

# **Bringing Science to the Market: An Overview of The NCI Small Business Innovation Research Program**

*September 28, 2011*

**Michael Weingarten**  
**Director, NCI SBIR Development Center**



- **General SBIR/STTR Program Overview**
- **NCI/NIH SBIR Funding Opportunities**
- **NCI Phase II Bridge Award**
- **A New Way of Managing SBIR at the NCI**
- **Program Initiatives**

## 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

**2.5%**

**0.3%**

**~\$110 million annually at the NCI**

**~\$680 million annually at the NIH**

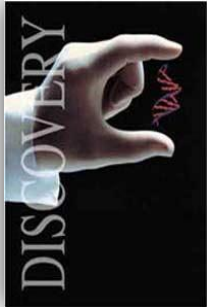
- **NCI's primary resource for enabling commercialization of high impact technologies that can benefit patients, such as:**
  - **Small Molecules and Biologics**
  - **Cancer Diagnostics**
  - **Cancer Imaging**
  - **Electronic Health & Education Tools**

- **One of the largest sources of early stage of life sciences funding in the country.**
  - **A stable and predictable source of funding**
- **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.)**

## Small Business Concern

- **For-profit U.S. business**
- **500 or fewer employees, including affiliates**
- **Must be:**
  - **At least 51% owned by US individuals and independently operated**  
**or**
  - **At least 51% owned and controlled by another 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 at the time of award**

- **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**



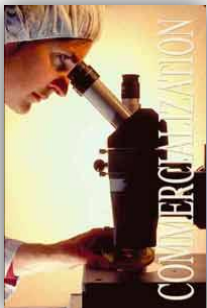
## PHASE I – R41, R43

- Feasibility Study
- \$150-250K, 6-12 months



## PHASE II – R42, R44

- Full Research/R&D
- \$1-2M, 2-3 years
- Commercialization plan required



## PHASE III

- Commercialization Stage
- Use of non-SBIR/STTR Funds

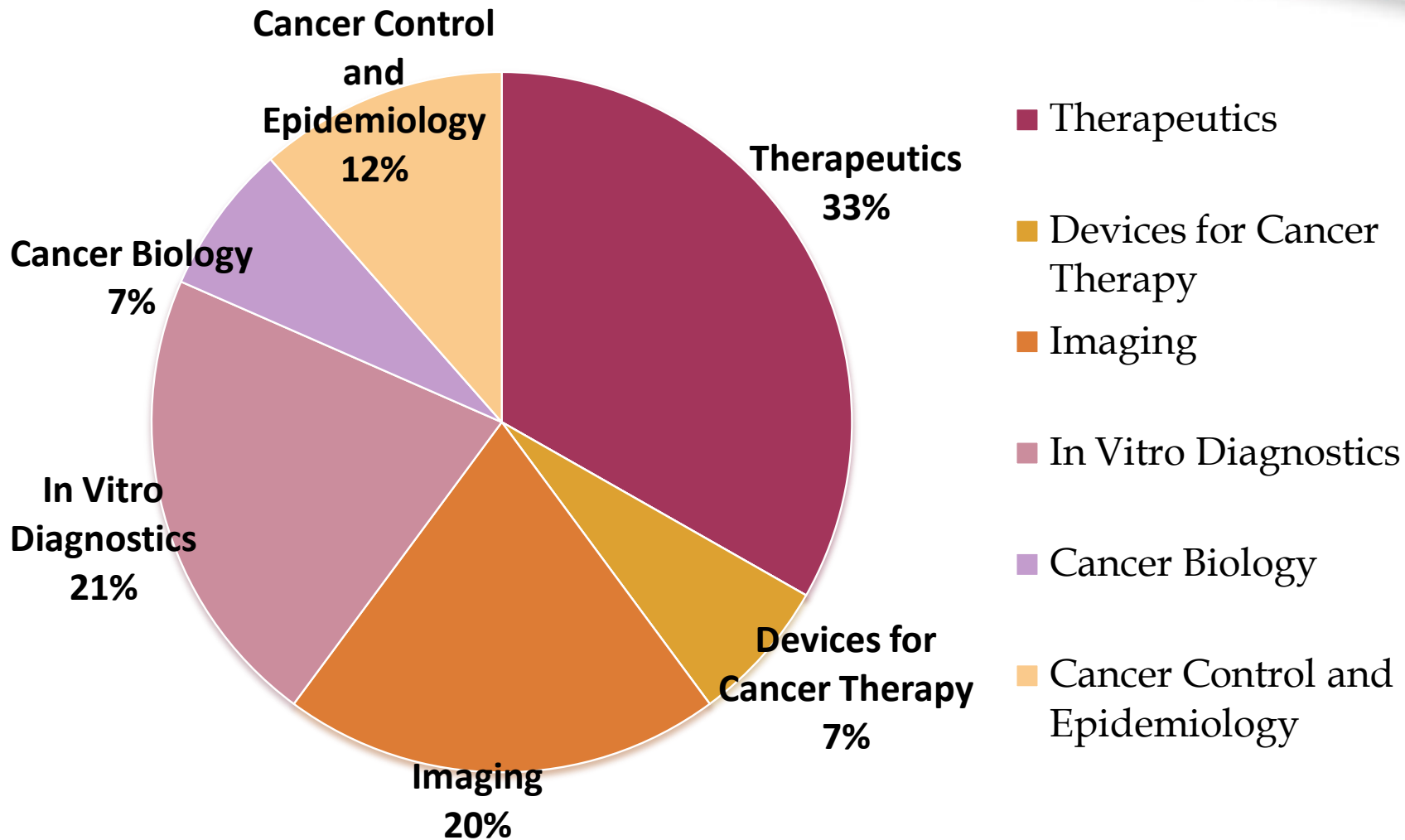
\* *These funding levels are guidelines. Companies should request the budget appropriate to accomplish the goals of the project.*



