for the commercialization of ASONEP™, a first-in-class monoclonal antibody against the angiogenic growth factor S1P

Oriental, NC $3.0M for the development of a photoacoustic computed tomography (CT) scanner for preclinical molecular imaging

Norcross, GA $2.5M for the development of LightTouch®, a point-of-care device for cervical cancer screening

Northridge, CA $3.0M for the development of a novel molecular breast imaging technique to guide early-stage patient care

Miramar, FL $3.0M for the development of ALT-801, a fusion protein consisting of IL-2 coupled with a soluble T-cell receptor fragment that recognizes a specific form of processed p53 antigen

West Henrietta, NY $3.0M for the development of a cone beam breast CT scanner

10 New Bridge Awards
FY2009 + FY2010

Investor Total (3 yrs) $62,950,000
NCI Total (3 yrs) $27,395,816
Leverage >2.3 to 1
NCI SBIR Investor Forum

Exclusive opportunity for 14 NCI-funded companies to showcase their technologies
http://sbir.cancer.gov/investorforum/

Featured Small Businesses
- Opportunity to pitch and network with >150 investors and potential strategic partners

Investors
- Opportunity to evaluate NCI’s top companies with innovative technologies
- Exclusive one-on-one meetings
SBIR Contract Solicitation
Funding Opportunity Summary

- PHS-2012-1 “Solicitation of NIH and CDC for SBIR Contract Proposals”

- ONE application receipt date per year: published in late August

  Receipt Date: November 7, 2011 (CLOSED)

- RFP can be found at:

- NCI published twelve topics in the areas:
  - Drugs
  - Diagnostics
  - Imaging
  - Health IT
  - Research tools
NCI Contract Funding Topics

- (*) 255 Development of Anticancer Agents
- (*) 277 Development of Companion Diagnostics
- (*) 291 Development of Radiation Modulators For Use During Radiotherapy
- 300 Reformulation of Cancer Therapeutics using Nanotechnology
- 301 Probing Tumor Microenvironment Using In-vivo Nanotechnology-based Sensors
- 306 Development of Innovative Algorithms for Processing & Analysis of In Vivo Images
- (*) 307 Novel Imaging Agents to Expand the Clinical Toolkit for Cancer Diagnosis, Staging, and Treatment
- 308 Automated Collection, Storage, Analysis, and Reporting Systems for Dietary Images
- 309 Development of Low Cost, Small Sample Multi-Analyte Technologies for Cancer Diagnosis, Prognosis and Early Detection
- (*) 310 Simplified Tissue Microarray Instrument For Clinical and Research Settings (NIH Technology Transfer)
- 311 High Throughput Isolation of Antigen Specific T-cells for Cancer Therapy (NIH Technology Transfer)
- 312 Generation and Qualification of Site-specific Post-translationally Modified Proteins for Use as Calibrators in Pharmacodynamic (PD) Assays
## Differences between SBIR grants and contracts

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<th>Omnibus Solicitation for SBIR Grants</th>
<th>Solicitation for SBIR Contracts</th>
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<tbody>
<tr>
<td><strong>Scope of the proposal</strong></td>
<td>Investigator-defined (within mission of NIH)</td>
<td>Defined by the NIH (focused topics)</td>
</tr>
<tr>
<td><strong>Questions during solicitation period?</strong></td>
<td>May speak with any Program Officer</td>
<td><strong>MUST</strong> contact the contracting officer</td>
</tr>
<tr>
<td><strong>Basis for Award</strong></td>
<td>Based on the score received during peer review</td>
<td>If proposal scores well during peer review, must then negotiate a contract with NIH</td>
</tr>
<tr>
<td><strong>Reporting</strong></td>
<td>Final report (Phase I); Annual progress reports (Phase II)</td>
<td>Monthly progress reports</td>
</tr>
<tr>
<td><strong>Phase II transition</strong></td>
<td>May apply as soon as Phase I aims are completed</td>
<td>Must be invited by the NIH to submit Phase II proposal</td>
</tr>
<tr>
<td><strong>Set-aside of funds for particular areas?</strong></td>
<td>NO</td>
<td><strong>YES</strong></td>
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Innovative Molecular Analysis Technologies (IMAT)

Mission:
Revolutionize the state-of-the-science by stimulating the early-stage development of next generation molecular and cellular analysis technologies

Goals:
• To focus innovative technology development efforts from multiple communities on cancer
• To accelerate the maturation and dissemination of meritorious technologies from feasibility to development and/or commercialization.

Key Features:
• Emphasis on technology development (vs. traditional hypothesis-driven)
• Investigator-initiated, NCI Trans-divisional Program
• All communities (industry/academic, international) are invited to apply
• Emphasis on high-risk, high-impact, and high-payoff technology development

http://innovation.cancer.gov
Scope of R21/R33 IMAT RFAs is limited to early-stage development of innovative technologies and prototype validation

- Does not support commercial validation activities.
- Thus, creates a significant funding gap for those who have a prototype but have not mitigated sufficient technical risk to attract investors.

SBIR/IMAT Collaborations:

- Catalyze targeted technology development and commercial validation in the area of molecular analysis technologies thru a set aside.
- Provide a cohesive program that is aligned with the goals of the IMAT R21/R33 programs
- Emphasis on the commercialization
Proof-of-principle to technical maturation

IMAT Pipeline

Idea
Proof Of Principle
Development
Prototype Validation
Product Development
Market

R21
Exploratory/Pilot Phase
Innovative Technology/approach
No Preliminary Data Required

R33
Developmental Phase
Prototype Validation
Completed Milestones

R43/44
Beyond Prototype Phase
Commercial Feasibility
Scale Up
What the SBIR Development Center will offer applicants/awardees

• SBIR outreach programs
  ▪ Workshops at scientific conferences and trade shows
  ▪ Events with State Bio organizations

• Active management of projects
  ▪ Mentorship of companies
  ▪ Improved oversight, one-on-one coaching

• Matchmaking and Relationship building
  ▪ Cultivating investor networks, (VCs & strategic partners)
  ▪ NCI Investor Forum

• Commercialization Assistance
  ▪ Phase IIb Bridge Award
  ▪ Regulatory Assistance Initiative
PI: Gary Latham, Ph.D

IMAT Award: Protein Profiling Arrays, Random Arrays for Gene Expression Profiling (R43 – 1998, R44- 1999)
PI: Mark Chee, Ph.D

IMAT Award: Sensitive, Multiplexed Analysis of Breast Cancer Markers (R44 - 1999)
Quantum Dot Corp, PI: Robert H. Daniels, Ph.D.
Multiple Funding Solicitations

- **NIH SBIR/STTR Omnibus Solicitations for Grant Applications**
  
  *Release:* January  
  *Receipt Dates:* April 5, August 5, and December 5

- **Solicitation of the NIH & CDC for SBIR Contract Proposals**
  
  *Release:* August  
  *Receipt Date:* Early November

- **See NIH Guide for various other Program Announcements (PAs) and Requests for Application (RFAs), i.e. other grants**
  
  *Release:* Weekly  
  *Receipt Dates:* Various

http://sbir.cancer.gov/funding/
http://sbir.cancer.gov

NCI SBIR Development Center
Phone: 301-594-7709
E-mail: ncisbir@mail.nih.gov

Register on web site for funding opportunity updates