# NCI SBIR Funding Opportunities



# NCI SBIR Portfolio Summary



As of 9/1/2011

# NCI has multiple SBIR solicitations that Companies can compete for



## **SBIR/STTR Omnibus Grant Solicitation (NIH)**

***Release:*** January

***Receipt Dates:*** April 5, August 5, and December 5

***Technology Areas:*** All, investigator-initiated R&D

## **Other Program Announcements, RFAs**

**E.g. Image-Guided Cancer Interventions (NCI)**

***Program Announcement #:*** PA-10-079, PA-10-080

***Release:*** January 2010

***Receipt Dates:*** April 5, August 5, and December 5

***Technology Areas:*** IGD, IGT, IGS

## **SBIR Contract Solicitation (RFP - NIH, CDC)**

***Release:*** ***New RFP August 2011***

***Receipt Date:*** November 7, 2011

***Technology Areas:*** Published in the RFP

- 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

# Example 1: Topic 307 Imaging Agents



- **Budget:** Phase I \$250,000 ; Phase II \$1,500,000
- **Number of Anticipated Awards:** 3-5
- **Project Goal:** Novel imaging agents for:
  - early detection of cancer
  - stratification of patients for selecting cancer therapy,
  - surgical planning
  - evaluation of tumor response to chemotherapy, radiation therapy,
  - detection of cancer recurrence, etc.
- **The work scope may include** animal testing, formulation, GMP production, pharmacokinetic, pharmacodynamic, toxicological studies, etc.

# Example 2: Topic 277 Companion Diagnostics



- **Budget:** Phase I \$200,000 ; Phase II \$1,500,000
- **Number of Anticipated Awards:** 4
- **Project Goal:**
  - Companion diagnostics for selecting patients for which a particular therapeutic regimen, including existing drugs and those in clinical development and radiation, will be safe and effective
- **Phase I Work Scope:**
  - Test development and analytical validation
  - If the drug is not commercially available – establish partnership w/ the source
- **Phase II Work Scope:**
  - Full clinical validation



The screenshot shows the National Cancer Institute (NCI) SBIR & STTR website. At the top, the NCI logo and name are on the left, and the U.S. National Institutes of Health website address is on the right. Below this is a dark blue navigation bar with the SBIR & STTR logo and a search bar. A light green navigation menu contains links for About, Funding Opportunities, Resource Center, News & Events, and Success Stories. The main content area features a large banner image of a scientist and a business leader shaking hands over a petri dish, with the text "Leading small business innovation and commercialization in the fight against cancer". Below the banner are two columns of content. The left column has a section titled "What are the NCI SBIR & STTR Programs?" with two paragraphs of text and a "Learn More" link. The right column has a section titled "Latest Announcements" with a link to "SBIR Program FY 2011 Contract Funding Available", a paragraph of text, a link to "PHS 2011-1, Solicitation for SBIR Contract Proposals", a "Receipt Date: November 8, 2010", and a "Register Today" button for the "2010 NCI SBIR Investor Forum" on November 9 in Stanford, CA. Below the button is another paragraph of text.

**National Cancer Institute** U.S. National Institutes of Health | [www.cancer.gov](http://www.cancer.gov)

**SBIR & STTR** Sign Up for Updates | Contact Us | Site Map

Search  Go

**About** Funding Opportunities Resource Center News & Events Success Stories

**Leading small business innovation and commercialization in the fight against cancer**

**What are the NCI SBIR & STTR Programs?**

The goal of the NCI is to eliminate the suffering and death due to cancer. The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs are NCI's engine of innovation for developing and commercializing novel technologies and products to prevent, diagnose, and treat cancer.

The SBIR & STTR Programs are one of the largest sources of early-stage technology financing in the United States. We welcome entrepreneurs and small business leaders to this website to explore grant and contract funding opportunities and a new spirit of collaboration with the NCI.

[\[Learn More\]](#)

**Sign up for Updates**

Sign up to receive updates and news about the NCI SBIR & STTR Programs and upcoming funding opportunities

**Latest Announcements**

**[SBIR Program FY 2011 Contract Funding Available](#)**

The FY 2011 NCI solicitation for SBIR contract proposals has been issued:

[PHS 2011-1, Solicitation for SBIR Contract Proposals](#)

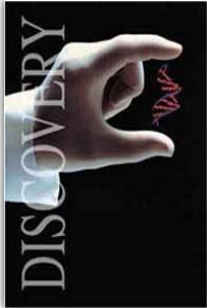
**Receipt Date: November 8, 2010**

**Register Today** 2010 NCI SBIR Investor Forum November 9 | Stanford, CA

The NCI SBIR will host its second Investor Forum designed to connect the strongest and most promising NCI SBIR funded companies with life science

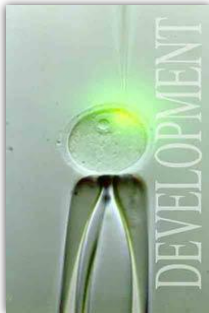
# **NCI SBIR Phase II Bridge Award**





## PHASE I – R41, R43

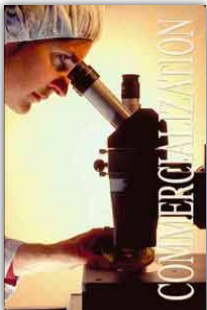
- Feasibility Study
- \$150-250K, 6-12 months



## PHASE II – R42, R44

- Full Research/R&D
- \$1-2 million and 2-3 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

## 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 equity investment
- Contract from strategic partner (partner helps to commercialize)

## Sources of Funds

- Another company, venture capital firm, individual “angel” investor, foundation, university, state or local government, or any combination

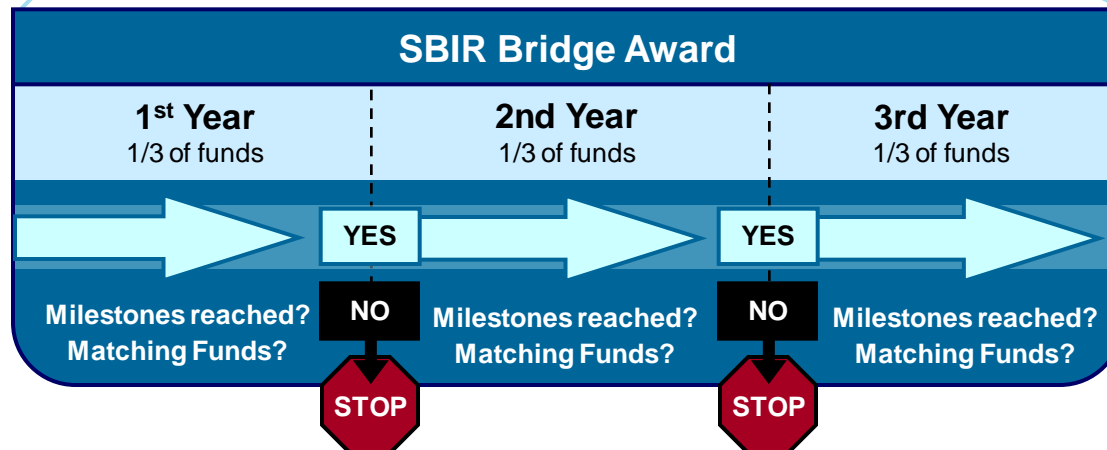
# Example: How the Bridge Award Would Apply in the Area of Drug Development



SBIR Bridge Award addresses the problem by bridging the “**Valley of Death**”

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

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



# Ten Bridge Awards: FY09/FY10

<b>FY</b>	<b>Company</b>	<b>Technology/Product</b>	<b>Award Size</b>
2009	<b>Lpath Therapeutics</b>	Humanized monoclonal antibody for treatment of prostate cancer	\$3,000,000
2009	<b>Optosonics</b>	Photoacoustic CT for preclinical molecular imaging	\$2,997,247
2009	<b>Guided Therapeutics</b>	Fluorescence/reflectance spectroscopy for detection of cervical cancer	\$2,517,125
2009	<b>Koning Corporation</b>	High-performance breast CT as diagnostic adjunct to mammography	\$2,986,453
2009	<b>Gamma Medica-Ideas</b>	Molecular imaging to detect metabolic activity of breast lesions	\$3,000,000
2009	<b>Altor BioScience</b>	Tumor-targeted immunotherapy for treatment of p53-positive cancers	\$2,969,291
2010	<b>20/20 GeneSystems</b>	mTOR companion diagnostic assay	\$2,750,000
2010	<b>Advanced Cell Diagnostics</b>	<i>In situ</i> RNA detection assay for analyzing circulating tumor cells	\$2,996,450
2010	<b>Ambergen</b>	Expression-based prognostic assay for recurrence of colorectal cancer	\$2,998,830
2010	<b>Praevium Research</b>	High-performance imaging engine for optical coherence tomography	\$1,180,420



**2 therapeutics**  
**5 imaging technologies**  
**3 diagnostics**

**Total \$27,395,816**

# **New Paradigm for Managing SBIR at NCI**



## **Goal: Enhance commercialization success of SBIR-funded projects**

- **10-member management team exclusively focused on the administration of NCI's SBIR/STTR portfolio**
- **Center staffed by program directors with industry experience and a broad range of scientific expertise**
- **Center collaborates with staff from across other NCI divisions to integrate the small business initiatives with the Institute's priorities**
- **Center is developing a range of new initiatives to help small businesses**



- **Active outreach to bring in a new class of commercially viable applicants**
- **Coaching companies on developing stronger applications**
- **Active management of projects and better oversight**
- **Mentor and guide companies throughout the award period**
- **Matchmaking with investors**

# SBIR Development Center Staff



**Michael Weingarten, MA** (*Director*)

*Previous*

- **NASA** – Program Manager, NASA Technology Commercialization Program



**Greg Evans, PhD** (*Branch Chief*)

*Previous*

- **NHLBI/NIH** – Program Director, Translational and Multicenter Clinical Research in Hemoglobinopathies
- **NHGRI/NIH** – Senior Staff Fellow



**Patti Weber, DrPH** (*Program Director*)

*Previous*

- **International Heart Institute of Montana** – Tissue Engineering and Surgical Research
- **Ribi ImmunoChem Research, Inc.** – Team Leader, Cardiovascular Pharmacology



**David Beylin, MS, MBA** (*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** (*Branch Chief*)

*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** (*Program Director*)

*Previous*

- **NIH** – AAAS Science & Technology Policy Fellow
- **Cedra Corporation** – Research Associate, Bio-Analytical Assays and Pharmacokinetics Analysis



**Jian Lou, PhD** (*Program Director*)

*Previous*

- **Johnson & Johnson** – Research Scientist, Target Validation & Biomarker Development
- **Lumicyte, Inc.** – Director, Molecular Biology Systems Analysis



**Todd Haim, PhD** (*Program Manager*)

*Previous*

- **National Academy of Sciences** – Christine Mirzayan Science and Technology Policy Fellow
- **Pfizer Research Laboratories** – Postdoctoral Fellow, Cardiac Pathogenesis & Metabolic Disorders



**Julienne Willis** (*Program Specialist*)



***Exclusive opportunity for 14 NCI awardees to showcase their companies to investors***

<http://sbir.cancer.gov/investorforum/>

## Featured Small Businesses

- Present to and network with close to 200 top investors and strategic partners
- Participate in panel discussion with successful Bridge awardees and their investors



## Investors

- Opportunity to evaluate NCI's top companies with innovative technologies
- Exclusive one-on-one meetings
- ***Follow-Up discussions, MTA's and Due Diligence now underway***



**Thank you!**

**Michael Weingarten**  
Director, SBIR Development Center  
weingartenm@mail.nih.gov

**Register to receive updates  
on funding opportunities at  
<http://sbir.cancer.gov>**